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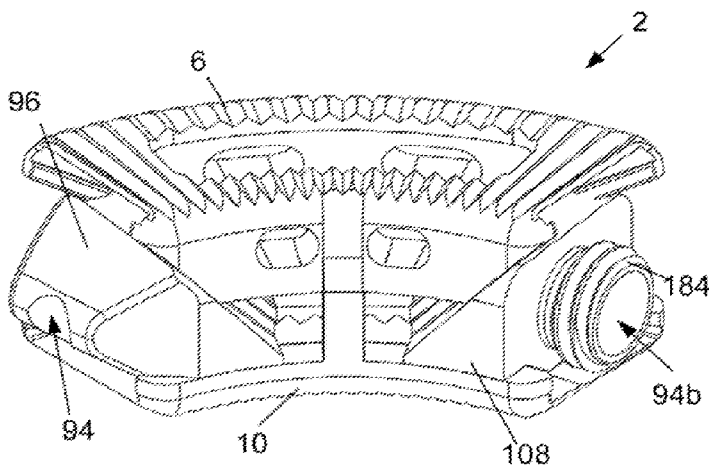


Fig. 49b

(57) Abstract: An implantable orthopedic stability device is disclosed. The device can have a contracted and an expanded configuration. A method of using the device between adjacent vertebral body surfaces for support and/or fixation of either or both of the adjacent vertebrae is also disclosed.



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TITLE OF THE INVENTION  
**FIXATION DEVICE AND METHOD**

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John-Paul Romano

BACKGROUND OF THE INVENTION

1. Technical field:

[0001] Devices and methods for fixation of tissue are disclosed. More specifically, the devices and methods can be for inter body vertebral fusion of vertebrae or fusion of other bones to one another.

2. Background of the Art:

[0002] A vertebroplasty device and method that eliminates or reduces the risks and complexity of the existing art is desired. A vertebroplasty device and method that may reduce or eliminate the need to inject a liquid directly into the compression fracture zone is also desired.

[0003] Other ailments of the spine result in degeneration of the spinal disc in the intervertebral space between the vertebral bodies. These include degenerative disc disease and traumatic injuries. In either case, disc degeneration can cause pain and other complications. . Conservative treatment can include non-operative treatment requiring patients to adjust their lifestyles and submit to pain relievers and a level of underlying pain. Operative treatment options include disc removal. This can relieve pain in the short term, but also often increases the risk of long-term problems and can result in motor and sensory deficiencies resulting from the surgery. Disc removal and more generally disc degeneration disease are likely to lead to a need for surgical treatment in subsequent years. The fusion or fixation will minimize or substantially eliminate relative motion between the fixed or fused vertebrae. In surgical treatments, adjacent vertebra can be fixated or fused to each other using devices or bone grafts. These may include, for example, screw and rod systems, interbody spacers (e.g., PEEK spacers or allograft bone grafts) threaded fusion cages and the like.

1 [0004] Some fixation or fusion devices are attached to the vertebra from the posterior  
2 side. The device will protrude and result in additional length (i.e., needed to overlap the  
3 vertebrae) and additional hardware to separately attach to each vertebrae. Fusion cages  
4 and allografts are contained within the intervertebral space, but must be inserted into the  
5 intervertebral space in the same dimensions as desired to occupy the intervertebral space.  
6 This requires that an opening sufficient to allow the cage or graft must be created through  
7 surrounding tissue to permit the cage or graft to be inserted into the intervertebral space.

8 [0005] A spinal fixation or fusion device that can be implanted with or without the need  
9 for additional hardware is desired. Also desired is a fixation or fusion device that can be  
10 deployed in a configuration where overlapping the fixated or fused vertebrae is not  
11 required.

12 [0006] Also desired is an intervertebral device the may be inserted in to the intervertebral  
13 space at a first smaller dimension and deployed to a second, larger dimension to occupy  
14 the intervertebral space. The ability to insert an intervertebral spacer at a dimension  
15 smaller than the deployed dimension would permit less disruption of soft and boney  
16 tissue in order to access the intervertebral space.

#### 17 18 SUMMARY OF THE INVENTION

19 [0007] A device that can replace or supplement the screw or rod elements of a typical  
20 fusion system is disclosed. The device can be placed in the inter-vertebral space to fuse  
21 adjacent vertebrae and/or create a bone mass within the inter-vertebral space in a  
22 patient's spine.

23 [0008] The device can be less invasive than typical existing devices. For example, the  
24 device can be in a compacted (i.e., small) configuration when inserted into a patient and  
25 transformed into an expanded (i.e., large) configuration when positioned at the target site.  
26 For example, the device can be expanded when the device is between the inferior and  
27 superior vertebral body surfaces. The device can create less soft tissue (e.g., bone)  
28 disruption than a typical fusion system. The device in an expanded configuration can  
29 improve anchoring within the joint, structural stability, and create an environment for  
30 bone healing and growth leading to fusion between adjacent vertebrae.

1 [0009] During deployment into tissue (e.g., bone), one, two or more holes can be drilled  
2 into the target site to create a deployment hole in which to insert the device. The  
3 deployment hole can be round or non-round (e.g., by drilling more than one overlapping  
4 or adjacent hole, or crafting a square or rectangular hole), for example to substantially  
5 match the transverse cross-section of the device in a contracted configuration.

6 [0010] The device can be cannulated, for example having a lateral (i.e., transverse or  
7 latitudinal) and/or lengthwise (i.e., longitudinal) channel through the device. The device  
8 can be deployed over a wire or leader, such as a guidewire. The device can be slid over  
9 the guidewire, with the guidewire passing through the longitudinal channel of the device.

10

#### 11 BRIEF DESCRIPTION OF THE DRAWINGS

12 [0011] Figure 1 is an exploded view of a variation of the expandable support device.

13 [0012] Figures 2 through 4 illustrate variations of cross-section A-A of Figure 1.

14 [0013] Figures 5 and 6 illustrate variations of cross-section B-B of Figure 1.

15 [0014] Figure 7 illustrates the variation of the expandable support device of Figure 1 with  
16 the ramps slidably attached to the base.

17 [0015] Figures 8 and 9 are perspective and side views, respectively, of the variation of  
18 the expandable support device of Figure 7 with the top and ramps in pre-assembly  
19 positions.

20 [0016] Figures 10, 11 and 12 are perspective, side and end views, respectively of the  
21 variation of the device of Figure 1 in an assembled configuration.

22 [0017] Figure 13 is a variation of close-up section E-E of Figure 12 in a first  
23 configuration.

24 [0018] Figure 14 is a variation of close-up section E-E of Figure 12 in a second  
25 configuration.

26 [0019] Figures 15 and 16 are a variation close-up section D-D of Figure 11 in first and  
27 second configurations, respectively.

28 [0020] Figures 17, 18, 20 and 21 are perspective, side, end and top views, respectively, of  
29 the variation of the device of Figure 1 in a pre-deployment configuration.

30 [0021] Figures 19 and 22 are side and top views, respectively, of a variation of the device  
31 of Figure 1 in a pre-deployment configuration.

1 [0022] Figure 23 illustrates a method of longitudinally compression and radially  
2 expanding the variation of the device of Figure 17, for example after deployment at a  
3 target site.

4 [0023] Figures 24 and 25 are perspective and top views, respectively, of the variation of  
5 the device of Figure 1 in a deployed configuration. Figure 22 is illustrated with the top  
6 and the base in see-through views for illustrative purposes.

7 [0024] Figures 26 and 27 illustrate variations of the locking pin.

8 [0025] Figures 28 and 29 illustrate a variation of a method for using the variation of the  
9 locking pin of Figure 26.

10 [0026] Figures 30 and 31 illustrate a variation of a method for using the variation of the  
11 locking pin of Figure 27.

12 [0027] Figures 32, 33 and 34 are top, side and end views, respectively, of a variation of  
13 the device with the locking pin.

14 [0028] Figures 35 and 36 are side and end views, respectively, of a variation of the  
15 device with the locking pin.

16 [0029] Figures 37 and 38 are side and end views, respectively, of a variation of the  
17 device with the locking pin.

18 [0030] Figures 39a, 39b and 39c are bottom perspective, end and side views,  
19 respectively, of a variation of the device in a longitudinally expanded configuration.

20 [0031] Figures 40a, 40b, and 40c are bottom perspective, end and side views,  
21 respectively, of the device of Figures 39a through 39c in a longitudinally compressed and  
22 radially expanded configuration.

23 [0032] Figures 41a through 41d are top, top perspective, side, and bottom perspective  
24 views, respectively, of a variation of the device in a longitudinally expanded and radially  
25 contracted configuration.

26 [0033] Figures 42a through 42c are top, side and top perspective views, respectively, of  
27 the variation of the device of Figures 41a through 41d with the side ramps not shown for  
28 illustrative purposes.

29 [0034] Figures 43a through 43d are top, top perspective, side, and bottom perspective  
30 views, respectively, of the device of Figures 41a through 41d in a longitudinally  
31 contracted and radially (e.g., height) expanded configuration.

1 [0035] Figures 44a through 44c are top, side and top perspective views, respectively, of  
2 the variation of the device of Figures 43a through 43d with the side ramps not shown for  
3 illustrative purposes.

4 [0036] Figures 45a and 45b are top and top perspective views, respectively, of a variation  
5 of the bottom plate.

6 [0037] Figures 46a and 46b are bottom and bottom perspective views, respectively, of a  
7 variation of the top plate.

8 [0038] Figures 47a and 47b are top perspective and bottom perspective exploded views,  
9 respectively, of the variation of the device of Figures 41a through 41d.

10 [0039] Figures 48a through 48d are top, top perspective, side, and bottom perspective  
11 views, respectively, of a variation of the device in a longitudinally expanded and radially  
12 contracted configuration.

13 [0040] Figures 49a through 49d are top, top perspective, side, and bottom perspective  
14 views, respectively, of the device of Figures 48a through 48d in a longitudinally  
15 contracted and radially (e.g., height) expanded configuration.

16 [0041] Figures 50a and 50b are side and top perspective views of the device of Figures  
17 49a through 49d in a longitudinally contracted configuration, with the top plate exploded  
18 away from the rest of the device.

19 [0042] Figures 51a and 51b are top and top perspective views, respectively, of a variation  
20 of the bottom plate.

21 [0043] Figures 52a through 52c are bottom, bottom perspective, and end perspective  
22 views, respectively, of a variation of the top plate.

23 [0044] Figures 53a through 53d are top, top perspective, side, and bottom perspective  
24 exploded views, respectively, of the variation of the device of Figures 48a through 48d.  
25 Figures 53c and 53d illustrate the device upside down compared to the orientation shown  
26 in Figures 53a and 53b.

27 [0045] Figure 54 illustrates a visualization of a variation of a method for deploying the  
28 device into the spine between adjacent vertebrae.

29 [0046] Figures 55a and 55b illustrate visualizations of variations of the device deployed  
30 into the spine between adjacent vertebrae.

1 [0047] Figures 56a and 56b illustrate variations of methods for inserting one or more  
2 devices into one or more target sites.

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#### DETAILED DESCRIPTION

5 [0048] A device 2 is disclosed that can be inserted into a target site 264 with the device 2  
6 in a compressed or contracted (i.e., small) configuration. Once positioned in the  
7 deployment site, the device 2 can be transformed into an expanded (i.e., larger, bigger)  
8 configuration. The device 2 can be inserted and expanded in orthopedic target sites 264  
9 for fixation and/or support. For example, the device 2 can be inserted and expanded over  
10 a guidewire between adjacent vertebral bodies.

11 [0049] Figure 1 illustrates that the device 2 can have a first longitudinal end and a second  
12 longitudinal end along a longitudinal axis 4. The longitudinal axis 4 can be straight or  
13 substantially straight. The device 2 can have a bottom or plate 286 (bottom and base  
14 plate are used interchangeably) and a top plate 6. The base 138 or bottom plate 10 and  
15 top plate 6 can be or have plates 286, panels, struts 216 (e.g., legs), ports, cells 88, and  
16 combinations thereof. The base plate 10 and top plate 6 can be configured to be slidably  
17 attachable to the other. For example, the base (or top) plate can have one or more  
18 stability bars 102. The top (or base) plate can have one or more stability grooves 128.  
19 The stability bars 102 can be configured to be slidably attachable to the stability grooves  
20 128.

21 [0050] The slidable attachment of the top and base plates can permit the base 138 to  
22 move radially (with respect to the longitudinal axis 4) relative to the top and vice versa.

23 [0051] The top plate 6 can have a high-friction and/or low-friction texture extending  
24 radially away from the base 138. For example, the top plate 6 can have one or numerous  
25 rows of top teeth 118. The bottom plate 10 can have a high-friction and/or low-friction  
26 texture extending radially away from the base plate. For example, the bottom plate 10  
27 can have one or numerous rows of bottom teeth 104. The top teeth 118 and the bottom  
28 teeth 104

29 [0052] The top plate 6 can have one or more side ports 114 and/or top ports. The base  
30 plate can have one or more base ports 120 and/or side ports 114. The base ports 120, side  
31 ports 114, and/or top ports can be ingrowth channels 28. The ports can be circular,

1 square, triangular, oval, elongated in the longitudinal direction, elongated in the radial  
2 direction, or combinations thereof.

3 **[0053]** The top plate 6 can have a top chamfer 156. The base plate can have a base  
4 chamfer. The chamfers can be atraumatic edges. The chamfers can extend along the  
5 perimeter of the base 138 and/or top.

6 **[0054]** The device 2 can have one, two or more wedges, for example a first or distal side  
7 ramp 96 on a first longitudinal side (e.g., the distal side) of the base plate and a second or  
8 proximal side ramp 108 on a second longitudinal side (e.g., the proximal side) of the base  
9 plate. The side ramps 96 and 108 can be configured to be slidably attachable to the base  
10 plate 10 and/or the top plate 6. The wedges or ramps 96 and 108 can be separate from  
11 each other. The ramps 96 and 108 can move independent of each other. The ramps 96  
12 and 108 can be constrained by the top and bottom plates 6 and 10 to move concurrently  
13 and at the same rate in opposite directions. The angled faces of the ramps 96 and 108 can  
14 face each other. The “pointed” ends of the ramps 96 and 108 can point toward each  
15 other.

16 **[0055]** The ramps 96 and 108 and top plate 6 can be brought within proximity of the base  
17 plate 10. The ramps 96 and 108 can be slidably attached to the base plate 10. The ramps  
18 96 and 108 can have ramp second tongues and grooves 98. The base plate 10 can have  
19 one or more base tongues and grooves 106. The ramp second tongues and grooves 98  
20 can be configured to slidably attach to the base tongues and grooves 106.

21 **[0056]** The ramps 96 and 108 can be configured to be slidably attachable to the top plate  
22 6. For example, the ramps 96 and 108 can have ramp first tongues and grooves 100. The  
23 top plate 6 can have top tongues and grooves 284. The ramp first tongues and grooves  
24 100 can slidably engage the top tongues and grooves 284.

25 **[0100]** The first tongues and grooves can be at a ramp angle 136 with respect to the  
26 second tongues and grooves. The ramp angle 136 can be from about 15° to about 75°,  
27 more narrowly from about 30° to about 60°, for example about 45°.

28 **[0101]** One or more of the ramps 96 and 108 can have a ramp locking plate port 110.  
29 The ramp locking plate ports 110 can each be configured to receive a ramp locking plate.  
30 The ramps 96 and 108 can each have ramp ports, such as the threaded ramp ports. The



1 threaded ramp ports can pass through the ramps 96 and 108, for example opening into the  
2 ramp locking plate port 110.

3 **[0102]** Figure 2 illustrates that each of the top, or base 138 or bottom plates can have a  
4 plate thickness 122. The plates 286 can be thinned adjacent to some or all ports. The  
5 plate thickness 122 can be substantially constant along the length of the top or base 138.  
6 The plate thickness 122 can be non-constant, for example along the length and/or width  
7 of the top port or base port 120 and the top teeth 118 or base teeth. Each plate 286 of the  
8 first side ramp 96 and the second side ramp 108 can have a substantially constant plate  
9 thickness 122 along the height of the plate 286 save for the respective ramp ports.

10 **[0103]** Figure 3 illustrates that the top and/or bottom plates can thin as the plate 286  
11 nears the port. For example, the plate 286 can have a maximum plate thickness 126 and a  
12 minimum plate thickness 124. The maximum plate thickness 126 and minimum plate  
13 thickness 124 can be measured with or without accounting for the change in thickness  
14 due to the teeth. The minimum plate thickness 124 can be substantially less than the  
15 maximum thickness 126. The minimum plate thickness 124 can be substantially 0. The  
16 plate 286 can slope outward (as shown), inward, or a combination of both (e.g., sloping  
17 inward and outward concurrently to form the rim of the port at a radius from the  
18 longitudinal axis between the radii of the outer and inner surfaces of the plate 286).

19 **[0104]** When the device 2 is in a deployed configuration in vivo, the device 2 can be  
20 partially or substantially filled with a liquid, gel, or solid (e.g., in small parts or granules)  
21 filler 262 material, or combinations thereof, such as bone morphogenic powder or any  
22 other material disclosed herein or combinations thereof. The filler 262 material can  
23 contact or be in near contact with the surrounding tissue near the edge of the ports, for  
24 example where the plate 286 is thinned. The filler 262 can be inserted into the device 2  
25 before, and/or during (i.e., prepacked) , and/or after the device 2 is inserted and/or  
26 expanded in the target site.

27 **[0105]** As the device 2 is expanded and contracted, the volume of the interior channel of  
28 the device (i.e., defined between the top and base plates and the opposing ramps) can  
29 remain constant. For example, filler can be inserted into the device 2 before the device is  
30 radially expanded. The device 2 can be longitudinally contracted and radially expanded  
31 (e.g., expanded in height). The ratio of the volume of filler to the volume of the interior

1 channel of the device can then remain substantially constant as the device is radially  
2 expanded . For example, the decrease in volume of the interior channel of the device  
3 caused by the contracting ramps can be substantially equivalent to the increase in volume  
4 of the interior channel of the device 2 caused by the radially expanding top and base  
5 plates.

6 **[0106]** Figure 4 illustrates that the plates 286 of the first side ramp 96 and/or the second  
7 side ramp 108 can thin as the plate 286 nears the threaded ramp port(s). The minimum  
8 plate thickness 124 can be substantially less than the maximum plate thickness 126. The  
9 minimum plate thickness 124 can be substantially 0. The plate 286 can slope outward (as  
10 shown), inward, or a combination of both (e.g., sloping inward and outward concurrently  
11 to form the rim of the port at a radius from the longitudinal axis between the radii of the  
12 outer and inner surfaces of the plate 286).

13 **[0107]** Figure 5 illustrates that the stability bars 102 can be configured to slide into the  
14 stability groove 128 when the top and base plates intersect. The radially inner surface of  
15 the stability bar 102 can be substantially the same or a greater radius from the  
16 longitudinal axis of the expandable support device 188 as the radius of the radially outer  
17 surface of the top plate 6 adjacent to the side port 114 (i.e., within the stability groove  
18 128). The stability bar 102 can be configured to not directly attach to the top plate 6  
19 when the top is translated into the base plate, or the stability bars 102 can be configured  
20 to bias inward against and frictionally hold the top when the top plate 6 is translated into  
21 the base plate.

22 **[0108]** Figure 6 illustrates that the stability bars 102 can have one or more latches 130  
23 along the length of the stability bar 102, for example at the terminal end of the stability  
24 bars 102, as shown. The latch 130 can be configured to attach to the top plate 6. The  
25 latch 130 can protrude radially inward. The latch 130 can have a latch top 288 and a  
26 latch bottom 134.

27 **[0109]** The latch top 288 can be configured to allow the top to pass over the latch 130.  
28 For example, the latch top 288 can be rounded and configured to push radially outward  
29 and clear of the top plate 6 when the top is pressed down into the latch top 288. The latch  
30 bottom 134 can be configured to grasp or otherwise attach to the top when the top is  
31 translated to a particular location into the base plate.

1 [0110] The stability bars 102 can be configured to resiliently bend radially outward  
2 and/or inward.

3 [0111] Figure 7 illustrates that the ramps 96 and 108 can be slidably attached, as shown  
4 by arrows, to the base plate 10 before the ramps 96 and 108 are slidably attached to the  
5 top plate 6. The ramp second tongues and grooves 98 can be slidably engaged with the  
6 base tongues and grooves 106, as shown in Figures 12, 13 and 14.

7 [0112] Figures 8 and 9 illustrate that the ramps 96 and 108 can be positioned, as shown  
8 by arrows, so that one or both ramp first tongues and grooves 100 can be aligned to  
9 slidably engage the top tongues and grooves 284 as the top plate 6 is translated toward  
10 the base plate, as shown by arrows. The stability bar 102 can be slid into the stability  
11 groove 128.

12 [0113] Figures 10 through 12 illustrate that as the top plate 6 is translated toward the base  
13 plate, as shown by arrows, the top plate 6 can slidably engage one or more of the ramps  
14 96 and 108. The first tongues and grooves can slidably engage the top tongues and  
15 grooves 284.

16 [0114] Figure 13 illustrates that there can be a substantial ramp gap 140 between the side  
17 ramp and the base plate, for example before the expandable support device 188 is  
18 completely deployed. The ramp gap 140 can have a ramp gap height 150. The ramp gap  
19 height 150 can vary, for example, from about 0 mm (0 in.) to about 4 mm (0.2 in.). The  
20 side ramps can substantially slide along the base plate. For example, the ramp second  
21 tongue and groove 98 can slide along the base tongue and groove 106, separated by the  
22 ramp gap 140. Most or all of the friction in this configuration can be created by the ramp  
23 second tongue in contact with the base tongue 148 and/or side of the base groove 146.

24 [0115] The wall of the base groove 146 can have an outwardly slanted configuration  
25 relative to the height of the wall of the base groove 146 from the bottom of the base plate.

26 [0116] Figure 14 illustrates that the first side ramp 96 and the base 138 can be pressed  
27 into or otherwise translated toward each other. For example, after implantation of the  
28 device 2, the surrounding tissue in the in vivo environment can naturally compress the  
29 device 2.

30 [0117] The ramp gap 140 can be substantially closed. The ramp gap height 150 can be  
31 substantially about 0. The side ramps can be substantially friction fit along the base

1 plate. For example, the friction in this configuration can be created along the top surface  
2 of substantially the entire base plate including the top of the base tongue 148, and the  
3 bottom surface of substantially the entire side ramps.

4 **[0118]** As the side ramp is pushed, as shown by arrows, toward the base plate, the ramp  
5 second tongues 144 can be pressed between the base grooves 146, for example,  
6 frictionally fitting the side ramps into the base plate. The base grooves 146 can be  
7 tapered, as shown, to force the ramp second tongues 144 to wedge fit or press fit into the  
8 base grooves 146 when the side ramp is pushed towards the base plate.

9 **[0119]** The side ramps can have less friction with the base plate in the configuration of  
10 the expandable support device 188 of Figure 13 than in the configuration of the  
11 expandable support device 188 of Figure 14.

12 **[0120]** Figure 15 illustrates that the second side ramp 108 (and/or the first side ramp 96,  
13 not shown) can have ramp bottom teeth 152 on the side of the second side ramp 108  
14 (and/or first side ramp 96) facing the base plate. The ramp bottom teeth 152 can extend  
15 into the ramp gap 140. Either or both side ramps can have teeth on any and/or all sides of  
16 the side ramp, for example the surfaces that contact the base plate and the top plate 6.  
17 The top plate 6 can have additional teeth, not shown, along surfaces that contact the side  
18 ramps.

19 **[0121]** The ramp bottom teeth 152 and/or base interior teeth 154 can be unidirectionally  
20 or bidirectionally oriented (i.e., providing additional resistance against movement in one  
21 direction, or substantially the same resistance against movement in either direction).

22 **[0122]** As the side ramp translates, as shown by arrows, with respect to the base plate, the  
23 ramp gap height 150 is substantially non-zero, as shown in Figures 13 and 15. When the  
24 ramp gap height 150 is substantially non-zero, the ramp bottom teeth 152 can slide over  
25 the base interior teeth 154.

26 **[0123]** Figure 16 illustrates that when the side ramp and base plate are pressed together,  
27 as shown by arrows, for example when deployed in vivo, the ramp gap height 150 can be  
28 minimized, for example approaching about 0 mm (0 in.). The ramp bottom teeth 152 can  
29 interlock with the base interior teeth 154. The interlocked ramp bottom teeth 152 and  
30 base interior teeth 154 can provide an interference fit or otherwise prevent or minimize  
31 the side ramp translating relative to the base plate.

1 [0124] In place of, or in addition to, the ramp bottom teeth 152 and/or the base top teeth,  
2 the respective surfaces can have high friction surfaces, for example a textured (e.g.,  
3 knurled) surface and/or coated with a high friction material. The respective surfaces can  
4 also be smooth, having no teeth or texturing.

5 [0125] The side ramp can be pulled away from the base plate by reducing the  
6 compressive force between the side ramp and the base plate and pulling or pushing the  
7 side ramp.

8 [0126] The side ramp can have a belt and suspenders lock with the base plate.

9 [0127] Figures 17, 18, and 20 illustrate that the ramps can be pushed outward, as shown  
10 by arrows, toward each ramp's respective longitudinal side of the base plate. The ramps  
11 96 and 108 can be pushed outward, for example, by a deployment or other tool. When  
12 the ramps 96 and 108 are slid outward, as shown, the top plate 6 and base plate can  
13 translate toward each other, as shown by arrow. The top plate 6 and base plate can then  
14 have a radially compressed (e.g., only in the "y"-axis or from the top of the page to the  
15 bottom of the page of Figures 17, 18, and 20) configuration. The top plate 6 can  
16 interference fit against the bottom plate 10 when the expandable support device 188 is  
17 fully radially compressed, as shown. The interference fit of the top against the bottom  
18 plate, and the slidable attachment of the ramps 96 and 108 to the top and the bottom plate  
19 10 can lock the top plate 6, base plate and ramps 96 and 108 together (e.g., not allowing  
20 any to separate). The device 2 can be attached to a deployment tool 80 (e.g., by  
21 removably attaching to one or more ramp ports) and/or delivered to a target site 264 in  
22 the radially compressed configuration.

23 [0128] Figures 19 and 22 illustrate that one or more locking pin channels 164 can be  
24 defined transversely through the device 2. A locking pin 162 can be inserted through  
25 each locking pin channel 164. The locking pin 162 can be inserted through the locking  
26 pin channel 164 after the device 2 has been inserted at the target site 264 and expanded.  
27 The locking pin channel 164 can be defined by locking pin ports 166 on the stability bars  
28 102 and the side port 114. The locking pin ports 166 can be circular, as shown, oval, or  
29 combinations thereof.

1 [0129] The locking pin 162 can be configured to limit the vertical expansion of the  
2 device 2. For example, the locking pin 162 can be configured to substantially prevent the  
3 device 2 from disassembling.

4 [0130] Figure 23 illustrates that the device 2 can be longitudinally compressed, as shown  
5 by arrows, resulting in radial and/or vertical expansion, as shown by arrow, for example  
6 performed after the device 2 is positioned within a vertebra or between vertebrae. The  
7 ramps 96 and 108 can be slidably translated along the longitudinal axis and inward and/or  
8 toward the center of the device 2. The expansion 92 of the device 2 can increase the  
9 height and provide structure support for a compressed or otherwise damaged vertebra  
10 (e.g., when the device 2 is deployed within a vertebra) and/or return adjacent vertebrae to  
11 a more natural/physiological configuration (e.g., when the device 2 is deployed between  
12 adjacent vertebrae).

13 [0131] Figure 24 and 25 illustrate the device 2 in a deployed configuration, for example  
14 after completion of the longitudinal compression 160 and radial and/or vertical expansion  
15 as shown in Figure 23.

16 [0132] Figure 26 illustrates a variation of the locking pin 162 that can have a pin shaft  
17 170 with a driver slot 172, for example, configured to receive a screw driver or drill bit.  
18 The pin shaft 170 can have pin thread 168 configured to releasably or fixedly attach to  
19 one or both of the ramp ports. The pin thread 168 can extend along all or part of the  
20 length of the pin shaft 170. The pin shaft 170 can be rotatably or fixedly attached to or  
21 integral with a locking plate 290. The locking plate 290 can be at the end of the pin shaft  
22 170 with the driver slot 172. The locking plate 290 can be at the same or opposite end of  
23 the pin shaft 170 from the thread.

24 [0133] Figure 27 illustrates that the pin shaft 170 can have no locking plate 290. The pin  
25 thread 168 can be at the end of the pin shaft 170 with the driver slot 172. One end of the  
26 pin shaft 170, for example opposite the driver slot 172, can be an abutment end 174.

27 [0134] Figure 28 illustrates that the locking pin 162 can be inserted, as shown by arrow,  
28 through the second side ramp 108. Figure 29 illustrates that the pin shaft 170 can be  
29 translated and rotated, as shown by arrows, to screw the pin thread 168 into the threaded  
30 distal ramp port 94 in the first side ramp 96. The ramp locking plate can fit into the ramp

1 locking plate port 110. The locking pin 162 can be screwed tightly enough to  
2 substantially fix the locking pin 162.

3 [0135] Figure 30 illustrates that the locking pin 162 can be inserted, as shown by arrow,  
4 through the threaded ramp port. The second side ramp 108 and/or the top and/or the  
5 bottom plates can have a ramp abutment section 180. The ramp abutment section 180  
6 can be configured to interference fit with and/or fixedly attach to the abutment end 174.

7 [0136] Figure 31 illustrates that the pin shaft 170 can be translated and rotated, as shown  
8 by arrows. The abutment end 174 can interference fit and/or fixedly attach to the ramp  
9 abutment section 180.

10 [0137] A biocompatible adhesive or epoxy can be applied to the pin thread 168, threaded  
11 ramp port, abutment end 174, ramp abutment section 180, or combinations thereof.

12 [0138] Figures 32, 33 and 34 illustrate that one, two or more locking pin channels 164  
13 can be defined longitudinally through the device 2. One, two or more locking pins 162  
14 can be inserted in each locking pin channel 164, for example during or after deployment  
15 of the remainder of the device 2. The locking pins 162 can prevent overexpansion and/or  
16 overcompression and/or disassembly of the device 2.

17 [0139] The locking pin channel 164 can have locking pin ports 166 through the top,  
18 and/or bottom plates, and/or either or both side ramps.

19 [0140] Two locking pin channel 164 can be located on opposite sides of the threaded  
20 ramp port. The locking pin channels 164 and ports can have a circular cross-section (i.e.,  
21 be cylindrical), as shown in Figure 34.

22 [0141] Figures 35 and 36 illustrates that the locking pin 162 can be cylindrical. The  
23 locking pin channel 164 and locking pin port 166 can have elongated cross-sections, such  
24 as an oval or rectangular or oblong cross-sections. The locking pin 162 can be free to  
25 move vertically within a range of motion within the locking pin port 166.

26 [0142] Figures 37 and 38 illustrate that the locking pin 162 can be a substantially similar  
27 shape and size as the locking pin channel 164. The locking pin 162 can be substantially  
28 unmovable within the locking pin port 166. The locking pin 162, locking pin channel  
29 164 and locking pin port 166 can all have elongated cross-sections, such as an oval or  
30 rectangular or oblong cross-sections.

1 [0143] One or both of the ramps 96 and 108 can have first fixing teeth 192. The first  
2 fixing teeth 192 can be in contact with the top and/or the bottom. The top and/or the  
3 bottom (shown as bottom only) plates 286 can have second fixing teeth 190.

4 [0144] The first fixing teeth 192 can mechanically interact with the second fixing teeth  
5 190 to allow relative translation in a first direction. The first fixing teeth 192 and the  
6 second fixing teeth 190 can interact to obstruct (e.g., by interference fitting the first fixing  
7 teeth 192 against the second fixing teeth 190) relative translation in a second direction.  
8 For example, the fixing teeth can obstruct the side ramps from moving longitudinally  
9 away from each other (i.e., and obstruct the top from moving closer to the bottom). Also  
10 for example, the fixing teeth can allow relative translation of the side ramps toward each  
11 other (i.e., and allow the top to move away from the bottom).

12 [0145] The second side ramp 108 can have a first end 186. The first end 186 can be  
13 configured to dissect tissue. The first end 186 can have a blunt or sharp point.

14 [0146] The second side ramp 108 can have a tool connector 184, such as an externally  
15 and/or internally threaded cylinder extending longitudinally from the second side ramp  
16 108 away from the first side ramp 96. The tool connector 184 can be configured to  
17 removably attach to a deployment tool 80.

18 [0147] The first side ramp 96 and second side ramp 108 can be longitudinally  
19 compressed toward each other. For example, an external deployment tool 80 can be  
20 attached to the first side ramp 96 and second side ramp 108 and apply a compressive  
21 force. The base 138 and top plates 6 can expand away from each other.

22 [0148] The first fixing teeth 192 can unidirectionally interference fit the second fixing  
23 teeth 190. The unidirectional interference fit of the first fixing teeth 192 and the second  
24 fixing teeth 190 can substantially impede or prevent the opposite ramps 96 and 108 from  
25 moving longitudinally away from each other, for example, therefore impede or  
26 preventing compression 196 of the top toward the bottom and vice versa.

27 [0149] The unidirectional interference fit of the first fixing teeth 192 and the second  
28 fixing teeth 190 can allow the opposite ramps 96 and 108 to move longitudinally toward  
29 each other, for example, therefore allowing the top to expand away from the bottom and  
30 vice versa.



1 [0150] The expandable support devices 188 can have textured and/or porous surfaces for  
2 example, to increase friction against bone surfaces, and/or promote tissue ingrowth. The  
3 expandable support devices 188 can be coated with a bone growth factor, such as a  
4 calcium base 138.

5 [0151] Figures 39a through 39c illustrate that the bottom ports can be one or more  
6 circular ports, for example six ports. The bottom ports can be aligned in a single row  
7 parallel with the longitudinal axis of the device 2.

8 [0152] The side ports 114 can open against the edge of the top plate 6 on one or more  
9 sides (e.g., the bottom sides, as shown) of the side ports 114.

10 [0153] The top plate 6 can have top plate side teeth 198 on the external lateral sides of  
11 the top plate 6. The bottom plate 10 can have bottom plate side teeth 202 on the external  
12 lateral sides of the bottom plate. The top plate side teeth 198 and/or the bottom plate side  
13 teeth 202 can be oriented from the top to the bottom of the device 2 (i.e., perpendicular to  
14 the longitudinal axis of the device 2). The top plate side teeth 198 can be aligned with  
15 the bottom plate side teeth 202.

16 [0154] The external lateral sides of the first side ramp 96 and/or second side ramp 108  
17 can have ramp side teeth 200. The ramp side teeth 200 can be oriented parallel with the  
18 longitudinal axis of the device 2. The top plate side teeth 198 and/or the bottom plate  
19 side teeth 202 can be oriented perpendicular to the orientation of the ramp side teeth 200.

20 [0155] Figures 40a through 40c illustrate that the top plate 6 and/or bottom plate 10 can  
21 be expanded away from each other in the directions of the orientation of the longitudinal  
22 axes of the top plate side teeth 198 and the bottom plate side teeth 202. The first and/or  
23 second side ramps 108 can be contracted toward one another in the direction of the  
24 orientation of the longitudinal axis of the ramp side teeth 200 of the first and second side  
25 ramps 108. The top plate side teeth 198, bottom plate side teeth 202, and ramp side teeth  
26 200 can act as low-friction rails 42 against surrounding tissue when the device 2 is  
27 radially expanded at the target site 264.

28 [0156] The side ports 114 that open to the bottom edge of the top plate 6 can create a  
29 single side port 114 that can extend to the bottom plate.

30 [0157] The plates 286 and wedges 18 can be rigid or exhibit ductile or deformable  
31 expansion 92 during deployment. The transverse cross-section of the device 2 can be

1 non-round. For example, The device 2 can have a square or rectangular transverse cross-  
2 section. The device 2 can have a substantially triangular or quadrilateral (e.g.,  
3 trapezoidal) cross-section. The device 2 can have a round, hexagonal, octagonal, or other  
4 transverse cross-sectional configuration.

5 **[0158]** Figures 41a through 41d illustrate that the device 2 can be curved, rounded (e.g., a  
6 continuous curvature along the entire length) or bent (e.g., at one or more angles at  
7 specific, discrete positions along the length). Any or all of the components of the device  
8 2 can be curved, for example the top plate 6, bottom plate 10, a distal ramp 96, the  
9 proximal ramp 108, and combinations thereof. During use, the device 2 can be inserted  
10 into a target site, for example intervertebrally, rotating and translating the device 2, so the  
11 concave aspect of the curvature can be positioned to miss nearby sensitive tissue (e.g., the  
12 spinal cord) during placement.

13 **[0159]** The longitudinal axis of the device 2 can have a device radius of curvature 300.  
14 The device radius of curvature 300 can be from about 0.5 cm (0.2 in.) to about 40 cm (16  
15 in.), more narrowly from about 1 cm (0.4 in.) to about 20 cm (8 in.), yet more narrowly  
16 from about 1.9 cm (0.75 in.) to about 7.0 cm (2.75 in.), for example about 3.2 cm (1.25  
17 in.).

18 **[0160]** The proximal ramp 108 can have one or more proximal protrusions 304. For  
19 example, a single protrusion can extend proximally from the proximal ramp 108 centered  
20 with or asymmetric or off-center (as shown) to the longitudinal axis 4. The protrusion  
21 304 can have a proximal ramp hole 302a, for example extending from the top of the  
22 protrusion 304 part or all of the way through the protrusion 304.

23 **[0161]** A deployment tool can releasably or fixedly attach to the proximal ramp hole  
24 302a and/or protrusion 304. For example, the deployment tool can be rotatably attached  
25 to the proximal ramp hole 302a. For example, the deployment tool can have a removable  
26 pin that can be inserted into the hole proximal ramp hole 302a. The pin, still fixed to the  
27 deployment tool, can then be press fit (e.g., friction fit or interference fit) or rotated inside  
28 of the hole 302a, acting as a rotatable hinge. The pin can rotationally stabilize the device  
29 2.

30 **[0162]** The pin can act as a stabilization device. The deployment tool can press on one or  
31 both sides of the protrusion 304 to rotate the device 2 about the proximal ramp hole 302a.

1 [0163] The distal ramp 96 can have a distal ramp keyhole 302b. The distal ramp keyhole  
2 302b can extend from the top of the distal ramp 96 part or all the way through the distal  
3 ramp 96. The distal ramp keyhole 302b can be cylindrical (as shown), square, triangular,  
4 oval, rectangular, or star-shaped in cross section. An attachment key 308 can be inserted  
5 into the distal ramp key hole 302b, as shown by arrow in Figure 41b. The inserted  
6 attachment key 308 can abut against the larger cylinder 170b and the distal

7 [0164] The attachment key 308 can have the same cross-section as the distal ramp key  
8 hole 302b.

9 [0165] The locking pin 162 can be straight (as shown) or curved, such as having a  
10 substantially equal radius of curvature to the longitudinal axis. The locking pin 162 can  
11 have a proximal locking head plate or tool interface proximal section 290a that can  
12 extend proximally of the proximal ramp 108 when the device 2 is in a radially contracted  
13 and longitudinally expanded configuration. The locking pin 162 can be fixedly or  
14 detachably attached to the distal ramp 96.

15 [0166]

16 [0167] Figures 42a through 42c illustrate that the locking pin 162 can have an adjustable  
17 length. The locking pin 162 can have a smaller cylinder or proximal locking pin shaft  
18 170a with radially outer threads and a larger outer cylinder or distal locking pin shaft  
19 170b with radially inner threads. The smaller cylinder 170a can helically (e.g.,  
20 threadably, as a screw or bolt) engage the larger cylinder 170b (e.g., as a nut).

21 [0168] The outside of the smaller cylinder 170a and the inside of the larger cylinder 170b  
22 can have a set of slidably engaging longitudinal ribs, slides, rails, guides, or combinations  
23 thereof.

24 [0169] The smaller cylinder 170a can be spring loaded with respect to the larger cylinder  
25 170b. The inside of the locking pin 162 can have hydraulic fluid and an internal seal  
26 and/or piston so the locking pin 162 can act as a hydraulic damper or shock absorber.

27 [0170] The locking pin 162 can have a distal locking head or plate 290b. The distal  
28 locking head 290b can have a larger diameter than the diameter of the distal locking pin  
29 shaft 170b and distal ramp port 94a. The distal locking head 290b can be releasably  
30 attached to or fixed in or distal to the distal ramp port 94a.

1 [0171] The locking pin 162 can have a proximal locking head or plate 290a. The  
2 proximal locking head 290a can have a larger diameter than the diameter of the proximal  
3 locking pin shaft 170a and the proximal ramp port 94b. When the locking pin 162 is  
4 shortened, the proximal locking pin head 170a can abut or interference fit with the  
5 proximal ramp 108, pushing the proximal ramp 108 toward the distal ramp 96,  
6 longitudinally contracting and radially expanding the device 2.

7 [0172] The distal locking head 290b can have a key interface 306. The key interface 306  
8 can be a notch, divot, threads, other engagement feature, or combinations thereof. The  
9 key interface 306 can slidably receive the attachment key 308, for example after the  
10 attachment key 308 is delivered into the distal keyhole 302b. The attachment key 308  
11 can fix the locking pin 162 to the distal ramp 96, for example transferring force from the  
12 distal locking plate 290a to the distal ramp, capable of translating the distal ramp 96  
13 proximally and distally with respect to the proximal ramp 108 when the length of the  
14 locking pin 162 is expanded and contracted..

15 [0173] Figures 43a through 43d and 44a through 44c illustrate that the locking pin 162  
16 can be attached to the distal ramp 96. The locking pin 162 can be longitudinally  
17 shortened. The distal ramp 96 can be contracted toward the proximal ramp 108, resulting  
18 in a longitudinal contraction of the device and a radial (e.g., height) expansion between  
19 the top plate 6 and the bottom plate 10. The ramps 96 and 108 can longitudinally  
20 contract along a straight or curved path (e.g., correlating with the shape of the grooves in  
21 the top plate, ramps and base plate) toward the center of the device 2.

22 [0174] The top plate 6 can extend in a parallel or non-parallel plane away from the  
23 bottom plate 10. A compressive force can be exerted between the proximal and distal  
24 ramps 108 and 96 along the longitudinal axis 4.

25 [0175] The attachment key 308 is not shown in Figure 44b and shown in phantom lines  
26 in Figure 44c for illustrative purposes.

27 [0176] Figures 45a and 45b illustrate that the base plate 10 can have proximal base  
28 grooves 106a and distal base grooves 106b. The proximal base grooves 106a can be a  
29 separate groove than the distal base grooves 106b. The proximal and distal base grooves  
30 106a and 106b can be substantially straight (as shown) or curved.

1 [0177] The longitudinal axis of the proximal base grooves 106a and the longitudinal axis  
2 of the distal base grooves 106b can form a base groove angle 310. The base groove angle  
3 310 can be from about 125° to about 175°, more narrowly from about 140° to about 160°,  
4 for example about 154°.

5 [0178] Figures 46a and 46b illustrate that the top plate 6 can have proximal top grooves  
6 284a and distal top grooves 284b. The proximal top grooves 284a can be separate from  
7 the distal top grooves 284b. The top grooves 284a and 284b can be substantially straight  
8 (as shown) or curved.

9 [0179] The longitudinal axis of the proximal top grooves 284a and the longitudinal axis  
10 of the distal top grooves 294b can form a top groove angle 312. The top groove angle  
11 312 can be equal to the bottom groove angle 310.

12 [0180] Figures 47a and 47b illustrate that the components of the device 2 can be slidably  
13 and rotatably assembled.

14 [0181] The outer locking pin shaft 170b can have an outer locking pin shaft channel 314.  
15 The inner locking pin shaft 170a can screw, slide, clip or otherwise engage into the outer  
16 locking pin shaft channel 314. The inner locking pin shaft 170a can be longitudinally  
17 translated within the locking pin shaft channel 314, for example by rotating the inner  
18 locking pin shaft 170a with respect to the outer locking pin shaft 170b. The total length  
19 of the locking pin 162 can be adjusted.

20 [0182] Figures 48a through 48d and 49a through 50a illustrate that the device can have a  
21 radius of curvature 300. A compressive force can be exerted onto the ramps 96 and 108  
22 along the longitudinal axis 4. For example, the locking pin and/or deployment tool can  
23 be flexible and/or have a rigid shape with a radius of curvature that matches the radius of  
24 curvature 300 of the device 2.

25 [0183] The ramps 96 and 108 can longitudinally contract along a curved path, such as  
26 along the longitudinal axis 4, toward the center of the device 4. During radial expansion,  
27 the top plate 6 can extend in a parallel plane away from the bottom plate 10.

28 [0184] The distal ramp 96 can have threading on inside of a distal ramp port 94a. The  
29 distal ramp port 94a can be aligned with the longitudinal axis 4.

30 [0185] The proximal ramp 108 can have threading on the radial exterior and/or interior of  
31 the tool connector 184. The proximal ramp 108 can have the tool connector 184, for

1 example extending proximally from the remainder of the device 2. The tool connector  
2 184 can be a cylindrical proximal extension from the proximal ramp 108. The threading on  
3 the radial outside of the tool connector 184 can, for example, removably attach to a  
4 deployment tool.

5 **[0186]** Figures 50a and 50b illustrate that the device can be assembled by sliding the  
6 iramps 96 and 108 onto the base plate. The ramps 96 and 108 can then be contracted to  
7 close to or at their respective inner-most positions on the base plate 10. The top plate 6  
8 can then be delivered, as shown by arrow, onto the ramps 96 and 108. The ramps 96 and  
9 108 can then be slid outward, extending away from the opposite ramp, as shown by  
10 arrows, engaging the top plate and pulling the top plate and the bottom plate together.

11 **[0187]** Figures 51a and 51b illustrate that the inner base groove 106' and/or outer base  
12 groove 106" can be curved along a part or the entire length of the respective base grooves  
13 106. The inner base groove 106' can have an inner base groove radius of curvature 316"  
14 from about 1.3 cm (0.5 in.) to about 6.4 cm (2.5 in.) for example about 2.5 cm (1.0 in.).  
15 The outer base groove 106" can have an outer base groove radius of curvature 316" from  
16 about 2.5 cm (1.0 in.) to about 7.6 cm (3.0 in.), for example about 3.8 cm (1.5 in.).

17 **[0188]** Figures 52a through 52c illustrate that the inner proximal and distal top grooves  
18 284a' and 284b' and outer proximal and distal top grooves 284a" and 284b" can be curved  
19 along a part or the entire length of the respective grooves.

20 **[0189]** The inner top grooves 284a' and 284b' can have inner top groove radii of  
21 curvature 318' from about 1.3 cm (0.5 in.) to about 6.4 cm (2.5 in.) for example about 2.5  
22 cm (1.0 in.). The inner top groove radii of curvature 318' can be the same or different for  
23 the inner proximal and distal top grooves 284a' and 284b'.

24 **[0190]** The outer top grooves 284a" and 284b" can have outer top groove radii of  
25 curvature 318" from about 2.5 cm (1.0 in.) to about 7.6 cm (3.0 in.), for example about  
26 3.8 cm (1.5 in.). The outer top groove radii of curvature 318" can be the same or  
27 different for the outer proximal and distal top grooves 284a" and 284b".

28 **[0191]** Figures 53a through 53d illustrate that that the components of the device 2 can be  
29 slidably assembled. A deployment tool and/or fixation rod can be inserted into the device  
30 after the component are assembled.

1 [0192] The device 2 can have one or more radiopaque and/or echogenic markers. For  
2 example, the device 2 can have aligned markers on the top plate 6, middle plate 8 and  
3 bottom plate. When the device 2 is in a contracted pre-deployment configuration, the  
4 markers can be located immediately adjacent to one another, for example appearing as a  
5 single marker. When the device 2 is in an expanded configuration, the markers can move  
6 apart from each other, indicating to a doctor performing the implantation and deployment  
7 procedure using visualization (e.g., x-ray or ultrasound-based) that the device 2 has  
8 expanded. Under visualization the markers can also indicate the location and orientation  
9 of the device 2.

10

## 11 METHOD OF USING

12 [0193] The devices can be made from PEEK, any medical grade polymer or metal, or any  
13 other material disclosed herein. For example, the side ramps can be made from titanium  
14 and/or a titanium alloy and the bottom and/or top plates can be made from PEEK. The  
15 device can be coated, for example with bone morphogenic protein (BMP), ceramic,  
16 and/or any other material disclosed herein, before, during or after deployment into the  
17 target site. The device can be deployed less (e.g., minimally) invasively, over the wire,  
18 percutaneously, used with a vertebral body replacement or fusion cage, or combinations  
19 thereof. The device can be expandable and un-expandable for removal or repositioning.

20 [0194] Figure 54 illustrates that the device can be removably attached to a delivery  
21 system or deployment tool. The deployment tool can insert the device into the target site.  
22 For example the deployment tool can be pushed over a guidewire.

23 [0195] When the device is positioned as desired (e.g., between adjacent vertebral plates)  
24 and expanded and/or locked, the deployment tool can then be released from the device.  
25 The device can be configured to lock itself into place with outward expansion, wedging,  
26 or interference force when receiving a release force from the deployment tool or  
27 otherwise. For example, the device can have unidirectionally sliding teeth oppositely  
28 located on the adjacent surfaces of the wedges and plates.

29 [0196] A leader or wire, such as a guidewire, can be inserted or otherwise deployed into  
30 the target site, for example, the wire can be percutaneously inserted in a minimally  
31 invasive procedure. The wire can be inserted into the intervertebral space, for example

1 between a first vertebral plate and an adjacent, second, vertebral plate. The wire can be  
2 anteriorly and/or posteriorly inserted. The wire can be laterally inserted.

3 [0197] Whether or not the device is inserted over or along the wire, the device can be  
4 inserted into the target site (e.g., between adjacent vertebral bodies) from an anterior,  
5 lateral, posterior, transforaminal approach, or combinations thereof.

6 [0198] Figure 54 illustrates the deployment tool inserted to a target site in vivo between a  
7 first vertebra and a second vertebra. For example, the device can be placed at the target  
8 site after a partial or complete discectomy. When the device is in a contracted  
9 configuration, the tool can position the device between a first vertebral body of the first  
10 vertebra and a second vertebral body of the second vertebra. The device can be inserted  
11 into the target site a direction substantially parallel to the surfaces of the vertebral body  
12 end plates. The device can be placed between a first vertebral end plate of the first  
13 vertebral body and the adjacent second vertebral end plate of the second vertebral body.  
14 In this inter-vertebral location, the top plate of the device can be in contact with or  
15 directly adjacent to the first vertebral end plate. The bottom plate of the device can be in  
16 contact with or directly adjacent to the second vertebral end plate.

17 [0199] Figures 55a and 55b illustrate that the deployment tool can radially expand the  
18 device between the first vertebral end plate and the second vertebral end plate. The top  
19 plate 6 can press against and/or embed into the first vertebral end plate 234. The bottom  
20 plate 10 can press against and/or embed into the second vertebral end plate 238. The  
21 device 2 can fuse or fix the first vertebra 234 to the second vertebra 238.

22 [0200] Figures 56a illustrates that one, two or more devices 2, such as a first device 2a  
23 and a second device 2b, can be inserted, deployed and/or implanted the target site, such  
24 as in a vertebral body 324 or on a vertebral body 324 (e.g., between adjacent vertebral  
25 bodies). The devices 2 can be oriented so the longitudinal axes 4 of the devices 2 are  
26 substantially parallel with an anterior-posterior axis 320 of the patient.

27 [0201] The first device 2a can be oriented so the first device longitudinal axis 4a can be  
28 substantially parallel with the anterior-posterior axis 320.

29 [0202] The second device 2b can be oriented so the second device longitudinal axis 4b  
30 can be substantially parallel with the anterior-posterior axis 320. The second device 2b



1 can be positioned in a substantially symmetric location and angular orientation to the first  
2 device 2a with respect to the anterior-posterior axis 320.

3 [0203] The concavity of the radius of curvature 300 of the device can face toward (as  
4 shown) or away from the medial direction (i.e., the central anterior-posterior axis 320).

5 [0204] After placed into position at the target site, the device 2 can be longitudinally  
6 contracted and radially expanded. For example, as shown, the second device 2b has been  
7 radially expanded, and the first device 4a has been delivered to the target site and not yet  
8 radially expanded. Multiple devices 4 can be delivered concurrently or sequentially.  
9 Multiple devices 4 can be radially expanded sequentially or concurrently.

10 [0205] The devices 4 can be inserted with a surgical technique such as an Anterior  
11 Lumbar Interbody Fusion (ALIF), shown by arrow 322a, Posterior Lumbar Interbody  
12 Fusion (PLIF), shown by arrow 322b, Transforaminal Lumbar Interbody Fusion (TLIF),  
13 shown by arrow 322c, a direct linear lateral delivery, as shown by arrow 322d, a  
14 curvilinear lateral delivery initially inserted posteriorly, as shown by arrow 322e, or other  
15 methods or combinations thereof.

16 [0206] Operative planning and templating can be performed using MRI and CAT  
17 imaging scans to determine what size device fits the patient's anatomy and pathology.

18 [0207] The disc (i.e., intervertebral) space or other target site can then be prepared. For  
19 PLIF procedures, the vertebrae can be accessed through an incision in the patient's back  
20 (i.e., posterior to the vertebrae). Depending on the number of vertebral levels to be fused,  
21 about a 3-6 inch incision can be made in the patient's back. The spinal muscles can then  
22 be retracted (or separated), for example, to allow access to the target vertebral discs. The  
23 lamina can then be removed (i.e., a laminectomy), for example, to be able to see and  
24 access the nerve roots. The facet joints, which can lie directly over the nerve roots, can  
25 be trimmed, for example, to allow more room for the nerve roots. The target disc and  
26 surrounding tissue can then be removed and the bone surfaces of adjacent vertebrae can  
27 be prepared (e.g., cleaned, abraded, debrided, textured, scored, coated with osteogenic  
28 powders or other agents, or combinations thereof).

29 [0208] The devices 2 can then be inserted into the target site. One or more devices 2  
30 and/or bone graft (e.g., autograft, allograft, xenograft), BMP, or combinations thereof,  
31 can be inserted into the target site or disc space, for example, to promote fusion between

1 the vertebrae. Additional instrumentation (e.g., rods or screws) can also be used at this  
2 time to further stabilize the spine.

3 [0209] TLIF can include delivering the device 2 to the spine in a path more from the side  
4 of the spinal canal than a PLIF approach and through a midline incision in the patient's  
5 back. TLIF can reduce the amount of surgical muscle dissection and can minimize  
6 nerve manipulation required to access the vertebrae, discs and nerves.

7 [0210] TLIF can include removing disc material from the spine and inserting the  
8 device(s) 2 and bone graft, BMP, screws, rods, or combinations thereof.

9 [0211] ALIF is performed inserting the from the front (anterior) of the body, usually  
10 through a 3-5 inch incision in the lower abdominal area or on the side. This incision may  
11 involve cutting through, and later repairing, the muscles in the lower abdomen.

12 [0212] A mini open ALIF approach can be performed. A mini open ALIF can preserve  
13 the muscles and allow access to the front of the spine through an incision. This approach  
14 maintains abdominal muscle strength and function and can be used to fuse the L5-S1 disc  
15 space., for example

16 [0213] Once the incision is made and the vertebrae are accessed, and after the abdominal  
17 muscles and blood vessels have been retracted, the disc material can be removed. The  
18 surgeon can then insert the devices 2 and/or bone graft, rods, screws, BMP, or  
19 combinations thereof, for example to stabilize the spine and facilitate fusion.

20 [0214] The target site for the device(s) 2 can be between sacral, lumbar, thoracic, cervical  
21 vertebrae, or combinations thereof. The target site can be between other bones, such as  
22 intercostal (between ribs), in the knee, elbow, wrist, ankle, or combinations thereof.

23 [0215] Figure 56b illustrates that one (as shown) or more devices 2 can be inserted into  
24 the target site, such as in a vertebral body or on a vertebral body (e.g., between adjacent  
25 vertebral bodies). The longitudinal axis 4 of the device 2 can be oriented substantially  
26 perpendicular to the anterior-posterior axis 320 (i.e., parallel to a lateral axis). The  
27 concavity of the radius of curvature 300 can face anteriorly or posteriorly.

28 [0216] The device 2 can be filled with a filled before or after radial expansion. Tissue  
29 ingrowth can occur into the top plate through the top ports, bottom plate through the  
30 bottom ports, and elsewhere through the device.

1 [0217] The device 2 can provide fusion between the adjacent vertebrae. The devices 2  
2 can have radiopaque and/or echogenic visualization markers, for example the markers  
3 can be along the top plate, bottom plate, and one or more panels of the plates. The  
4 deployment tool can also have one or more markers. The devices 2 can be inserted into  
5 multiple interbody target sites of the spine to provide fusion between adjacent vertebral  
6 bodies. A first device can be inserted into a first interbody site and a second device can  
7 be inserted into a second interbody site. The first and second devices can be inserted  
8 bilaterally, for example both devices can be inserted between the same first vertebra and  
9 second vertebra from opposite lateral sides.

10 [0218] Any or all elements of the device 2 and/or other devices or apparatuses described  
11 herein can be made from, for example, a single or multiple stainless steel alloys, nickel  
12 titanium alloys (e.g., Nitinol), cobalt-chrome alloys (e.g., ELGILOY® from Elgin  
13 Specialty Metals, Elgin, IL; CONICHROME® from Carpenter Metals Corp.,  
14 Wyomissing, PA), nickel-cobalt alloys (e.g., MP35N® from Magellan Industrial Trading  
15 Company, Inc., Westport, CT), molybdenum alloys (e.g., molybdenum TZM alloy, for  
16 example as disclosed in International Pub. No. WO 03/082363 A2, published 9 October  
17 2003, which is herein incorporated by reference in its entirety), tungsten-rhenium alloys,  
18 for example, as disclosed in International Pub. No. WO 03/082363, polymers such as  
19 polyethylene terephthalate (PET), polyester (e.g., DACRON® from E. I. Du Pont de  
20 Nemours and Company, Wilmington, DE), poly ester amide (PEA), polypropylene,  
21 aromatic polyesters, such as liquid crystal polymers (e.g., Vectran, from Kuraray Co.,  
22 Ltd., Tokyo, Japan), ultra high molecular weight polyethylene (i.e., extended chain, high-  
23 modulus or high-performance polyethylene) fiber and/or yarn (e.g., SPECTRA® Fiber  
24 and SPECTRA® Guard, from Honeywell International, Inc., Morris Township, NJ, or  
25 DYNEMA® from Royal DSM N.V., Heerlen, the Netherlands), polytetrafluoroethylene  
26 (PTFE), expanded PTFE (ePTFE), polyether ketone (PEK), polyether ether ketone  
27 (PEEK), poly ether ketone ketone (PEKK) (also poly aryl ether ketone ketone), nylon,  
28 polyether-block co-polyamide polymers (e.g., PEBAX® from ATOFINA, Paris, France),  
29 aliphatic polyether polyurethanes (e.g., TECOFLEX® from Thermedics Polymer  
30 Products, Wilmington, MA), polyvinyl chloride (PVC), polyurethane, thermoplastic,  
31 fluorinated ethylene propylene (FEP), absorbable or resorbable polymers such as

1 polyglycolic acid (PGA), poly-L-glycolic acid (PLGA), polylactic acid (PLA), poly-L-  
2 lactic acid (PLLA), polycaprolactone (PCL), polyethyl acrylate (PEA), polydioxanone  
3 (PDS), and pseudo-polyamino tyrosine-based acids, extruded collagen, silicone, zinc,  
4 echogenic, radioactive, radiopaque materials, a biomaterial (e.g., cadaver tissue, collagen,  
5 allograft, autograft, xenograft, bone cement, morselized bone, osteogenic powder, beads  
6 of bone) any of the other materials listed herein or combinations thereof. Examples of  
7 radiopaque materials are barium sulfate, zinc oxide, titanium, stainless steel, nickel-  
8 titanium alloys, tantalum and gold.

9 **[0219]** The device 2 can be made from substantially 100% PEEK, substantially 100%  
10 titanium or titanium alloy, or combinations thereof.

11 **[0220]** Any or all elements of the device 2 and/or other devices or apparatuses described  
12 herein, can be, have, and/or be completely or partially coated with agents for cell  
13 ingrowth.

14 **[0221]** The device 2 and/or elements of the device and/or other devices or apparatuses  
15 described herein can be filled, coated, layered and/or otherwise made with and/or from  
16 cements, fillers, and/or glues known to one having ordinary skill in the art and/or a  
17 therapeutic and/or diagnostic agent. Any of these cements and/or fillers and/or glues can  
18 be osteogenic and osteoinductive growth factors.

19 **[0222]** Examples of such cements and/or fillers includes bone chips, demineralized bone  
20 matrix (DBM), calcium sulfate, coralline hydroxyapatite, biocoral, tricalcium phosphate,  
21 calcium phosphate, polymethyl methacrylate (PMMA), biodegradable ceramics,  
22 bioactive glasses, hyaluronic acid, lactoferrin, bone morphogenic proteins (BMPs) such  
23 as recombinant human bone morphogenetic proteins (rhBMPs), other materials described  
24 herein, or combinations thereof.

25 **[0223]** The agents within these matrices can include any agent disclosed herein or  
26 combinations thereof, including radioactive materials; radiopaque materials; cytogenic  
27 agents; cytotoxic agents; cytostatic agents; thrombogenic agents, for example  
28 polyurethane, cellulose acetate polymer mixed with bismuth trioxide, and ethylene vinyl  
29 alcohol; lubricious, hydrophilic materials; phosphor cholene; anti-inflammatory agents,  
30 for example non-steroidal anti-inflammatories (NSAIDs) such as cyclooxygenase-1  
31 (COX-1) inhibitors (e.g., acetylsalicylic acid, for example ASPIRIN® from Bayer AG,

1   Leverkusen, Germany; ibuprofen, for example ADVIL® from Wyeth, Collegeville, PA;  
2   indomethacin; mefenamic acid), COX-2 inhibitors (e.g., VIOXX® from Merck & Co.,  
3   Inc., Whitehouse Station, NJ; CELEBREX® from Pharmacia Corp., Peapack, NJ; COX-  
4   1 inhibitors); immunosuppressive agents, for example Sirolimus (RAPAMUNE®, from  
5   Wyeth, Collegeville, PA), or matrix metalloproteinase (MMP) inhibitors (e.g.,  
6   tetracycline and tetracycline derivatives) that act early within the pathways of an  
7   inflammatory response. Examples of other agents are provided in Walton et al, Inhibition  
8   of Prostaglandin E<sub>2</sub> Synthesis in Abdominal Aortic Aneurysms, *Circulation*, July 6, 1999,  
9   48-54; Tambiah et al, Provocation of Experimental Aortic Inflammation Mediators and  
10  Chlamydia Pneumoniae, *Brit. J. Surgery* 88 (7), 935-940; Franklin et al, Uptake of  
11  Tetracycline by Aortic Aneurysm Wall and Its Effect on Inflammation and Proteolysis,  
12  *Brit. J. Surgery* 86 (6), 771-775; Xu et al, Sp1 Increases Expression of Cyclooxygenase-2  
13  in Hypoxic Vascular Endothelium, *J. Biological Chemistry* 275 (32) 24583-24589; and  
14  Pyo et al, Targeted Gene Disruption of Matrix Metalloproteinase-9 (Gelatinase B)  
15  Suppresses Development of Experimental Abdominal Aortic Aneurysms, *J. Clinical*  
16  *Investigation* 105 (11), 1641-1649 which are all incorporated by reference in their  
17  entireties.

18  **[0224]** Any elements described herein as singular can be pluralized (i.e., anything  
19  described as “one” can be more than one). Any species element of a genus element can  
20  have the characteristics or elements of any other species element of that genus. The  
21  above-described configurations, elements or complete assemblies and methods and their  
22  elements for carrying out the invention, and variations of aspects of the invention can be  
23  combined and modified with each other in any combination.

## CLAIMS

1  
2 We claim:

3 1. A method of using an orthopedic support device comprising:

4       positioning the device at a target site, wherein the device has a longitudinal axis,  
5 and wherein the longitudinal axis has a radius of curvature less than about 40 cm, and  
6 wherein the device comprises a first plate, a second plate opposite to the first plate, a first  
7 wedge between the first plate and the second plate at a first end of the device, and a  
8 second wedge between the first plate and the second plate at a second end of the device,  
9 wherein the first plate has a first extension extending in the direction of the second plate,  
10 and wherein the second plate has a first receiver configured to receive the first extension;  
11 and

12       expanding the device at the target site, wherein expanding the target site  
13 comprises longitudinally moving the first wedge and the second wedge toward the  
14 longitudinal middle of the device, and wherein the first extension slides in the first  
15 receiver during the expansion of the device.

16  
17 2. The method of Claim 1, wherein expanding further comprises restricting longitudinal  
18 translation between the first plate and the second plate.

19  
20 3. The method of Claim 2, wherein the restricting longitudinal translation comprises  
21 sliding of the first extension in the first receiver.

22  
23 4. An implantable orthopedic device having a longitudinal axis comprising:

24       a first plate having a longitudinal axis having a radius of curvature less than about  
25 40 cm;

26       a second plate opposite to the first plate;

27       a first wedge between the first plate and the second plate at a first longitudinal end  
28 of the device; and

29       a second wedge between the first plate and the second plate at a second  
30 longitudinal end of the device;

1            wherein the first plate has a first extension extending in the direction of the  
2 second plate, and wherein the second plate has a first receiver configured to slidably  
3 receive the first extension; and

4            wherein the first wedge is longitudinally translatable toward the second wedge,  
5 and wherein the first extension slides.

6

7            5. The device of Claim 4, wherein the first plate has a first plate face substantially  
8 defining a first plane, and wherein the first extension extends away from the first plate  
9 face in a direction perpendicular to the first plane.

10

11            6. The device of Claim 5, wherein the second plate has a second plate face substantially  
12 defining a second plane, and wherein the first receiver is configured to slidably receive  
13 the first extension in a slidable direction perpendicular to the second plane.

14

15            7. The device of Claim 6, wherein the second plane is parallel with the first plane.

16

17

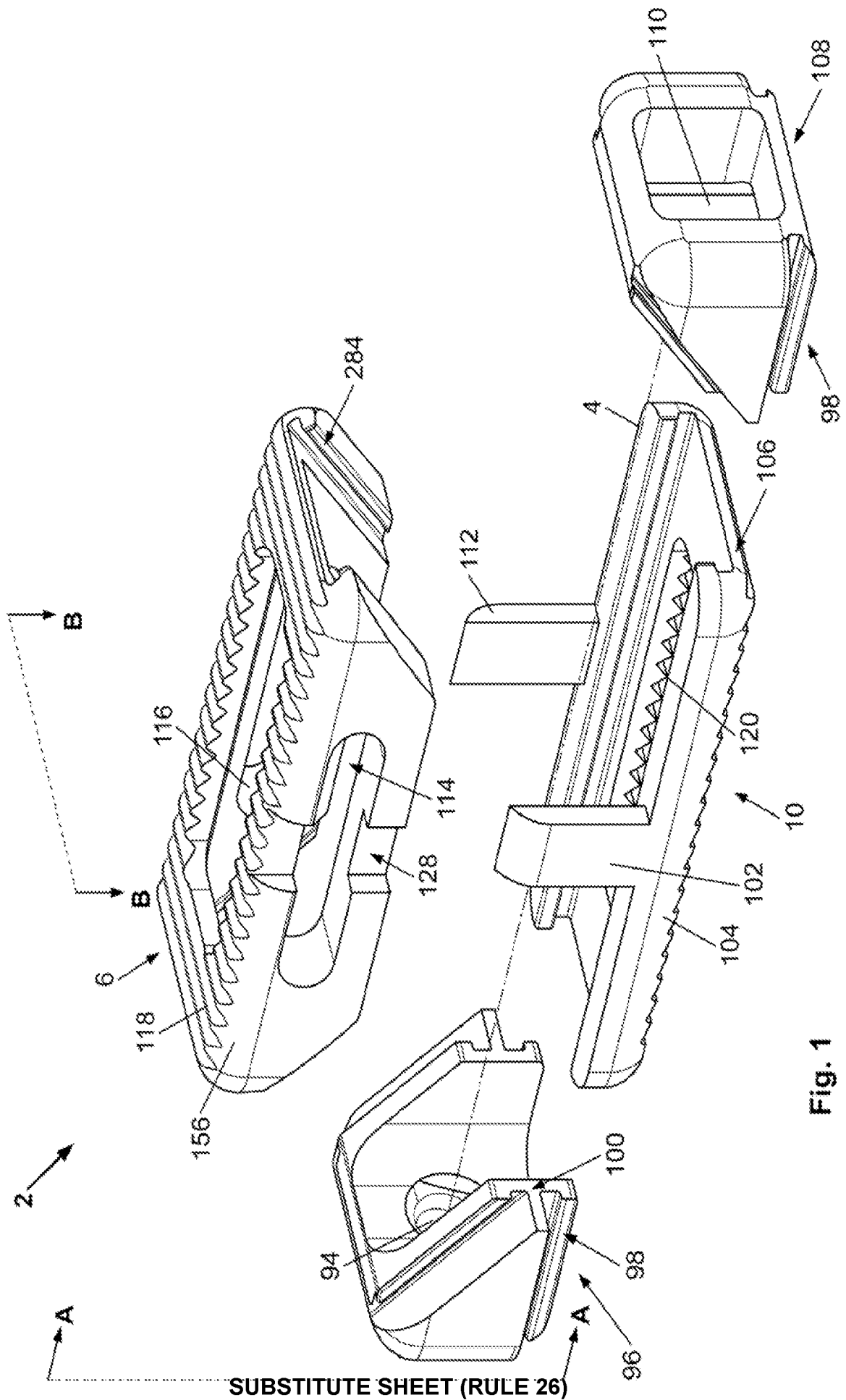


Fig. 1



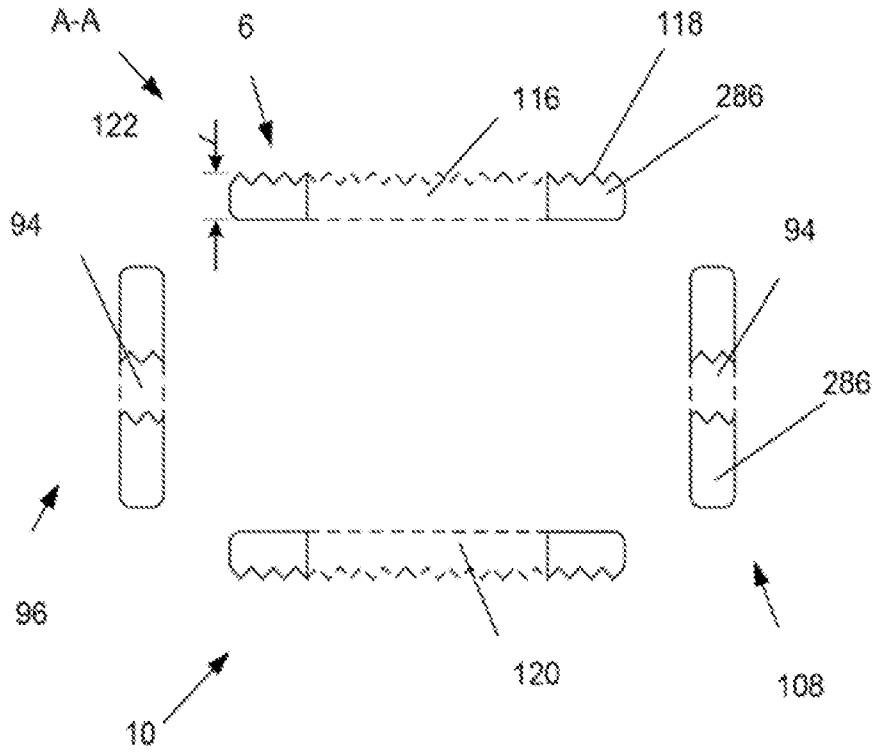


Fig. 2

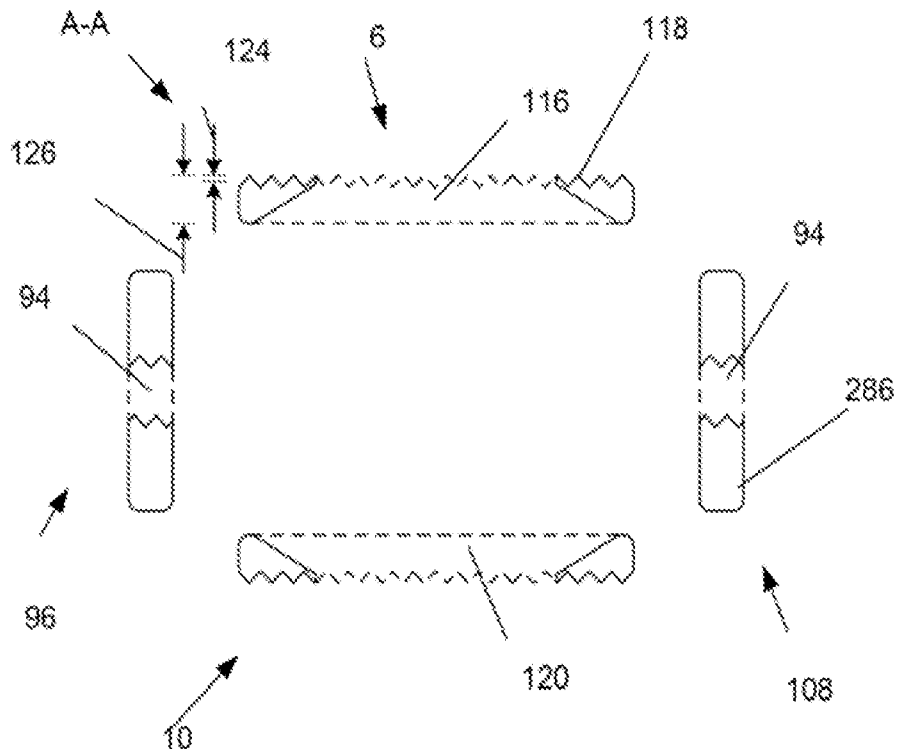


Fig. 3

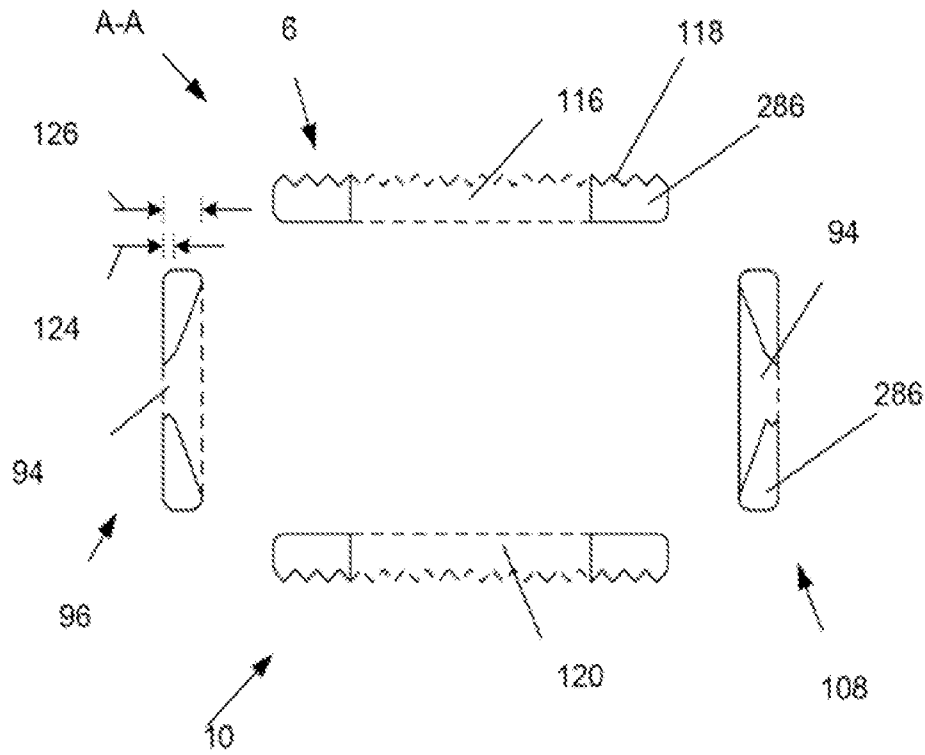


Fig. 4

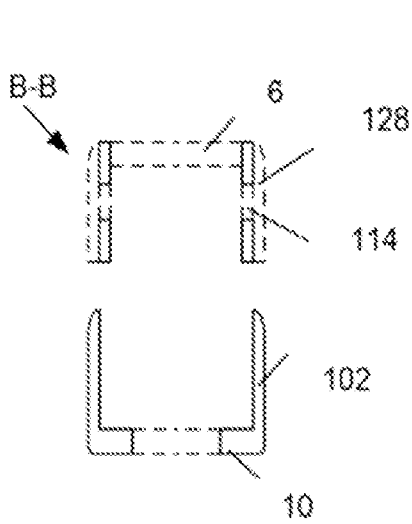


Fig. 5

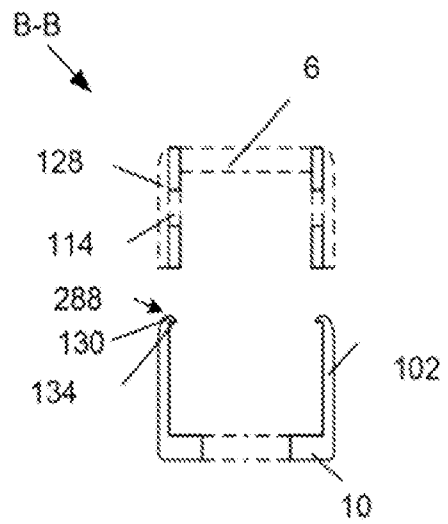
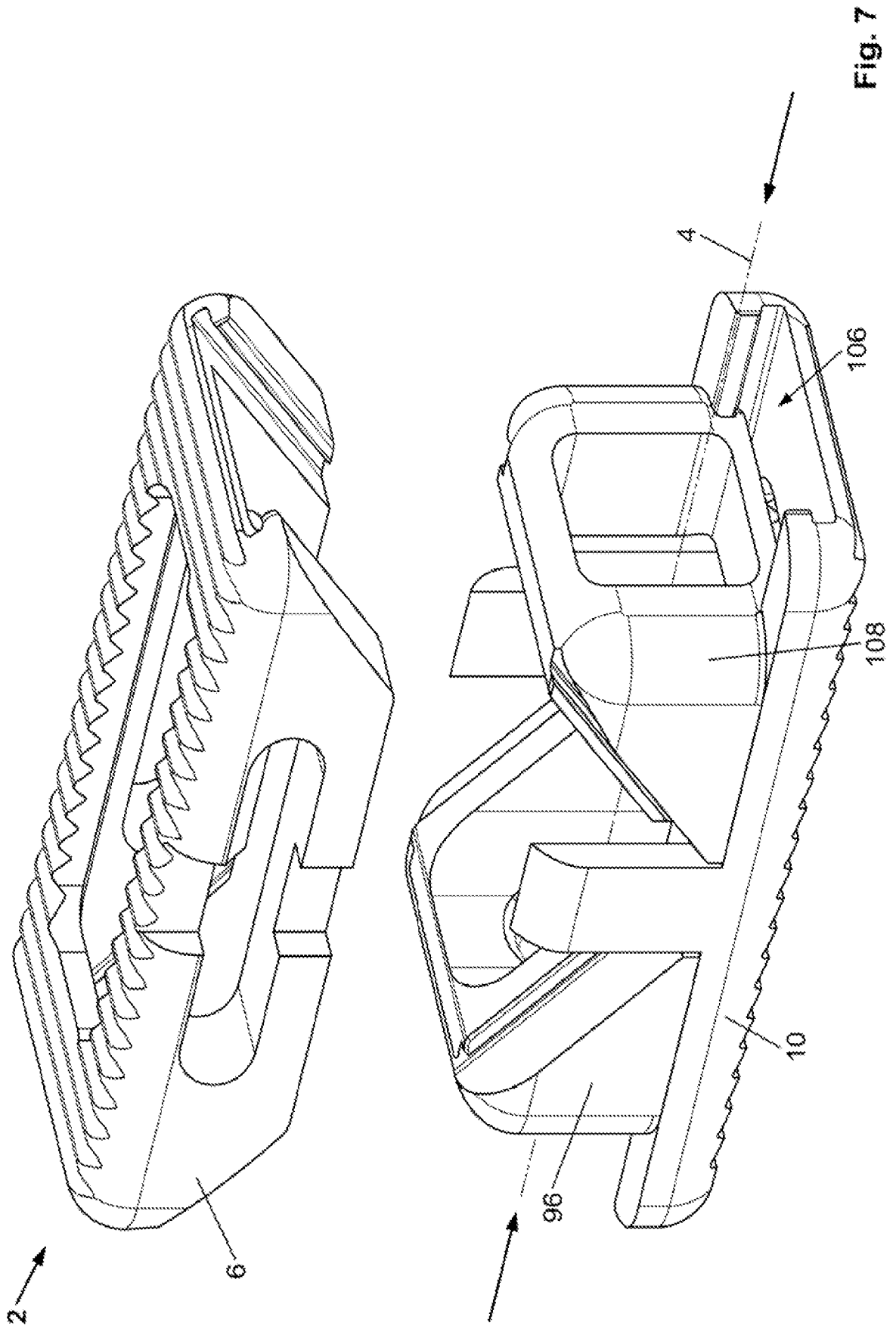


Fig. 6



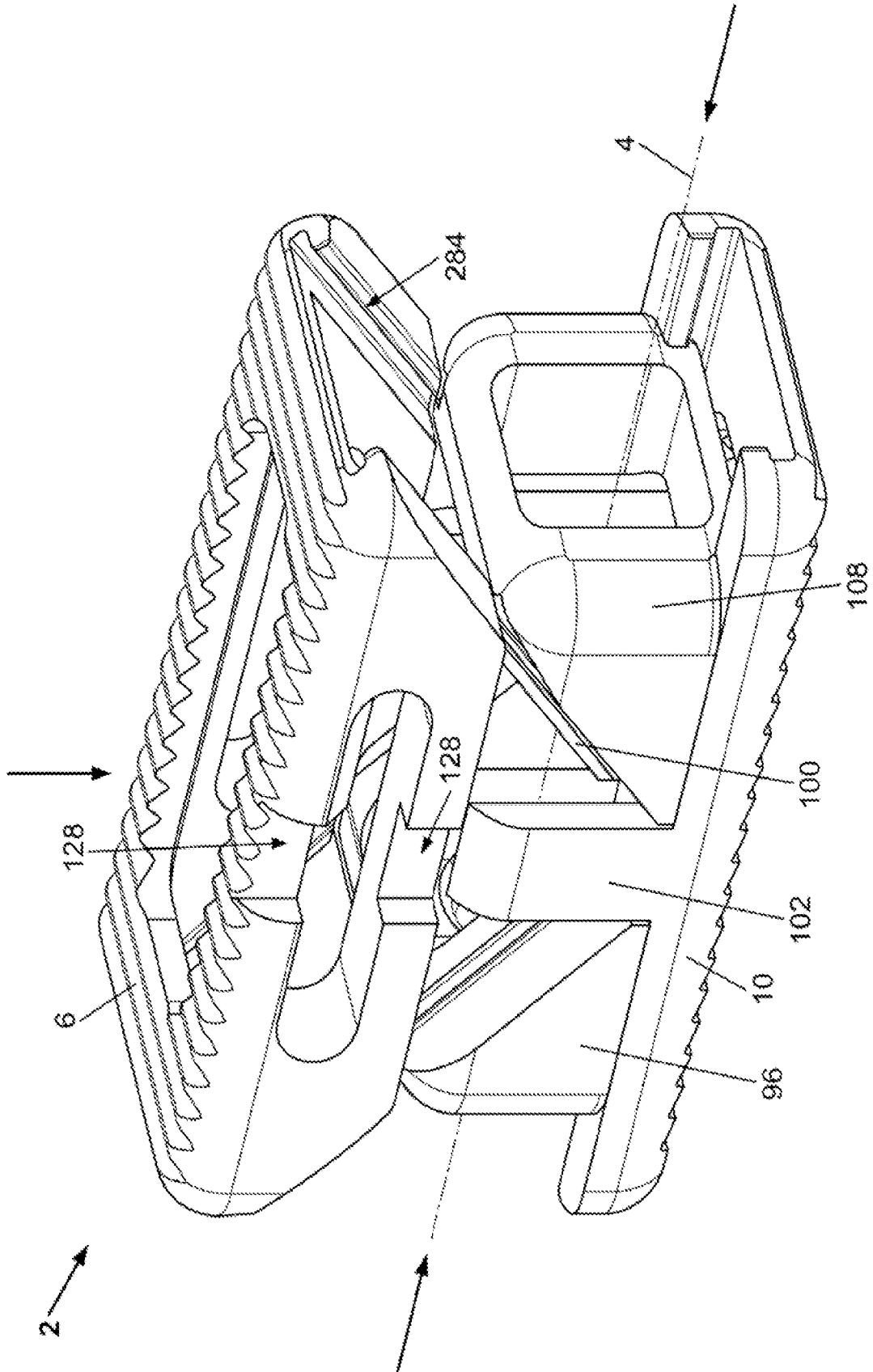


Fig. 8

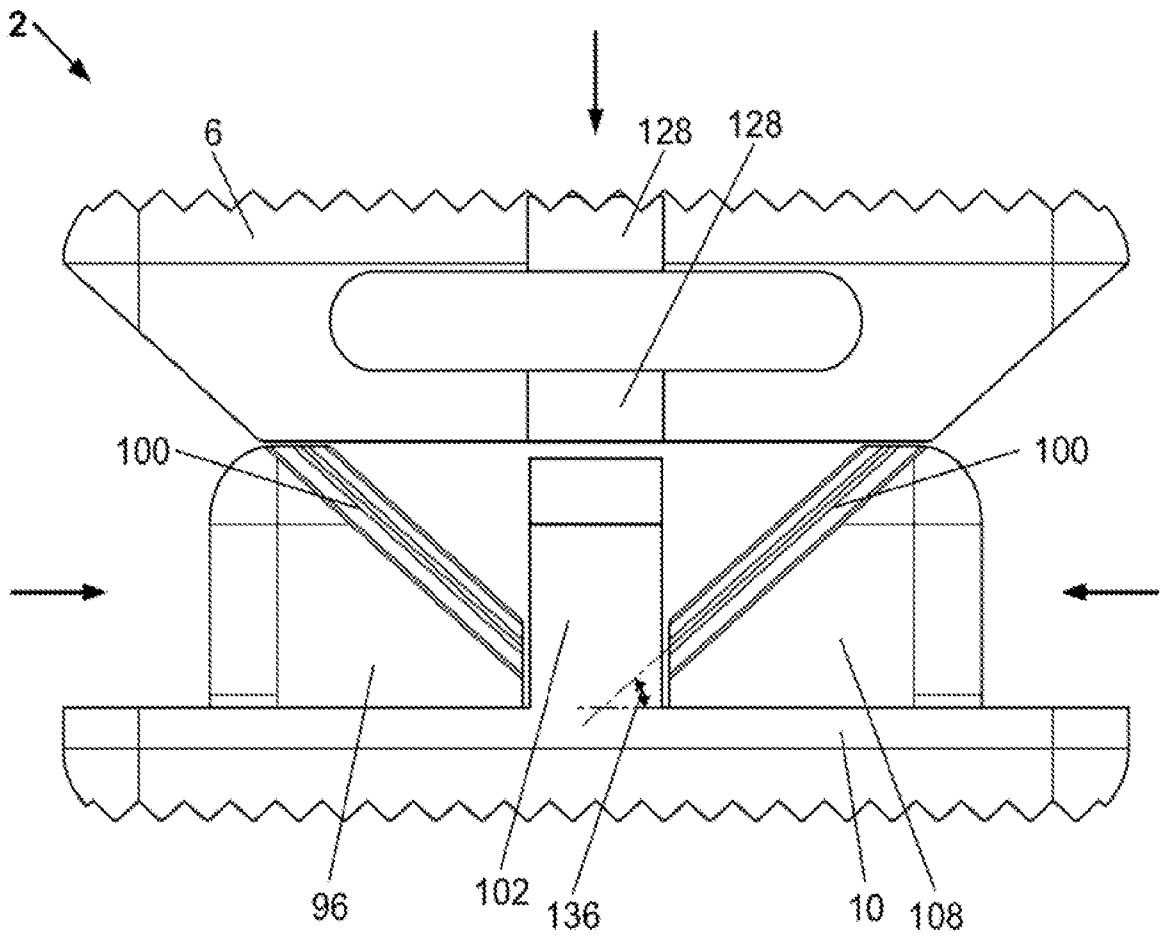
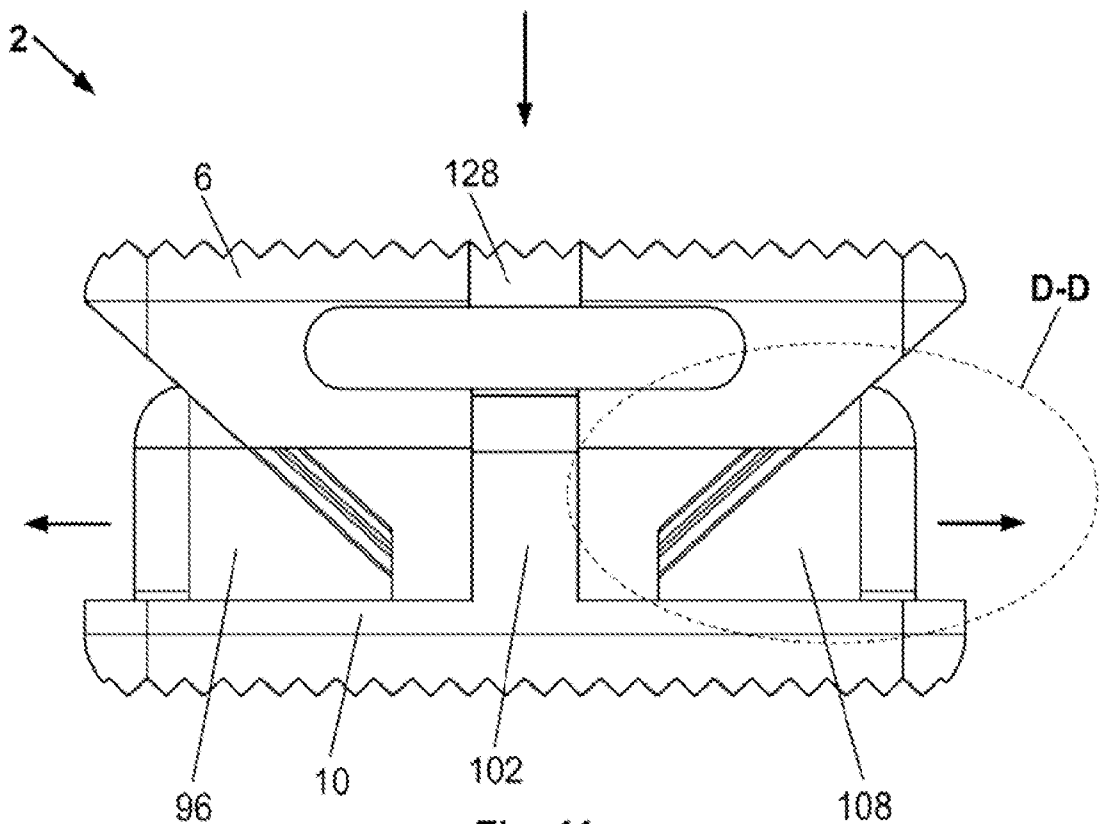


Fig. 9



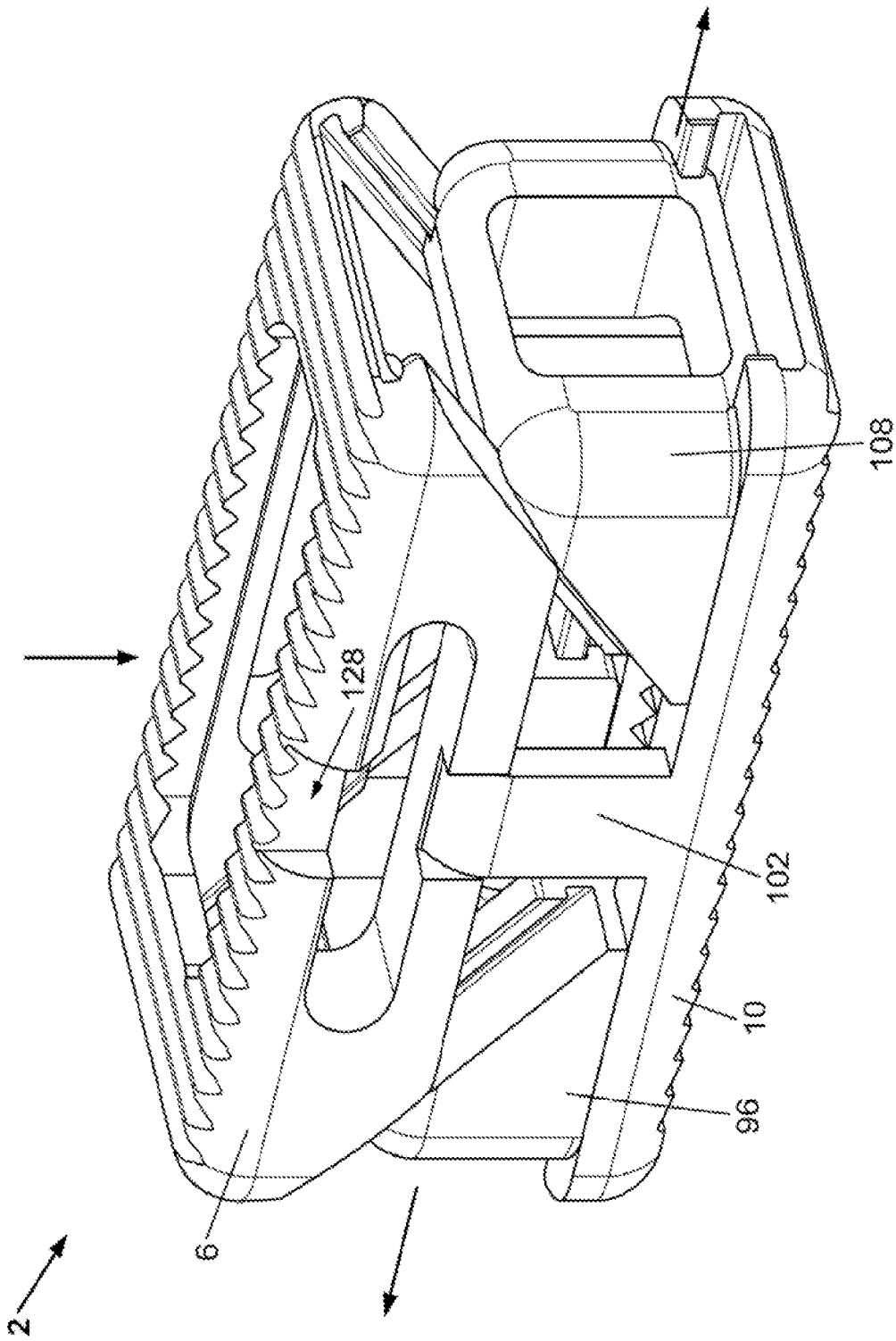


Fig. 10

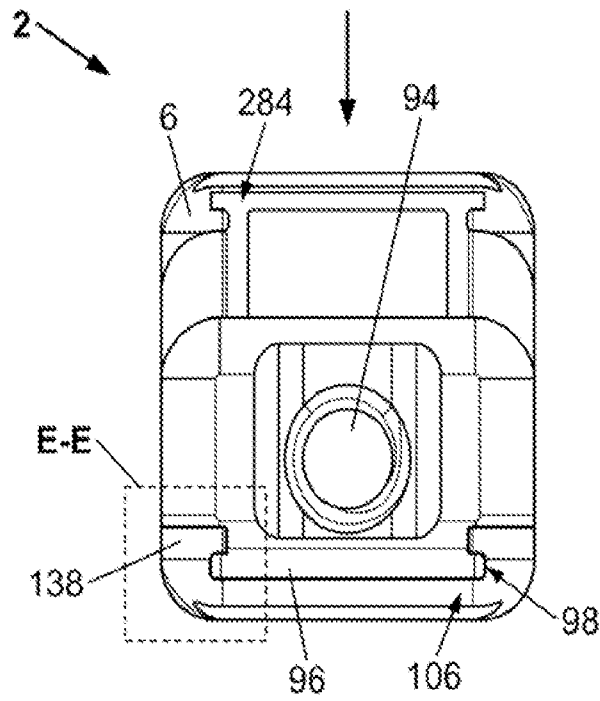


Fig. 12

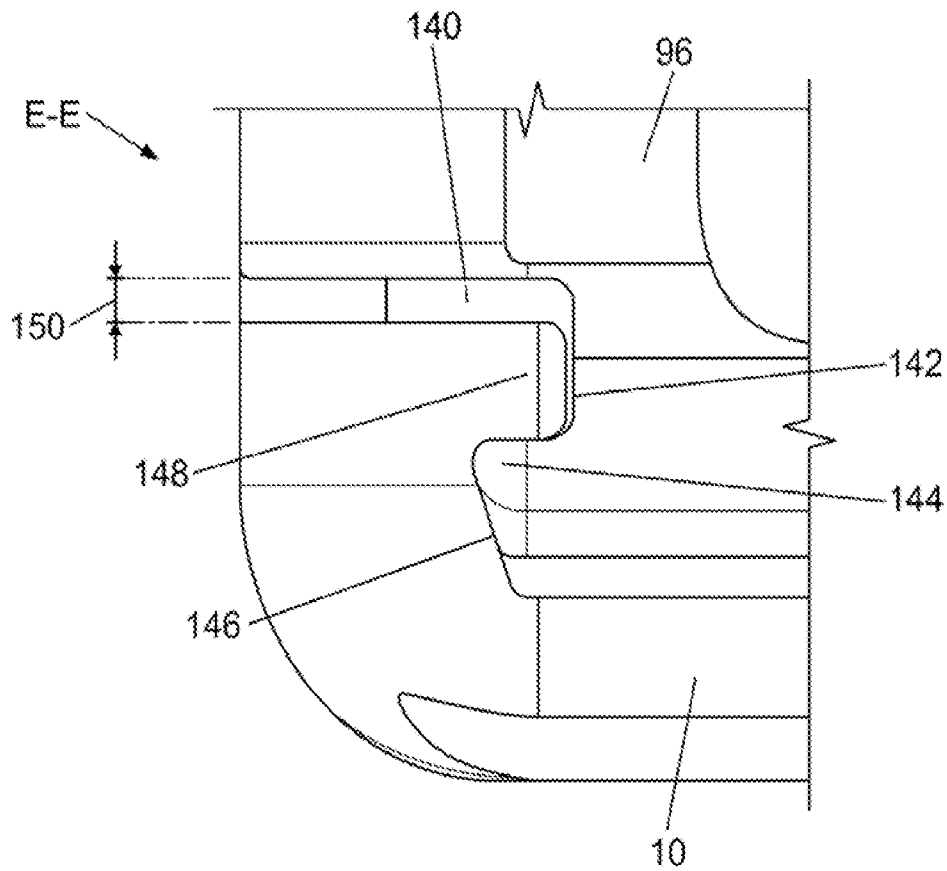


Fig. 13

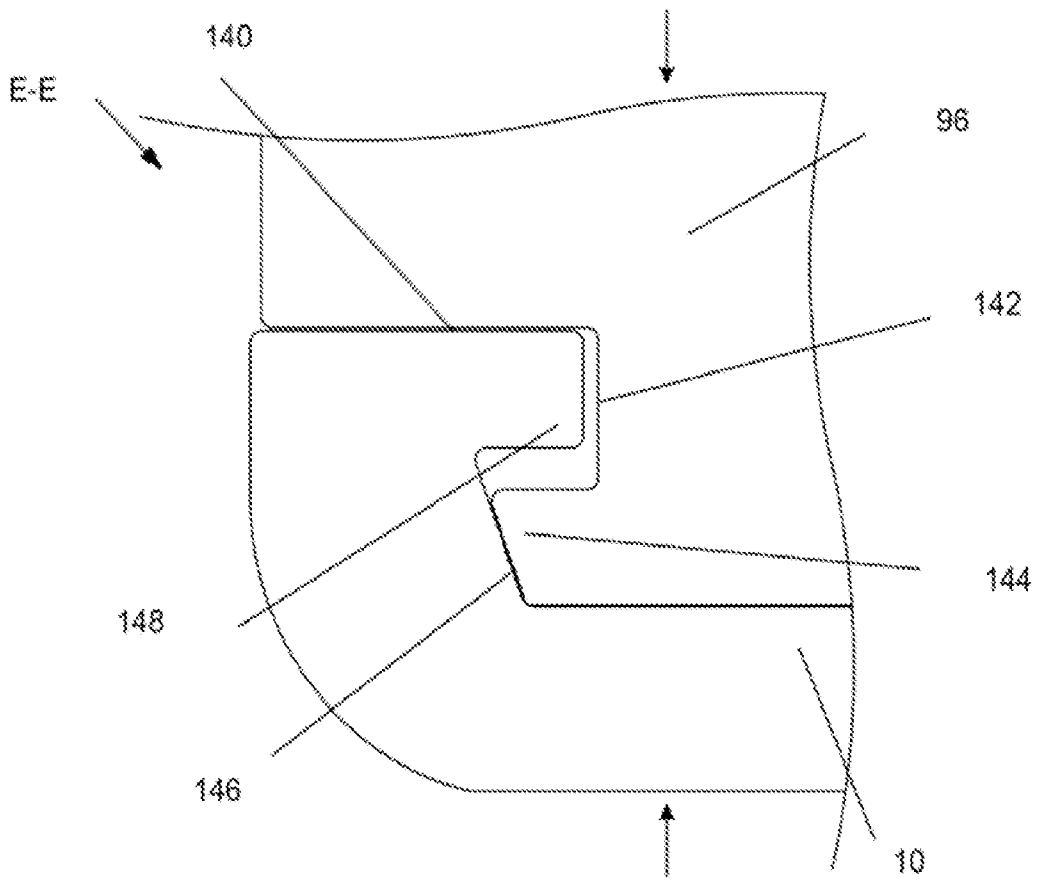


Fig. 14



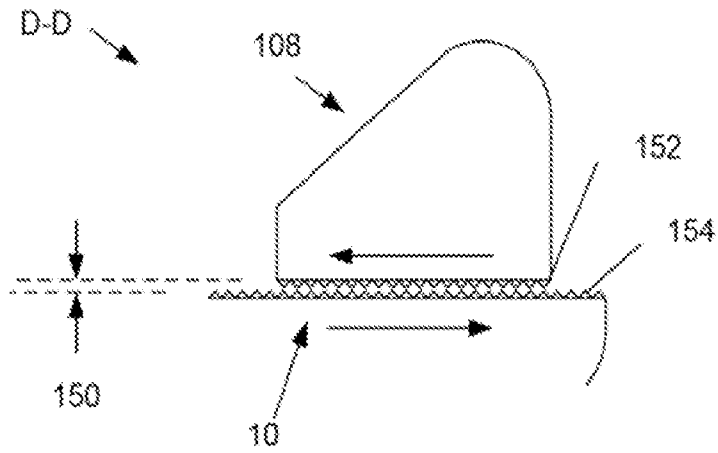


Fig. 15

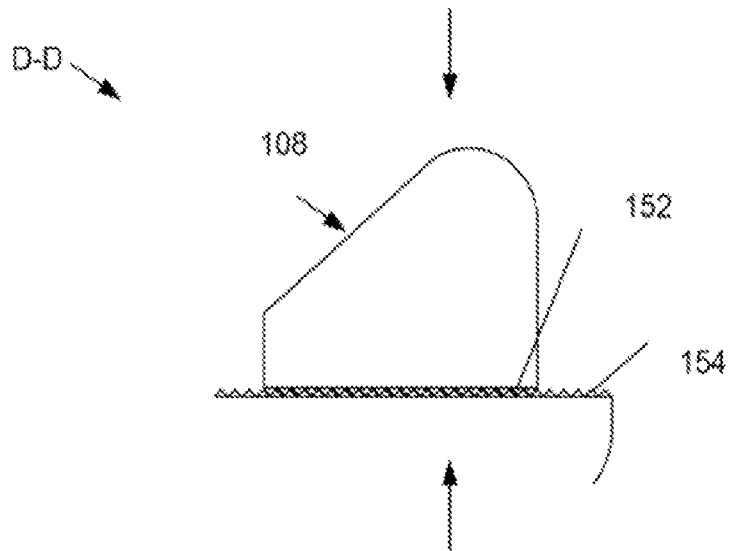


Fig. 16

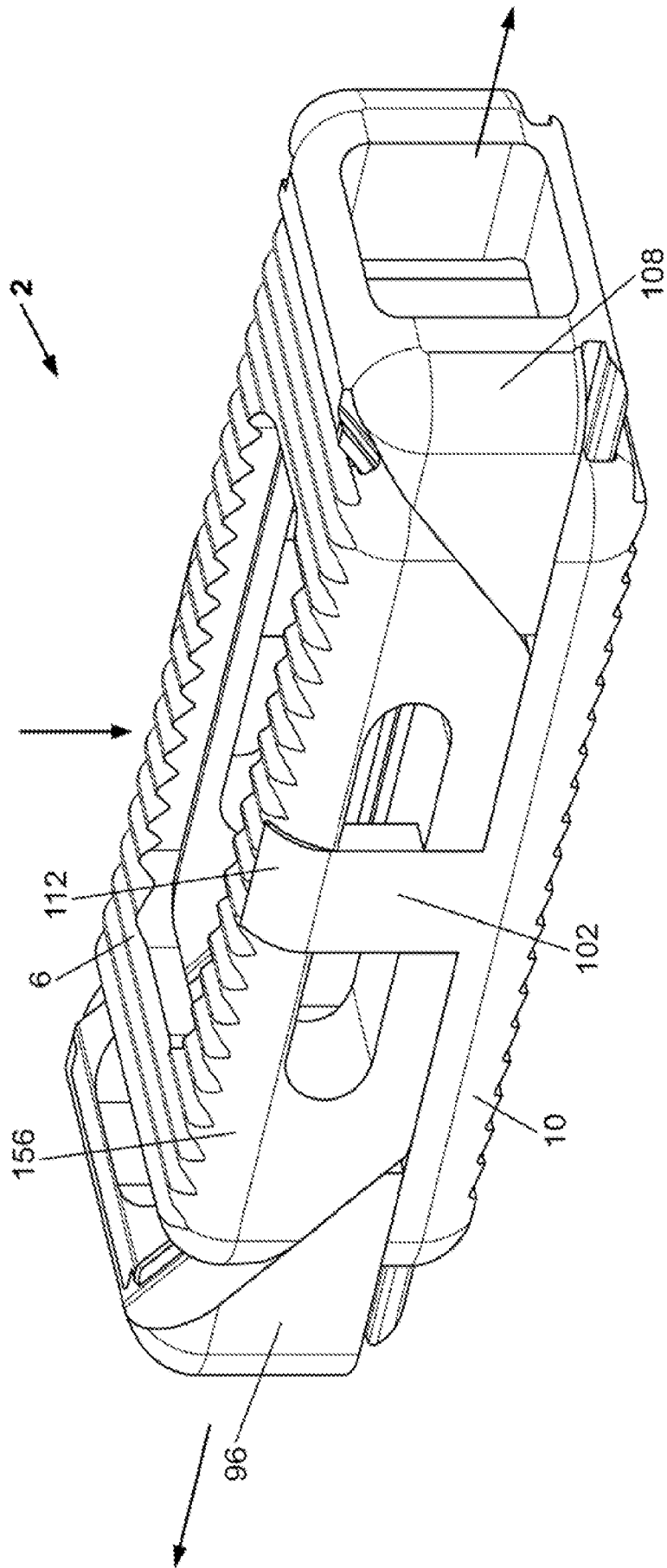


Fig. 17

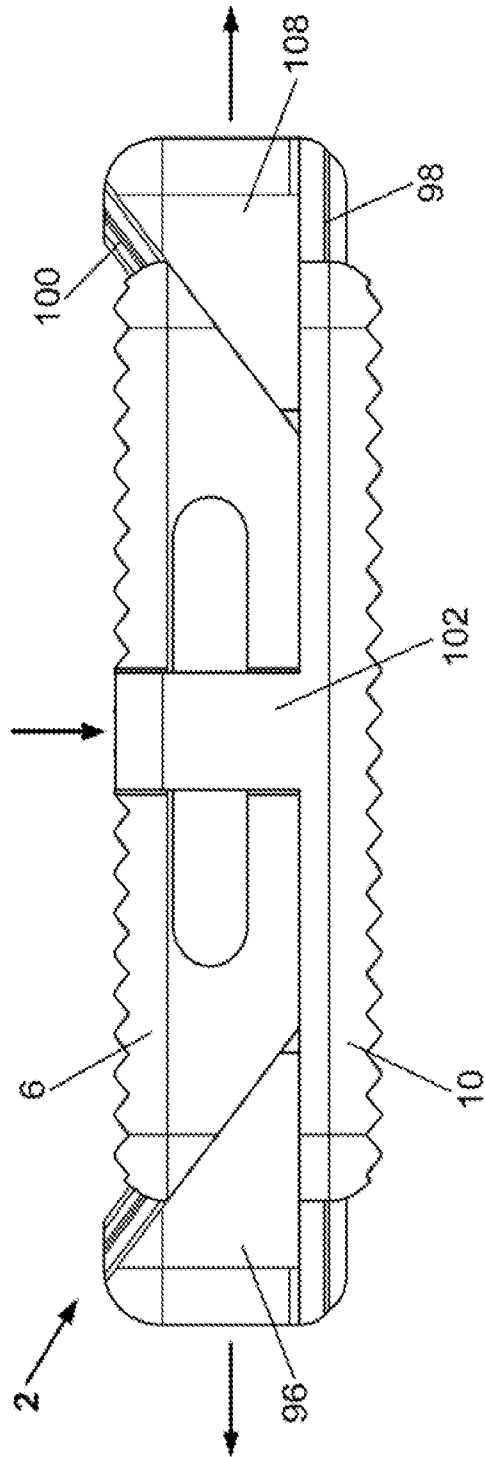


Fig. 18

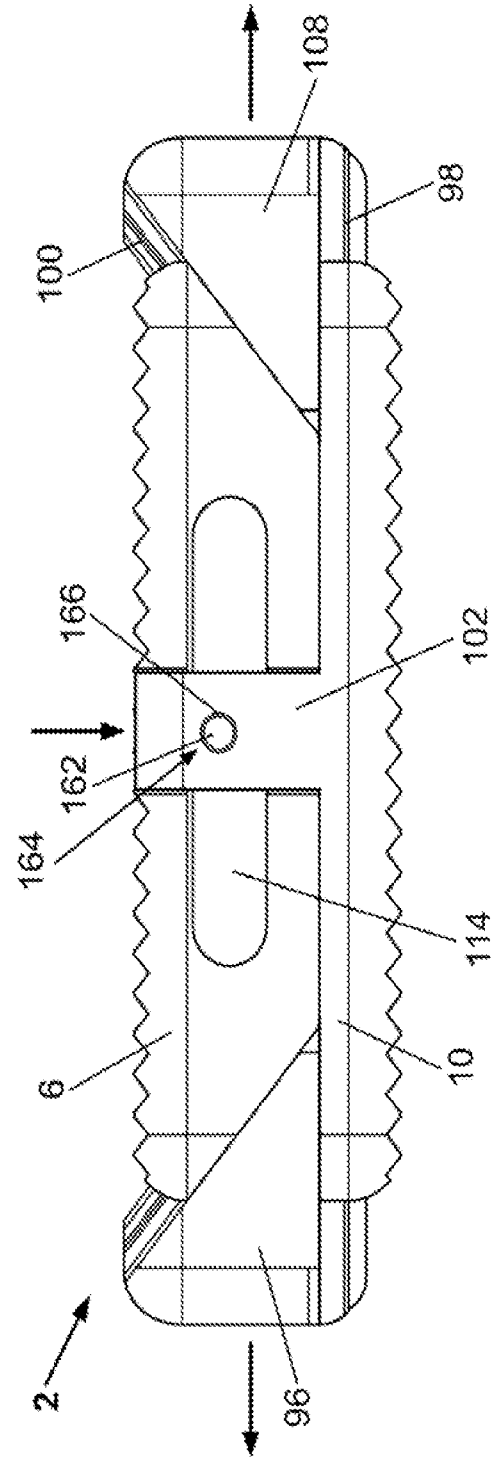


Fig. 19

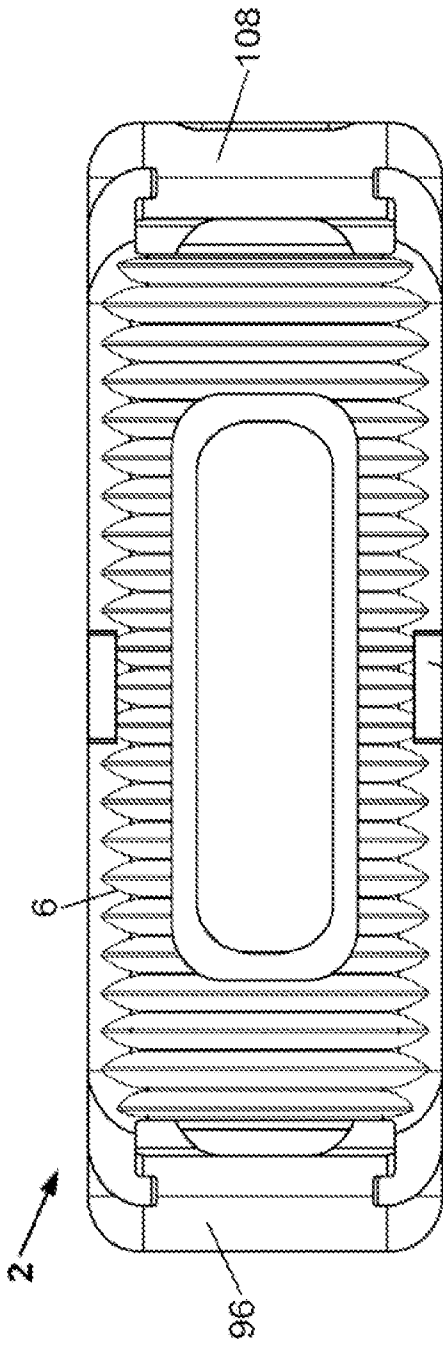


Fig. 21

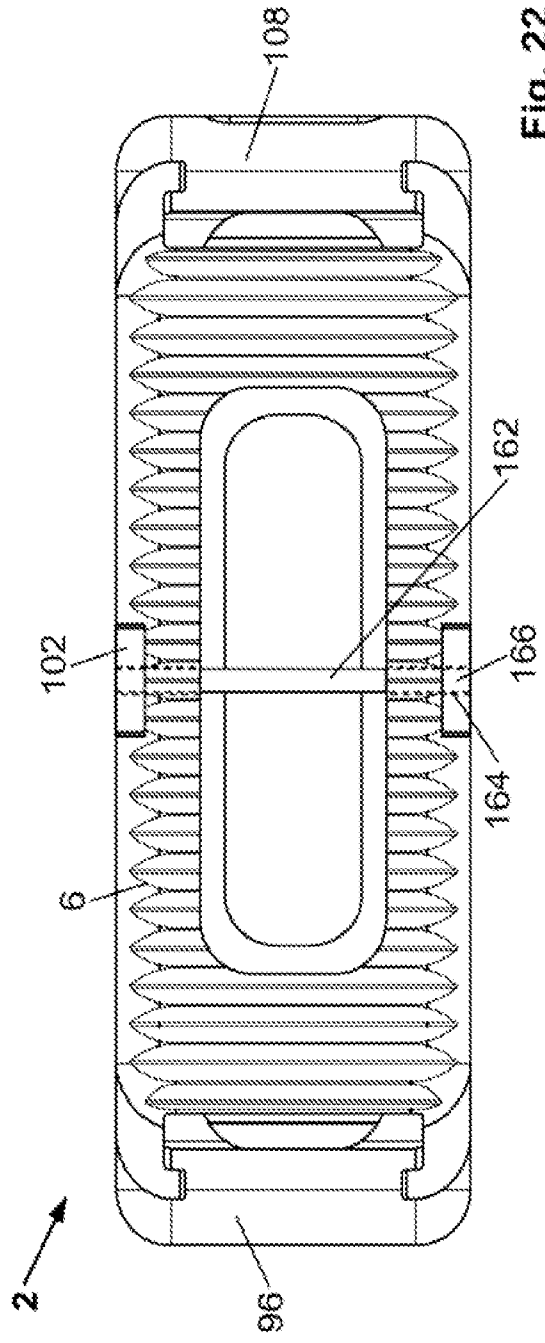


Fig. 22

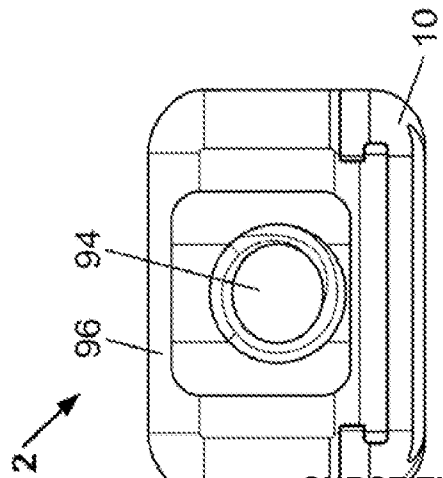


Fig. 20

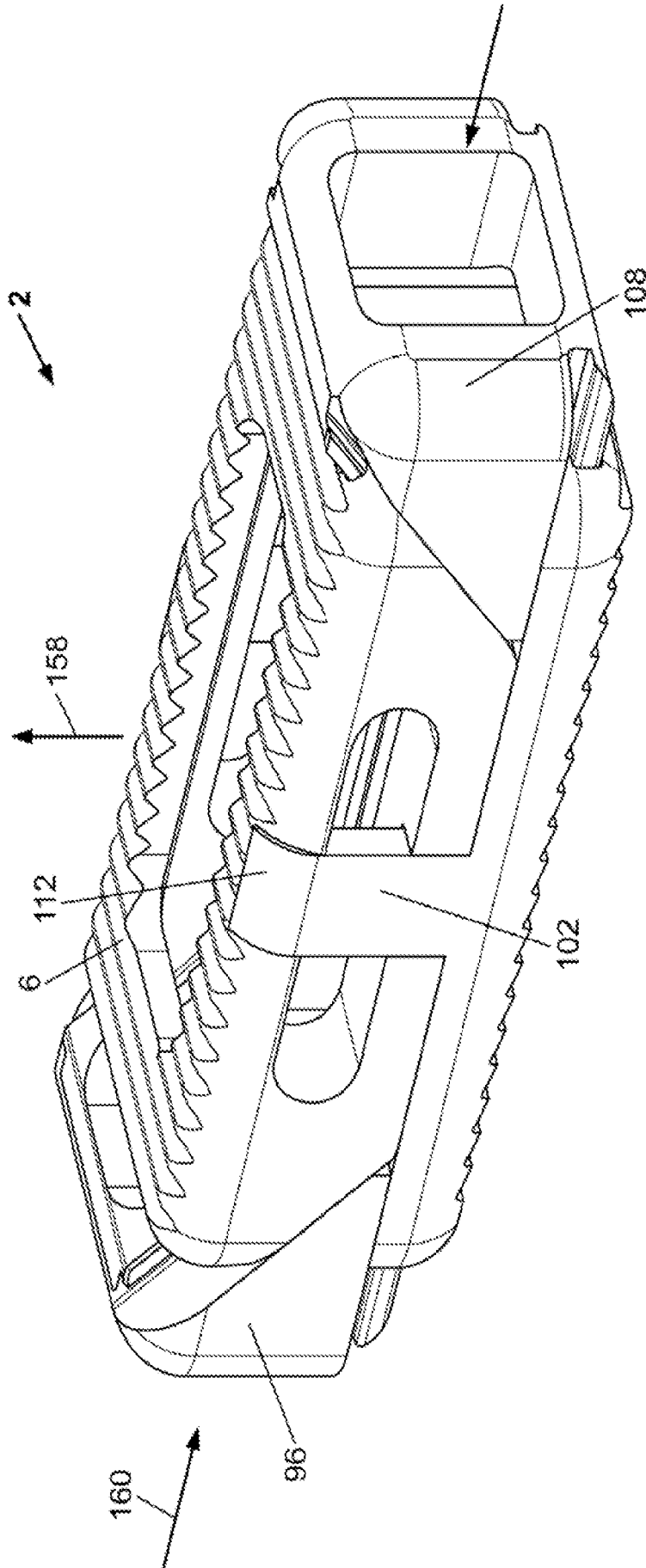


Fig. 23

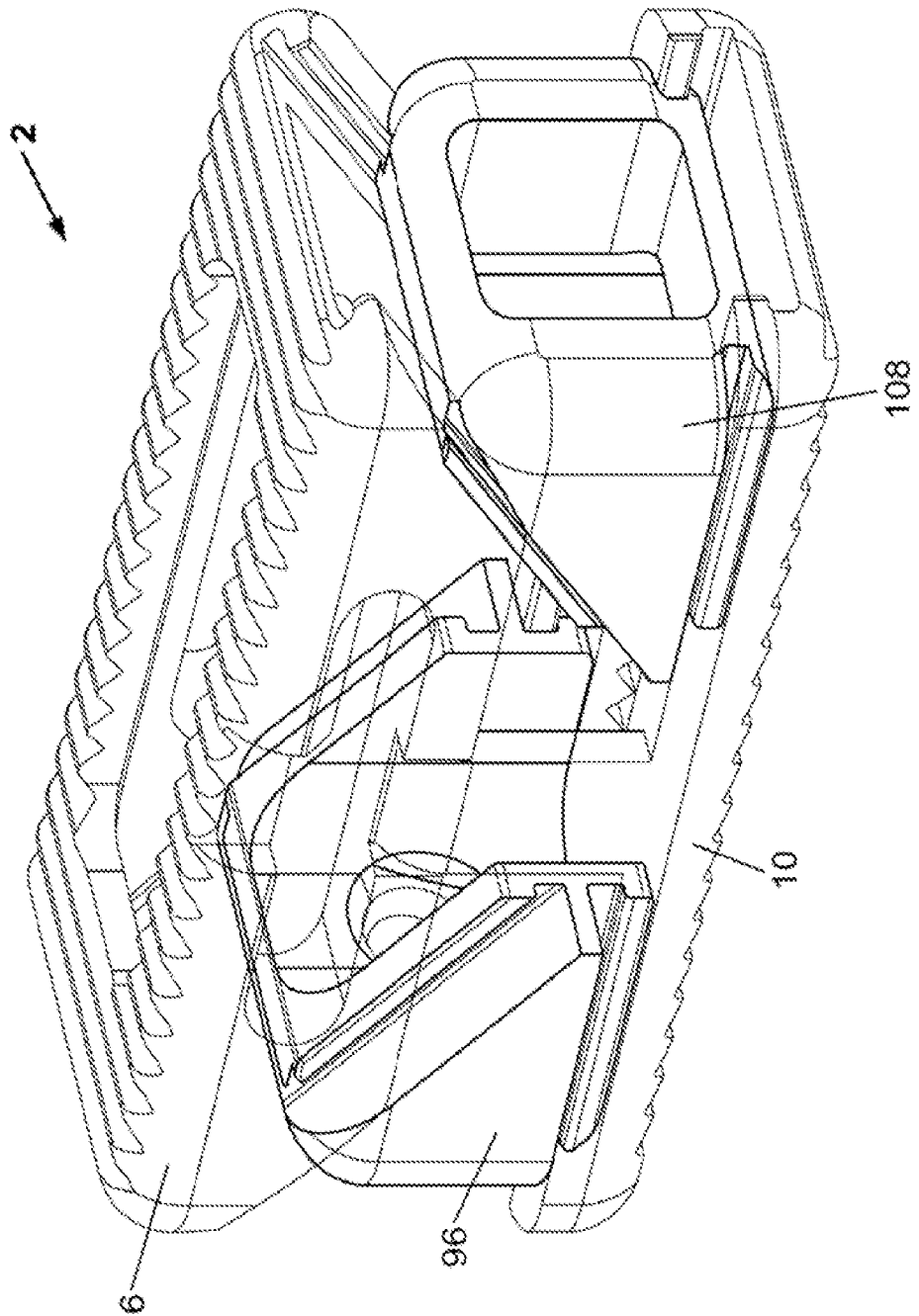


Fig. 24

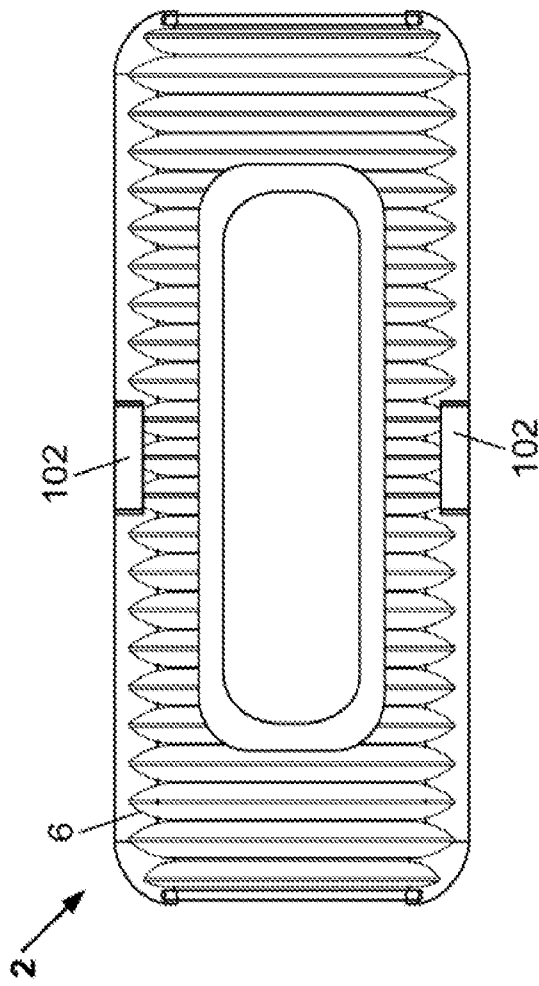


Fig. 25

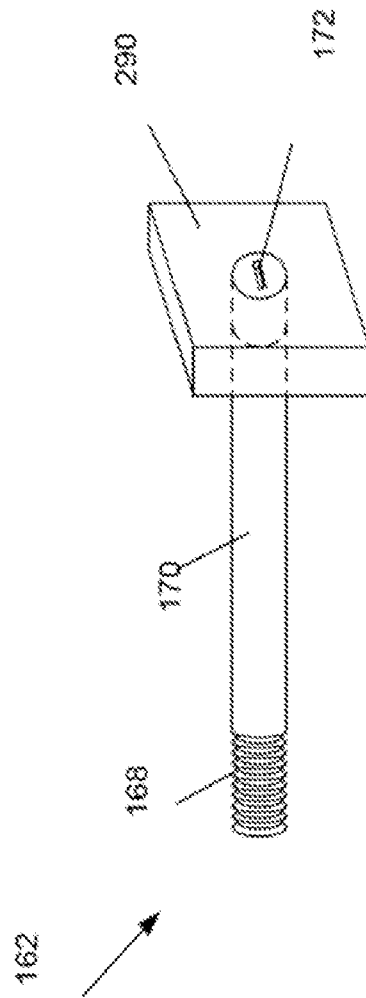


Fig. 26

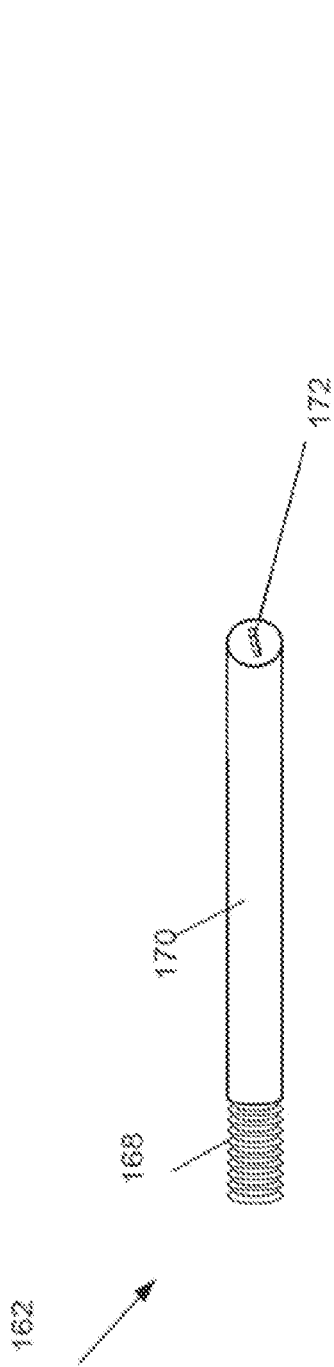


Fig. 27

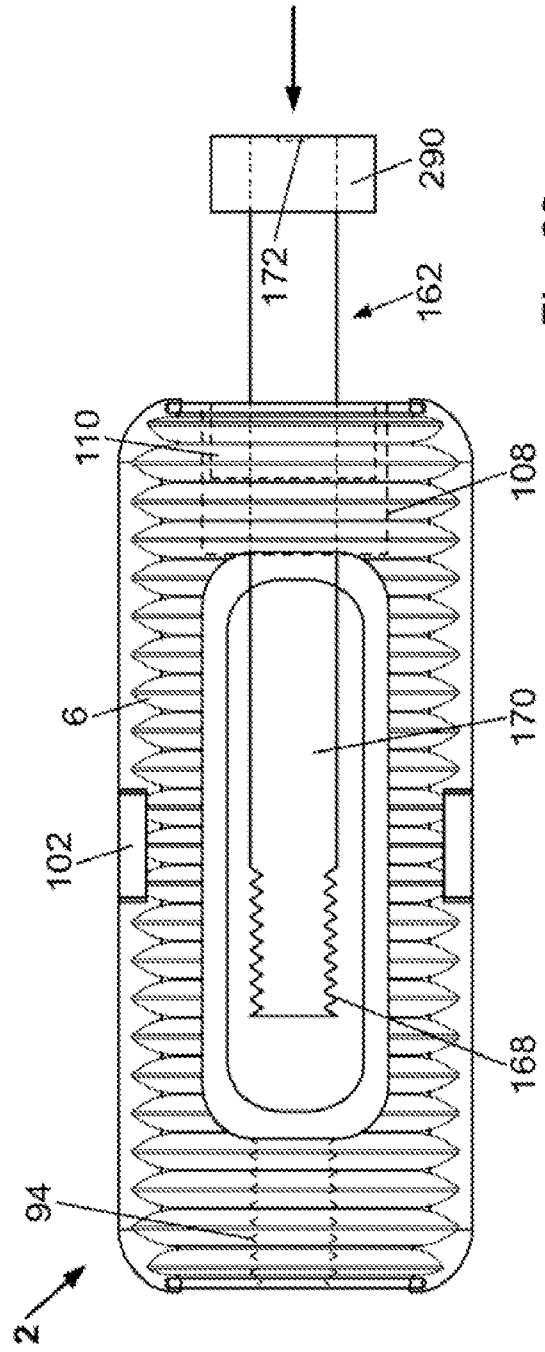


Fig. 28



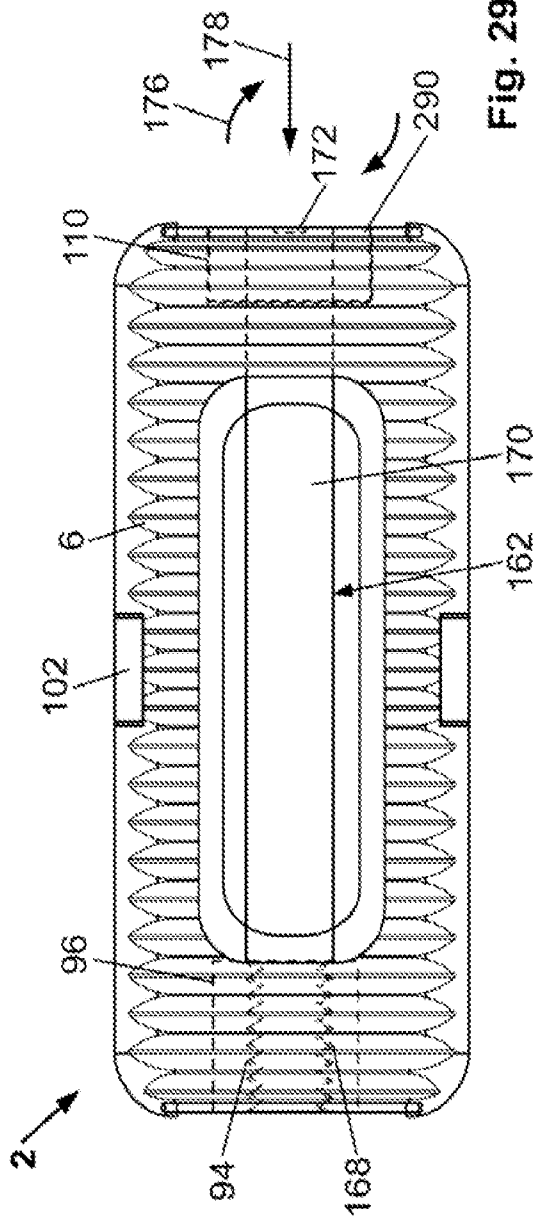


Fig. 29

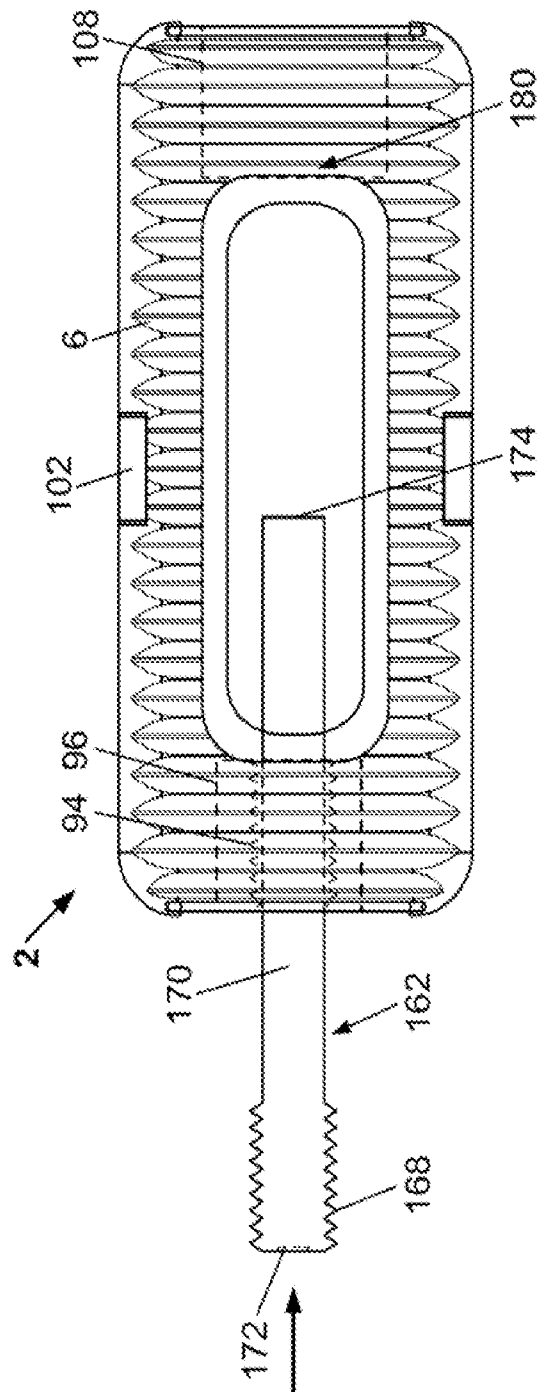


Fig. 30

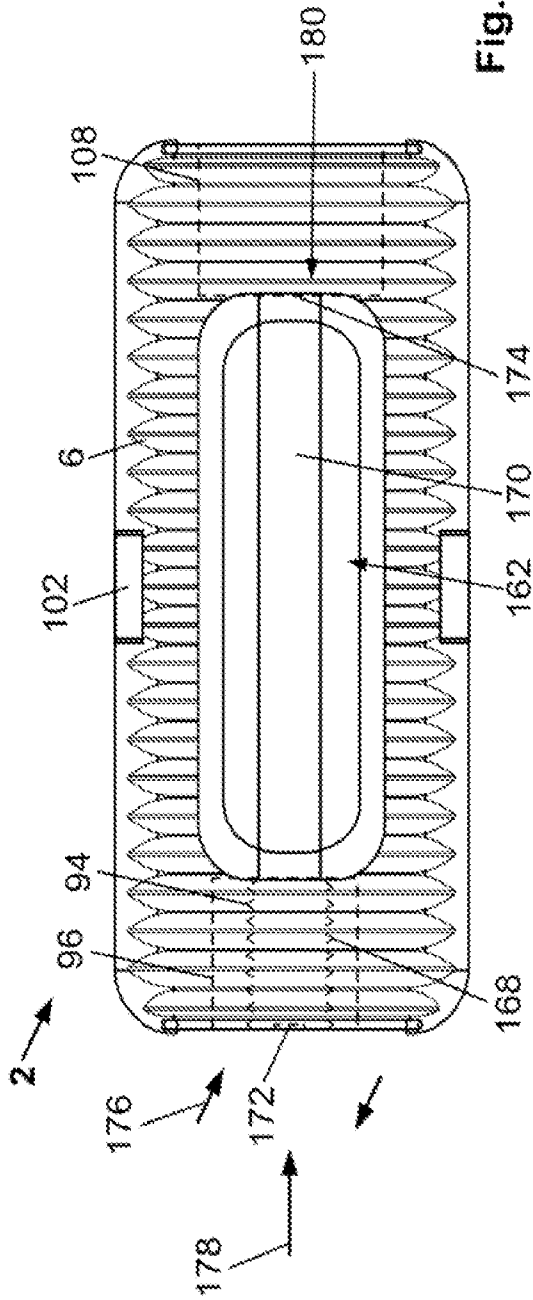


Fig. 31

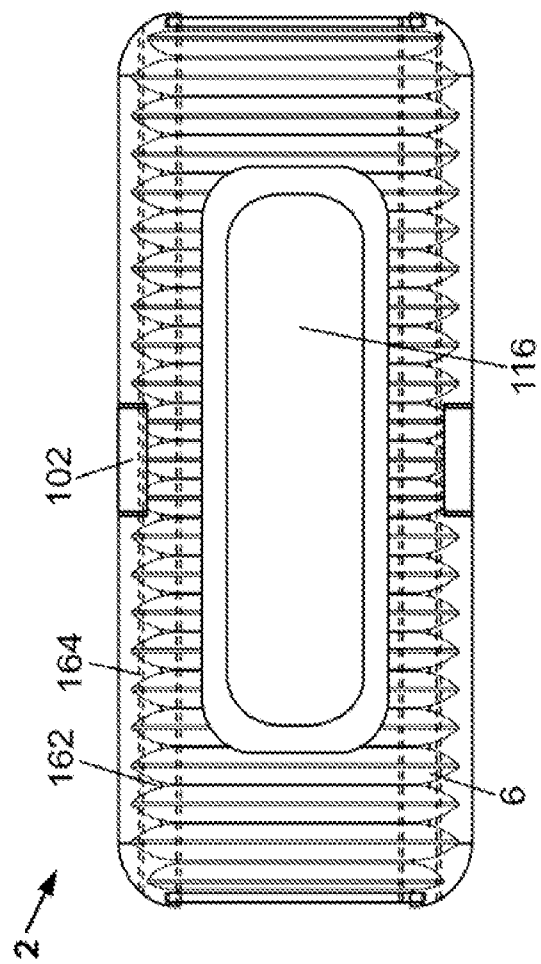


Fig. 32

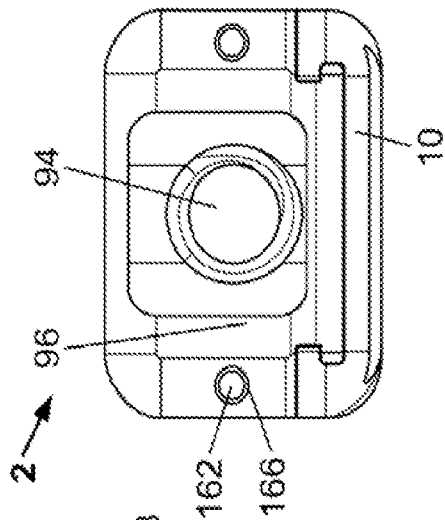


Fig. 34

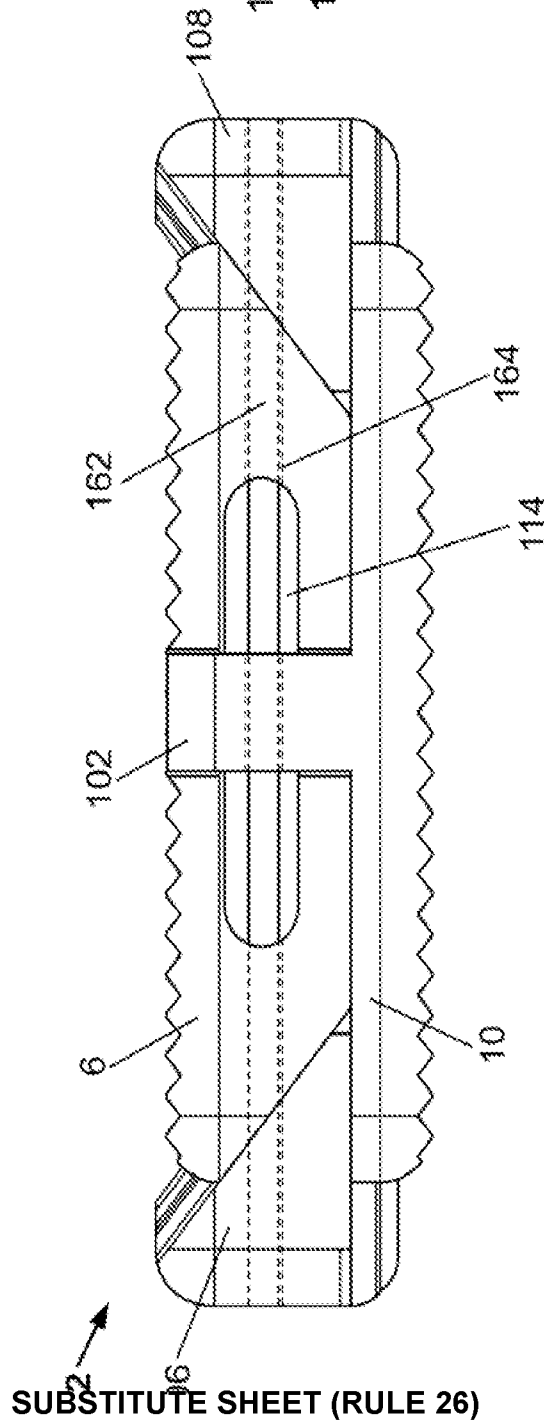


Fig. 33

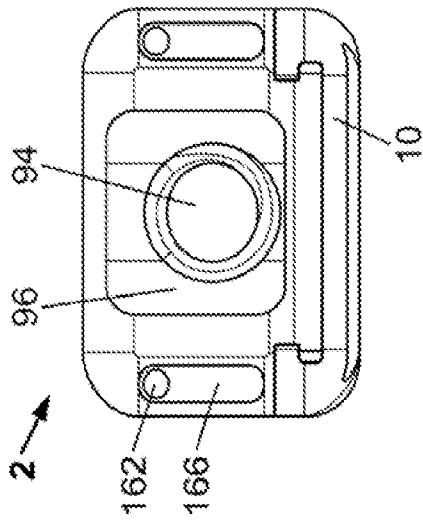


Fig. 36

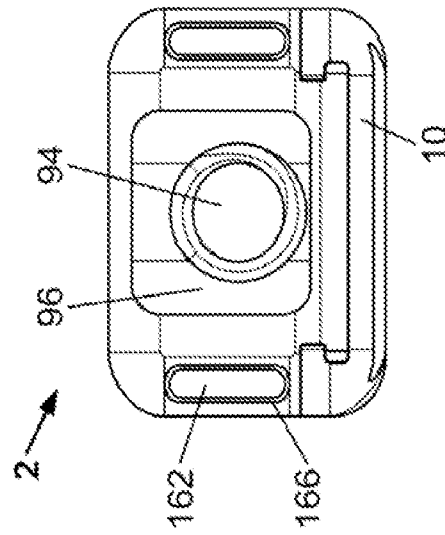


Fig. 38

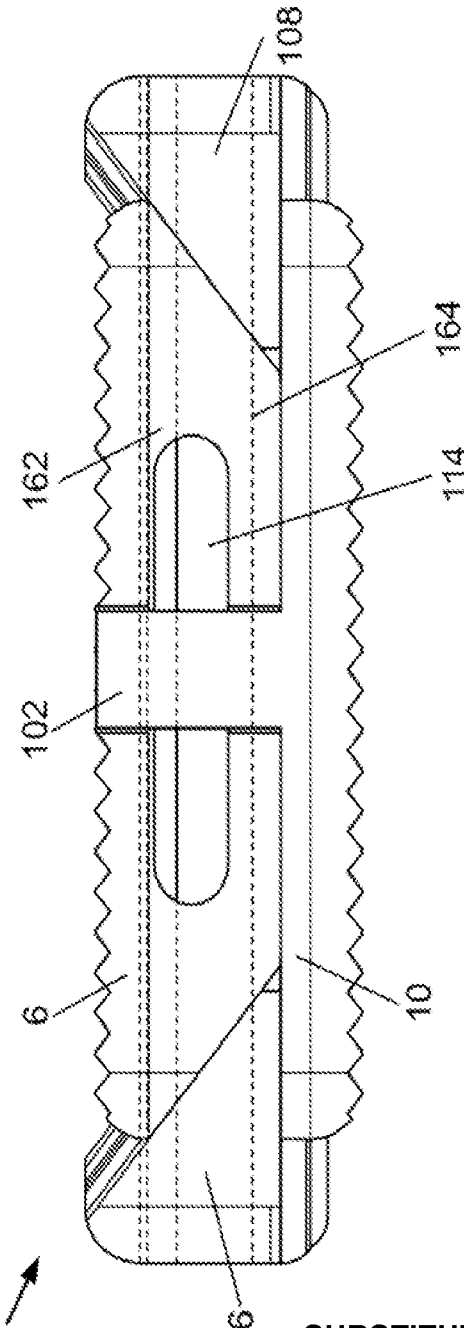


Fig. 35

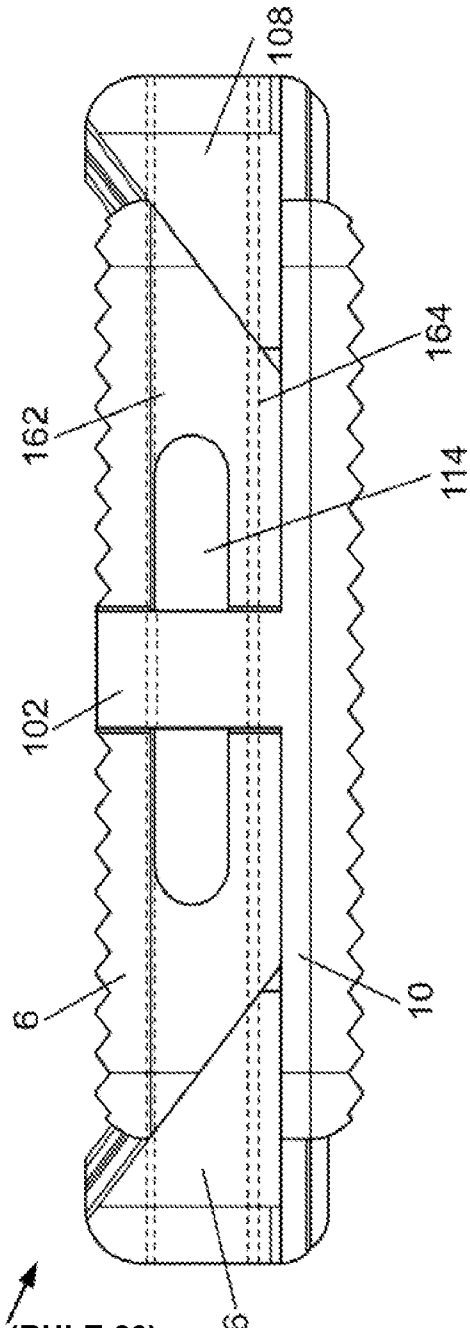


Fig. 37

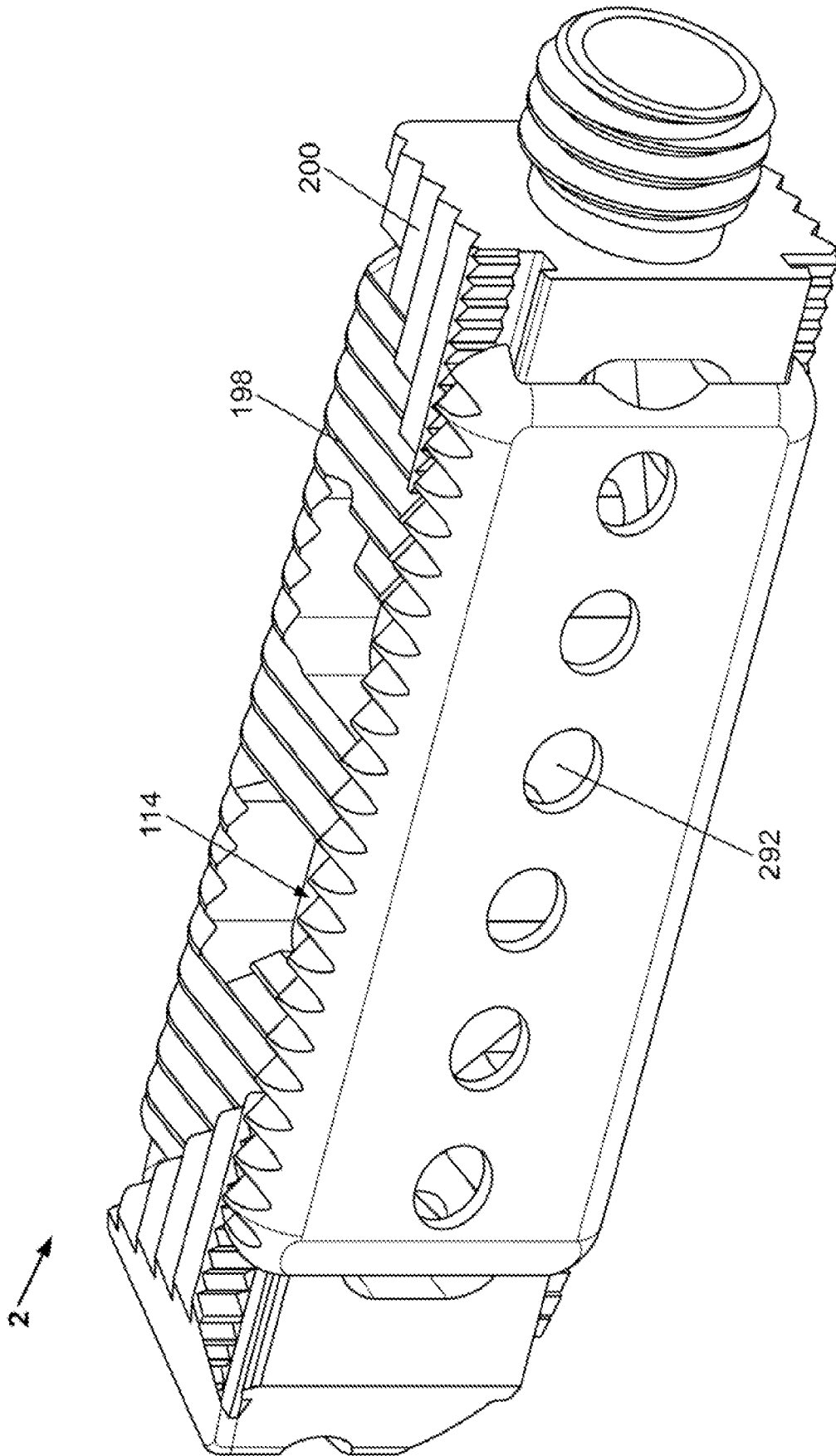


Fig. 39a

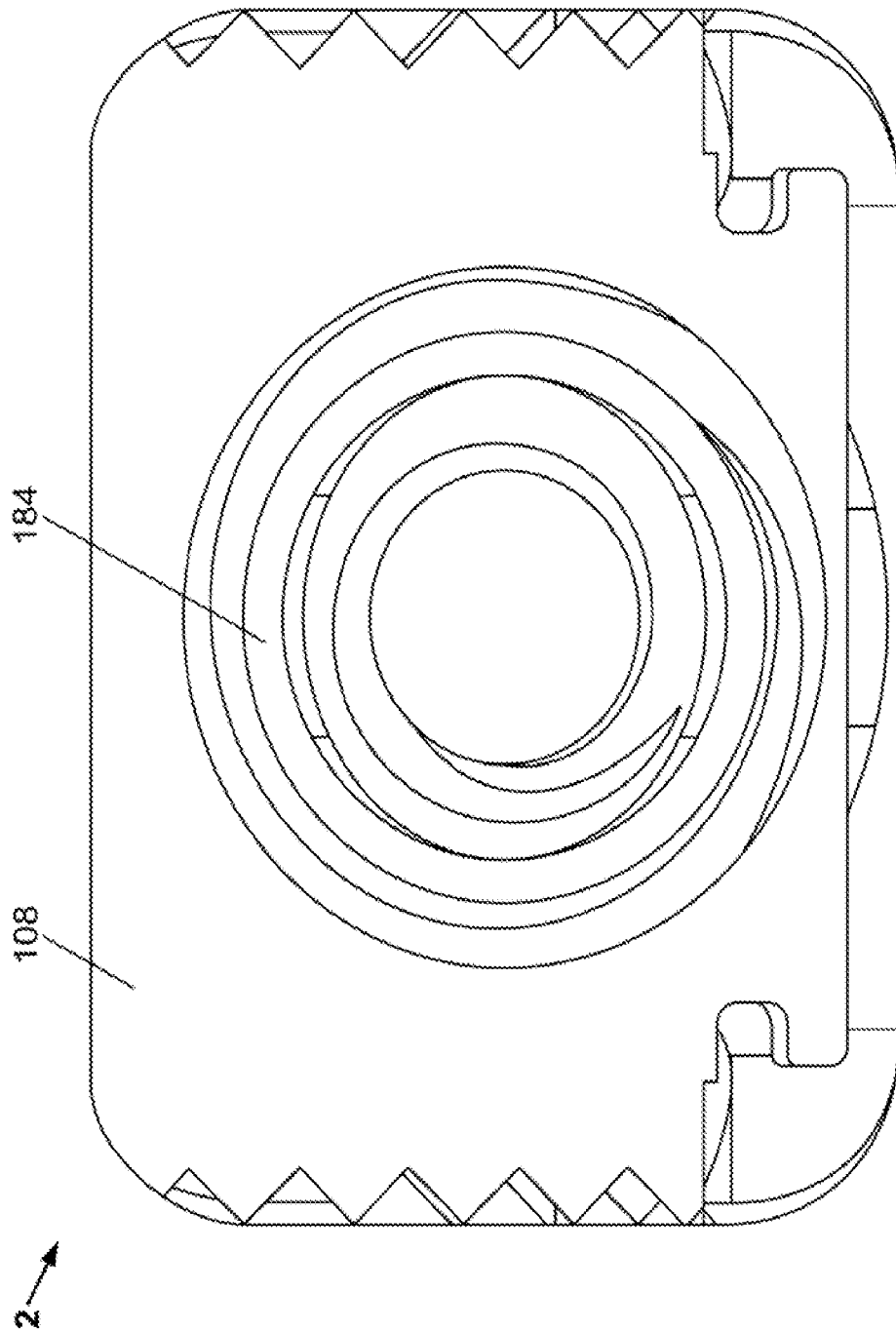


Fig. 39b



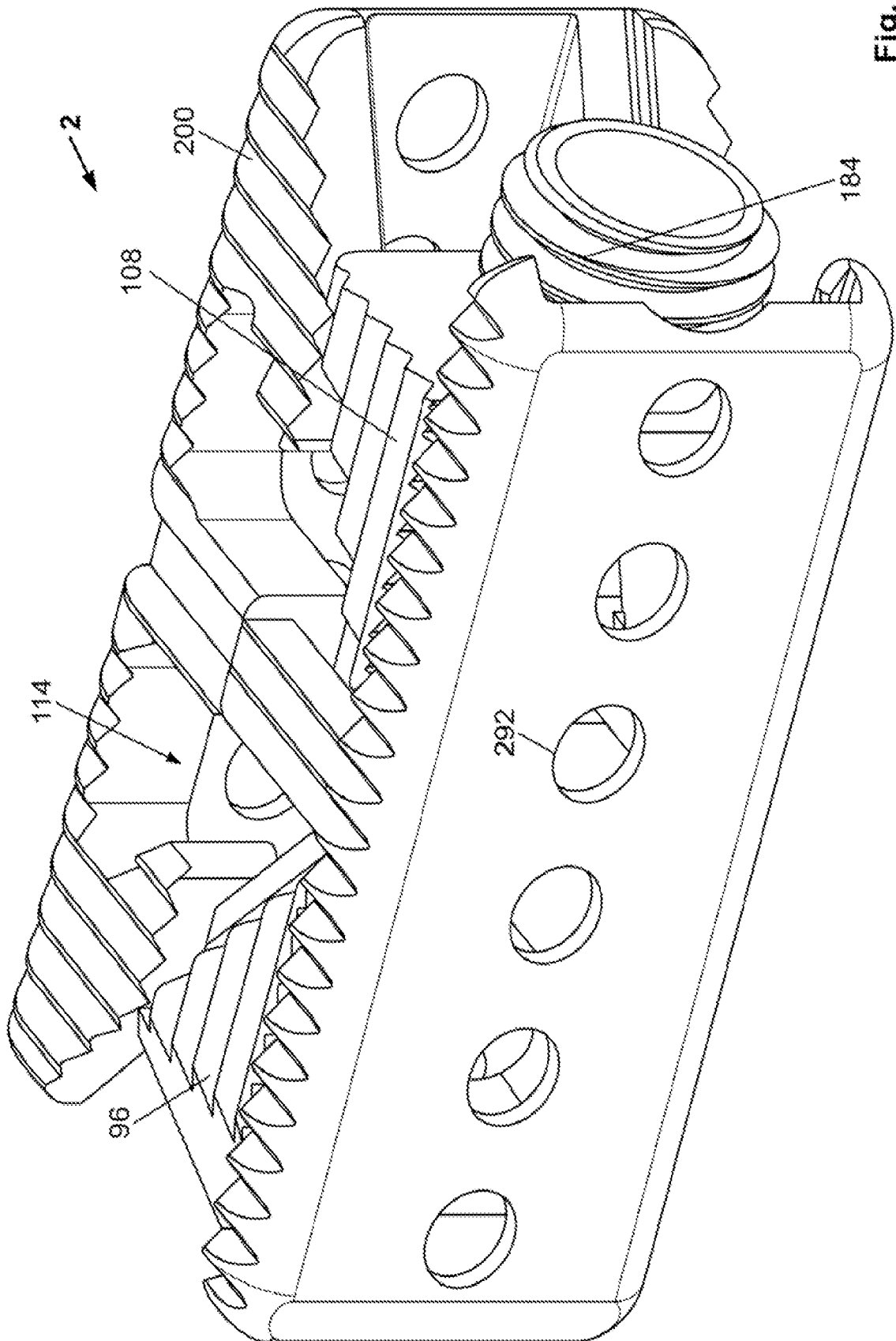


Fig. 40a



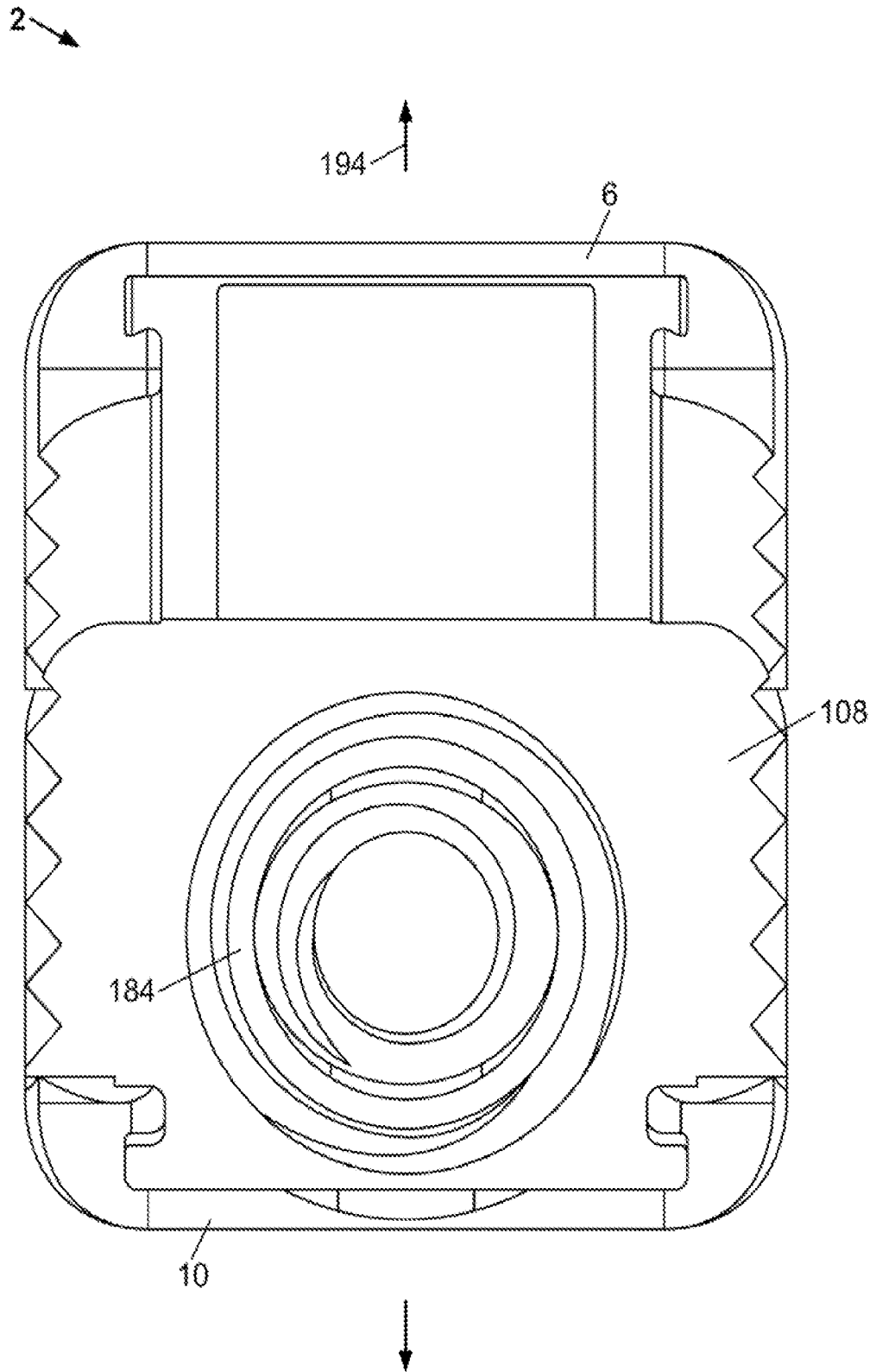
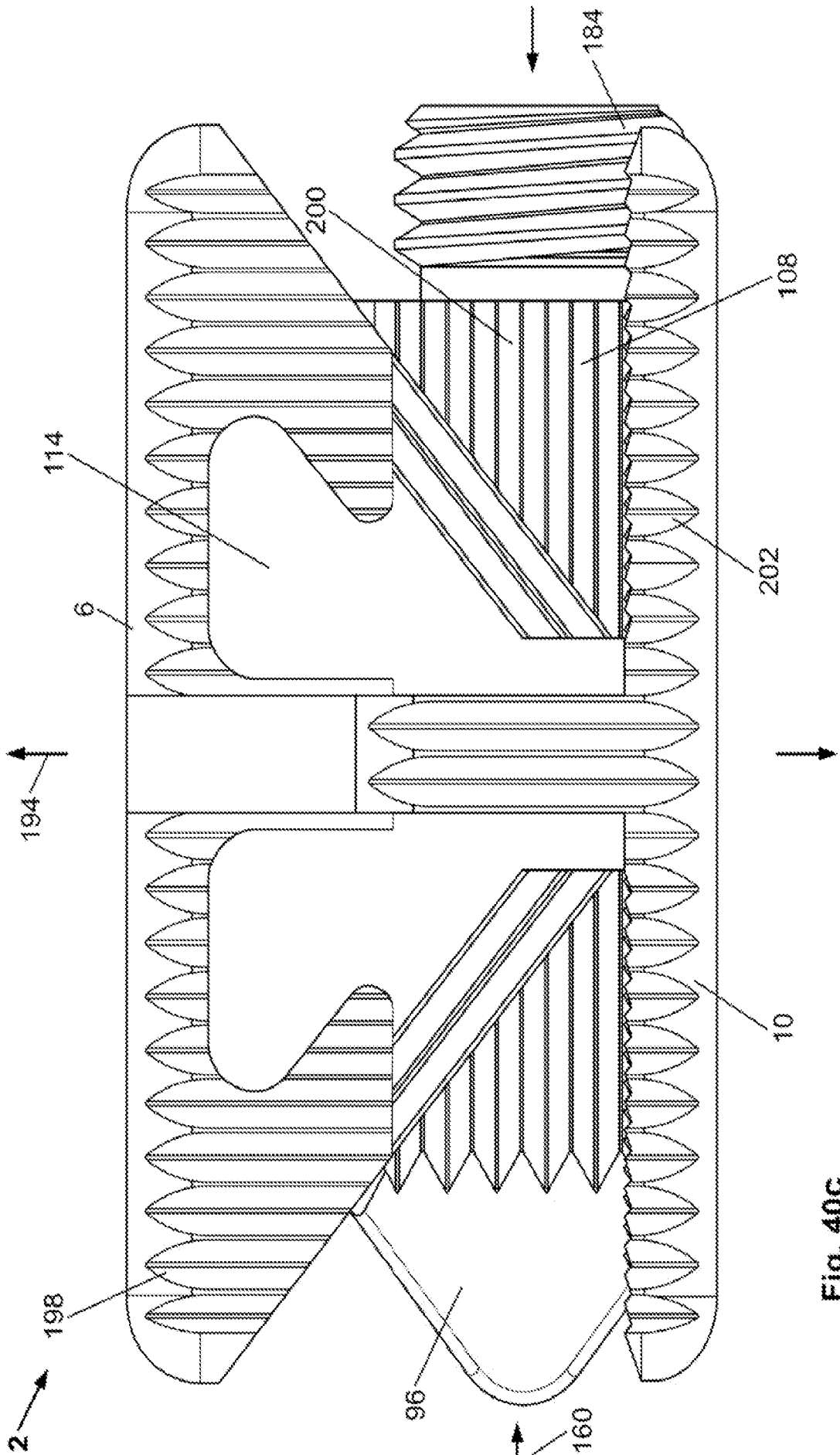


Fig. 40b



SUBSTITUTE SHEET (RULE 26)

Fig. 40C

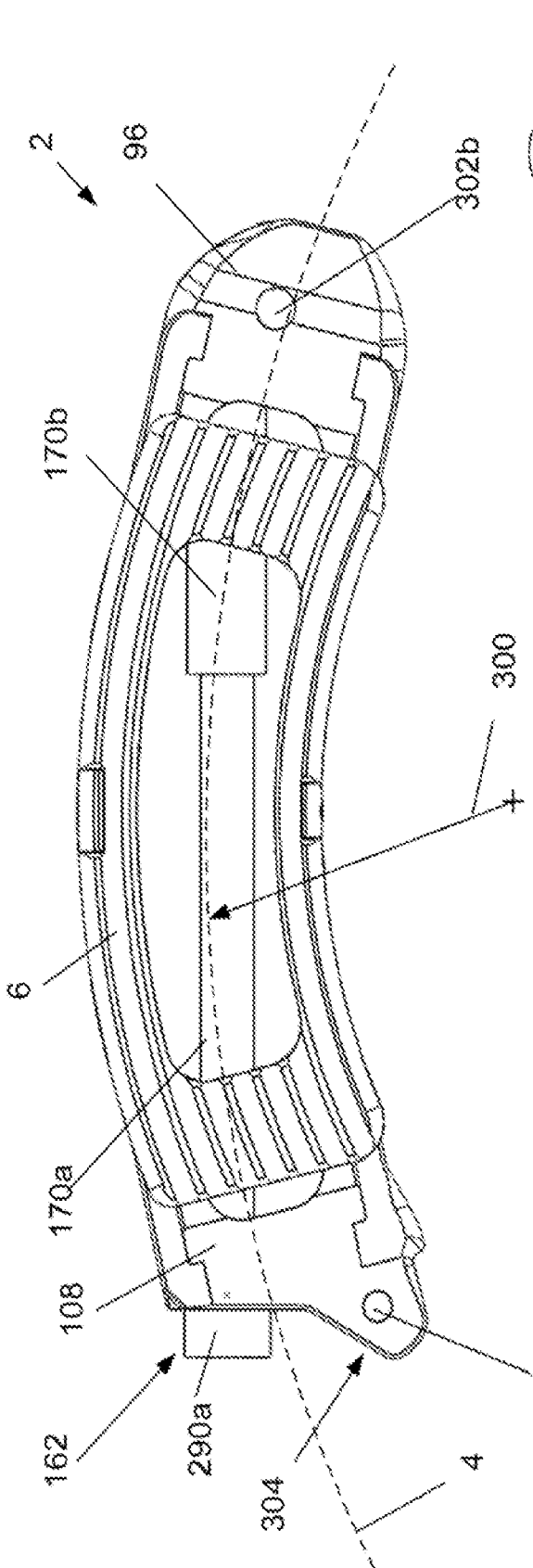


Fig. 41a

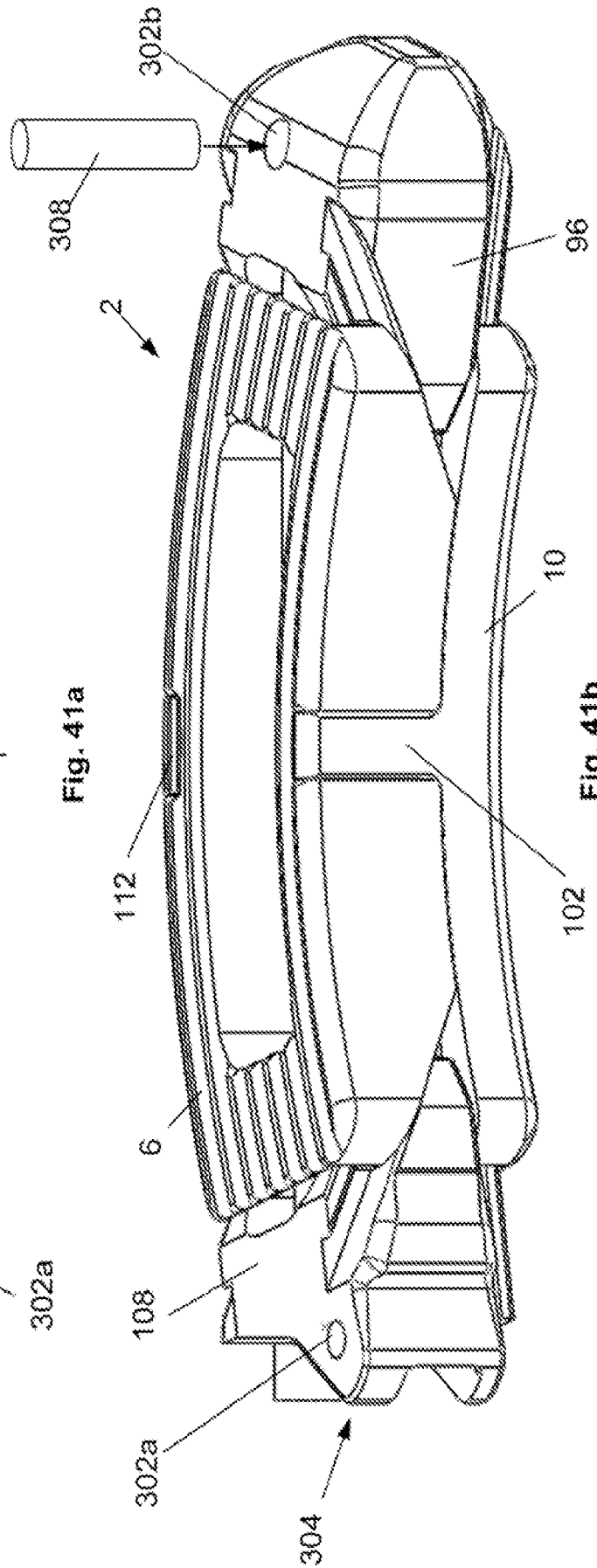


Fig. 41b

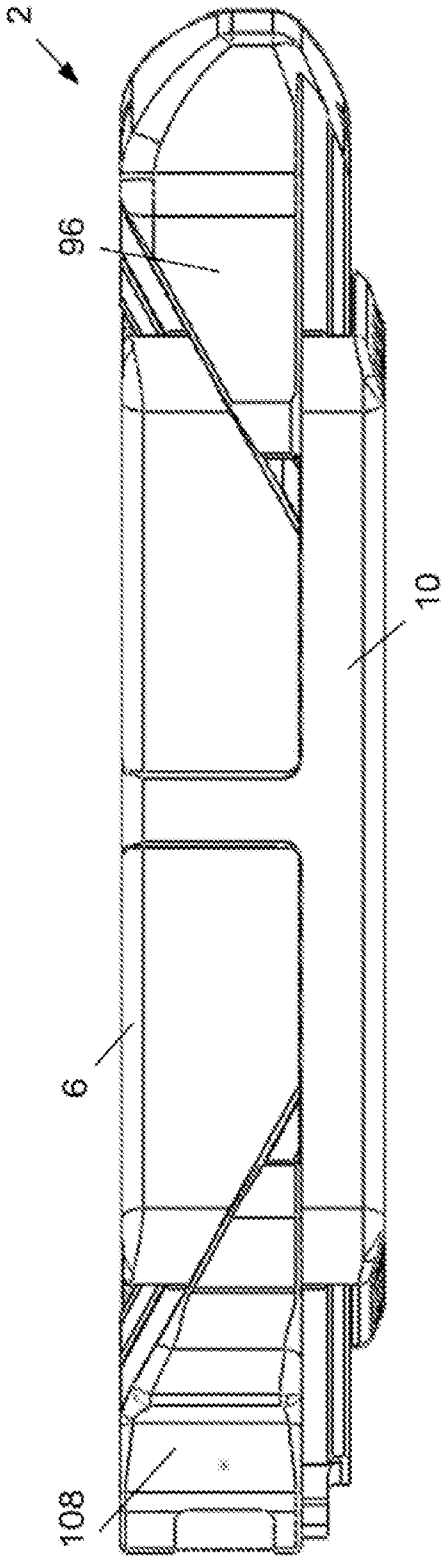


Fig. 41c

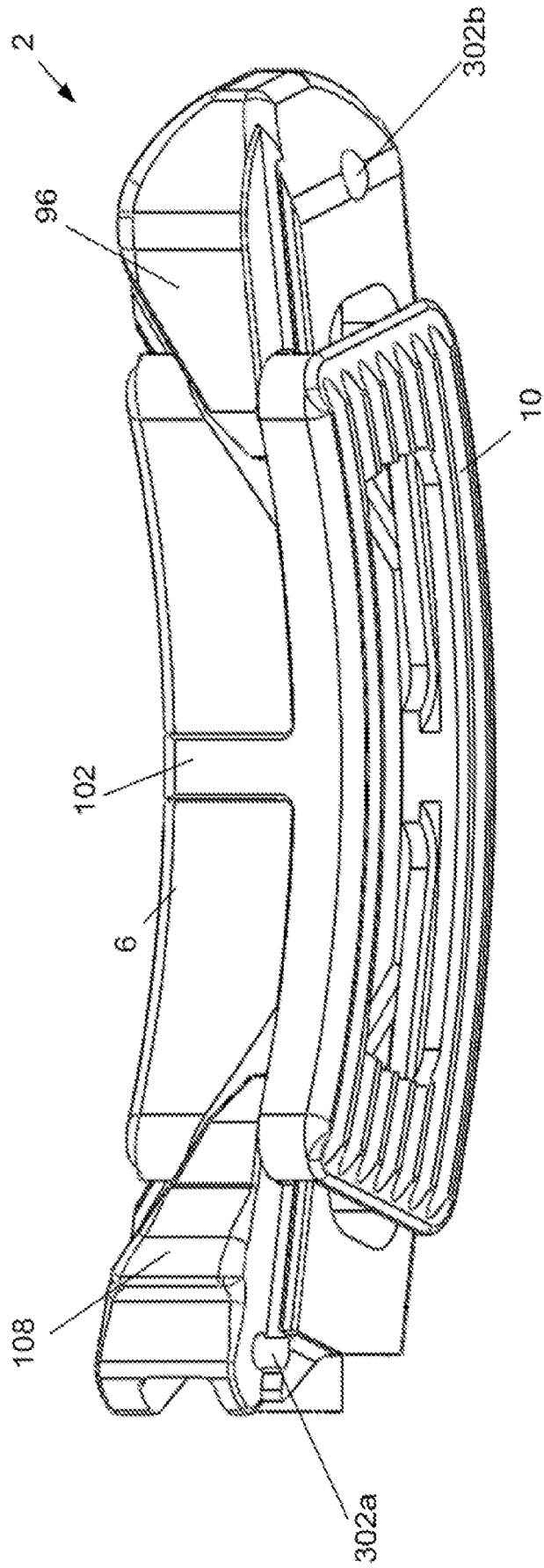


Fig. 41d

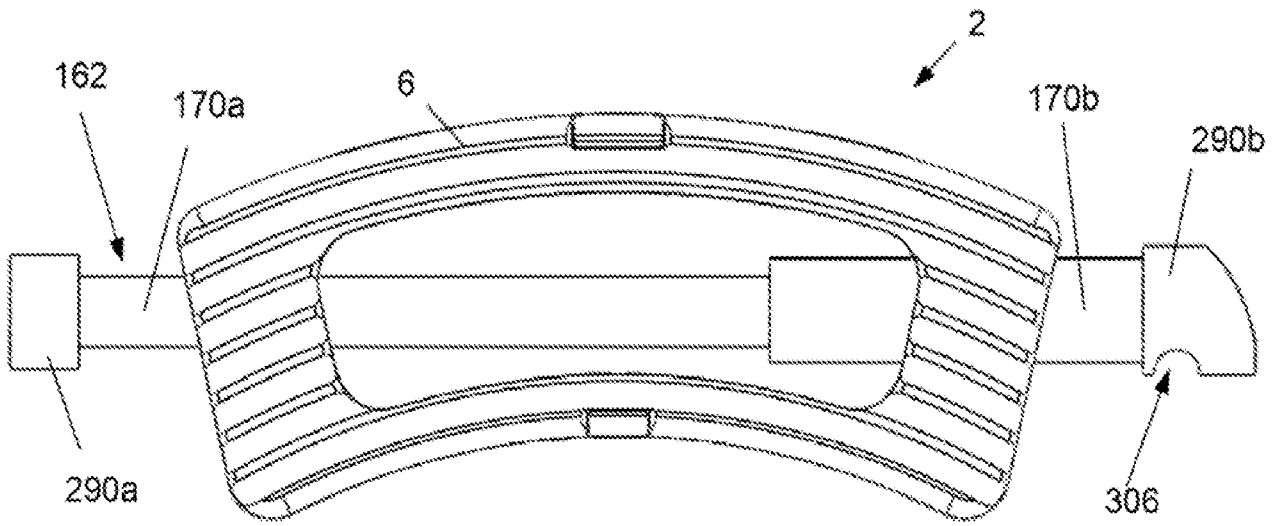


Fig. 42a

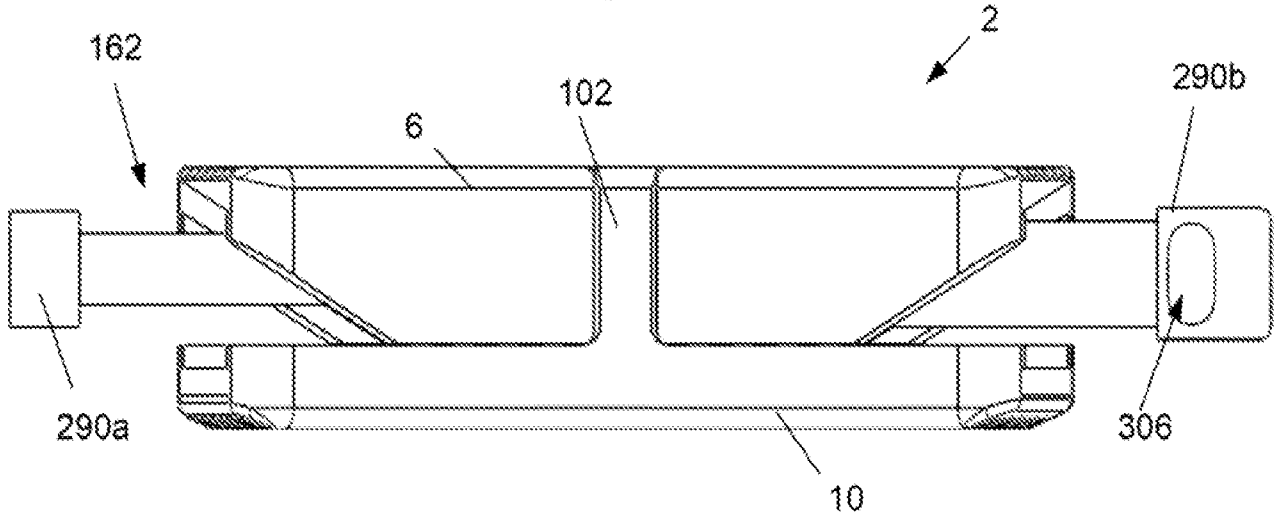


Fig. 42b

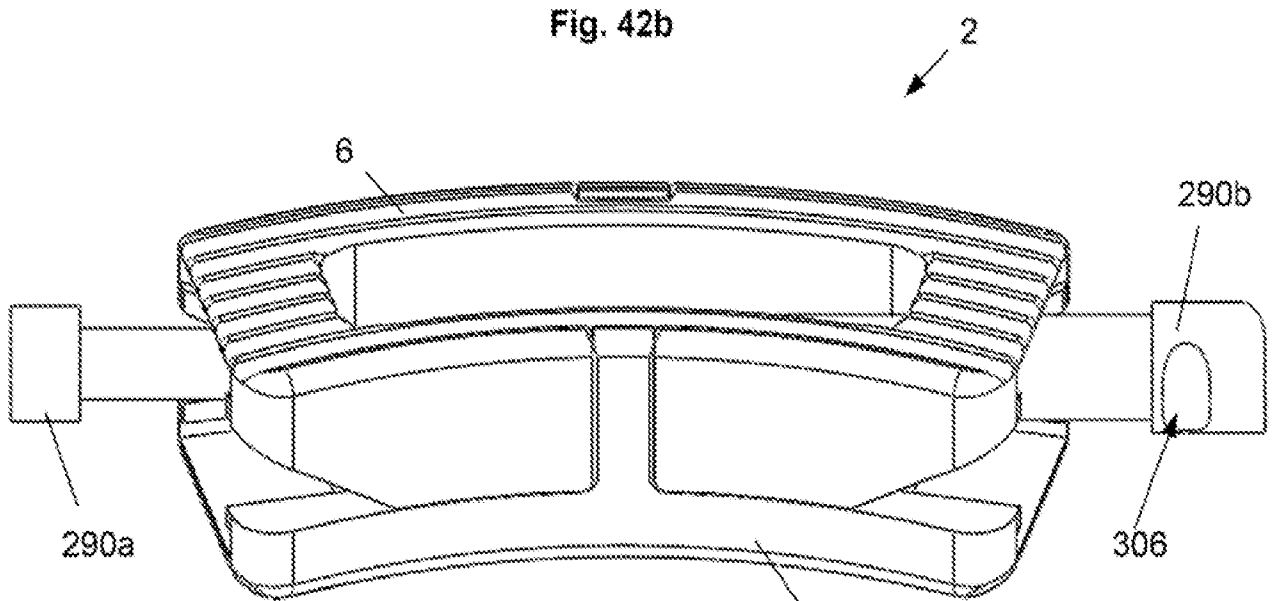


Fig. 42c

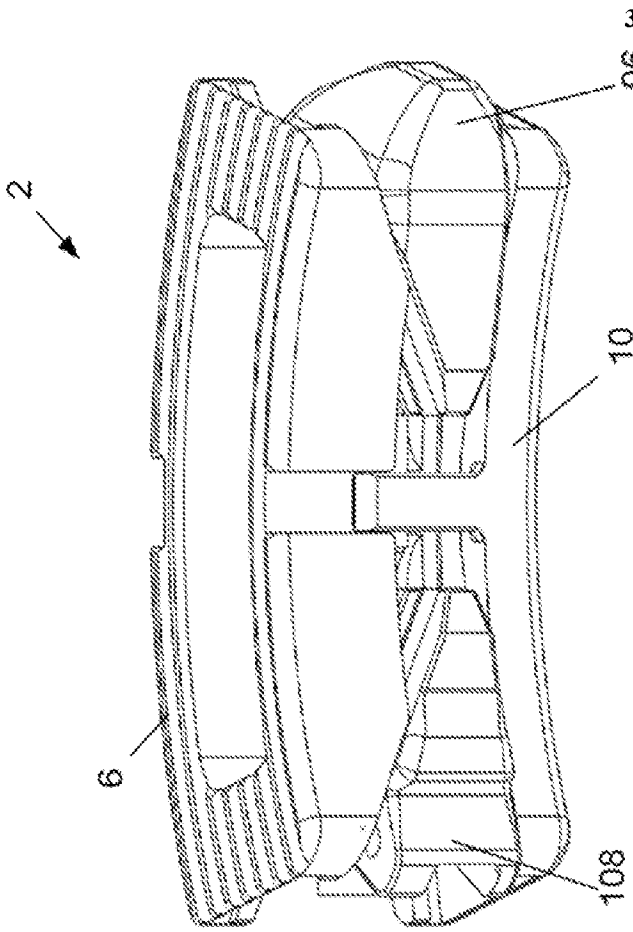


Fig. 43b

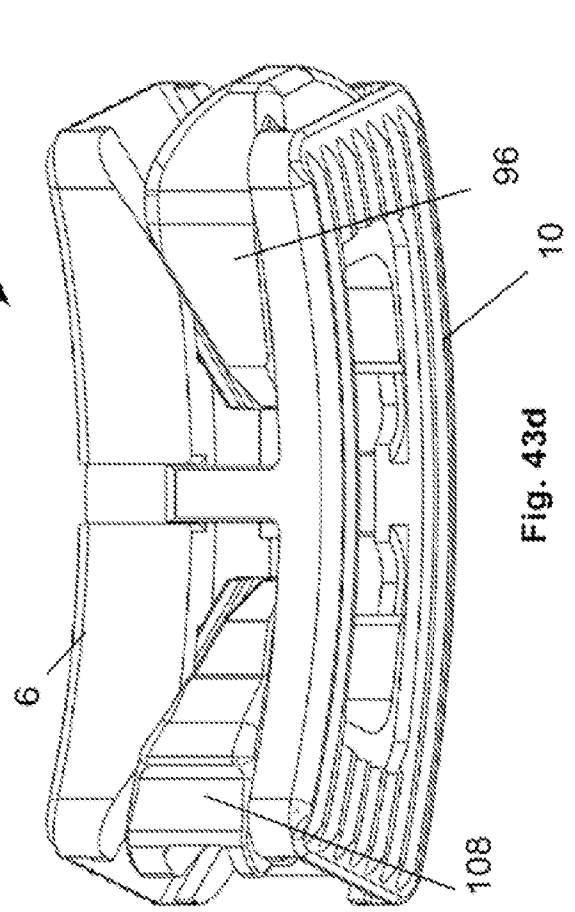


Fig. 43d

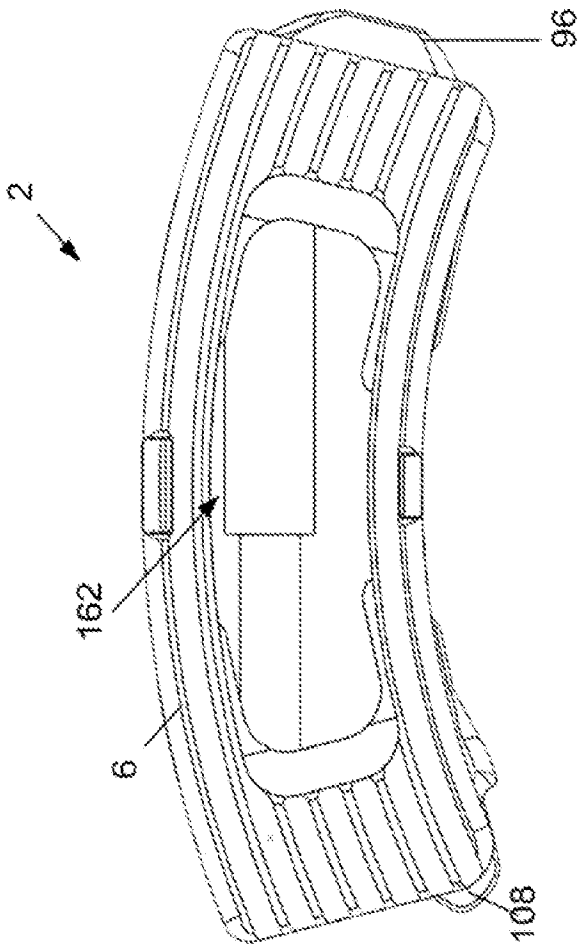


Fig. 43a

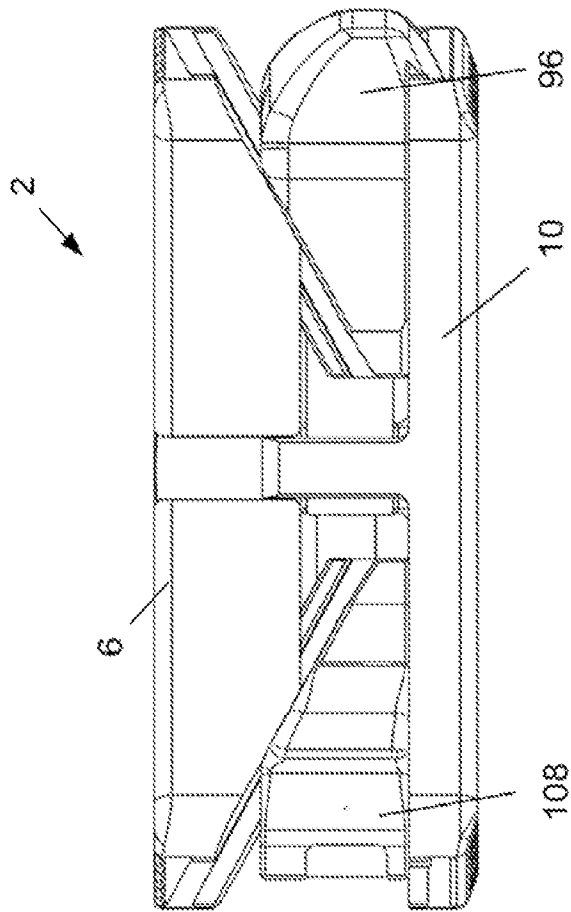


Fig. 43c

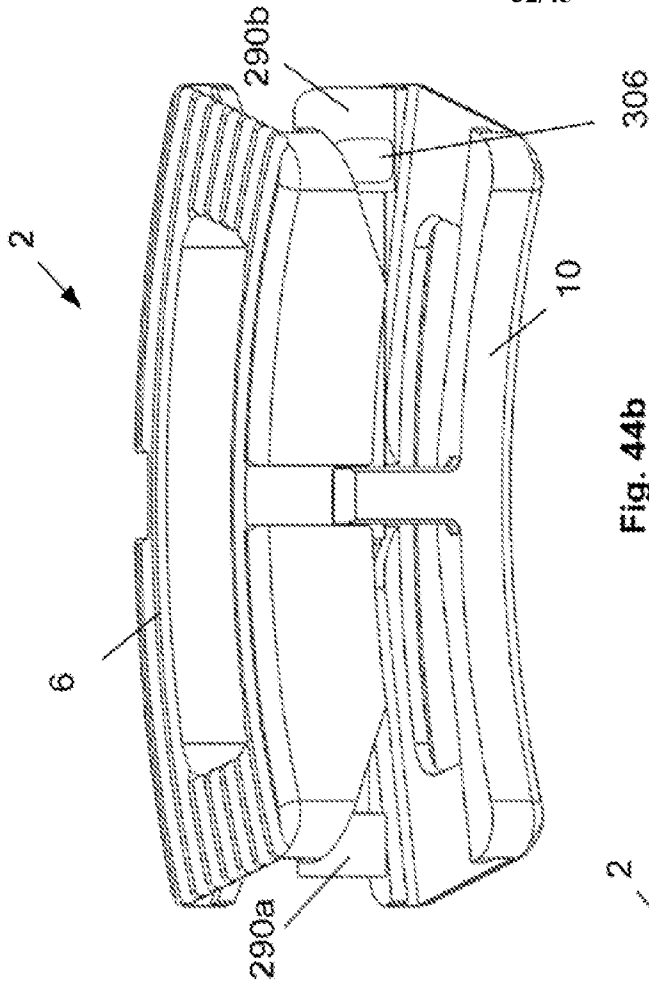


Fig. 44b

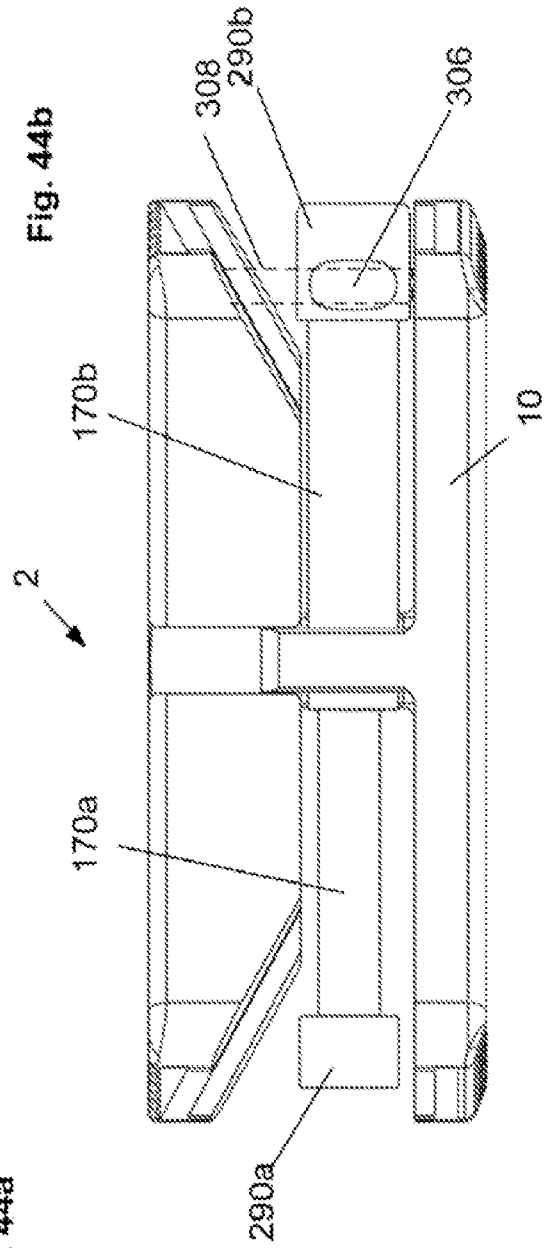


Fig. 44c

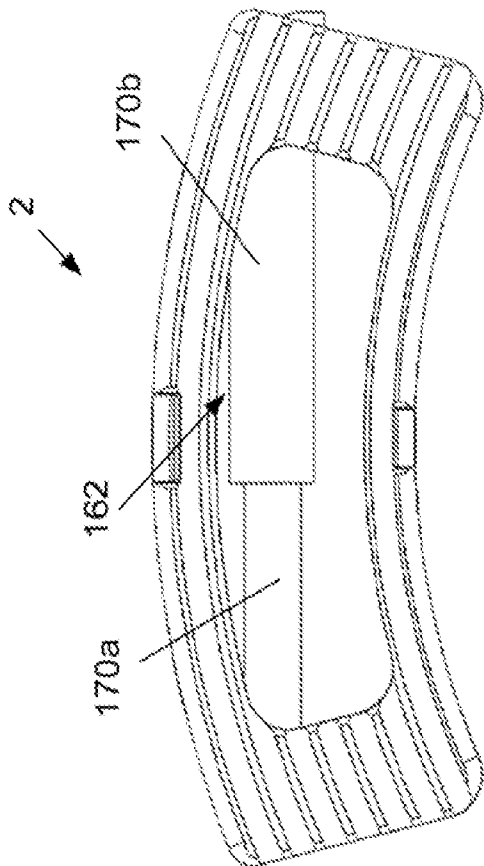


Fig. 44a

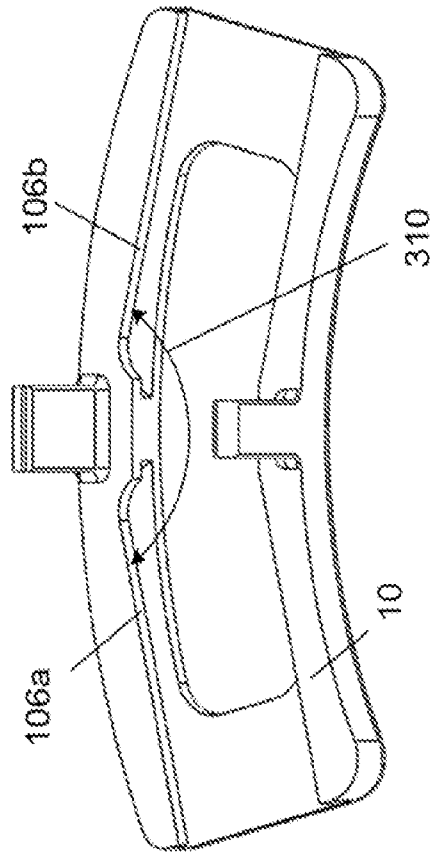


Fig. 45b

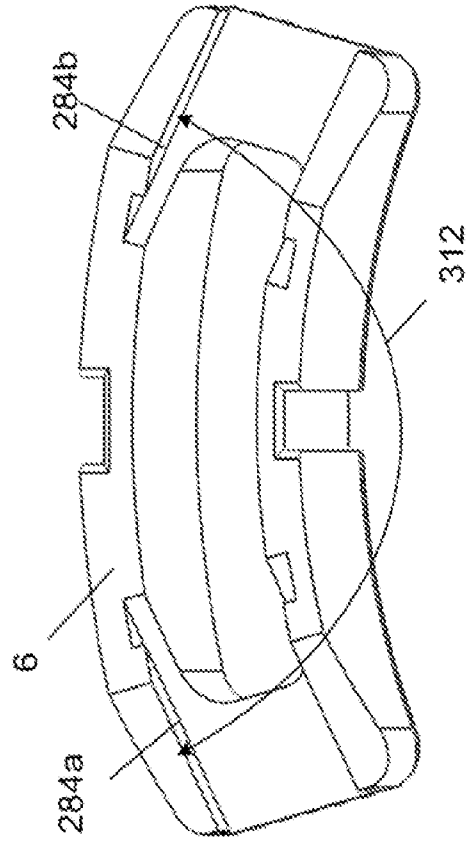


Fig. 46b

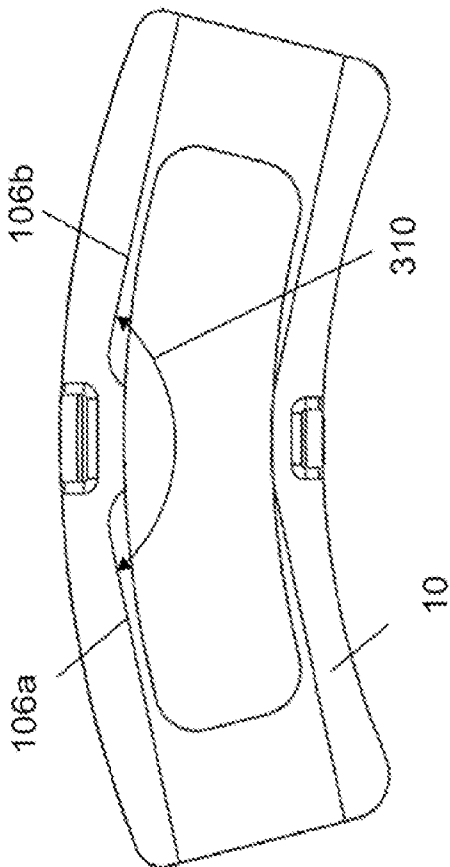


Fig. 45a

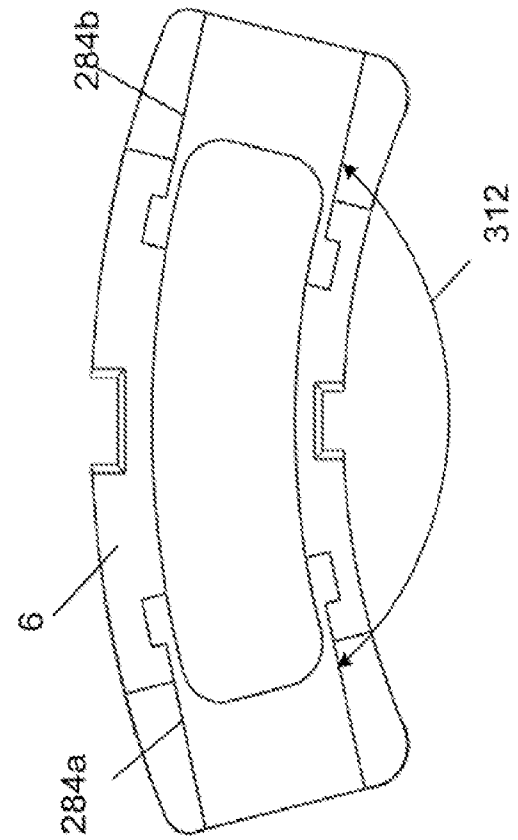


Fig. 46a



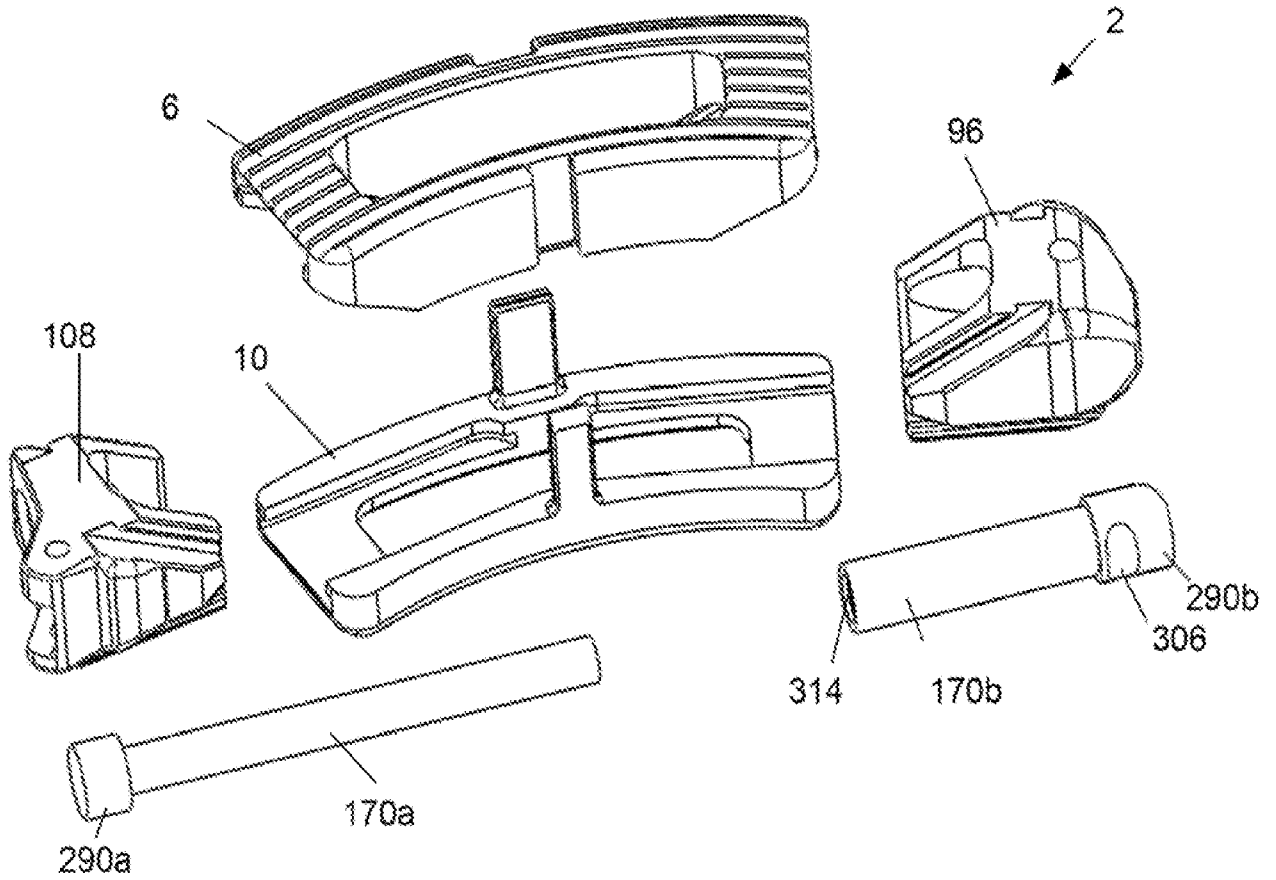


Fig. 47a

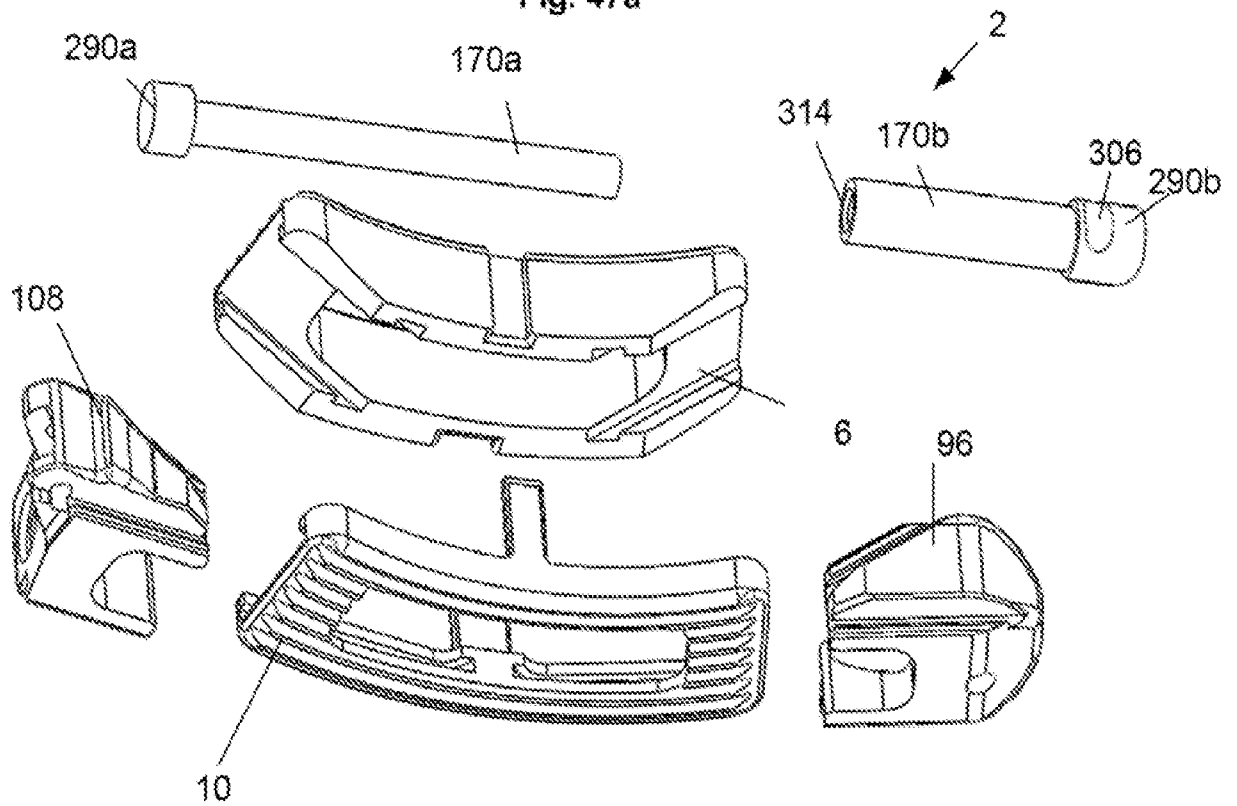


Fig. 47b

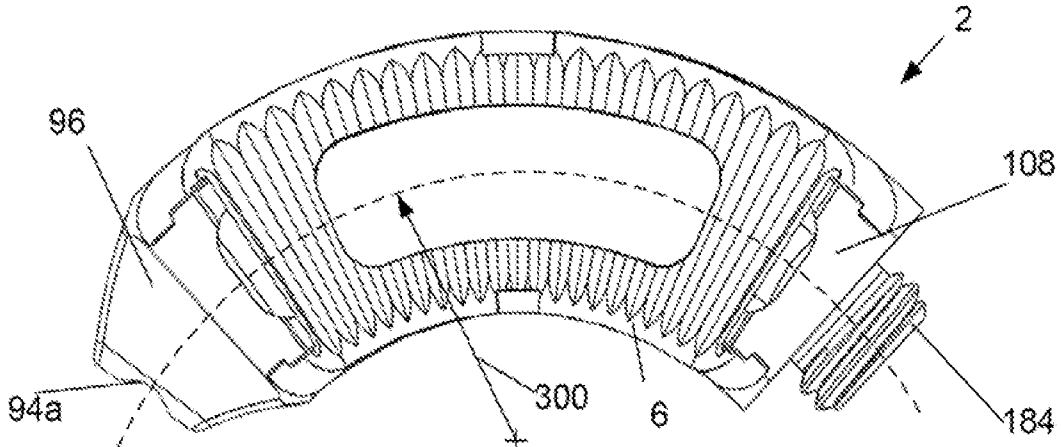


Fig. 48a

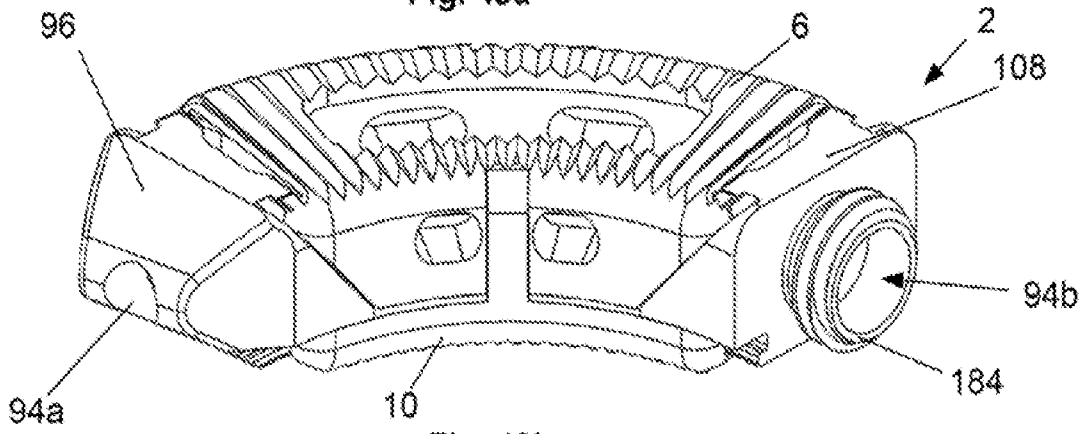


Fig. 48b

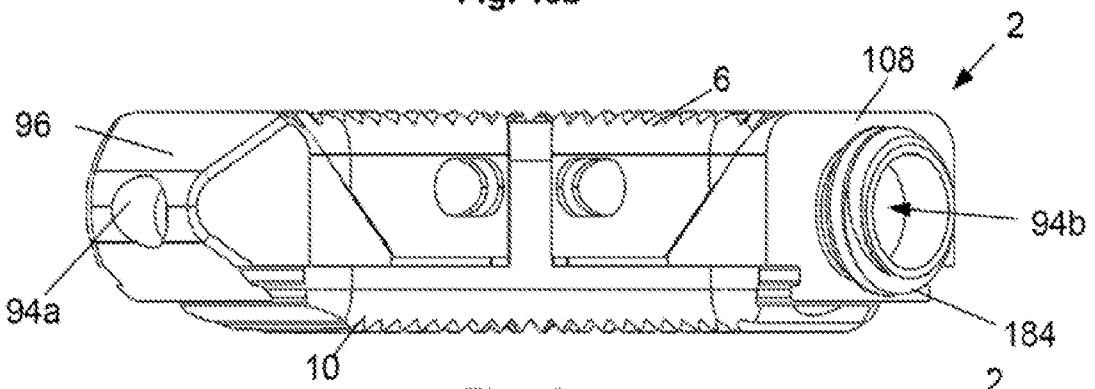


Fig. 48c

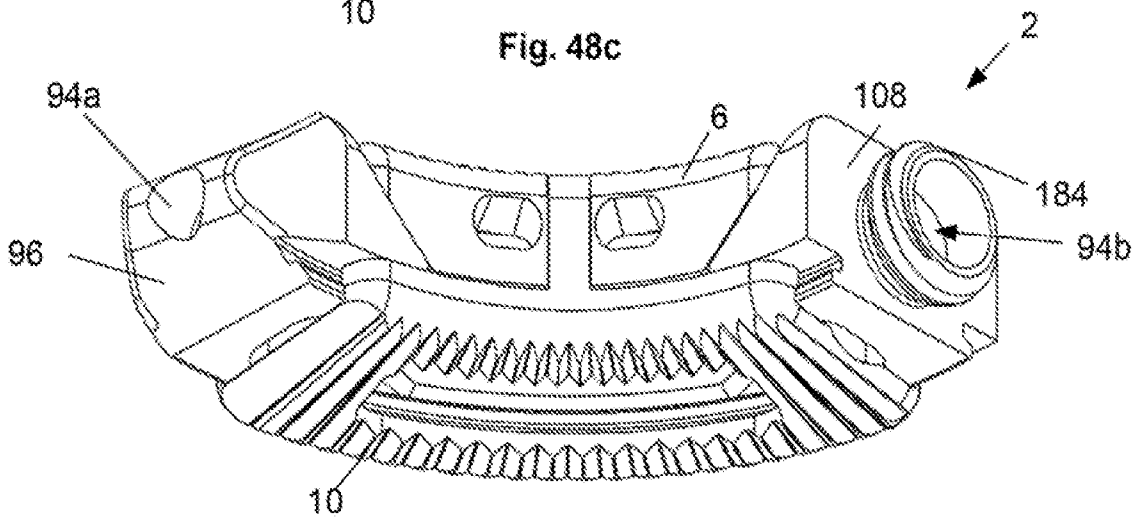


Fig. 48d

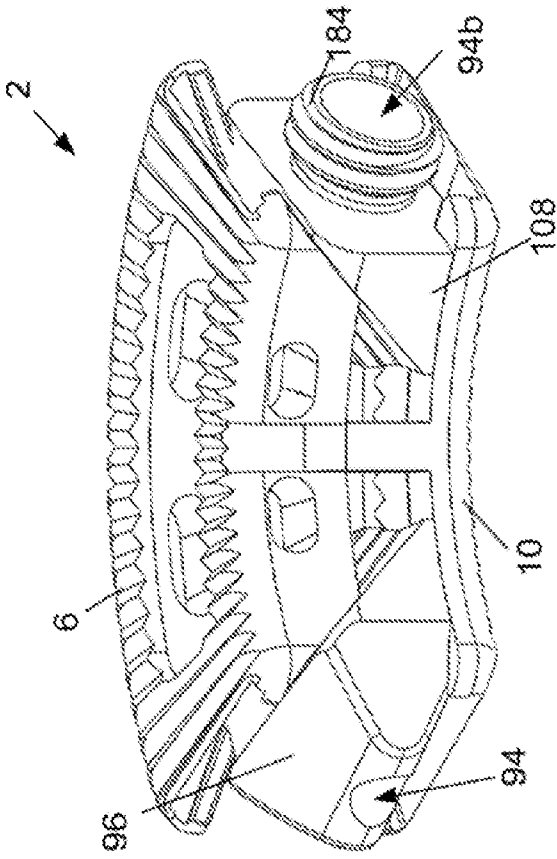


Fig. 49a

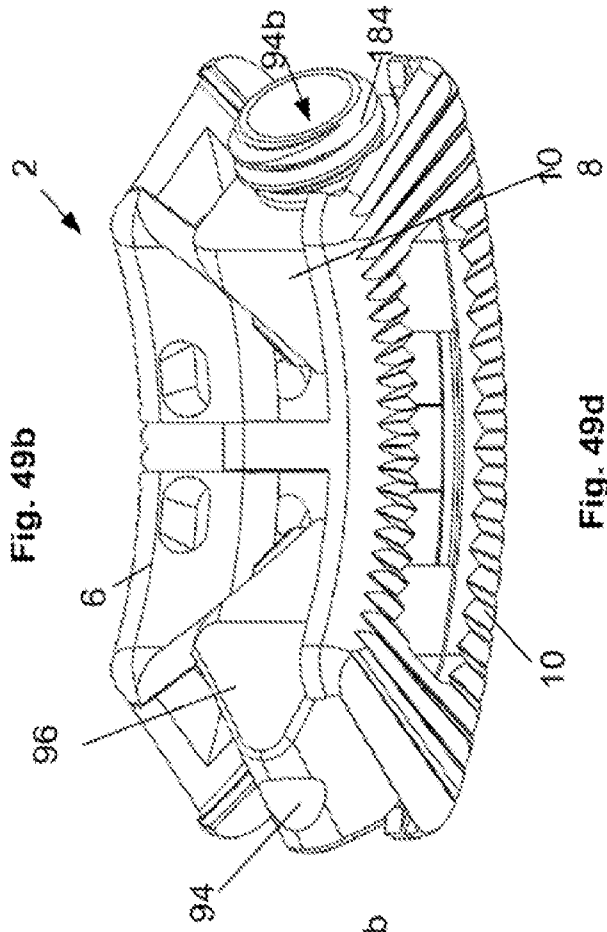


Fig. 49b

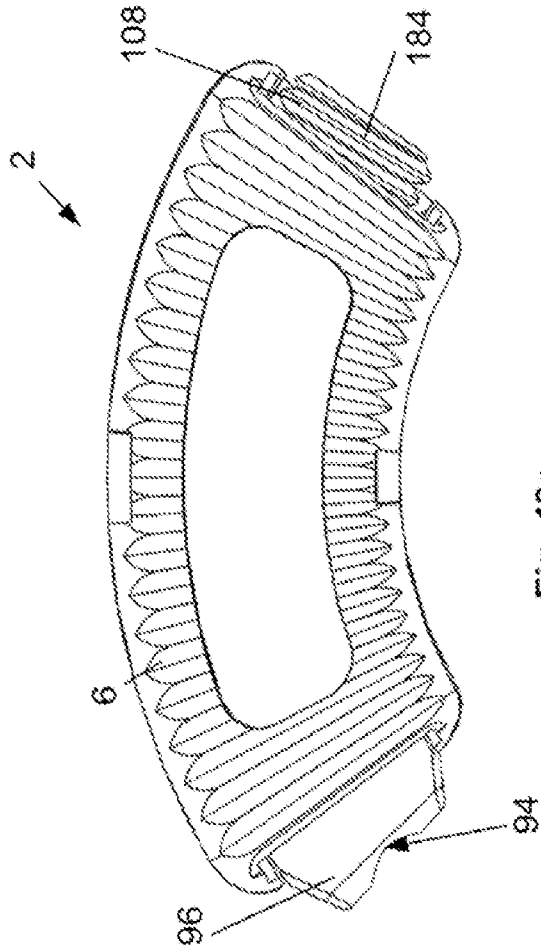


Fig. 49c

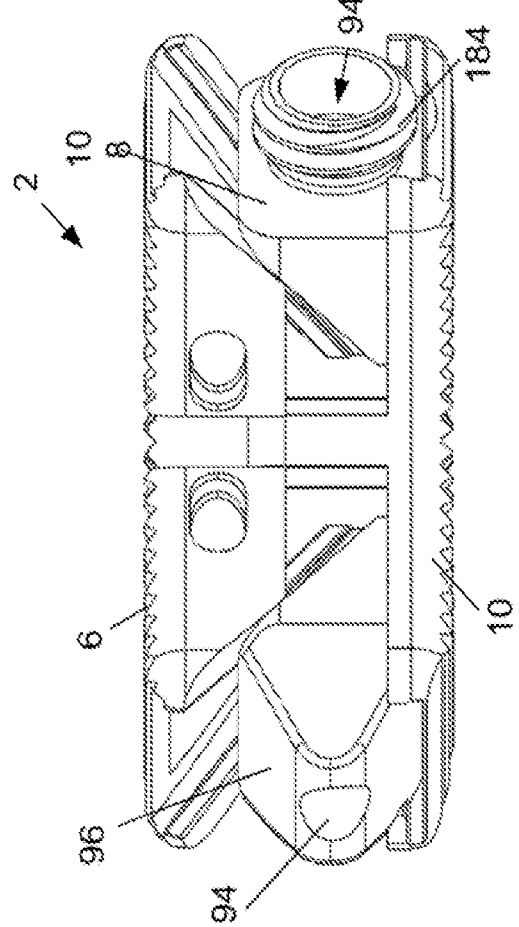


Fig. 49d

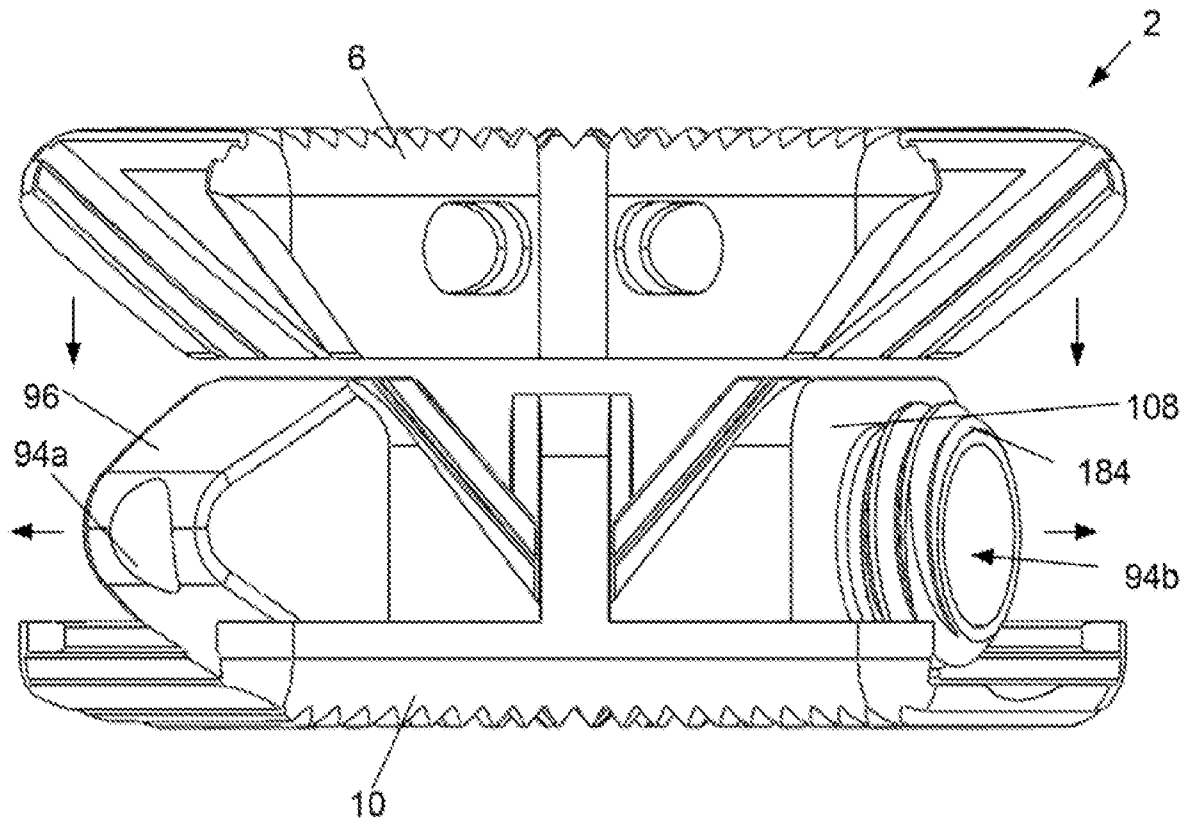


Fig. 50a

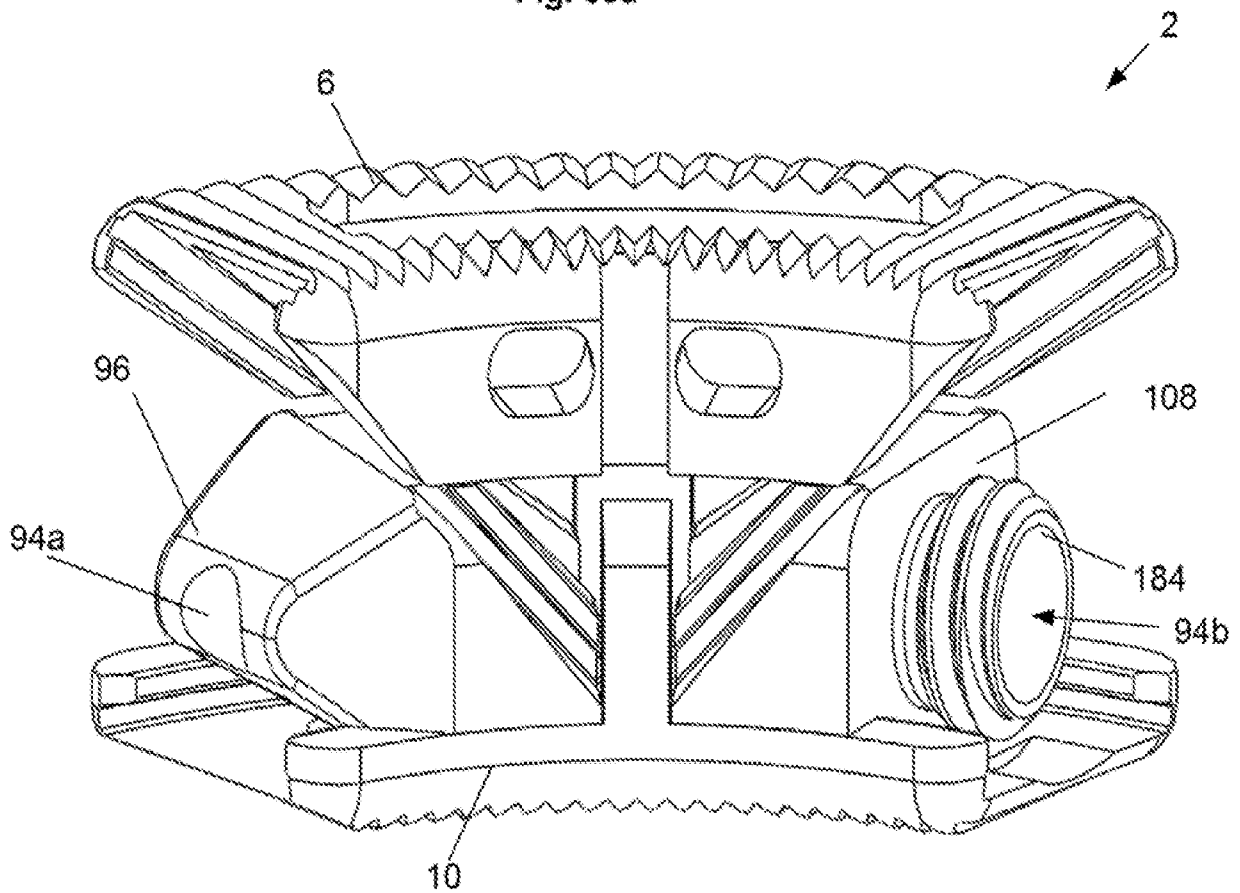


Fig. 50b

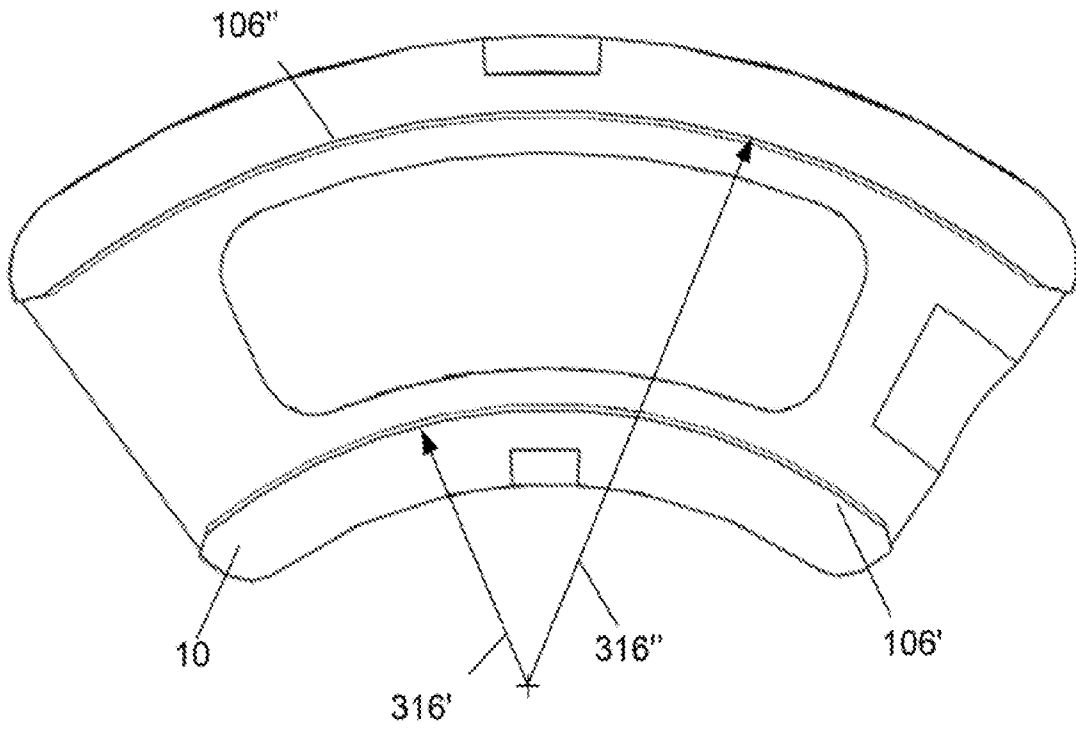


Fig. 51a

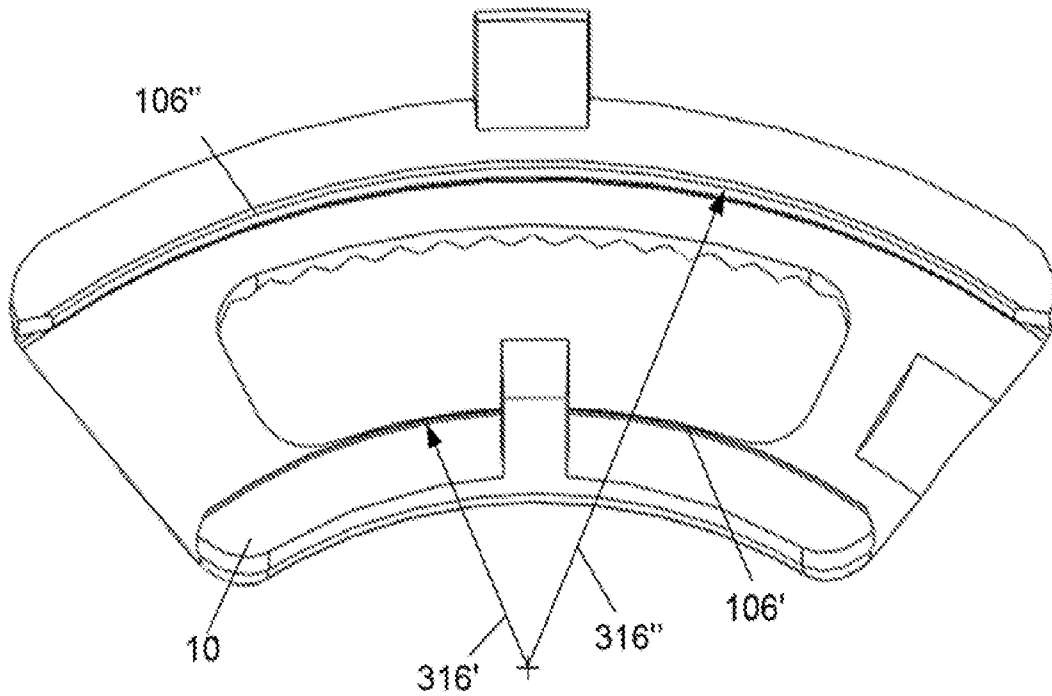
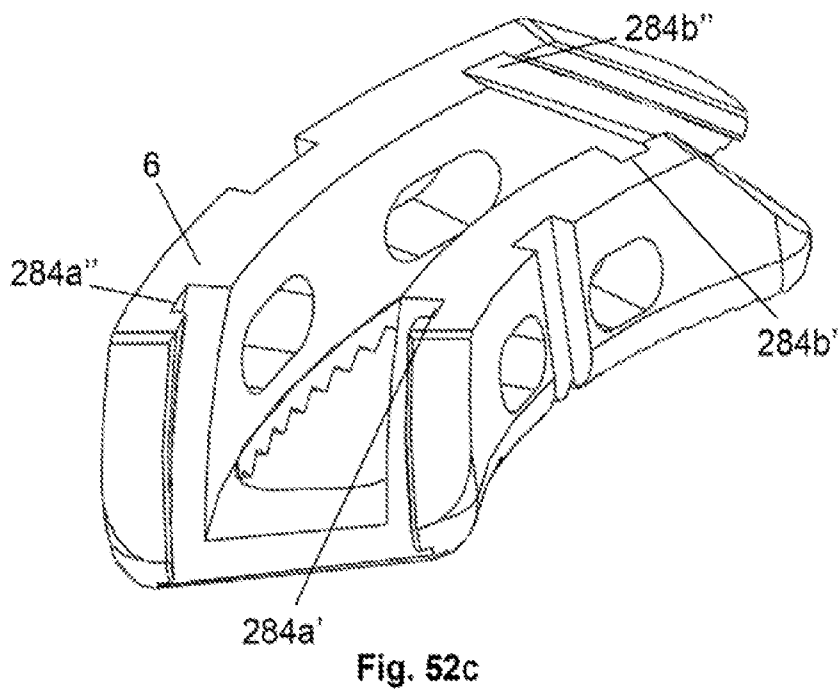
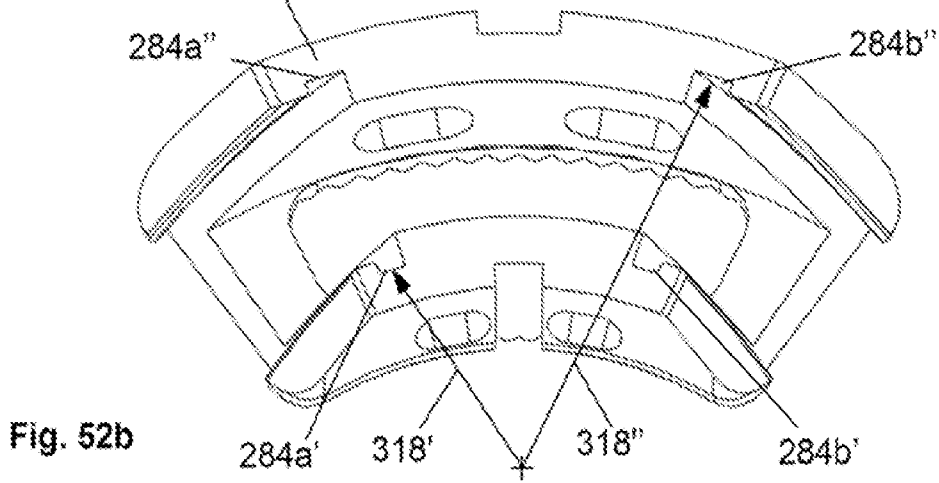
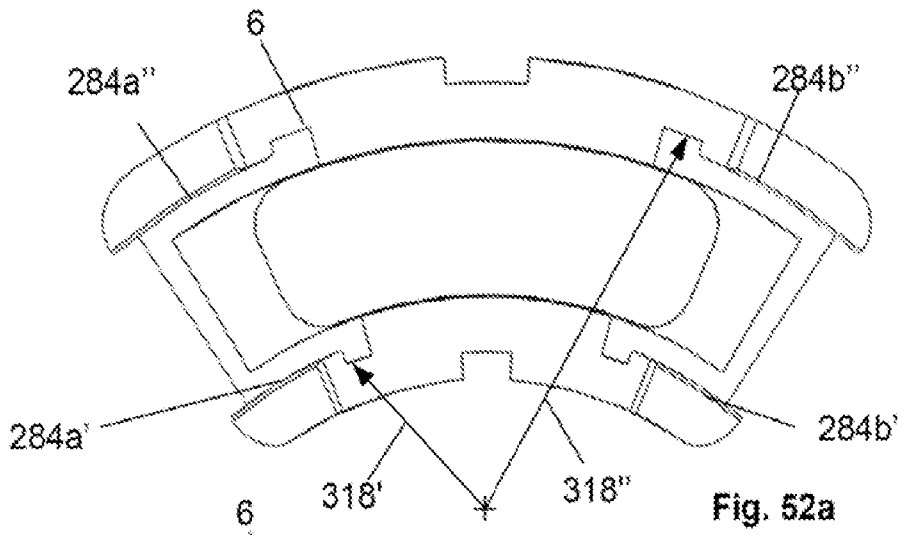


Fig. 51b



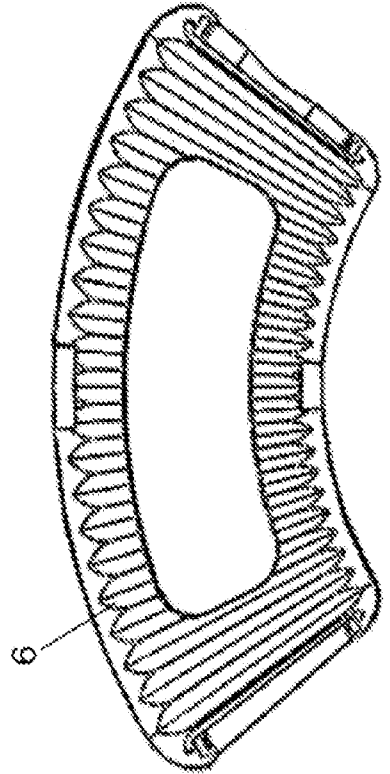
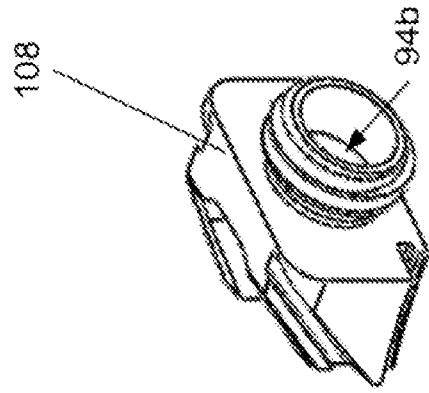
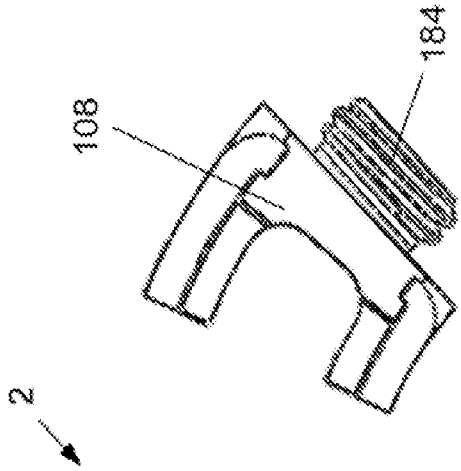


Fig. 53a

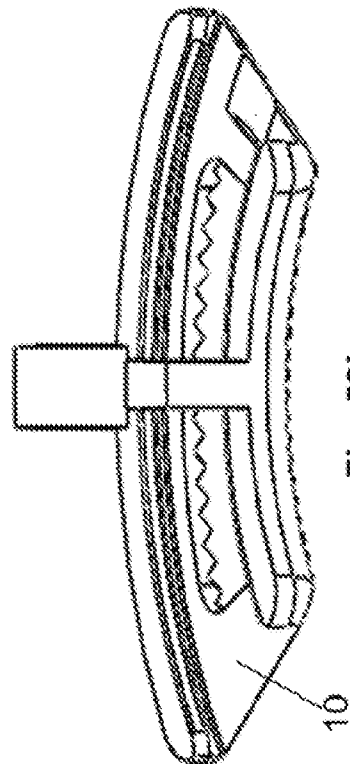
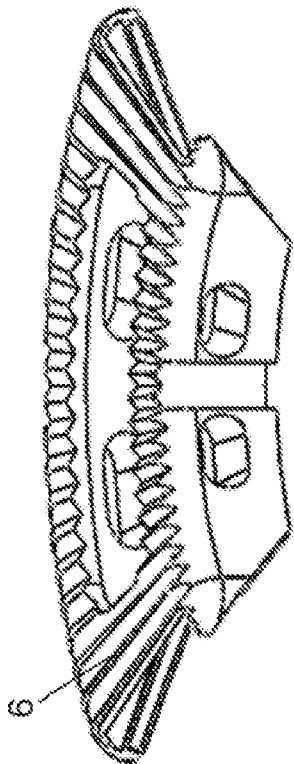
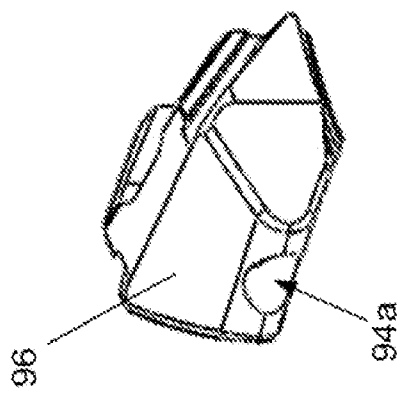
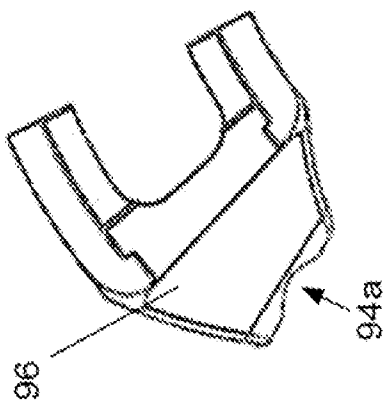


Fig. 53b



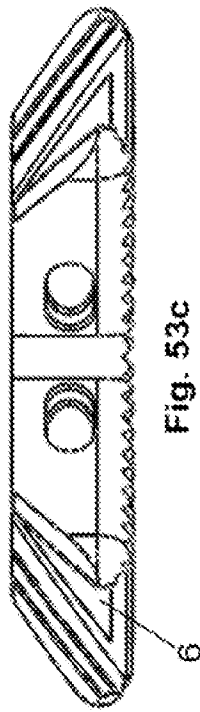
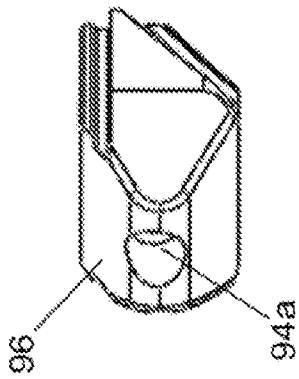
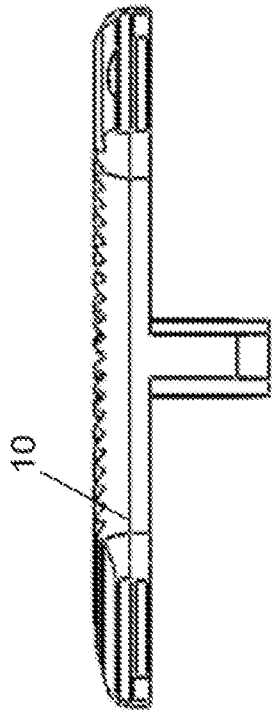
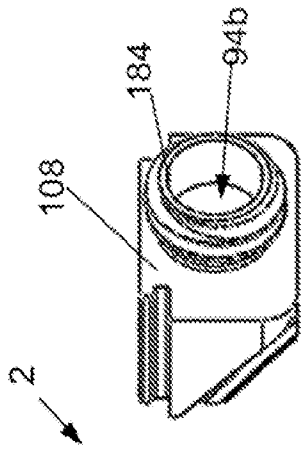


Fig. 53c

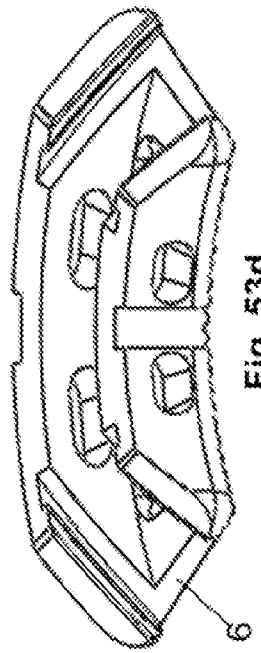
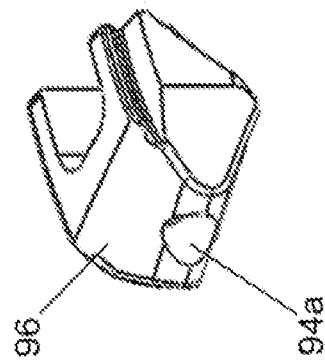
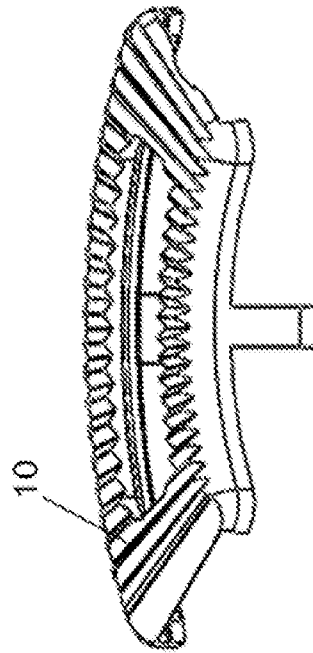
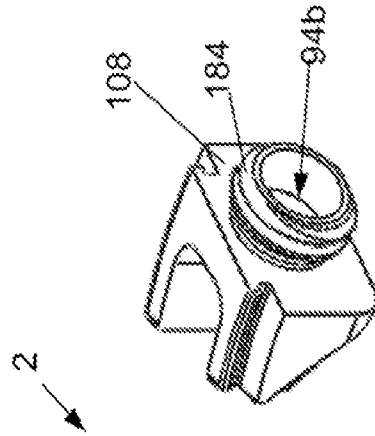


Fig. 53d



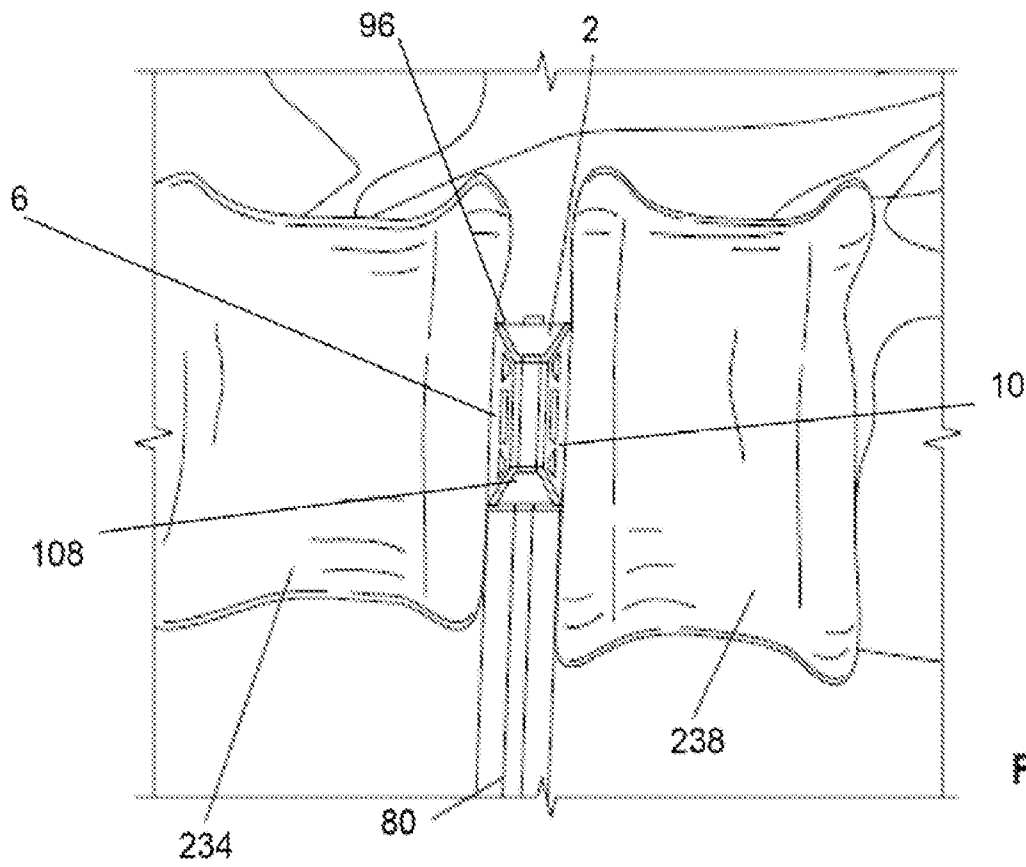


Fig 54

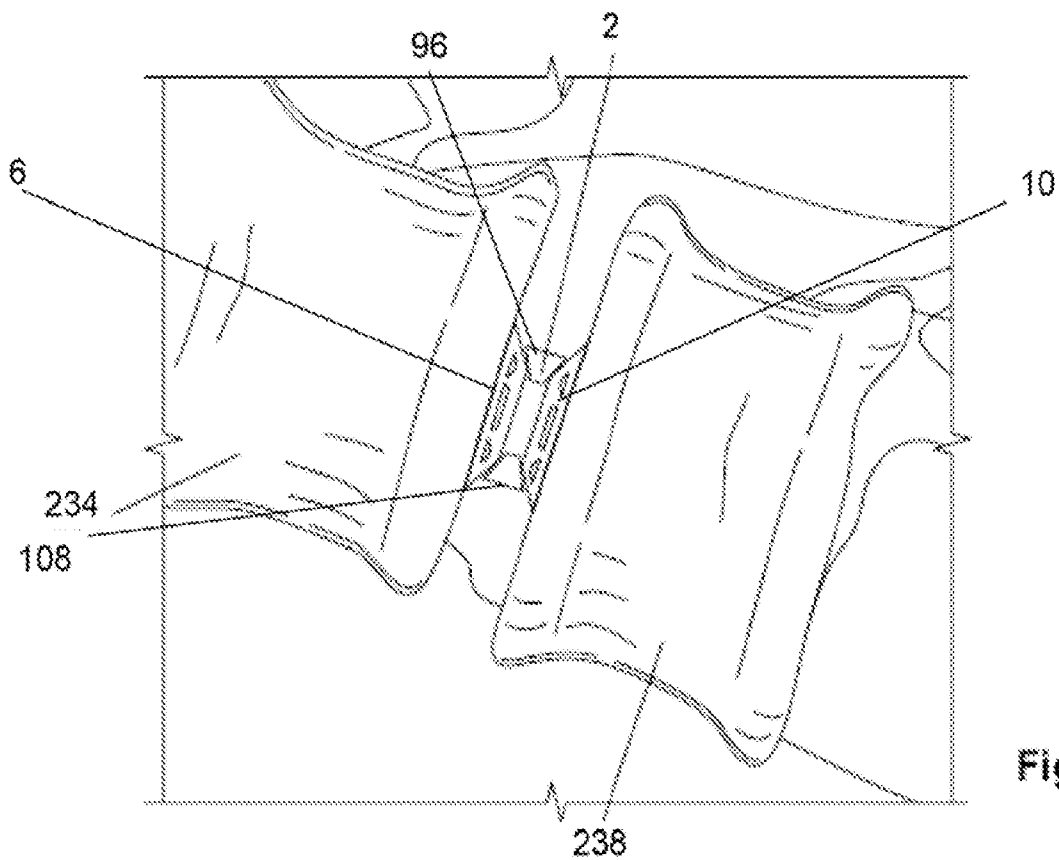


Fig. 55a

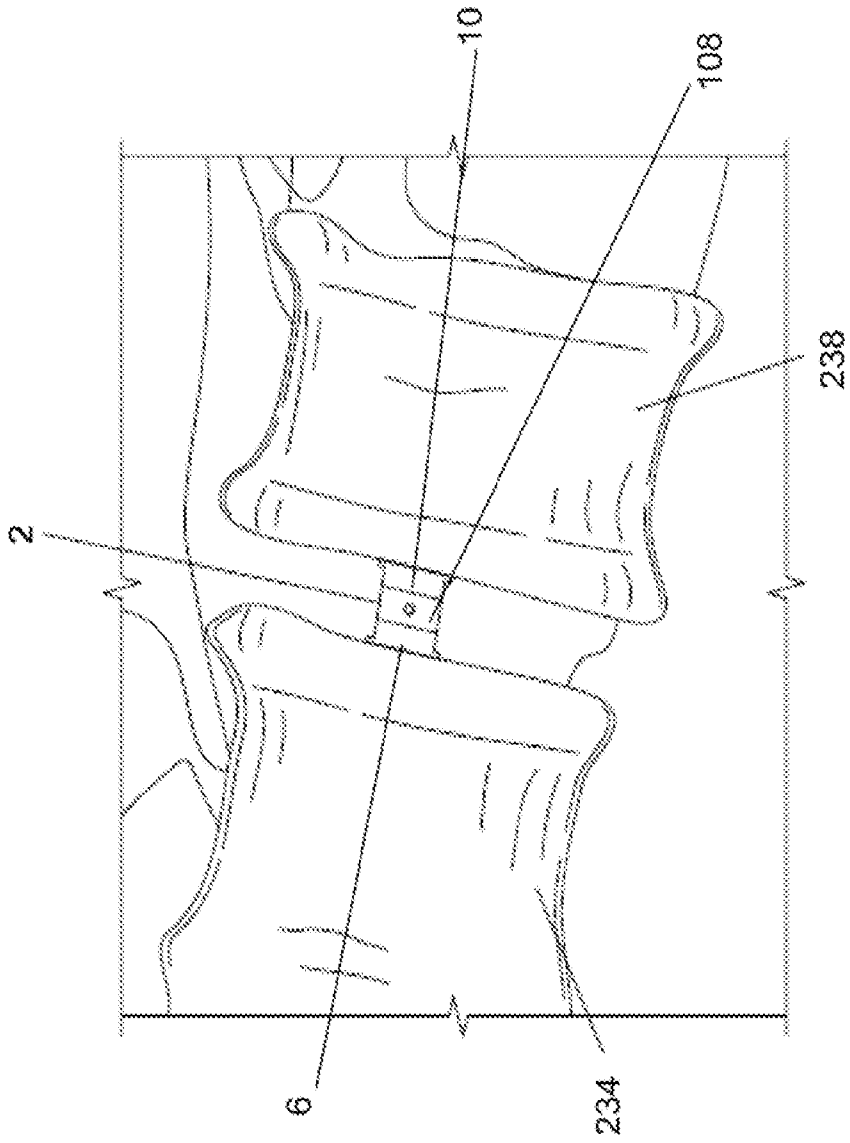


Fig. 55b

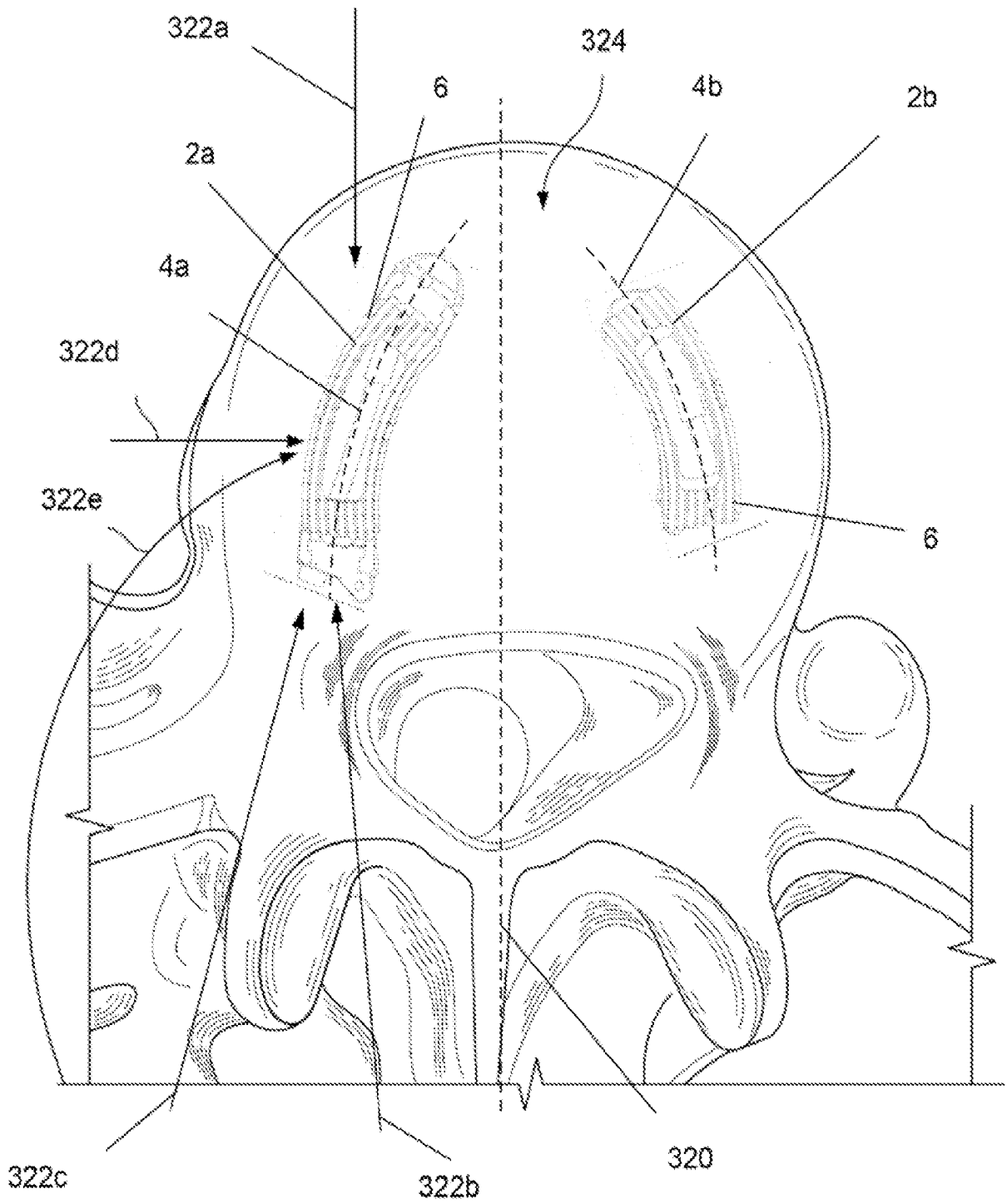


Fig. 56a

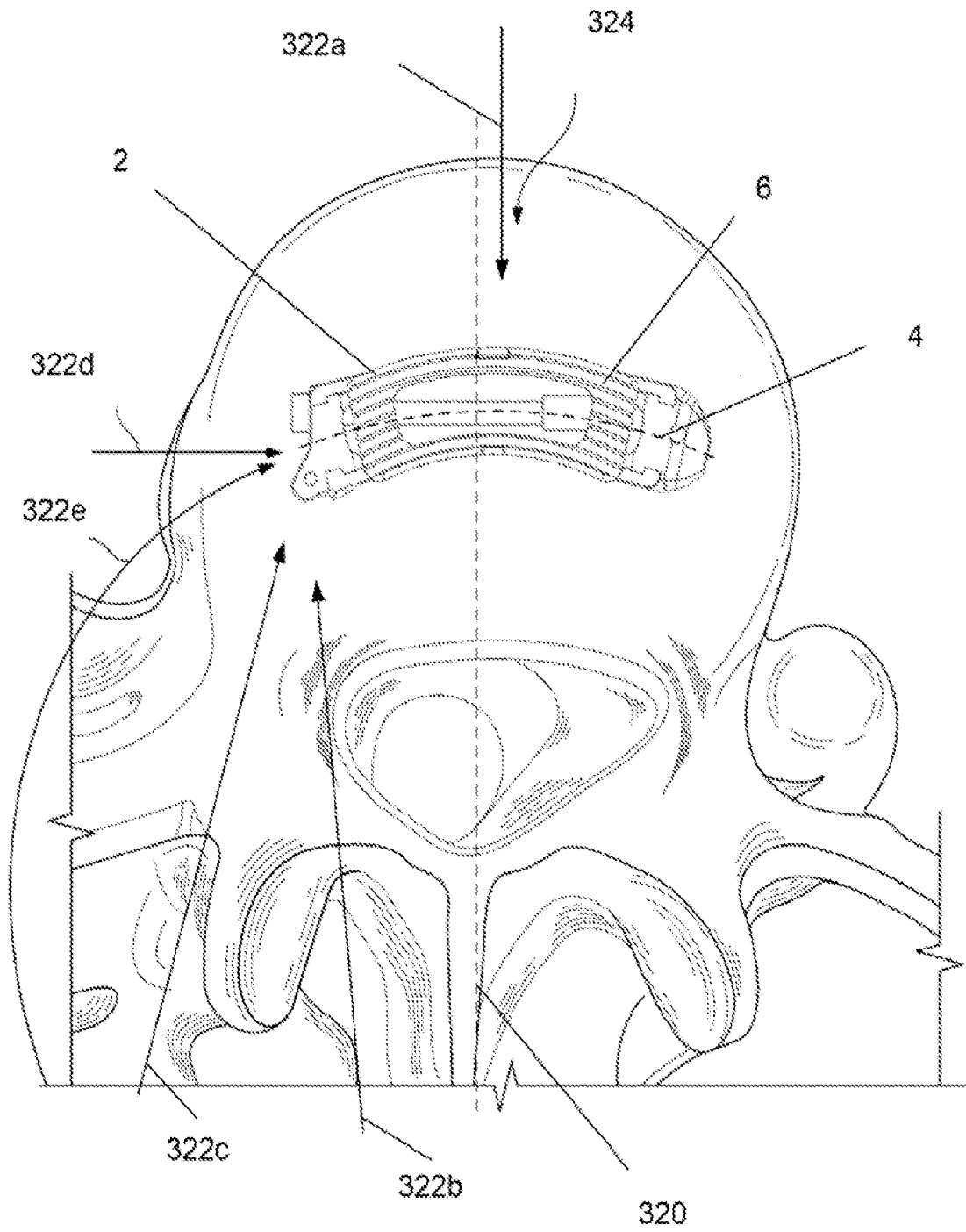


Fig. 56b

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2010/034788

<b>A. CLASSIFICATION OF SUBJECT MATTER</b> IPC(8) - A61B 17/66 (2010.01) USPC - 606/282 According to International Patent Classification (IPC) or to both national classification and IPC		
<b>B. FIELDS SEARCHED</b> Minimum documentation searched (classification system followed by classification symbols) IPC(8) - A61B 17/66 (2010.01) USPC - 606/105, 282 Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) Micropatent, Google Patent, PatBase		
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2010/0016905 A1 (GREENHALGH et al) 21 January 2010 (21.01.2010) entire document	1-7
Y	US 5,895,387 A1 (GUERRERO et al) 20 April 1999 (20.04.1999) entire document	1-7
A	US 2010/0082109 A1 (GREENHALGH et al) 01 April 2010 (01.04.2010) entire document	1-7
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/>		
* Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family		
Date of the actual completion of the international search 30 June 2010		Date of mailing of the international search report <b>08 JUL 2010</b>
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201		Authorized officer: Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774