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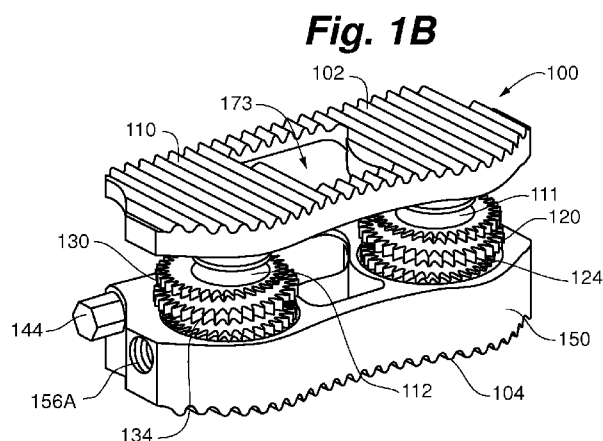
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(54) Title: METHODS AND APPARATUSES FOR VERTEBRAL BODY DISTRACTION AND FUSION EMPLOYING A COAXIAL SCREW GEAR SLEEVE MECHANISM



(57) Abstract: Improved methods and apparatuses for vertebral body distraction and fusion in accordance with various embodiments of the present invention employ one or more coaxial screw gear sleeve mechanisms. In various embodiments, coaxial screw gear sleeve mechanisms include a post with a threaded exterior surface and a corresponding sleeve configured to surround the post, the corresponding sleeve having a threaded interior surface configured to interface with the threaded exterior surface of the post and a geared exterior surface. A drive mechanism can be configured to interface with the geared exterior surface of the sleeve, causing the device to distract.

METHODS AND APPARATUSES FOR VERTEBRAL BODY DISTRACTION AND FUSION EMPLOYING A COAXIAL SCREW GEAR SLEEVE MECHANISM

5 RELATED APPLICATION

The present application claims the benefit of U.S. Provisional Application No. 61/271,548, filed July 22, 2009, and U.S. Provisional Application No. 61/365,131, filed July 16, 2010.

10 Field of the Invention

The present invention relates to the distraction and fusion of vertebral bodies. More specifically, the present invention relates to devices and associated methods for distraction and fusion of vertebral bodies that utilize coaxial screw gear sleeve mechanisms.

15 Background of the Invention

The concept of intervertebral fusion for the cervical and lumbar spine following a discectomy was generally introduced in the 1960s. It involved coring out a bone graft from the hip and implanting the graft into the disc space. The disc space was prepared by coring out the space to match the implant. The advantages of this concept were that it provided a large surface
20 area of bone to bone contact and placed the graft under loading forces that allowed osteoconduction and induction enhancing bone fusion. However, the technique is seldom practiced today due to numerous disadvantages including lengthy operation time, destruction of a large portion of the disc space, high risk of nerve injury, and hip pain after harvesting the bone graft.

25 Presently, at least two devices are commonly used to perform the intervertebral portion of an intervertebral body fusion: the first is the distraction device and the second is the intervertebral body fusion device, often referred to as a cage. Cages can be implanted as standalone devices or as part of a circumferential fusion approach with pedicle screws and rods. The concept is to introduce an implant that will distract a collapsed disc and decompress the
30 nerve root, allow load sharing to enhance bone formation and to implant a device that is small enough to allow implantation with minimal retraction and pulling on nerves.

In a typical intervertebral body fusion procedure, a portion of the intervertebral disc is first removed from between the vertebral bodies. This can be done through either a direct open approach or a minimally invasive approach. Disc shavers, pituitary rongeurs, curettes, and/or
35 disc scrapers can be used to remove the nucleus and a portion of either the anterior or posterior

annulus to allow implantation and access to the inner disc space. The distraction device is inserted into the cleared space to enlarge the disc space and the vertebral bodies are separated by actuating the distraction device. Enlarging the disc space is important because it also opens the foramen where the nerve root exists. It is important that during the distraction process one does not over-distract the facet joints. An intervertebral fusion device is next inserted into the distracted space and bone growth factor, such as autograft, a collagen sponge with bone morphogenetic protein, or other bone enhancing substance may be inserted, either before or after insertion of the device into the disc space, into the space within the intervertebral fusion device to promote the fusion of the vertebral bodies.

Intervertebral fusion and distraction can be performed through anterior, posterior, oblique, and lateral approaches. Each approach has its own anatomic challenges, but the general concept is to fuse adjacent vertebra in the cervical thoracic or lumbar spine. Devices have been made from various materials. Such materials include cadaveric cancellous bone, carbon fiber, titanium and polyetheretherketone (PEEK). Devices have also been made into different shapes such as a bean shape, football shape, banana shape, wedge shape and a threaded cylindrical cage.

It is important for a device that is utilized for both intervertebral body fusion and distraction to be both small enough to facilitate insertion into the intervertebral space and of sufficient height to maintain the normal height of the disc space. Use of an undersized device that cannot expand to a sufficient height can result in inadequate fusion between the adjacent vertebrae and lead to further complications for the patient, such as migration of the device within or extrusion out of the disc space. Addressing these issues can require the use of multiple devices of varying sizes to be used serially to expand the disc space the proper amount, which increases the time required to carry out the procedure, increasing the cost and risk associated with the procedure.

Accordingly, there is a need in the art for a device of sufficient strength that can distract from a beginning size small enough to initially fit into the disc space to a height sufficient to reestablish and maintain the normal height of the disc space.

Summary of the Invention

Improved methods and apparatuses for vertebral body distraction and fusion in accordance with various embodiments of the present invention employ one or more coaxial screw gear sleeve mechanisms. In various embodiments, coaxial screw gear sleeve mechanisms includes a post with a threaded exterior surface and a corresponding sleeve configured to surround the post, the corresponding sleeve having a threaded interior surface configured to

interface with the threaded exterior surface of the post and a geared exterior surface. A drive mechanism can be configured to interface with the geared exterior surface of the sleeve, causing the device to distract.

5 In one embodiment, a device is used for both intervertebral distraction and fusion of an intervertebral disc space. The device can include a first bearing surface and a second bearing surface with at least one coaxial screw gear sleeve mechanism disposed in between. The coaxial screw gear sleeve mechanism includes a post with a threaded exterior surface projecting inwardly from one of the bearing surfaces and a corresponding sleeve configured to surround the post. The sleeve can project inwardly from the other of the bearing surfaces and have a threaded
10 interior surface configured to interface with the threaded exterior surface of the post and a geared exterior surface. The device can further include a drive mechanism having a surface configured to interface with and drive the geared exterior surface of the sleeve, which causes a distraction of the first bearing surface and the second bearing surface.

In another embodiment, a method of intervertebral body distraction and fusion involves
15 implantation of a distractible intervertebral body fusion device into an intervertebral disc space. The device is inserted such that a first bearing surface interfaces with an end plate of a superior vertebra of the intervertebral disc space and a second bearing surface interfaces with an end plate of an inferior vertebra of the disc space. At least one coaxial screw gear sleeve mechanism is disposed between the bearing surfaces and includes a threaded post, a corresponding sleeve
20 having an interior thread mating with the threaded post and an exterior gear mating with a drive mechanism. The method includes distracting the device from a collapsed configuration to an expanded configuration by operating the drive mechanism to rotate the sleeve relative to the post, thereby expanding the first bearing surface with respect to the second bearing surface.

The above summary of the various embodiments of the invention is not intended to
25 describe each illustrated embodiment or every implementation of the invention. This summary represents a simplified overview of certain aspects of the invention to facilitate a basic understanding of the invention and is not intended to identify key or critical elements of the invention or delineate the scope of the invention.

30 Brief Description of the Drawings

The invention may be more completely understood in consideration of the following detailed description of various embodiments of the invention in connection with the accompanying drawings, in which:

Figure 1A is perspective view of a distractible intervertebral body fusion device according to an embodiment of the present invention in a collapsed configuration.

Figure 1B is a perspective view of the distractible intervertebral body fusion device of Figure 1A in an expanded configuration.

5 Figure 1C is an exploded view of the distractible intervertebral body fusion device of Figure 1A.

Figure 1D is a partial sectional view of the distractible intervertebral body fusion device of Figure 1A.

10 Figure 2A is a partial side view of a distractible intervertebral body fusion device according to an embodiment of the present invention.

Figure 2B is a partial side view of the distractible intervertebral body fusion device of Figure 2A.

Figure 3A is a partial side view of a distractible intervertebral body fusion device according to an embodiment of the present invention..

15 Figure 3B is a partial side view of the distractible intervertebral body fusion device of Figure 3A.

Figure 4A is a partial top view of a distractible intervertebral body fusion device according to an embodiment of the present invention.

20 Figure 4B is a partial top view of the distractible intervertebral body fusion device of Figure 4A.

Figure 5A is a perspective view of an insertion tool and a distractible intervertebral body fusion device according to an embodiment of the present invention.

Figure 5B is a perspective view of an insertion tool and a distractible intervertebral body fusion device according to an embodiment of the present invention.

25 Figure 5C is a perspective view of an insertion tool and a distractible intervertebral body fusion device according to an embodiment of the present invention.

Figure 5D is a partial perspective view of an insertion tool according to an embodiment of the present invention.

30 Figure 6A is an end view of a distractible intervertebral body fusion device according to an embodiment of the present invention.

Figure 6B is a cross-sectional end view of the distractible intervertebral body fusion device of Figure 6A taken looking into the page.

Figure 7A is a front view of a distractible intervertebral body fusion device according to an embodiment of the present invention.

Figure 7B is a cross-sectional view of the distractible intervertebral body fusion device of Figure 7A taken along the lines 7B-7B.

Figure 8A is a front view of a distractible intervertebral body fusion device according to an embodiment of the present invention.

5 Figure 8B is a cross-sectional view of the distractible intervertebral body fusion device of Figure 8A taken along the lines 8A-8A.

Figure 9A is an exploded view of a distractible intervertebral body fusion device according to an embodiment of the present invention.

10 Figure 9B is a perspective view of the distractible intervertebral body fusion device of Figure 9A.

Figure 9C is a front view of the distractible intervertebral body fusion device of Figure 9A.

Figure 9D is a cross-sectional view of the distractible intervertebral body fusion device of Figure 9A taken along the lines 9D-9D in Figure 9C.

15 Figure 10A is an exploded view of a distractible intervertebral body fusion device according to an embodiment of the present invention.

Figure 10B is a perspective view of the distractible intervertebral body fusion device of Figure 10A.

20 Figure 10C is a bottom view of the distractible intervertebral body fusion device of Figure 10A.

Figure 10D is a cross-sectional view of the distractible intervertebral body fusion device of Figure 10A taken along the lines 10D-10D in Figure 10C.

Figure 11A is a perspective view of a distractible intervertebral body fusion device according to an embodiment of the present invention.

25 Figure 11B is a front view of the distractible intervertebral body fusion device of Figure 11A.

Figure 11C is a cross-sectional view of the distractible intervertebral body fusion device of Figure 11A taken along the lines 11C-11C in Figure 11B.

30 Figure 11D is a cross-sectional view of the distractible intervertebral body fusion device of Figure 11A taken along the lines 11D-11D in Figure 11B.

Figure 12A is a perspective view of a distractible intervertebral body fusion device according to an embodiment of the present invention.

Figure 12B is a side view of the distractible intervertebral body fusion device of Figure 12A.

Figure 13A is a perspective view of a distractible intervertebral body fusion device according to an embodiment of the present invention.

Figure 13B is a side view of the distractible intervertebral body fusion device of Figure 13A.

5 Figure 14A is a perspective view of a distractible intervertebral body fusion device according to an embodiment of the present invention.

Figure 14B is a side view of the distractible intervertebral body fusion device of Figure 14A.

10 Figure 15 is a perspective view of a pair of distractible intervertebral body fusion devices according to an embodiment of the present invention.

Figure 16A is a top view of a distractible device according to an embodiment of the present invention in a compressed configuration.

Figure 16B is a top view of the distractible device of Figure 16A in an expanded configuration.

15 Figure 17A is perspective view of a distractible device according to an embodiment of the present invention.

Figure 17B is a partial cutaway view of the distractible device of Figure 17A.

Figure 18A is a perspective view of a distractible device according to an embodiment of the present invention.

20 Figure 18B is a partial view of the distractible device according to Figure 18A.

Figure 18C is a partial view of the distractible device according to Figure 18A.

Figure 18D is a partial view of the distractible device according to Figure 18A.

25 While the invention is amenable to various modifications and alternative forms, specifics thereof have been shown by way of example in the drawings and will be described in detail. It should be understood, however, that the intention is not to limit the invention to the particular embodiments described. On the contrary, the intention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the invention.

Detailed Description of the Drawings

30 In the following detailed description of the present invention, numerous specific details are set forth in order to provide a thorough understanding of the present invention. However, one skilled in the art will recognize that the present invention may be practiced without these specific details. In other instances, well-known methods, procedures, and components have not been described in detail so as to not unnecessarily obscure aspects of the present invention.

Referring to Figures 1A-1C, there can be seen a distractible intervertebral body fusion device 100 adapted for implantation into an intervertebral disc space of a patient according to an embodiment of the present invention. Figure 1A shows the device 100 in a fully compressed configuration, Figure 1B shows the device 100 in a fully expanded configuration, and Figure 1C shows an exploded view of the device 100.

Device 100 includes a first member 110 having a bearing surface 102 configured to interface with an end plate of one of a superior or an inferior vertebra of the intervertebral disc space and a second member 150 having a bearing surface 104 configured to interface with an end plate of the other of the superior or inferior vertebra. In one embodiment, the bearing surfaces 102, 104 can include a textured surface, such as that provided by corrugations 114, to create friction with the end plates of the vertebra to prevent accidental extrusion of the device 100. The radii of the corrugation 114 valley and the corrugation 114 top width can be maximized to minimize the notch factor and reduce stress while still providing a corrugation design that reduces the propensity of the device 100 to extrude from the disc space. One or both of the members 110, 150, can also include an opening 173, 153 extending through the member for facilitating bone growth through the device 100. In other embodiments, opening can be filled with a gel, rubber, or other compliant material that can replicate the nucleus of an intervertebral disc and supplement the strength of the device in compressive, shear, and torsional loading conditions. Alternatively, a generally solid surface, a textured or etched surface, a scored or notched surface, or a surface with multiple openings can be provided on each member 110, 150.

Device 100 can also include a pair of coaxial screw gear sleeve mechanisms including threaded post members 111, 112 extending from first member 110 and a pair of threaded geared sleeves 120, 130 configured to surround the post members 111, 112. Threaded post members 111, 112 can have threads 113, 115 defined on an exterior surface thereof. Threaded geared sleeves 120, 130 can have both interior threads 122, 132 configured to interface with the threads 113, 115 of threaded post members 111, 112 and exterior threads 121, 131. In one embodiment, both the exterior 121 and interior 122 threads of one of the sleeves 120 are of an opposite hand to the threads 131, 132 of the other sleeve 130. External threads 121, 131 of sleeves 120, 130 can have gear teeth 124, 134 cut into the thread. In one embodiment, the gear teeth 124, 134 are not cut down to the root, or minor diameter, of the threads 121, 131 in order to maximize the strength of the threads. In the compressed configuration, threaded geared sleeves 120, 130 can fit within sleeve openings of 161, 162 in second member 150. Openings 161, 162 can include threaded portions 151, 152 that mesh with exterior threads 121, 131 of threaded geared sleeves 120, 130. In one embodiment, sleeve openings 161, 162 extend all the way through bearing

surface 104 of second member 150. In some embodiments, as pictured, threaded geared sleeves 120, 130 can be substantially solid. In other embodiments, threaded geared sleeves can include one or more slots through the sleeve for mass reduction and material savings or to promote bone in-growth.

5 The device 100 can be expanded with the aid of a worm 140 that extends through a worm aperture 154 in the device 100. The worm 140 can have first 142 and second 141 opposing threaded sections configured to interface with the exterior threads having gear teeth 124, 134 of threaded geared sleeves 120, 130 through a pair of apertures 157, 158 in threaded portions 151, 152 of sleeve openings 161, 162. The worm 140 can include a hex 143, 144 at each end of the
10 worm 140 that allows it to be driven by a delivery system (described below). Such a delivery system can also be attached to the device 100 when driving the worm 140 at tapped hole 156A or tapped hole 156B to stabilize the delivery system. Device 100 can include a hex 143, 144 and tapped hole 156A, 156B at each end of device, so that the device 100 can be inserted and driven from either end, or can include a hex and tapped hole at only one side of the device, limiting the
15 device to insertion and distraction from a single direction. Bottom member 150 can also include one or more scallops 155 above the worm aperture 154 that provide increased strength and thickness while still allowing the threaded geared sleeves 120, 130 to rotate.

 A partial sectional view of a distractible intervertebral body fusion device 100 in Figure 1D, helps illustrate how the device can employ multiple coaxial screw gear sleeve mechanisms
20 as telescoping mechanisms utilizing the threaded post members 111, 112, threaded geared sleeves 120, 130 and the worm 140 to expand the first member 110 and second member 150 relative to each other. By turning hex 144 counterclockwise, and therefore the worm 140 counterclockwise, first threaded section 142 of worm 140 pulls the gear teeth 134 of threaded geared sleeve 130 towards the hex head 144. This causes the sleeve 130 to translate upward
25 from the second member 150 along internal threads 152. As the sleeve 130 rotates while it translates upward, the threaded post member 112 extending from the first member 110, which is unable to turn, also translates upward with respect to the sleeve 130 and the second member 150. This second translation results from the opposite handed external threads 115 of the threaded post member 112 being driven by the matching internal threads 132 of the sleeve 130. The same
30 mechanics are occurring on the other side of the device with oppositely threaded sleeve 120 having external threads 121 and internal threads 122, post member 111 having external threads 113 and second threaded section 141 of worm 140.

 Because the threads for like components for each device are opposite handed, the threads 142 on one side of the worm 140 will be pulling the gear teeth 134 of the threaded geared sleeve

130 while the threads 141 on the other side of the worm 140 will be pushing the gear teeth 124 on the other sleeve 120, or vice versa depending on the direction of rotation of the worm 140. These opposing forces applied to the worm 140 by the threaded geared sleeves 120, 130 are carried in either tension or compression by the worm 140. Therefore, the worm 140 is not
5 substantially driven into or out of the worm aperture 154 as the device 100 is expanded or contracted. This is advantageous in that a pin or other retainer is not required to retain the worm and balance the forces in the device. Such a pin can be a point of excessive wear which can cause the life cycle of the device to be shorter lived. In some embodiments, a pin can be employed to prevent the worm 140 from being able to be pulled or pushed axially, which can
10 cause the device to become jammed.

Alternative drive mechanisms to worm drive include piezoelectric actuators and any momentum imparting collision mechanism or configuration. Additionally, a drive mechanism, such as a worm, could be an integrated part of a delivery system. In such an embodiment, the external threads of the threaded geared sleeves would both be of the same hand and the worm
15 would be screwed into the compressed device in the worm aperture. As the worm is turned, the axial position of the worm would be constrained by the delivery system, instead of a pin, resulting in distraction of the device. Once the device reached the desired height, the worm could be screwed out of the worm aperture and the device could be locked in place by screwing in a threaded locking worm. The locking worm could have an additional threaded or snapping
20 feature that enables it to be permanently, or in a removable fashion, attached to the device. The locking worm could be made from a radio transparent material such as PEEK, which would therefore allow imaging through the worm. The locking worm would only need to be strong enough to inhibit the threaded geared sleeves from turning into or out of the device, and would not need to be strong enough to cause the device to distract. A larger radio transparent window
25 could be formed by removing a portion of the sides of the bottom member on either side of the opening in the bottom member along the length of the device, so long as the device retained a necessary amount of stiffness.

Referring now to Figures 2A and 2B, a preferred fit of gear teeth 124, 134 of threaded geared sleeves 120, 130 in internal threaded portions, 151, 152 of second member 150 is shown.
30 As the gear teeth 124, 134 are thrust towards the internal threads 151, 152 of the second member 150 by the worm, the load between the gear teeth 124, 134 and threads 151, 152 is balanced by the bearing surfaces 163, 164 between the components, which results in the ability of the device 100 to distract a substantial load. This fit between the gear teeth 124, 134 and the internal threads 151, 152 can be contrast with the fit shown in Figures 3A and 3B. In those figures, when

the gear teeth 124', 134' of the threaded geared sleeves 120', 130' are thrust towards the internal threads 151', 152' of the second member 150', the force is not balanced by bearing surfaces as in Figure 2B, but by the force the internal threads 151', 152' apply to the gear teeth 124', 134'. This can result in the gear teeth 124', 134' acting as a wedge and becoming jammed against the internal threads 151', 152', which dramatically reduces the ability of the device to distract substantial loads and makes the device more sensitive to friction between components. Optionally, a liquid or gas lubricant, such as silicon lubricant, may be used to reduce friction in the mechanism. Saline may also be used as a lubricant.

It should be noted that although the threads depicted in the Figures are all screw threads in the form of projecting helical ribs, "thread" for the purposes of the present invention can also refer to any other mechanism that translates rotational force into translational or longitudinal movement. For example, in some embodiments threads can be comprised of a recirculating or spiral arrangement of bearings or any other low friction arrangement, such as cooperating magnets.

In one embodiment, the height of the device 100 between the bearing surfaces 102, 104 in the fully compressed configuration is 6.5 millimeters and the maximum fully distracted height is 12 millimeters, thus providing a very large amount of distraction relative to the initial height of the device. The maximum height is defined by the largest height at which the device can meet the dynamic compressive, shear, and torsional requirements for implantable intervertebral body fusion devices. Variables that determine this height include the width of the threaded geared sleeves, which is limited by the desired width of the device, and the material from which the device is made. With regard to the material for the device, materials with higher fatigue performance allow the maximum height of the device to be taller even with a narrower width. In one embodiment, the device is made from titanium. The device may also be made from cobalt chrome, MP35N, or PEEK, for increased strength characteristics or increased radiolucent characteristics, depending on the material. X-ray transparency is a desirable property because it allows for the fusing bone to be imaged through the device. In one embodiment, the device can be designed such that in the compressed configuration the threaded geared sleeves project through the bearing surface of second member in order to provide for an even greater amount of distraction. To accommodate the device on implantation, openings configured to contain the projecting portions of the sleeves can be cut into the adjacent vertebral end plate.

Once distracted, device 100 does not require a locking mechanism to maintain the desired height within the body. This is because, when driven backwards, the device exhibits a very high gear ratio which causes even the slightest friction in the system to overwhelm any amount of

compression, torsion, or shear loading that might be applied to the device. In dynamic testing in shear, torsion, and compression, the maximum amount by which the height of the device changed was by approximately 0.01 millimeter. The device 100, because height can be maintained at any point along the threaded geared sleeves, therefore also exhibits very high resolution height control, on the order of 1 micrometer.

In one embodiment, the external threads 121, 131 and gear teeth 124, 134 on the threaded geared sleeves 120, 130 can be substantially trapezoidal in shape. In one embodiment, the thread is a trapezoidal 8 millimeter by 1.5 millimeter metric thread. A trapezoidal design enables a relatively large gear tooth size and, accordingly, a larger area over which the distraction loading is distributed. Additionally, with precise manufacturing, multiple gear teeth 124, 134 on the threaded geared sleeves 120, 130 can be engaged by the worm 140 at the same time along the pressure angle ANG, as shown in Figures 4A and 4B. Distributing the distraction load over multiple teeth of the sleeves 120, 130 and the worm 140 is critical to achieve the minimum device size while providing a maximum amount of distraction and load capacity.

A delivery system 200 for implanting a distractible intervertebral body fusion device according to an embodiment of the present invention is depicted in Figures 5A (compressed configuration), 5B (partially distracted configuration, and 5C (fully distracted configuration). Delivery system 200 also includes an actuation tool 300 for actuating the distraction.

To distract the device 100, a hex 143 or 144 of device is first connected to the delivery system 200 via a socket driver on an end 201 of delivery shaft 203. In order to more securely attach the device 100 and the delivery system 200, a threaded end 202 of delivery shaft 204 can be threaded into one of tapped holes 156A or 156B in second member 150 of device 100. The device 100 can then be inserted into the body via a standard transforaminal lumbar interbody fusion (TLIF) or posterior lumbar interbody fusion (PLIF) procedure using the delivery system 200. A lateral interbody fusion through the lateral retroperitoneal corridor is another approach. The delivery system 200 can guide the location of the device 100 as it is being inserted with use of handle 213.

Delivery system 200 includes a hex 215 and a circumferential groove 214 at the near end of delivery shaft 204, and also has a hex and circumferential groove (not pictured) at the end of delivery shaft 203. Once the device 100 is in the disc space, the actuation tool 300 can be connected to the delivery system by engaging an internal hex socket driver of the actuation tool with the hex on the end of the delivery shaft 203, 204. In some embodiments, an internal snap ring or circumferential spring in actuation tool 300 can engage the circumferential groove on

delivery shaft 203 to ensure that the actuation tool 300 does not become accidentally disengaged during use.

By turning the actuation tool 300, the user transmits torque down the delivery shaft 203 to the worm 140, which distracts the device 100. As the delivery shaft 203 is turned, a slider 206 advances along threads 209 on shaft 203. The height of the device 100 as it is expanded can be represented on the delivery system 200 by the position of the slider 206 along the delivery shaft 204 with fiducial marks 208, as shown best in Figure 5D. Marks 208 may be positioned at any desirable interval along delivery shaft 204, and the slider 206 may include a viewing slot 207 for more complete viewing of the marks 208 as they are reached by slider 206. In one embodiment, each mark 208 can represent a distracted height of 1 millimeter.

Delivery system 200 can be configured so that when the device 100 reaches its maximum desired height, slider 206 abuts stop 205 so that it can be advanced no further, thus limiting the height of the device 100. By allowing the delivery system 200 to limit the expansion, any damage due to excessive torque is immediately apparent in the delivery system 200, so no damage is sustained by the device 100. In another embodiment, the device 100 can limit its own expansion by welding two of the gear teeth 124, 134 on one of the threaded geared sleeves 120, 130 together so that they bind with the worm 140 when the device 100 has reached its maximum desired height. Similarly, in other embodiments, one or more of the gear teeth 124, 134 can be omitted or a small post can be inserted into the interstitial space between two gear teeth to limit the expansion of the device.

In one embodiment, a lever for applying torque to the shaft 204 may be affixed to the hex 215 at the end of shaft 204. The lever may be shaped and oriented such that when the device 100 is appropriately engaged with the delivery system 200, the position of the lever allows access to the drive shaft 203, whereas when the device is not appropriately engaged, the lever does not allow access to the drive shaft 203. In another embodiment, the slider 206 may be contained with the handle 213 in order to reduce the length of the delivery system 200. In another embodiment, a tube able to carry loading in torsion may be implemented around one of the shafts 203, 204 to add to the structural rigidity of the delivery system. A small foot may be affixed to the tube to additionally support the ability of the delivery system to carry, and transmit, loading in torsion by and to the device. In another embodiment, the shaft of the delivery system 200 can be curved or bayonet in shape to allow visualization through a minimally invasive system and working channel.

The actuation tool 300 can include a recess or loop 304 that allows that user to spin the actuation tool 300 with a single finger and/or large gripping surfaces 301 that the user can grasp

to turn the actuation tool 300. In one embodiment, the loop may be lined with a slippery or bearing surface to enable the loop to spin easily around the user's gloved finger(s). The actuation tool 300 can also include a broad surface 303 designed to receive the impact of a hammer for implantation. Recesses 302 can also be included on actuation tool 300 to afford the user an improved view of the device 100 while it is being implanted. Actuation tool 300 can span both delivery shafts 203, 204 and may extend over and/or receive handle 213 of delivery system 200. In another embodiment, rather than being driven by manual actuation tool 300, the device 100 can be driven by a powered actuation implement such as a pneumatic or electric drill or a motorized screwdriver mechanism, which, in some embodiments, can allow the tool to be controlled remotely.

In other embodiments, the actuation tool, manual or automatic, employs sensors in the device to transmit data regarding the implantation parameters and environment, such as device load and muscular tension, to an operator or operating system to improve the performance of the surgical procedure and outcome. The delivery system 200 could use small strain gauges located on the device 100 and/or load cells attached to the delivery shafts 203, 204 and actuation tool to measure loads present during the implantation and distraction process. These gauges and/or load cells could be monitored by a microcontroller board located on the delivery system 200 and the information fed back to a monitoring computer via a standard interface such as a USB or wireless connection. This information could be used to closely monitor a procedure's progress, warn of impending problems and improve future procedures. If not fully bridged, the gauges could be configured as half bridges within the device and completed outside of the device. Standard signal conditioning amplifiers could be used to excite and condition the signal to yield a measurable output of voltage and current.

In one embodiment, the device 100 can have a strengthened second member 150 as shown in Figures 6A and 6B. This can be done by lowering the worm aperture 154, and therefore the worm 140, such that when the device 100 is expanded to its full height, the worm 140 engages a full gear tooth 134A on the threaded geared sleeve 130 closest to the bottom 136 of the threaded geared sleeve 130. This allows a top surface 166 of the second member 150 to be lowered, which allows the first member 110 to be thicker, and therefore stronger, while maintain the same initial height. In addition, this allows the material 168 between the top surface 166 of the second member 150 and the worm aperture 154 to be made thicker. A further advantage of this configuration is that at least one full internal thread 152A of the second member 150 is in engagement with the threaded geared sleeve 134 when the device is fully distracted. In such a configuration, an additional thickness 167 can be added to the side of

second member 150 opposite of the worm aperture 154 to what was previously described as the top surface 166A of that side of the second member 150. This allows for a full internal thread 152B to engage the threaded geared sleeve 130 on the side opposite of internal thread 152A. By capturing the threaded geared sleeve with a full thread on both sides, when the device is loaded with shear and torsion, a maximum amount of material is resisting the load, which minimizes the resulting stress and increases the fatigue life of the device 100.

Figures 7A and 7B depict another embodiment of the present invention where in threaded posts 111, 112 employ a buttress thread 113A, 115A (compare threads 113A in Figure 7B to threads 113, 115 in Figure 1D). A buttress thread configuration results in the load bearing thread face being perpendicular to the screw axis of the post 111, 112, which increases the axial strength of the device. Figures 8A and 8B depict a further embodiment that utilizes a standard 60 degree thread 113B, 115B on threaded posts 111, 112. 60 degree threads are considered industry standard and can therefore be created with common machining practices. This can result in a device that can be more quickly and inexpensively produced.

Referring now to Figures 9A-9D, another embodiment of a distractible intervertebral body fusion device 400 includes a single pair of threaded geared posts 423 extending between first member 410 and second member 450 rather than the separate threaded geared sleeves 120, 130 and threaded posts 111, 112 described previously. Threaded geared posts 423 each include a threaded geared portion 421 and a post portion 411. Threaded geared portions 421 fit within openings 461 in second member 450 and interface with worm 440 and internal threads 451 to cause the device 400 to distract. Post portions 411 fit within openings 416 in first member 410 and can be attached to washers 418. Washers 418 keep the first member 410 in place relative to the threaded geared posts 423 as the threaded geared posts 423 rotate freely independent of the first member 410 when the device 400 is actuated. Thus, as seen in Figures 9C and 9D, the distraction between the first member 410 and the second member 450 is caused by the thicker threaded geared portions 421 while the post portions 411 remain within the openings 416 in first member 410. This leads to a device 400 having increased axial strength.

Figures 10A-10D depict a further embodiment of a distractible intervertebral body fusion device 500 that allows for differential adjustment of the threaded geared sleeves 520. Threaded posts 511 can each include an arched portion 515 that corresponds to an arched recess 517 in first member 510. The arched interface between the threaded posts 511 and the first member 510 created by the corresponding arched portions 515 and arched recesses 517 allows the first member 510 to rotate and become angled relative to the second member 550. A pin joint utilizing a pivot pin 572 can be used to keep one interface between the first member 510 and a

threaded post 511 stationary, while the other interface is allowed to slide due to the arched surfaces. A placement pin 570 is used to prevent the worm 540 from sliding out of the second member 550 when distracting the device. Worm 540 can be a two-part worm including a first portion 546 having a first threaded section 543 and second portion 548 having a second threaded section 544 that fits onto a post 547 of first portion 546. The two portions 546, 548 can therefore be rotated independently of each other, with each driving a separate threaded geared sleeve 520. Because each threaded geared sleeve 520 can be engaged separately, they can be distracted different amounts, resulting in an angled first member 510 as shown most clearly in Figure 10D. Such a configuration accommodates lordotic or kyphotic geometry. Optionally, the arched recesses 517 in the first member 550 and arched surfaces 515 of the posts 511 could be replaced with flexural joints or ball or cylinder and socket joints.

A distractible intervertebral body fusion device 600 according to another embodiment of the present invention is depicted in Figures 11A-11D. Device 600 uses three coaxial screw gear sleeve mechanisms, each having a threaded geared sleeve 620 and a threaded post 621, between first member 610 and second member 650. As seen in Figures 11C and 11D, to distract the device, the worm drive 640 is rotated and it engages one of the threaded geared sleeves 620, causing it to rotate. As the first threaded geared sleeve 620 rotates, it engages the other two threaded geared sleeves 620, causing them to rotate and the device 600 to distract. The rotation of the threaded geared sleeves 620 also causes the threaded posts 621 to distract, as described previously. Use of three coaxial screw gear sleeve mechanisms provides for a device having increased strength in the axial direction, a broader surface area for supporting the endplate of the vertebral body, and a more shapely geometry. Optionally, each of the three distraction mechanisms could be actuated independently to adjust the surface of the device in additional degrees of freedom. To achieve some geometries, the drive mechanisms may need to be flexible, in which case a bellows or spiral laser-cut drive mechanism capable of bending and transmitting torque could be implemented. More specifically, one such drive mechanism could wrap around many distraction mechanisms, and distract each one with only one input. In another embodiment, a flexible drive mechanism could be useful in actuating multiple drive mechanisms separately to control the members of the device in many spatial degrees.

Figures 12A and 12B depict a distractible intervertebral body fusion device 700 that employs only a single coaxial screw gear mechanism having a threaded geared sleeve 720 and a threaded post 721 for distracting first member 710 relative to second member 750 with worm 740. Device 700 also can include first 774 and second 776 telescoping support elements. Telescoping support elements 774, 776 serve to maintain the relative rotational positioning of the

first member 710 with respect to the second member 750, enabling the threaded geared sleeve 720 to rotate with respect to both the first member 710 and second member 750 to distract the device 700. Figures 13A and 13B depict a further variation of device 700 that utilizes a plurality of spikes 778 extending from the first member 710 and second member 750 to rotationally constrain the first member 710 and second member 750. In operation, the spikes 778 contact the adjacent vertebral end plates and fix themselves to the end plates to prevent the first member 710 and second member 750 from rotating relative to each other. A further embodiment is depicted in Figures 14A and 14B. This embodiment includes only a threaded geared sleeve 720 between first member 710 and second member 750 and allows the first member 710 to rotate with the sleeve 720 as the device 700 is distracted via rotation of the worm 740. Optionally, first member 710 could be rotationally free with respect to the threaded geared sleeve 720 so that the first member 710 is allowed to engage and not rotate against the endplate of the vertebral body.

In one embodiment, distractible intervertebral body fusion devices as described herein can be made of titanium and the delivery system can be made primarily out of stainless steel. Components of each mechanism that slide against each other can be made of different types of the general material. For example, the first member can be made from Ti 6Al 4V standard titanium, which has high smooth fatigue performance, while the threaded geared sleeves can be made from Ti 6Al 4V ELI, which has high notched fatigue performance. Such a combination results in each component being made out of a preferred material for its fatigue notch factor while the overall mechanism implements different materials where components are slidably arranged.

In various embodiments, device is shaped to be ergonomic. Device can have various shapes, such as, for example, rectangular, kidney, or football shaped. A kidney or football shaped device maximizes contact between the device and the vertebral bodies because the end plates of vertebrae tend to be slightly concave. One or both ends of the device may also be tapered in order to facilitate insertion. This minimizes the amount of force needed to initially insert the device and separate the vertebral bodies. In addition, the device may be convex along both its length and its width, or bi-convex. Device can be constructed in various sizes depending on the type of vertebra and size of patient with which it is being used.

Device can be manufactured in various ways with, in some embodiments, different components of the device can be manufactured in different ways. In one embodiment, thread milling can be implemented to manufacture the various threads in device. Wire EDM can be utilized to manufacture some or all of the holes and openings in the device. Assembly jigs and

post processing steps can also be utilized to allow the device to be manufactured to exacting standards.

In some embodiments, following distraction of the device, a bone growth stimulant, such as autograft, bone morphogenic protein, or bone enhancing material, may be delivered into device. In one embodiment, bone growth stimulant is delivered through a hollow chamber in insertion tool before insertion tool is disengaged from device. The device supports in-vivo loads during the time fusion occurs between the vertebral bodies.

In one embodiment, the surface of the device can be treated to minimize surface roughness or to reduce pitting of the material within the body. A rough surface or pits can increase the stress on the device, which can result in shortening of the fatigue life and/or reduce fatigue strength. In one embodiment, the surface can be treated with electro-polishing, both removing burrs from the edges of the device and finishing the surface. In another embodiment, the surface can be left untreated because a rough surface on the end plates helps prevent accidental extrusion of the device. In one embodiment, the device can also be coated with a highly elastic, impermeable material to extend its fatigue life. Specifically, the impermeable material would prevent the corrosive properties of blood from degrading the device. In another embodiment, the device can be comprised of a biocompatible material, so that no coating is necessary. In a further embodiment, the device can be made of a biodegradable material designed to degrade in the body at a selected stage of the healing process, such as after bone fusion.

In various embodiments, devices as described herein can be used with various bone growth stimulants. In one embodiment, a 3D premineralized silk fibroin protein scaffold carrier can be carried on the surface of or within the device to deliver a bone morphogenetic protein (BMP), which can optionally be combined with modified bone marrow stromal cells (bMSCs) to improve fusion. In other embodiments, a composite chitosan 3D fiber mesh scaffold or a gelatin scaffold can be used. The device can also utilize vascular endothelial growth factor (VEGF) by depositing immobilized VEGF on titanium alloy substrates coated with thin adherent polydopamine film to increase the attachment, viability and proliferation of human dermal cells to promote the development of blood supply to the fused bone through revascularization around the implant. In some embodiments, certain polymers such as biodegradable PLGA could be used to make a scaffold for VEGF to enhance neovascularization and bone regeneration. In some embodiments, VEGF can be used in conjunction with BMPs to inhibit the function of BMPs of promoting osteogenesis to allow the device to be continually adjusted over time. In various embodiments, scaffolds on or around the device could be seeded with bone marrow

derived stem cells, dental pulp derived stem cells and adipose derived stem cells. Scaffolds can also be comprised of various materials including polyester (e.g., polylactic acid-co-glycolic acid or poly3-hydroxybutyrate-co-3-hydroxyvalerate), silk (e.g., biomimetic, apatite-coated porous biomaterial based on silk fibroin scaffolds), hydrogels such as polycaprolactone, polyepsilon-caprolactone/collagen (mPCL/Col) cospun with PEO or gelatin, mPCL/Col meshes with micron-sized fibers, and mPCL/Col microfibers cosprayed with Heprasil, and porous titanium and titanium alloys (such as a titanium-niobium-zirconium alloy) functionalized by a variety of surface treatments, such as a VEGF or calcium phosphate coating.

In some embodiments, device can include structure adapted to retain bone within an interior of or adjacent to the implant. Such structure can include a micro-level matrix or scaffolding or kerfs, divots, or other similar features in the body of device. Bone may also be retained through use of a porous material such that bone is retained in the interstitial spaces of the material. Larger, extending features may also be implemented. Such features, such as a circumferential shroud, could also have the added function of stiffening the device in torsion.

In some embodiments, more than one distractible intervertebral body fusion device according to the present invention can be implanted into the disc space. As shown in Figure 15, in one embodiment a pair of devices 100 can be implanted such that the outer surface 104 of the second member 150 of one of the devices 100 directly interfaces with the outer surface 102 of the first member 110 of the other device 100. Such a configuration can allow for use of a smaller access channel for implanting the devices. In one embodiment, the cooperating surfaces 102, 104 of the two devices are flat. Devices 100 can be actuated simultaneously or separately. Devices could also be flipped with respect to each other in order to have both drive mechanisms centrally located. In addition, the devices could be configured to rotate or flex with respect to each other to allow for the bearing surfaces of the devices to adjust their position to comfortably engage with the endplates of the vertebral bodies, or to preserve motion of the spine.

In one embodiment, a rod and screws can be used with the device as part of an assembly affixed to the vertebral body. Specifically, posterior fixation, whereby rod(s) and screws are used to supplement the spine, may be used in combination with the device. In one embodiment, the rod(s) and screws may be affixed to, or designed to engage, the implant. In another embodiment, the members of the device may be extended and, effectively, folded over the sides of the adjacent vertebral bodies so that the device may be affixed to the vertebral bodies with screws placed through the extensions of the members of the device substantially parallel to the plane formed by the endplates of the vertebral bodies. In other embodiments, an adhesive, which may support osteogenesis, may be used to adhere the device to or within the spine.

In another embodiment distractible intervertebral body fusion device can comprise an endplate enhanced with flexures to be capable of tilting front to back and/or side to side. Additionally, coaxial screw gear sleeve mechanisms utilizing at least in part a flexible material can be oriented around the periphery of the device to allow for tilting in a variety of axes.

- 5 Generally, a device capable of tilting can be beneficial in that providing additional degrees of flexibility built into the device can promote bone growth, distribute stress across the surface of the end plates, and allow the device to adjust to the curvature of an individual's spine.

In one embodiment, the device could be placed within a small sock-like slip made from, for example, silk, which could be filled with bone. As the device expands and the volume of the device increases, the sock would prevent the bone from falling out of the implant and/or allow
10 for more bone to be introduced into the implant from the space around the implant within the sock. Such a sock could be closeable at one end and could attach to the delivery system during implantation of the device. The sock could be released from the delivery system during any of the later steps of implantation.

- 15 A device in accordance with the various embodiments can be used for a variety of intervertebral fusion applications, including, for example, cervical, thoracic anterior lumbar, trans-foraminal lumbar, extreme lateral lumbar, and posterior lumbar. Various embodiments of implantation procedures for these applications may be as follows:

Cervical: The device is implanted via an anterior approach at the C3 to C7 levels using
20 autograft. The device is used with supplemental anterior plate fixation.

Trans-foraminal lumbar: The device is implanted via a posterior approach from the L2 to S1 levels using autograft. The device is used with supplemental posterior rod fixation.

Posterior lumbar: The device is implanted via a posterior approach from the L2 to S1 levels using autograft. Two devices are implanted; one on the left side of the disc space and the
25 other on the right side of the disc space. The device is used with supplemental posterior rod fixation.

Anterior lumbar: The device is implanted via an anterior approach from the L3 to S1 levels using autograft. The device is used with supplemental anterior plating fixation of posterior rod fixation.

- 30 Extreme lateral lumbar: The device is implanted via a lateral approach from the T12 to L4 levels using autograft. The device is used with supplemental posterior rod fixation.

In another embodiment, the device can be used in vertebral body replacement. After resection of a vertebral body or multiple vertebrae due to fracture or tumor, the device can be distracted to bridge two separate vertebrae. The distracted device bridges and supports the void

left after resection. The device can be constructed in different sizes to accommodate the size difference of cervical, thoracic and lumbar vertebrae.

In another embodiment, the device can be used as an interspinous distraction device as shown in Figures 16A and 16B. The device 800 can be placed between two adjacent spinous processes 801a, 801b through a minimal access system. The device can be inserted in a collapsed configuration to allow ease of placement. Once in position, the device can be actuated to an expanded configuration with coaxial screw gear sleeve mechanisms 804 to lock the vertebrae in a distracted position. Coaxial screw gear sleeve mechanisms 804 can be configured as described previously herein. The device can have gripping teeth 800 at the point of contact with the spinous processes 801a, 801b to help fix it in place.

In another embodiment, the device can be used for interspinous fusion. The device can be placed between two adjacent spinous processes through a minimal access system in a collapsed configuration. Once in position, the device can be actuated to lock the vertebra in a distracted position. The device can have a bolt locking mechanism or similar locking arrangement to lock the device in the distracted position and to lock the locking plates through the spinous processes. The device can also have gripping corrugations or features on the outside to help keep it in place. Autograft or bone fusion enhancing material can be placed in the open space in device.

In another embodiment, the device can be used as a distractible fracture reducing device for osteoporotic bone. The device can be inserted beneath an end plate fracture through a minimally invasive pedicle approach. The device is then actuated with a delivery system actuator. Once the fracture is reduced, the device is explanted and the void is filled with acrylic cement or another bone filler that will strengthen the bone.

In another embodiment, the device can be used in facet joint replacement. After resection of a hypertrophic facet joint, the device can be actuated. Each member can be fixed to adjacent vertebrae with a pedicle screw. This will allow motion similar to that of a facet joint and prevent instability. The device can be part of a soft fusion device system and can be used in combination with an intervertebral disc replacement device. The coaxial screw gear sleeve mechanism or threaded post may also be used to make intervertebral disc replacement devices expandable.

In another embodiment, the device can be used as a programmable distraction cage with a dynameter and bone stimulator. A programmable micro-machine actuator device can be implanted within the device. The device is distracted during implantation and can provide force readings through a radio frequency communicator post-surgery. The shape of the device can be

altered while it is implanted by distracting the members with the actuator device, which can result in lordosis, kyphosis, further distraction, or less distraction. In one embodiment, a battery device powers the system and can also form a magnetic field that works as a bone stimulator. The battery life may be limited to a short period of time, such as one week. Small movements of the device can be used to generate electrical energy with piezo-electrics or conducting polymers that may be used to recharge the batteries, capacitors, or other such power storage devices. Alternatively, the device may be powered through an RF inductive or capacitatively coupled arrangement.

In another embodiment, the device can be a self-actuating distractible cage. The device can be inserted into the disc space in a collapsed state. Once the device is released, it can slowly distract to a preset height.

In another embodiment, the device can be used in facial maxillary surgery as a fracture lengthening device for mandibular fractures. The device can be designed with narrow members having perpendicular plates with holes that allow fixation of each member to either a proximal or distal fracture. The device can be actuated to a preset height. This will allow lengthening of the defect in cases of fracture bone loss, dysplasia, or hypoplasia.

In another embodiment, device can be used in orthopedic applications as a lengthening nail for distraction of long bone fractures. After an orthopedic fracture occurs with bone loss, a distractible elongating nail can be placed to lengthen the bone. The elongation occurs over a few days with micrometer movements. This application will involve a distraction device inserted in between the moving portion of the nails exerting counter-distraction forces, which will provide lengthening of the bone.

In another embodiment, the device can be used to replace phalangeal joints in the hand, metatarsal joints in the foot, or calcaneal-talus joints. These joints can have implants that will allow motion of adjacent bones and limit hyper-extension or hyper-flexion.

Figures 17A and 17B depict a distractible device 900 including an enveloping coaxial screw gear sleeve with recirculating bearings according to another embodiment of the present invention. Device 900 includes a post 910, an enveloping coaxial screw gear sleeve 920, a worm 930 and a housing 940. Post 910 includes a smooth outer surface 912 and a machined helical raceway 911 for bearings 913. A helical raceway (not shown) is also machined into inner surface of enveloping coaxial screw gear sleeve 920 that is complementary to helical raceway 911 for accommodating bearings 913. The inner surface of coaxial screw gear sleeve 920 also includes a machined tunnel for recirculation of bearings 913 as the post 910 moves with respect to the sleeve 920. The recirculating bearings are depicted as bearings 914 in Figure 17B. The

outer surface of the enveloping coaxial screw gear sleeve also includes a helical raceway 921 for recirculating bearings 914 and an enveloping screw gear 922. The worm 930 has a helical thread configured to engage the enveloping screw gear 922 of the sleeve 920. The inner surface of the housing 940 has a helical raceway (not shown) that cooperates with helical raceway 921 to retain bearings 914 and a tunnel for recirculating bearings 914 as the coaxial screw gear sleeve 920 moves with respect to the housing 940. Optionally, the coaxial screw gear sleeve 920 could have recirculating bearings both on the inside and the outside of the sleeve and the recirculation tunnel could be between the inside and the outside of the sleeve, facilitating assembly and manufacturing.

To expand the device 900, the worm 930 is rotated clockwise to engage the enveloping screw gear 922 to rotate and translate the enveloping coaxial screw gear sleeve 920 out of the housing 940. This simultaneously causes the post 910 to translate (but not rotate) out of the enveloping coaxial screw gear sleeve 920 and away from the housing 940. Bearings 913, 914 enable the rotation of the enveloping coaxial screw gear sleeve 920 with very little friction, enabling the device 900 to exhibit a very high mechanical advantage and displacement control with very high resolution. The use of the enveloping screw gear 922 enables the interface between the worm 930 and the enveloping coaxial screw gear sleeve 920 to carry substantially higher loading.

Referring now to Figures 18A-18D, there can be seen another distractible device 1000 utilizing a coaxial screw gear sleeve according to an embodiment of the present invention. Device 1000 includes an enveloping coaxial screw gear 1010, a housing 1020 and a worm 1030. The outer surface of enveloping coaxial screw gear sleeve 1010 includes a helical groove having a series of enveloping coaxial screw gear teeth 1014. The helical groove can cooperate with an internal thread 1021 on the inner surface 1022 of housing 1020 to allow the device 1000 to carry an axial load. In another embodiment, the gear teeth 1014 can be machined directly into the outer surface of the enveloping coaxial screw gear sleeve 1010. In one embodiment, the outer surface of the enveloping coaxial screw gear sleeve 1010 can be a smooth machined surface that acts like a bearing surface when configured with a similar smooth bearing surface on the inner surface 1022 of housing 1020 to enable the device 1000 to carry a lateral load.

To expand the device 1000, the worm 1030 is rotated to engage the enveloping coaxial screw gear teeth 1014 to rotate and translate the enveloping coaxial screw gear sleeve 1010 with respect to the housing 1020. In one embodiment, the inner surface 1010 and center bore 1012 can be configured to contain a post similar to the post 910 described in Figures 17A and 17B to compound the distraction of the device. In one embodiment, no thread 1021 is present on the

inner surface 1022 of housing 1020, so the helical groove and/or gear teeth 1014 of the enveloping coaxial screw gear sleeve 1010 cause the sleeve 1010 to translate with respect to the housing 1030 as the sleeve 1010 rotates. In such a configuration, the worm 1030 would carry any axial load, unassisted by an inclined interface between the enveloping coaxial screw gear sleeve 1010 and the housing 1020.

Various embodiments of systems, devices and methods have been described herein. These embodiments are given only by way of example and are not intended to limit the scope of the present invention. It should be appreciated, moreover, that the various features of the embodiments that have been described may be combined in various ways to produce numerous additional embodiments. Moreover, while various materials, dimensions, shapes, implantation locations, etc. have been described for use with disclosed embodiments, others besides those disclosed may be utilized without exceeding the scope of the invention.

CLAIMS

1. A distractible intervertebral body fusion device adapted for implantation into an intervertebral disc space of a patient, comprising:

a first bearing surface configured to interface with an end plate of a superior vertebra of the intervertebral disc space;

a second bearing surface configured to interface with an end plate of an inferior vertebra of the intervertebral disc space; and

at least one coaxial screw gear sleeve mechanism disposed between the first bearing surface and the second bearing surface, the coaxial screw gear sleeve mechanism including:

a post having a threaded exterior surface on a portion of the post projecting inwardly from one of the first bearing surface and the second bearing surface; and

a corresponding sleeve configured to surround the post and having:

a threaded interior surface on a portion of the sleeve projecting inwardly from the other of the first bearing surface and the second bearing surface and configured to interface with the threaded exterior surface of the post; and

a geared exterior surface on a portion of the sleeve; and

a drive mechanism having a surface configured to interface with and drive the geared exterior surface of the sleeve,

such that selective operation of the drive mechanism causes a distraction of the first bearing surface and the second bearing surface with respect to the superior vertebra and the inferior vertebra of the intervertebral disc space.

2. The distractible device of claim 1, wherein the geared exterior surface of the sleeve has a screw pitch orientation generally opposite of a screw pitch orientation of the threaded exterior surface of the post and the threaded interior surface of the sleeve.

3. The distractible device of claim 1, wherein there are a pair of coaxial screw gear sleeve mechanisms disposed between the first bearing surface and the second bearing surface that are driven by a common drive mechanism.

4. The distractible device of claim 3, wherein the threaded interior surface and geared exterior surface of the sleeve of one of the coaxial screw gear sleeve mechanisms have a screw pitch orientation generally opposite of a screw pitch orientation of the threaded interior surface and geared exterior surface of the other coaxial screw gear sleeve mechanism.

5. The distractible device of claim 1, wherein the drive mechanism is a worm drive.

6. The distractible device of claim 3, wherein the drive mechanism is a worm drive having a
5 pair of threaded sections, each threaded section configured to interface with one of the coaxial screw gear sleeve mechanisms.

7. The distractible device of claim 1, wherein the drive mechanism is translationally stationary as the drive mechanism drives the geared exterior surface of the sleeve.

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8. The distractible device of claim 1, wherein the first bearing surface is an outer surface of a first member and the second bearing surface is an outer surface of a second member, and wherein the sleeve fits within a sleeve opening in the one of the first member or second member corresponding to the bearing surface from which the sleeve projects, such that the geared exterior
15 surface of the sleeve interfaces with an internal thread in the sleeve opening.

9. The distractible device of claim 8, wherein the drive mechanism interfaces with the geared exterior surface of the sleeve through an aperture in the internal thread of the sleeve opening.

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10. The distractible device of claim 1, wherein a portion of the sleeve also projects outwardly through the other of the first bearing surface and the second bearing surface.

11. The distractible device of claim 1, wherein at least one of the first bearing surface and the
25 second bearing surface includes structure adapted to retain bone therein.

12. A method of intervertebral body distraction and fusion comprising:

inserting a distractible intervertebral body fusion device into an intervertebral disc space defined between adjacent vertebrae, the distractible device including a first bearing surface
30 configured to interface with an end plate of a superior vertebra of the intervertebral disc space, a second bearing surface configured to interface with an end plate of an inferior vertebra of the intervertebral disc space, and at least one coaxial screw gear sleeve mechanism disposed between the first bearing surface and the second bearing surface, the coaxial screw gear sleeve

mechanism including a threaded post, a corresponding sleeve having an interior thread mating with the threaded post and an exterior gear mating with a drive mechanism; and

distracting the distractable device from a collapsed configuration to an expanded configuration by operating the drive mechanism to rotate the sleeve relative to the post, thereby
5 expanding the first bearing surface with respect to the second bearing surface to distract the end plate of the superior vertebra relative to the end plate of the inferior vertebra of the intervertebral disc space.

13. The method of claim 12, wherein the step of operating the drive mechanism to rotate the
10 sleeve relative to the post causes the sleeve to distract relative to the second bearing surface and the post to simultaneously distract relative to the second bearing surface and the sleeve.

14. The method of claim 12, wherein the step of operating the drive mechanism comprises rotating a worm drive having a threaded section that interfaces with the exterior gear of the
15 sleeve.

15. The method of claim 12, further comprising connecting a delivery system to the device and the step of inserting includes using the delivery system to insert the device.

16. The method of claim 15, wherein the step of connecting the delivery system to the device
20 comprises connecting an end of a delivery shaft of the delivery system to the drive mechanism.

17. The method of claim 16, wherein the step of distracting the device includes rotating the delivery shaft to rotate the drive mechanism.

18. The method of claim 12, wherein the step of distracting the device includes distracting the device until a height-indicating mechanism of the delivery system indicates that the device has expanded to a desired height.

19. The method of claims 18, wherein the height-indicating mechanism includes a height-limiting mechanism adapted to preclude the device from being expanded beyond a pre-determined maximum height.

20. A distraction device, comprising:

a first bearing surface;

a second bearing surface; and

at least one coaxial screw gear sleeve mechanism disposed between the first bearing surface and the second bearing surface, the coaxial screw gear sleeve mechanism including:

5 a threaded post;

a corresponding sleeve having an interior thread mating with the threaded post and an exterior gear; and

10 a drive mechanism mating with the exterior gear of the sleeve to cause the threaded post and the corresponding sleeve to distract the first and second bearing surfaces.

21. The distractible device of claim 20, wherein the exterior gear of the sleeve has a screw pitch orientation generally opposite of a screw pitch orientation of the threaded post and the interior thread of the sleeve.

15 22. The distractible device of claim 20, wherein there are a pair of coaxial screw gear sleeve mechanisms disposed between the first bearing surface and the second bearing surface that are driven by a common drive mechanism.

20 23. The distractible device of claim 22, wherein the interior thread and exterior gear of the sleeve of one of the coaxial screw gear sleeve mechanisms have a screw pitch orientation generally opposite of a screw pitch orientation of the interior thread and exterior gear of the other coaxial screw gear sleeve mechanism.

25 24. The distractible device of claim 20, wherein the drive mechanism is a worm drive.

25. The distractible device of claim 22, wherein the drive mechanism is a worm drive having a pair of threaded sections, each threaded section configured to interface with one of the coaxial screw gear sleeve mechanisms.

30 26. The distractible device of claim 20, wherein the drive mechanism is translationally stationary as the drive mechanism drives the exterior gear of the sleeve.

27. The distractible device of claim 20, wherein the first bearing surface is an outer surface of a first member and the second bearing surface is an outer surface of a second member, and wherein the sleeve fits within a sleeve opening in one of the first member or the second member, such that the exterior gear of the sleeve interfaces with an internal thread in the sleeve opening.

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28. The distractible device of claim 27, wherein the drive mechanism interfaces with the exterior gear of the sleeve through an aperture in the internal thread of the sleeve opening.

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29. The distractible device of claim 27, wherein a portion of the sleeve extends through the outer surface in the one of the first member or second member.

30. The distractible device of claim 20, wherein at least one of the first member and the second member includes structure adapted to retain bone therein.

15 31. A method comprising:

providing a distractible intervertebral body fusion device, the device including a first bearing surface configured to interface with an end plate of a superior vertebra of an intervertebral disc space, a second bearing surface configured to interface with an end plate of an inferior vertebra of the intervertebral disc space, and at least one coaxial screw gear sleeve mechanism disposed between the first bearing surface and the second bearing surface, the
20 coaxial screw gear sleeve mechanism including a threaded post, a corresponding sleeve having an interior thread mating with the threaded post and an exterior gear mating with a drive mechanism;

providing instructions for performing an intervertebral body fusion and distraction
25 procedure with the distractible intervertebral body fusion device, the instructions comprising:

inserting the distractible intervertebral body fusion device in a compressed configuration into an intervertebral disc space of a patient defined between adjacent vertebrae such that the first bearing surface interfaces with an end plate of a superior vertebra of the intervertebral disc space and the second bearing surface interfaces with an
30 end plate of an inferior vertebra of the intervertebral disc space;

distracting the device into an expanded configuration by operating the drive mechanism to rotate the sleeve relative to the post, thereby expanding the first bearing surface with respect to the second bearing surface to distract the end plate of the superior vertebra relative to the end plate of the inferior vertebra of the intervertebral disc space.

32. The method of claim 31, wherein the step of operating the drive mechanism to rotate the sleeve relative to the post causes the sleeve to distract relative to the second bearing surface and the post to simultaneously distract relative to the second bearing surface and the sleeve.

5

33. The method of claim 31, wherein the step of operating the drive mechanism comprises rotating a worm drive having a threaded section that interfaces with the exterior gear of the sleeve.

10 34. The method of claim 31, further comprising providing a delivery system and the instructions further comprise connecting the delivery system to the device and inserting the device with the delivery system.

15 35. The method of claim 34, wherein the step of distracting the device includes rotating a delivery shaft of the delivery system to rotate the drive mechanism.

36. A size-adjustable implant positionable between adjacent first and second vertebral bodies, the implant comprising:

a first member, sized and shaped to contact the first vertebral body;

a second member, sized and shaped to contact the second vertebral body; and

a size-adjustable support, engaging the first and second members to provide an adjustable separation distance between the first and second members, the support comprising commonly-actuated, coaxial first and second axially rotatable joints to provide the adjustable separation distance.

37. The implant of claim 36, wherein the support comprises a sleeve member with one of:

an external thread including a plurality of superimposed teeth and an internal thread; or

an internal thread including a plurality of superimposed teeth and an external thread.

38. The implant of claim 37, wherein one of the internal thread and the external thread of the sleeve member engages a mating thread located on or coupled to the first member to provide the first joint; and

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wherein the other of the internal thread and the external thread of the sleeve member engages a mating thread located on or coupled to the second member to provide the second joint.

39. The implant of claim 38, wherein the mating thread of the first member includes a threaded lumen within the first member, and wherein the mating thread of the second member includes a post member including a thread.

40. The implant of claim 39, wherein the post member is rotationally mounted, on a first end, with the internal thread of the sleeve member and fixedly mounted, on a second end, to the second member.

41. The implant of claim 37, wherein the external thread is of a first hand and the internal thread is of a second opposite hand.

42. The implant of claim 37, wherein the teeth are formed by removing a portion of the thread on which they are superimposed to a depth less than a root depth of the thread.

43. The implant of claim 37, wherein the teeth include a trapezoidal shape.

44. The implant of claim 37, wherein a pitch of the external thread is different than a pitch of the internal thread.

5

45. The implant of claim 37, comprising a drive member configured to engage the teeth of the sleeve member.

46. The implant of claim 45, wherein rotation of the drive member causes the sleeve member to axially displace in a first direction relative to the first member, and causes a post member to axially displace in the first direction relative to the sleeve member.

47. The implant of claim 36, wherein the support comprises a first and a second sleeve member, the first sleeve member rotationally mounted in a first threaded lumen within the first member and the second sleeve member rotationally mounted in a second, substantially parallel threaded lumen within the first member.

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48. The implant of claim 47, wherein the first sleeve member includes an external thread of a first hand and including a plurality of superimposed teeth, and an internal thread of a second opposite hand; and

wherein the second sleeve member includes an external thread of the second opposite hand and including a plurality of superimposed teeth, and an internal thread of the first hand.

49. The implant of claim 48, comprising a drive member including a first and a second threaded section, the first threaded section including a thread of a first hand and engageable with the teeth of the first sleeve member, and the second threaded section including a thread of a second opposite hand and engageable with the teeth of the second sleeve member.

50. The implant of claim 36, wherein the second member is configured to move from a first position, adjacent to the first member, to a second position spaced from the first member.

51. The implant of claim 50, comprising a height of less than or equal to about 6.5 millimeters in the first position and a height of at least 12 millimeters in the second position.

52. The implant of claim 38, wherein a portion of the size-adjustable support extends through an outer surface in one of the first member or second member.

5

53. The implant of claim 38, wherein at least one of the first member and the second member includes structure adapted to retain bone therein.

54. A size-adjustable implant positionable between adjacent first and second vertebral bodies, the implant comprising:

a first member, sized and shaped to contact the first vertebral body;

a second member, sized and shaped to contact the second vertebral body;

a size-adjustable support, engaging the first and second members to provide an adjustable separation distance between the first and second members, the support comprising a first sleeve or post member and a second sleeve or post member, each of the sleeve or post members having one of an external helical thread including a plurality of superimposed teeth or an internal helical thread including a plurality of superimposed teeth; and

a drive member configured to engage the teeth of the first and second sleeve or post members.

55. The implant of claim 54, wherein rotation of the drive member causes the first and second sleeve or post members to axially displace in a first direction relative to the first member.

56. The implant of claim 54, wherein the drive member includes a first and a second threaded section, the first threaded section including a helical thread of a first hand and engageable with the teeth of the first sleeve or post member, and the second threaded section including a helical thread of a second opposite hand and engageable with the teeth of the second sleeve or post member.

57. The implant of claim 54, wherein the second member is configured to move from a first position, adjacent to the first member, to a second position spaced from the first member.

58. The implant of claim 57, comprising a height of less than or equal to about 6.5 millimeters in the first position and a height of at least 12 millimeters in the second position.

59. A distractible intervertebral body fusion device adapted for implantation into an intervertebral disc space of a patient having a first bearing surface configured to interface with an end plate of a superior vertebra of the intervertebral disc space and a second bearing surface configured to interface with an end plate of an inferior vertebra of the intervertebral disc space, further characterized in that the device includes:

at least one coaxial screw gear sleeve mechanism disposed between the first bearing surface and the second bearing surface, the coaxial screw gear sleeve mechanism including:

10 a post having a threaded exterior surface on a portion of the post projecting inwardly from one of the first bearing surface and the second bearing surface; and

a corresponding sleeve configured to surround the post and having:

a threaded interior surface on a portion of the sleeve projecting inwardly from the other of the first bearing surface and the second bearing surface and configured to interface with the threaded exterior surface of the post; and

15 a geared exterior surface on a portion of the sleeve; and

a drive mechanism having a surface configured to interface with and drive the geared exterior surface of the sleeve,

such that selective operation of the drive mechanism causes a distraction of the first bearing surface and the second bearing surface with respect to the superior vertebra and the inferior vertebra of the intervertebral disc space.

5 60. The distractible device of claim 59, wherein the geared exterior surface of the sleeve has a screw pitch orientation generally opposite of a screw pitch orientation of the threaded exterior surface of the post and the threaded interior surface of the sleeve.

10 61. The distractible device of claim 59, wherein there are a pair of coaxial screw gear sleeve mechanisms disposed between the first bearing surface and the second bearing surface that are driven by a common drive mechanism.

15 62. The distractible device of claim 61, wherein the threaded interior surface and geared exterior surface of the sleeve of one of the coaxial screw gear sleeve mechanisms have a screw pitch orientation generally opposite of a screw pitch orientation of the threaded interior surface and geared exterior surface of the other coaxial screw gear sleeve mechanism.

63. The distractible device of claim 59, wherein the drive mechanism is a worm drive.

20 64. The distractible device of claim 61, wherein the drive mechanism is a worm drive having a pair of threaded sections, each threaded section configured to interface with one of the coaxial screw gear sleeve mechanisms.

25 65. The distractible device of claim 59 or 61, wherein the drive mechanism is translationally stationary as the drive mechanism drives the geared exterior surface of the sleeve.

30 66. The distractible device of claim 59, wherein the first bearing surface is an outer surface of a first member and the second bearing surface is an outer surface of a second member, and wherein the sleeve fits within a sleeve opening in the one of the first member or second member corresponding to the bearing surface from which the sleeve projects, such that the geared exterior surface of the sleeve interfaces with an internal thread in the sleeve opening.

67. The distractible device of claim 66, wherein the drive mechanism interfaces with the geared exterior surface of the sleeve through an aperture in the internal thread of the sleeve opening.

5 68. The distractible device of claim 59, wherein a portion of the sleeve also projects outwardly through the other of the first bearing surface and the second bearing surface.

69. A method of using the distractible device of claim 59 to perform an intervertebral body distraction and fusion, comprising:

10 providing the distractible device; and
providing instructions for performing an intervertebral body fusion and distraction with the apparatus, the instructions comprising:

15 inserting the distractible intervertebral body fusion device in a compressed configuration into an intervertebral disc space of a patient defined between adjacent vertebrae such that the first bearing surface interfaces with an end plate of a superior vertebra of the intervertebral disc space and the second bearing surface interfaces with an end plate of an inferior vertebra of the intervertebral disc space;

20 distracting the device into an expanded configuration by operating the drive mechanism to rotate the sleeve relative to the post, thereby expanding the first bearing surface with respect to the second bearing surface to distract the end plate of the superior vertebra relative to the end plate of the inferior vertebra of the intervertebral disc space.

70. The method of claim 69, wherein providing instructions for operating the drive mechanism to rotate the sleeve relative to the post provides instructions to cause the sleeve to
25 distract relative to the second bearing surface and the post to simultaneously distract relative to the second bearing surface and the sleeve.

71. The method of claim 69, wherein providing instructions for operating the drive mechanism provides instructions to rotate a worm drive having a threaded section that interfaces
30 with the exterior gear of the sleeve.

72. The method of claim 69, further comprising providing a delivery system and the instructions further comprise connecting the delivery system to the device and inserting the device with the delivery system.

73. The method of claim 72, wherein providing instructions for distracting the device provides instructions to rotate a delivery shaft of the delivery system to rotate the drive mechanism.

Fig. 1A

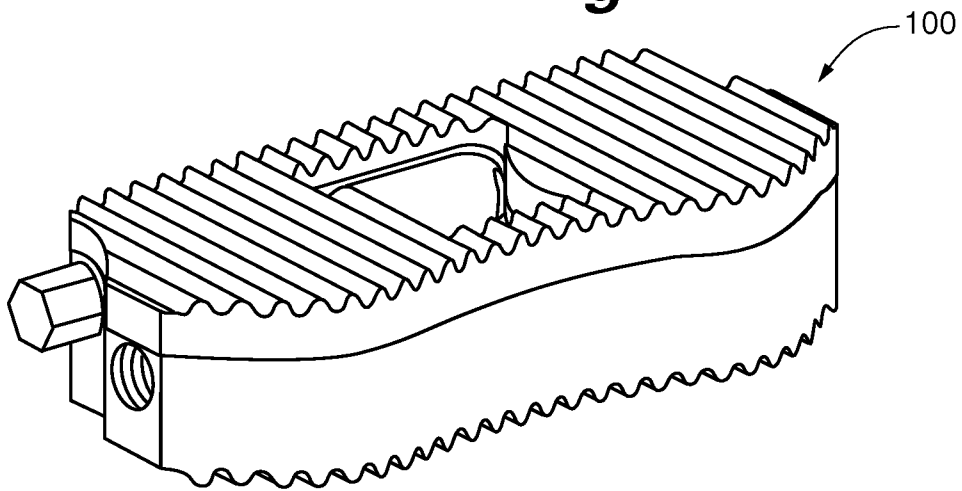
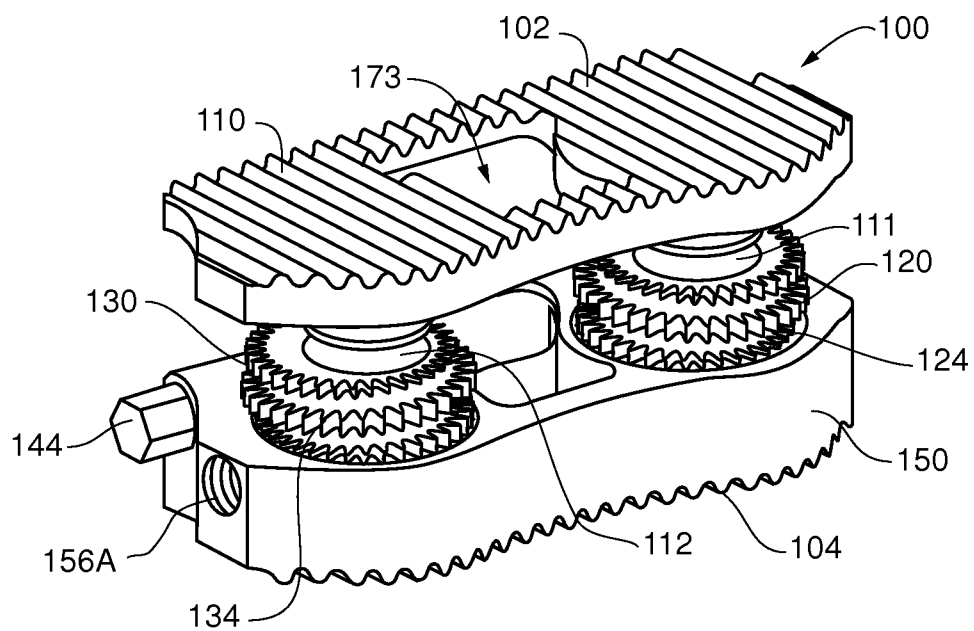
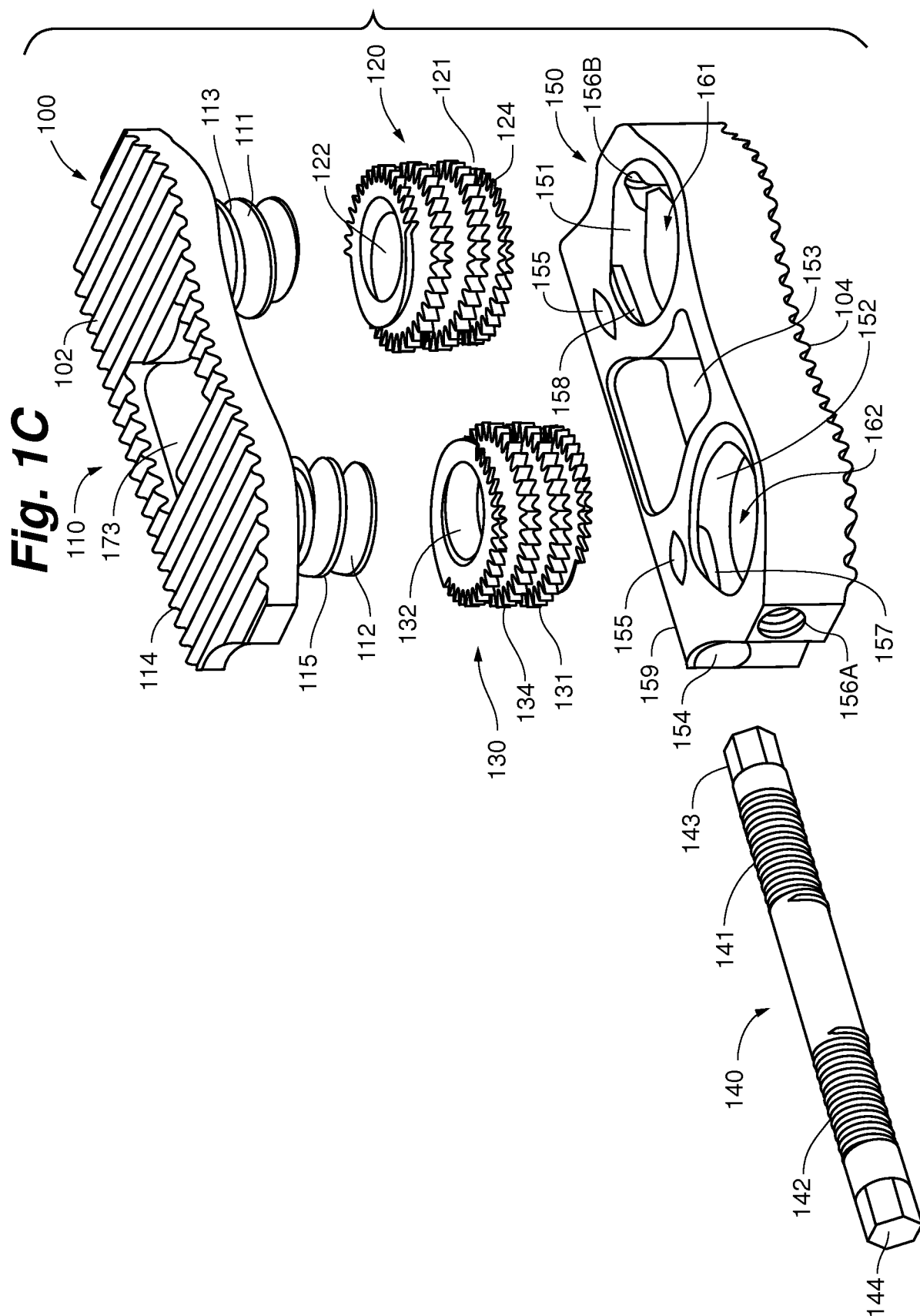


Fig. 1B





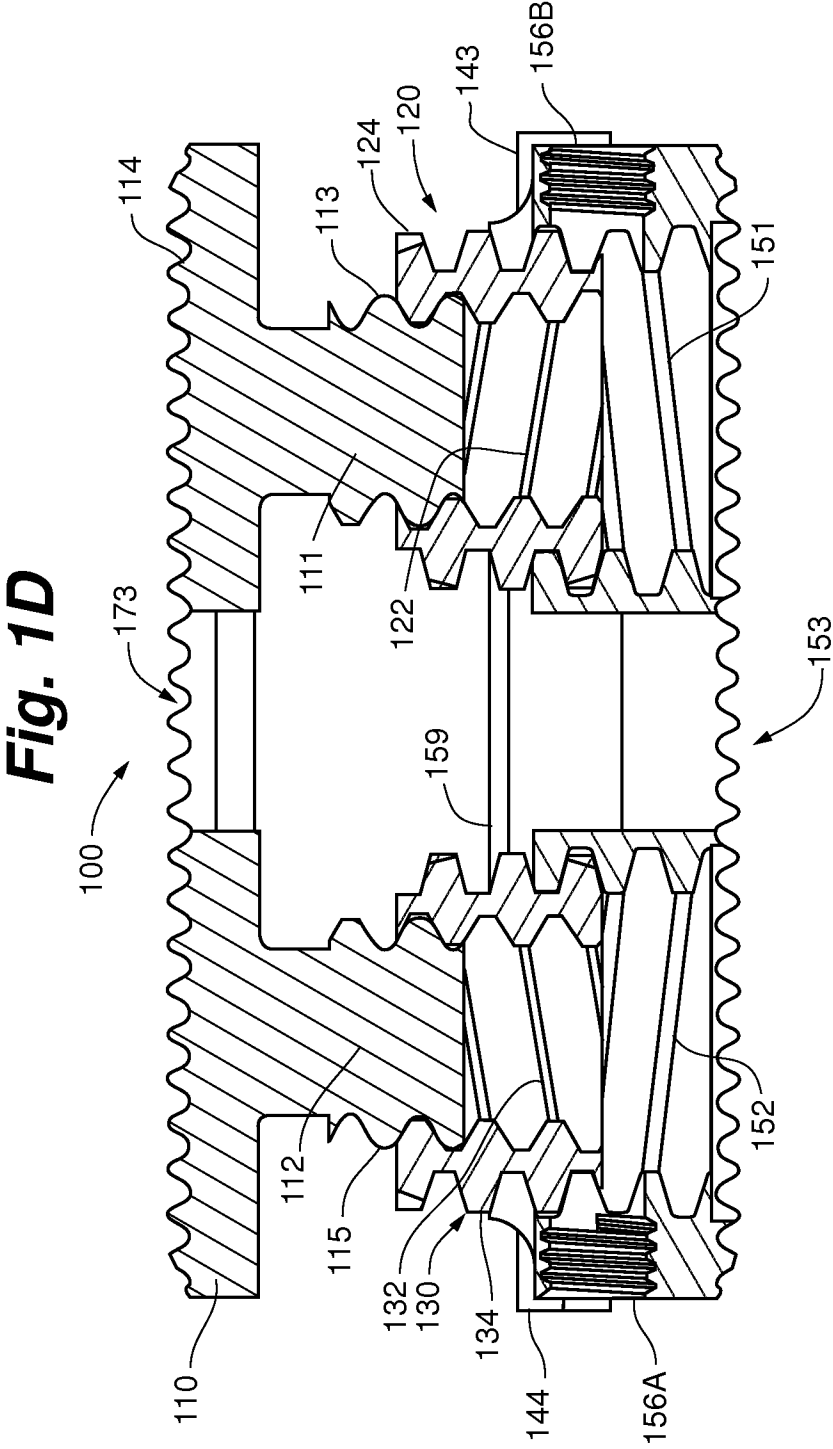


Fig. 2A

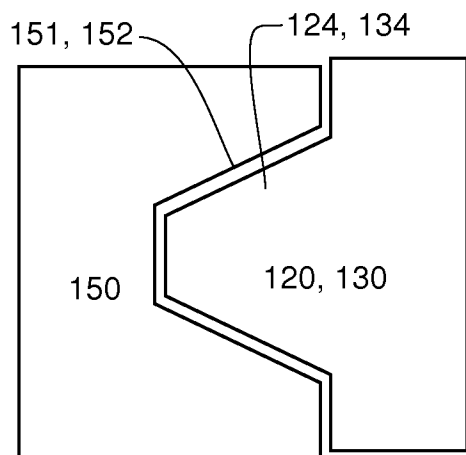


Fig. 2B

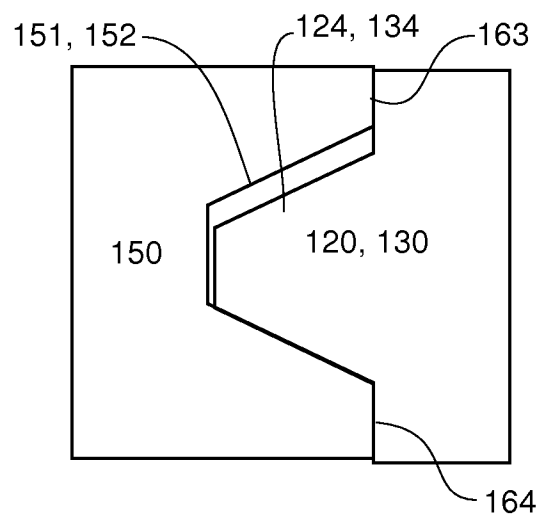


Fig. 3A

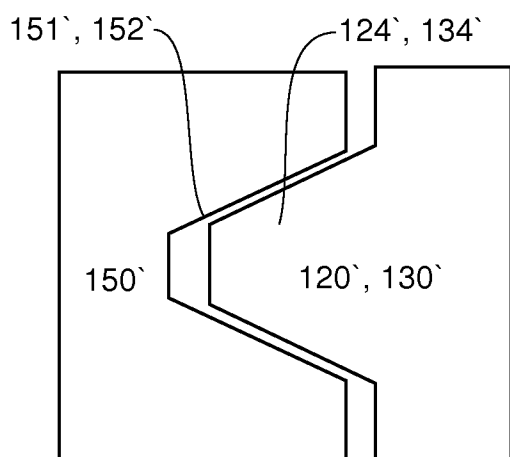
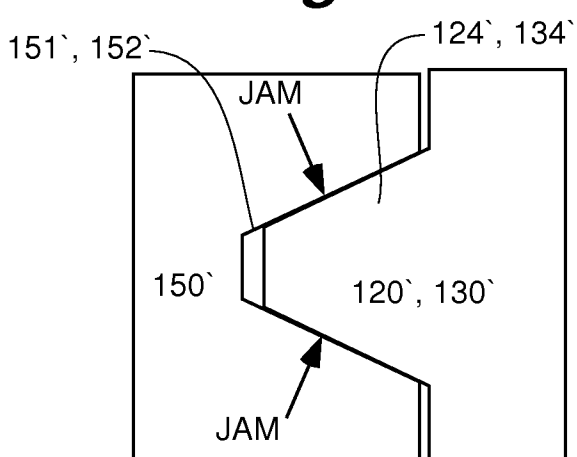
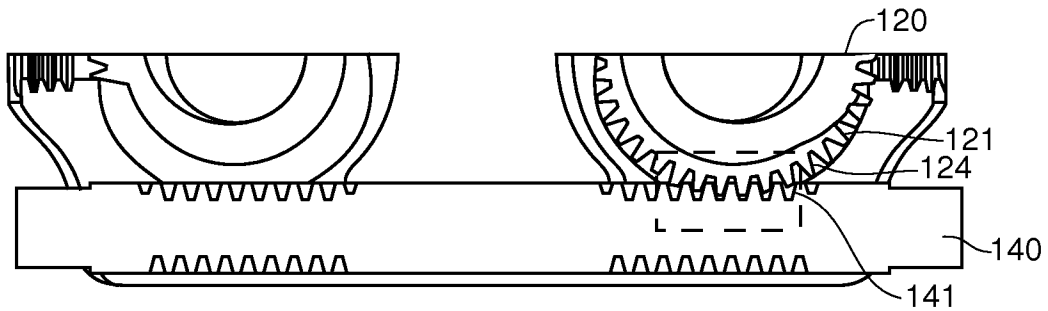
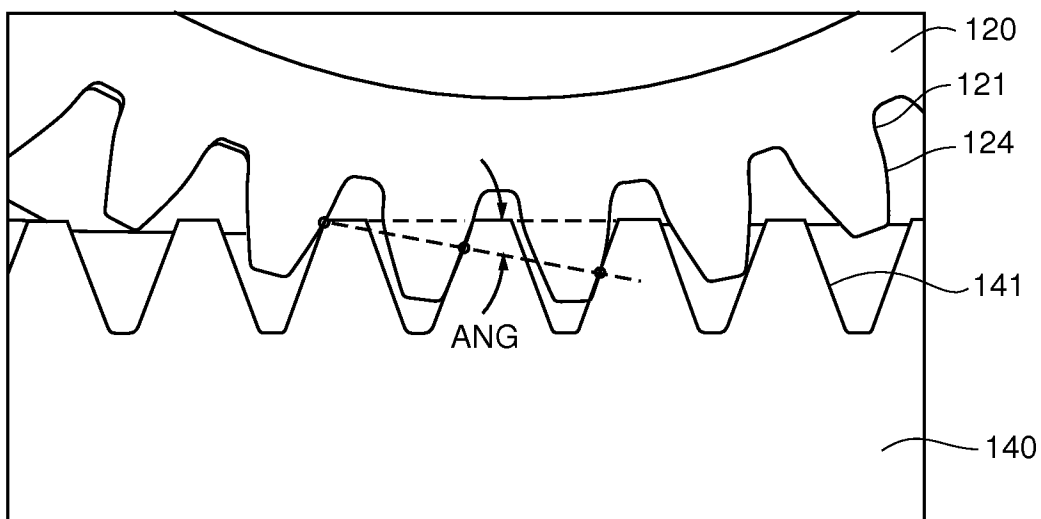


Fig. 3B



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Fig. 4A**Fig. 4B**

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Fig. 5A

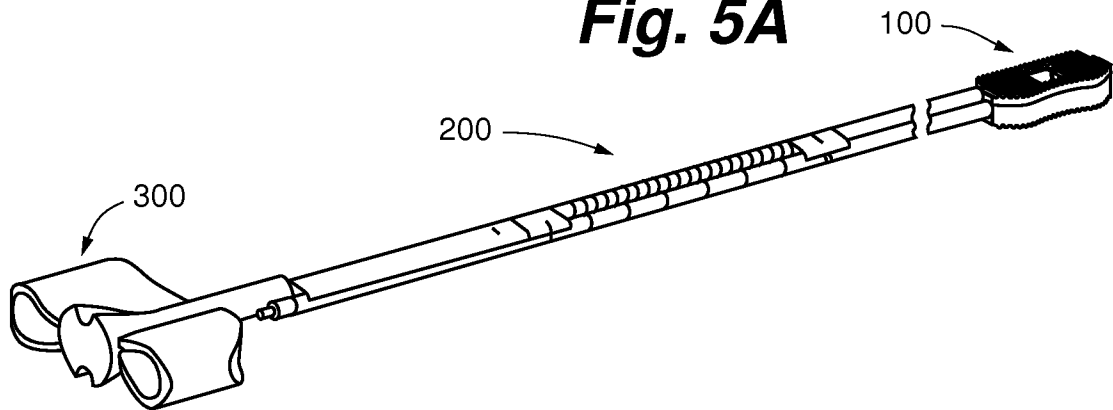


Fig. 5B

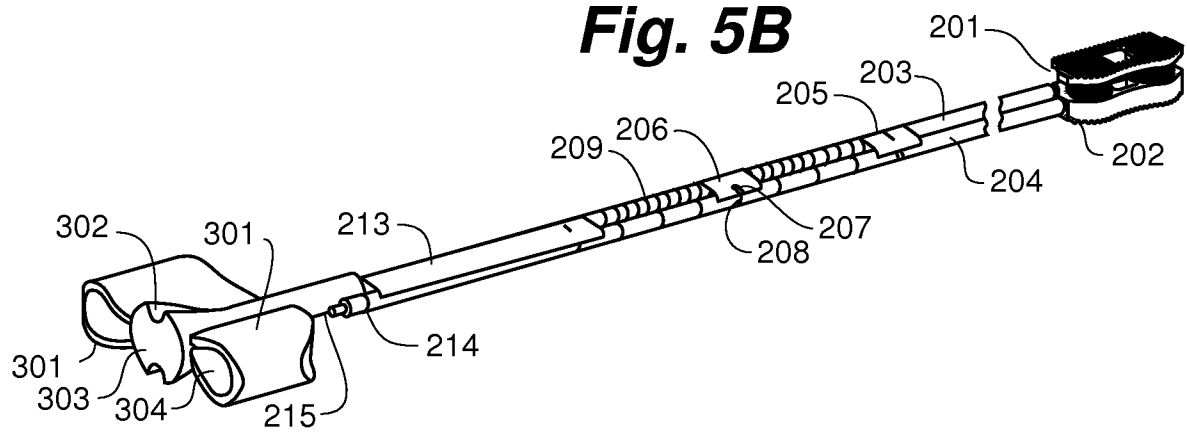
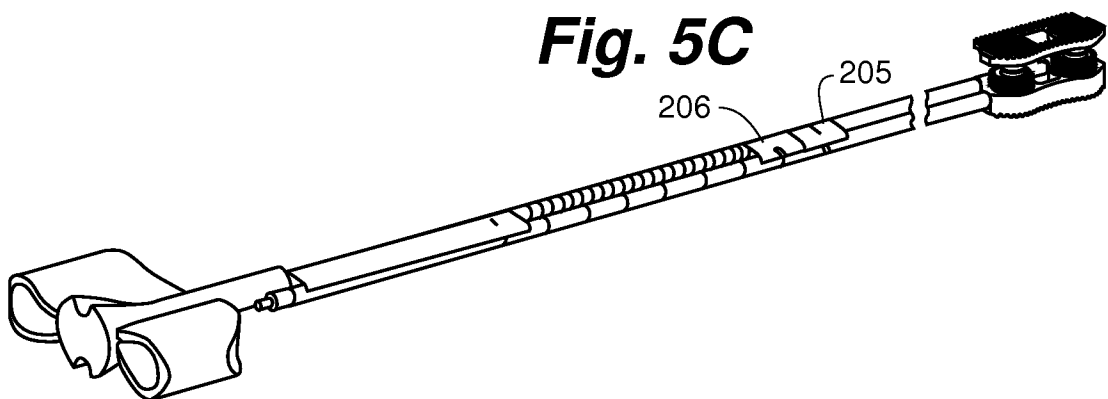
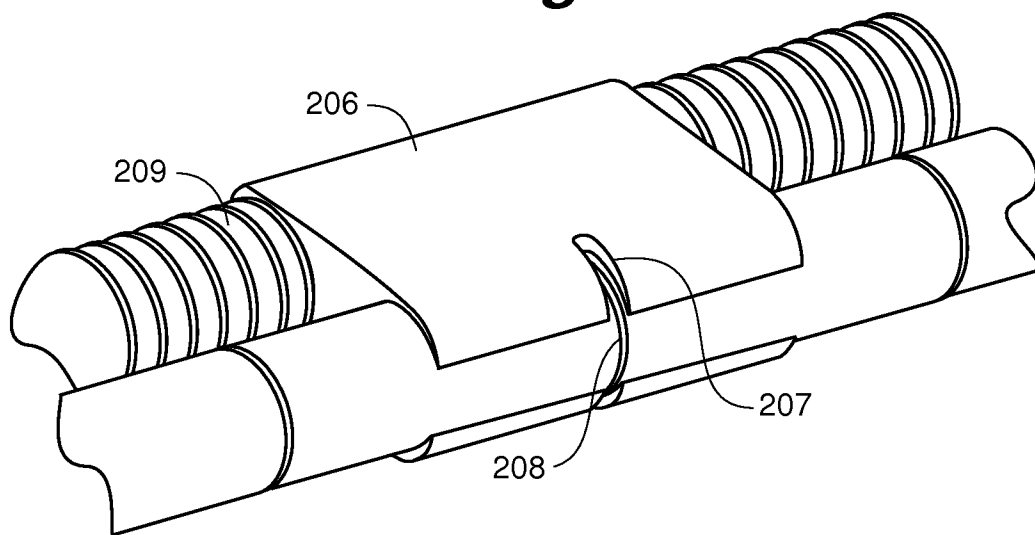


Fig. 5C

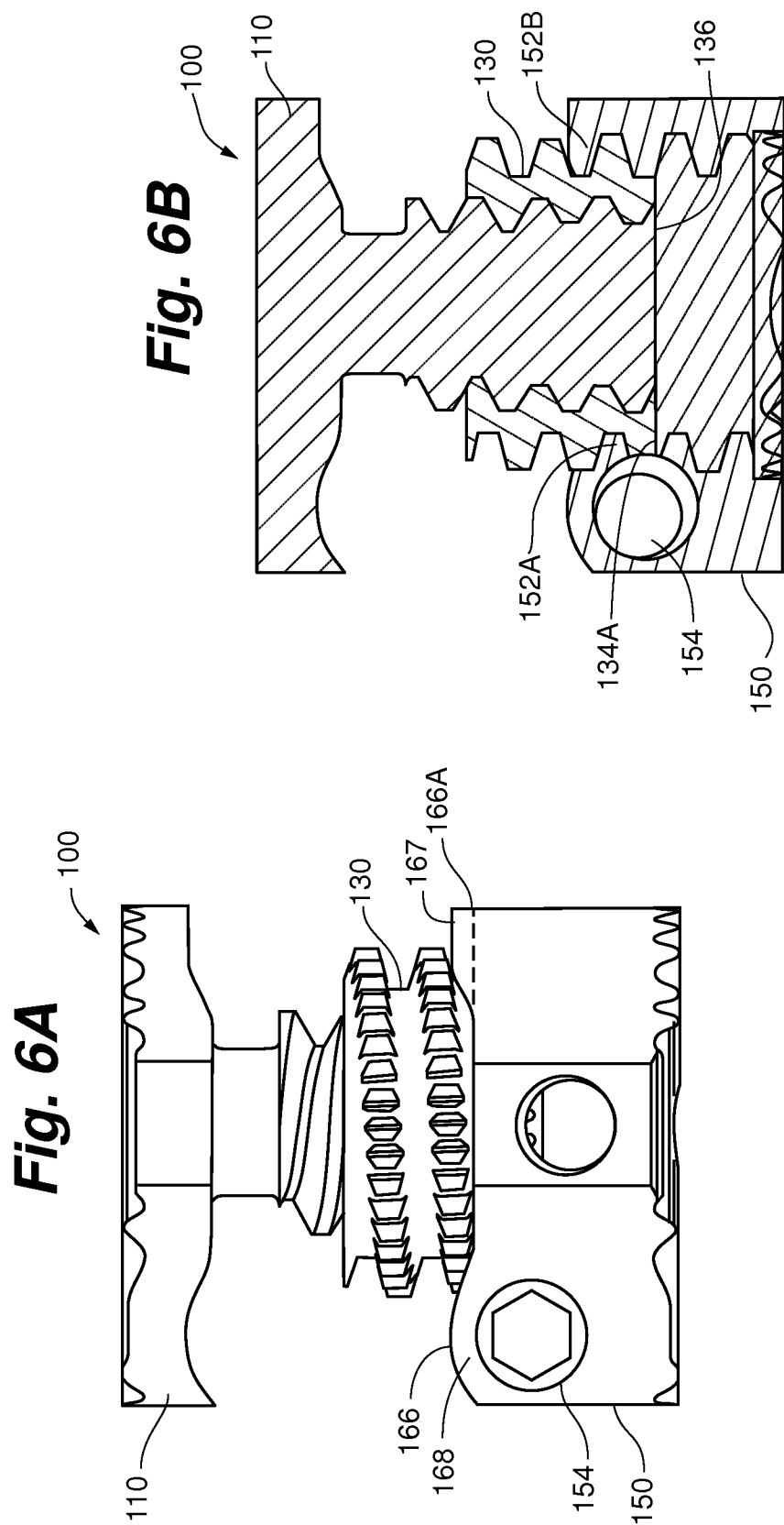


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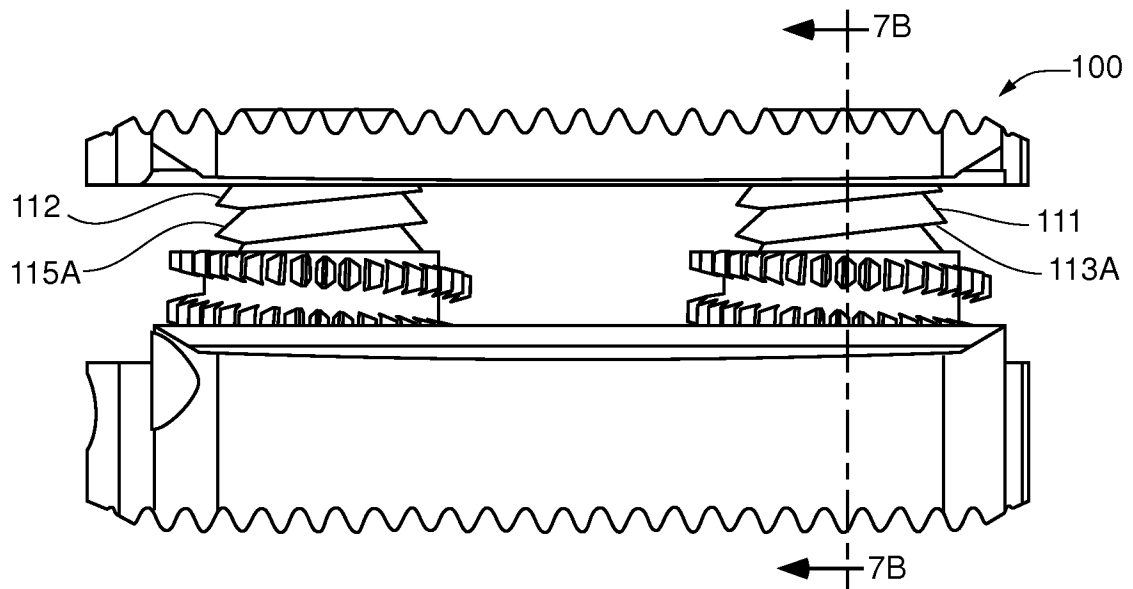
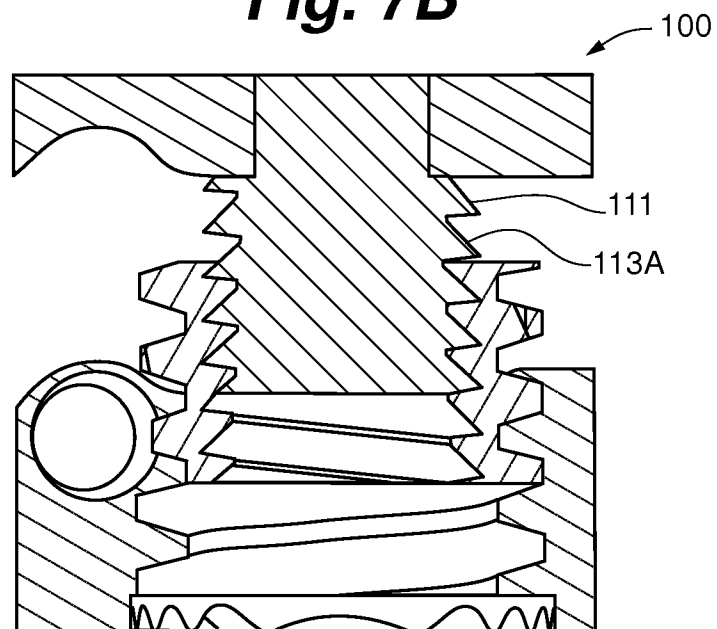
Fig. 5D



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Fig. 7A**Fig. 7B**

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Fig. 8A

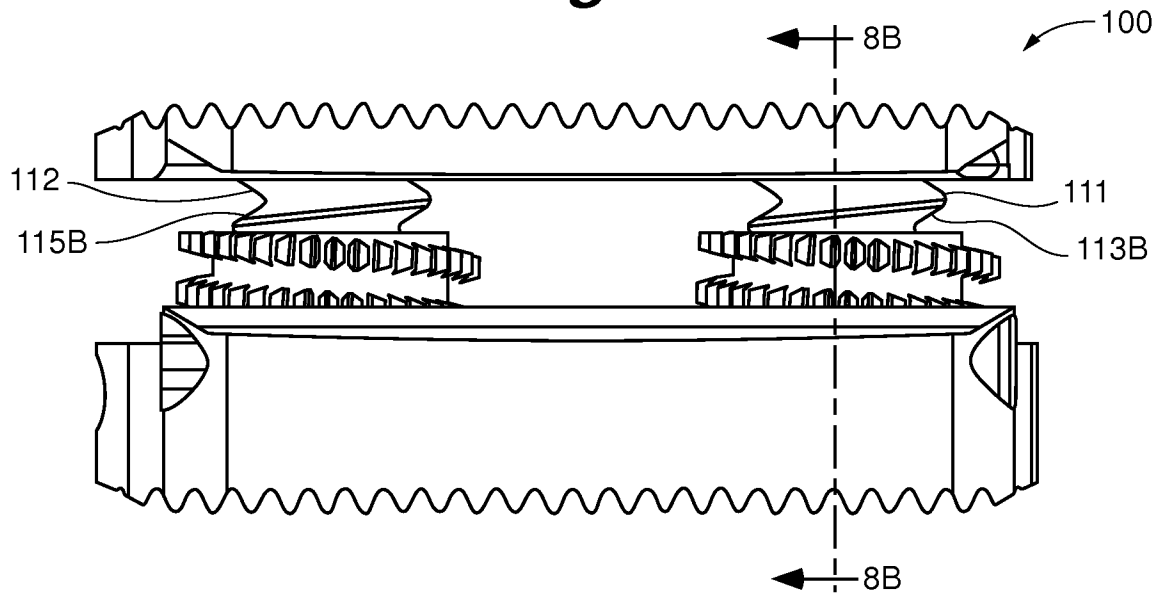
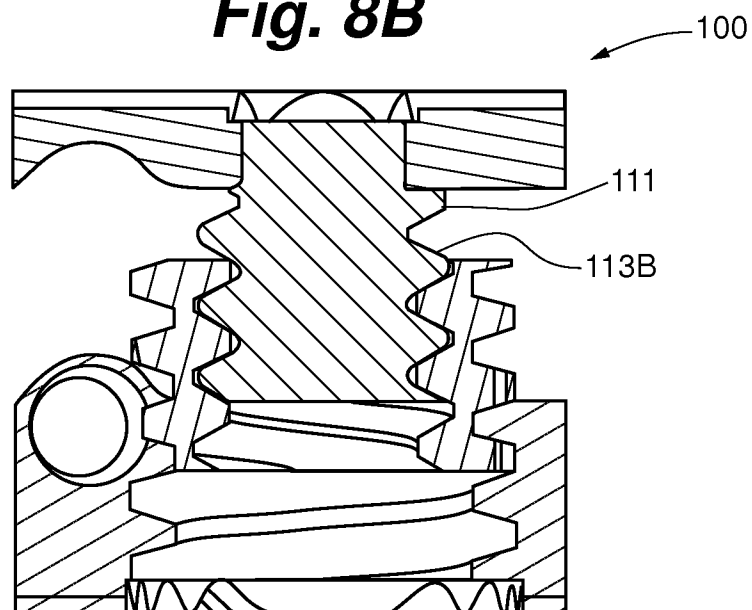
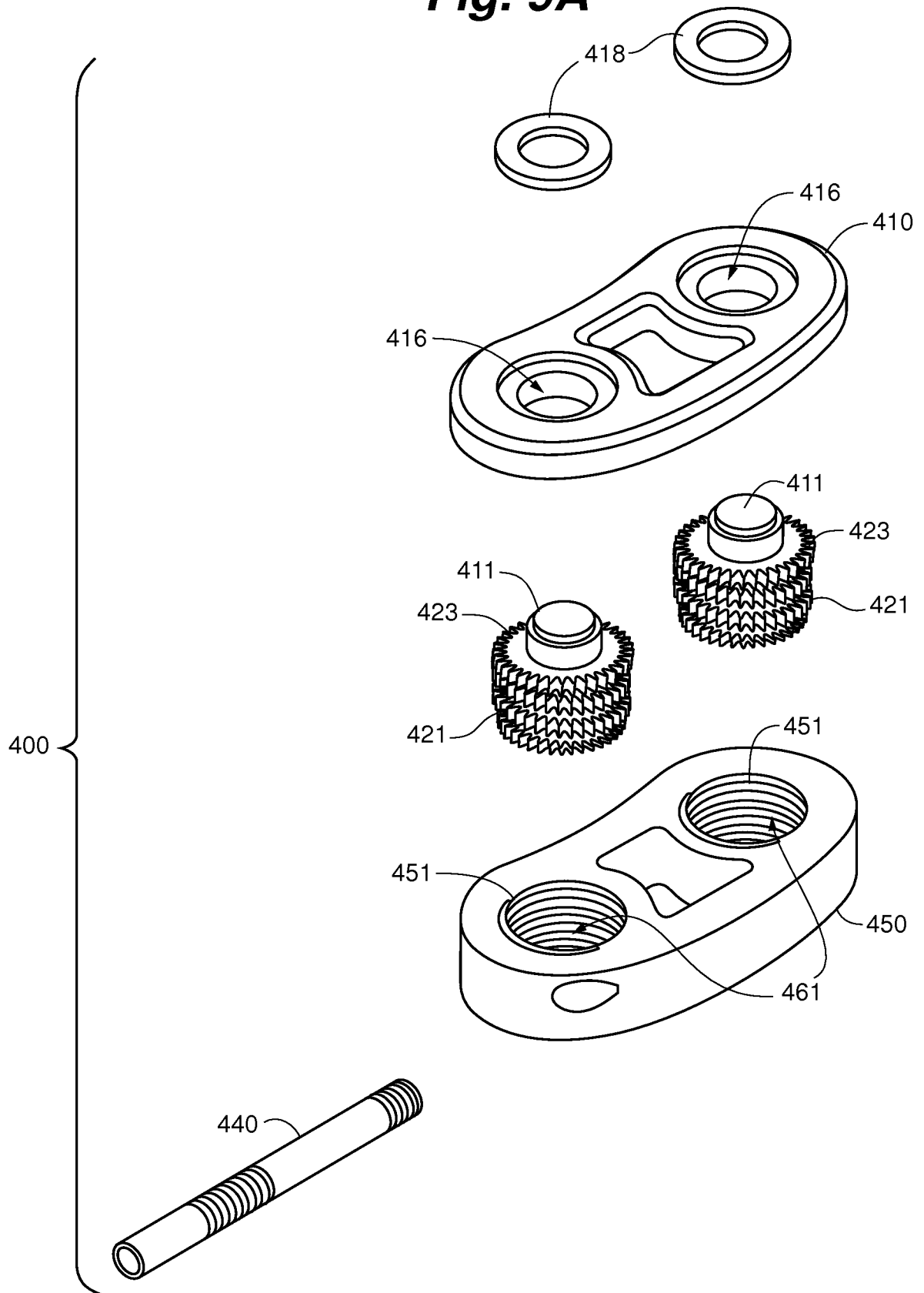


Fig. 8B



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Fig. 9A



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Fig. 9B

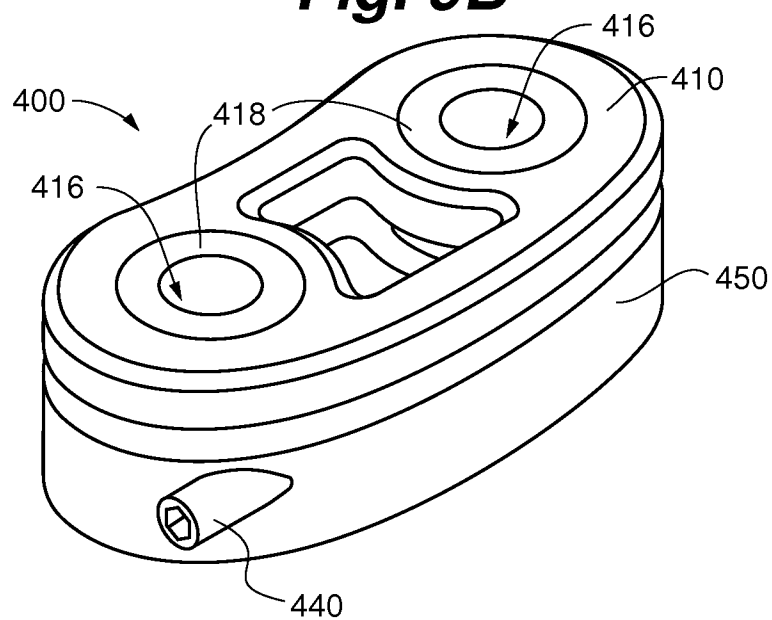


Fig. 9C

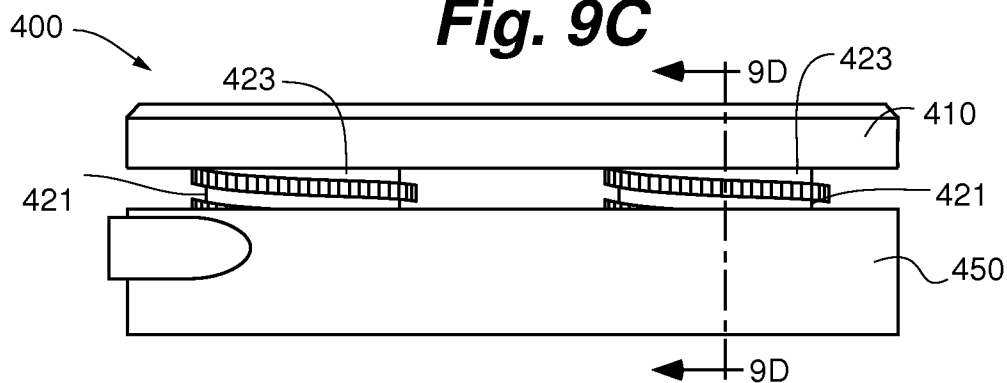
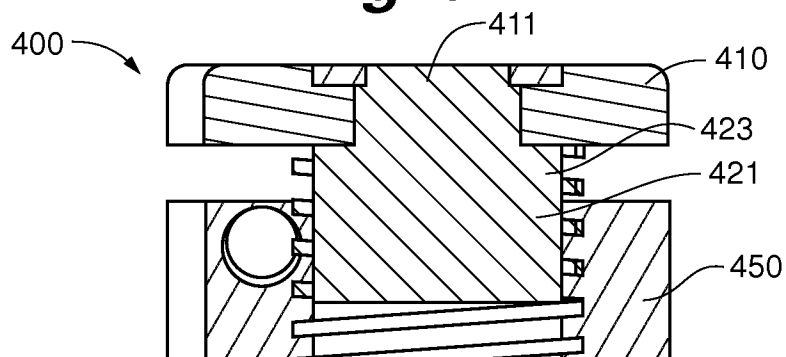
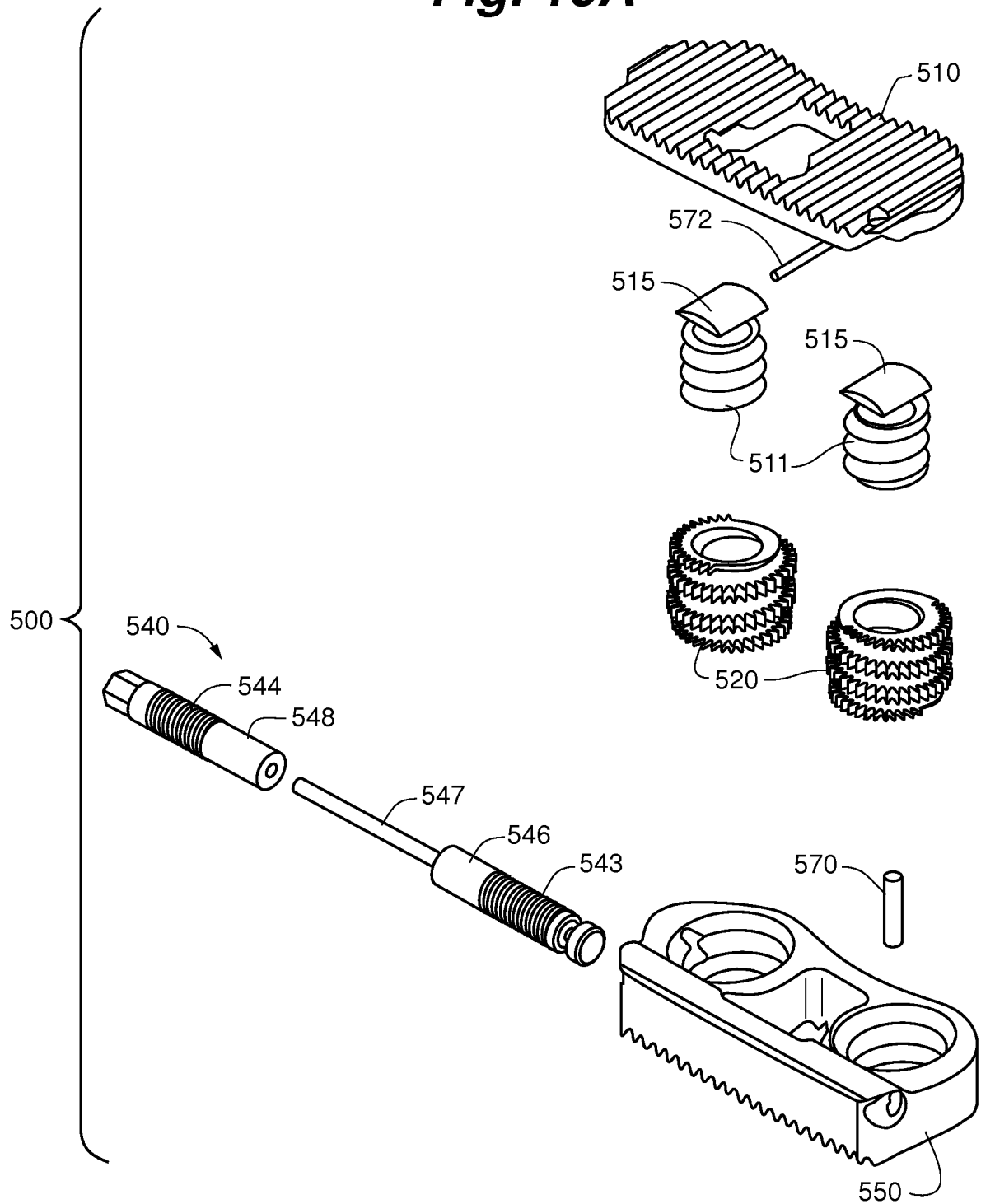


Fig. 9D



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Fig. 10A

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Fig. 10B

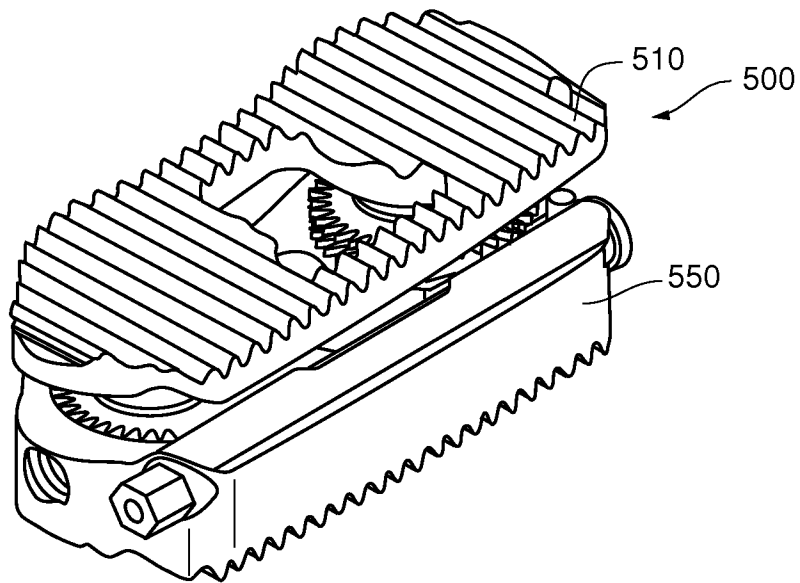


Fig. 10C

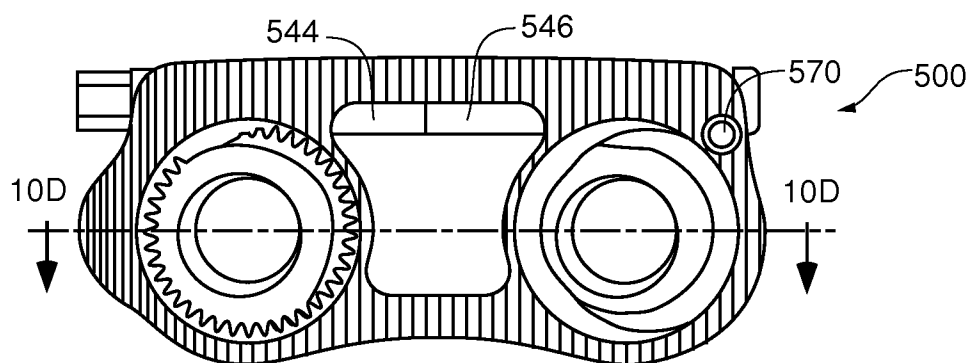
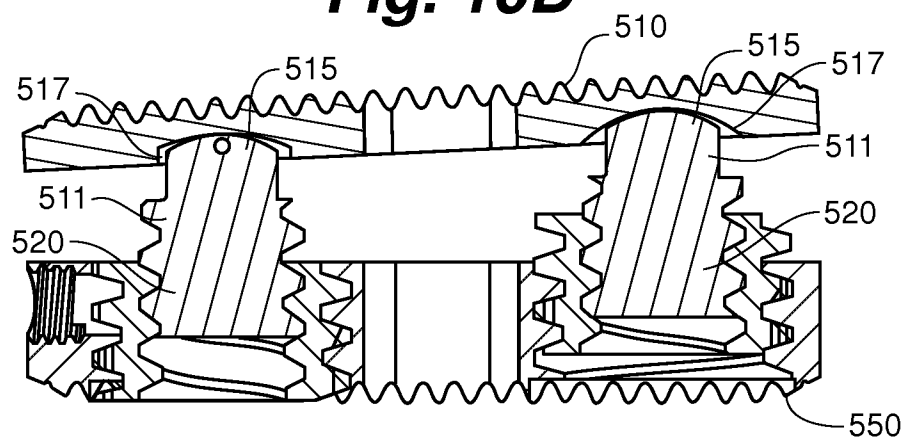


Fig. 10D



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Fig. 11A

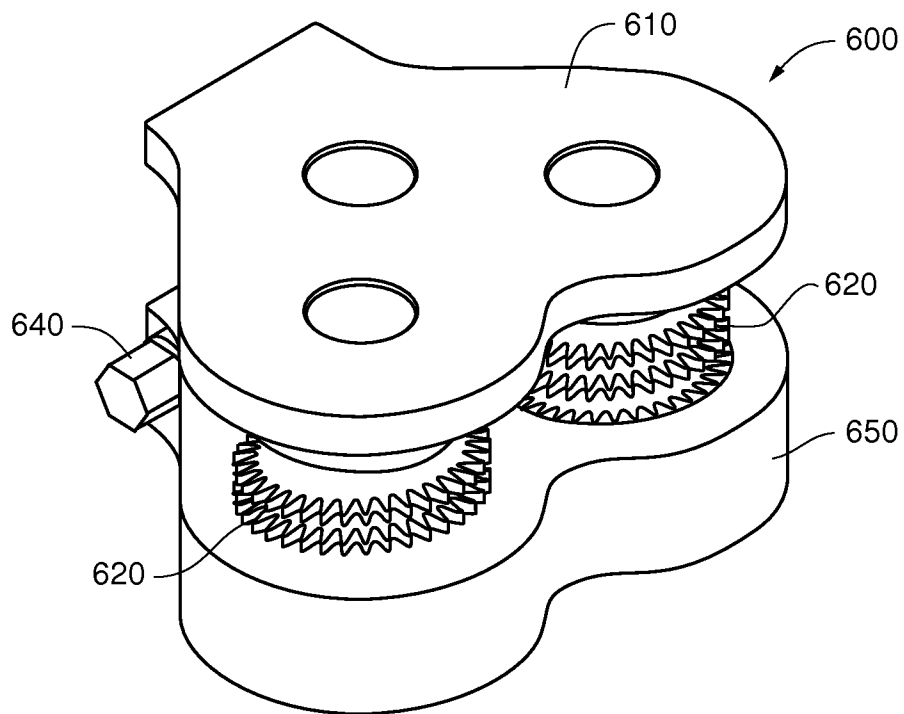
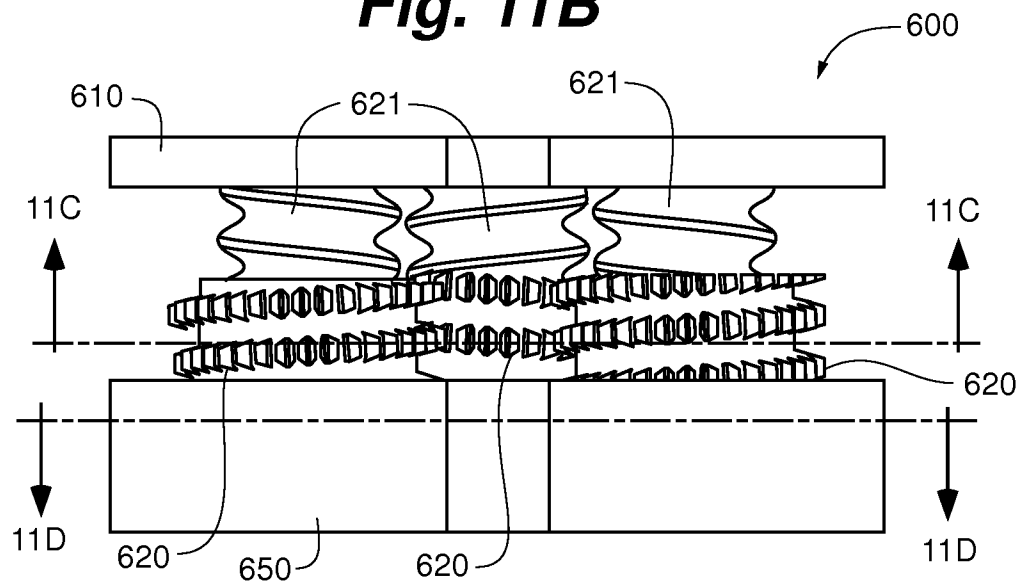


Fig. 11B



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Fig. 11C

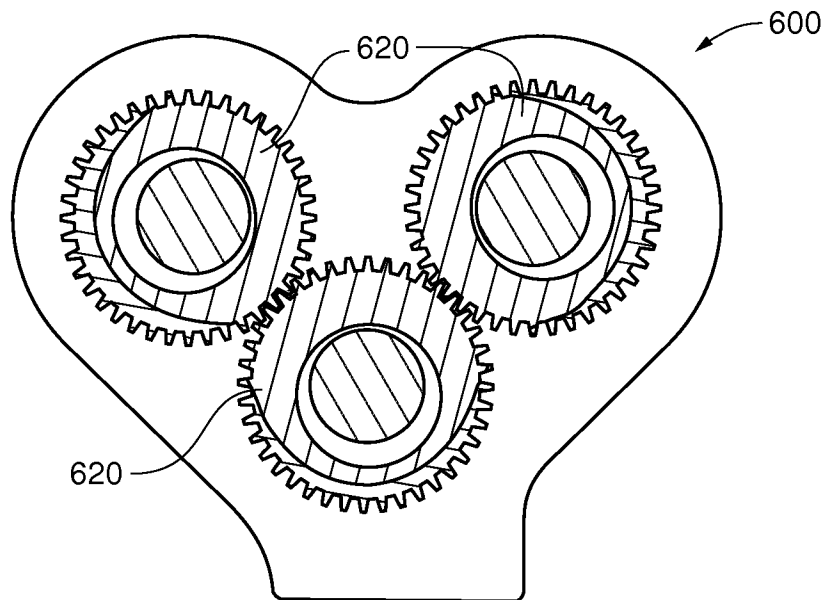
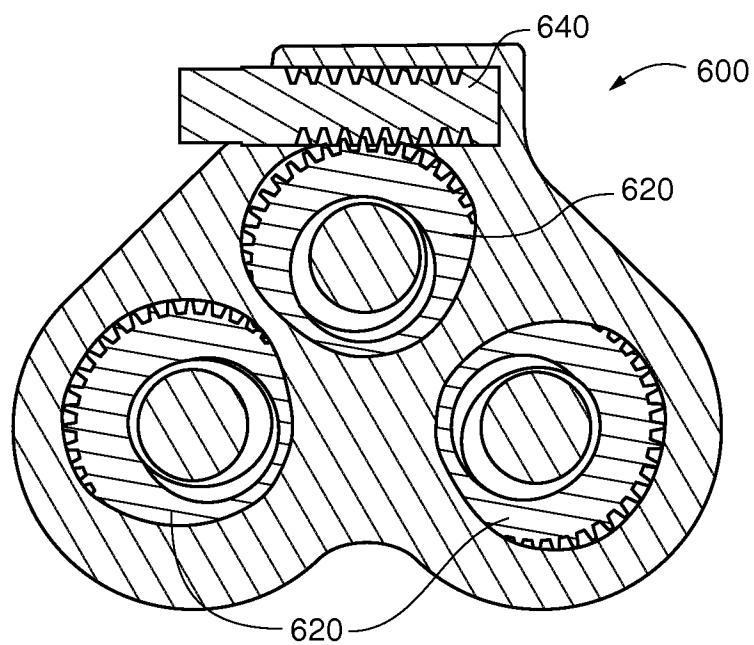


Fig. 11D



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Fig. 12A

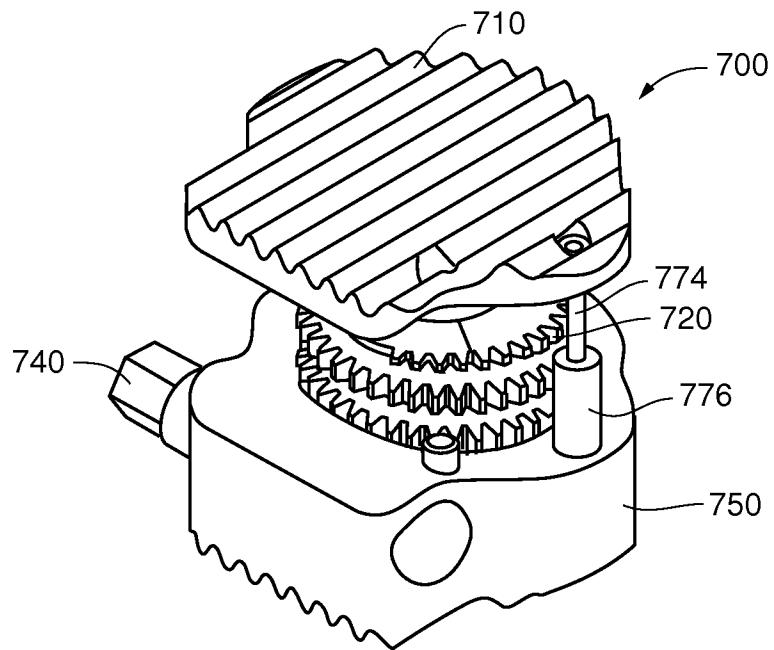
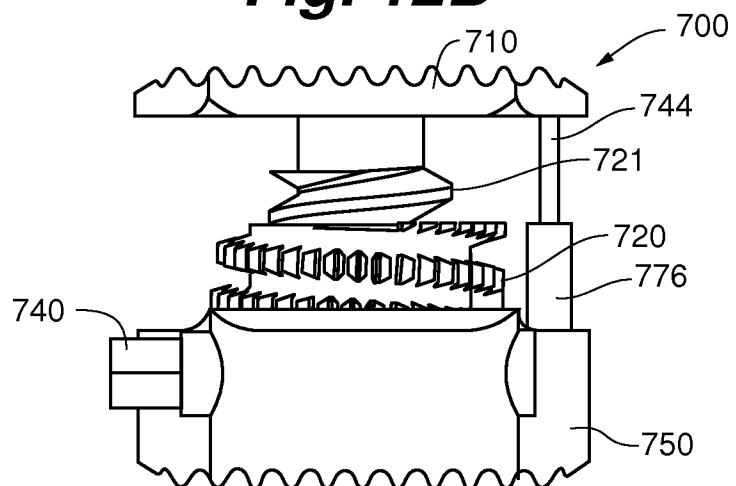


Fig. 12B



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Fig. 13A

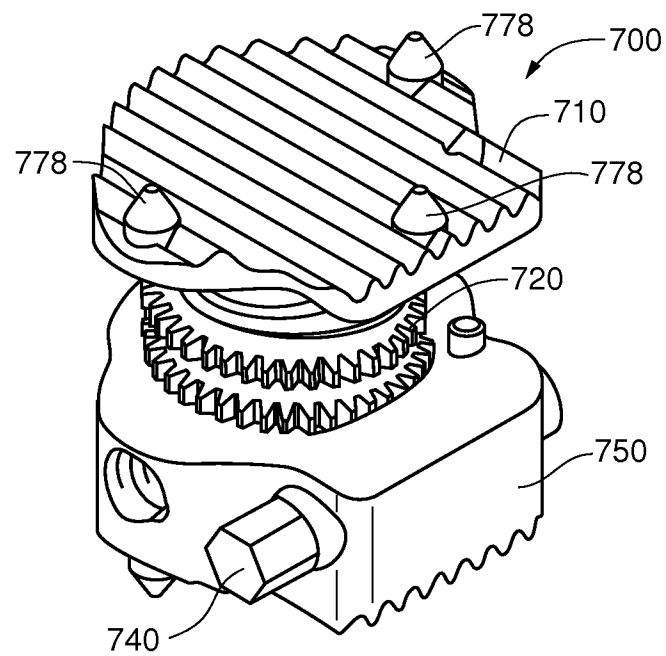


Fig. 13B

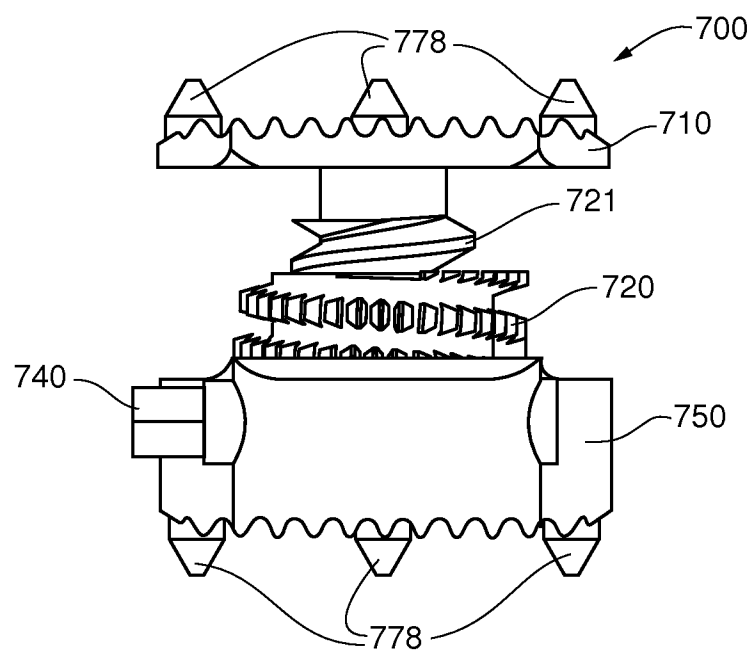


Fig. 14A

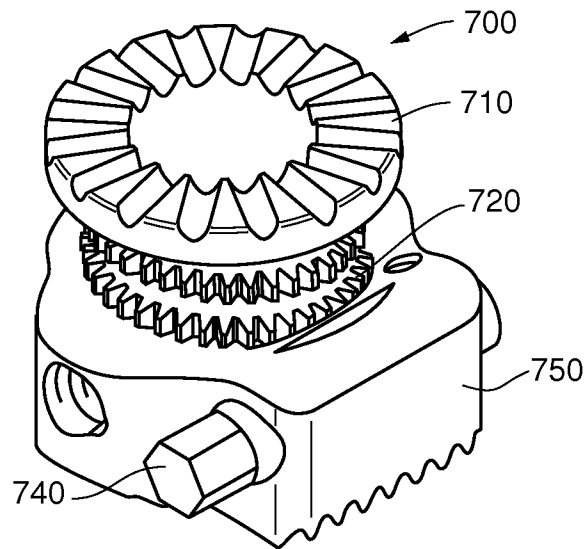


Fig. 14B

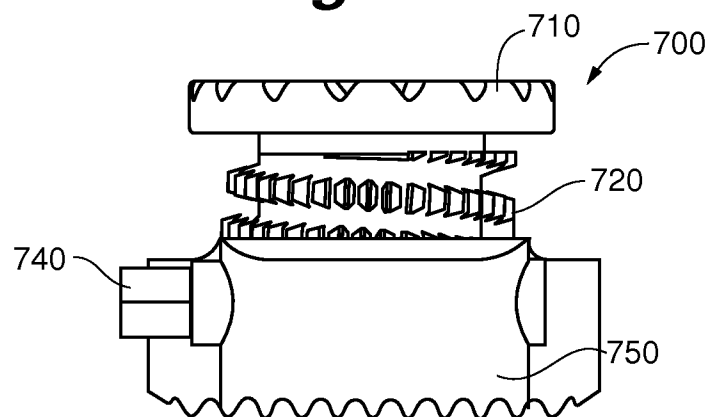
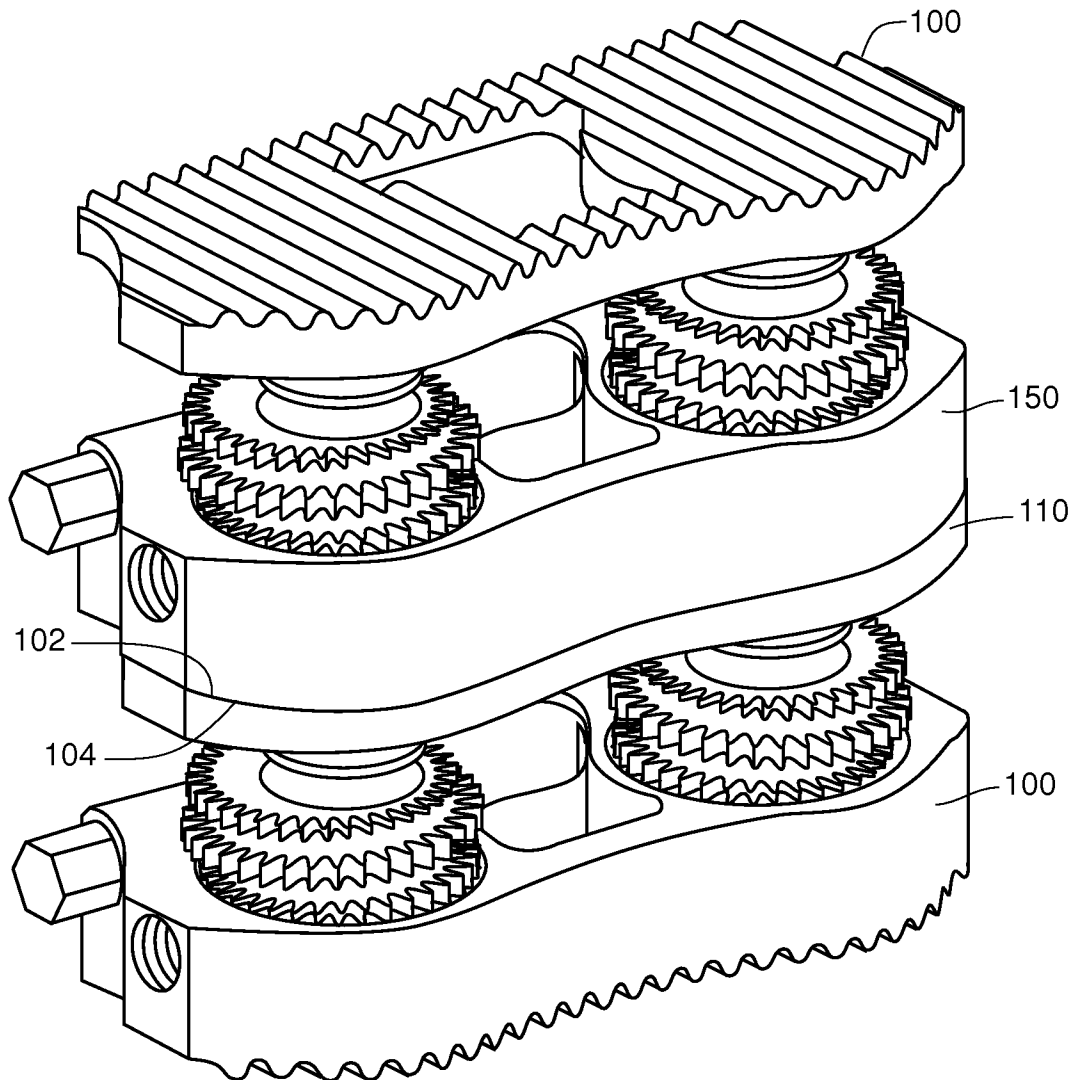
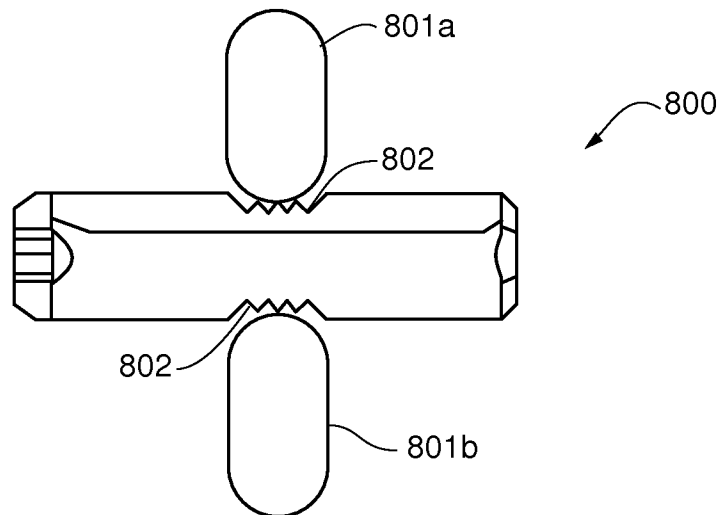
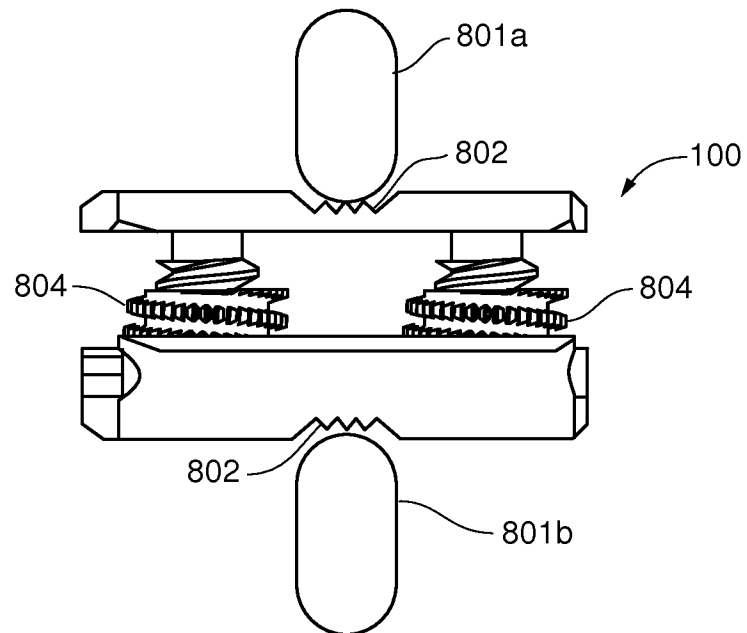


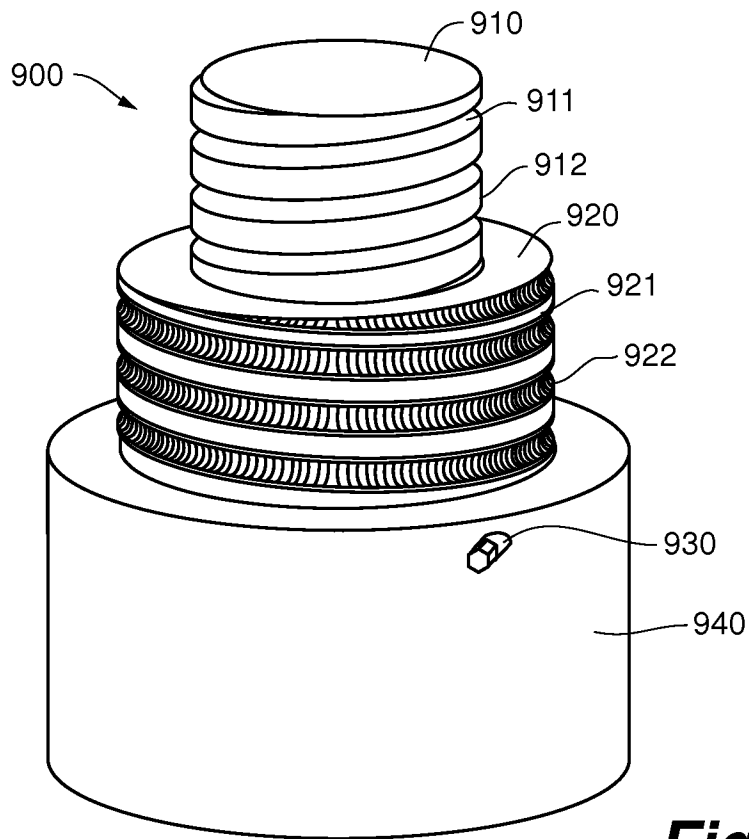
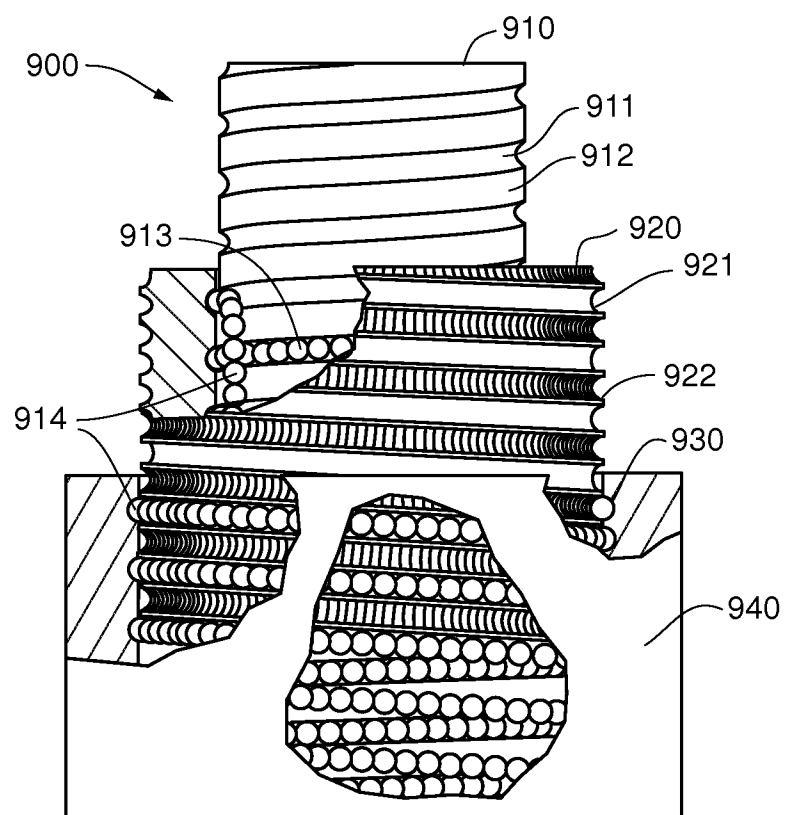
Fig. 15



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Fig. 16A**Fig. 16B**

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Fig. 17A**Fig. 17B**

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Fig. 18A

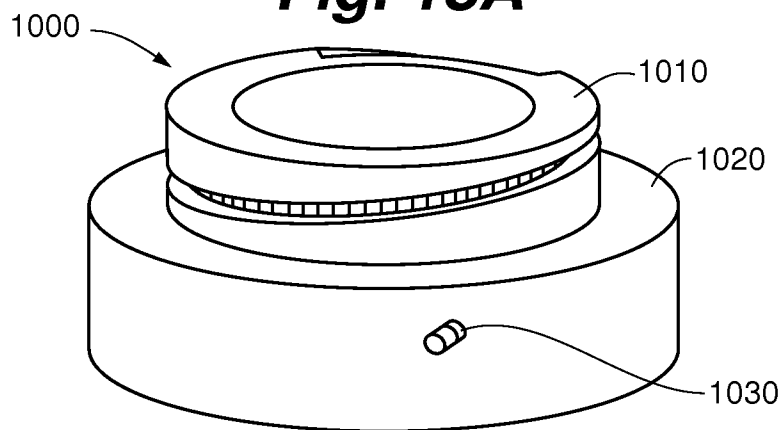


Fig. 18B

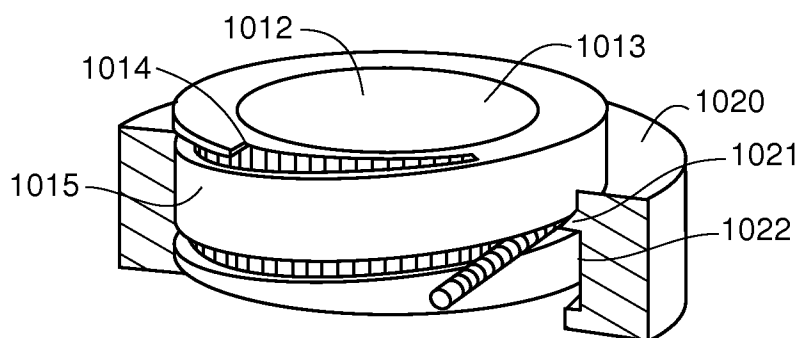


Fig. 18C

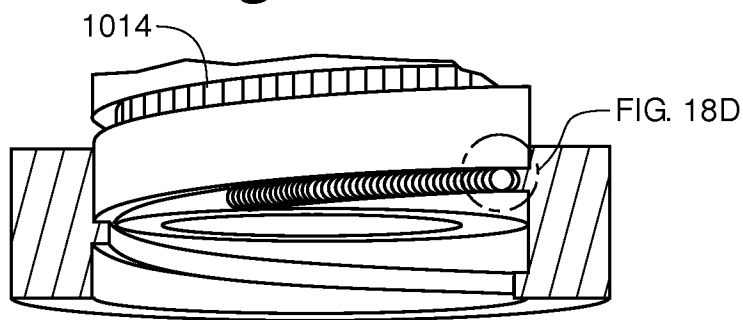


Fig. 18D

