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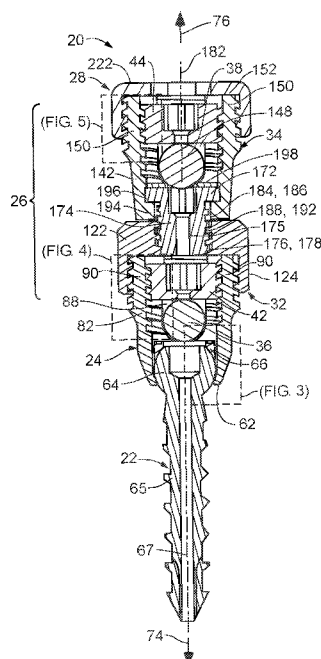
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EXTENSION READY SPINAL SUPPORT SYSTEMS

RELATED APPLICATIONS

This patent application claims the benefit of U.S. Provisional Patent Application No. 62/500,820 filed on May 3, 2017, and U.S. Provisional Patent Application No. 62/500,719, also filed May 3, 2017, the disclosures of which are hereby incorporated by reference in their entirety.

FIELD OF THE DISCLOSURE

The present disclosure relates to spinal support systems and more particularly to a spinal support systems and method that are extensible.

BACKGROUND OF THE DISCLOSURE

Implementation of various spinal surgical techniques often require the use of spinal support rods that are anchored to the vertebrae through the use of pedicle screws to provide stabilization of the spine during healing or correction. Examples include maintaining adjacent vertebrae stationary so that bone growth tissue can bridge the vertebrae in a spinal fusion process. Another example is the use of spinal support rods to apply a coercive force to the spine for corrective purposes (e.g., correction of scoliosis).

Such spinal support systems typically utilize pedicle screws and spinal rods disposed in rod receptacles. The rod receptacles typically define diametrically oppose slots, with the spinal rod extending through the slots. The formation of the slots further define opposed wall segments that extend proximally on lateral sides of the spinal rod. The spinal rod is typically held within the slots with a set screw that threadably engages the wall segments. Over time, creep stresses may cause the wall segments to deflect radially outward and away from the set screw, with an accompanying decrease the clamping force of the set screw against the spinal rod. This can cause loosening of the assembly and slippage of the resident spinal rod within the spinal rod receptacle. In some instances, torque requirements, particularly where the spinal rods are subject to high tension forces, can cause the set screw to slip within the spinal rod receptacle during implantation.

In some cases, surgery is later required to treat other vertebrae of the same patient. "Extension" systems have been developed which enable additional spinal support rods to be coupled to existing spinal rods or pedicle screws of the previous surgery, thereby reducing surgical trauma and recovery times. Such an extension system is found, for example, at U.S. Patent Application Publication No. 2016/0242817 to Abbasi entitled "Spinal Rod Support Structure with Clamp," owned by the owner of the current application, the contents of which

are incorporated by reference herein except for patent claims and express definitions contained therein.

The present application identifies shortcomings and limitations in the art of spinal rod extension systems and provides improvements to remedy such shortcomings and limitations.

SUMMARY OF THE DISCLOSURE

Various embodiments of the present disclosure provides an “extension ready” spinal support system that enables the extension to be accomplished with minimal disturbance to an existing spinal support structure to which the extension system is coupled. In some embodiments, existing connections between the existing spinal support rod and pedicle screws can remain intact while extension rod receptacles are mounted directly to the existing base rod receptacles. In some embodiments, the extension receptacle may be polyaxial with respect to the base receptacle. In other embodiments, the extension receptacle is provided with a low profile (i.e., shortened axial projection length from the base rod receptacle) relative to the polyaxial embodiment by eliminating polyaxial structure between the base receptacle and the extension receptacle and the additional axial lengths associated therewith and providing a monoaxial structure that rotates about but does not pitch relative to extension axis.

In various embodiments of the disclosure, a spinal support system is disclosed where a unitary reinforcement cap threadably engages both the internal and the external surfaces of the wall segments of the rod receptacle. By doubling the number of threads that are engaged, additional strength and structural integrity are realized over standard set screw arrangements. Also, because of the unitary construction, wherein an internal set screw portion and an external skirt portion are integral to the reinforcement cap, lateral movement between the set screw portion and the skirt portion is limited.

In some embodiments, the unitary reinforcement cap does not threadably engage the external surface, but instead slidingly engages the external surface to provide support to the rod receptacle. Accordingly, such embodiments do not require the presence of threads on the external surface of the rod receptacle, and can be configured for a retrofit of conventional rod receptacles.

In some embodiments, the threads are of a canted cantilever construction, wherein the interfaces of threadably engaged components are tailored to generate reaction force vectors that prevent slippage at the interfaces.

Conventional spinal rod extension systems exist where extension spinal support rod receptacles (also referred to as extension “tulips” in the parlance of the spinal support arts)

can be mounted “piggyback” to an existing or “base” spinal support rod receptacle. However, conventional systems require that the connection between the base spinal support rod receptacle must be disturbed or modified. For example, in some systems, the set screw securing the base spinal rod to the base receptacle must be removed so that the extension
5 receptacle can utilize the interior threads of the base receptacle. This releases the base spinal support rod from the base receptacle, thus requiring that the base spinal support rod be reset before the surgeon can proceed with implantation of the extension system. Often, the required structure that extends from the base receptacle is of undesirable axial length, causing concealment issues.

10 Another drawback of conventional rod receptacle arrangements is the separation or “splaying” of the tulip. When a conventional set screw is seated on the inside of a conventional tulip, forces are generated on the tulip wall portions that force the tulip wall sections away from each other. This separation of the tulip walls is referred to as “splaying.”

Various embodiments of the disclosure alleviate one or more of these shortcomings
15 and limitations. The disclosed embodiments enable extension of the spinal support structure without need for removing the tulips or pedicle screws of the already-implanted spinal support structure. Certain embodiments alleviate the need to remove the set screw from the interior threads of the base receptacle. As with conventional rod receptacles, the disclosed base rod receptacle includes interior threads to which a set screw is coupled for securing the
20 base spinal support rod. In addition, the disclosed system further includes exterior threads to which an optional extension assembly can be mounted at a later time. By utilizing the exterior threads for mounting the extension system, the set screw that secures the base spinal support rod to the base rod receptacle does not have to be removed from the interior threads of the base rod receptacle. In this way, the base spinal support system can remain intact and
25 undisturbed as the extension system is coupled thereto.

Other embodiments involve removal of the set screw from the base receptacle, but utilizes a reinforced, dual threaded or capped base that is stronger and more robust than standard set screw arrangements and prevents splaying of the tulip.

Structurally, a spinal support system is disclosed, comprising a first rod receptacle for
30 mounting to a pedicle screw, the first rod receptacle having a first side wall that includes a first interior surface and a first exterior surface. The first side wall defines a first pair of diametrically opposed slots that extend axially along the first side wall and are open at a proximal end of the first rod receptacle, the first interior surface defining first interior threads. A first set screw includes threads configured to mate with the first interior threads of the first

rod receptacle. The first exterior surface defines first exterior threads. An extension assembly including a base portion mounted to a second rod receptacle, the base portion including a mounting platform and a skirt portion that extends from the mounting platform, the skirt portion including interior threads for mating with the first exterior threads of the first rod
5 receptacle, the second rod receptacle having a second side wall that includes a second interior surface and a second exterior surface. The second exterior surface of the second rod receptacle may include second exterior threads. The second side wall defines a second pair of diametrically opposed slots that extend axially along the second side wall and are open at a proximal end of the second rod receptacle, the second interior surface defining second
10 interior threads. A second set screw includes threads configured to mate with the second interior threads of the second rod receptacle.

The extension assembly may include a pivot member that attaches the second rod receptacle to the base portion, the pivot member including a head portion and a shaft portion, the shaft portion including shaft threads formed on an exterior surface thereof, the shaft
15 portion defining a pivot axis. In some embodiments, the second rod receptacle defines an opening at a distal end thereof, the opening sized to accommodate passage of the shaft portion of the pivot member. The mounting platform of the base portion may define a center hole for receiving the pivot member, and may include interior threads for mating with the external shaft threads. In some embodiments, the center hole is a through hole.

20 In some embodiments, the second rod receptacle includes an internal flange having an interior face, the head portion of the pivot member being dimensioned to register against the interior face of the internal flange to secure the second rod receptacle to the base portion. The head portion of the pivot member may be one of a flat head and a countersink head, and the interior face of the internal flange of the second rod receptacle may conform to the head
25 portion to enable selective monoaxial rotation about the pivot axis.

In some embodiments, a pedicle screw coupled to a distal end portion of the first rod receptacle. The pedicle screw and the first rod receptacle may be configured for polyaxial rotation of the first rod receptacle about a head of the pedicle screw. In some embodiments, a lock ring configured to engage a spinal support rod, the lock ring including a distal face that
30 conforms to the pedicle screw and a proximal face that includes one or more malleable features for engaging the spinal support rod. The one or more malleable features may be plastically deformable. In some embodiments, the one or more malleable features includes a raised ridge. In some embodiments, the raised ridge is an annular ring.

Some embodiments include a cap including a skirt portion having interior threads for mating with the second exterior threads of the second rod receptacle. In some embodiments, the skirt is not threaded, but instead provides a sliding fit over the exterior of the base rod receptacle to prevent splaying. An exterior surface of the skirt portion may define a plurality of flats, each of said plurality of flats being parallel to the pivot axis. In some embodiments, one or more of the first interior threads, the first exterior threads, the second interior threads, the second exterior threads, and the internal threads of the center hole define a canted cantilever profile. The canted cantilever profile may extend radially and in a distal direction.

In various embodiments of the disclosure, a spinal rod support system comprises an extension rod receptacle, a base portion including a mounting platform that defines a center hole accessible from a proximal face of the mounting platform, and means for coupling the extension rod receptacle to the base portion. In some embodiments, the means for coupling the extension rod receptacle to the base portion includes a pivot member threadably engaged with the center hole. In some embodiments, the means for coupling the extension rod receptacle to the base portion includes a pivot member swaged to the center hole. In some embodiments, the means for coupling the extension rod receptacle to the base portion includes a pivot member fused to the center hole. The pivot member may be welded to the center hole at a distal face of the base portion, for example, a distal face of the mounting platform.

The spinal support system may further comprise a base rod receptacle, and means for coupling the base portion to the base rod receptacle. In some embodiments, the base portion includes a skirt portion, and the means for coupling the base portion to the base rod receptacle includes threaded engagement of the skirt portion to the base rod receptacle. In some embodiments, the base portion includes a set screw portion that is unitary with and extends from a distal face of the mounting platform, and the means for coupling the base portion to the base rod receptacle includes threaded engagement of the set screw portion to the base rod receptacle. In some embodiments, the set screw portion and the base portion include mating threads that define canted cantilever profiles for the threaded engagement. The canted cantilever profiles may extend radially and in a distal direction. In some embodiments, the spinal support system comprises a base spinal support rod disposed in the base rod receptacle, the set screw portion being configured to clamp the base spinal support rod within the base rod receptacle. In some embodiments, the base portion includes a set screw portion that is unitary with and extends from a distal face of the mounting platform, and the means for coupling the base portion to the base rod receptacle includes threaded

engagement of the set screw portion to the base rod receptacle. In some embodiments, the means for coupling the extension rod receptacle to the base portion enables only monoaxial rotation of the extension rod receptacle about a pivot axis.

5 In various embodiments of the disclosure, a method of fabricating an extension assembly for a spinal support system comprises: inserting a pivot member into a rod receptacle so that a shaft portion of the pivot member extends from a distal end of the rod receptacle; disposing the shaft portion in a center hole of a base portion so that an internal flange of the rod receptacle is captured between a head portion of the pivot member and the base portion so that an axial gap dimension defined between the head portion and the base member is greater than an axial thickness of the internal flange; and securing the pivot member to the base portion. In some embodiments, the step of disposing and the step of securing includes threadably engaging the shaft portion with the center hole. In some embodiments, the step of disposing includes registering a stop on the pivot member against the base portion to define the axial gap dimension. In some embodiments, the step of
10 securing includes one of fusing and swaging the shaft member to the base portion.
15

In various embodiments of the disclosure, a reinforcement cap is disclosed for a spinal support system, comprising: a platform portion including a distal face and a proximal face separated by a perimeter portion; a skirt portion that extends from the distal face of the platform portion, the skirt portion including an interior surface, at least a portion of the interior surface including interior threads formed thereon; and a set screw portion that
20 extends from the distal face of the platform portion, the set screw portion being surrounded by the skirt portion and including an exterior surface that faces radially outward, at least a portion of the exterior surface including exterior threads formed thereon, the set screw portion defining a rotation axis, the set screw portion and the skirt portion being concentric
25 about the rotation axis to define an annular gap between the exterior threads of the set screw portion and the interior threads of the skirt portion. The skirt portion may include an exterior surface that is tangential with the perimeter portion. In some embodiments, the set screw portion extends distally beyond the skirt portion. The skirt portion may include an exterior surface that defines a plurality of flats, each of the plurality of flats being parallel to the
30 rotation axis.

In some embodiments, the exterior threads of the set screw portion define a canted cantilever profile. Likewise, in some embodiments, the interior threads of the skirt portion define a canted cantilever profile. The canted cantilever profile of the set screw portion may

slope in a distal direction and toward the rotation axis. The canted cantilever profile of the set screw portion may slope in a distal direction and away from the rotation axis.

In some embodiments, the platform portion defines a socket accessible from the proximal face, the socket being concentric with and extending along the rotation axis. The platform portion may also define a tapped center hole accessible from the proximal face, the tapped center hole being concentric with and extending along the rotation axis, the socket extending distally from the tapped center hole. The reinforcement cap may further define a center passage concentric with the rotation axis and extending from the socket through a distal end of the set screw portion.

In various embodiments of the disclosure, a spinal support system comprises the reinforcement cap as described above; and a spinal rod receptacle having a side wall that includes an interior surface and an exterior surface, the side wall defining a pair of diametrically opposed slots that extend axially along the side wall and are open at a proximal end of the spinal rod receptacle, the interior surface of the spinal rod receptacle defining interior threads, the exterior surface of the spinal rod receptacle defining first exterior threads, wherein the interior threads of the spinal rod receptacle are configured to mate with the exterior threads of the set screw portion of the reinforcement cap, and the exterior threads of the spinal rod receptacle are configured to mate with the interior threads of the skirt portion of the reinforcement cap. In various embodiments, a spinal rod is configured for insertion into the diametrically opposed slots. A pedicle screw may be disposed within the spinal rod receptacle, a shaft of the pedicle screw extending distally from the spinal rod receptacle.

In various embodiments of the disclosure, a method for securing a spinal support rod to a spinal rod receptacle is disclosed, comprising: (a) disposing a spinal support rod through diametrically opposed slots of a spinal rod receptacle; (b) threadably engaging interior threads of a skirt portion of a reinforcement cap with exterior threads of the spinal rod receptacle; (c) simultaneously with step (b), threadably engaging exterior threads of a set screw portion of the reinforcement cap with interior threads of the spinal rod receptacle; and (d) tightening the reinforcement cap against the spinal support rod. In some embodiments, step (d) includes driving the reinforcement cap with a tool that mates with a socket formed on the reinforcement cap. In some embodiments, step (d) includes driving the reinforcement cap with a tool that engages flats formed on the skirt portion of the reinforcement cap.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG.1 is a perspective view of an extension ready base assembly according to an embodiment of the disclosure;

FIG. 1A is an upper perspective view of a base rod receptacle of FIG. 1 in isolation according to an embodiment of the disclosure;

FIG. 2 is a sectional view of an extensible spinal support system in full assembly with the extension ready base assembly of FIG. 1 according an embodiment of the disclosure;

5 FIG. 3 is an enlarged, partial sectional view of a lock ring in the assembly of FIG. 2 according to an embodiment of the disclosure;

FIG. 4 is an enlarged, partial sectional view of a threaded wall portion of a base rod receptacle of the assembly of FIG. 2 according to an embodiment of the disclosure;

10 FIG. 5 is an enlarged, partial sectional view of a threaded wall portion of an extension rod receptacle of the assembly of FIG. 2 according to an embodiment of the disclosure;

FIGS. 6 through 8 are sectional views of alternative extensible spinal support systems in full assembly with the extension ready base assembly of FIG. 1 according embodiments of the disclosure;

15 FIG. 9 is a perspective view of a platform of an extensible spinal support system with exterior wrench flats according to an embodiment of the disclosure;

FIGS. 10 and 11 are sectional views depicting assembly of an extension sub-assembly having a threaded pivot member according to an embodiment of the disclosure;

FIGS. 12 and 13 are sectional views depicting assembly of an extension sub-assembly having a welded pivot member according to an embodiment of the disclosure;

20 FIGS. 14 and 15 are sectional views depicting assembly of an extension sub-assembly having a riveted pivot member according to an embodiment of the disclosure;

FIGS. 16 and 17 are sectional views of extension sub-assemblies with base portions that have integral set screw portions according to an embodiment of the disclosure;

25 FIG. 18 is a perspective view of the pedicle screw of FIGS. 1 and 2 according to an embodiment of the disclosure;

FIG. 19 is a top axial view of the pedicle screw of FIG.18 according to an embodiment of the disclosure;

FIG. 20 is a sectional view of the pedicle screw at plane XX-XX of FIG. 18 according to an embodiment of the disclosure;

30 FIG. 21 is a top axial view of a set screw according to an embodiment of the disclosure;

FIG. 22 is a section view of the set screw XXII-XXII of FIG. 21 at plane according to an embodiment of the disclosure;

FIG. 23 is a perspective view of the set screw of FIG. 21 according to an embodiment of the disclosure;

FIG. 24 is a perspective view of a lock ring according to an embodiment of the disclosure;

5 FIG. 25 is an upper perspective view of a spinal support system according to an embodiment of the disclosure;

FIG. 26 is a partial sectional view of the spinal support system of FIG. 25 according to an embodiment of the disclosure;

10 FIG. 27 is a lower perspective view of a reinforcement cap according to an embodiment of the disclosure;

FIG. 28 is a sectional view of the reinforcement cap of FIG. 27 according to an embodiment of the disclosure;

FIG. 29 is a sectional view of a reinforcement cap having a tapped center hole according to an embodiment of the disclosure;

15 FIG. 30 is a lower perspective view of a reinforcement cap according to an embodiment of the disclosure;

FIG. 31 is a sectional view of the reinforcement cap of FIG. 30 according to an embodiment of the disclosure;

20 FIG. 32 is an upper perspective view of a reinforcement cap with flats according to an embodiment of the disclosure;

FIG. 33 is a sectional view of a conventional rod receptacle in assembly;

FIG. 33A is an enlarged, partial view of FIG. 33;

FIG. 34 is a sectional view of a rod receptacle in assembly having threads that define a canted cantilever profile according to an embodiment of the disclosure; and

25 FIG. 34A is an enlarged, partial view of FIG. 34 according to an embodiment of the disclosure.

DETAILED DESCRIPTION OF THE FIGURES

Referring to FIGS. 1 through 5, an extensible spinal support system 20 is depicted according to an embodiment of the disclosure. The extensible spinal support system 20 as depicted includes an extension ready base assembly 21 including a pedicle screw 22, a first or base rod receptacle 24, a first or base set screw 42, and a first spinal support rod 36 (FIG. 1). The extensible spinal support system 20 further includes an extension subassembly 26 and a cap 28 (FIG. 2). The extension subassembly 26 includes a base portion 32 and a second or extension rod receptacle 34. The base rod receptacle 24 is configured to receive the first or

base spinal support rod 36, and the extension rod receptacle 34 is configured to receive a second or extension spinal support rod 38. In the depicted embodiments, the base spinal support rod 36 is retained within the base rod receptacle 24 with the base set screw 42. Likewise, for the extensible spinal support system 20, the extension spinal support rod 38 is retained within the extension rod receptacle 34 with a second or extension set screw 44.

The pedicle screw 22 includes a head portion 64 and a threaded shaft portion 65 centered about a central axis 67. The pedicle screw 22 extends from a distal end 62 of the base rod receptacle 24, the head portion 64 being captured within the distal end 62 of the base rod receptacle 24. In some embodiments, a lock ring 66 is disposed interstitially between the base spinal support rod 36 and the head portion 64 of the pedicle screw 22. In the depicted embodiment, the head portion 64 of the pedicle screw 22 defines a spherical surface portion 68, with the base rod receptacle 24 including a complementary mating surface 72 that engages and conforms to the spherical surface portion 68 of the head portion 64 of the pedicle screw 22.

Functionally, the spherical surface portion 68 of the head portion 64 of the pedicle screw 22 and conforming mating surface 72 of the base rod receptacle 24 enable the base rod receptacle 24 to pitch about the head portion 64 of the pedicle screw 22 relative to the central axis 67, and to rotate about the head portion 64 in any of the pitched orientations. By this arrangement, the pedicle screw 22 and the base rod receptacle 24 are configured for polyaxial rotation of the base rod receptacle 24 about the head portion 64 of the pedicle screw 22.

Herein, "proximal" refers to a direction 76 that is toward a surgeon during operation or implantation and away from a bone or patient. "Distal" refers to a direction 74 that is away from the surgeon during operation or implantation and toward the bone or patient to which the extensible spinal support system 20 is implanted (i.e., a direction opposite the distal direction 76).

The base rod receptacle 24 includes a side wall 82 having an interior surface 84 and an exterior surface 86 (FIG. 1A). A pair of diametrically oppose slots 88 are defined on the side wall 82, the slots 88 extending axially along the side wall 82 and being open at a proximal end 92 of the base rod receptacle 24. By formation of the diametrically opposed slots 88, the side wall 82 defines diametrically opposed wall segments 90 on opposing sides of the diametrically opposed slots 88. The interior surface 84 extends axially along the side wall 82 and includes interior threads 94 formed thereon. The exterior surface 86 also extends axially and includes exterior threads 96 formed thereon. The base portion 32 of the extension subassembly 26 includes a mounting platform 122 and a skirt portion 124 that extends from

the mounting platform 122 in the distal direction 74. The skirt portion 124 includes an interior surface 123 and an exterior surface 125.

The extension rod receptacle 34 includes a side wall 142 having an interior surface 144 and an exterior surface 146. A pair of diametrically opposed slots 148 are defined on the side wall 142, the slots 148 extending axially along the side wall 142 and being open at a proximal end 152 of the extension rod receptacle 34. By formation of the diametrically opposed slots 148, the side wall 142 defines diametrically opposed wall segments 150 on opposing sides of the diametrically opposed slots 148. The interior surface 144 extends axially along the side wall 142 and includes interior threads 154 formed thereon (FIG. 5). The exterior surface 146 also extends axially and includes exterior threads 156 formed thereon.

In the depicted embodiment, the extension subassembly 26 includes a pivot member 170 that attaches the extension rod receptacle 34 to the base portion 32, the pivot member 170 including a head portion 172 and a shaft portion 174 and defining a through passage 175. The shaft portion defines a pivot axis 182. The extension rod receptacle 34 defines an opening 184 at a distal end 186 thereof. The opening 184 is sized to accommodate passage of the shaft portion 174 of the pivot member 170.

In the depicted embodiment, the mounting platform 122 of the base portion 32 defines a center hole 188 for receiving the pivot member 170. The extension rod receptacle 34 may include an internal flange 194 having an interior face 196, the head portion 172 of the pivot member 170 being dimensioned to extend radially over the interior face 196 of the internal flange 194 to loosely secure the extension rod receptacle 34 to the base portion 32. The head portion 172 of the pivot member 170 may be one of several head styles available to the artisan, for example a flat head (depicted), a socket head, a countersink head, or a spherical head. The interior face 196 of the internal flange 194 may be configured to conform to the head portion 172. In some embodiments, a collet 198 is disposed interstitially between the extension spinal support rod 38 and the head portion 172. The collet 198 may be a disc spring (depicted), lock washer, or other that exerts a bias force parallel to the pivot axis 182 when compressed between the support rod 38 and the head portion 172. The cap 28 includes a top portion 222 and a skirt portion 224 that extends from the mounting platform 222. The skirt portion 224 includes interior threads 226 for mating with the exterior threads 156 of the extension rod receptacle 34.

In operation, the pedicle screw 22 is inserted into the base rod receptacle 24 so that the head portion 64 of the pedicle screw 22 can be registered against the mating surface 72 of

the base rod receptacle 24. The pedicle screw 22 is set into the bone of a vertebrae. The lock ring 66, if utilized, is disposed within the base rod receptacle 24 and arranged for contact with the head portion 64 of the pedicle screw 22. The base rod receptacle 24 is arranged in a desired orientation on the head portion 64 of the pedicle screw 22 and the base spinal support rod 36 disposed in the base rod receptacle 24. The lock ring 66 is thereby disposed between the base spinal support rod 36 and the head portion 64 of the pedicle screw 22. The base set screw 42 is threadably engaged with the interior threads 94 of the side wall 82 and tightened so that the base spinal support rod 36 is clamped between the base set screw 42 and the lock ring 66 (if utilized) or, alternatively, the head portion 64 of the pedicle screw 22. The tightening of the base set screw 42 also seats the head portion 64 of the pedicle screw 22 against the mating surface 72 of the base rod receptacle 24 to secure the base rod receptacle 24 in the desired orientation relative to the head portion 64.

Referring to FIGS. 6 and 7 and again to FIG. 2, extensible spinal support systems 20 having alternative embodiments for the base portion 32 are presented according to embodiments of the disclosure. In FIGS. 2, 6, and 7, the extensible spinal support systems and their associated base portions are referred to collectively and generically by reference characters 20 and 32, respectively, and specifically by the reference characters 20 and 32 followed by a letter suffix (e.g., extensible spinal support system 20a and the associated base portion 32a). Several components and attributes are common to all extensible spinal support systems 20, which are indicated with same numbered reference characters.

For the extensible spinal support system 20a (FIG. 2), the base portion 32a and the base set screw 42 are separate components that are installed independently of each other. For the extensible spinal support systems 20a and 20b, the skirt portion 124 includes interior threads 126 for mating with the exterior threads 96 of the base rod receptacle 24. For the extensible support system 20b (FIG. 6), the base portion 32b additionally includes a set screw portion 228 that is integral therewith, the set screw portion 228 having external threads 232 that mate with the interior threads 94 of the side wall 82 of the base rod receptacle 24. Accordingly, for the extensible spinal support system 20b, the external threads 232 of the set screw portion 228 and the interior threads 226 of the skirt portion 124 of the base portion 32b are threaded simultaneously. For the extensible spinal support system 20c (FIG. 7), the base portion 32c also includes the set screw portion 228 that is integral therewith, and having external threads 232 that mate with the interior threads 94 of the side wall 82 of the base rod receptacle 24. However, for the extensible spinal support system 20c, an inner surface 234 the skirt portion 124 is smooth (does not include interior threads), such that the skirt portion

124 rotates about and slides over but does not threadably engage the exterior threads 96 of the base rod receptacle 24. Accordingly, the base portion 32c mates only with the interior threads 94 of the side wall 82.

By integrating the set screw portion 228 with the mounting platform 122 as in subassemblies 26b and 26c, and skirt portion 124 the structural integrity of the extensible spinal support system 20 is enhanced. For example, lateral forces applied to the extensible spinal support system 20 will incur greater resistance because the integrated set screw portion 228 is unitary with the mounting platform 122, establishing a shear stress at the junction of the integrated set screw portion 228 and the mounting platform 122 that provides additional resistance to deformation relative to the extension subassemblies 26 of FIGS. 10 through 15.

Functionally, each of the extensible support systems 20 provide a unique advantage. Extensible spinal support system 20a enables mounting of the extension assembly 26 without disturbing the base set screw 42, eliminating the need to reset the base spinal support rod 36. The extensible spinal support system 20a may find application where disturbance of the base spinal support system is not necessary or is ill advised. Extensible spinal support system 20b provides a dual threaded arrangement that enhances structural integrity of the extension assembly 26 to the base rod receptacle 24. Such enhancement of the structural integrity may be advantageous for high torque and high stress applications, such as scoliosis correction. Extensible spinal support system 20c also includes the integrated set screw portion 228 and attendant benefit while the smooth, sliding fit of the skirt portion 124 enables easier installation where the dual threaded arrangement of the extensible spinal support system 20b may be unnecessary or difficult. The sliding fit of the skirt portion 124 for the extensible spinal support system 20c effectively captures the side walls 82 of the base rod receptacle 24 to limit splaying. The extensible spinal support system 20c can also be configured for retrofitting with tulips of other spinal support systems that are not extension ready.

Referring to FIG. 8, an extensible spinal support system 20d is depicted according to an embodiment of the disclosure. As depicted the extensible spinal support system 20d includes many of the same components and attributes as the extensible spinal support system 20a, which are indicated with same numbered referenced characters. While components and attributes of the extensible spinal support system 20a are presented in the extensible spinal support system 20d, such components and attributes are not limiting. That is, the extensible spinal support system 20d may implement various aspects of the extensible spinal support systems 20b and 20c as well.

For the extensible spinal support system 20d, the head portion 172 of the pivot member 170d is spherical, and the extension rod receptacle 34 is configured as discussed above for the base rod receptacle 24. By this arrangement, the pivot member 170 and the extension rod receptacle 34 are configured for polyaxial rotation of the extension rod receptacle 34 about the head portion 172 of the pivot member 170.

Referring to FIG. 9, the skirt portion 124 of the base portion 34 is depicted with flats 240 according to an embodiment of the disclosure. The flats 240 are parallel to the pivot axis 182 and may be implemented with any of the depicted or contemplated embodiments. The embodiment of FIG. 9 depicts a total of six flats 240 as a non-limiting example. In some embodiments the number of flats 240 is in a range of six to twelve inclusive. In some embodiments, the skirt portion 124 defines two flats 240 that are diametrically opposed. In some embodiments, the skirt portion 124 defines four flats 240 that are distributed as two diametrically opposed pairs that are rotationally offset at 90 degrees with respect to each other.

Referring to FIGS. 10 through 17, assembly of various extension subassemblies 26 are depicted according to embodiments of the disclosure. In FIGS. 10 through 17, the extension subassemblies and their associated pivot members are referred to collectively and generically by reference characters 26 and 170, respectively, and specifically by the reference characters 26 and 170 followed by a letter suffix (e.g., extension subassembly 26a and the associated pivot member 170a). Several components and attributes are common to all extension subassemblies 26, which are indicated with same numbered reference characters.

For the extension subassembly 26a (FIGS. 10 and 11), the pivot member 170a defines exterior shaft threads 176 formed on an exterior surface 178 of the shaft portion 174. The center hole 188 of the mounting platform 122 includes internal threads 192 for mating with the exterior shaft threads 176. In some embodiments, the pivot member 170a includes a stop 242, such as a shoulder 244 having a diameter 246 that is greater than the diameter of the exterior shaft threads 176. The stop 242 cooperates with the head portion 172 to define an axial gap dimension 248 that is greater than an axial thickness 250 of the internal flange 194.

In assembly, the pivot member 170a is inserted through the extension rod receptacle 34 and into the opening 184 so that the shaft portion 174 extends from the distal end 186 of the extension rod receptacle 34 and the head portion 172 of the pivot member 170a is within the extension rod receptacle 34. The shaft portion 174 of the pivot member 170a and the center hole 188 of the mounting platform 122 of the base portion 32a are then aligned and the exterior shaft threads 176 of the shaft portion 174 threaded into the internal threads 192 of the

center hole 188. In some embodiments, the pivot member 170a is threaded into the center hole 188 until the stop 242 is firmly seated against the platform 122 over the mouth of the center hole 188 to define the axial gap dimension 248. Alternatively, the pivot member 170a may otherwise engage the base portion 32a in a manner that causes the pivot member 170a to stop within the center hole 188; for example, the threads 176 may cease at a point on the pivot shaft 174 that provides the desired axial gap dimension 248. Having secured the pivot member 170a to the mounting platform 122, the extension rod receptacle 34 is coupled to the base portion 32.

For the extension subassembly 26b (FIGS. 12 and 13), the shaft portion 174 of the pivot member 170b is a right cylinder 252, defining a smooth exterior surface 178. The center hole 188 of the mounting platform 122 is also right cylindrical, and may be dimensioned to provide a close sliding fit with the shaft portion 174. In some embodiments, the pivot member 170a includes a stop (not depicted) akin to pivot member 170a.

In assembly, the pivot member 170b is inserted through the extension rod receptacle 34 and into the opening 184 so that the shaft portion 174 extends from the distal end 186 of the extension rod receptacle 34 and the head portion 172 of the pivot member 170b is within the extension rod receptacle 34. The shaft portion 174 of the pivot member 170b and the center hole 188 of the mounting platform 122 of the base portion 32 are then aligned and the shaft portion 174 positioned within the center hole 188 so that the axial gap dimension 248 is defined between the head portion 172 and the mounting platform 122. In some embodiments, the pivot member 170a is threaded into the center hole 188 until the stop 242 is firmly seated against the platform 122 over the mouth of the center hole 188, thereby defining the axial gap dimension 248. In some embodiments, the length of the shaft portion 174 is dimensioned to provide the desired axial gap dimension 248 when a distal end 253 of the shaft portion 174 is flush with a distal face 256 of the platform 122.

With the pivot member 170b positioned in the center hole 188 to define the axial gap dimension 248 greater than the axial thickness 250 of the internal flange 194, the pivot member 170b is secured to the platform 122. In the depicted embodiment, the distal end 253 of the pivot member 170b is welded to the distal face 256 of the mounting platform 122 to form a weld 254 at the perimeter of the center hole 188. The weld 254 may be continuous, a stitch weld, or a tack weld. The welding operation may be performed with welding techniques available to the artisan, including but not limited to electron beam welding. Alternatively, instead of welding, the pivot member 170b may be secured by other bonding or fusion techniques, such as brazing, soldering, or gluing. Upon securing the pivot member

170b to the base portion 32, the internal flange 294 of the extension rod receptacle 34, being captured between the head portion 172 and the mounting platform 122, is coupled to the base portion 32.

For the extension subassembly 26c (FIGS. 12 and 13), the shaft portion 174 of the
5 pivot member 170c is also the right cylinder 252, defining the smooth exterior surface 178. The center hole 188 of the mounting platform 122 is also right cylindrical, and may be dimensioned to provide a close sliding fit with the shaft portion 174. Similar to the pivot member 170a, the pivot member 170c may include the stop 242 such as the shoulder 244 with diameter 246, the diameter 246 being greater than the diameter of the center hole 188.
10 As with the subassembly 26a, the stop 242 of the subassembly 26c cooperates with the head portion 172 to define an axial gap dimension 248 that is greater than an axial thickness 250 of the internal flange 194. The distal face 256 of the mounting platform 122 may define a recessed lead in 258 that surrounds the center hole 188.

In assembly, the pivot member 170c is inserted through the extension rod receptacle
15 34 and into the opening 184 so that the shaft portion 174 extends from the distal end 186 of the extension rod receptacle 34 and the head portion 172 of the pivot member 170c is within the extension rod receptacle 34. The shaft portion 174 of the pivot member 170c and the center hole 188 of the mounting platform 122 of the base portion 32 are then aligned and the shaft portion 174 positioned within the center hole 188 so that the axial gap dimension 248 is
20 defined between the head portion 172 and the mounting platform 122. In some embodiments, the pivot member 170c is inserted into the center hole 188 until the stop 242 registers against the platform 122 over the mouth of the center hole 188, thereby defining the axial gap dimension 248. In some embodiments, the length of the shaft portion 174 is dimensioned to provide the desired axial gap dimension 248 when the distal end 253 is flush with the distal
25 face 256 of the platform 122.

With the pivot member 170c positioned in the center hole 188 to define the axial gap dimension 248 greater than the axial thickness 250 of the internal flange 194, the pivot member 170c is secured to the platform 122 by a swaging process. The swaging process deforms the distal end 253 of the shaft portion 174 into the recessed lead in 258. In this way,
30 the mounting platform 122 is swaged between the stop 242 and the deformed distal end 253 of the pivot member 170c, akin to a rivet. The internal flange 294 is captured between the head portion 172 of the pivot member 170c and the mounting platform 122 of the base portion 32, thereby coupling the extension rod receptacle 34 to the base portion 32.

The depictions of FIGS. 10 through 15 present base portions 32 akin to base portion 32a, i.e., without an integral set screw portion. However, the assembly techniques for the subassemblies 26 described above are readily implemented for base portions 32 that include the set screw portion 228 integral therewith, akin to base portions 32b and 32c. The
5 embodiments of FIGS. 6 and 7 depict the threaded pivot member 170a in combination with the integral set screw portion 228. The embodiments of FIGS. 16 and 17 depict the pivot members 170b and 170c with longer shaft portions 174 having distal ends 253 that reach the distal faces 257 of the integral set screw portions 228. The weld 254 (FIG. 16) and the recessed lead in 258 (FIG. 17) are formed on the distal faces 257 of the integral set screw
10 portion 228. Accordingly, the subassemblies 26 may be fabricated with any of the base portions 32 described and depicted herein.

For the various subassemblies 26, because the axial gap dimension 248 is greater than the axial thickness 250 of the internal flange 194, monoaxial rotation of the extension rod receptacle 34 about the pivot axis 182 is achieved. That is, the internal flange 194, though
15 effectively captured between the head portion 172 of the pivot member 170 and the base portion 32 of the extension subassembly 26, can be rotated about the pivot axis 182. In the depicted embodiment, movement of the of the extension rod receptacle 34 relative to the base portion 32 is effectively limited to rotation about the pivot axis 182, i.e., a “monoaxial” rotation.

For the subassemblies 26a and 26b, because of the exterior threads 96 on the side wall 82 of the base rod receptacle 24, the extension rod receptacle 34 can be mounted to the base rod receptacle 24. That is, the extension subassemblies 26a and 26b can be mounted directly to the exterior threads 96 of the base rod receptacle 24. For the subassembly 26c, the extension rod receptacle 24 can be mounted to the interior threads of the base rod receptacle
20 24, without need for exterior threads on the sidewall 82. Accordingly, because of the subassemblies 26, the base rod receptacle 24 is referred to as “extension ready.”

For the pre-assembled extension subassembly 26a, the base portion 32 is aligned with the base rod receptacle 24 and the interior threads 126 of the skirt portion 124 of the base portion 32 threaded over the exterior threads 96 of the base rod receptacle 24. For the pre-
30 assembled extension subassembly 26b, the base portion 32 is aligned with the base rod receptacle 24 and both the interior threads 126 of the skirt portion 124 and the exterior threads external threads 232 of the set screw portion 228 are threadably engage with the exterior threads 96 of the base rod receptacle 24 and the internal threads 192 of the center hole 188, respectively. Because the pivot member 170 is in fixed relationship with the base

portion 32, the base portion 32 may be drawn tight against the proximal end 92 of the base rod receptacle 24 by with a driver inserted in the socket of the pivot member 170. For monoaxial embodiments, the extension rod receptacle 34 may be rotated to a desired angular orientation about the pivot axis 182. The extension spinal support rod 38 is inserted into the extension rod receptacle 34, extending laterally through the diametrically opposed slots 148. The extension set screw 44 or, alternatively, the set screw portion 228, is threadably engaged with the interior threads 154 of the side wall 142 and tightened. When the set screw 44 is tightened against the extension spinal support rod 38, the extension rod receptacle 34 is drawn in the proximal direction (upward in FIG. 2) so that the internal flange 194 is drawn tight against the head portion 172, thereby locking the extension rod receptacle 34 in place and in a fixed rotational orientation relative to the head portion 172..

In some embodiments, in the absence of the extension subassembly 26, the cap 28 can be mounted to the exterior threads 96 of the base rod receptacle 24. Functionally, this arrangement provides support against outward lateral deflections (splaying) of the wall segments 90 would otherwise be provided by the skirt portion 124 of the mounting platform 122 of the extension subassembly 26a. Various reinforcement caps 28 that can be implemented with either the base rod receptacle 24 or the extension rod receptacle 34 are described below attendant to FIGS. 25 - 32.

Similar to the extensible spinal support system 20a of FIG. 2, the extensible spinal support systems 20b and 20c of FIGS. 6 and 7 may be mounted to a previously implanted extension ready base assembly without need for removing or otherwise releasing the base spinal support rod 36. The base portions 32b and 32c of the extension subassemblies 26b and 26c may be mounted to the extension ready base assembly 21 of FIG. 1 instead of the set screw 42, the base portions 32b and 32c serving as a cap for securing the base spinal rod 36 to the base rod receptacle 24. The extension rod receptacle 34 can later be mounted directly to the center hole 188 of the mounting platform 122 of the base portion 32b with the pivot member 170a, thereby leaving the arrangement of the base rod receptacle 24 the base portions 32b, 32c and the base spinal support rod 36 intact. Accordingly, the base rod receptacle 24 in combination with the base portions 32b or 32c is also referred to as "extension ready." In such an embodiment, the extension subassemblies 26b and 26c are not pre-assembled, but instead assembled on the existing base portion 32b, 32c, being built up from the mounting platform 122 as described above.

Referring to FIGS. 18 through 20, the pedicle screw 22 is depicted in isolation in an embodiment of the disclosure. In addition to the components and attributes discussed above,

the pedicle screw 22 may define a socket 262 in the head portion 64, accessible from a proximal end 264 of the pedicle screw 22. The threaded shaft portion 65 may be double threaded as depicted. In some embodiments, a center passage 266 extends through the head portion 64 and threaded shaft portion 65. In the depicted embodiment, the socket 262 is hexagonal, but other geometries, such as a square, rectangle, cross, or star pattern may be utilized.

Functionally, the socket 262 accommodates driving of the pedicle screw 22 with an appropriate mating wrench (e.g., hexagonal wrench for the depicted embodiment, or a square bit, rectangular bit, cross (PHILLIPS) bit, or star (TORX®) bit as appropriate). The center passage 266 may be sized, for example, to accommodate sliding passage of a Kirschner wire or a larger diameter rod.

Referring to FIGS. 21 through 23, the base or extension set screw 42, 44 is depicted in isolation in an embodiment of the disclosure. In the depicted embodiments, the base and extension set screws 42 and 44 are identical and are referred to collectively and generically as the "set screw 42, 44". The set screw 42, 44 includes exterior threads 268 that mate with the interior threads 94, 154 of the base or extension rod receptacle 24, 34. The set screw 42, 44 may define a socket 272, accessible from a proximal end 274 of the set screw 42, 44. In some embodiments, a center passage 276 extends from the socket 272 through a distal end 278 of the set screw 42, 44. In the depicted embodiment, the socket 272 is hexagonal, but other geometries, such as a square, rectangle, cross, or star pattern may be utilized.

Functionally, the socket 272 accommodates driving of the set screw 42, 44 with an appropriate mating wrench (e.g., hexagonal wrench for the depicted embodiment, or a square bit, rectangular bit, cross (PHILLIPS) bit, or star (TORX®) bit as appropriate). The center passage 276 may be sized, for example, to accommodate sliding passage of a Kirschner wire or larger diameter rod.

Referring to FIG. 24, the lock ring 66 is depicted in an embodiment of the disclosure. In some embodiments, the lock ring 66 includes a distal face 282 and a proximal face 284 separated by a perimeter portion 286. The distal face 282 may be convex and define a spherical profile 288. The proximal face 284 may include one or more malleable features 292 for engaging the base spinal support rod 36. The distal face 282 terminates at a distal edge 294 of the perimeter portion 286. In the depicted embodiment, a plurality of relief slots 296 are defined that are open at the distal edge 294 and extend axially into the perimeter portion 286. In some embodiments, the one or more malleable features 292 are plastically deformable. The one or more malleable features 292 may define a raised ridge 298, for

example an annular ring as depicted in FIG. 24. In some embodiments, the lock ring 66 includes a radial detent 299 that extends radially outward from the perimeter portion 286.

Functionally, the convexity of the distal face 282 that accommodates and can slide over the spherical profile of the head portion 64 of the pedicle screw 22, thereby enabling the polyaxial movement of the base rod receptacle 24 relative to the head portion 64. The one or more malleable features 292 conform to the shape of the base spinal support rod 36 when the set screw 42 is tightened to secure the base spinal support rod 36 in place. The conformance of the malleable feature(s) 292 acts to grip the base spinal support rod 36, thereby inhibiting the base support rod 36 from rotating or sliding within the diametrically opposed slots 88 of the base rod receptacle 24. Upon tightening of the base set screw 42, the relief slots 296 enable the perimeter portion 286 to conform to the head portion 64 at the distal edge 294 for more effective gripping of the head portion 64 of the pedicle screw 22. The conformance of the malleable feature(s) 292 and perimeter portion 286 act to secure and inhibit movement between the head portion 64, the base spinal support rod 36, and the base rod receptacle 24. The radial detent 299 may interface with internal features 297 (FIG. 3) within the base rod receptacle 24, such as an internal inset flange (depicted) or optionally a groove (not depicted). The internal features 297 restrains the proximal face 284 from deflecting proximally (upward in FIGS. 2 and 3) when the lock ring 66 is deformed under the clamping force between the base spinal support rod 36 and the head portion 64, thereby maintaining gripping contact between the head portion 64 and the proximal face 284 of the lock ring 66.

Referring to FIGS. 25 and 26, the extension ready base assembly 21 is depicted with the reinforcement cap 28 coupled to the base rod receptacle 24. Referring to FIGS. 27 and 28, a reinforcement cap 28a is depicted according to an embodiment of the disclosure. Herein, various reinforcement caps are presented and referred to collectively and generically by reference character 28, and specifically by the reference character 28 followed by a letter suffix (e.g., reinforcement cap 28a). The reinforcement cap 28a includes a platform portion 322 including a distal face 324 and a proximal face 326 separated by a perimeter portion 328 (FIGS. 26, 27, and 28). A skirt portion 332 extends from the distal face 324 of the platform portion 322 portion, the skirt portion 332 including an interior surface 334, at least a portion of which includes interior threads 336 formed thereon. A set screw portion 342 extends from the distal face 324 of the platform portion 322, the set screw portion 342 being surrounded by the skirt portion 332 and including an exterior surface 338 that faces radially outward. At least a portion of the exterior surface 338 includes exterior threads 344 formed thereon. The set screw portion 342 defines a rotation axis 346 about which the set screw portion 342 and

the skirt portion 332 are concentric. An annular gap 348 is defined between the exterior threads 344 of the set screw portion 342 and the interior threads 336 of the skirt portion 332.

The reinforcement cap 28a may define a socket 272 accessible from the proximal face 326 of the cap 28a. In the depicted embodiment, the socket 272 is hexagonal, but other geometries, such as a square, rectangle, octagon, cross, or star pattern may be utilized. In some embodiments, a center passage 276 extends from the socket 272 through a distal end 278 of the set screw portion 342.

Referring to FIG. 29, a reinforcement cap 28b modified to define a tapped center hole 360 is depicted according to an embodiment of the disclosure. The reinforcement cap 28b includes many of the same components and attributes as the reinforcement cap 28a, which are indicated with same-numbered numerical characters. The tapped center hole 360 is characterized as having an inner wall 362 on which threads 364 are formed, and a bottom surface 366. The socket 272 extends distally from the bottom surface 366.

Referring to FIGS. 30 and 31, a reinforcement cap 28c is depicted according to an embodiment of the disclosure. The reinforcement cap 28c includes many of the same components and attributes as the reinforcement cap 28a and 28b, which are indicated with same-numbered reference characters. A distinction of the reinforcement cap 28c is that the skirt portion 332 does not include interior threads, such that the skirt portion 332 slidably engages and rotates about the exterior threads 96 of the base rod receptacle 24 but does not threadably engage the exterior threads 96. Accordingly, the reinforcement cap 28c threadably engages only with the interior threads 94 of the side wall 82. In some embodiments, the skirt portion 332 may define an inner diameter 372 that slides over the exterior threads 96 with a close, sliding fit.

Referring to FIG. 32, the skirt portion 332 of the reinforcement cap 28 is depicted with flats 374 according to an embodiment of the disclosure. The flats 374 extend parallel to the rotation axis 346 and may be implemented with any of the depicted or contemplated reinforcement caps 28. The embodiment of FIG. 32 depicts a total of six flats 374 as a non-limiting example. In some embodiments the number of flats 374 is in a range of six to twelve inclusive. In some embodiments, the skirt portion 332 defines two flats 374 that are diametrically opposed. In some embodiments, the skirt portion 332 defines four flats 374 that are distributed as two diametrically opposed pairs that are rotationally offset at 90 degrees with respect to each other.

Functionally, the interior threads 94 of the base rod receptacle 24 are configured to mate with the exterior threads 344 of the set screw portion 342 of the reinforcement cap 28.

For the reinforcement caps 28a and 28b, the exterior threads 96 of the base rod receptacle 24 are configured to mate with the interior threads 336 of the skirt portion 332 of the reinforcement cap 28, 28b. The socket 272 accommodates driving of the reinforcement cap 28, 28b with an appropriate mating wrench (e.g., hexagonal wrench for the depicted
5 embodiment, or a square bit, rectangular bit, cross (PHILLIPS) bit, or star (TORX®) bit as appropriate). The flats 374, when implemented, provide an alternative way to apply torsion to the reinforcement cap 28, for example by use of socket tool that slides over and engages the flats 374. The flats 374 can also be used in so-called rescue situations, providing alternative gripping surfaces for removal of components of the spinal support system 20. The
10 center passage 276 may be sized, for example, to accommodate sliding passage of a Kirschner wire or a guide rod.

The unitary structure of the set screw portion 342 with the platform portion 322 and skirt portion 344 provides additional structural strength and integrity relative to a separate cap and set screw arrangement. For example, the spinal support system 20 provides greater
15 resistance to lateral forces because the set screw portions 342 is integrated with the platform portion 322, establishing a shear stress at a junction 368 of the screw portion 342 and the platform portion 322 that provides additional resistance to deformation relative to an assembly where the cap and set screw are separate components. The added strength and structural integrity provided by the integrated arrangement of the reinforcement cap 28 may
20 be advantageous for high torque and high stress applications, such as scoliosis correction.

Referring to FIGS. 33, 33A, 34, and 34A, threads defining a canted cantilever profile 450 and the advantage provided over conventional threaded arrangements are depicted and described according to embodiments of the disclosure. A conventional threaded
arrangements 400, schematically depicted at FIGS. 33 and 33A, may include, for example,
25 exterior threads 402 of a set screw 404 that are engaged with interior threads 406 of a wall segment 408 of a spinal rod receptacle 410 (akin to opposed wall segments 90 and 150 of the rod receptacles 24 and 34 of the extensible spinal support system 20). Both the set screw 404 and the wall segment 408 are concentric about a central axis 412 that defines the z-axis of a right-cylindrical coordinate system 424 having an axial coordinate z and a radial coordinate r.
30 When the set screw 404 is tightened a first direction 416 to set against a spinal support rod 415, a clamping force vector FC is generated, for which there is an equal and opposite force vector FC' in a second direction 418 that is opposite the first direction 416. The force vector FC' in turn generates reaction force vectors FR generated at contact interfaces 422 between the exterior threads 402 of the set screw 404 and the interior threads 406 of the wall segment

408. The reaction forces FR generate an axial component FRZ and radial component FRR. Because of the standard shape of the threads 402 and 406, the radial components FRR generate a radial outward force FRO, i.e., away from the central axis 412.

For configurations such as the depicted extensible spinal support system 20, the wall segment 408 (e.g., wall segment 90 of the extensible spinal support system 20) is, in some embodiments, not supported by any structure. In such embodiments, the wall segment 408 will tend to cause deflections δo that deflect radially outward in response to the radial outward force FRO. As the wall segment 408 deflects radially outward, the overlap between the threads 406 and 408 at the interfaces 422 is reduced, thereby weakening the coupling between the set screw 404 and the wall segment 408. The tighter the draw on the set screw 404, the greater the radial outward force FRO and the greater the deflection of the wall segment 408, further decreasing the overlap at the interfaces 422. Accordingly, as the torque requirements of the conventional set screw 404 are increased, the coupling between the set screw 404 and the wall segment 408 becomes more tenuous. Over time, creep stresses may cause the deflection of the wall segment 408 and the attendant decrease in the overlap at the interfaces 422, causing the clamping force FC to reduce. This can cause loosening of the assembly and slippage of the resident spinal rod within the spinal rod receptacle 410. In some instances, torque requirements can cause the set screw 404 to slip within the spinal rod receptacle 410 during implantation.

A threaded arrangement utilizing threads having the canted cantilever profile arrangement 450 is depicted at FIGS. 34 and 34A. The various threads 94, 96, 126, 154, 156, and 268 (FIGS. 2, 4, and 5) of the extensible spinal support system 20 may utilize a canted cantilever profile arrangement.

The canted cantilever profile arrangement 450, schematically depicted at FIGS. 34 and 34A, may include, for example, exterior threads 452 of a set screw 454 that are engaged with interior threads 456 of a wall segment 458 of a spinal rod receptacle 460 (akin to opposed wall segments 90 and 150 of the rod receptacles 24 and 34 of the extensible spinal support system 20). Both the set screw 454 and the wall segment 458 are concentric about a central axis 462 that defines the z-axis of a right-cylindrical coordinate system 464 having an axial coordinate z and a radial coordinate r. When the set screw 454 is tightened a first direction 466 to set against a spinal support rod 465, the clamping force vector FC is generated, for which there is the equal and opposite force vector FC' in a second direction 468 that is opposite the first direction 466. The force vector FC' in turn generates reaction

force vectors FR generated at contact interfaces 472 between the exterior threads 452 of the set screw 454 and the interior threads 456 of the wall segment 458. The reaction forces FR generate an axial component FRZ and radial component FRR.

However, unlike the conventional threaded arrangements 400, the contact interfaces 472 of the canted cantilever profiles 450 are sloped radially inward (i.e., toward the central axis 462) in the first direction 466. By this arrangement, the radial component FRR is vectored inward, toward the center axis 466. The forces so generated will tend to cause deflections δ_i of the wall segment 458 that is radially inward in response to the radial inward force FRI. Because of the radial inward deflections δ_i , the wall segments 458 tend to be supported by the set screw 454. Accordingly, the coupling between the set screw 454 and the spinal rod receptacle 460 provided by the canted cantilever profile arrangement 450 is stronger and can provide a greater clamping force FC than can the conventional threaded arrangement 400 of spinal rod receptacle 410.

For the extensible spinal support system 20, the interior threads 94, 154 of the base and extension rod receptacle 24, 34 interact with the set screws 42, 44 in the manner described attendant to the canted cantilever profile arrangement 450 of FIGS. 34 and 34A. The exterior threads 96, 156 of the base and extension rod receptacle 24, 34 may also implement a canted cantilever arrangement (see, e.g., FIGS. 2, 4, and 5), but may be configured to generate different forces and deflections. For example, the exterior threads 96, 156 of the base and extension rod receptacle 24, 34 are sloped radially outward (i.e., away the central axis 462) in the distal direction 74. By this arrangement, the radial components of the reaction forces at the interface of the exterior threads 96, 156 and the interior threads 126, 226 of the skirt portions 124, 224 is vectored outward, away from the center axis 67. The forces so generated will tend to cause splaying of the rod receptacle 24, 34, i.e., to cause the wall segments 90, 150 to deflect radially outward. Because of the radial outward deflections, the wall segments 90, 150 tend to be supported by the skirt portions 124, 224. The skirt portions 124, 224, being tangentially continuous, incurs a hoop stress that further counters the outward radial forces and limits splaying. The outward radial forces at the exterior threads 96, 156 also tend to counter and can be tailored to balance the inward radial forces FRI to further reduce overall radial deflection (splaying) and deformation of the wall segments 90, 150.

Alternatively, the exterior threads 96, 156 of the receptacles 24, 34 and the interior threads 126, 226 of the skirt portions 124, 224 may be of a conventional arrangement.

Conventional threads, as described attendant to FIGS. 33 and 33A, provide radial outward forces that are subsequently supported by the skirt portions 124, 224 and as a counter to the radial inward force FRI, to prevent splaying.

Each of the additional figures and methods disclosed herein can be used separately, or in conjunction with other features and methods, to provide improved devices and methods for making and using the same. Therefore, combinations of features and methods disclosed herein may not be necessary to practice the disclosure in its broadest sense and are instead disclosed merely to particularly describe representative and preferred embodiments.

Various modifications to the embodiments may be apparent to one of skill in the art upon reading this disclosure. For example, persons of ordinary skill in the relevant arts will recognize that the various features described for the different embodiments can be suitably combined, un-combined, and re-combined with other features, alone, or in different combinations. Likewise, the various features described above should all be regarded as example embodiments, rather than limitations to the scope or spirit of the disclosure.

Persons of ordinary skill in the relevant arts will recognize that various embodiments can comprise fewer features than illustrated in any individual embodiment described above. The embodiments described herein are not meant to be an exhaustive presentation of the ways in which the various features may be combined. Accordingly, the embodiments are not mutually exclusive combinations of features; rather, the claims can comprise a combination of different individual features selected from different individual embodiments, as understood by persons of ordinary skill in the art.

Any incorporation by reference of documents above is limited such that no subject matter is incorporated that is contrary to the explicit disclosure herein. Any incorporation by reference of documents above is further limited such that no claims included in the documents are incorporated by reference herein. Any incorporation by reference of documents above is yet further limited such that any definitions provided in the documents are not incorporated by reference herein unless expressly included herein.

Unless indicated otherwise, references to “embodiment(s)”, “disclosure”, “present disclosure”, “embodiment(s) of the disclosure”, “disclosed embodiment(s)”, and the like contained herein refer to the specification (text, including the claims, and figures) of this patent application that are not admitted prior art.

For purposes of interpreting the claims, it is expressly intended that the provisions of 35 U.S.C. 112(f) are not to be invoked unless the specific terms “means for” or “step for” are recited in the respective claim.

CLAIMS

What is claimed is:

1. A spinal support system, comprising:

a first rod receptacle for mounting to a pedicle screw, said first rod receptacle having a first side wall that includes a first interior surface and a first exterior surface, said first side wall defining a first pair of diametrically opposed slots that extend axially along said first side wall and are open at a proximal end of said first rod receptacle, said first interior surface defining first interior threads, said first exterior surface defining first exterior threads; and

an extension assembly including a second rod receptacle mounted to a base portion, said base portion including a mounting platform and a skirt portion that extends from said mounting platform, said skirt portion including interior threads for mating with said first exterior threads of said first rod receptacle, said second rod receptacle having a second side wall that includes a second interior surface and a second exterior surface, said second side wall defining a second pair of diametrically opposed slots that extend axially along said second side wall and are open at a proximal end of said second rod receptacle, said second interior surface defining second interior threads.

2. The spinal support system of claim 1, wherein:

said extension assembly includes a pivot member that attaches said second rod receptacle to said base portion, said pivot member including a head portion and a shaft portion, said shaft portion being in fixed relationship with said mounting platform and defining a pivot axis;

said second rod receptacle defines an opening at a distal end thereof, said opening sized to accommodate passage of said shaft portion of said pivot member; and

said mounting platform of said base portion defines a center hole for receiving said pivot member.

3. The spinal support system of claim 2, wherein said skirt portion includes an exterior surface that defines a plurality of flats, each of said plurality of flats being parallel to said pivot axis.

4. The spinal support system of claim 2, wherein said second rod receptacle includes an internal flange having an interior face, said head portion of said pivot member being dimensioned to extend over said interior face of said internal flange to couple said second rod receptacle and said base portion.
5. The spinal support system of claim 4, wherein said shaft portion includes external shaft threads formed on an exterior surface thereof, and said center hole includes interior threads for mating with said external shaft threads.
6. The spinal support system of claim 4, wherein said shaft portion is right cylindrical and includes a smooth exterior surface, and said center hole is right cylindrical and dimensioned for a sliding fit with said shaft portion.
7. The spinal support system of claim 6, wherein:
 - said head portion of said pivot member is one of a flat head and a countersink head;
 - said interior face of said internal flange of said second rod receptacle conforms to said head portion to enable selective monoaxial rotation about said pivot axis; and
 - said pivot member includes a stop that cooperates with said base portion to define an axial gap dimension between said head portion and said mounting platform, said axial gap being greater than an axial thickness of said internal flange to enable monoaxial rotation of said extension rod receptacle about said pivot axis.
8. The spinal support system of claim 6, wherein said shaft portion is welded to said base portion.
9. The spinal support system of claim 6, wherein said shaft portion is swaged to said base portion.
10. The spinal support system of claim 6, wherein said center hole is a through hole.
11. The spinal support system of claim 1, wherein a set screw portion is integral with and extends from a distal face of said mounting platform, said set screw portion including threads configured to mate with said first interior threads of said first rod receptacle.

12. The spinal support system of claim 11, wherein said threads of said set screw portion and said first interior threads of said first rod receptacle define canted cantilever profiles configured to threadably engage each other.
13. The spinal support system of claim 12, wherein said canted cantilever profiles extend radially and in a distal direction.
14. The spinal support system of claim 1, comprising a pedicle screw coupled to a distal end portion of said first rod receptacle.
15. The spinal support system of claim 14, comprising a lock ring configured to engage a spinal support rod, said lock ring including a distal face that conforms to said pedicle screw and a proximal face that includes one or more malleable features for engaging said spinal support rod.
16. The spinal support system of claim 15, wherein said one or more malleable features are plastically deformable.
17. The spinal support system of claim 15, wherein said one or more malleable features includes a raised ridge.
18. The spinal support system of claim 15, wherein said raised ridge is an annular ring.
19. The spinal support system of claim 1, wherein said second exterior surface of said second rod receptacle includes second exterior threads.
20. The spinal support system of claim 19, comprising a cap including a skirt portion having interior threads for mating with said second exterior threads of said second rod receptacle.
21. The spinal support system of claim 1, wherein said first exterior threads and said interior threads of said skirt portion define canted cantilever profiles configured to threadably engage each other.

22. The spinal support system of claim 21, wherein said canted cantilever profiles extend radially and in a distal direction.
23. The spinal support system of claim 1, comprising a first set screw having threads configured to mate with said first interior threads of said first rod receptacle.
24. A spinal rod support system, comprising:
an extension rod receptacle;
a base portion including a mounting platform that defines a center hole accessible from a proximal face of said mounting platform; and
means for coupling said extension rod receptacle to said base portion.
25. The spinal support system of claim 24, wherein said means for coupling said extension rod receptacle to said base portion includes a pivot member threadably engaged with said center hole.
26. The spinal support system of claim 24, wherein said means for coupling said extension rod receptacle to said base portion includes a pivot member swaged to said center hole.
27. The spinal support system of claim 24, wherein said means for coupling said extension rod receptacle to said base portion includes a pivot member fused to said center hole.
28. The spinal support system of claim 27, wherein said pivot member is welded to said center hole at a distal face of said base portion.
29. The spinal support system of claim 28, wherein said distal face of said base portion is a distal face of said mounting platform.
30. The spinal support system of claim 24, comprising:
a base rod receptacle; and
means for coupling said base portion to said base rod receptacle.

31. The spinal support system of claim 30, wherein:
said base portion includes a skirt portion; and
said means for coupling said base portion to said base rod receptacle includes threaded engagement of said skirt portion to said base rod receptacle.
32. The spinal support system of claim 31, wherein:
said base portion includes a set screw portion that is unitary with and extends from a distal face of said mounting platform; and
said means for coupling said base portion to said base rod receptacle includes threaded engagement of said set screw portion to said base rod receptacle.
33. The spinal support system of claim 32, wherein said set screw portion and said base portion include mating threads that define canted cantilever profiles for said threaded engagement.
34. The spinal support system of claim 33, wherein said canted cantilever profiles extend radially and in a distal direction.
35. The spinal support system of claim 32, comprising a base spinal support rod disposed in said base rod receptacle, said set screw portion being configured to clamp said base spinal support rod within said base rod receptacle.
36. The spinal support system of claim 30, wherein:
said base portion includes a set screw portion that is unitary with and extends from a distal face of said mounting platform; and
said means for coupling said base portion to said base rod receptacle includes threaded engagement of said set screw portion to said base rod receptacle.
37. The spinal support system of claim 36, comprising a base spinal support rod disposed in said base rod receptacle, said set screw portion being configured to clamp said base spinal support rod within said base rod receptacle.

38. The spinal support system of claim 24, wherein said means for coupling said extension rod receptacle to said base portion enables only monoaxial rotation of said extension rod receptacle about a pivot axis.
39. A method of fabricating an extension assembly for a spinal support system, comprising:
inserting a pivot member into a rod receptacle so that a shaft portion of said pivot member extends from a distal end of said rod receptacle;
disposing said shaft portion in a center hole of a base portion so that an internal flange of said rod receptacle is captured between a head portion of said pivot member and said base portion so that an axial gap dimension defined between said head portion and said base member is greater than an axial thickness of said internal flange; and
securing said pivot member to said base portion.
40. The method of claim 39, wherein the step of disposing and the step of securing includes threadably engaging said shaft portion with said center hole.
41. The method of claim 39, wherein the step of disposing includes registering a stop on said pivot member against said base portion to define said axial gap dimension.
42. The method of claim 39, wherein the step of securing includes one of fusing and swaging said shaft member to said base portion.
43. A reinforcement cap for a spinal support system, comprising:
a platform portion including a distal face and a proximal face separated by a perimeter portion;
a skirt portion that extends from said distal face of said platform portion, the skirt portion including an interior surface, at least a portion of said interior surface including interior threads formed thereon; and
a set screw portion that extends from said distal face of said platform portion, said set screw portion being surrounded by said skirt portion and including an exterior surface that faces radially outward, at least a portion of said exterior surface including exterior threads formed thereon, said set screw portion defining a rotation axis, said set screw portion and said skirt portion being concentric about said rotation axis to define an

annular gap between said exterior threads of said set screw portion and said interior threads of said skirt portion.

44. The reinforcement cap of claim 43, wherein said skirt portion includes an exterior surface that is tangential with said perimeter portion.

45. The reinforcement cap of claim 43, wherein said skirt portion includes an exterior surface that defines a plurality of flats, each of said plurality of flats being parallel to said rotation axis.

46. The reinforcement cap of claim 43, wherein said exterior threads of said set screw portion define a canted cantilever profile.

47. The reinforcement cap of claim 46, wherein said interior threads of said skirt portion define a canted cantilever profile.

48. The reinforcement cap of claim 46, wherein said canted cantilever profile of said set screw portion slopes in a distal direction and toward said rotation axis.

49. The reinforcement cap of claim 48, wherein said interior threads of said skirt portion define a canted cantilever profile.

50. The reinforcement cap of claim 48, wherein said canted cantilever profile of said set screw portion slopes in a distal direction and away from said rotation axis.

51. The reinforcement cap of claim 43, wherein said platform portion defines a socket accessible from said proximal face, said socket being concentric with and extending along said rotation axis.

52. The reinforcement cap of claim 51, wherein said platform portion defines a tapped center hole accessible from said proximal face, said tapped center hole being concentric with and extending along said rotation axis, said socket extending distally from said tapped center hole.

53. The reinforcement cap of claim 43, wherein said reinforcement cap defines a center passage concentric with said rotation axis and extending from said socket through a distal end of said set screw portion.

54. The reinforcement cap of claim 43, wherein said platform portion defines a tapped center hole accessible from said proximal face, said tapped center hole being concentric with and extending along said rotation axis.

55. The reinforcement cap of claim 43, wherein said set screw portion extends distally beyond said skirt portion.

56. A spinal support system, comprising:

- a platform portion including a distal face and a proximal face separated by a perimeter portion;

- a skirt portion that extends from said distal face of said platform portion, the skirt portion including an interior surface, at least a portion of said interior surface including interior threads formed thereon;

- a set screw portion that extends from said distal face of said platform portion, said set screw portion being surrounded by said skirt portion and including an exterior surface that faces radially outward, at least a portion of said exterior surface including exterior threads formed thereon, said set screw portion defining a rotation axis, said set screw portion and said skirt portion being concentric about said rotation axis to define an annular gap between said exterior threads of said set screw portion and said interior threads of said skirt portion; and

- a spinal rod receptacle having a side wall that includes an interior surface and an exterior surface, the side wall defining a pair of diametrically opposed slots that extend axially along the side wall and are open at a proximal end of the spinal rod receptacle, the interior surface of the spinal rod receptacle defining interior threads, the exterior surface of the spinal rod receptacle defining first exterior threads,

wherein said interior threads of said spinal rod receptacle are configured to mate with said exterior threads of said set screw portion of said reinforcement cap, and said exterior threads of said spinal rod receptacle are configured to mate with said interior threads of said skirt portion of said reinforcement cap.

57. The spinal support system of claim 56, comprising a spinal rod configured for insertion into said diametrically opposed slots.

58. The spinal support system of claim 56, comprising a pedicle screw disposed within said spinal rod receptacle, a shaft of the pedicle screw extending distally from said spinal rod receptacle.

59. A method for securing a spinal support rod to a spinal rod receptacle, comprising:

- (a) disposing a spinal support rod through diametrically opposed slots of a spinal rod receptacle;
- (b) threadably engaging interior threads of a skirt portion of a reinforcement cap with exterior threads of said spinal rod receptacle;
- (c) simultaneously with step (b), threadably engaging exterior threads of a set screw portion of said reinforcement cap with interior threads of said spinal rod receptacle; and
- (d) tightening said reinforcement cap against said spinal support rod.

60. The method of claim 59, wherein the step (d) includes driving said reinforcement cap with a tool that mates with a socket formed on said reinforcement cap.

61. The method of claim 59, wherein step (d) includes driving said reinforcement cap with a tool that engages flats formed on said skirt portion of said reinforcement cap.

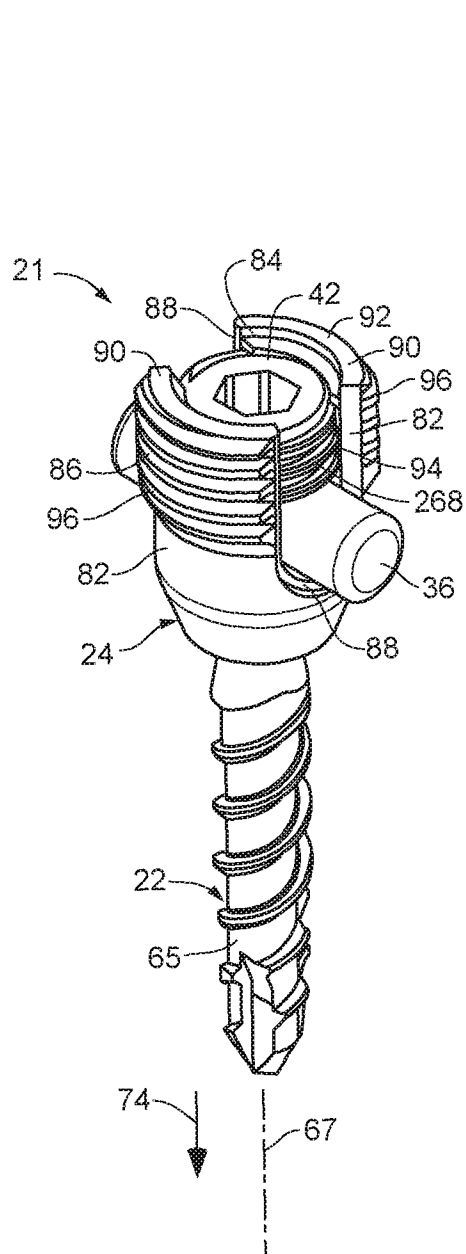


FIG. 1

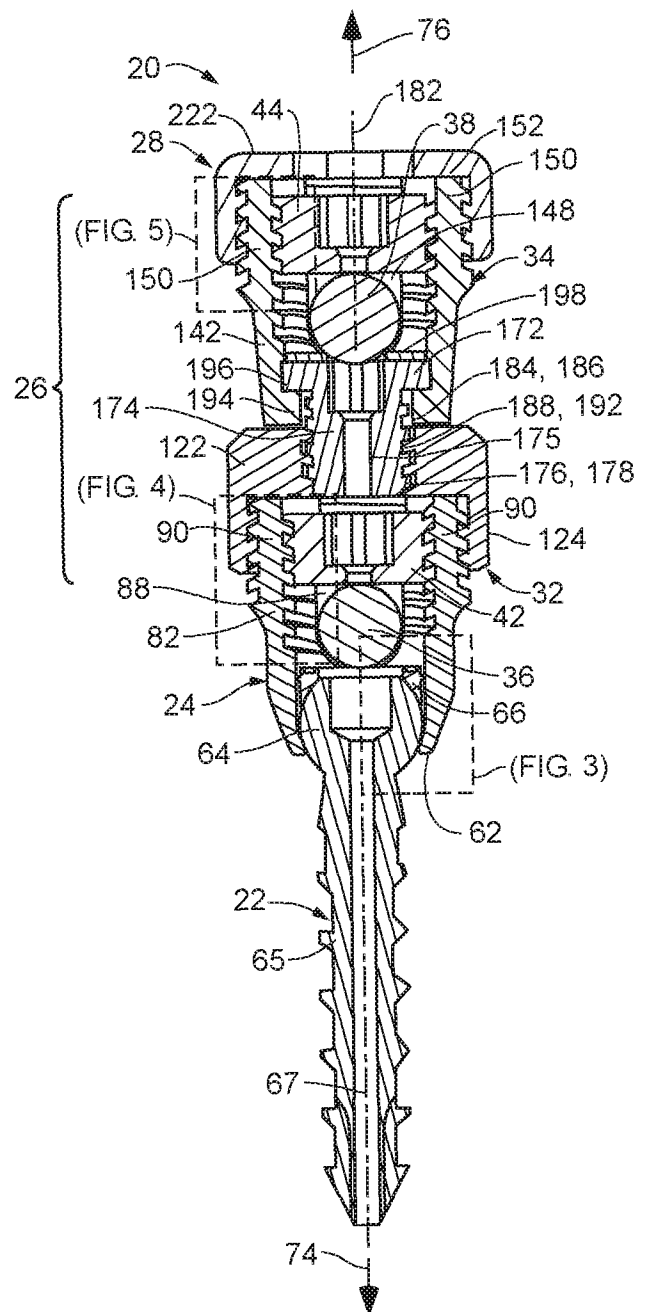


FIG. 2

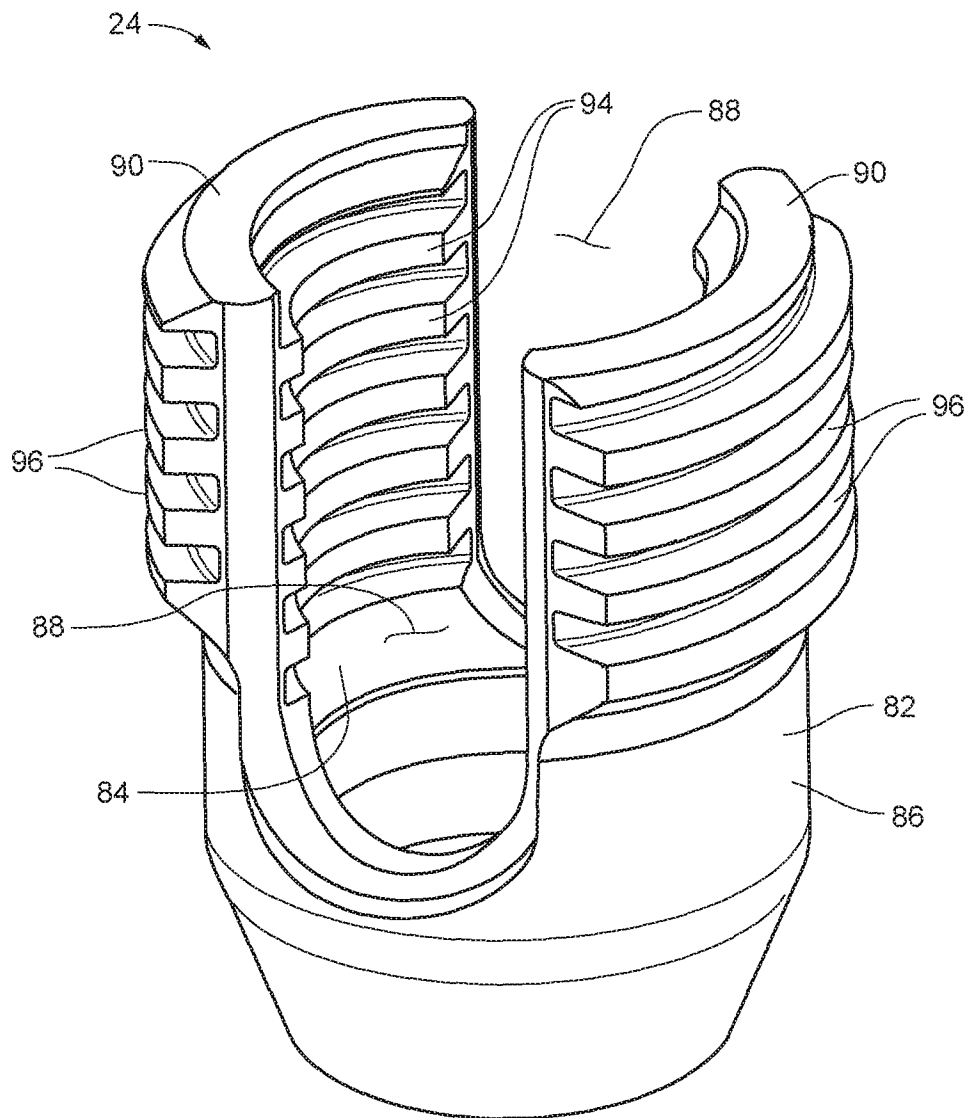
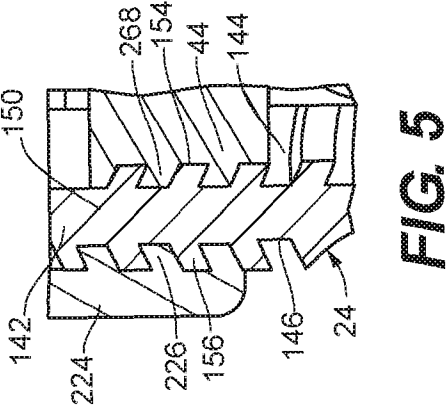
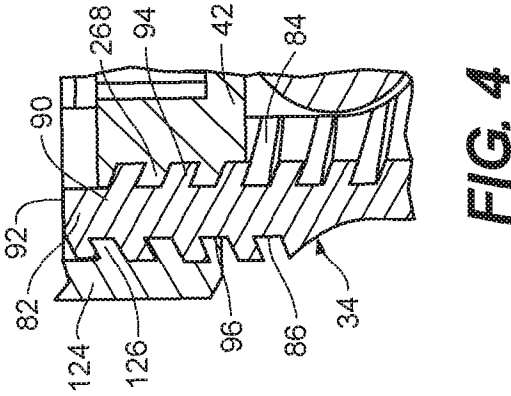
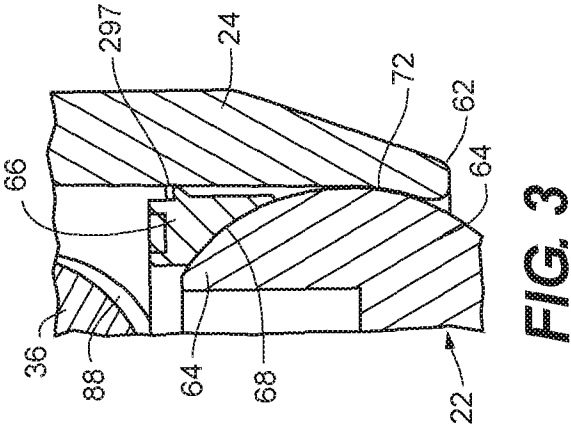


FIG. 1A



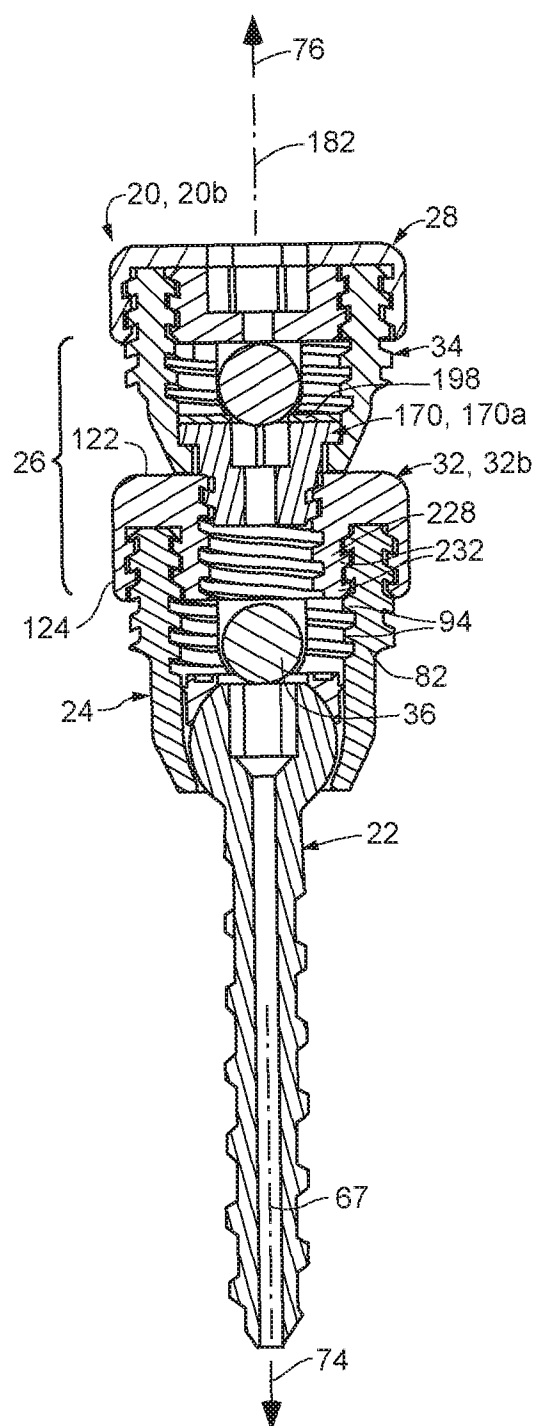


FIG. 6

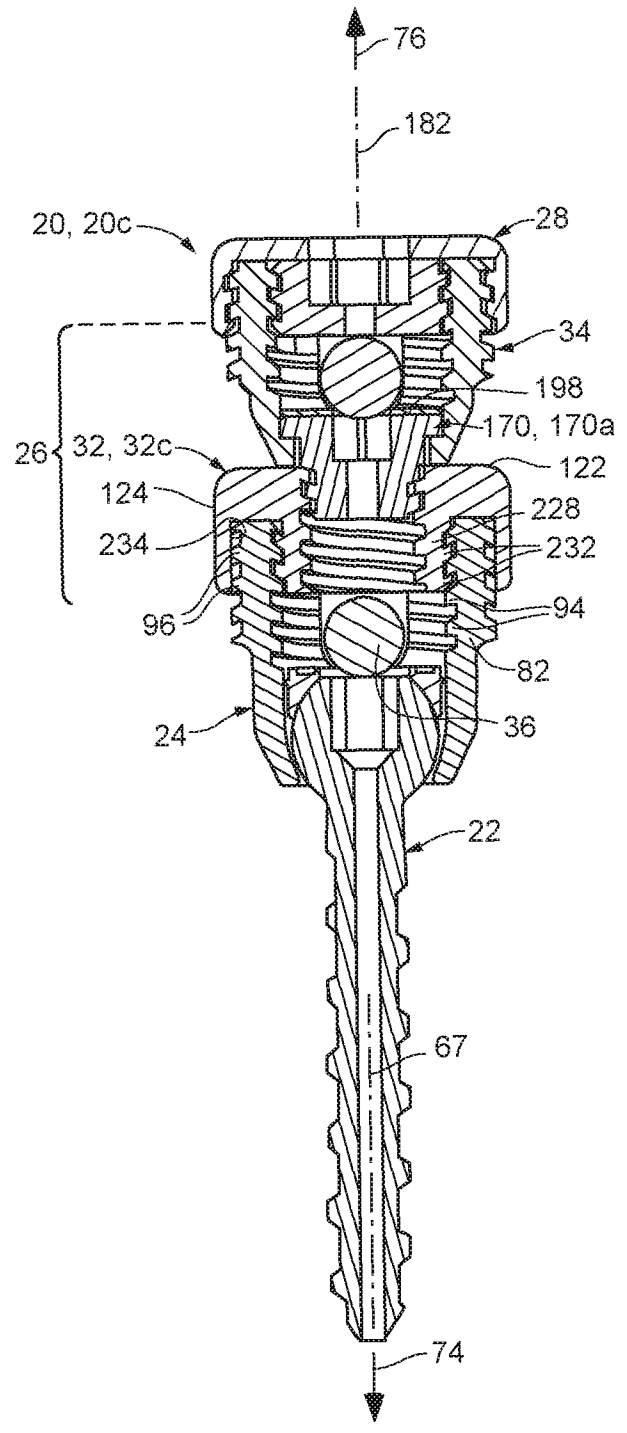
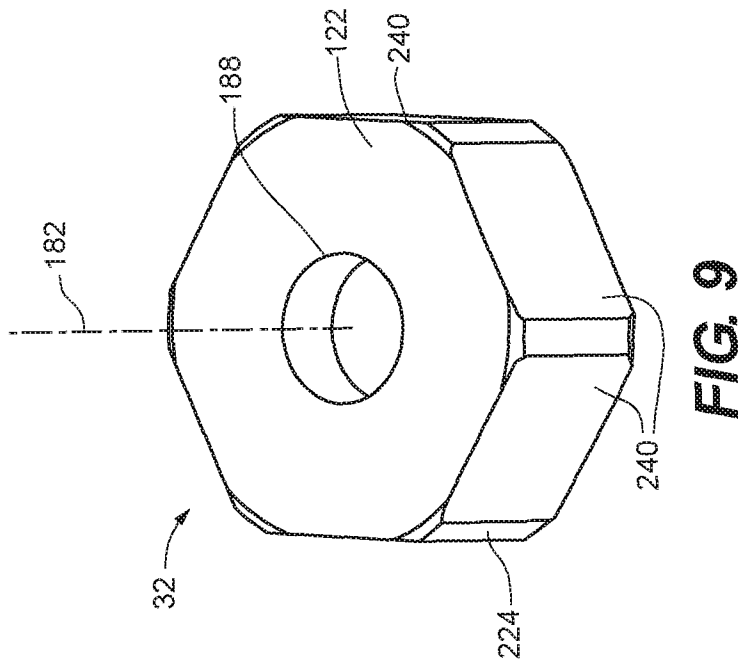
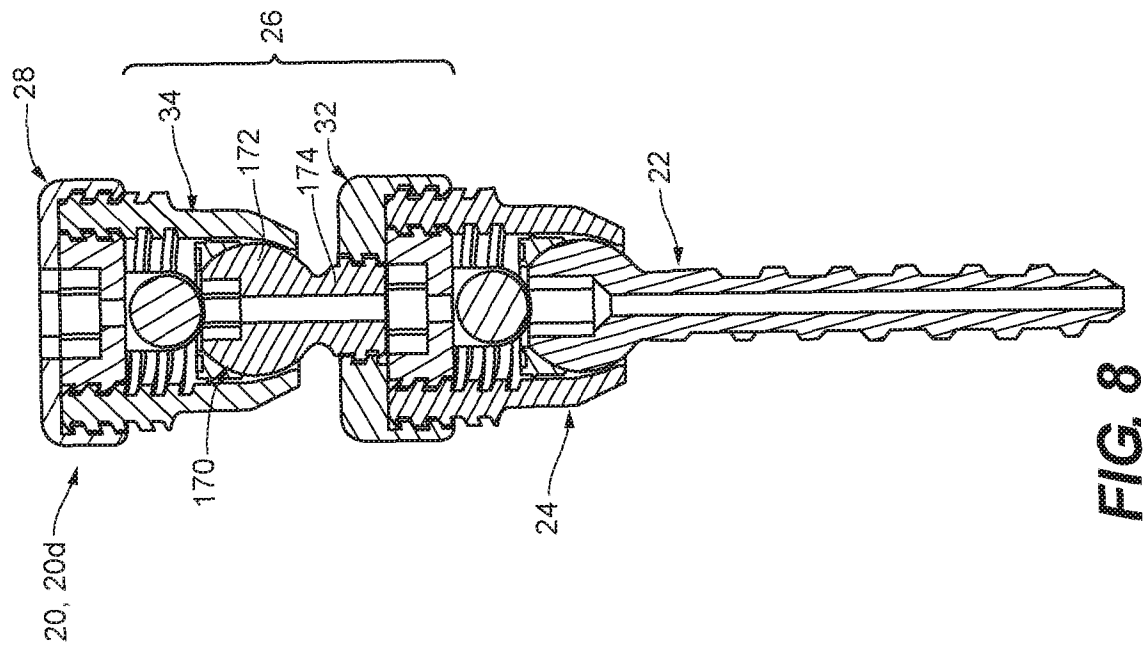
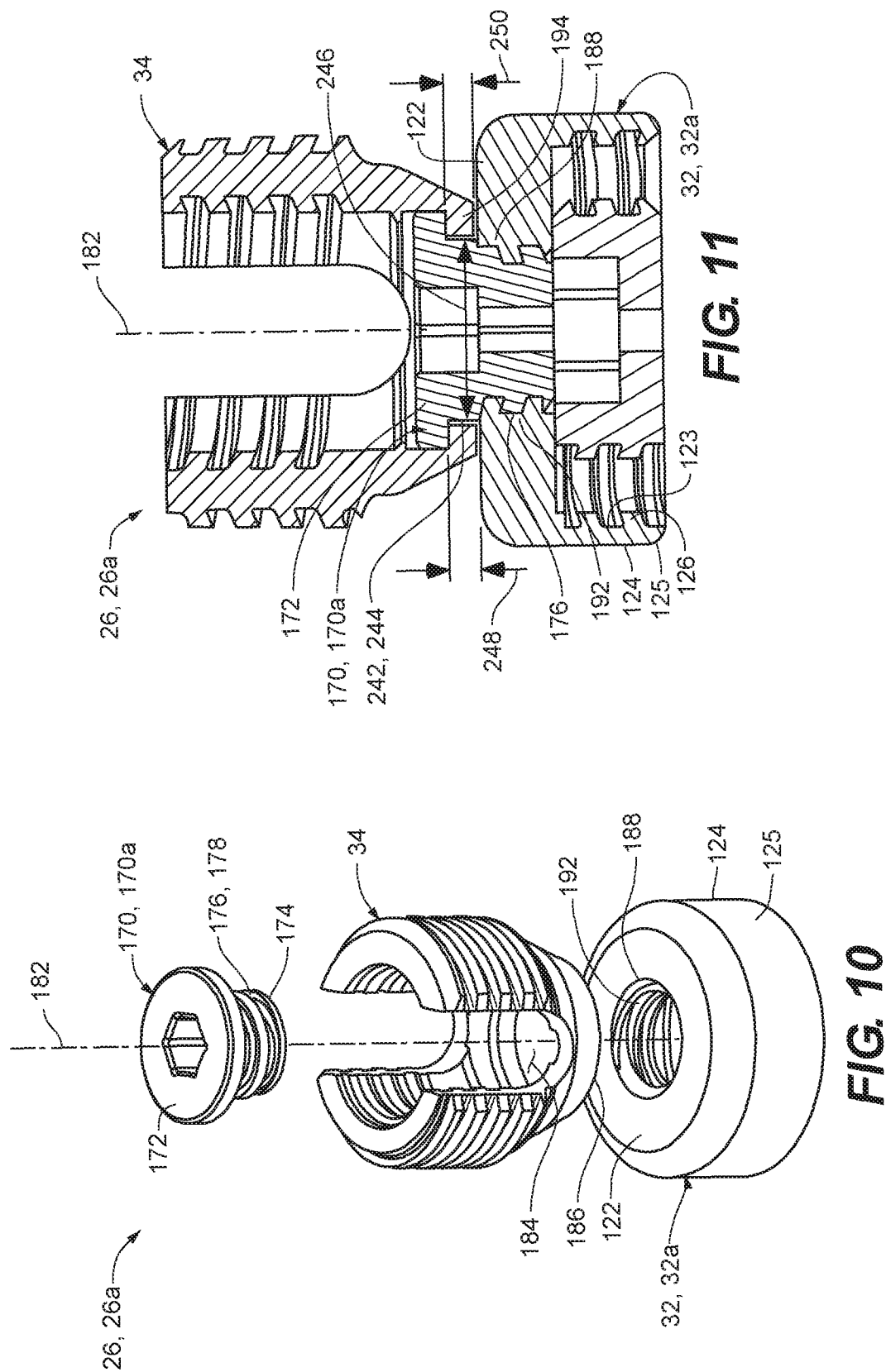


FIG. 7



6/19



7/19

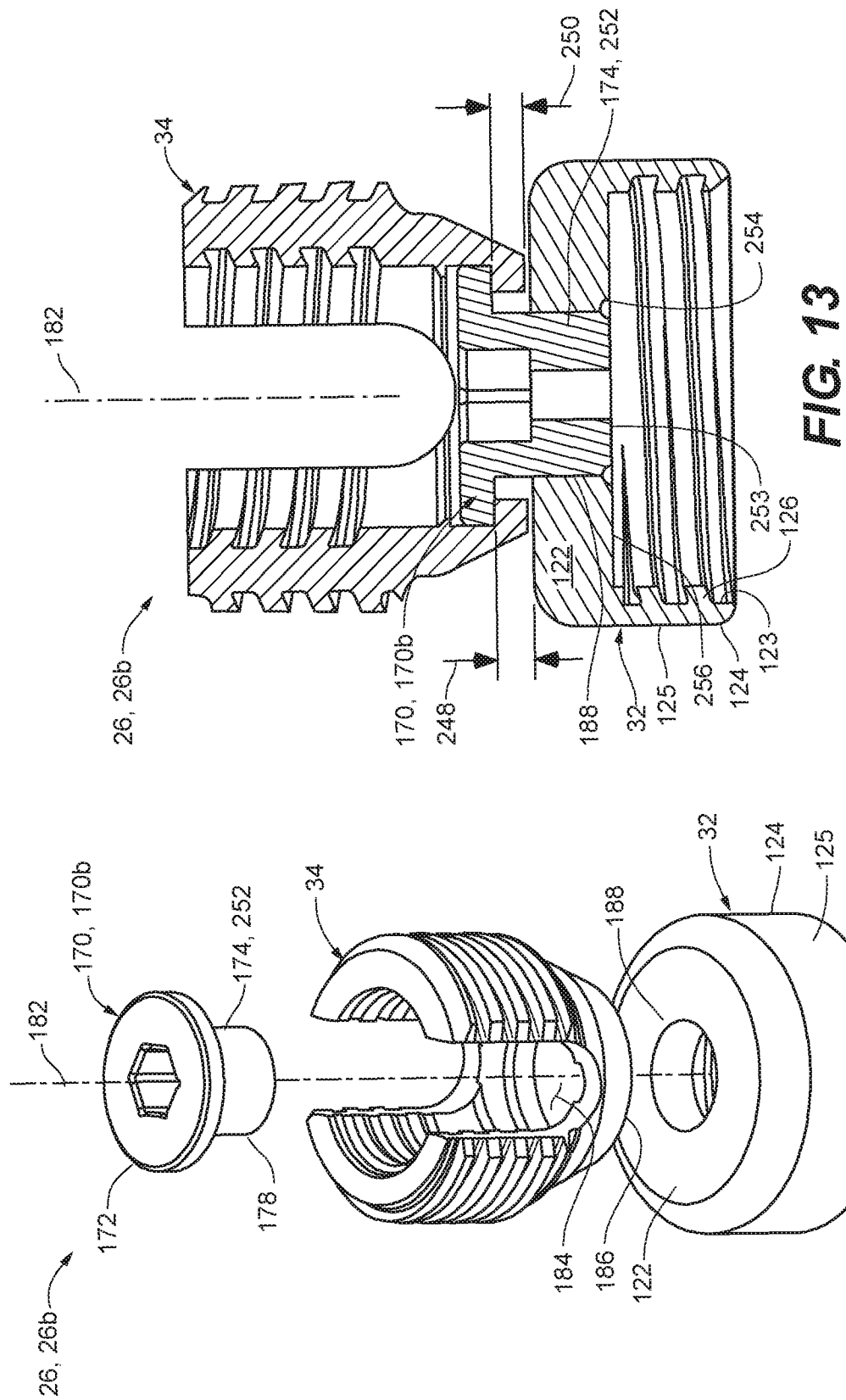
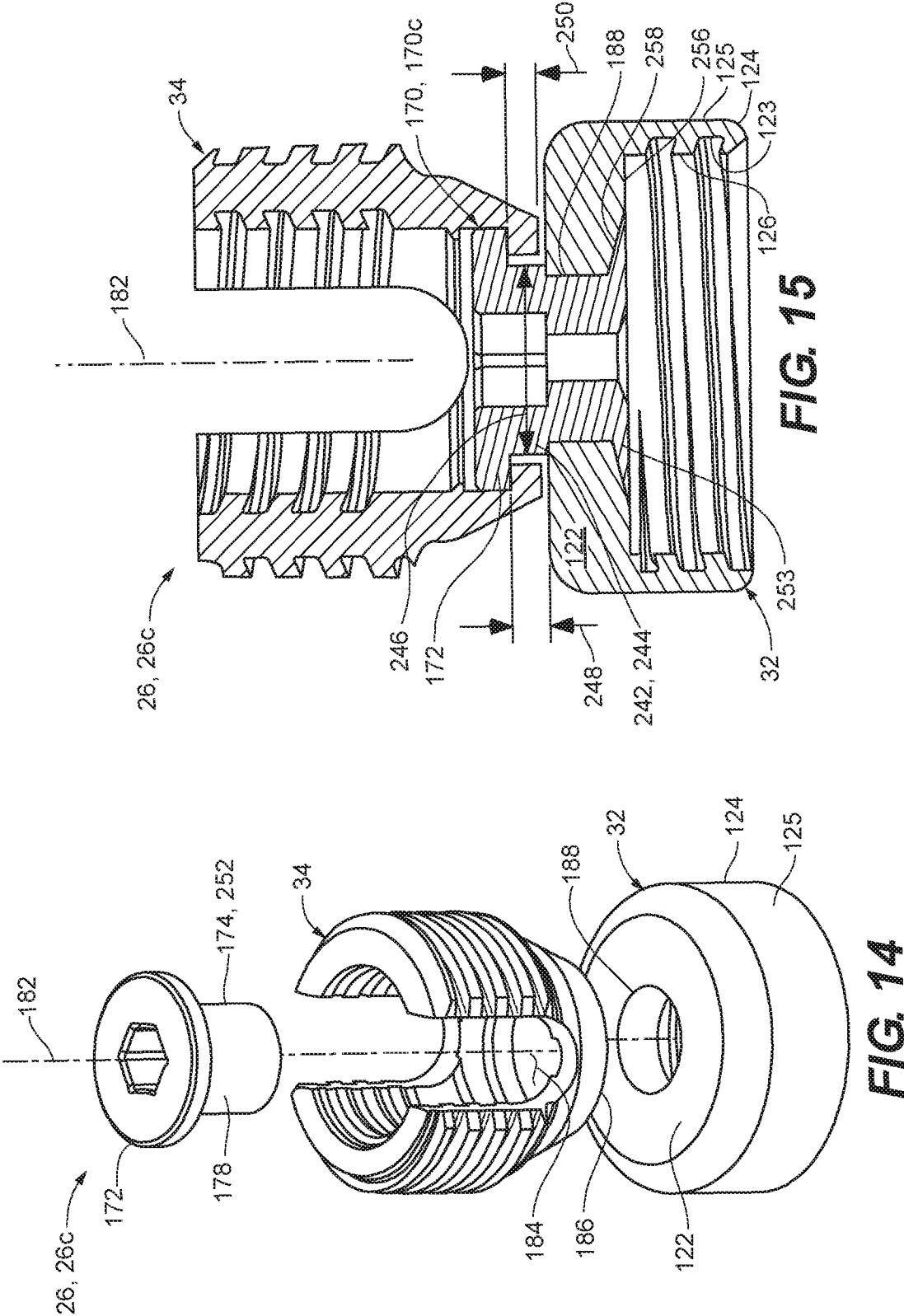


FIG. 13

FIG. 12



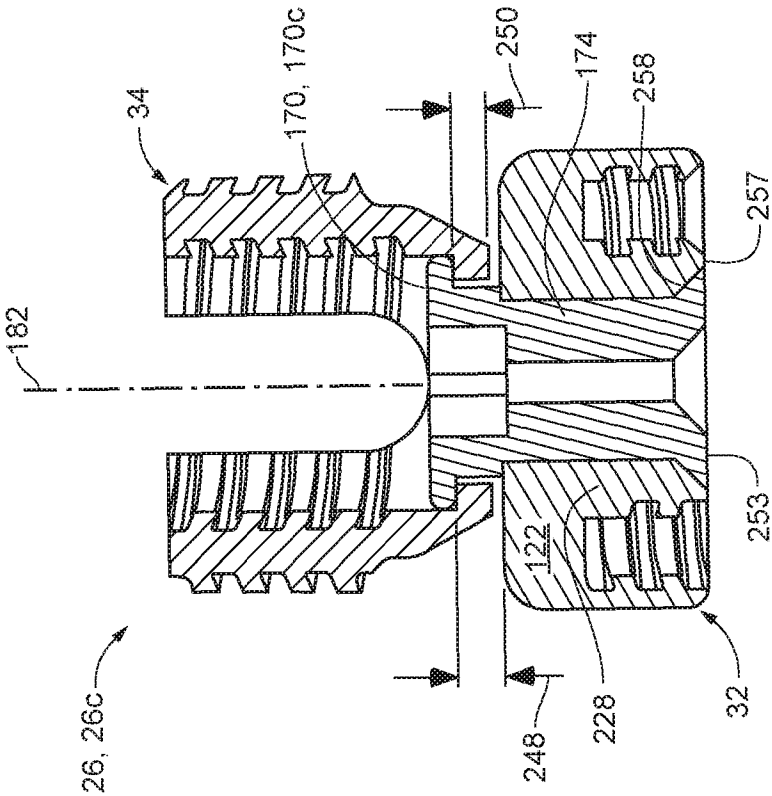


FIG. 17

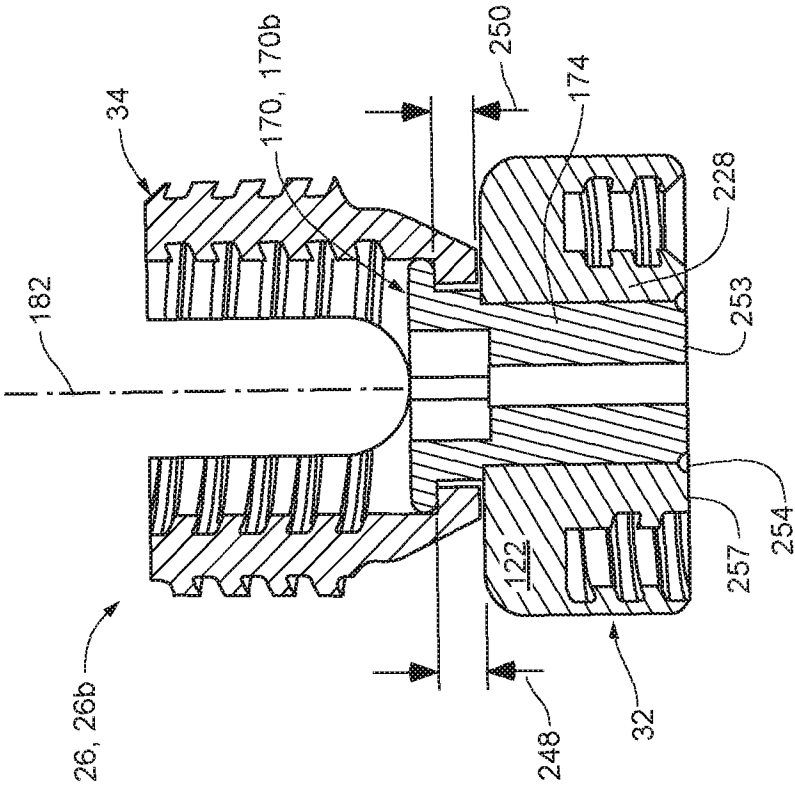
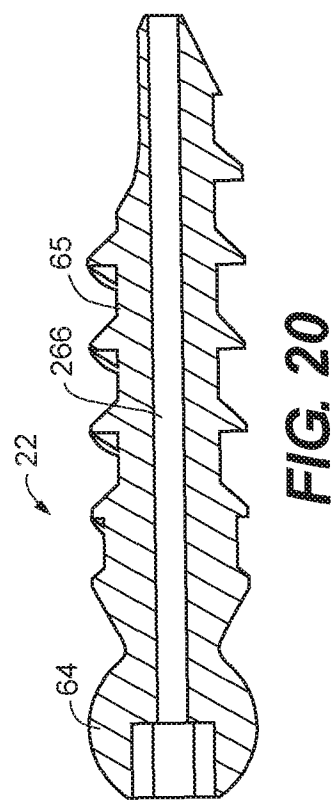
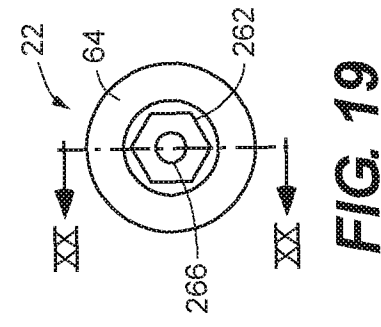
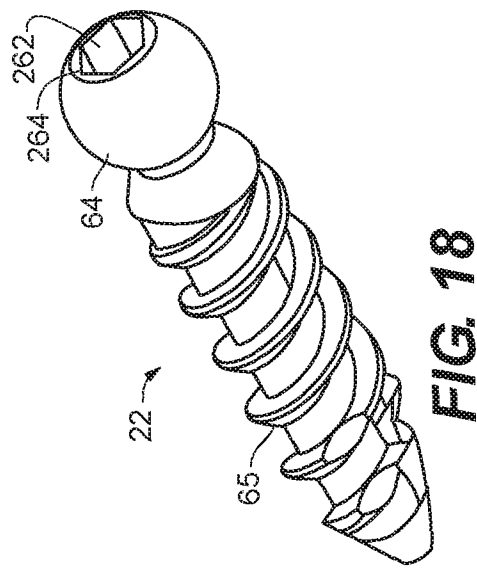


FIG. 16



11/19

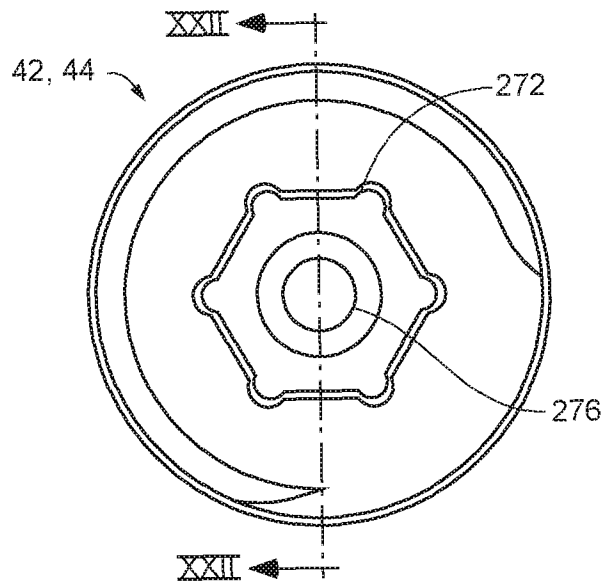


FIG. 21

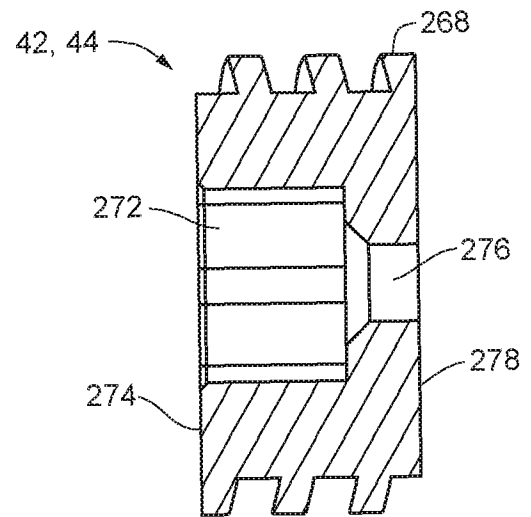


FIG. 22

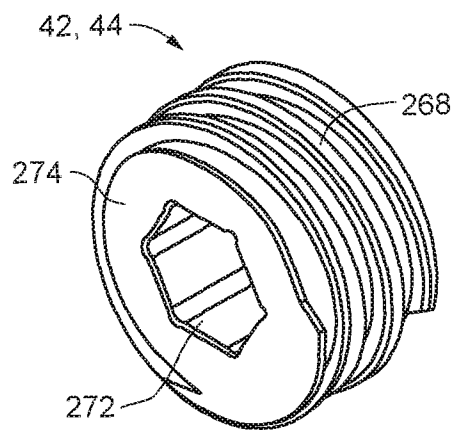


FIG. 23

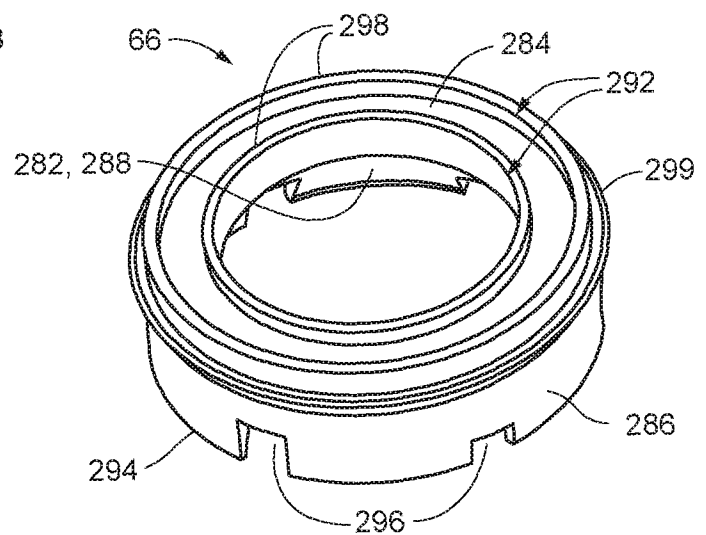
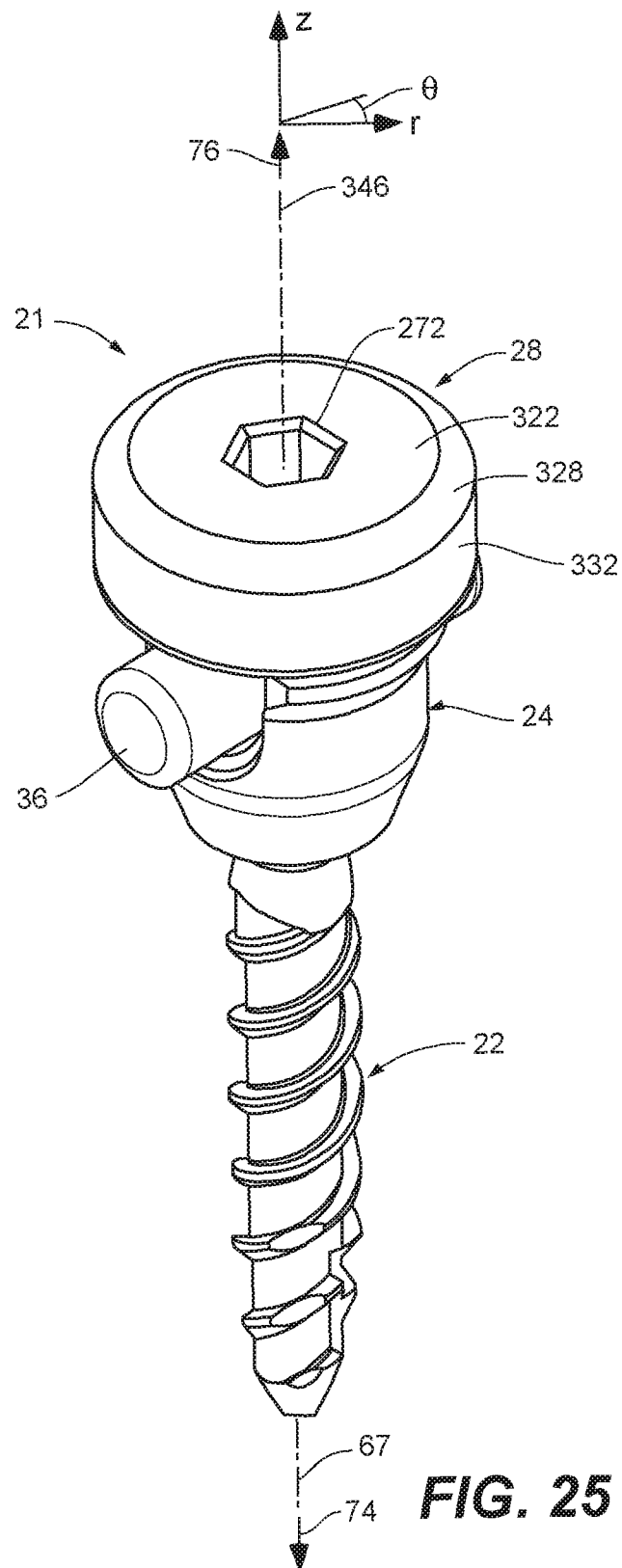


FIG. 24

12/19



13/19

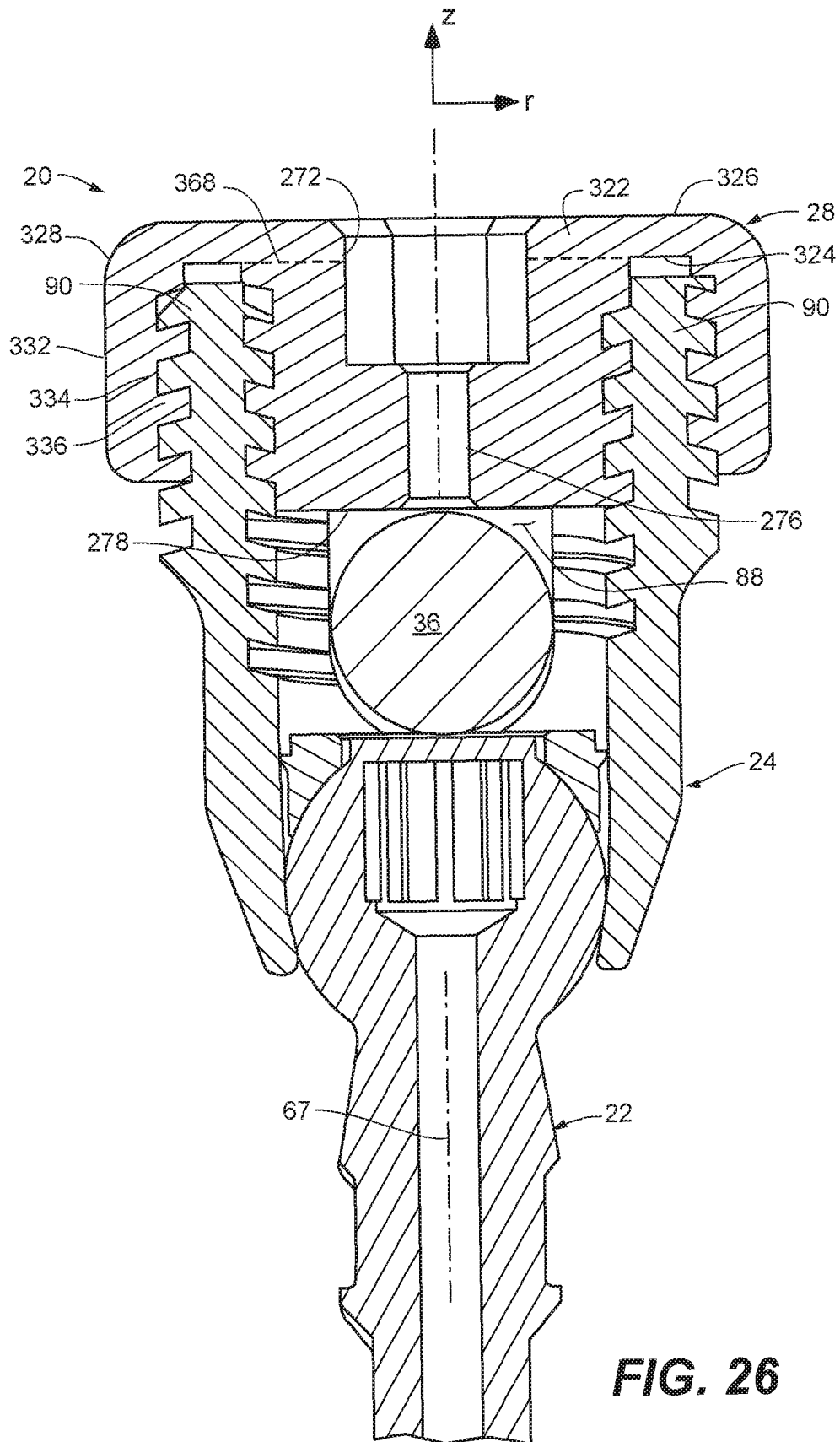


FIG. 26

14/19

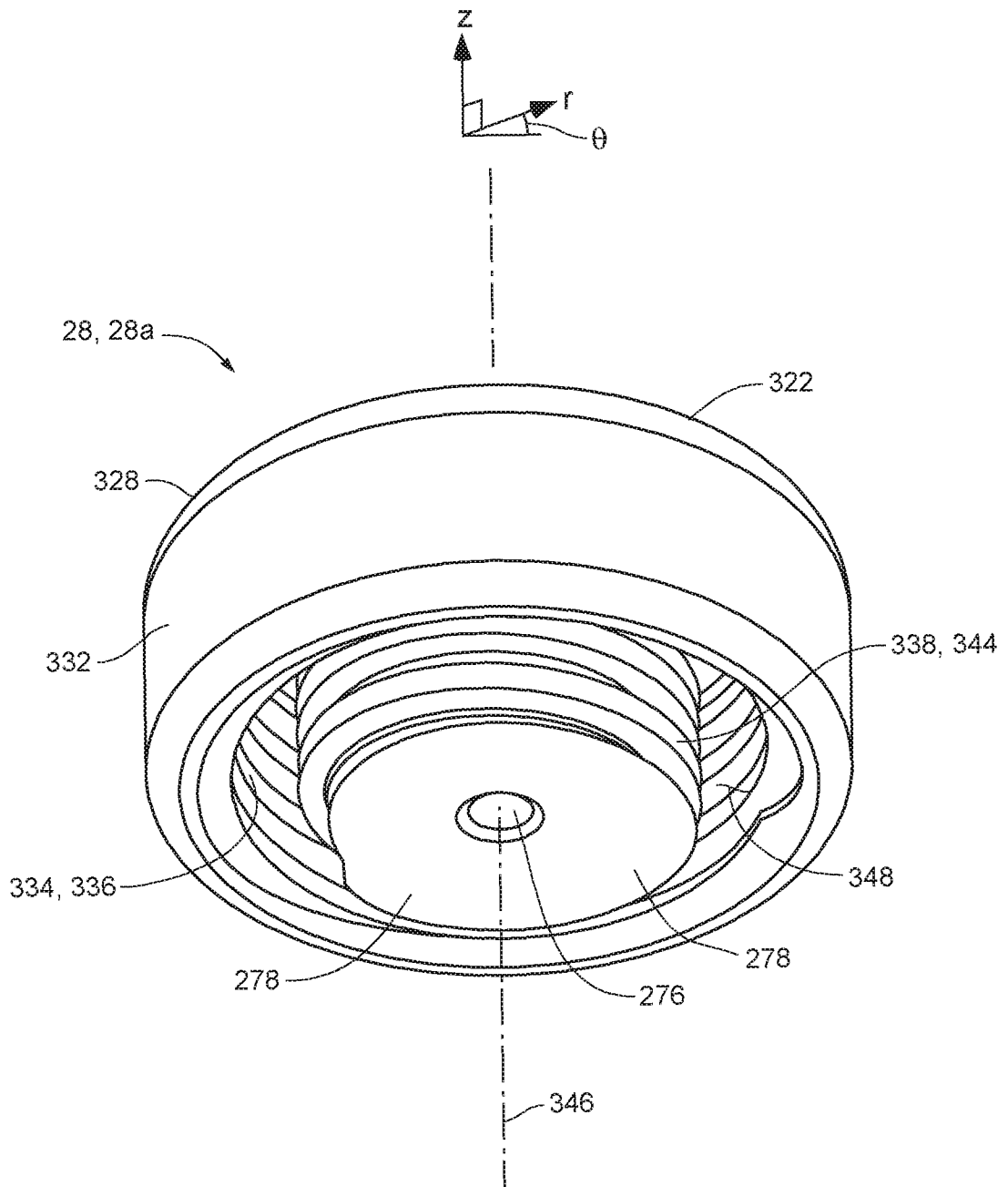


FIG. 27

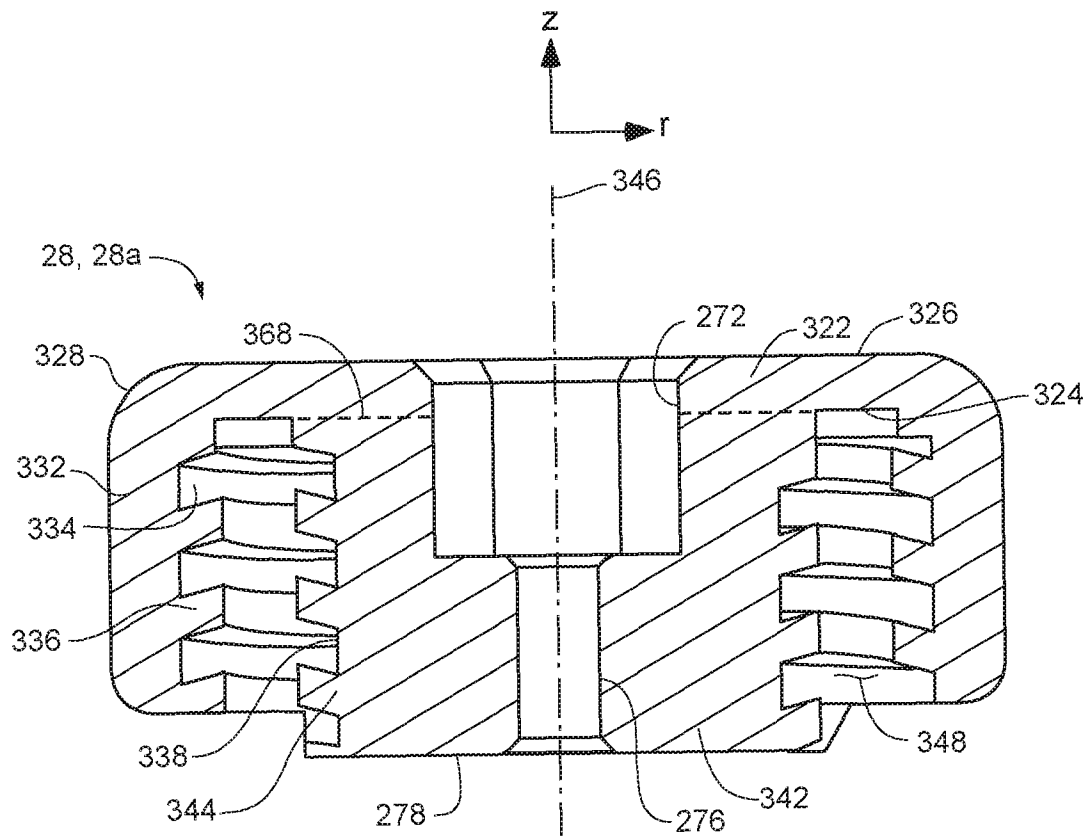


FIG. 28

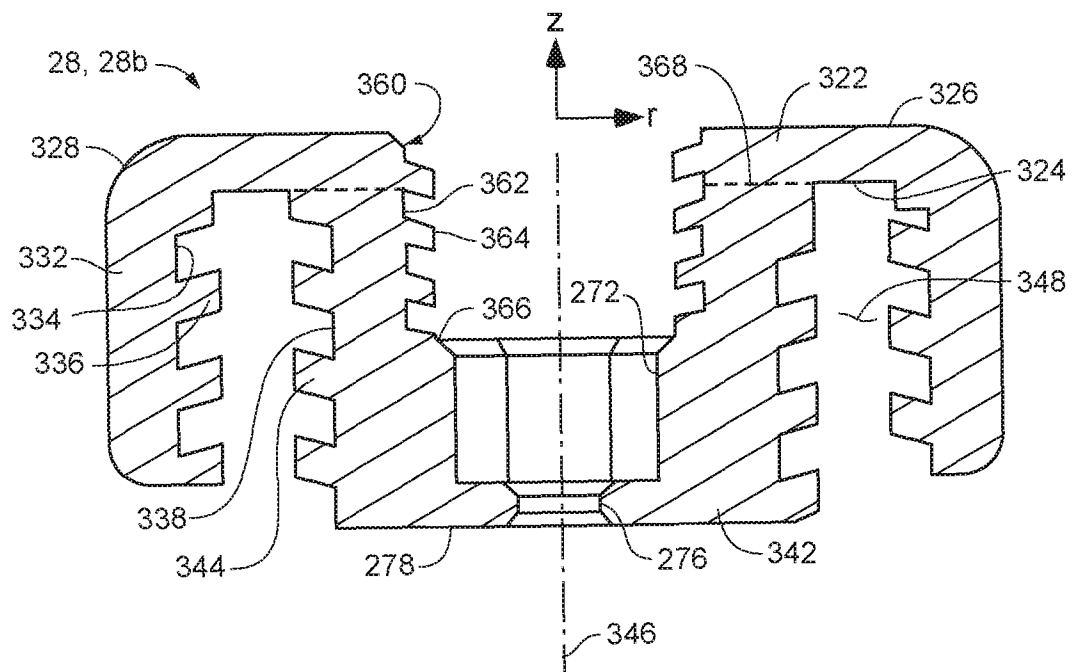


FIG. 29

17/19

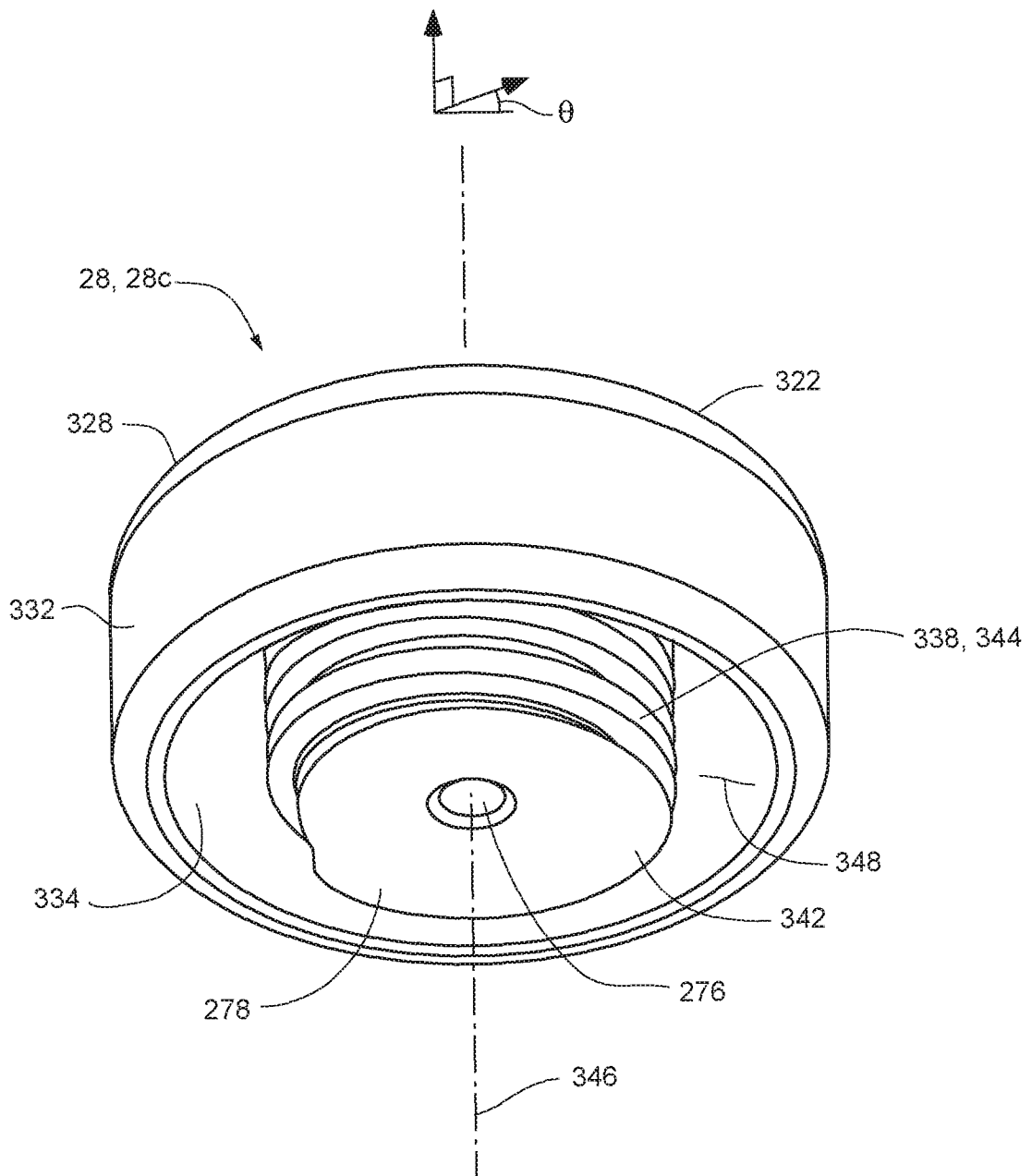


FIG. 30

18/19

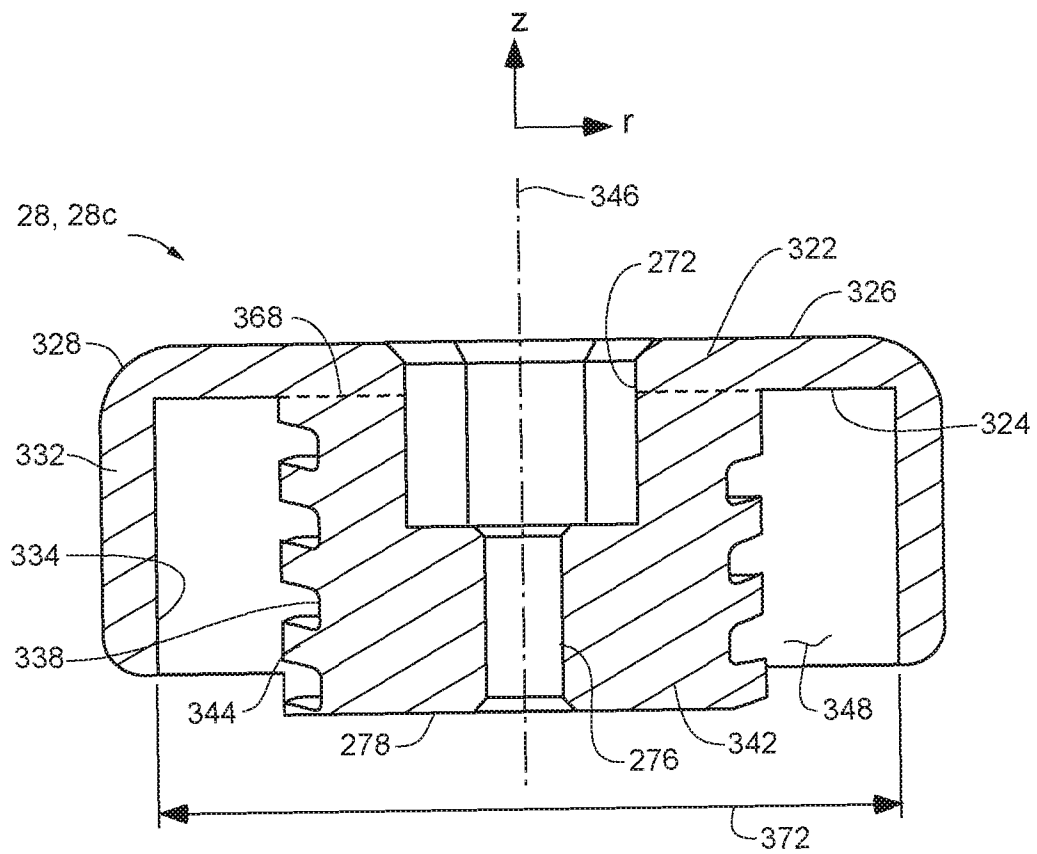


FIG. 31

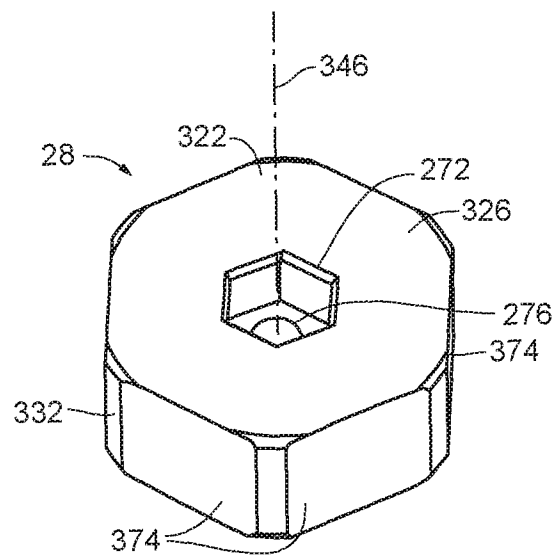


FIG. 32

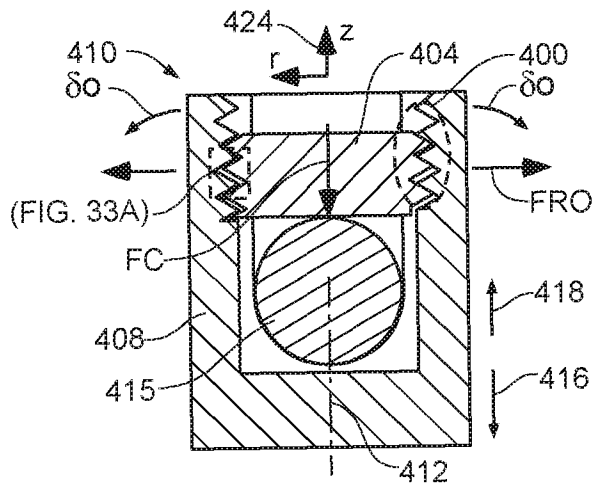


FIG. 33
Prior Art

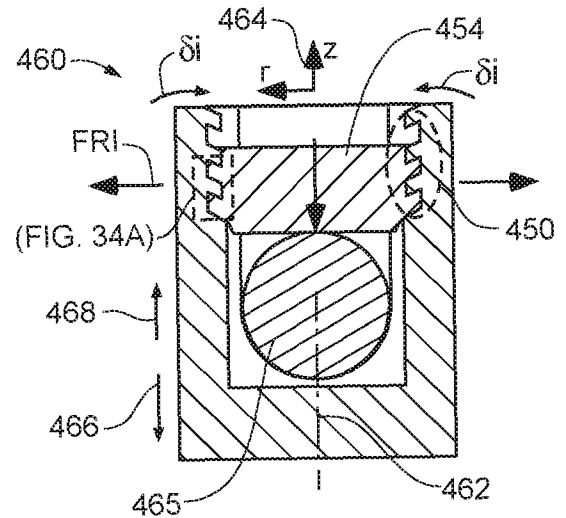


FIG. 34

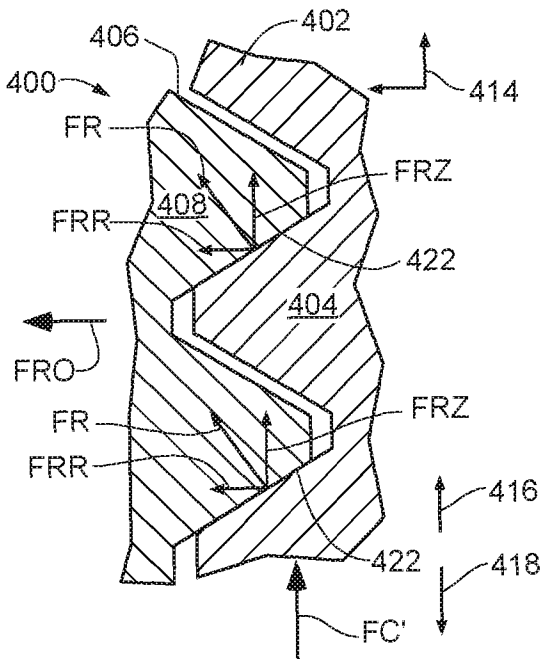


FIG. 33A
Prior Art

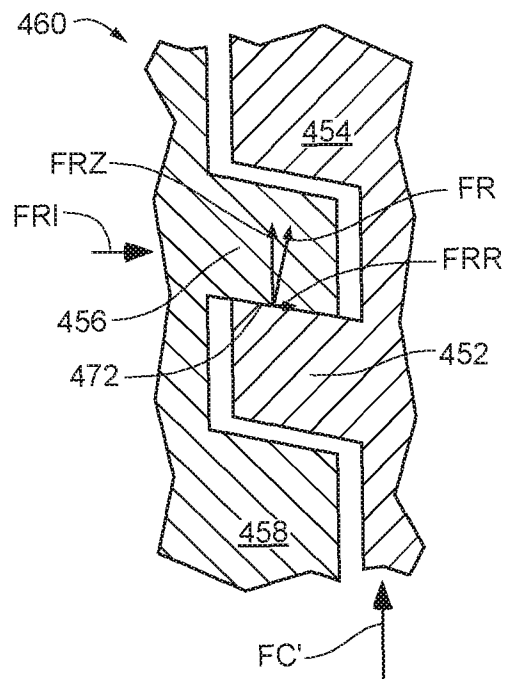


FIG. 34A

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2018/030928**A. CLASSIFICATION OF SUBJECT MATTER****A61B 17/70(2006.01)i**

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B 17/70; A61B 17/86

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

Korean utility models and applications for utility models

Japanese utility models and applications for utility models

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

eKOMPASS(KIPO internal) & Keywords: spinal, extension, cap, thread, pivot

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2014-0135839 A1 (BLACKSTONE MEDICAL, INC.) 15 May 2014 See paragraphs [0018]–[0039] and figures 3–8.	24–38
Y		39–55
A		1–23, 56–61
Y	US 2011-0190821 A1 (KINGSLEY R. CHIN et al.) 04 August 2011 See paragraphs [0007], [0030]–[0037] and figures 3, 6a–6b.	39–55
A	US 2016-0242817 A1 (HAMID R. ABBASI) 25 August 2016 See the whole document.	1–61
A	US 2014-0316475 A1 (ALPHATEC SPINE, INC.) 23 October 2014 See the whole document.	1–61
A	KR 10-2010-0119303 A (L&K BIOMED CO., LTD.) 09 November 2010 See the whole document.	1–61



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents:

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"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

27 September 2018 (27.09.2018)

Date of mailing of the international search report

27 September 2018 (27.09.2018)

Name and mailing address of the ISA/KR

International Application Division

Korean Intellectual Property Office

189 Cheongsa-ro, Seo-gu, Daejeon, 35208, Republic of Korea



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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/US2018/030928

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