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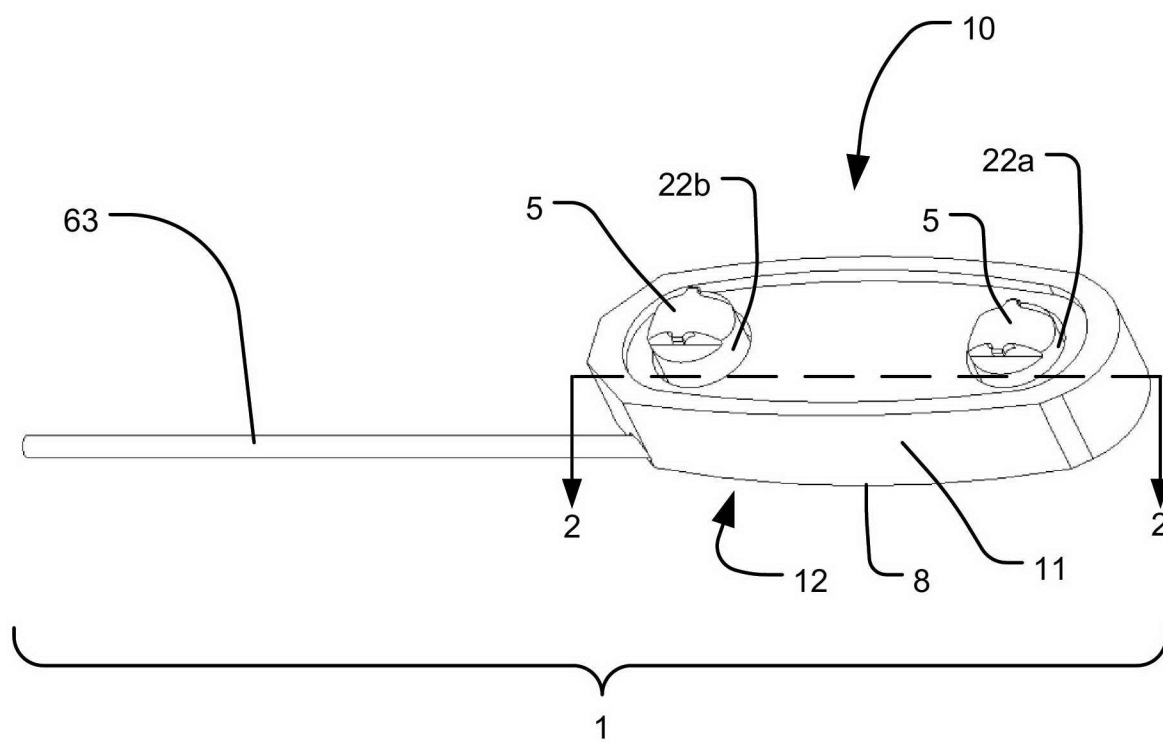
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ABSTRACT

Expandable spinal interbody implants (10) include a body (11) and at least one extendable support element (22a) connected thereto. Such an implant (10) may include a second extendable support element (22b) and a tool (63) selectively positionable with respect to the implant (10) so as to independently or simultaneously expand both extendable support elements (22a, 22b). In another example, such an implant may include, at each of a first and second location, a respective movable member and a respective locking element. The at least one extendable support element (22a, 22b) may be actuatable to expand so as to induce movement of at least one of the movable members away from the body. The locking elements at each of the first and second locations may be selectively lockable such that, when locked, the locking element restrains movement of the associated movable member at that location away from the body without restraining movement of the other movable member away from the body.

Fig. 1

FIG. 1



CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of the filing date of United States Provisional Patent Application No. 62/393,380 filed September 12, 2016, the disclosure of which is hereby explicitly incorporated herein by direct cross reference.

DEFINITION

[0002] In the present description and claims, the term “comprising” shall be understood to have a broad meaning similar to the term “including” and will be understood to imply the inclusion of a stated integer or step or group of integers or steps but not the exclusion of any other integer or step or group of integers or steps. This definition also applies to variations on the term “comprising” such as “comprise” and “comprises”.

BACKGROUND OF THE DISCLOSURE

[0003] Intervertebral implants are commonly used in spinal surgery, such as in interbody fusion procedures, in which an implant (*e.g.*, a spacer or cage) is placed in the disc space between two vertebrae to be fused together. At least a portion of the disc is typically removed before the implant is positioned in the intervertebral space, and the implant may be supplemented with bone graft material to promote fusion of the vertebrae. Interbody fusion procedures may also be performed in conjunction with other types of fixation, such as pedicle screw fixation, to provide additional stability, particularly while the vertebrae fuse together.

[0004] Different interbody fusion procedures can be distinguished by their location along the spine (*e.g.*, in the cervical, thoracic, or lumbar regions); by the type of implant used; and by the surgical approach to the intervertebral space, in which different surgical approaches often imply different structural characteristics of the implant or implants used. Different surgical approaches to the spine include anterior, posterior, and lateral. Examples of interbody fusion techniques performed along a posterior approach include posterior lumbar interbody fusion (PLIF) and transforaminal lumbar interbody fusion (TLIF). PLIF techniques typically include positioning two intervertebral implants into the intervertebral space along a posterior to anterior direction, with one implant being positioned towards the left side of the spine and one implant being positioned towards the right side of the spine. The implants used in such PLIF techniques typically have a straight shape, in that they extend

along a central axis. TLIF techniques, by contrast, typically include positioning one intervertebral implant into the intervertebral space (often towards the anterior portion of the intervertebral space) from the posterior of the patient, but the spine is approached on one side from a more lateral position than in PLIF techniques. The implants used in such TLIF techniques are often curved, such that they have an overall kidney bean-like shape. Interbody fusion techniques performed along a lateral approach, on the other hand, often involve implants that are generally symmetric along their linear longitudinal axis (*e.g.*, having a substantially rectangular or oval shape), but the implants are typically larger than those used in PLIF or TLIF techniques. That is, intervertebral implants used in lateral approaches often cover a substantial portion of the disc space.

[0005] Included among the different types of intervertebral implants are expandable implants. Such implants often have an initially contracted configuration, such that they have a low profile in the superior-inferior direction, in order to ease insertion into the intervertebral space. Such expandable implants can then be expanded in the superior-inferior direction after implantation, so as to securely engage and stabilize the vertebrae on both sides of the intervertebral space. Examples of expandable intervertebral implants are disclosed in U.S. Patent No. 8,992,620 (“the ’620 Patent”) and in U.S. Patent Application No. 15/481,854 filed on April 7, 2017, entitled Expandable Interbody Implant (hereinafter “the ’854 Application”), the disclosures of which are hereby incorporated by reference herein as if fully set forth herein.

[0006] Although considerable effort has been devoted in the art to optimization of such intervertebral systems and methods, still further improvement would be desirable.

[0007] The reference to prior art in this specification is not and should not be taken as an acknowledgment or any form of suggestion that the referenced prior art forms part of the common general knowledge in Australia or in any other country.

BRIEF SUMMARY OF THE DISCLOSURE

[0008] Applicant recognizes that although considerable effort has been devoted in the prior art to such intervertebral systems and methods, further development would be beneficial.

[0009] The present disclosure relates to expandable spinal interbody implants, as well as to systems comprising the same and methods of operating the same.

[0010] In one aspect of the disclosure there is provided a spinal implant for placement between first and second vertebral bodies, comprising a body having a first surface for engaging a first vertebral body; a first movable member having a first end movable away from the body at a first location; a second movable member having a second end movable away from the body at a second location. The implant has at least one extendable support element connected to the body, the first extendable support element being actuatable to expand so as to induce movement of at least one of the first and second ends of the respective first and second movable members away from the body. The implant also includes a first locking element at the first location and a second locking element at the second location. The first locking element is selectively lockable such that, when locked, the first locking element restrains movement of the first movable member away from the body without restraining movement of the second movable member away from the body. The second locking element is selectively lockable such that, when locked, the second locking element restrains movement of the second movable member away from the body without restraining movement of the first movable member away from the body.

[0011] Also disclosed is a spinal implant system, comprising the spinal implants as disclosed herein, a first control rod adapted to selectively lock the first locking element of the spinal implant and a second control rod adapted to selectively lock the second locking element of the spinal implant.

[0012] In accordance with aspects of the disclosure, a spinal implant for placement between first and second vertebral bodies preferably includes a body and at least first and second extendable support elements connected to the body at respective first and second locations. The body may have a first surface for engaging the first vertebral body. The first and second extendable support elements are each desirably configured to expand such that a respective first and second end of the extendable support element moves away from the body. A spinal implant system comprising such a spinal implant preferably further includes a tool selectively positionable with respect to the implant to independently or simultaneously expand the first and second extendable support elements.

[0013] According to some further aspects of the above spinal implant system, the spinal implant may be configured to allow the tool to move within the spinal implant to expand the first and second extendable support elements. In some yet further aspects of such spinal implant system, the spinal implant may be configured to allow the tool to move

longitudinally within the spinal implant to expand the first and second extendable support elements. According to some even further aspects, such spinal implant may include a channel extending between the first and second extendable support elements, such that the longitudinal movement of the tool is within the channel.

[0014] According to some other aspects of the above spinal implant system, each of the first and second extendable support elements may include a piston slidably received within a cylinder. In some yet further aspects of such spinal implant system, the first and second extendable support elements may be configured to be extended by a fluid. According to some even further aspects, the spinal implant may include a channel extending between the first and second extendable support elements. In some such aspects, the tool may supply the fluid to the first and second extendable support elements, and the channel of the spinal implant may be configured to allow the tool to move therealong to selectively supply the fluid to the first and second extendable support elements. In some other of such aspects, the tool may include an internal fluid passageway. In some even further aspects, the channel of the spinal implant may be adapted to receive the tool therein, and, when the tool is received within the channel, an exterior fluid passageway may be defined between an inner surface of the channel and an exterior surface of the tool. That exterior fluid passageway may communicate with the internal fluid passageway via at least one exit port of the tool. In some further aspects of such spinal implant system, the tool may be longitudinally movable along the channel, such that the exterior fluid passageway can be moved to selectively communicate with either or both of the first and second expandable support elements. In some other further aspects of the spinal implant system, the exterior fluid passageway may be defined between a first seal member and a second seal member spaced apart along a length of the tool, which seal members may be configured to sealingly engage the inner surface of the channel. In some yet other further aspects of the spinal implant system, the exterior fluid passageway may be at least partially defined by a recessed portion of the exterior surface of the tool.

[0015] According to some other aspects of the above spinal implant system, the first end of the first extendable support element and the second end of the second extendable support element may be connected by a plate having a second surface for engaging the second vertebral body. In some yet further aspects of such spinal implant system, the first end of the first extendable support element may be connected to the plate by a first pivotable

connection and the second end of the second extendable support element may be connected to the plate by a second pivotable connection.

[0016] In accordance with other aspects of the disclosure, a spinal implant for placement between first and second vertebral bodies preferably includes a body, at least one extendable support element connected to the body, first and second movable members having respective first and second ends movable away from the body, and first and second locking elements. The first movable member and the first locking element are preferably at a first location, and the second movable member and the second locking element are preferably at a second location. The first and second locking elements are desirably selectively lockable such that, when the first locking element is locked, the first locking element restrains movement of the first movable member away from the body without restraining movement of the second movable member away from the body, and, when the second locking element is locked, the second locking element restrains movement of the second movable member away from the body without restraining movement of the first movable member away from the body.

[0017] According to some further aspects of the above spinal implant, the first locking element, when locked, may restrain movement of the first movable member away from the body by defining a maximum amount of permitted movement of the first movable member away from the body, and the second locking element, when locked, may restrain movement of the second movable member away from the body by defining a maximum amount of permitted movement of the second movable member away from the body. In some yet further aspects of such spinal implant, the first locking element may be configured to selectively vary the maximum amount of permitted movement of the first movable member away from the body when the first locking element is locked, and the second locking element may be configured to selectively vary the maximum amount of permitted movement of the second movable member away from the body when the second locking element is locked.

[0018] According to some other aspects of the above spinal implant, the first and second locking elements may each be rotatable so as to move between a locked configuration and an unlocked configuration. In some yet further aspects of such spinal implant, the first and second locking elements may each have a cylindrical shape defining an open interior space. According to some even further aspects, the extendable support element may include a first extendable support element and a second extendable support element, with the first extendable support element being received within the open interior space of the first locking

element, and the second extendable support element being received within the open interior space of the second locking element. In some even further aspects, an inner surface of the first locking element may include a first inner projecting feature, and an outer surface of the first extendable support element may include a first outer projecting feature. The first inner projecting feature and the first outer projecting feature may be arranged to selectively engage and disengage one another based on a rotational position of the first locking element. An inner surface of the second locking element may similarly include a second inner projecting feature, and an outer surface of the second extendable support element may include a second outer projecting feature. The second inner projecting feature and the second outer projecting feature may likewise be arranged to selectively engage and disengage one another based on a rotational position of the second locking element. In some such aspects, the first inner projecting feature, the first outer projecting feature, the second inner projecting feature, and the second outer projecting feature may each include a plurality of projecting ribs. In some other of such aspects, the first inner projecting feature may include a series of first projecting ribs, each of which may extend to a different radial position along the inner surface of the first locking element, and the second inner projecting feature may include a series of second projecting ribs, each of which may extend to a different radial position along the inner surface of the second locking element. According to some aspects, the first locking element may include a plurality of teeth along an outer surface of the first locking element, which teeth may be adapted for engagement by a first control tool to rotate the first locking element so as to move the first locking element between a locked configuration and an unlocked configuration.

[0019] According to some other aspects of the above spinal implant, the extendable support element may include a first extendable support element and a second extendable support element, with the first movable member being a portion of the first extendable support element, and the second movable member being a portion of the second extendable support element.

[0020] According to some other aspects of the above spinal implant, the first and second movable members may be connected by a plate having a second surface for engaging the second vertebral body. In some yet further aspects of such spinal implant, the first and second movable members are connected to the plate by a respective first and second pivotable connection.

[0021] In accordance with yet other aspects of the disclosure, a spinal implant system may comprise a spinal implant, as described above, and first and second control rods. The first and second control rods are desirably adapted to selectively lock the respective first and second locking elements of the implant.

[0022] According to some further aspects of the above spinal implant system, the first and second control rods may be adapted to selectively lock the respective first and second locking element by linear movement of the respective first and second control rod within the spinal implant. In some yet further aspects of such spinal implant system, the first and second control rods may each include a plurality of teeth arranged to engage the respective first and second locking elements so as to control the selective locking of the respective first and second locking elements.

[0023] According to a further aspect of the disclosure there is provided a spinal implant system, comprising: spinal implant for placement between first and second vertebral bodies, the spinal implant comprising: a body having a first surface for engaging a first vertebral body; a first movable member having a first end movable away from the body at a first location; a second movable member having a second end movable away from the body at a second location; at least one a first extendable support element connected to the body at a first location, the first extendable support element being actuatable configured to expand so as to induce movement of at least one of the such that a first and second ends of the respective first and second movable members extendable support element moves away from the body; and a first locking element at the first location; and a second locking extendable support element connected to the body at the a second location; wherein the first locking element is selectively lockable such that, when locked, the first locking element restrains movement of the first movable member away from the body without restraining movement of the second movable member away from the body; and wherein the second locking element is selectively lockable such that, when locked, the second locking element restrains movement of the second movable member away from the body without restraining movement of the first movable member away from the body the second extendable support element being configured to expand such that a second end of the second extendable support element moves away from the body; and a tool selectively positionable with respect to the spinal implant so as to independently or simultaneously expand the first and second extendable support elements, wherein when the tool is in a first position with respect to the

spinal implant the first and second extendable support elements independently expand, and wherein when the tool is in a second position with respect to the spinal implant the first and second extendable support elements simultaneously expand.

[0024] According to a yet further aspect of the disclosure, there is provided a system, comprising: an implant for placement between first and second vertebral bodies, comprising: a body having a first surface for engaging a first vertebral body; a first extendable support element connected to the body and having a first end movable away from the body at a first location, the first extendable support element being operable between an activated control state, in which the first extendable support element is actuatable to expand so as to induce movement of the first end away from the body, and a deactivated control state, in which the first extendable support element is not actuatable to expand; a second extendable support element connected to the body and having a second end movable away from the body at a second location, the second extendable support element being operable between an activated control state, in which the second extendable support element is actuatable to expand so as to induce movement of the second end away from the body, and a deactivated control state, in which the second extendable support element is not actuatable to expand; and a tool for controlling the expansion of the first and second extendable support elements, wherein the tool is selectively positionable with respect to the body in one of a plurality of pre-defined positions, each of the plurality of pre-defined positions being defined by a different combination of activated and deactivated control states of the first and second extendable support elements.

[0025] According to a yet further aspect of the disclosure, there is provided a method of expanding a spinal implant positioned between a first vertebral body and a second vertebral body, comprising: positioning a tool with respect to the spinal implant to a selected one of a plurality of pre-defined positions, wherein the spinal implant includes a body having a first surface for engaging the first vertebral body, a first extendable support element connected to the body at a first location, and a second extendable support element connected to the body at a second location, each of the first and second extendable support elements being operable between an activated control state, in which expansion of the respective extendable support element is controllable by the tool, and a deactivated control state, in which expansion of the respective extendable support element is not controllable by the tool, and wherein each of the plurality of pre-defined positions of the tool is defined by a different

combination of activated and deactivated control states of the first and second extendable support elements; and expanding at least one of the first or second extendable support elements such that the first or second end of the respective first or second extendable support element moves away from the body.

BRIEF DESCRIPTION OF THE DRAWINGS

[0026] FIG. 1 is a perspective view of a spinal implant system in accordance with one embodiment of the present disclosure.

[0027] FIGS. 2A-C are cross-sectional plan views about line 2-2 of the embodiment of FIG. 1 in different configurations.

[0028] FIG. 3A is a side elevation view of an embodiment of a spinal implant system having a top end plate.

[0029] FIG. 3B is a perspective view of the spinal implant system of FIG. 3A.

[0030] FIG. 4 is an exploded, perspective view of a spinal implant system in accordance with another embodiment of the present disclosure.

[0031] FIG. 5 is a perspective view of the spinal implant system of FIG. 4.

[0032] FIG. 6 is a perspective, side cross-sectional view about the longitudinal axis of the spinal implant system of FIG. 4.

[0033] FIG. 7 is a cross-sectional side elevation view about the longitudinal axis of the spinal implant system of FIG. 4.

[0034] FIG. 8 is a cross-sectional rear elevation view about line 8-8 in FIG. 7.

[0035] FIG. 9 is a perspective, bottom cross-sectional view of the spinal implant system of FIG. 7 about line 9-9.

[0036] FIG. 10 is a cross-sectional side elevation view about the longitudinal axis of a variation on the embodiment of FIG. 4.

[0037] FIG. 11 is a perspective, top cross-sectional view of the spinal implant system of FIG. 7 about line 11-11.

[0038] FIGS. 12A-B are plan views of locking components of the embodiment of FIG. 4 in different configurations.

[0039] FIG. 13A is a cross-sectional plan view about line 13-13 of the alternative locking component illustrated in FIG. 10 in a locked configuration.

[0040] FIG. 13B is a side, cross-sectional view about the implant's longitudinal axis of the locking component of FIG. 13A in a locked configuration.

[0041] FIG. 13C is a cross-sectional plan view about line 13-13 of the alternative locking component illustrated in FIG. 10 in an unlocked configuration.

[0042] FIG. 13D is a side, cross-sectional view about the implant's longitudinal axis of the locking component of FIG. 13A in an unlocked configuration.

[0043] FIG. 14 is a perspective view of the spinal implant system of FIG. 4 including a delivery tool.

[0044] FIG. 15 is a perspective view of a locking element in accordance with another embodiment of the disclosure.

[0045] FIGS. 16A-B are exploded, perspective views (taken from different angles) of a spinal implant system in accordance with an embodiment of the disclosure including the locking element of FIG. 15.

[0046] FIG. 17 is a cross-sectional plan view about line 17-17 of the spinal implant system of FIG. 16B.

[0047] FIG. 18 is a cross-sectional side elevation view about the longitudinal axis of the spinal implant system of FIG. 17.

[0048] FIG. 19 is a bottom cross-sectional view about line 19-19 of the spinal implant system of FIG. 16B.

[0049] FIG. 20 is a cross-sectional side elevation view about the longitudinal axis of a spinal implant system in accordance with another embodiment of the present disclosure.

DETAILED DESCRIPTION

[0050] FIGS. 1-3 illustrate components of an intervertebral implant system 1 in accordance with an embodiment of the present disclosure. The system 1 includes an implant 10 having a body or housing 11 and multiple extendable support elements that are expandable such that their top ends 5 are movable away from the housing 11. The extendable support elements may be in the form of any of the extendable support elements disclosed in the '620 Patent or the '854 Application. For example, as shown, the extendable support elements are in the form of pistons 22a and 22b slidably received within a corresponding pair of cylinders 16a and 16b defined within the housing 11. The sliding of the pistons 22a, 22b along the cylinders 16a, 16b results in the translation of the top ends 5 of the pistons

22a, 22b so as to expand the implant 10. The pistons 22a, 22b and cylinders 16a, 16b may operate as part of a hydraulic system, in which the sliding of the pistons 22a, 22b away from the bottoms of the cylinders 16a, 16b is driven by pressurized fluid within the cylinders, as discussed in the '620 Patent and the '854 Application. Although not shown in FIGS. 1-3, the implant 10 may also include a locking system to lock the positions of the pistons 22a, 22b, at least by preventing them from translating back towards the housing 11 once expanded. The locking system may include any of the structures of the locking systems disclosed in the '620 Patent and the '854 Application, and the locking system may also be unlockable to allow the pistons to collapse (*e.g.*, to reposition the implant 10 or to remove it from the body).

[0051] As discussed below, each extendable support element (*e.g.*, piston 22) can be independently actuated so as to independently expand with respect to the housing 11. The bottom 12 of the housing 11 has a bottom end surface 8, which is a bone engaging surface for engaging a vertebra on one side (*e.g.*, the inferior side) of the intervertebral space within which the implant 10 is positioned. The top ends 5 of the pistons 22a, 22b may represent bone engaging surfaces of the implant 10 for engaging a vertebra on the opposite side of the intervertebral space from the bottom end surface 8 (*e.g.*, the superior side). Alternatively, each piston top end 5 may be connected to a respective plate element (not shown) that has a top end surface representing a bone engaging surface for engaging the vertebra on the opposite side of the intervertebral space from the bottom end surface 8, similar to the plate elements in the embodiment of FIGS. 4-8. In yet a further alternative, both piston top ends 5 may be connected to a common top end plate 13 having a top end surface 9 representing a bone engaging surface for engaging the vertebra on the opposite side of the intervertebral space from the bottom end surface 8, as shown in FIGS. 3A-B. In such an embodiment, the top end plate 13 may be connected to each piston 22a, 22b by a pivotable connection, such as a rotatable pin connection, so that the top end plate 13 can be angled with respect to each piston 22a, 22b to accommodate different amounts of translation of each piston 22a, 22b.

[0052] The intervertebral implant system 1 in accordance with the present disclosure also includes a tool for actuating the expansion of the extendable support elements. The tool may include a fluid delivery cannula 63 for delivering a pressurized fluid to the cylinders 16a, 16b in order to drive the translation of the pistons 22a, 22b. The fluid delivery cannula 63 is in the form of a shaft having an internal fluid passageway 65 extending along its length.

The fluid delivery cannula 63 is desirably configured to independently control the expansion of each extendable support element. The fluid delivery cannula 63 may also be configured to control the expansion of both extendable support elements at the same time. For example, the fluid delivery cannula 63 is selectively positionable within a pressure channel 41 extending between both of the cylinders 16a, 16b, which channel 41 communicates with each of the cylinders 16a, 16b via a respective opening 71. The fluid delivery cannula 63 can thus selectively communicate with either or both of the cylinders 16a, 16b based on its longitudinal position within the channel 41. In that regard, when the fluid delivery cannula 63 is received within the channel 41, an exterior fluid passageway 67 is defined between an inner surface of the channel 41 and an exterior surface of the fluid delivery cannula 63. The longitudinal extent of the exterior fluid passageway 67 may be defined by a distal seal member 73, which may be in the form of an O-ring positioned around the exterior surface of the fluid delivery cannula 63 towards its distal end, and a proximal seal member 75, which may also be in the form of an O-ring positioned around the exterior surface of the fluid delivery cannula 63 and spaced proximally from the distal seal member 73. The volume of the exterior fluid passageway 67 may also be defined by a recessed groove 69 within the exterior surface of the fluid delivery cannula 63. As shown in FIGS. 2A-C, that recessed groove 69 may be an annular groove that extends entirely around the circumference of the fluid delivery cannula 63 between the distal and proximal seal members 73, 75. The fluid from the internal fluid passageway 65 may thus be communicated to the external fluid passageway 67 via at least one exit port 77 in the fluid delivery cannula 63.

[0053] In order to selectively actuate the extendable support elements, the fluid delivery cannula 63 can be appropriately positioned along the channel 41 as shown in FIGS. 2A-C. That is, as shown in FIG. 2A, when the fluid delivery cannula 63 is positioned at the distal-most end of the channel 41, the external fluid passageway 67 between the distal and proximal seal members 73, 75 communicates with the opening 71 of the distal cylinder 16a, but not with the opening 71 of the proximal cylinder 16b. Thus, the supply of pressurized fluid through the fluid delivery cannula 63 in the position illustrated in FIG. 2A will cause expansion of the distal piston 22a only. By retracting the fluid delivery cannula 63 to the position illustrated in FIG. 2B, the external fluid passageway 67 communicates with the openings 71 of both the distal and proximal cylinders 16a, 16b. Thus, in the position illustrated in FIG. 2B, the supply of pressurized fluid through the fluid delivery cannula 63

will cause expansion of both pistons 22a, 22b. Finally, further retraction of the fluid delivery cannula 63 to the position illustrated in FIG. 2C will cause the external fluid passageway 67 to communicate with the opening 71 of the proximal cylinder 16b but not the distal cylinder 16a. Thus, supply of pressurized fluid through the fluid delivery cannula 63 in the position illustrated in FIG. 2C will cause expansion of the proximal piston 22b only.

[0054] By manipulating the fluid delivery cannula 63 as discussed above, the expansion of the different extendable support elements can be individually controlled. That may be useful, for example, in order to adjust the height of each extendable support element to best fit the anatomy of the patient. Individual adjustment may also be useful for providing a specific angular correction to the patient's spine. For example, by providing greater expansion at the anterior portion of the spine than the posterior portion of the spine, the implant 10 may decompress nerve roots while also providing lordosis correction.

[0055] The above-described embodiment illustrated in FIGS. 1-3 is desirably structured to be used in a PLIF technique. That is, the generally linear shape of the implant 10 between the distal and proximal ends of the implant may be particularly suitable for inserting two such implants 10 into an intervertebral space (one on either side of the spine) along a posterior to anterior direction, such that the distal end of the implant is positioned more anteriorly with respect to the spine than the more posteriorly positioned proximal end of the implant. However, the same operative components discussed above can also be included in implants structured to be used in a TLIF technique or along a lateral approach. For example, an implant structured to be used in a lateral approach may have a similar configuration to that discussed above, but may be sized to cover a substantial portion of the disc space. As for an implant structured to be used in a TLIF technique, the same operative components discussed above can be incorporated into an implant having an overall kidney bean-like shape. In such an embodiment, the channel for receiving the fluid delivery cannula may be linear between the cylinders, as shown in the above-discussed figures, or it may follow an arcuate path. If the channel is arcuate, the fluid delivery cannula may have a corresponding arcuate shape or may be flexible to conform to the path of the channel.

[0056] Although the embodiment of FIGS. 1-3 allows for individual control of the amount of expansion at different locations along the implant 10 by allowing for individual actuation of the extendable support elements positioned at different locations within the implant 10, similar individual control of the amount of expansion at different locations along

the implant 10 may be provided in other ways. For example, in the embodiment of FIGS. 4-12, discussed below, the same expansion pressure may be simultaneously applied to the different locations along the implant 110, while those different locations can be individually locked to restrain expansion at the selected location(s) during the application of such expansion pressure.

[0057] FIGS. 4-5 illustrate components of an intervertebral implant system 101 in accordance with another embodiment of the present disclosure. The system 101 includes an implant 110 having a body or housing 111 and multiple extendable support elements that are each expandable such that their top ends 105 are movable away from the housing 111. The extendable support elements may be in the form of any of the extendable support elements disclosed in the '620 Patent or the '854 Application. The extendable support elements may also be in the form of pistons 122a and 122b slidably received around associated cylindrical posts 116a, 116b affixed to the housing 111, as shown in FIGS. 4 and 6-8. For example, in the illustrated embodiment, the pistons 122a and 122b may be hollow, cylindrical structures received around associated posts 116a, 116b, which posts 116a, 116b may also be hollow, cylindrical structures having respective pressure channels 141a at their bottom ends for supplying pressurized fluid. A seal member 123, which may be in the form of an o-ring, may be positioned so as to seal the sliding interfaces between the pistons 122a, 122b and the respective posts 116a, 116b, in order to prevent the pressurized fluid from escaping through those interfaces. The pistons 122a, 122b and posts 116a, 116b may thus operate as part of a hydraulic system like that discussed in the '620 Patent and the '854 Application. In particular, when pressurized fluid is supplied to the area defined between the posts 116a, 116b and respective pistons 122a, 122b, the pressurized fluid will drive the pistons 122a, 122b to slide outward from the housing 111.

[0058] As shown in FIGS. 4 and 6-9, the posts 116a, 116b may be portions of respective plug elements 114a, 114b affixed to the housing 111 by being secured within respective cylindrical bores 115a, 115b formed through the housing 111. The plug elements 114a, 114b may have wide, circular base plates 117a, 117b, which may be secured within the bottoms of the respective bores 115a, 115b. Separate alignment rings 119a, 119b may be secured (*e.g.*, welded) within the tops of the respective bores 115a, 115b after the pistons 122a, 122b have been positioned within the bores 115a, 115b, in order to secure and align the pistons 122a, 122b within the implant. Such alignment rings 119a, 119b may have outer dimensions

matching the inner dimensions of the bores 115a, 115b, and inner dimensions matching the outer profiles of the respective pistons 122a, 122b. For example, the inner profiles of the alignment rings 119a, 119b may include inwardly projecting portions or flat surfaces 124 that match recesses 146 along the outer surfaces of the pistons 122a, 122b, in order to constrain the rotational orientations of the pistons 122a, 122b. The alignment rings 119a, 119b may also act as a stop to prevent further expansion of the pistons 122a, 122b beyond a predetermined height. For example, the pistons 122a, 122b may each include at least one projecting feature that will engage the underside of the respective alignment rings 119a, 119b to prevent further expansion of the pistons. The posts 116a, 116b of the plug elements 114a, 114b may have pressure channels 141a formed therein, which communicate with a network of pressure channels 141b and 141c formed in the housing 111, as shown in FIGS. 8-9. That is, the housing 111 includes a longitudinal pressure channel 141b communicating with a pressure input port 138, into which the pressurized fluid is supplied. The network of pressure channels formed in the housing 111 may also include transverse pressure channels 141c extending from the longitudinal pressure channel 141b and communicating with the pressure channels 141a formed in the base plates 117a, 117b of the plug elements 114a, 114b. The longitudinal and transverse pressure channels 141b, 141c may be formed by drilling bores into sidewalls of the housing 111, after which plugs (not shown) may be inserted into the resulting openings formed in the sidewalls, such that the only remaining openings into the channel system are the pressure input port 138 and the exits into the pistons 122a, 122b.

[0059] The bottom 112 of the housing 111 has a bottom end surface 108, which is a bone engaging surface for engaging a vertebra on one side (*e.g.*, the inferior side) of the intervertebral space within which the implant 110 is positioned. The top ends 105 of the pistons 122a, 122b may represent bone engaging surfaces of the implant 110 for engaging a vertebra on the opposite side of the intervertebral space from the bottom end surface 108 (*e.g.*, the superior side). Alternatively, the top end 105 of each piston 122a, 122b may be connected to a respective plate element 113a, 113b that has a top end surface 109 representing a bone engaging surface for engaging the vertebra on the opposite side of the intervertebral space from the bottom end surface 108, as shown in FIGS. 4-8. In yet a further alternative, both piston top ends 105 may be connected to a common top end plate 113 having a top end surface 109 representing a bone engaging surface for engaging the vertebra on the opposite side of the intervertebral space from the bottom end surface 108, as shown

in FIG. 10. In such an embodiment, the top end plate 113 may be connected to each piston 122a, 122b by a pivotable connection 107a, 107b, such as a rotatable pin connection, so that the top end plate 113 can be angled with respect to each piston 122a, 122b to accommodate different amounts of translation of each piston 22a, 22b.

[0060] The implant 110 also includes a locking system having multiple locking elements 120a, 120b secured to the housing 111 and configured to lock the translational positions of the pistons 122a, 122b. The locking elements 120a, 120b may have a cylindrical shape configured to be positioned around the respective pistons 122a, 122b. The locking elements 120a, 120b may include at least one feature projecting inwardly from an inner surface thereof, and the pistons 122a, 122b may include at least one corresponding feature projecting outwardly from an outer surface thereof. Those features are configured to engage and disengage one another by rotation of the locking elements 120a, 120b with respect to the pistons 122a, 122b. For example, as shown in FIG. 4, the pistons 122a, 122b may each include a series of spaced apart ribs 118 projecting from their outer surfaces, and the inner surfaces of the locking elements 120a, 120b may each include a series of spaced apart ribs 121. In particular rotational orientations of each locking element 120a, 120b (referred to as a “locked configuration”), the ribs 121 of the locking element 120a, 120b mesh with the ribs 118 of the associated piston 122a, 122b, thus preventing expansion the piston 122a, 122b. The ribs 121 of the locking elements 120a, 120b may be structured and arranged to align and fit within the recesses 146 along the outer surfaces of the pistons 122a, 122b at particular rotational positions of each locking element 120a, 120b (referred to as an “unlocked configuration”). In the unlocked configuration, there is clearance between the ribs 118 of a piston 122a, 122b and the ribs 121 of the associated locking element 120a, 120b, thus leaving the pistons 122a, 122b free to translate outwardly under the influence of the pressurized fluid, or free to translate back inwardly so as to collapse the implant if the fluid is depressurized or withdrawn.

[0061] A rack-and-pinion arrangement may be used to control the rotational positions of the locking elements 120a, 120b, and thus the locked and unlocked status of the associated pistons 122a, 122b, as shown in FIG. 11. For example, each locking element 120a, 120b may include a plurality of teeth 164 on the outer surface thereof, in order to engage teeth 170 of a corresponding control rod 168a, 168b, such that the rotational position of each locking element 120a, 120b may be controlled by the linear position of the control rod 168a, 168b

within a channel 166a, 166b in the implant housing 111. As shown in FIG. 12A, in which the control rods 168a, 168b are advanced to a distal-most position, the locking elements 120a, 120b are in an unlocked configuration, such that the ribs 121 of the locking elements 120a, 120b are aligned with the recesses 146 of the pistons 122a, 122b, and thus the pistons 122a, 122b are free to translate outwardly. By retracting the control rods 168a, 168b proximally, as shown in FIG. 12B, the locking elements 120a, 120b are moved to a locked configuration, such that the ribs 121 of the locking elements 120a, 120b are rotated into engagement with the ribs 118 of the pistons 122a, 122b, thus preventing the pistons 122a, 122b from translating outwardly.

[0062] In the arrangement of FIGS. 12A-B, each piston 122a, 122b includes two, diametrically opposed recesses 146, and the locking elements 120a, 120b each include two corresponding sets of ribs 121. In an alternative arrangement, rather than a series of spaced apart ribs 118, only a single rib 118 may be provided on each piston 122a, 122b. That single rib 118 may be discontinuous in particular circumferential regions with which the ribs 121 of the locking elements 120a, 120b align in the unlocked configuration, so that there is clearance for the pistons 122a, 122b to translate. As shown in FIGS. 13A-D, which are views of such an alternative arrangement as incorporated into the embodiment of the implant 110 of FIG. 10, the pistons 122a, 122b may include three such discontinuous regions, although more or fewer discontinuous regions are also within the scope of the present disclosure. As illustrated in the locked configuration shown in FIGS. 13A-B, the ribs 121 of the locking element 120 are rotationally aligned with the solid portions of the rib 118 of the piston 122, and thus the piston 122 is prevented from translating outwardly. As for the unlocked configuration illustrated in FIGS. 13C-D, the ribs 121 of the locking element 120 have rotated into alignment with the discontinuous regions of the rib 118 of the piston 122, such that the piston 122 is free to translate outwardly. The reverse arrangement (not shown) is also within the scope of the present disclosure. That is, instead of a series of spaced apart ribs 121 on the locking elements 120a, 120b, only a single rib 121 having discontinuous regions may be provided on the inner surface of each locking element 120a, 120b. Thus, in order to lock one of the pistons 122a, 122b at its current level of displacement, the rib 121 of one of the locking elements 120a, 120b may be rotated into engagement with whichever rib 118 of the associated piston 122a, 122b is at that level.

[0063] By manipulating the control rods, and thus the locked and unlocked configurations of the pistons, as discussed above, the expansion of the different pistons can be individually controlled while applying a single fluid pressure to all the pistons. For example, by applying a pressure to the pressure channels sufficient to expand all of the pistons, any one or more of the pistons can be selectively locked by appropriate manipulation of the position of the associated control rod, such that the remaining unlocked pistons continue to translate outward from the implant housing.

[0064] In order to control the translational position of the control rods 168a, 168b, a delivery tool 100 for inserting and positioning the implant 110 within the intervertebral space may include respective sliders 105a, 105b linearly movable by a user along at least a portion of the delivery tool 100, as shown in FIG. 14. The delivery tool 100 may be securely attached to the proximal end of the implant 110 by a delivery tool anchor 137 (see FIGS. 4-7), which may include a threaded bore formed in the implant 110. In addition, the delivery tool 100 may include a conduit for communicating with the pressure input port 138, in order to supply the pressurized fluid to the implant 110. The delivery tool anchor 137 having a threaded bore for secure attachment to the delivery tool 100 need not be a separate opening in the implant 110 from the pressure input port 139 for supplying pressurized fluid, and both functions can be performed by a common opening, as shown in the embodiment of FIGS. 16-19. The locking elements 120a, 120b are desirably configured such that fully retracting the associated control rods 168a, 168b from the implant 110, such as when the delivery tool 100 is disconnected and removed from the patient's body, will leave the locking elements 120a, 120b in a locked configuration.

[0065] A further alternative embodiment in accordance with the present disclosure includes rotatable locking elements 220 similar to those of the embodiment of FIGS. 4-13D, except that the locking elements 220 are configured to selectively define a maximum amount of permitted movement of the associated piston 222, rather than locking the position of the associated piston 222. For example, as shown in FIG. 15, the inner surface of the locking element 220 includes a series of spaced apart ribs 221, where each successive rib 221 extends to a different, increasing circumferential position along the inner surface of the locking element 220. Moreover, the associated piston 222 may include a pin 218 projecting from its outer surface. Thus, each locking element 220 can be rotated to a desired position so as to define a maximum amount of expansion of the associated piston 222, by aligning the rib 221

corresponding to the desired height such that it is vertically above the pin 218. In that manner, expansion of the piston 222 by the pressurized fluid will cause the piston to translate until it engages and stops at the aligned rib 221. The height of the piston 222 may then be locked at that position by fully retracting the associated control rod 268, thus rotating the locking element 220 until the pin 218 is constrained between two adjacent ribs 221. Each locking element 220 and piston 222 combination need not have only one pin 218 and one corresponding series of ribs 221, however. In alternative embodiments, multiple pins 218, each with a corresponding series of ribs 221, may be equally spaced apart about the circumference of the piston 218 and locking element 220. For example, the embodiment illustrated in FIGS. 16-17 has three pins 218 equally spaced about the circumference of each piston 222.

[0066] FIGS. 16-19, in which reference numerals like those in earlier embodiments refer to analogous elements (and therefore not all numbered elements will be separately discussed again), illustrate an embodiment of an implant 210 having distal and proximal locking elements 220a, 220b like that shown in FIG. 15. Thus, in such an embodiment, the locking elements 220a, 220b may be individually controlled by respective control rods 268a, 268b so that the associated pistons 222a, 222b can be expanded to different desired heights, and the bone engaging component(s) (*e.g.*, top end plate 213) can thus be translated and angled, as with the previously-discussed embodiments. Many of the other structures of the embodiment of FIGS. 16-19 are substantially the same as those of the embodiment of FIGS. 4-13D, except that, instead of the posts 116a, 116b along which the pistons 122a, 122b slide being portions of respective plug elements 114a, 114b, the posts 216a, 216b of the embodiment of FIGS. 16-19 may be portions of a single bottom plate element 214. As shown in FIG. 19, that plate element 214 may include a network of longitudinal and transverse pressure channels 241b, 241c similar to those of the embodiment of FIGS. 4-13D, such that the network of channels communicates the pressurized fluid from a pressure input port 238 to the pistons 222a, 222b. The pressure input port 238 may include a threaded section for secure attachment to a delivery tool for delivering the implant 210, such that the pressure input port 238 also functions like the delivery tool anchor 137 discussed above. A sealing member, such as O-ring 239, may also be provided within the pressure input port 238, so as to seal the fluid connection between the pressure input port 238 and the delivery tool.

[0067] Other differences between the embodiment of FIGS. 16-19 and the embodiment of FIGS. 4-13 include the fact that the embodiment of FIGS. 16-19 does not have separate alignment rings like those illustrated in FIGS. 16A-B. Instead, similarly shaped alignment components may be integrally formed with the housing 211 of the implant 210, or the bores 215a, 215b through the housing 211 may be shaped to constrain the rotational orientations of the pistons 222a, 222b. Also, as shown in FIG. 16A, the channel 266a for the control rod 268a that controls the distal locking element 220a opens outwardly through a side wall of the housing 211 along a portion of the longitudinal extent of the housing 211. Such extended opening into the channel 266a through the side wall, which may beneficially allow for more clearance between the control rod 268a and the proximal locking element 220b that it bypasses, may also be included in the embodiment of FIGS. 4-13, although not shown in those figures. The embodiment of FIGS. 16-19 also includes friction rings 225a, 225b compressed between the tops of the locking elements 220a, 220b and the underside of the top of the housing 221 in the assembled configuration. The friction rings 225a, 225b may be made out of rubber or a polymeric material that has a relatively high coefficient of friction, so that there is enough resistance to rotation of the locking elements 220a, 220b that their rotational positions are maintained when not intentionally rotated by the user using the control rods 268a, 268b. Such friction rings, although not shown in FIGS. 4-13, can also be used in the embodiment of those figures.

[0068] The above-described embodiments illustrated in FIGS. 4-19 are desirably structured to be used in a PLIF technique. That is, the generally linear shape of each of the implants 110, 210 between the distal and proximal ends of the implant may be particularly suitable for inserting two such implants 110, 210 into an intervertebral space (one on either side of the spine) along a posterior to anterior direction, such that the distal end of the implant is positioned more anteriorly with respect to the spine than the more posteriorly positioned proximal end of the implant. However, the same operative components discussed above can also be included in implants structured to be used in a TLIF technique or along a lateral approach. For example, an implant structured to be used in a lateral approach may have a similar configuration to one of those discussed above, but may be sized to cover a substantial portion of the disc space. As for an implant structured to be used in a TLIF technique, the same operative components discussed above can be incorporated into an implant having an overall kidney bean-like shape. In such an embodiment, the channels for receiving the

control rods may be linear between the locking elements, as shown in the above-discussed figures, or the channels may follow an arcuate path. If the channels are arcuate, the control rods may have a corresponding arcuate shape or may be flexible to conform to the paths of the channels.

[0069] Although the locking elements in the embodiments of FIGS. 4-19 are structured to surround the associated pistons, alternative embodiments in accordance with the present disclosure need not be arranged in that manner. For example, in another embodiment of the disclosure illustrated in FIG. 20, a single extendable support element, which may include a translating piston 322 driven by a pressurized fluid, may be provided between a housing 311 of the implant 310 and a top end plate 313. Reference numerals in FIG. 20 that are like those in earlier embodiments refer to analogous elements, and therefore not all numbered elements will be separately discussed again. The implant of FIG. 20 may include two or more locking elements 320 similar to those discussed above at different locations across the implant 310, in order to individually control the amount of expansion of the top plate 313 at the location of each locking element 320. For example, the implant 310 may include a distal locking element 320a and a proximal locking element 320b, with the extendable support element (*e.g.*, piston 322) being centrally located therebetween. In operation, the extendable support element may be actuated to drive the movement of the top end plate 313 away from the housing of the implant, and each locking element 320a, 320b can be individually manipulated to control the amount of expansion of the top end plate 313 at the distal and proximal ends. Rather than engaging extendable support elements positioned therein, the locking elements 320a, 320b may each be configured to lock the expanded position of the top end plate 313 at the location of the locking element by lockingly engaging a structure connected to the top end plate 313. For example, the top end plate 313 may include downwardly extending shafts 326a, 326b coupled thereto, which shafts have outer surfaces with similar configurations to the pistons described above (*i.e.*, each having a series of spaced apart ribs projecting from the outer surface), where the shafts 326a, 326b are received within open interior regions of the respective locking elements 320a, 320b and are lockingly engageable by the locking elements in similar ways to those described above (*e.g.*, by rotational engagement with inwardly projecting ribs 321 of the locking elements). The top end plate 313 may be indirectly coupled to the housing 311 (*e.g.*, via the extendable support element and/or locking elements) by pivotable connections, so that the top end plate 313 can

achieve angled orientations with respect to the housing 311 and so that the top end plate 313 can continue to translate at the location of a locking element 320 that is in an unlocked configuration, even when the other locking element is in a locked configuration. For example, as shown in FIG. 20, the shafts 326a, 326b may be coupled to the top end plate 313 by respective pivotable connections 307a, 307b, such as rotatable pin connections, and the piston 322 may contact the plate 313 in such a way that the contact point can slide along the plate, so as to not over-constrain the top end plate 313.

[0070] Although the invention herein has been described with reference to particular embodiments, it is to be understood that these embodiments are merely illustrative of the principles and applications of the present invention. It is therefore to be understood that numerous modifications may be made to the illustrative embodiments and that other arrangements may be devised without departing from the spirit and scope of the present invention as defined by the appended claims.

CLAIMS:

1. A spinal implant system, comprising:
a spinal implant for placement between first and second vertebral bodies, the spinal implant comprising:
a body having a first surface for engaging a first vertebral body;
a first extendable support element connected to the body at a first location, the first extendable support element being configured to expand such that a first end of the first extendable support element moves away from the body; and
a second extendable support element connected to the body at a second location, the second extendable support element being configured to expand such that a second end of the second extendable support element moves away from the body; and
a tool selectively positionable with respect to the spinal implant so as to independently or simultaneously expand the first and second extendable support elements, wherein when the tool is in a first position with respect to the spinal implant the first and second extendable support elements independently expand, and wherein when the tool is in a second position with respect to the spinal implant the first and second extendable support elements simultaneously expand.
2. The spinal implant system of claim 1, wherein the spinal implant is configured to allow the tool to move within the spinal implant to expand the first and second extendable support elements.
3. The spinal implant system of claim 2, wherein the spinal implant is configured to allow longitudinal movement of the tool within the spinal implant to expand the first and second extendable support elements.
4. The spinal implant system of claim 3, wherein the spinal implant includes a channel extending between the first and second extendable support elements, such that the longitudinal movement of the tool is within the channel.
5. The spinal implant system of any one of claims 1 to 4, wherein each of the first and second extendable support elements includes a piston slidably received within a cylinder.

6. The spinal implant system of claim 5, wherein the first and second extendable support elements are configured to be extended by a fluid.
7. The spinal implant system of claim 6, wherein the spinal implant includes a channel extending between the first and second extendable support elements.
8. The spinal implant system of claim 7, wherein the tool supplies the fluid to the first and second extendable support elements, and wherein the channel of the spinal implant is configured to allow the tool to move therealong to selectively supply the fluid to the first and second extendable support elements.
9. The spinal implant system of claim 7 or claim 8, wherein the tool includes an internal fluid passageway.
10. The spinal implant system of claim 9, wherein, the channel of the spinal implant is adapted to receive the tool therein, and wherein, when the tool is received within the channel, an exterior fluid passageway is defined between an inner surface of the channel and an exterior surface of the tool, the exterior fluid passageway communicating with the internal fluid passageway via at least one exit port of the tool.
11. The spinal implant system of claim 10, wherein the tool is longitudinally movable along the channel, such that the exterior fluid passageway can be moved to selectively communicate with either or both of the first and second extendable support elements.
12. The spinal implant system of claim 10 or claim 11, wherein the exterior fluid passageway is defined between a first seal member and a second seal member spaced apart along a length of the tool, the first and second seal members being configured to sealingly engage the inner surface of the channel.

13. The spinal implant system of any one of claims 10 to 12, wherein the exterior fluid passageway is at least partially defined by a recessed portion of the exterior surface of the tool.

14. The spinal implant of any one of claims 1 to 13, wherein the first end of the first extendable support element and the second end of the second extendable support element are connected by a plate having a second surface for engaging a second vertebral body.

15. The spinal implant of claim 14, wherein the first end of the first extendable support element is connected to the plate by a first pivotable connection and the second end of the second extendable support element is connected to the plate by a second pivotable connection.

16. A system, comprising:

an implant for placement between first and second vertebral bodies, comprising:

a body having a first surface for engaging a first vertebral body;

a first extendable support element connected to the body and having a first end movable away from the body at a first location, the first extendable support element being operable between an activated control state, in which the first extendable support element is actuatable to expand so as to induce movement of the first end away from the body, and a deactivated control state, in which the first extendable support element is not actuatable to expand;

a second extendable support element connected to the body and having a second end movable away from the body at a second location, the second extendable support element being operable between an activated control state, in which the second extendable support element is actuatable to expand so as to induce movement of the second end away from the body, and a deactivated control state, in which the second extendable support element is not actuatable to expand; and

a tool for controlling the expansion of the first and second extendable support elements, wherein the tool is selectively positionable with respect to the body in one of a plurality of pre-defined positions, each of the plurality of pre-defined positions being defined

by a different combination of activated and deactivated control states of the first and second extendable support elements.

17. The system of claim 16, wherein the tool is configured to actuate the expansion of the first and second extendable support elements.

18. The system of claim 16 or 17, wherein the implant further includes a channel configured to guide movement of the tool between the plurality of pre-defined positions.

19. The system of any one of claims 16 to 18, wherein the first and second extendable support elements are configured to be extended by fluid.

20. A method of expanding a spinal implant positioned between a first vertebral body and a second vertebral body, comprising:

positioning a tool with respect to the spinal implant to a selected one of a plurality of pre-defined positions, wherein the spinal implant includes a body having a first surface for engaging the first vertebral body, a first extendable support element connected to the body at a first location, and a second extendable support element connected to the body at a second location, each of the first and second extendable support elements being operable between an activated control state, in which expansion of the respective extendable support element is controllable by the tool, and a deactivated control state, in which expansion of the respective extendable support element is not controllable by the tool, and wherein each of the plurality of pre-defined positions of the tool is defined by a different combination of activated and deactivated control states of the first and second extendable support elements; and

expanding at least one of the first or second extendable support elements such that the first or second end of the respective first or second extendable support element moves away from the body.

FIG. 1

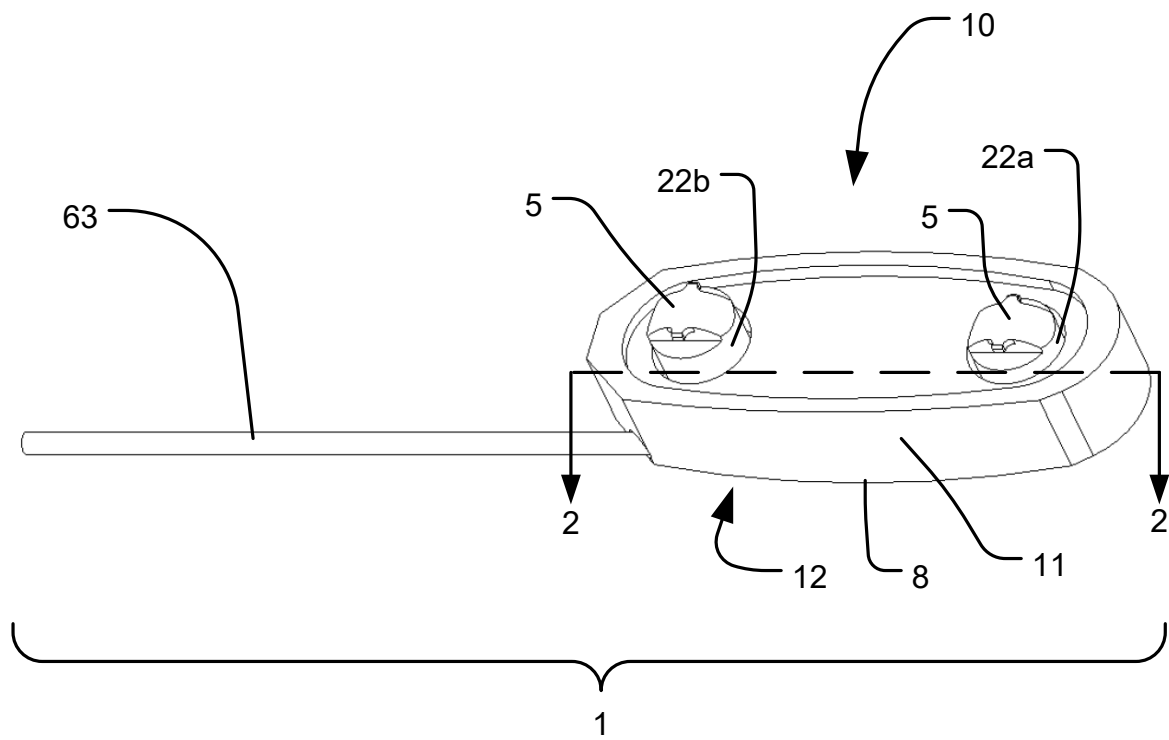


FIG. 3A

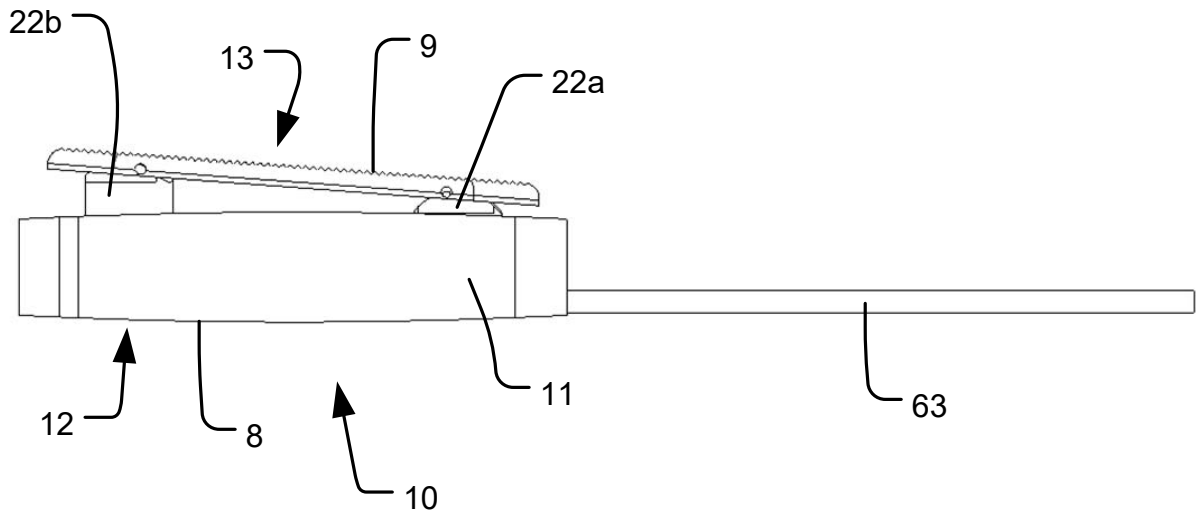
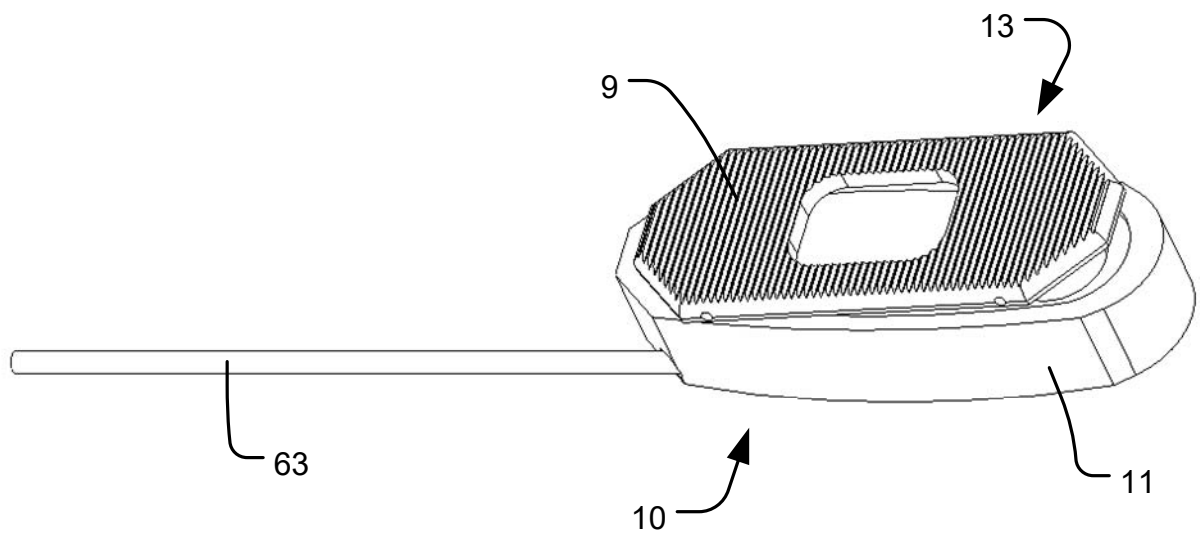


FIG. 3B



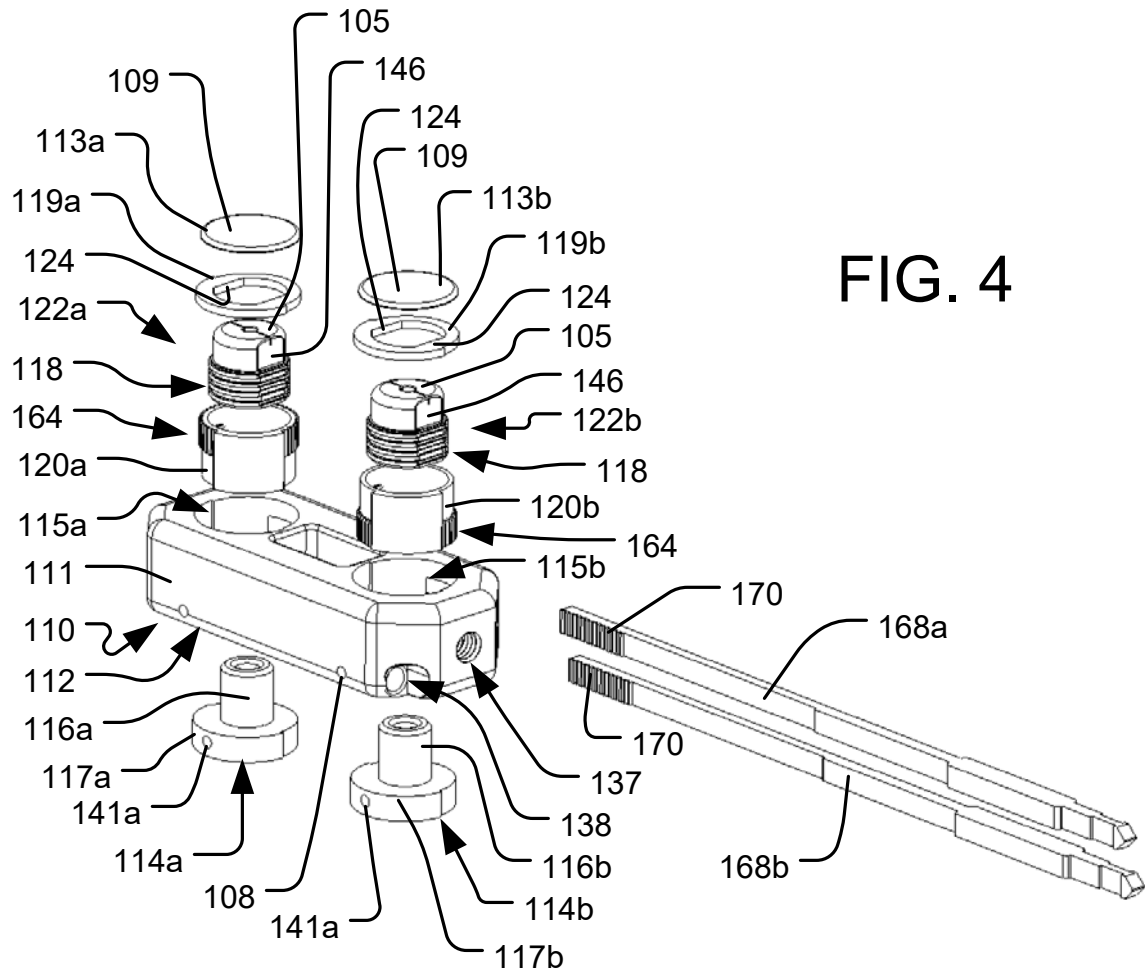


FIG. 4

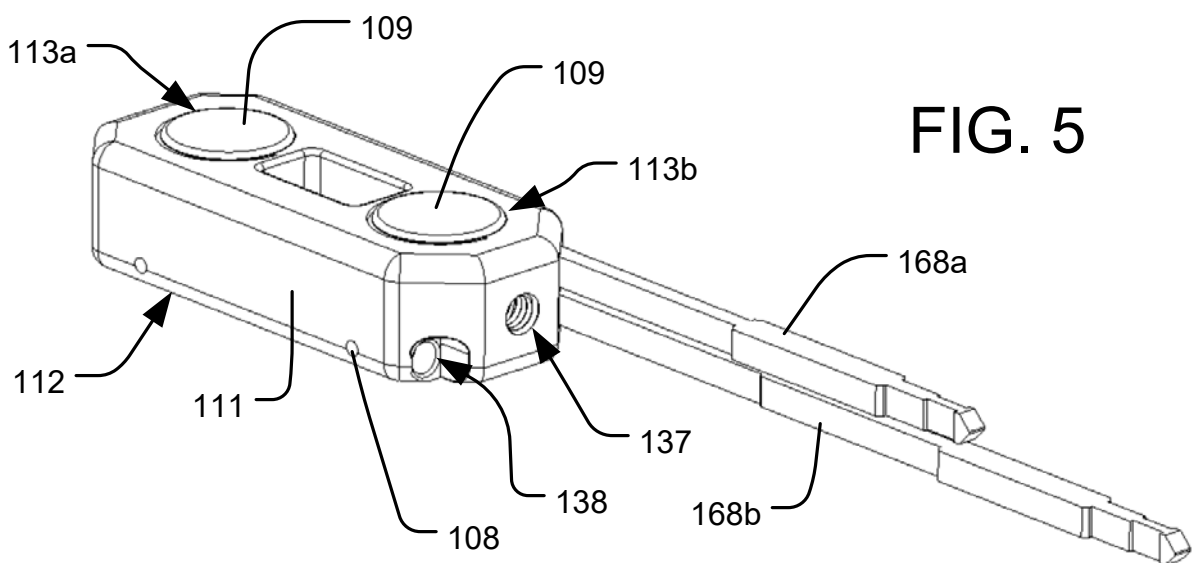


FIG. 5

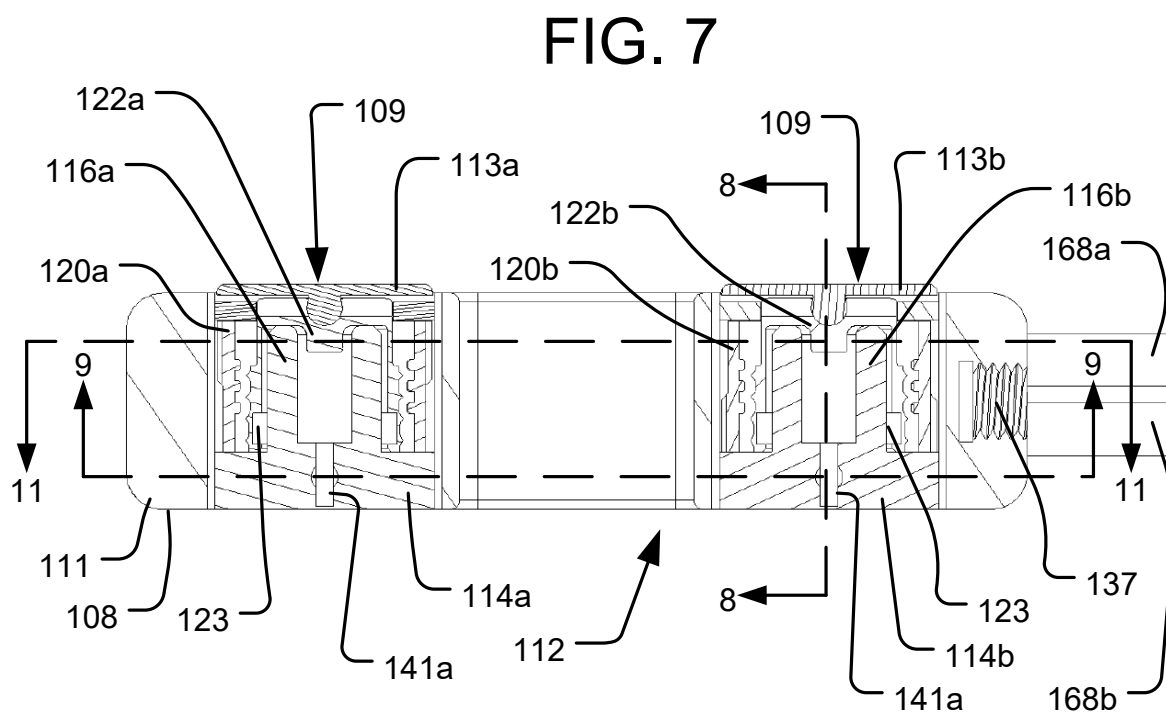
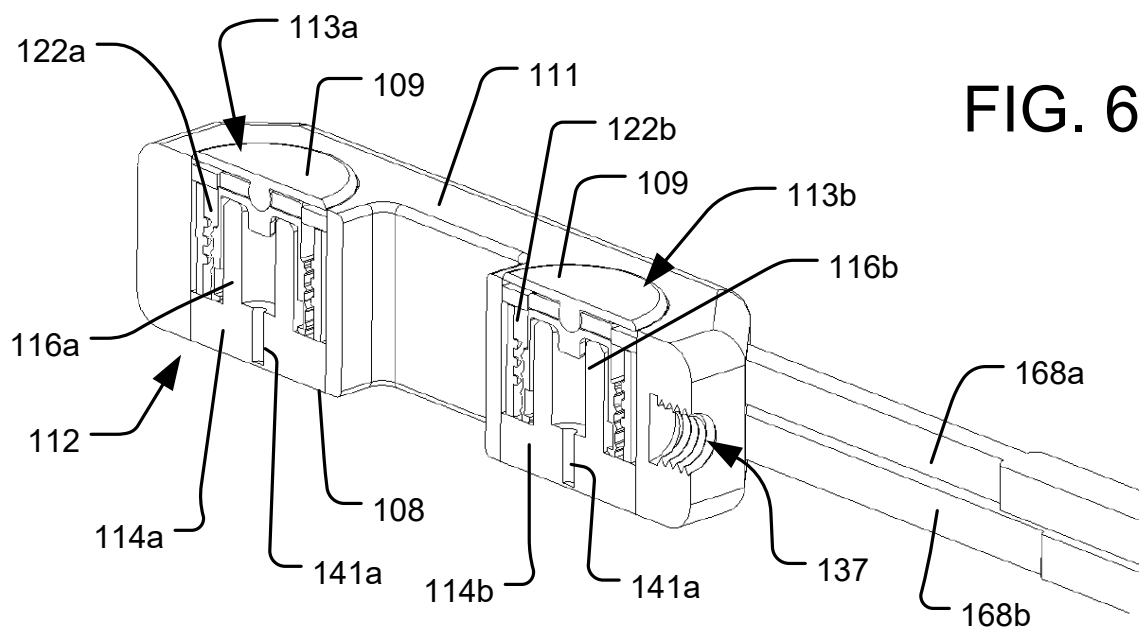


FIG. 8

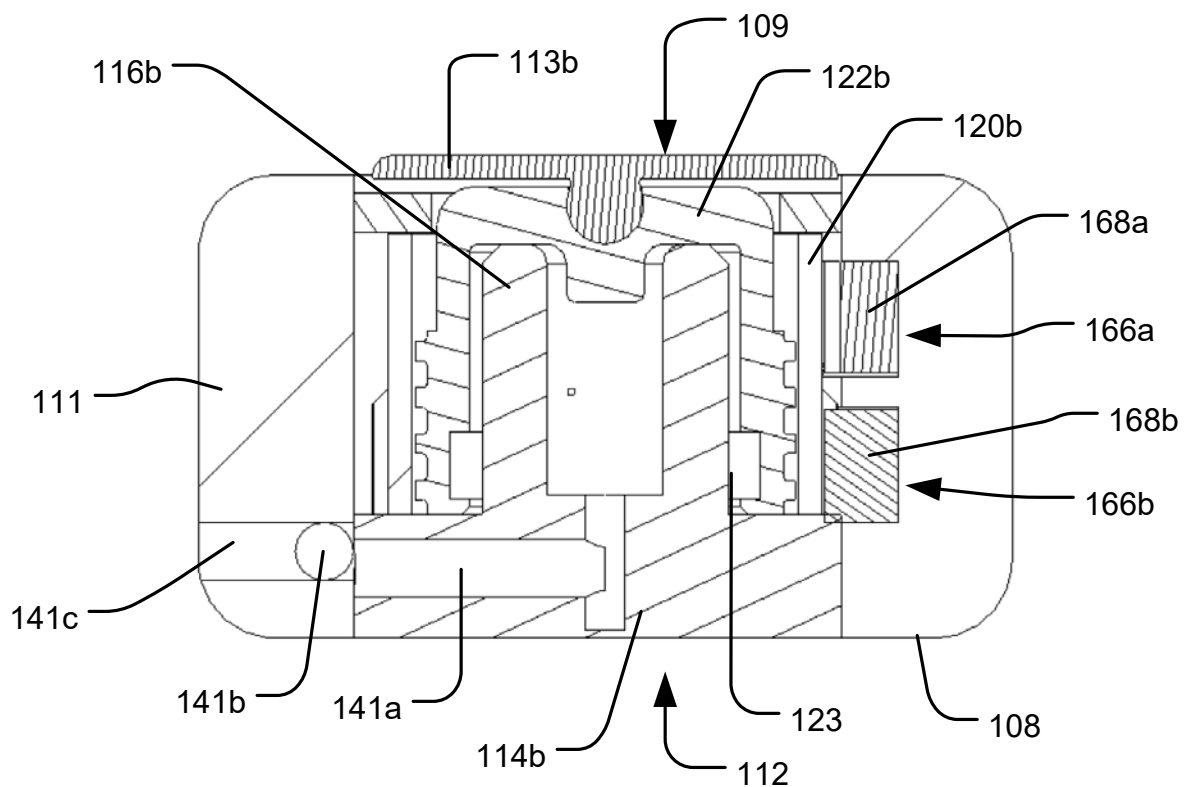


FIG. 9

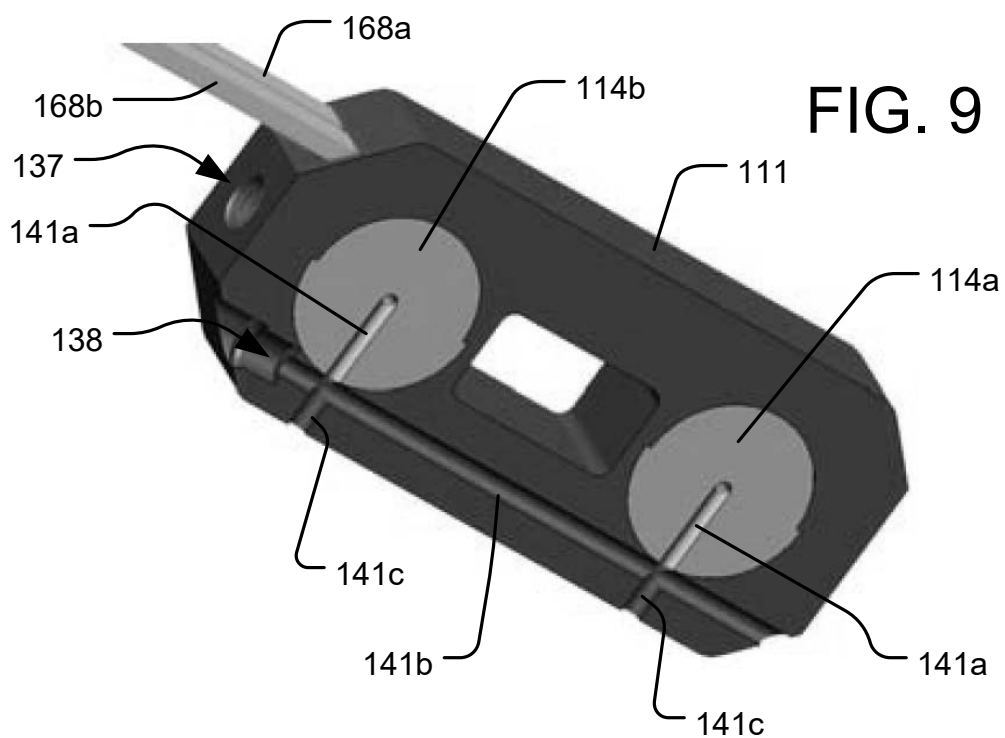


FIG. 11

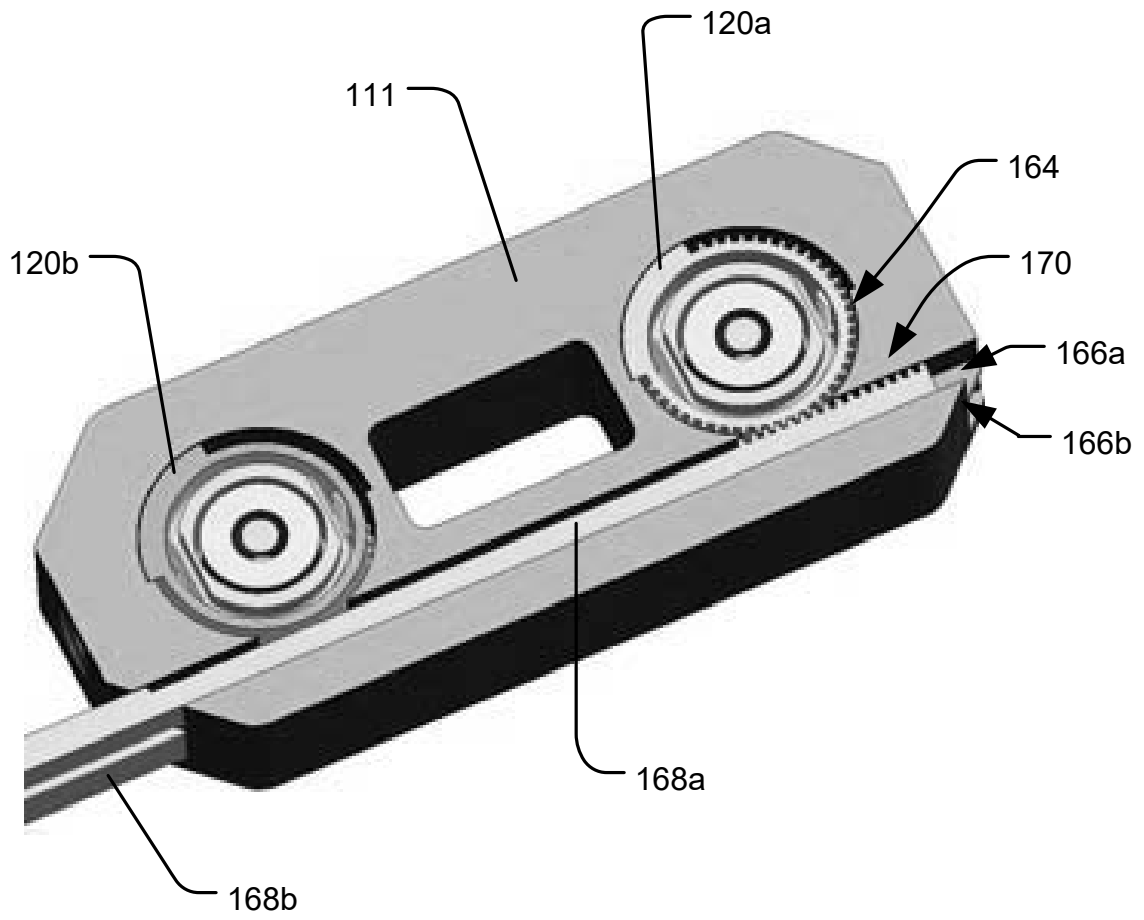


FIG. 12A

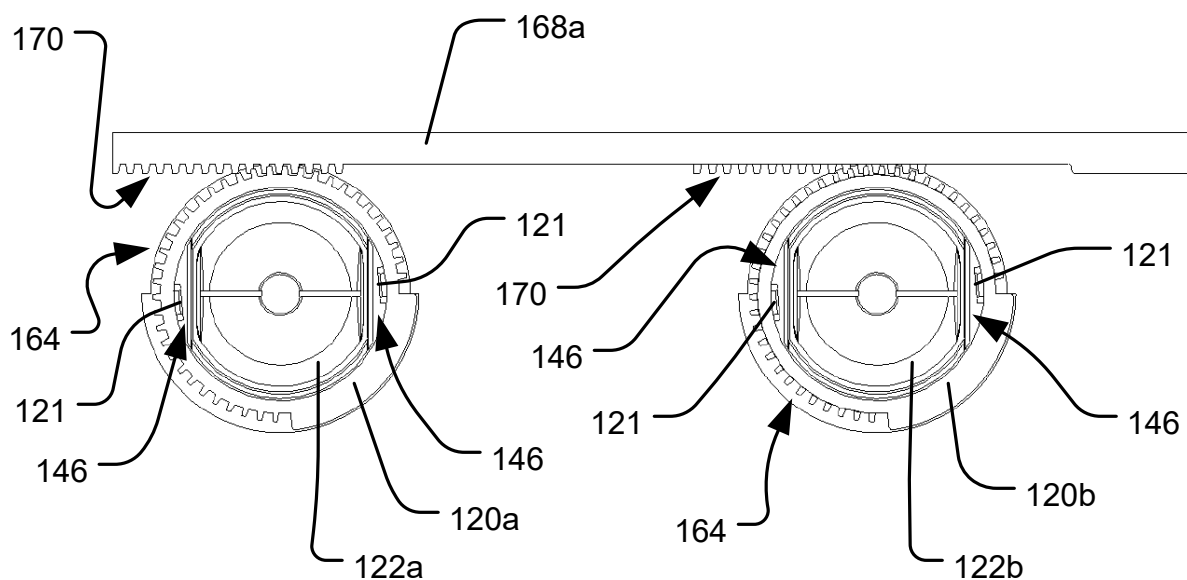


FIG. 12B

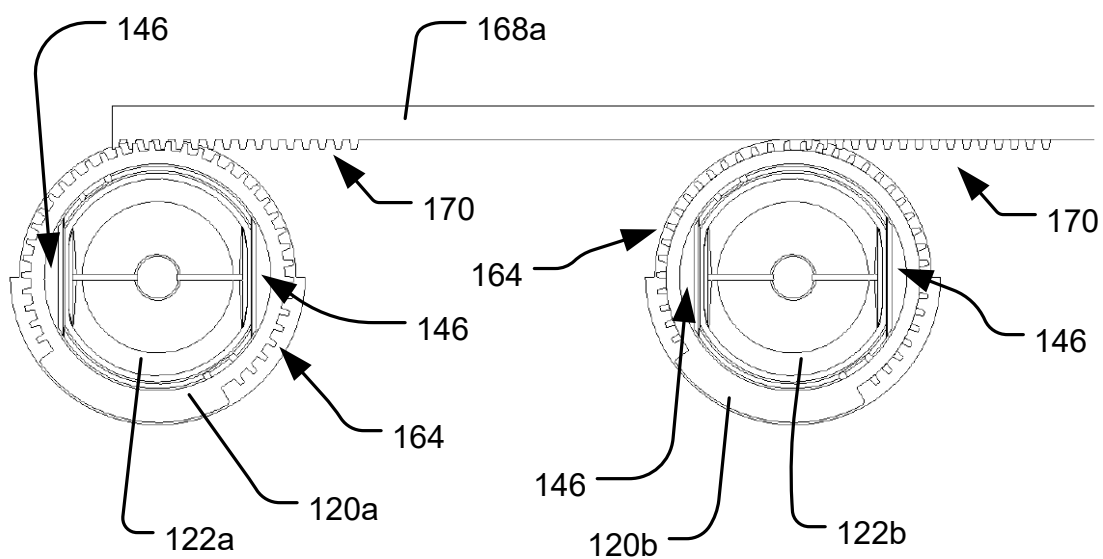


FIG. 13A

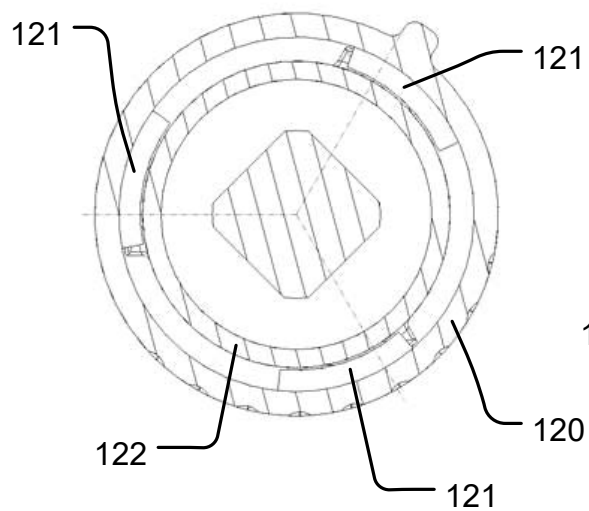


FIG. 13C

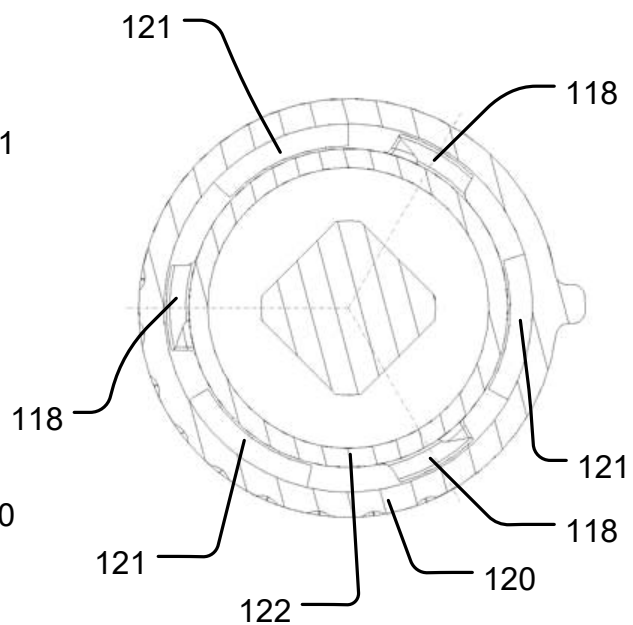


FIG. 13B

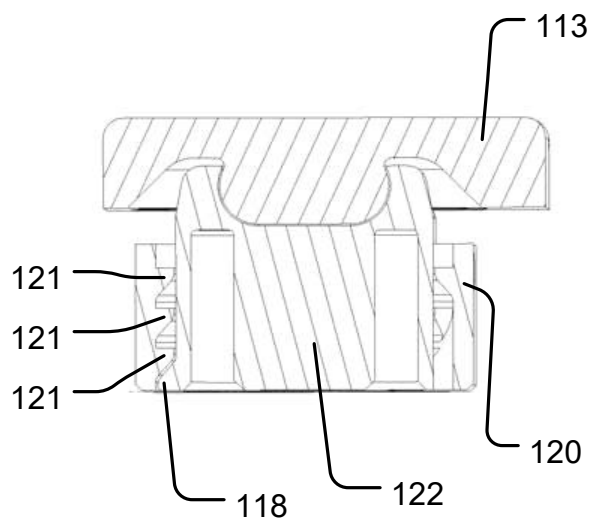


FIG. 13D

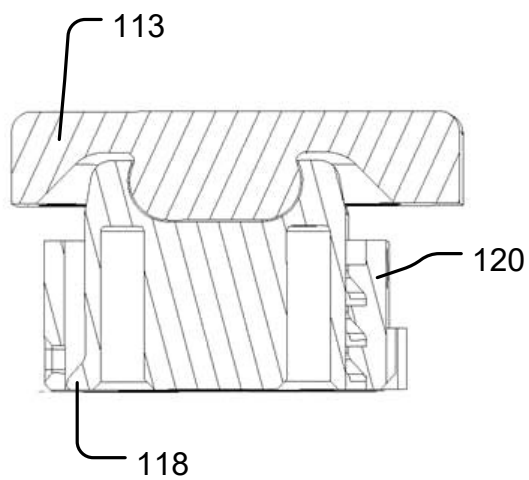


FIG. 14

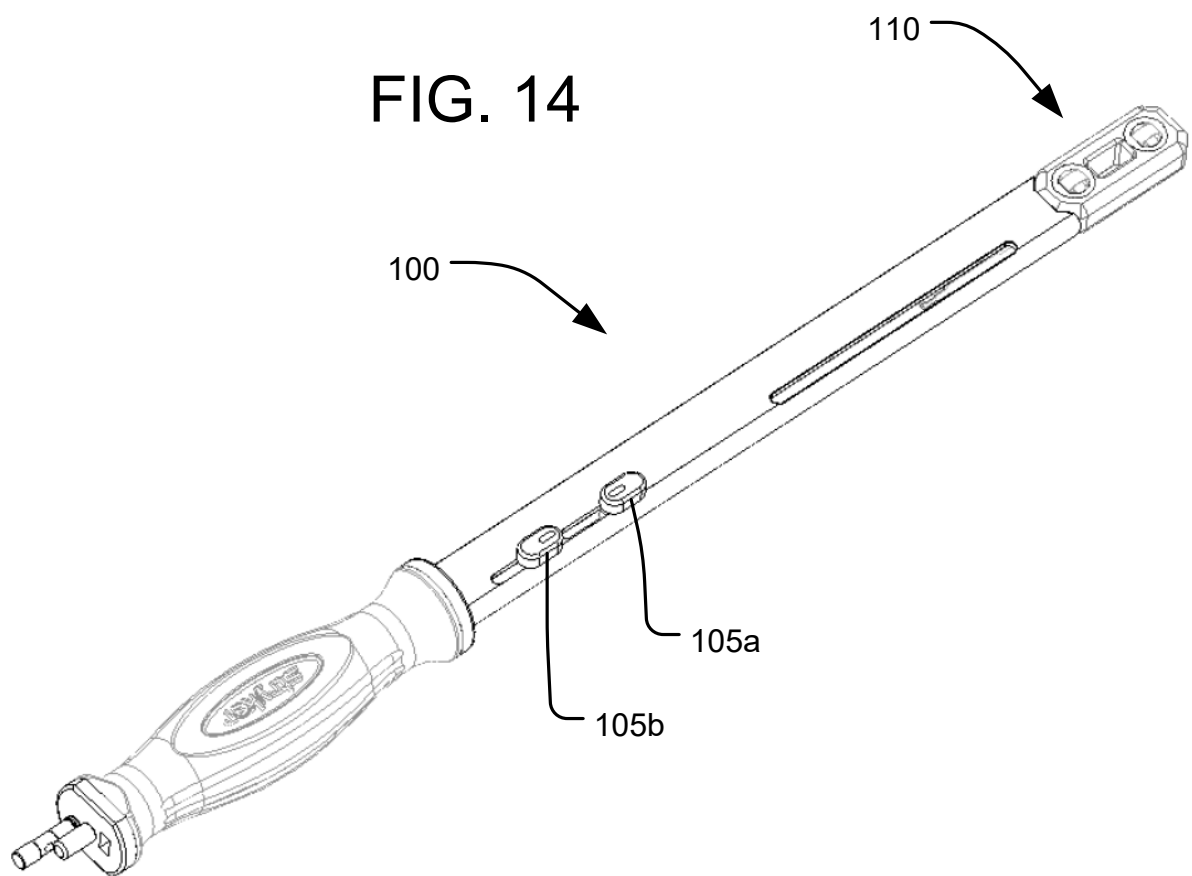


FIG. 15

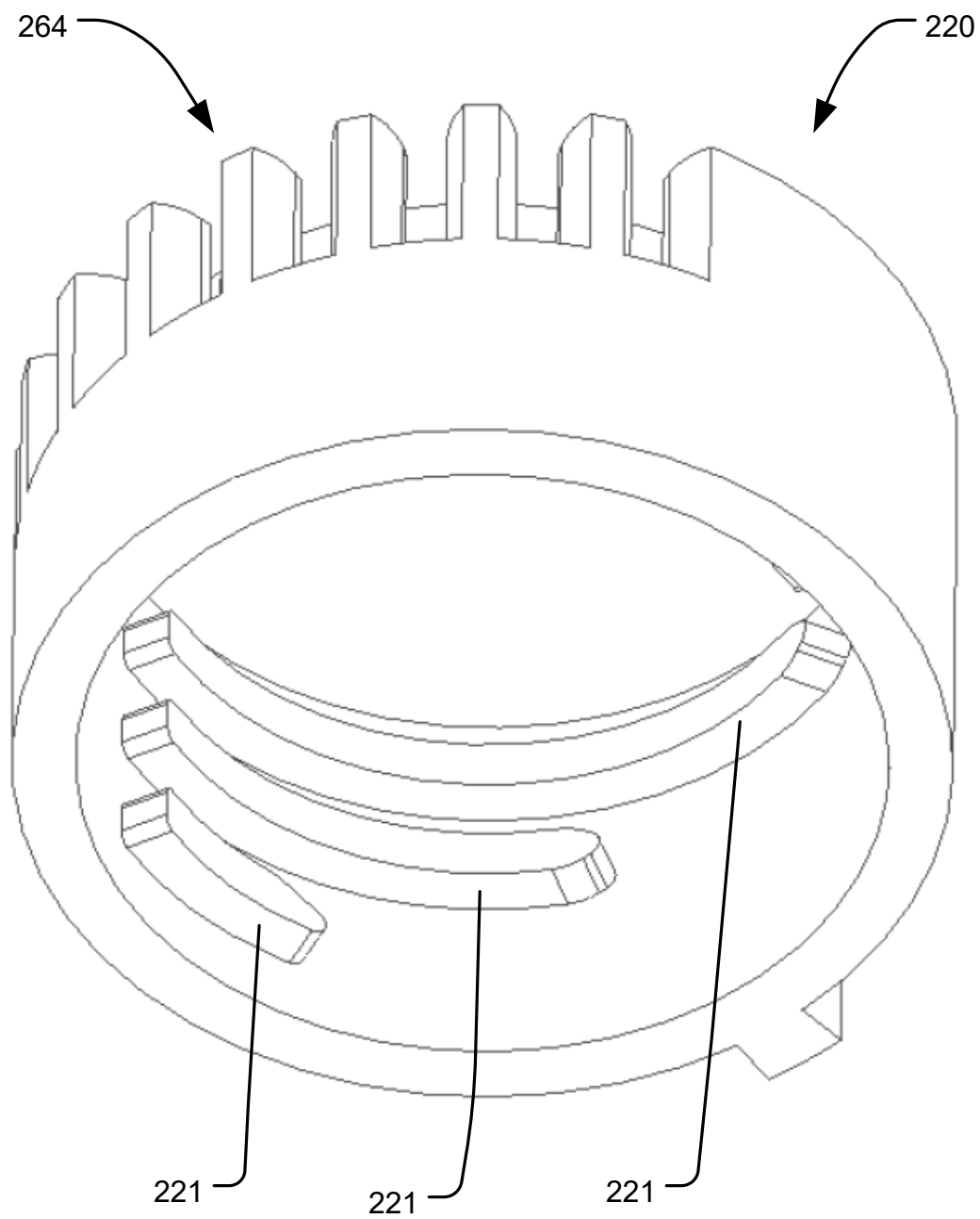


FIG. 16A

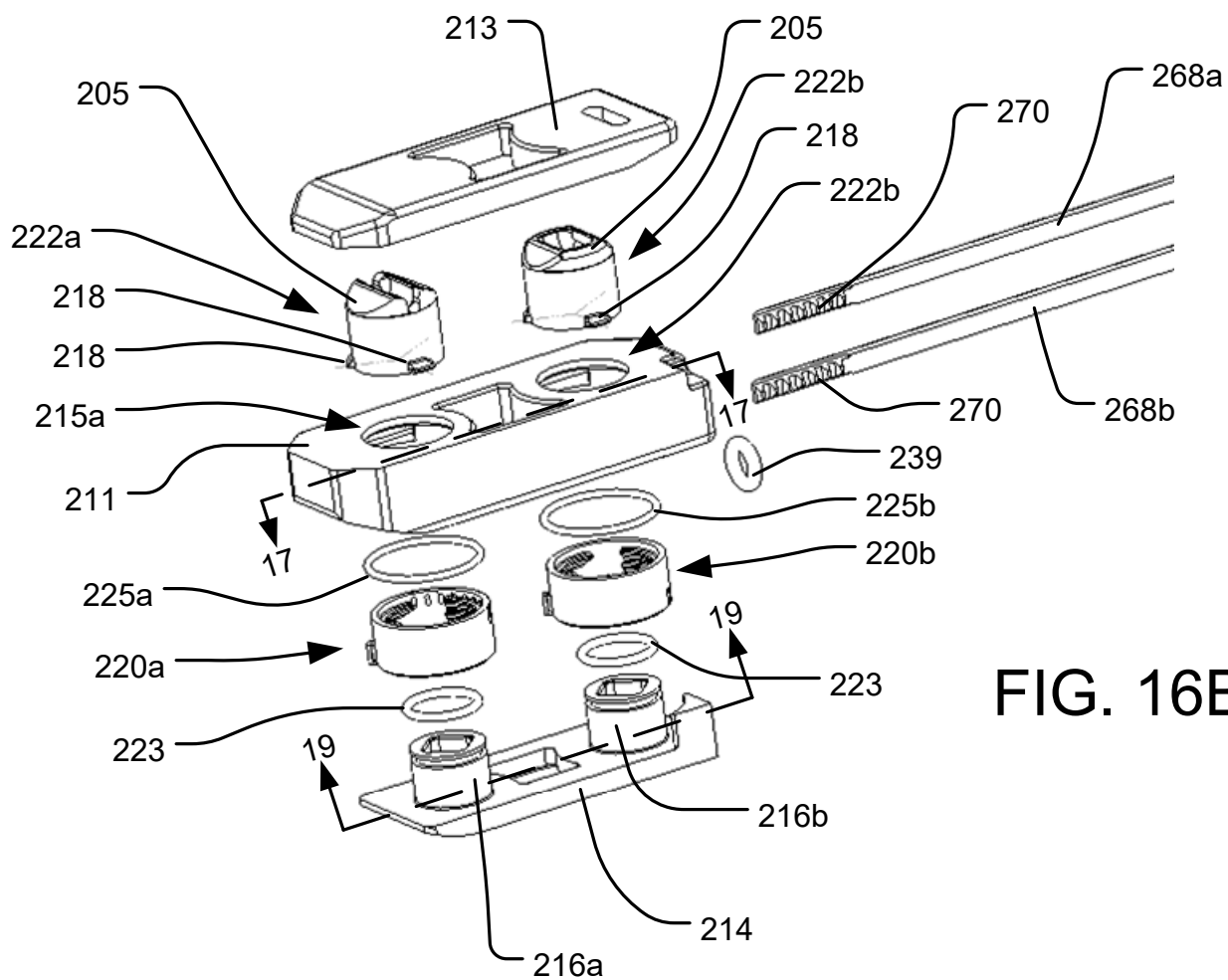
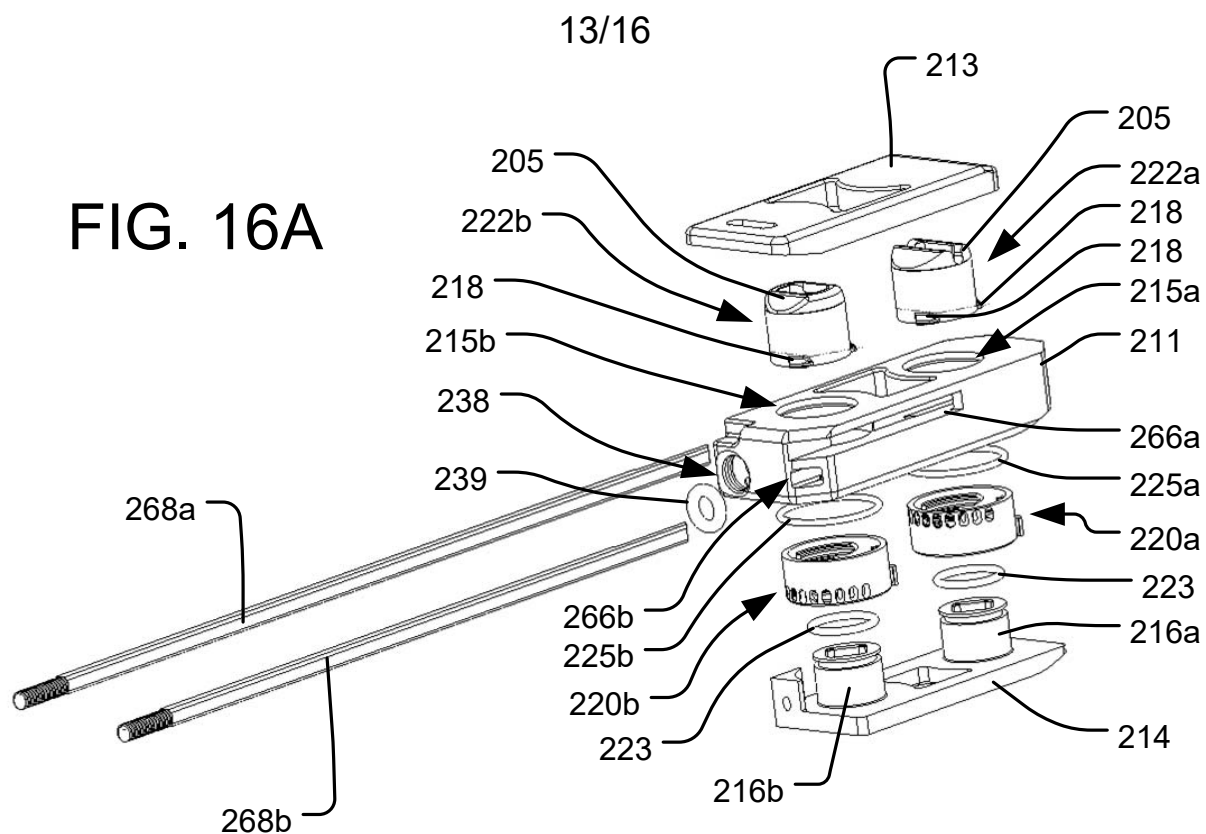


FIG. 16B

FIG. 17

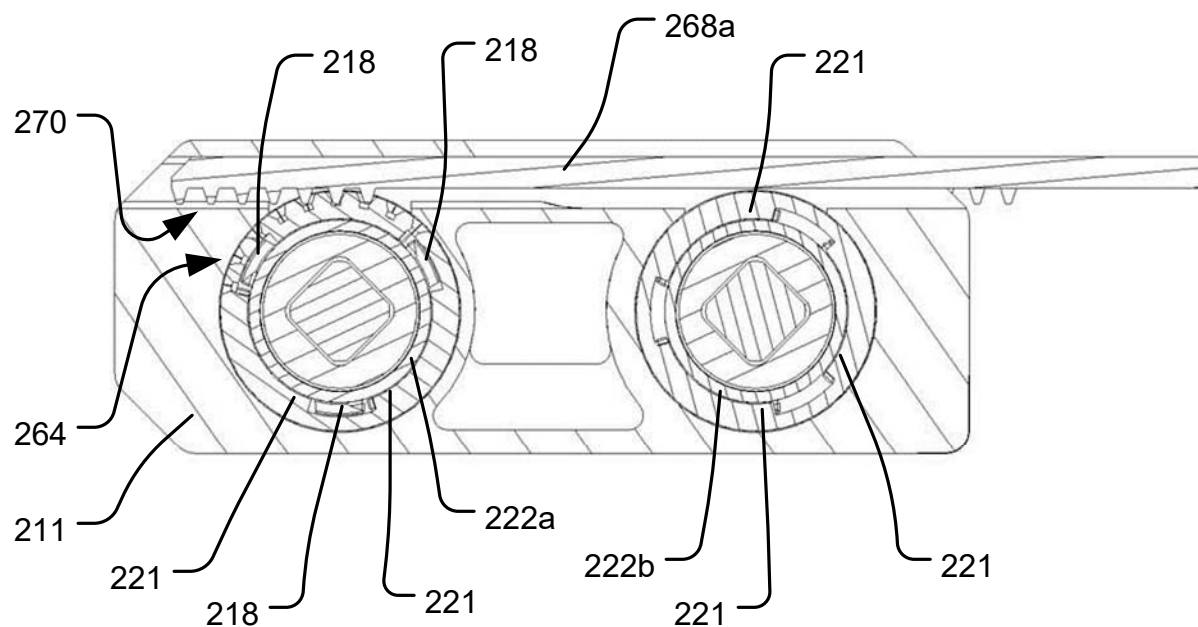


FIG. 18

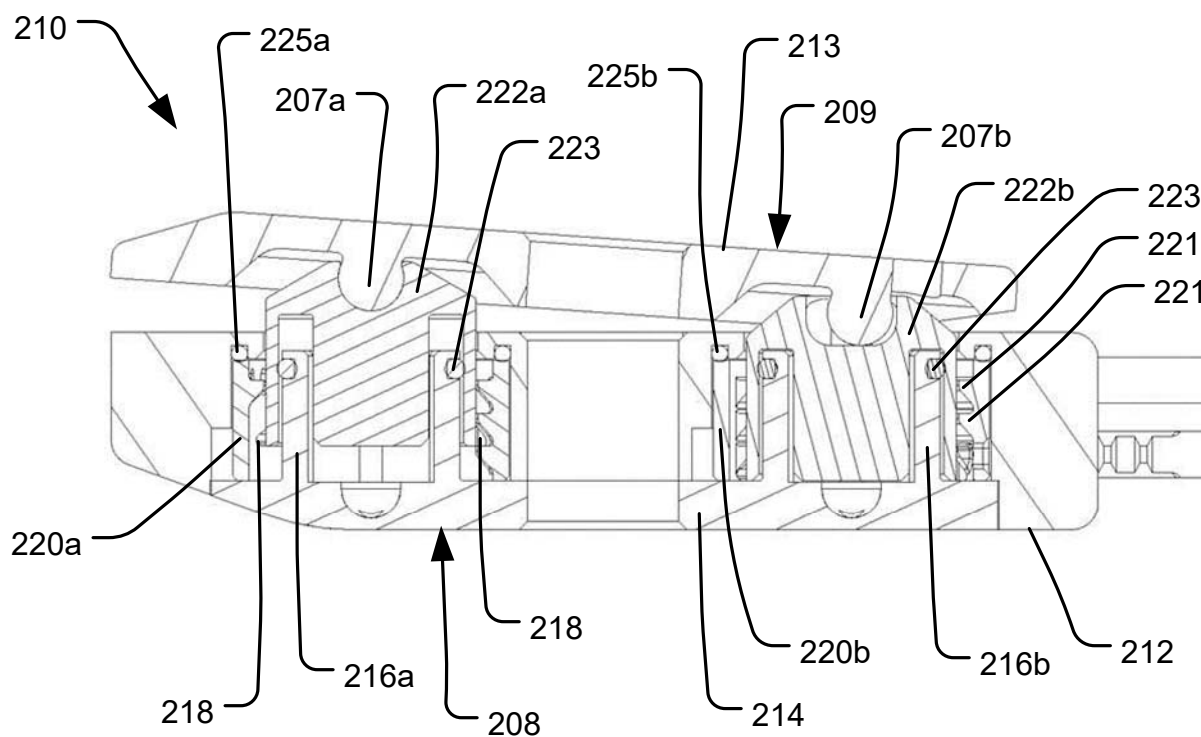


FIG. 19

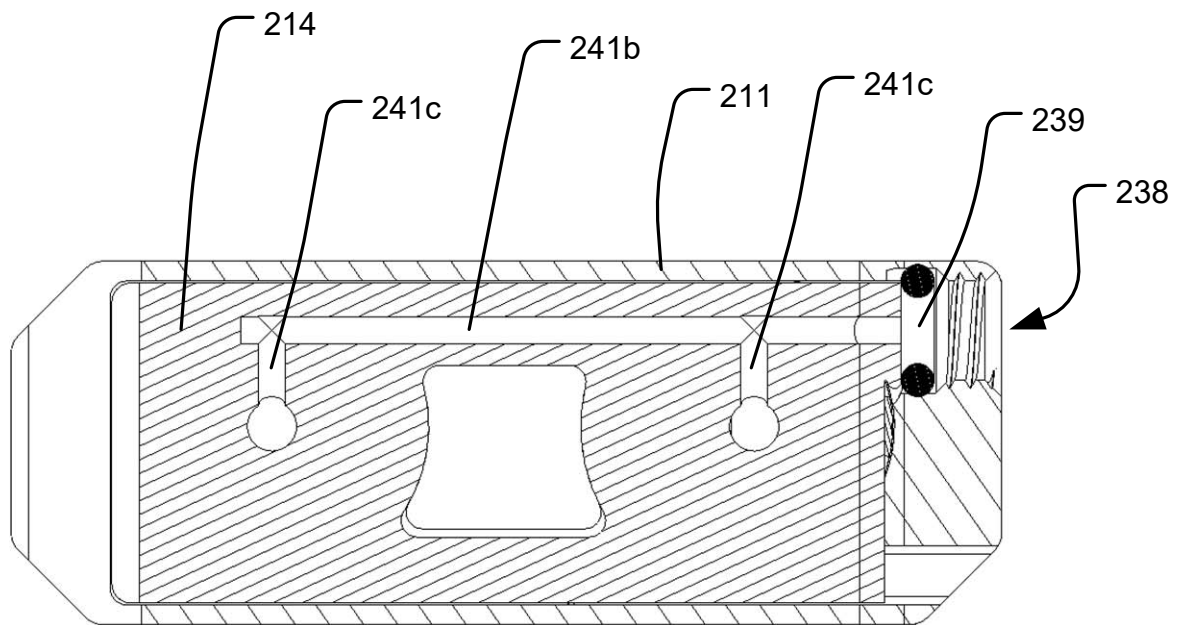


FIG. 20

