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(54) PEDICLE SCREW ASSEMBLY

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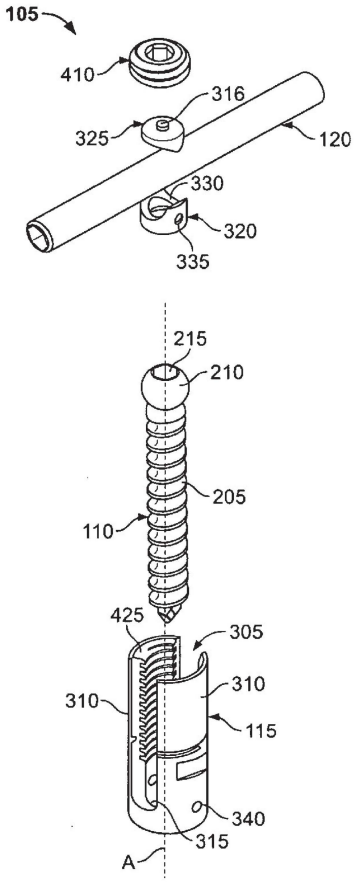
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A61F 2/30 (2006.01)

(52) **U.S. Cl.** **606/61**

(57) **ABSTRACT**

Disclosed are bone stabilization assemblies for use in skeletal systems. A bone stabilizer assembly includes a fixation element, a coupling element, a saddle, a compression nut, and retention means for retaining the saddle in the coupling element in a floating configuration that permits a predetermined amount of movement between the saddle and the coupling element. The fixation element is adapted to engage a bone and has a head portion and shank portion. The coupling element has an internal bore sized to receive the shank portion of the fixation element and a seat adapted to support the head portion of the fixation element. The coupling element is also adapted to receive a stabilizer rod. The saddle is movably mounted in the coupling element below the stabilizer rod when the stabilizer rod is in the coupling element. The compression nut is engagable with the coupling element. The compression nut is adapted to rotatingly move distally into the coupling element to translate a force to the head portion through the rod and the saddle such that the head portion is forced against the seat of the coupling element to prevent relative movement between the fixation element and the coupling element.



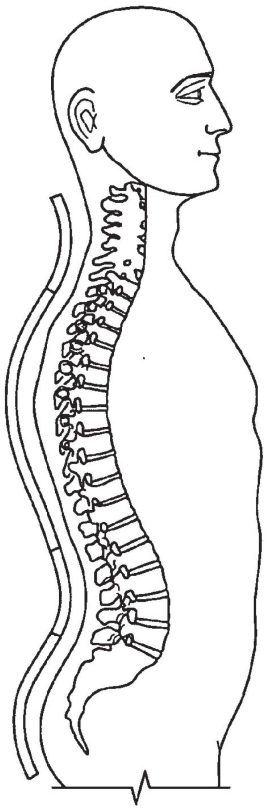


FIG. 1A

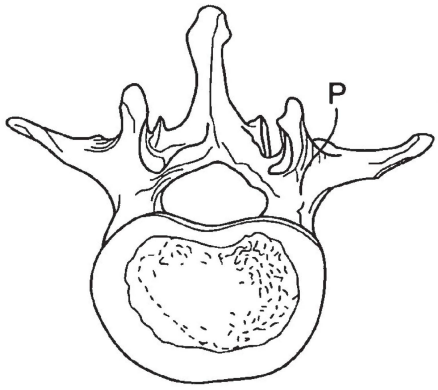


FIG. 1B

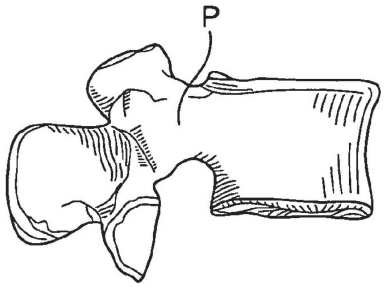


FIG. 1C

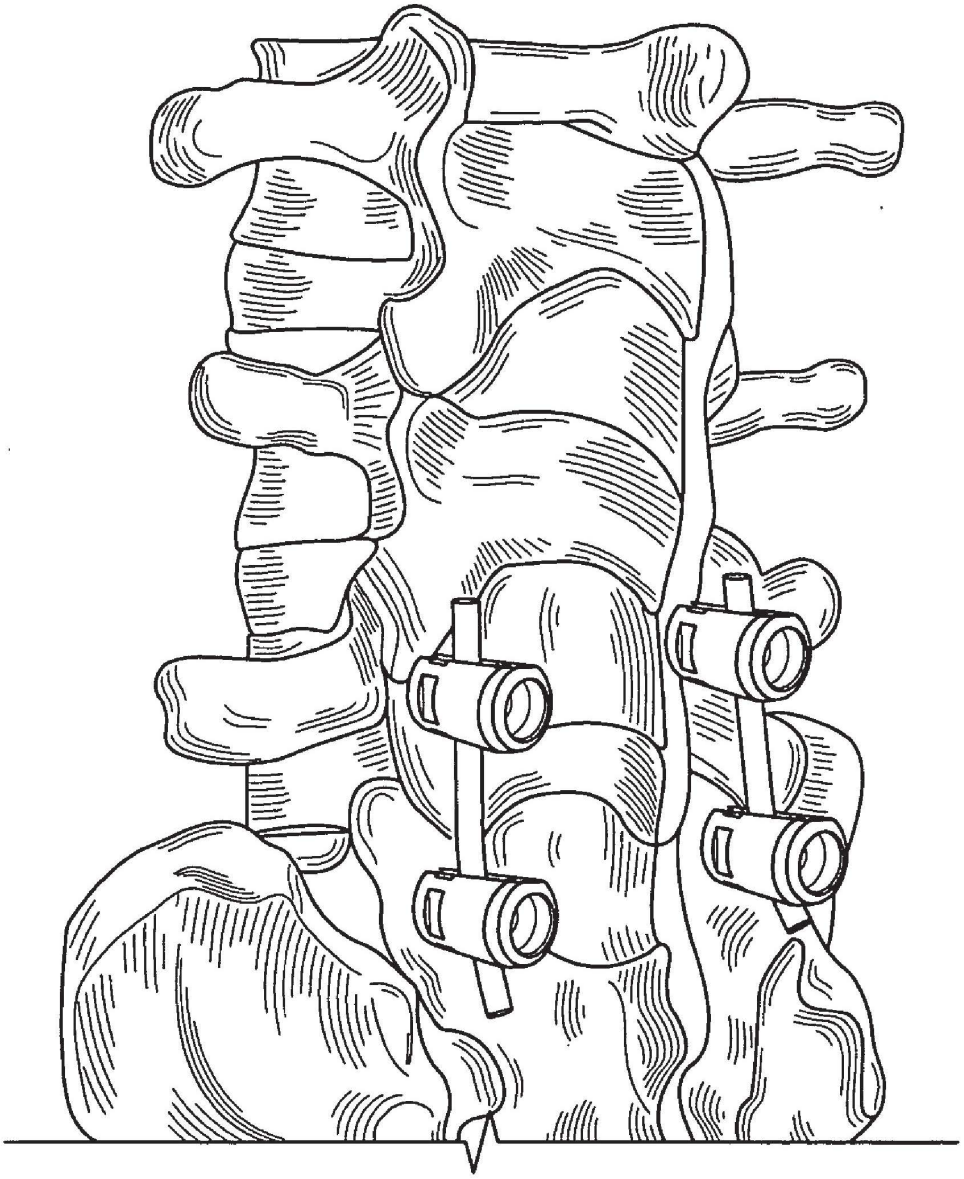


FIG. 2

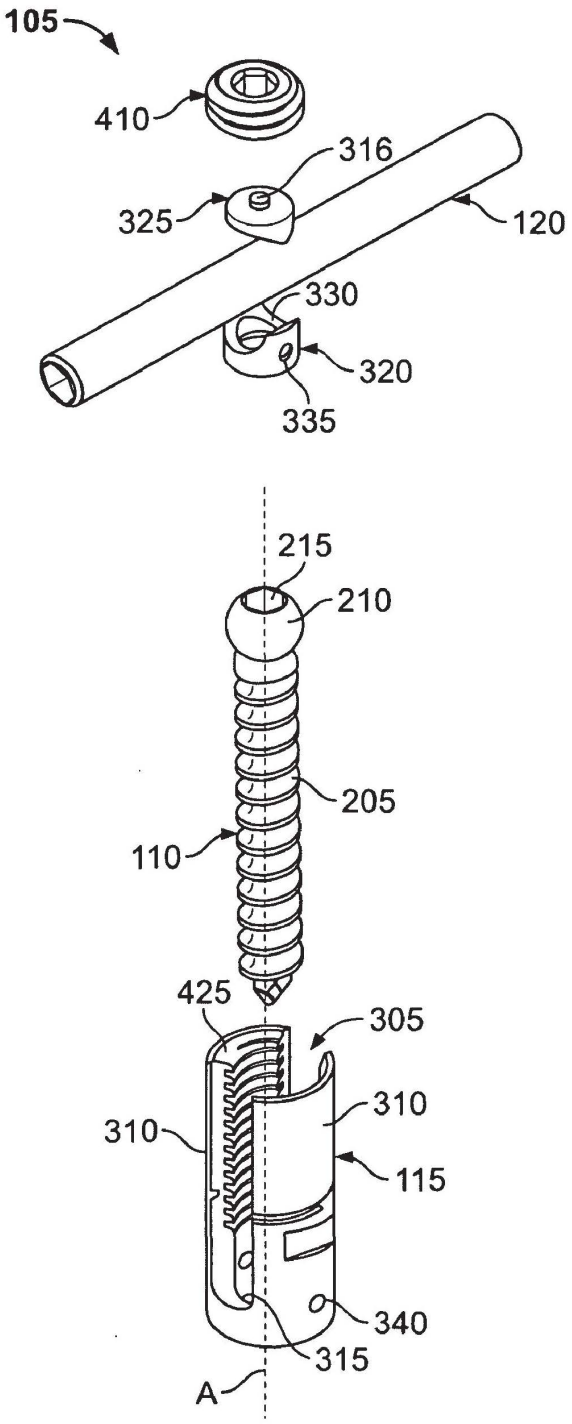

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FIG. 3

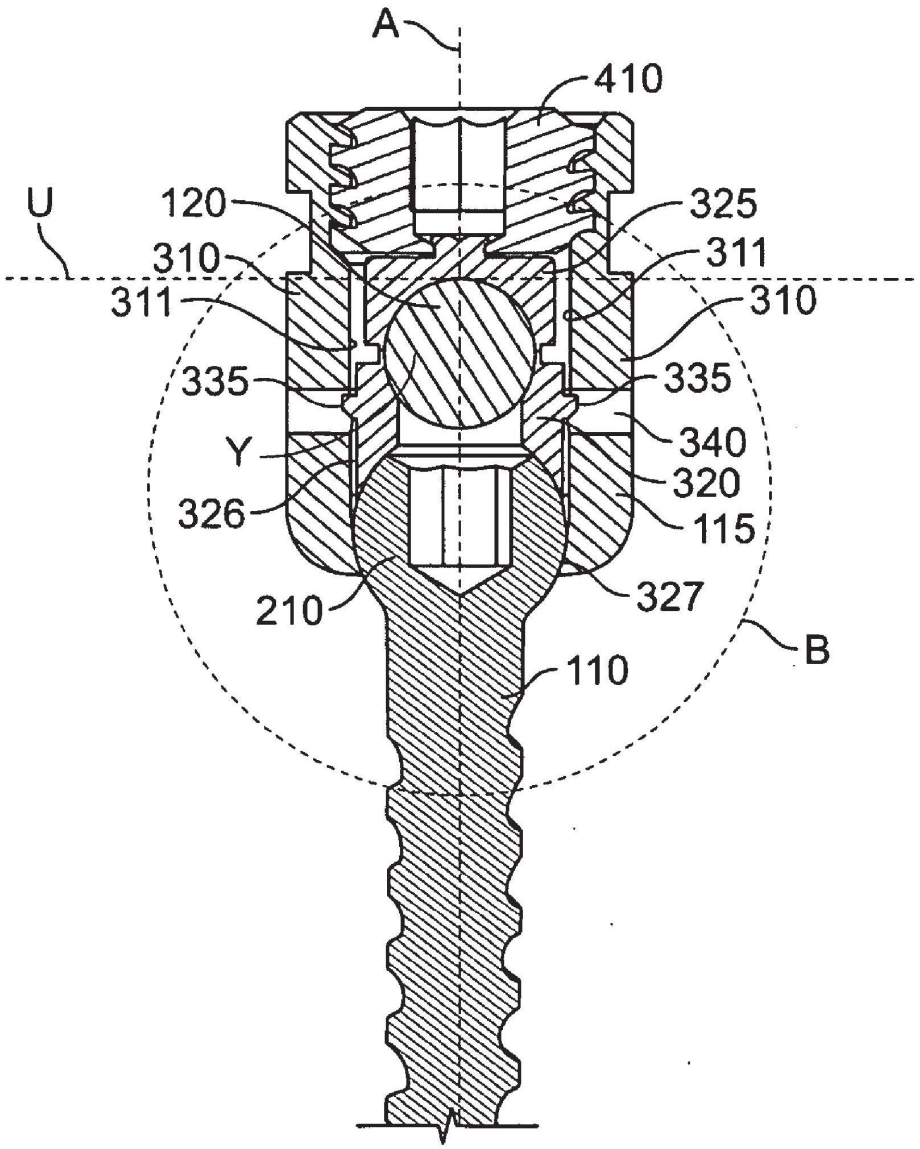

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FIG. 4

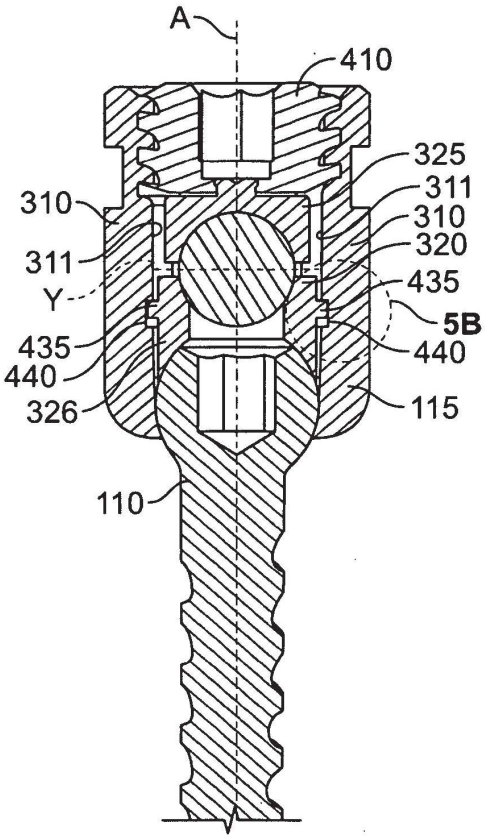

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FIG. 5A

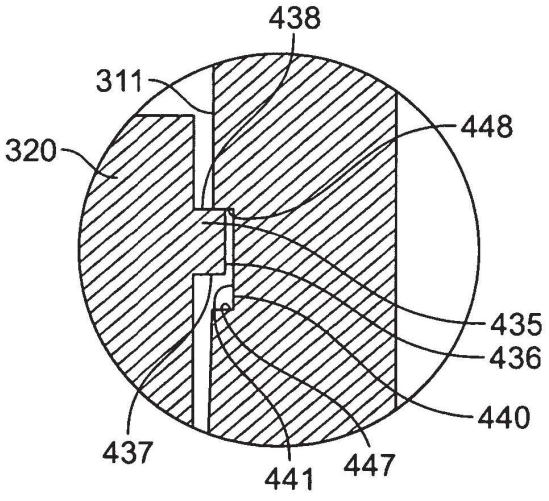

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FIG. 5B

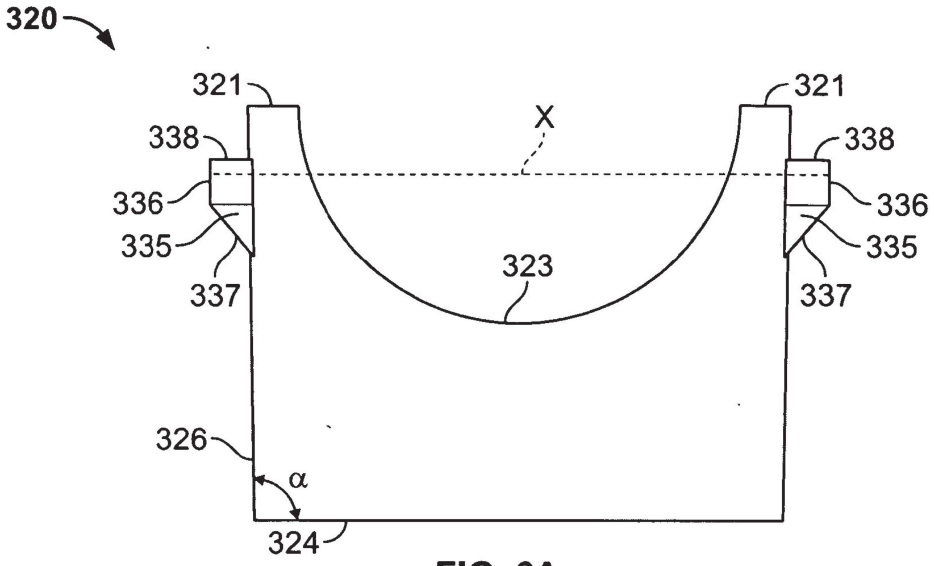

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FIG. 6A

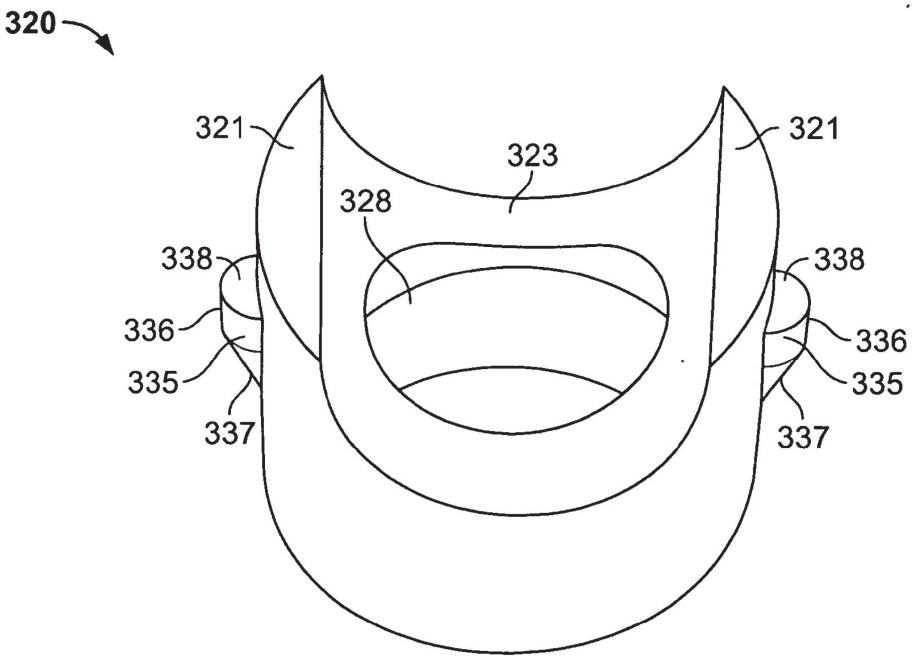

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FIG. 6B

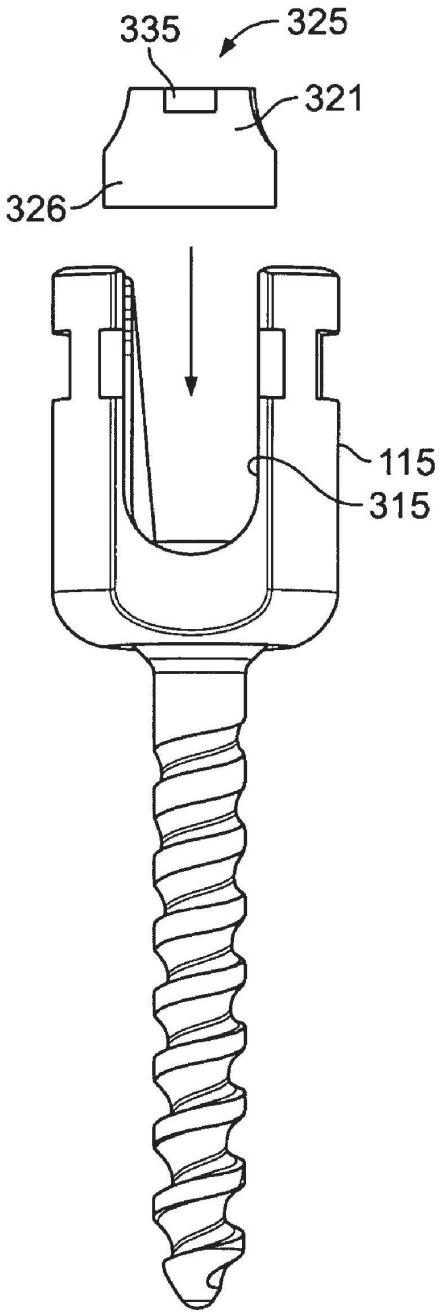


FIG. 7

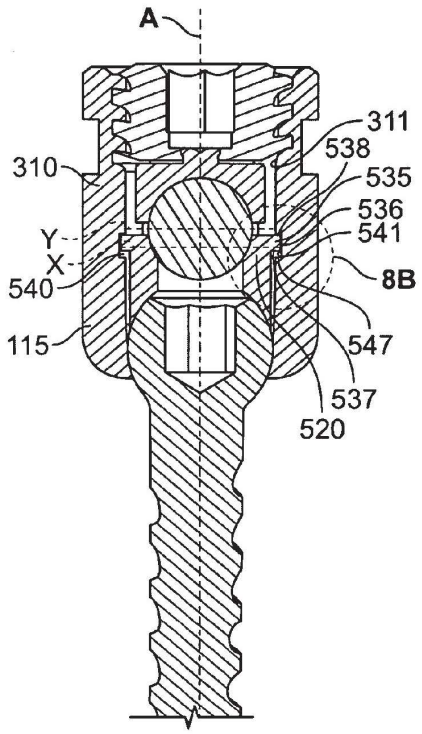

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FIG. 8A

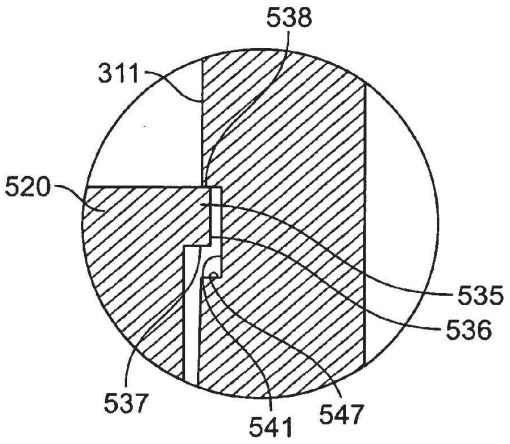

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FIG. 8B

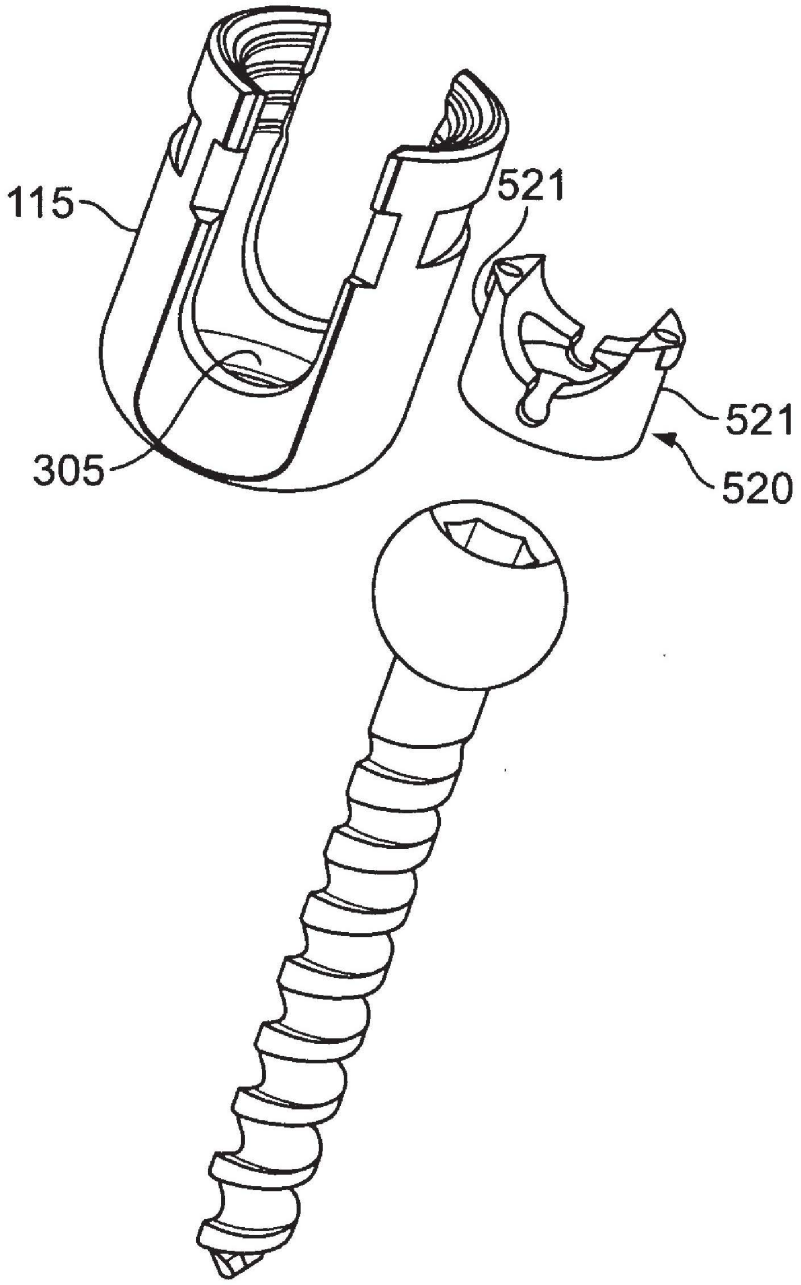


FIG. 9

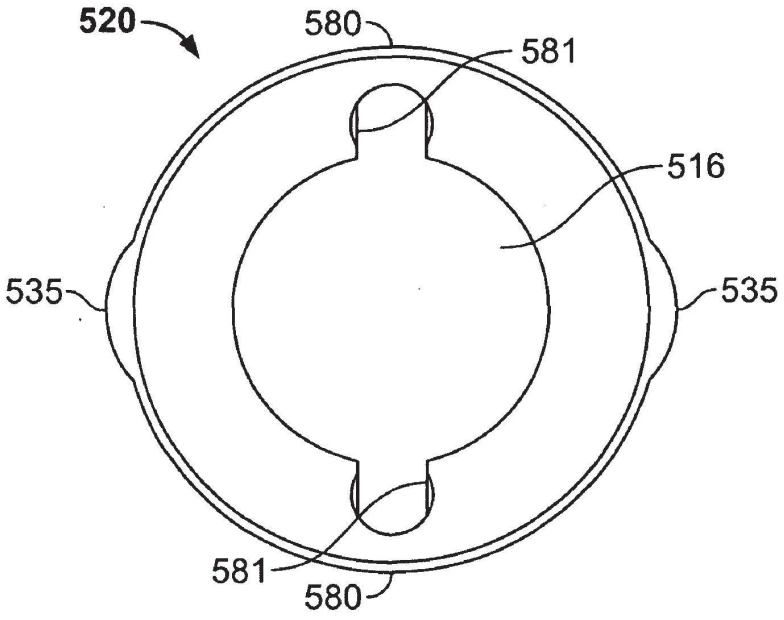


FIG. 10A

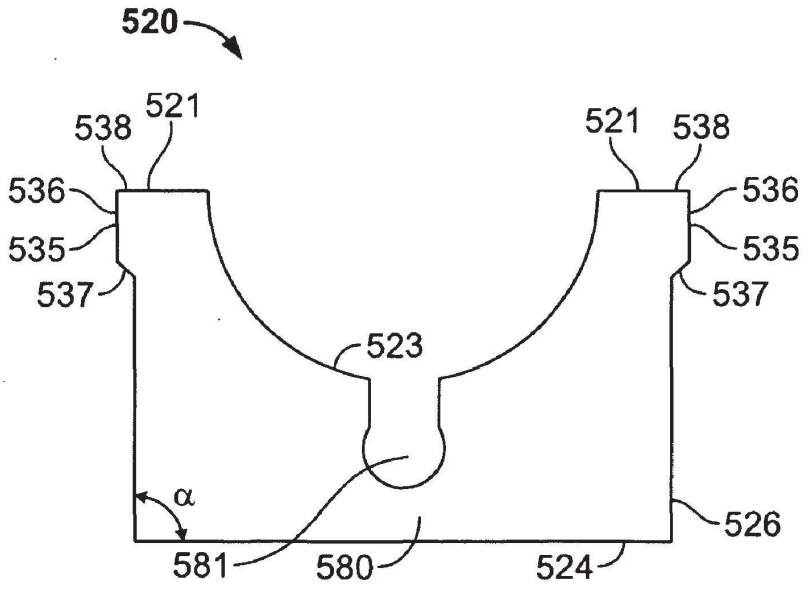


FIG. 10B

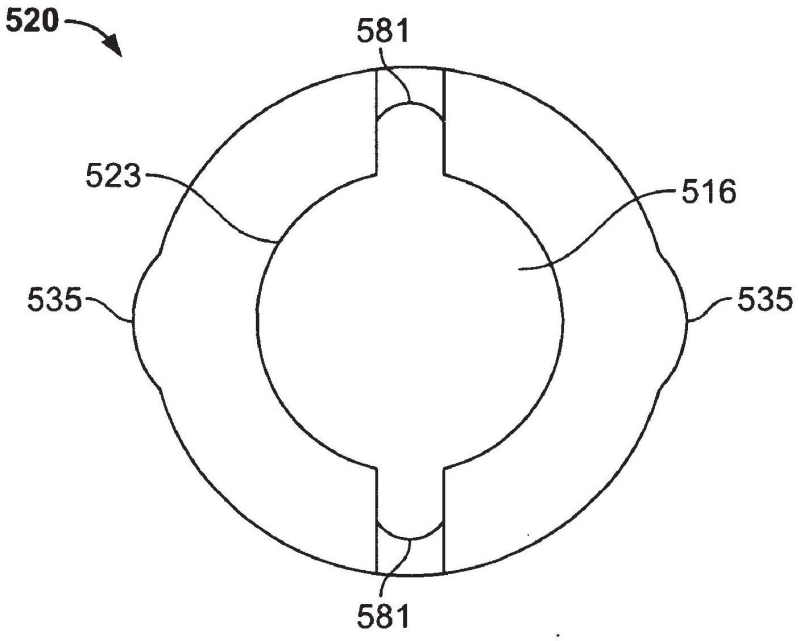


FIG. 10C

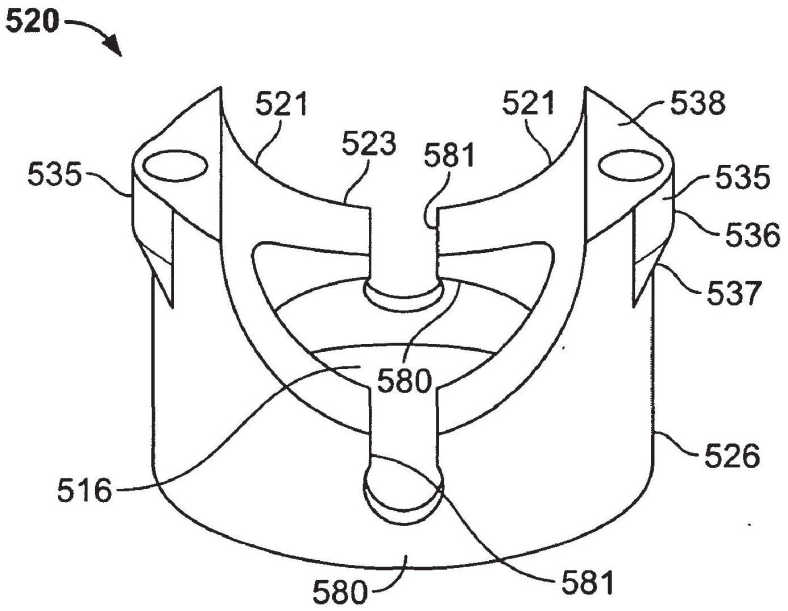


FIG. 10D

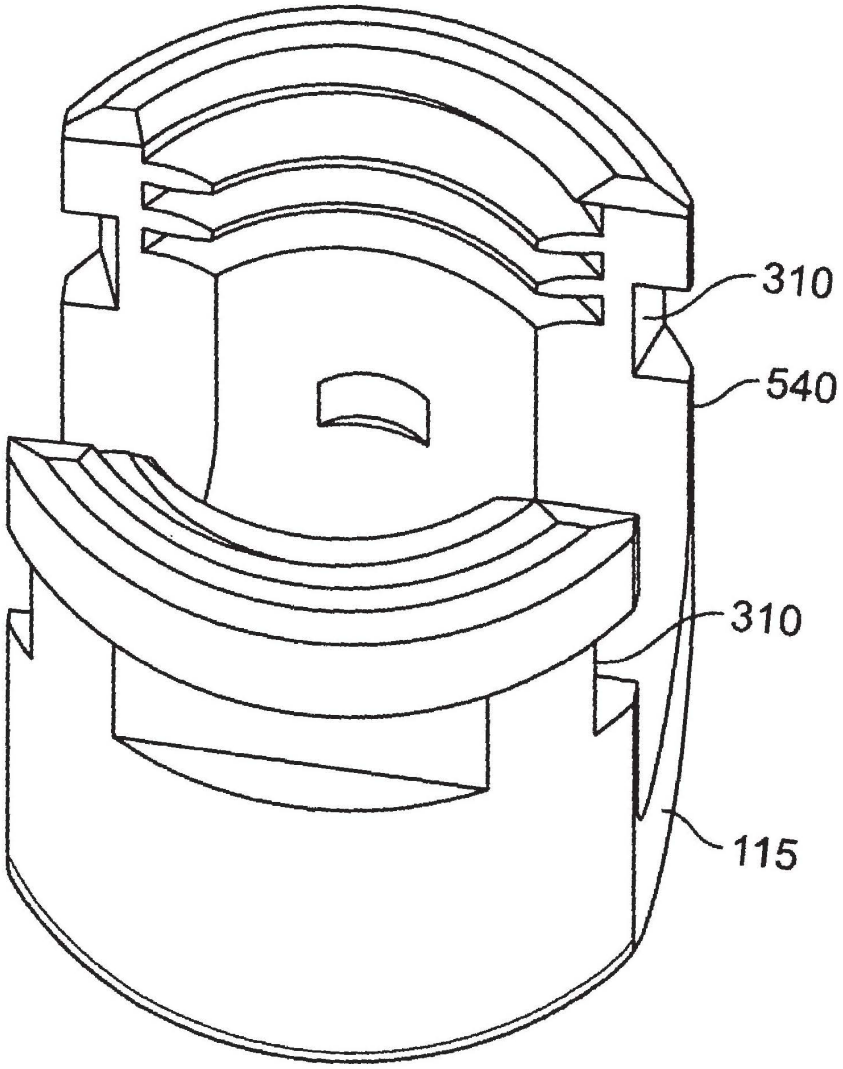


FIG. 11

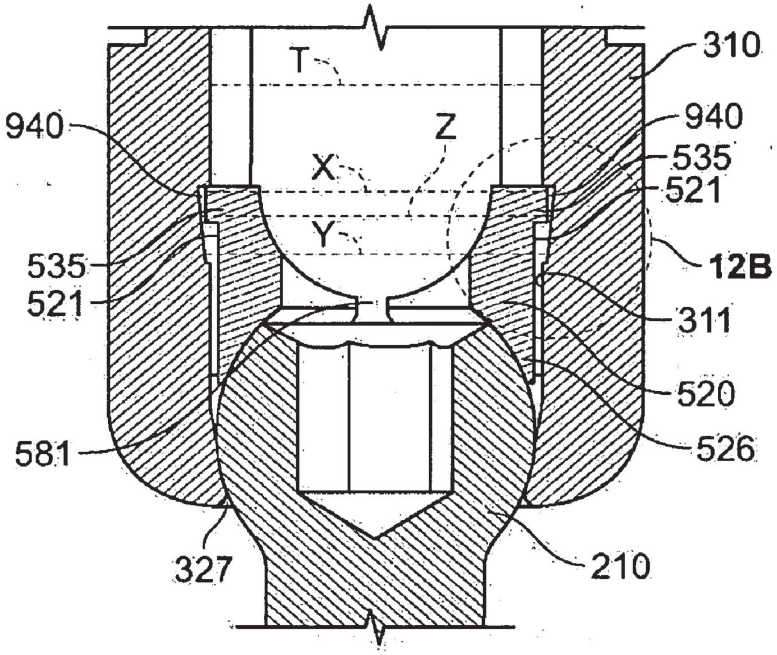


FIG. 12A

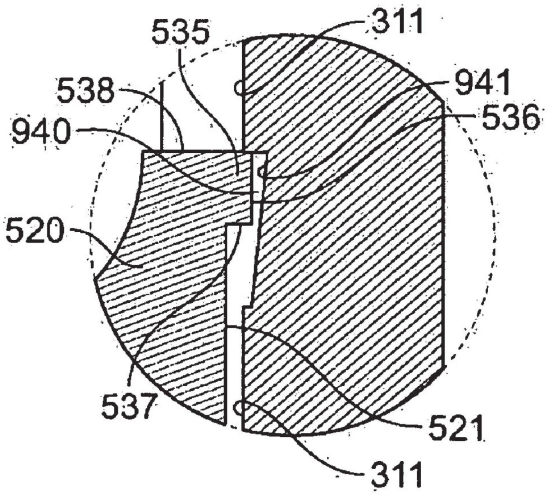


FIG. 12B

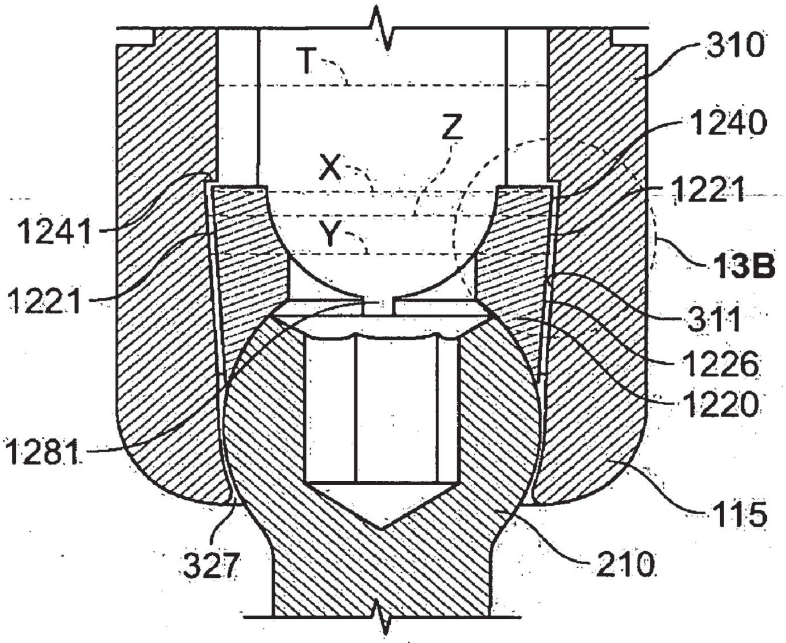


FIG. 13A

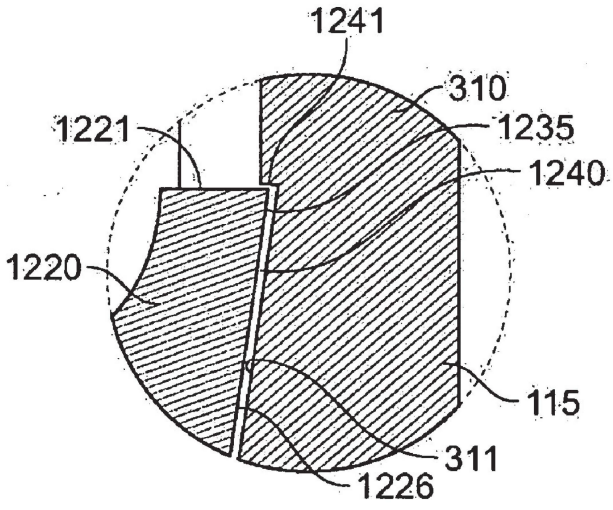


FIG. 13B

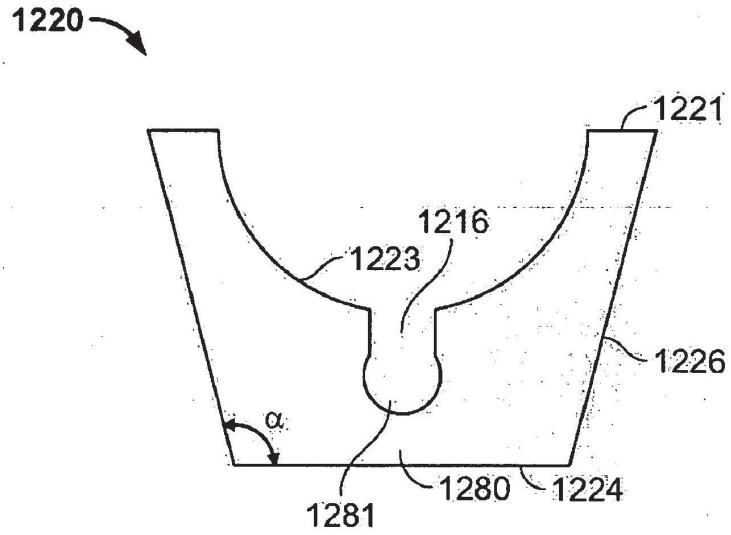


FIG. 14A

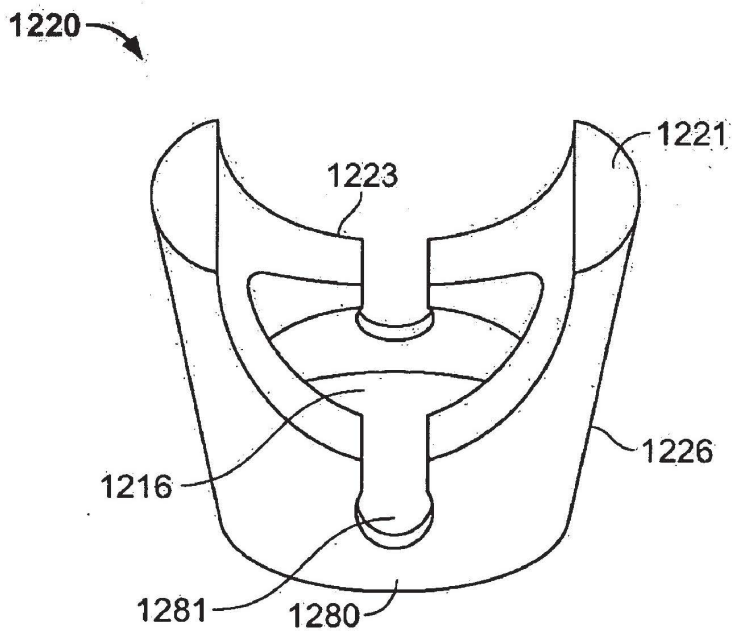


FIG. 14B

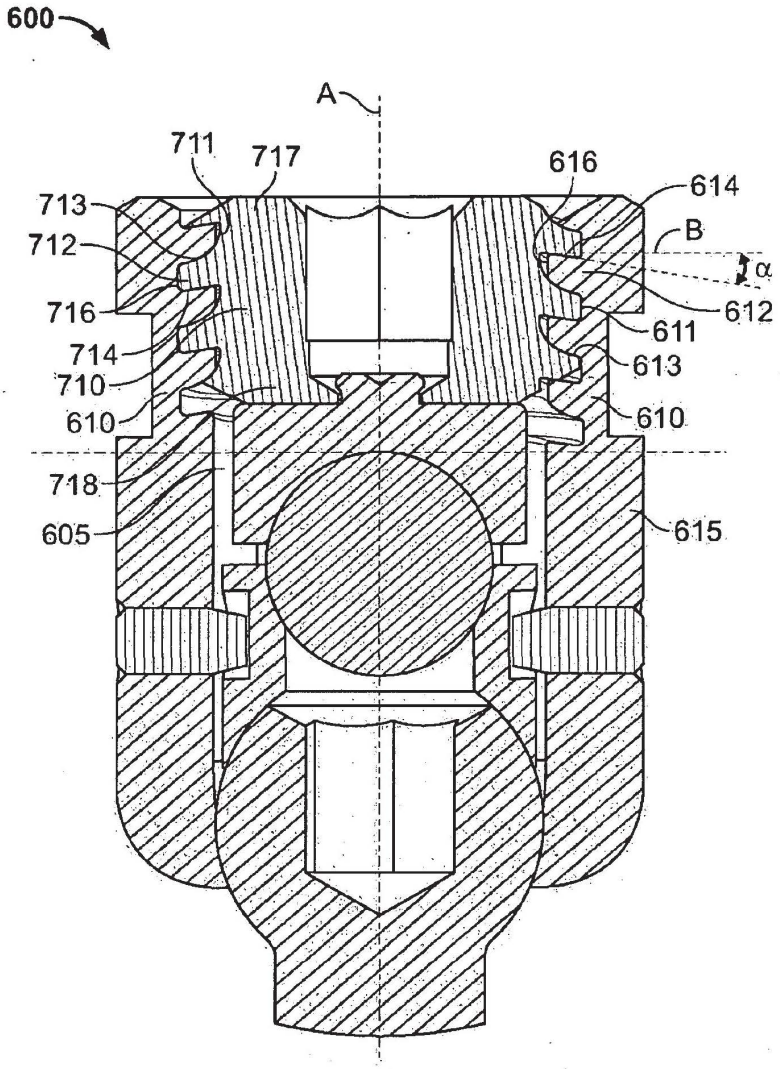


FIG. 15a

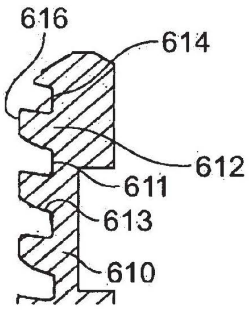


FIG. 15b

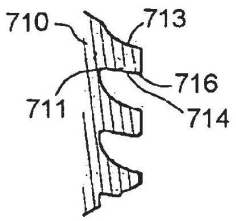


FIG. 15c

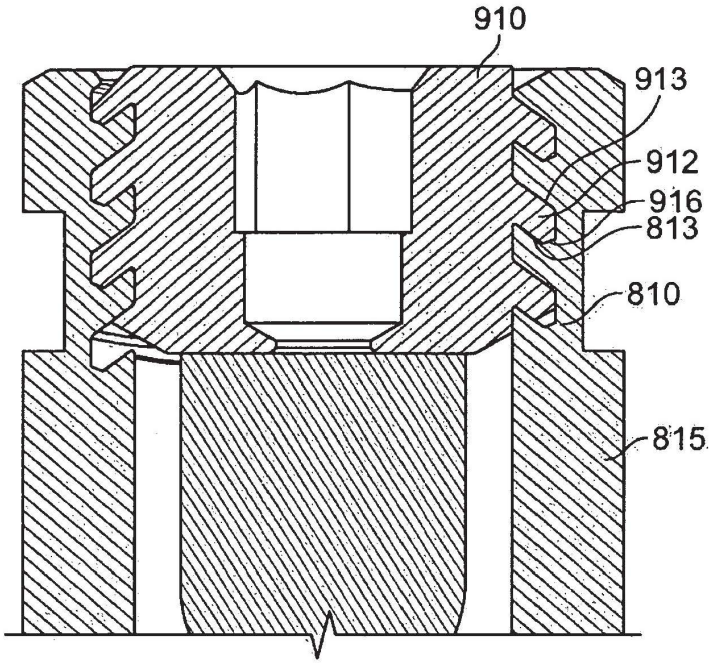


FIG. 16

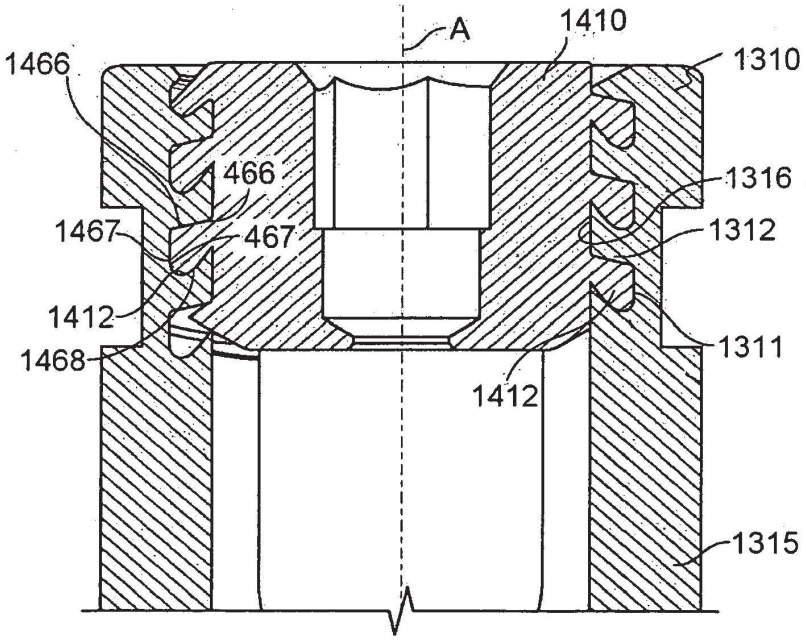


FIG. 17a

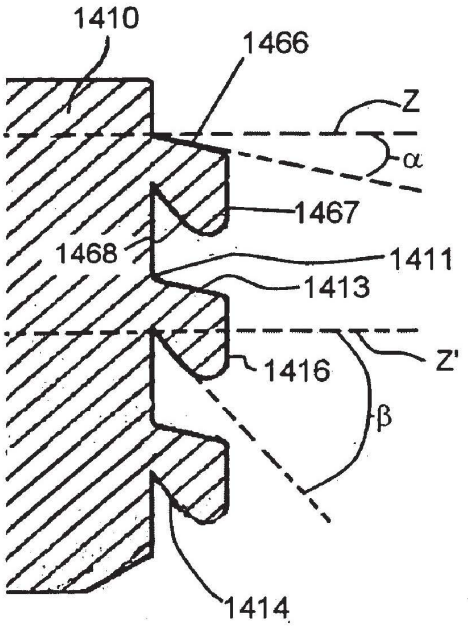


FIG. 17B

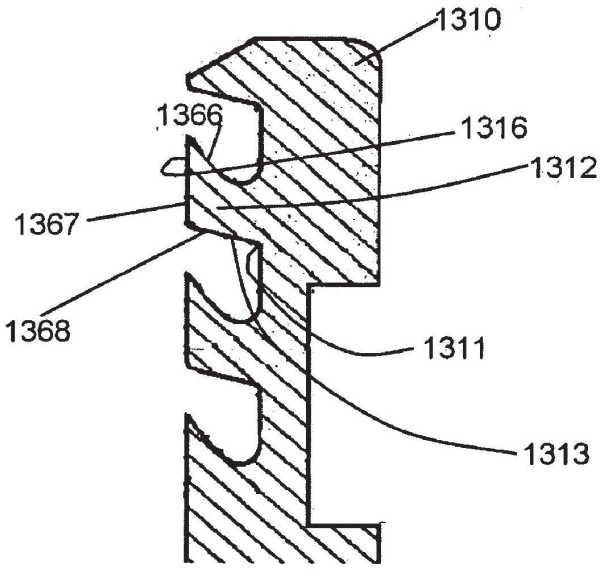


FIG. 17C

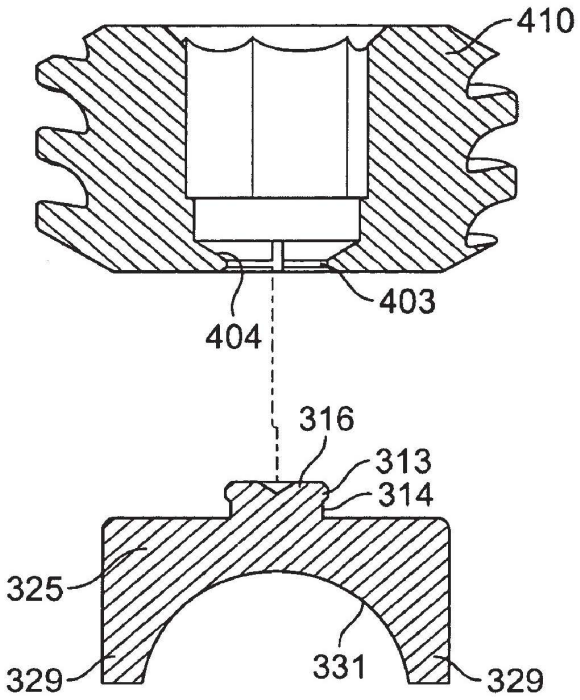


FIG. 18A

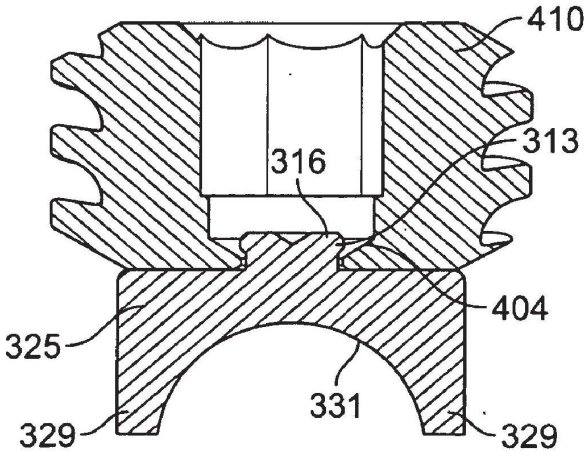


FIG. 18B

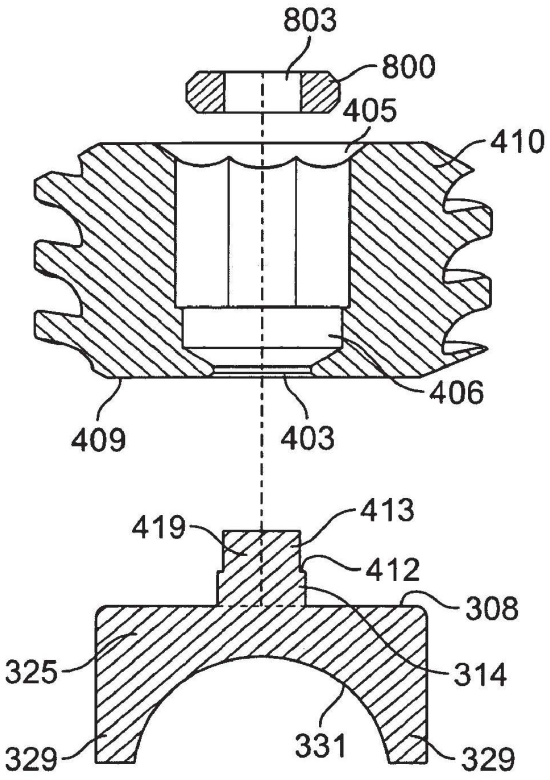


FIG. 19A

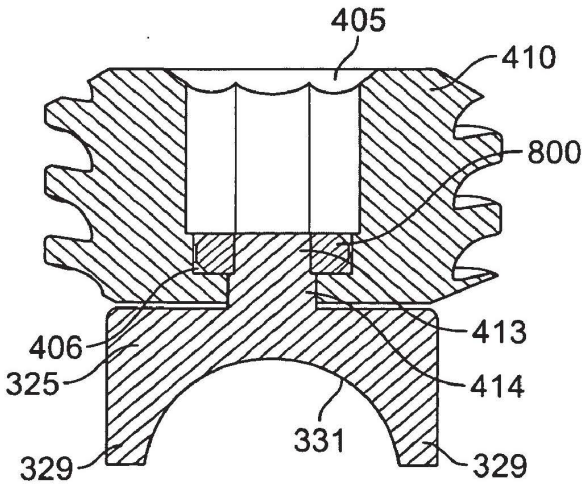


FIG. 19B

PEDICLE SCREW ASSEMBLY

BACKGROUND

[0001] This disclosure is directed at skeletal bone fixation systems, and more particularly to a fixation assembly for vertebrae of a spinal column.

[0002] Spinal fixation systems are used to secure sections of the spinal column, such as vertebral bodies, into a fixed position to correct spinal injuries and defects. Internal fixation is used most frequently in the spine in conjunction with vertebral fusion, and also for the manipulation of the spine to correct spinal deformities. A typical spinal fixation assembly includes a fixation device, such as a screw or hook, that can be attached to a portion of a first vertebral body. The screw can be coupled to a stabilization member, such as an elongate rod, that can be linked to one or more additional vertebral bodies using additional screws.

[0003] Pursuant to a general process, two or more bone screws and/or hooks are secured to a vertebral body that is to be stabilized. After the screws are secured to the vertebral bodies, the screws are coupled to a spinal stabilization rod that restricts movement of the stabilized vertebra. It is important that the screws have a secure coupling with the spinal stabilization rod in order to prevent movement of the rod relative to the screw after placement.

[0004] In several available pedicle screw systems, a tulip-like coupling element with opposing upright arms or walls is used to secure the pedicle screw to the rod. The coupling element and pedicle screw are configured to be coupled to an elongate stabilizer, such as a rod, that is positioned above the head of the pedicle screw. A compression member, such as a compression nut, is configured to mate with the coupling element and provides a compressive force to the rod. The rod is then forced against the head of the pedicle screw, and that force is translated to the coupling element. Accordingly, the forces generated by the compression nut clamp the rod and pedicle screw head together within the coupling element.

[0005] One of the problems with this type of arrangement has been that the shape of the rod and the shape of the pedicle screw head are typically such that the amount of surface area contact between the two is limited. Rods are usually cylindrical and pedicle screw heads are usually either flat or hemispherical. The resulting contact area is relatively small, increasing the potential for slippage and failure in the pedicle screw system.

[0006] Another problem is that the upright legs or walls of the coupling element can experience splaying after implantation. Significant splaying of the arms generally results in failure of the coupling element, since the compression member or nut can no longer be retained in the coupling element to clamp the rod against the pedicle screw head. As a result, the rod is free to move relative to the coupling element, causing a failure that reduces or eliminates the effectiveness of the pedicle screw system.

[0007] Yet another problem is that the forces exerted on the coupling element can cause minute movement or rotation in the compression nut. As a result, the clamping force on the rod is reduced, potentially causing a failure in the pedicle screw system that can reduce or eliminate the effectiveness of the system.

[0008] Pedicle screw implantation procedures are costly, risky and result in painful and lengthy recovery for the patient. Thus, it is important that multiple surgeries to resolve failures in the implants be avoided. Furthermore, it can be a tedious process to position the screws on the vertebral bodies and to interconnect them with the stabilizing rod. Thus, it is desirable that the screws be easily attached to the rods and that, once attached, the coupling between the screw and rod be secure and not prone to failure. In view of the foregoing, there is a need for improved pedicle screw systems.

SUMMARY

[0009] Disclosed are bone stabilization assemblies for use in skeletal systems. In one aspect, a bone stabilizer assembly includes a fixation element, a coupling element, a saddle, a compression nut, and retention means for retaining the saddle in the coupling element in a floating configuration that permits a predetermined amount of movement between the saddle and the coupling element. The fixation element is adapted to engage a bone and has a head portion and shank portion. The coupling element has an internal bore sized to receive the shank portion of the fixation element and a seat adapted to support the head portion of the fixation element. The coupling element is also adapted to receive a stabilizer rod. The saddle is movably mounted in the coupling element below the stabilizer rod when the stabilizer rod is in the coupling element. The compression nut is engagable with the coupling element. The compression nut is adapted to rotatingly move distally into the coupling element to translate a force to the head portion through the rod and the saddle such that the head portion is forced against the seat of the coupling element to prevent relative movement between the fixation element and the coupling element.

[0010] In another aspect, a bone stabilizer assembly includes a fixation element, a coupling element, and a saddle. The fixation element is adapted to engage a bone and has a head portion and shank portion. The coupling element has an internal bore sized to receive the shank portion of the fixation element and a seat adapted to support the head portion of the fixation element. The coupling element further includes a pair of opposed walls separated by a stabilizer rod-receiving channel. Inner surfaces of the opposed walls include inner threads for mating with a compression nut and opposing indentations located below the inner threads. The saddle is movably mounted in the coupling element below the stabilizer rod when the stabilizer rod is in the coupling element. The saddle includes a pair of opposed walls separated by a rod-receiving region. Outer surfaces of the opposed walls include opposing protrusions that extend laterally from the walls. The protrusions are adapted to engage the opposing indentations in the opposed walls of the coupling element so as to retain the saddle within the coupling element when the stabilizer rod is disengaged from the coupling element.

[0011] In another aspect, a bone stabilizer assembly includes a coupling element and a compression nut. The coupling element includes a plurality of wall sections defining a longitudinal bore. The coupling element also includes a transverse channel substantially perpendicular to the bore. The compression nut includes a substantially cylindrical engagement portion having a longitudinal axis. A thread is formed on the engagement portion so that the engagement

portion is adapted to be threadedly engaged within the bore to the wall sections. The thread has a profile that has a rotation stiffening component and an anti-splay component. The rotation stiffening component and the anti-splay component are integrated.

[0012] In another aspect, a bone stabilizer assembly includes a coupling element, and a compression nut. The coupling element includes a plurality of wall sections defining a longitudinal bore and a transverse channel substantially perpendicular to the bore. The compression nut includes a substantially cylindrical engagement portion having a longitudinal axis and a thread formed on the engagement portion so that the engagement portion is adapted to be threadedly engaged within the bore to the wall sections. The thread is sloped in a distal direction from a root of the thread to a crest of the thread.

[0013] The details of one or more embodiments are set forth in the accompanying drawings and the description below. Other features, objects, and advantages will be apparent from the description and drawings, and from the claims.

DESCRIPTION OF DRAWINGS

[0014] FIG. **1***a* is an illustration of a human vertebral column.

[0015] FIG. **1***b* is a superior view of a typical human vertebra.

[0016] FIG. **1***c* is a lateral view of the vertebra depicted in FIG. **1***b*.

[0017] FIG. **2** is an illustration of a set of pedicle screws implanted into a human vertebral column

[0018] FIG. **3** shows an exploded view of a bone fixation assembly according to one embodiment.

[0019] FIG. **4** shows a cross-sectional view of the bone fixation assembly depicted in FIG. **3**.

[0020] FIG. **5***a* shows a cross-sectional view of a bone fixation assembly according to another embodiment.

[0021] FIG. **5***b* is a magnified view of region **5***b* depicted in FIG. **5***a*.

[0022] FIG. **6***a* is a side view of the bottom saddle depicted in FIGS. **3**, **4** and **5**.

[0023] FIG. **6***b* is a perspective view of the bottom saddle depicted in FIGS. **3**, **4** and **5**.

[0024] FIG. **7** is a side elevation view of the bottom saddle depicted in FIGS. **6***a* and **6***b* as it is loaded into a bone fixation assembly.

[0025] FIG. **8***a* shows a cross-sectional view of a bone fixation assembly according to another embodiment.

[0026] FIG. **8***b* is a magnified view of region **8***b* depicted in FIG. **8***a*.

[0027] FIG. **9** shows an exploded view of the bone fixation assembly depicted in FIG. **8**.

[0028] FIGS. **10***a*-**10***d* show various views of the saddle depicted in the bone fixation assembly depicted in FIGS. **8** and **9**.

[0029] FIG. **11** is a perspective view of the coupling element depicted in the bone fixation assembly depicted in FIGS. **8** and **9**.

[0030] FIG. **12***a* is a cross-sectional view of a bone fixation assembly according to another embodiment.

[0031] FIG. **12***b* is a magnified view of region **12***b* depicted in FIG. **12***a*.

[0032] FIG. **13***a* is a cross-sectional view of a bone fixation assembly according to another embodiment.

[0033] FIG. **13***b* is a magnified view of region **13***b* depicted in FIG. **13***a*.

[0034] FIG. **14***a* is a side view of the saddle depicted in the bone fixation assembly depicted in FIGS. **13***a* and **13***b*.

[0035] FIG. **14***b* is a perspective view of the saddle depicted in FIG. **14***a*.

[0036] FIG. **15***a* is a cross-sectional view of a bone fixation assembly according to another embodiment.

[0037] FIG. **15***b* is a cross-sectional view of the external threads of the compression nut depicted in FIG. **15***a*.

[0038] FIG. **15***c* is a cross-sectional view of the internal threads of the coupling element depicted in FIG. **15***a*.

[0039] FIG. **16** is a cross-sectional view of a compression element of a bone fixation assembly according to one embodiment.

[0040] FIG. **17***a* is a cross-sectional view of a compression element of a bone fixation assembly according to another embodiment.

[0041] FIG. **17***b* is a cross-sectional view of the external threads of the compression nut depicted in FIG. **17***a*.

[0042] FIG. **17***c* is a cross-sectional view of the internal threads of the coupling element depicted in FIG. **17***a*.

[0043] FIG. **18***a* is a cross-sectional exploded view of a compression nut and top saddle according to one embodiment.

[0044] FIG. **18***b* is a cross-sectional view of the compression nut and top saddle depicted in FIG. **18***a*.

[0045] FIG. **19***a* is a cross-sectional exploded view of a compression nut and top saddle according to another embodiment.

[0046] FIG. **19***b* is a cross-sectional view of the compression nut and top saddle depicted in FIG. **19***a*.

DETAILED DESCRIPTION

[0047] Before discussing the embodiments in detail, it may be helpful to first briefly review the basic devices and concepts used in orthopedic surgery, and particularly spine surgery. Bone stabilization assemblies are commonly used throughout the skeletal system to stabilize broken, fractured, diseased or deformed bones. In particular, pedicle screw systems are particularly well adapted for the fixation and manipulation of the bones of the vertebral column.

[0048] A vertebral pedicle is a dense stem-like structure that projects from the posterior of a vertebra. There are two pedicles per vertebra that connect to other structures (e.g. lamina, vertebral arch). The location of a pedicle P is

illustrated in FIGS. **1***b* and **1***c*, which illustrate a typical vertebral column, a superior view of a typical vertebra, and a lateral view of a typical vertebra, respectively.

[**0049**] Bone screws have been used in spinal instrumentation since the 1960s. A pedicle screw is a particular type of bone screw designed for implantation into a vertebral pedicle. Monoaxial pedicle screws are still used quite often, but the current standard for implantation is a polyaxial pedicle screw made of titanium or titanium alloy. Titanium alloy is useful, because it is highly resistant to corrosion and fatigue, and is MRI compatible. The screw is threaded and the head is moveable, allowing it to swivel so as to defray vertebral stress. Polyaxial pedicle screw lengths range from about 30 mm to about 60 mm with diameters ranging from about 5.0 mm to about 8.5 mm.

[**0050**] Pedicle screws are used to correct deformity, and or to treat trauma. They can be used in instrumentation procedures to affix rods and plates to the spine. They can also be used to immobilize part of the spine to assist fusion by holding bony structures together. Although pedicle screws are most often used in the lumbar (lumbosacral) spine, they can be implanted in the thoracic and sacral vertebra. The surgeon uses fluoroscopy, conventional x-ray, and sometimes computer-assisted visualization to determine the depth and angle for screw placement. A receiving channel is drilled and the screw is inserted. The screws themselves do not fixate the spinal segment, but act as firm anchor points that can then be connected with a rod. As shown in FIG. **2**, the screws are placed down the small bony tube created by the pedicle on each side of the vertebra, between the nerve roots. This allows the screws to grab into the bone of the vertebral body, giving them a solid hold on the vertebra. Once the screws are placed, one in each of the two pedicles of each vertebra, they are attached to metal rods that connect the screws together. The screws are placed at two or more consecutive spine segments (e.g., lumbar segment **5** and **6**) and connected by the rods.

[**0051**] Generally, a poly-axial pedicle screw assembly, as described in more detail below, includes a tulip-like coupling element that can be coupled to a fixation element, such as, for example, a screw with a head that removably mates with the coupling element. The coupling element and fixation element are configured to be coupled to an elongate stabilizer, such as a rod, that is positioned between a top and a bottom saddle or between a compression member and bottom saddle. A compression member, such as a compression nut, is configured to mate with the coupling element and provides a compressive force to the top and bottom saddles or to the top of the elongate stabilizer rod to secure the elongate stabilizer rod therebetween. The top and bottom saddles are movably positioned within the coupling element such that they can gradually reposition into a secure engagement with the stabilizer as the compression member provides the compressive force.

[**0052**] Turning now to FIG. **3**, a pedicle screw assembly includes an anchor **105** having a fixation element **110** that is removably coupled to a coupling element **115**. The assembly further includes a stabilizer, such as an elongate rod **120**, that can be compressively secured to the anchor **105**, as described below. As described in detail below, the fixation element **110** can be coupled to a skeletal structure, such as a spinal vertebra by being drilled or screwed into, e.g., a pedicle of a vertebra. The coupling element **115** is used to couple the fixation element **110** to the stabilizer, which can be coupled to multiple fixation elements using additional coupling elements **115**.

[**0053**] The fixation element or pedicle screw **110** can include, for example, an elongate screw having a threaded shank portion **205** with external threads that can be screwed into the bone structure, e.g., pedicle, of a vertebra. A head **210** is positioned at the upper end of the shank portion **205**. The head **210** has a shape, such as a rounded shape, that is configured to mate with a correspondingly-shaped seat structure in the coupling element **115**, as described below. A drive coupler, such as a drive cavity **215** is located within or on the head **210** of the fixation element **110**. The drive cavity **215** has a shape that is configured to receive a device that can impart rotational movement to the fixation element **110** in order to screw the fixation element **110** into a bone structure. For example, the drive cavity **215** can have a hexagonal shape that is configured to receive therein an allen-style wrench.

[**0054**] It should be appreciated that the drive coupler need not be a cavity that mates with an allen-style wrench and that other types of drive couplers can be used. Moreover, the fixation element **110** can be in forms other than a shank, including, for example, a hook or clamp. Indeed, it should be appreciated that any structure or component configured for attachment to a bone structure can be used in place of the shank portion of the fixation element.

[**0055**] The coupling element **115** is configured to receive the fixation element **110** and the elongate rod **120**. The coupling element **115** has an internal bore **305** that extends through the coupling element **115** along an axis A (the axis A is shown in FIGS. **3** and **4**). The internal bore **305** is sized to receive at least the shank portion **205** of the fixation element therethrough. A pair of laterally-opposed, upwardly extending projections **310** is separated by the bore **305**. The projections **310** have internal, threaded surfaces. In addition, a pair of U-shaped channels **315** extends through the coupling element for receiving therein the rod **120**, which extends along an axis that is transverse to the axis A of the bore **305**.

[**0056**] The upper ends of the projections **310** define an entry port that is sized to receive therein a compression nut **410**, as described below. The compression nut **410** is described herein as having outer threads that are configured to mate with the inner threads on the opposed inner surfaces of the projections **310** of the coupling element **115**. As described below, the entry port is sized and shaped to facilitate an easy entry of the compression nut **410** into or over the projections **310** of the coupling element.

[**0057**] A bottom saddle **320** and a top saddle **325** are configured to be positioned within the coupling element **115**. The saddles each define a contact surface **330** (shown in FIG. **3**) that has a contour selected to complement a contour of the outer surface of the rod **120**. In one embodiment, the contact surfaces **330** have rounded contours that complement the rounded, outer surface of the rod **120**. However, the contact surfaces **330** can have any shape or contour that complement the shape and contour of the rod **120**. The contact surfaces **330** can also be roughed, serrated, ribbed, or otherwise finished to improve the frictional engagement between the saddles **320**,**325** and the rod. The rod **120** can

also be correspondingly roughed, serrated, ribbed, or otherwise finished to further improve the frictional engagement between saddles **320**, **325** and the rod.

[**0058**] The complementing shapes and contours between the contact surfaces **330** and rod **120** provide a maximum amount of contact area between the saddles **320**, **325** and rod **120**. For example, the rod **120** is shown having a rounded or convex outer surface. The contact surfaces **330** of the saddles **320**, **325** are correspondingly rounded or concave such that the elongate rod **120** can fit snug between the saddles **320**, **325** with the contact surfaces **330** of the saddles **320**, **325** providing a wide area of contact with the outer surface of the elongate rod **120**. It should be appreciated that the contour and shape of the contact surfaces **330** can be varied to match any contour of the outer surface of the elongate rod **120** or in any manner to maximize the amount of grip between the saddles and the elongate rod.

[**0059**] During assembly of the device, the shank portion **205** of the fixation element **110** is inserted through the bore **305** in the coupling element **115**. The rounded head **210** abuts against and sits within a correspondingly-shaped seat **327** in the bottom of the coupling element **115** in a ball/socket manner, as shown in the cross-sectional view of FIG. **4**. The seat **327** can have a rounded shape that is configured to provide a secure fit between the head **210** and the coupling element **115**. Because the seat **327** is rounded, the head **210** can be rotated within the seat **327** to move the axis of the shank portion **205** to a desired orientation relative to the coupling element **115** and thereby provide a poly-axial configuration.

[**0060**] With the fixation element **110** seated in the coupling element **115**, an operator can position the assembly relative to a bone structure such as a vertebra. When the device is fully assembled, the operator can couple a drive device (such as an Allen wrench) to the drive cavity **215** in the head **210** and rotate the fixation element **110** to drive the shank portion **205** into a vertebra or other bone structure. As mentioned, the bottom saddle **320** has an internal bore that is sized to receive therethrough the drive device to provide access to the head **210** of the fixation element **110**.

[**0061**] The rod **120** is loaded into the coupling element **115** by inserting the rod downwardly between the projections **310** through the u-shaped channels **315**, as shown in FIG. **3**. As the rod **120** is moved downwardly into the coupling element **115**, the outer surface of the rod **120** will eventually abut and sit against the corresponding rounded contact surface **330** of the bottom saddle **320**. The compression nut **410** and attached upper saddle **325** are then threaded downward into the coupling element **115** by mating the external threads on the compression nut **410** with the internal threads on the projections **310** of the coupling element **115**. The compression nut **410** can be threaded downward until the rod **120** is compressed between the top and bottom saddles, with the compression nut **410** providing the compression force.

[**0062**] As mentioned, the coupling element **115** has an entry port for the compression nut **410** that facilitates entry or coupling of the compression nut **410** into the coupling element **115**. The entry port is defined by the upper edges of the projections **310**. The entry port has a structure that guides the compression nut into a proper engagement with the coupling element **115**. For example, one or more large chamfers **425** are located on the upper, inner edge of the projections **310** of the coupling element **115** to provide ease of entry for the compression nut **410** into the coupling element **115**. In one embodiment, the chamfers **425** are angled with the angle being in the range of thirty degrees to sixty degrees relative to vertical axis A, although the angle can vary. The chamfers **425** guide the compression nut **410** into proper alignment with the coupling element **115** such that the threads on the compression nut properly engage the threads on the opposed projections **310** without any cross-threading.

[**0063**] The compression nut **410** is then threaded downwardly by repeatedly rotating the compression nut **410** about a 360 degree rotation. As the compression nut **410** lowers into the coupling element, the rounded contact surface **330** of the top saddle **325** abuts the rod **120** and compresses the rod **120** against the rounded contact surface **330** of the bottom saddle **320**, as shown in FIG. **4**. As mentioned the bottom saddle **320** has a floating arrangement with the coupling element **115** and the top saddle **325** is movable and rotatable relative to the compression nut **410**. This permits the saddles to gradually reposition themselves into a secure purchase with the rod **120** as the compression nut **410** moves downward. The contact surfaces **330** of the saddles **320**, **325** provide a continuous and maximized area of contact between the saddles **320**, **325** and the rod **120** for a secure and tight fit therebetween.

[**0064**] Moreover, the top saddle **325** is shaped so that opposed wings or protrusions **329** are located on opposed sides of the top saddle **325** (see FIGS. **16-17**). The opposed protrusions **329** are positioned on either side of the rod **120** so as to automatically guide the saddle **325** into alignment with the rod **120** as the saddle **325** lowers onto the rod. Because the top saddle **325** can freely rotate as the compression nut lowers onto the rod **120**, the protrusions **329** will abut opposed sides of the rod **120** as the top saddle **325** is lowered into the coupling element **115**. The top saddle **325** thus self-aligns into a secure engagement with the rod **120** as the top saddle **325** is lowered onto the rod **120**.

[**0065**] In one embodiment, the protrusions **329** of the top saddle are formed by a concave contour of the top saddle contact surface **330**. It should be appreciated that the protrusions **329** need not be formed from curved surfaces, but can also be formed from straight surfaces. Moreover, the protrusions **329** need not be formed from a continuous, elongated surface, but can rather comprise one or more discrete protrusions, such as spikes, that extend downwardly from the top saddle **325**.

[**0066**] As the compression nut **410** is threaded downward, the downward force of the compression nut **410** is transferred to the bottom saddle **320** via the top saddle **325** and the rod **120**. This causes the bottom saddle **320** to also move downward so as to press downward against the head **210** of the fixation element **110**. The head **210** is thereby pressed downward into the seat **327** in a fixed orientation. In this manner, the position of the fixation element **110** relative to the coupling element **115** is fixed. That is, the head **210** of the fixation element **110** is pressed downward into the seat **327** of the coupling element **115** with a force sufficient to lock the position of the head **210** relative to the coupling element **115**.

[**0067**] The compression nut **410** can be tightened to provide a sufficient downward force that locks the positions

of the saddles **320**, **325** relative to the coupling element **115** and the elongate rod **120**. The compression nut **410** thereby provides a downward force that locks the relative positions of the elongate rod **120**, saddles **320**, **325**, coupling element **115**, and fixation element **110**. After this is complete, the upper portion of the opposed projections **310** of the coupling element can be snapped off at a predetermined location along the length of the projections **310**.

[**0068**] As discussed, inner threads are located on the opposed inner faces of the projections **310**. The threads extend downwardly along the projections **310** to a depth that is sufficient to provide secure engagement between the threads on the projections **310** and the threads on the compression nut **410** when the compression nut **410** is fully tightened. It should be appreciated that the threads do not have to extend to a depth below the upper surface (identified by line U in FIG. **4**) of the rod **120** when the rod **120** is positioned in the coupling element **115**. In one embodiment, the threads extend to a depth that is above the upper surface (identified by line U) of the rod **120**. The top saddle **325** provides a spacing between the rod **120** and the compression nut **410**, which permits such thread depth.

[**0069**] As shown in FIGS. **3**, **6***a* and **6***b*, the bottom saddle **320** has an internal bore **316** that axially aligns with the bore **305** in the coupling element **115** when the bottom saddle **320** is placed in the coupling element **115**. The bottom saddle **320** has a cylindrical outer surface **326** forming a pair of opposed walls **321** separated by the internal bore **316** and a rod-receiving region **323**. Outer surfaces of the opposed walls **321** include opposing projections **335** that extend laterally from the walls **321**. Each of the projections **335** aligns with a corresponding hole or aperture **340** (shown in FIGS. **3** and **4**) that extends through the coupling element **115**. The opposed walls are generally perpendicular to the base **324** of the saddle **320**, as indicated by angle α shown in FIG. **6**A.

[**0070**] As shown in FIG. **4**, the bottom saddle **320** is secured within the coupling element **115** by positioning the saddle between the projections **310** such that each projection **335** in the bottom saddle **320** is inserted into a corresponding aperture **340** in the coupling element **115**. The bottom saddle **320** is inserted into the coupling element **115** by forcing the saddle **320** down through the projections **310** of the coupling element. The distance X, depicted in FIG. **6***a*, represents the distance between the outer ends **336** of the projections **335**. Distance Y, depicted in FIG. **4**, represents the distance between the inner surfaces **311** of the projections **310** of the coupling element **115**. Distance X is slightly greater than distance Y. Therefore, saddle **320** must be inserted into the coupling element **115** by forcing it downward through the projections **310** against which the projections **335** will scrape. Once the saddle **320** has been pushed down far enough inside the coupling element **115** that the projections **335** line up with the corresponding apertures **340**, the projections **335** will pop into the apertures **340**. The projections **335** are shaped to facilitate insertion and retention of the saddle **320** within the coupling element **115**. As shown in FIGS. **6***a* and **6***b*, the projections **335** have a flat or horizontal proximal surface **338**, a rounded side or lateral surface **336**, and an angled or ramped distal surface **337**. The flat proximal surface **338** prevents the saddle **320** from sliding out of the coupling element **115** in the proximal direction. The angled or ramped distal surface **337** allows the saddle to be guided into the coupling element. The opposed walls **321** can be slightly flexible so that during insertion the walls **321** flex inward toward each other to allow the saddle **320** to be pushed down into the coupling element **115**. Once the projections **335** of the saddle **320** reach the apertures **340** of the coupling element, the walls **321** flex back to their natural position and the projections **335** pop into the apertures **340**.

[**0071**] The apertures **340** can be round, rectangular, square, oval or any other shape that can receive the projections **335** in a manner that allows the saddle **320** to float in the coupling element **115**. Likewise, rather than the shape described above, the projections **335** can be cylindrical, conical, block (rectangular or square), or any other shape that fits within the apertures **340** in a manner that allows the saddle to float in the coupling element **115**.

[**0072**] Alternatively, the saddle **320** can be inserted into the coupling element **115** in the manner shown in FIG. **7**. The saddle **320** is first rotated so that the walls **321** are aligned with the U-shaped channels **315** rather than the projections **310** of the coupling element **115**. The diameter of the cylindrical outer surface **326** of the saddle **320** is slightly smaller than the distance Y between the inner surfaces **311** of the projections **310** of the coupling element **115** so that the saddle **320** slides freely into the coupling element **115** without any significant frictional engagement between the saddle **320** and coupling element **115**. Once the projections **335** are at the same level as the apertures **340**, the saddle **320** is rotated about 90° until the projections **335** pop into the apertures **340**. As the saddle is rotated, the projections **335** will scrape against the inner surfaces **311** of the projections **310**. The rounded lateral surface **336** of the projections **335** facilitate the rotation of the saddle **320**.

[**0073**] As best seen in FIG. **4**, the diameter of the aperture **340** can be greater than the distance between the proximal end **338** of the projection **335** and the distal end **337** of the projection **335** by between about 1.0 mm and about 3 mm. In one embodiment, the diameter of the aperture **340** is about 1.0 mm greater than the distance between the proximal end **338** of the projection **335** and the distal end **337** of the projection **335**, allowing about 1.0 mm of play between the bottom saddle **320** and the coupling element **115**. The diameter of the cylindrical outer surface **326** of the bottom saddle is also less than distance Y between the projections **310**. These dimensions permit the bottom saddle **320** to "float" in the coupling element **115** such that the position and the orientation of the bottom saddle **320** can be varied slightly. That is, the bottom saddle **320** can be moved slightly upward or downward and from side to side when mounted in the coupling element **115**. The bottom saddle **320** can also rotate slightly when mounted in the coupling element **115**. Thus, the bottom saddle **320** can movingly adjust into a secure engagement with the elongate rod **120** when compressed against the elongate rod **120** during assembly, as described below. It can also movingly adjust into a secure engagement with the head portion **210** of the fixation element **110** when pushed down against the head portion **210** by the elongate rod **120**.

[**0074**] In another embodiment, as shown in FIGS. **5***a* and **5***b*, the coupling element **115** has a channel **440** rather than apertures **340**. Each of the projections **310** of the coupling element **115** has a channel **440** bored into it, and the channels

440 are aligned with one another and face one another as shown in FIG. **5***a*. The projections **435** of the saddle **320** can be mated with the channels **440** so as to retain the bottom saddle **320** within the coupling element **115**. The saddle **320** shown in FIGS. **5***a* and **5***b* can have the same projections **335** as shown in FIGS. **6***a* and **6***b*, or it can have square or rectangular block projections **435** as shown in FIGS. **5***a* and **5***b*.

[**0075**] As shown in closer detail in FIG. **5***b*, the lateral ends **436** of the saddle **320** do not make contact with the lateral surface **441** of the channel **440**. In other words the distance between the lateral surfaces **441** of the two projections **310** is greater than the distance between the lateral ends **436** of the projections **435** of the bottom saddle **320**. Thus, there is no axial force or frictional engagement between the projections **435** and the channels **440**. This permits some play between the bottom saddle **320** and the coupling element **115**. In addition, the height of the projections **435** (i.e., the distance between the proximal surface **438** and distal surface **437** of the projections **435**) is between about 1.0 mm and 3.0 mm less than the height of the channels **440** (i.e., the distance between the proximal inner surface **448** and distal inner surface **447** of the channels **440**). In one embodiment, the height of the channels **440** is about 1.0 mm greater than the height of the projections **435**, allowing about 1.0 mm of play between the bottom saddle **320** and the coupling element **115**. The diameter of the cylindrical outer surface **326** of the bottom saddle is also less than distance Y between the projections **310**. These dimensions permit the bottom saddle **320** to "float" in the coupling element **115** such that the position and the orientation of the bottom saddle **320** can be varied slightly. That is, the bottom saddle **320** can be moved slightly upward or downward and from side to side when mounted in the coupling element **115**. The bottom saddle **320** can also rotate slightly when mounted in the coupling element **115**. Thus, the bottom saddle **320** can movingly adjust into a secure engagement with the elongate rod **120** when compressed against the elongate rod **120** during assembly, as described below. It can also movingly adjust into a secure engagement with the head portion **210** of the fixation element **110** when pushed down against the head portion **210** by the elongate rod **120**.

[**0076**] The saddle **320** can be inserted into the coupling element **115** in a manner similar to that shown in FIG. **7**. The saddle **320** is first rotated so that the walls **321** are aligned with the U-shaped channels **315** rather than the projections **310** of the coupling element **115**. The diameter of the cylindrical outer surface **326** of the saddle **320** is slightly smaller than the distance Y between the inner surfaces **311** of the projections **310** of the coupling element **115** so that the saddle **320** slides freely into the coupling element **115** without any significant frictional engagement between the saddle **320** and coupling element **115**. Once the projections **435** are at the same level as the channels **440**, the saddle **320** is rotated until the projections **435** slide into the channels **440**. The channels **440** can extend along the entire circumference or length of the inner surfaces **311** of the projections **435** so that the projections **435** slide into the channels **440** without running into or contacting the projections **435**.

[**0077**] FIGS. **8-11** describe another embodiment, which differs from the other embodiments only with respect to the bottom saddle **520** and retention means for the bottom saddle **520** within the coupling element **115**. The bottom saddle depicted in FIGS. **8-11** is designed to permit the opposed walls **521** to tilt toward one another in response to compression forces, and to spring back to their original or resting parallel orientation in the absence of compression forces.

[**0078**] As shown in FIGS. **10***a*-**10***d*, the bottom saddle **520** has an internal bore **516** that axially aligns with the bore **305** in the coupling element **115** when the bottom saddle **520** is placed in the coupling element **115**. The bottom saddle **520** has a cylindrical outer surface **526** forming a pair of opposed walls **521** separated by the internal bore **516** and a rod-receiving region **523**. Opposed walls **521** are generally perpendicular to the base **524** of the bottom saddle **520**, as indicated by angle α shown in FIG. **10**A. Outer surfaces of the opposed walls **521** include opposing projections **535** that extend laterally from the walls **521**. Each of the projections **535** aligns with a corresponding cavity **540** (shown in FIG. **11**) that is carved into each of the projections **310** of the coupling element **115**. The opposed walls **521** of the saddle **520** are connected to one another by a pair of flexible joints **580** that permit the opposing walls **521** to tilt toward one another in response to compression forces, and to spring back to their original or resting parallel orientation in the absence of compression forces. The flexible joints **580** are formed by a pair of keyhole slots **581** carved into the cylindrical portion **526** of the bottom saddle **520**. The keyhole slots **581** are opposite each other and are each aligned about 90° away from each of the projections **535**. Consequently, the flexible joints **580** are opposite each other and are each aligned about 90° away from each of the projections **535**. The keyhole slots **581** and the flexible joints **580** permit the opposed walls **521** to be squeezed toward one another in response to a compressive force and to spring back into a resting parallel orientation in the absence of a compressive force.

[**0079**] As shown in FIG. **8**, the bottom saddle **520** is secured within the coupling element **115** by positioning the saddle between the projections **310** such that each projection **535** in the bottom saddle **520** is inserted into a corresponding cavity **540** in the coupling element **115**. The bottom saddle **520** is inserted into the coupling element **115** by forcing the saddle **520** down through the projections **310** of the coupling element. The distance X, depicted in FIG. **8***a*, represents the distance between the lateral surface **536** of the projections **535**. Distance Y, depicted in FIG. **8***a*, represents the distance between the inner surfaces **311** of the projections **310** of the coupling element **115**. Distance X is slightly greater than distance Y. Therefore, the saddle **520** must be inserted into the coupling element **115** by forcing it downward through the projections **310** against which the projections **535** will scrape. The opposed walls **521** of the saddle **520** can be squeezed toward one another because of the flexible joints **580** and keyhole slots **581** (shown in FIG. **10***b*). Once the saddle **520** has been pushed down far enough inside the coupling element **115** that the projections **535** line up with the corresponding cavities **540**, the projections **535** will pop into the cavities **540**. The projections **535** are shaped to facilitate insertion and retention of the saddle **520** within the coupling element **115**. As shown in FIGS. **10***c* and **10***d*, the projections **535** have a flat or horizontal proximal surface **538**, a rounded side or lateral surface **536**, and an angled or ramped distal surface **537** (alternatively, the distal surface **537** can be horizontal or flat). The flat proximal surface **538** prevents the saddle **520** from sliding out of the coupling

element **115** in the proximal direction. The angled or ramped distal surface **537** allows the saddle to be guided into the coupling element **115**. The opposed walls **521** are flexible so that during insertion the walls **521** flex inward toward each other to allow the saddle **520** to be pushed down into the coupling element **115**. Once the projections **535** of the saddle **520** reach the cavities **540** of the coupling element **115**, the walls **521** flex back to their natural or resting position and the projections **535** pop into the cavities **540**.

[**0080**] The cavities **540** can be round, rectangular, square, oval or any other shape that can receive the projections **535** in a manner that allows the saddle **520** to float in the coupling element **115**. Likewise, rather than the shape described above, the projections **535** can be cylindrical, conical, block (rectangular or square), or any other shape that fits within the cavities **540** in a manner that allows the saddle **520** to float in the coupling element **115**.

[**0081**] Alternatively, the saddle **520** can be inserted into the coupling element **115** in the manner shown in FIG. **7**. The saddle **520** is first rotated so that the walls **521** are aligned with the U-shaped channels **315** rather than the projections **310** of the coupling element **115**. The diameter of the cylindrical portion **526** of the saddle **520** is slightly smaller than the distance Y between the inner surfaces **311** of the projections **310** of the coupling element **115** so that the saddle **520** slides freely into the coupling element **115** without any significant frictional engagement between the saddle **520** and coupling element **115**. Once the projections **535** are at the same level as the cavities **540**, the saddle **520** is rotated about 90° until the projections **535** pop into the cavities **540**. As the saddle is rotated, the projections **535** will scrape against the inner surfaces **311** of the projections **310**. The rounded lateral surface **536** of the projections **535** facilitate the rotation of the saddle **520**.

[**0082**] As shown in closer detail in FIG. **5***b*, the lateral ends **436** of the saddle **320** do not make contact with the lateral surface **441** of the cavities **440**. In other words the distance between the lateral surfaces **441** of the two projections **310** is greater than the distance between the lateral ends **436** of the projections **435** of the bottom saddle **320**. Thus, there is no axial force or frictional engagement between the projections **435** and the channels **440**. This permits some play between the bottom saddle **320** and the coupling element **115**. In addition, the height of the projections **435** (i.e., the distance between the proximal surface **438** and distal surface **437** of the projections **435**) is between about 1.0 mm and 3.0 mm less than the height of the channels **440** (i.e., the distance between the proximal inner surface **448** and distal inner surface **447** of the channels **440**). In one embodiment, the height of the channels **440** is about 1.0 mm greater than the height of the projections **435**, allowing about 1.0 mm of play between the bottom saddle **320** and the coupling element **115**. The diameter of the cylindrical portion **326** of the bottom saddle is also less than distance Y between the projections **310**. These dimensions permit the bottom saddle **320** to "float" in the coupling element **115** such that the position and the orientation of the bottom saddle **320** can be varied slightly. That is, the bottom saddle **320** can be moved slightly upward or downward and from side to side when mounted in the coupling element **115**. The bottom saddle **320** can also rotate slightly when mounted in the coupling element **115**. Thus, the bottom saddle **320** can movingly adjust into a secure engagement with the elongate rod **120** when compressed against the elongate rod **120** during assembly, as described below. It can also movingly adjust into a secure engagement with the head portion **210** of the fixation element **110** when pushed down against the head portion **210** by the elongate rod **120**.

[**0083**] Referring now to FIGS. **12***a* and **12***b*, the bottom saddle **520** is the same or substantially the same as bottom saddle **520** shown in FIGS. **8***a*-**10***d*. The bottom saddle **520** is secured within the coupling element **115** by positioning the saddle between the projections **310** such that each projection **535** in the bottom saddle **520** is inserted into a corresponding cavity **940** in the coupling element **115**. The bottom saddle **520** is inserted into the coupling element **115** by forcing the saddle **520** down through the projections **310** of the coupling element. The distance X, depicted in FIG. **12***a*, represents the distance between the outer ends **436** of the projections **535**. Distance T, depicted in FIG. **12***a*, represents the distance between the inner surfaces **311** of the projections **310** of the coupling element **115**. Distance X is slightly greater than distance T. Therefore, saddle **520** must be inserted into the coupling element **115** by forcing it downward through the projections **310** against which the projections **335** will scrape. The opposed walls **521** of the saddle **520** can be squeezed toward one another because of the flexible joints **580** and keyhole slots **581**. Once the saddle **520** has been pushed down far enough inside the coupling element **115** that the projections **535** line up with the corresponding cavities or indentations **940**, the projections **535** will pop into the cavities **940**. The projections **535** are shaped to facilitate insertion and retention of the saddle **520** within the coupling element **115** as described with respect to FIGS. **10***c* and **10***d* above. The opposed walls **521** are flexible so that during insertion the walls **521** flex inward toward each other to allow the saddle **520** to be pushed down into the coupling element **115**. Once the projections **535** of the saddle **520** reach the cavities or indentations **940** of the coupling element **115**, the walls **521** flex back to their natural or resting position and the projections **535** pop into the cavities **940**.

[**0084**] The cavities **940** are aligned with one another, but they are not parallel with one another. Instead, as shown in more detail in FIG. **12***b* and further described below, the cavities **940** are sloped or ramped toward one another in the distal direction.

[**0085**] The cavities **940** each have a proximal region, which is near the top end of the coupling element **115**, a middle region distal the proximal region, and a distal region, which is distal the middle region. The distance Z between the proximal regions of the cavities **940** is greater than the distance X between the outer ends **536** of the projections **535**, and the distance X is greater than the distance Y between the distal regions of the cavities **940**. The proximal region of the cavities **940** each includes a ridge with a drop-off as shown in FIG. **12***b*. A middle region of the cavities **940**, distal the proximal region, forms a ramp that is sloped inward toward a distal direction, wherein the proximal end of the ramp starts at the drop-off and a distal end of the ramp terminates in a distal region that joins the ramp to the inner surface **311** of the wall of the coupling element **115**.

[**0086**] In the proximal regions of the cavities, because distance X is less than distance Z, the projections **535** do not make contact with the inner surface **941** of the cavities.

Thus, there is no axial force or frictional engagement between the projections **535** and the inner surface **941** of the cavities **940** in the proximal region. This permits some play between the bottom saddle **520** and the coupling element **115** when the bottom saddle is in the proximal region of the cavities **940**. In addition, the height of the projections **535** (i.e., the distance between the proximal surface **538** and distal surface **537** of the projections **535**) is between about 1.0 mm and 3.0 mm less than the height of the proximal region of the cavities **940**. In one embodiment, the height of the proximal region of the cavities **940** is about 1.0 mm greater than the height of the projections **535**, allowing about 1.0 mm of play between the bottom saddle **520** and the coupling element **115** when the projections are situated in the proximal region of the cavities **940**. The diameter of the cylindrical portion **526** of the bottom saddle is also less than distance Y between the projections **310**. These dimensions permit the bottom saddle **520** to "float" in the coupling element **115** such that the position and the orientation of the bottom saddle **520** can be varied slightly while the projections **535** are situated in the proximal region of the cavities **940**. That is, the bottom saddle **520** can be moved slightly upward or downward and from side to side when mounted in the coupling element **115** when the projections **535** are situated within the proximal region of the cavities **940**. The bottom saddle **520** can also rotate slightly when mounted in the coupling element **115** when the projections **535** are situated within the proximal region of the cavities **940**.

[**0087**] As the saddle **520** is forced downward in the distal direction, the distance between the inner surfaces **941**, which are in opposite projections **310**, becomes smaller because of the sloped ramps. At some point in the middle region of the cavities **940** the projections **535** make contact with the inner surfaces **941** of the cavities **940**. As the saddle **520** is further forced in the distal direction, inward axial forces are exerted on the projections **535** and the walls **521** are squeezed into frictional engagement with the sloped ramps. The frictional engagement between the opposing projections **535** and the distal region of the opposing cavities **940** maintains the saddle **520** in frictional engagement with the head portion **210** of the fixation element **110** to prevent relative movement between the fixation element **110** and the coupling element **115** when the stabilizer rod is disengaged from the saddle **520** and the saddle **520** engages the fixation element **110**. The fixation element **110** and the coupling element **115** are still manually movable relative to each other in opposition to the frictional engagement when the stabilizer rod is disengaged from the saddle.

[**0088**] FIGS. **13**A-**14**B describe another embodiment, which differs from the previous embodiments only with respect to the bottom saddle **1220** and retention means for the bottom saddle **1220** within the coupling element **115**. Like the bottom saddle shown in FIGS. **10**A-**10**D, the bottom saddle **1220** depicted in FIGS. **13**A-**14**B is designed to permit the opposed walls **1221** to tilt toward one another in response to compression forces, and to spring back to their original or resting parallel orientation in the absence of compression forces. The bottom saddle **1220**, however, does not have projections that extend laterally from its opposed walls **1221**. Instead, the outer surface **1226** of the opposed walls are at an angle α, as shown in detail in FIGS. **14**A and **14**B. In other words, the walls **1221** are not parallel to one another when the walls **1221** are in a resting or uncompressed state. Instead, they extend away from one another from bottom to top such that the angle α between the base **1224** of the bottom saddle **1220** and the outer surface of the walls **1226** is an obtuse angle or greater than 90° when the walls **1221** are in a resting or uncompressed state.

[**0089**] As with previous embodiments, the bottom saddle **1220** has an internal bore **1216** that axially aligns with the bore **305** in the coupling element **115** when the bottom saddle **1220** is placed in the coupling element **115**. The bottom saddle **1220** has a frustoconical outer surface **1226** forming a pair of opposed walls **1221** separated by the internal bore **1216** and a rod-receiving region **1223**. Outer surfaces of the opposed walls **1221** are angled toward one another as explained above. The opposed walls **1221** of the saddle **1220** are connected to one another by a pair of flexible joints **1280** that permit the opposing walls **1221** to tilt toward one another in response to compression forces, and to spring back to their original or resting parallel orientation in the absence of compression forces. The flexible joints **1280** are formed by a pair of keyhole slots **1281** carved into the frustoconical portion **1226** of the bottom saddle **1220**. The keyhole slots **1281** are opposite each other. The keyhole slots **1281** and the flexible joints **1280** permit the opposed walls **1221** to be squeezed toward one another in response to a compressive force and to spring back into a parallel orientation in the absence of a compressive force.

[**0090**] As shown in FIG. **13***a*, the bottom saddle **1220** is secured within the coupling element **115** by positioning the saddle between the projections **310** such that each of the walls **1221** of the bottom saddle is inserted into a corresponding retention region **1240** in the coupling element **115**. The bottom saddle **1220** is inserted into the coupling element **115** by forcing the saddle **1220** down through the projections **310** of the coupling element. The distance X, depicted in FIG. **13***a*, represents the distance between the outer surface **1226** of walls **1221** in the proximal region **1235** of the walls. Distance T, depicted in FIG. **13***a*, represents the distance between the inner surfaces of the projections **310** of the coupling element **115** in a region proximal the retention region of the projections **310**. The inner surfaces of the projections **310** in a region proximal the retention region form a cylinder, such that the walls are parallel to one another. Distance X is slightly greater than distance T. Therefore, the saddle **1220** must be inserted into the coupling element **115** by forcing it downward through the projections **310** against which the proximal region **1235** of the walls **1221** will scrape. The opposed walls **1221** of the saddle **1220** can be squeezed toward one another because of the flexible joints **1280** and keyhole slots **1281**.

[**0091**] The retention region **1240** of the coupling element **115** begins at a proximal ridge **1241** that forms a pop-out with inner surfaces **311**. The inner surfaces **311** are not parallel to one another. Instead, they are angled toward one another from a proximal to a distal direction. The inner surfaces **311** can be parallel with the opposed walls **1221** of the saddle such that opposed walls **1221** and inner surfaces **311** are at the same angle relative to the base **1224** of the saddle. For example, if the walls **1221** are at an angle of about 100° to the base **1224**, then the inner surfaces **311** can also be at an angle of about 100° relative to the base **1224** of the saddle. Alternatively, the inner surfaces **311** can form a greater angle relative to the base **1224** than the opposed walls **1221**, so that the opposed walls **1221** are not parallel to the base **1224**. For example, if the walls **1221** are at an

angle of about 100° to the base **1224**, then the inner surfaces **311** can be at an angle of, e.g., **1050** to the base. The retention regions **1240** of the projections **310** each have a proximal region, which is near the top end of the coupling element **115** just distal the ridge **1241**, a middle region distal the proximal region, and a distal region, which is distal the middle region. The distance X between the proximal regions of the retention region **1240** is greater than the distance X between the outer proximal region **1235** of the walls **1221**. Distance Z decreases in the distal direction, such that distance Y is less than distance X and distance Z. Thus, once the saddle **1220** has been pushed down far enough inside the coupling element **115** that it reaches the retention region **1240**, proximal region **1235** of the walls **1221** will pop into the retention region **1240**. In other words, once the proximal region **1235** of the walls **1221** of the saddle **1220** reach the retention region **1240** of the coupling element **115**, the walls **1221** flex back to their natural or resting position and pop into the proximal region of the retention region **1240** where there is no compressive force against the walls **1221**. Alternatively, the saddle **1220** can be inserted into the coupling element **115** in the manner shown in FIG. **7** and described above.

[**0092**] In the proximal regions of the retention regions **1240**, because distance X is less than distance Z, the proximal region **1235** of the walls **1221** do not make contact with the inner surface **311** of the proximal regions of the retention regions **1240**. Thus, there is no axial force or frictional engagement between the proximal region **1235** and the inner surface **311** of the retention region **1240**. This permits some play between the bottom saddle **1220** and the coupling element **115** when the bottom saddle is in the proximal region of the retention region **1240**. At about 1.0 mm below the ridge **1241**, the distance between the inner surfaces **311**, at distance Y, becomes equal to or less than the distance X, and the proximal region **1235** of the walls **1221** makes contact with the inner surface **311** of the retention regions **1240**. This allows about 1.0 mm of play between the bottom saddle **1220** and the coupling element **115** when the proximal regions **1235** of the walls **1221** are situated in the proximal region of the retention region **1240**. These dimensions permit the bottom saddle **1220** to "float" in the coupling element **115** such that the position and the orientation of the bottom saddle **1220** can be varied slightly while the proximal regions **1235***s* are situated in the proximal region of the retention region **1240**. That is, the bottom saddle **1220** can be moved slightly upward or downward and from side to side when mounted in the coupling element **115** when the proximal regions **1235** are situated within the proximal region of the retention region **1240**. The bottom saddle **1220** can also rotate slightly when mounted in the coupling element **115** when the proximal regions **1235** are situated within the proximal region of the retention region **1240**.

[**0093**] As the saddle **1220** is forced downward in the distal direction, the distance between the inner surfaces **311**, which are opposite projections **310**, becomes smaller because of the angled or sloped inner surfaces **311**. At some point in the middle region of the retention region **1240**, as explained above, the proximal regions **1235** make contact with the inner surfaces **311** of the retention region **1240**. As the saddle **1220** is further forced in the distal direction, inward axial forces are exerted on the proximal regions **1235** of the walls **1221**, and the walls **1221** are squeezed into frictional engagement with the sloped surfaces **311** of the retention region **1240**. The frictional engagement between the proximal regions **1235** and the distal region of the retention region **1240** maintains the saddle **1220** in frictional engagement with the head portion **210** of the fixation element **110** to prevent relative movement between the fixation element **110** and the coupling element **115** when the stabilizer rod is disengaged from the saddle **1220** and the saddle **1220** engages the fixation element **110**. The fixation element **110** and the coupling element **115** are still manually movable relative to each other in opposition to the frictional engagement when the stabilizer rod is disengaged from the saddle **1220**.

[**0094**] Referring now to FIGS. **18***a* and **18***b*, the top saddle **325** is rotatingly mounted within a compression nut **410** that has outer threads that are configured to mate with the threads on the internal surface of the opposed projections **310** of the coupling element **115**. In this regard, the top saddle **325** has an upper projection **316** that rotatingly mates with the compression nut **410** and permits the top saddle **325** to rotate and/or tilt relative to the compression nut **410** when attached thereto. The projection **316** has a lip portion **313** and a neck portion **314** connecting the lip portion to the saddle **325**. The lip portion **313** of the projection **316** can be snapped into an opening **403** in the bottom of the compression nut **410**. Once snapped in, the lip portion **313** rests against an angled ledge **404** formed in a bore just above the opening **403** of the compression nut **410**. When attached, the top saddle **325** is positioned immediately below the compression nut **410** and can rotate relative to the compression nut **410**.

[**0095**] In another embodiment shown in FIGS. **19***a* and **19***b* the top saddle **325** has a projection **316** with a neck portion **314** and an lip portion **313**. The circumference of the neck portion **314** is greater than the circumference of the lip portion **313** and a step **312** is formed therebetween. The neck portion **314** and lip portion **313** are inserted through an opening **403** in the bottom of the compression nut **410** that leads to a chamber **406** for receiving a friction nut **800**. The friction nut **800** is inserted through a top opening **405** in the compression nut **410**. The friction nut **800** has a center bore **803** with a circumference that is slightly smaller than the circumference of the lip portion **313** of the projection **316** and significantly smaller than the circumference of the neck portion **314**. The outer circumference of the friction nut **800** is slightly smaller than the circumference of the chamber **406**. The portion of the engagement portion **314** that is inserted into the chamber **406** is threaded through the central bore **803** of the friction nut **800**. The neck portion **314** and central bore **803** are forced into tight frictional engagement with one another so that they cannot be disengaged without significant forces acting on them. The bottom end of the friction nut abuts the step **312**. The circumference of the friction nut **800** allows it to rotate within the chamber **406**. The circumference of the neck portion **314** is dimensioned so that it can rotate within the opening **403**. The neck portion **314** is long enough so that there is a small gap between the top surface **308** of the top saddle **325** and the bottom surface **409** of the compression nut **410**. These dimensions permit the bottom saddle **325** to rotate relative to the compression nut **410**.

[**0096**] In another embodiment, the top saddle **325** is fixedly attached to the compression nut **410** such that it does not rotate relative to the compression nut. In another

embodiment, there is no top saddle and the compression nut directly contacts the stabilizer rod.

[0097] When the compression nut **410** is attached to the top saddle **325**, the compression nut **410** is rotatingly coupled to the coupling element **115** by mating the outer threads of the compression nut **410** with the inner threads of the coupling element **115**. The compression nut **410** is repeatedly rotated over a 360 degree rotational angle to lower the compression nut into the coupling element. The compression nut **410** is described herein as having outer threads that mate with inner threads on the opposed projections **310**. As described below, this advantageously permits a thread configuration that prevents projections **310** from spreading apart from one another as the compression nut **410** is screwed into the coupling element **115**. However, it should be appreciated that the compression nut **410** can be modified to have an annular shape with internal threads that mate with corresponding outer threads on the opposed projections **310**.

[0098] As best shown in FIG. **4**, the threads on the inner surfaces of the projections **310** of the coupling element **115** are tilted inwardly with respect to a horizontal axis (a horizontal axis is perpendicular to the axis A shown in FIGS. **3** and **4**). The threads on the exterior of the compression nut **410** are correspondingly tilted. The tilted thread configuration causes the compression nut **410**, when screwed into the coupling element **115**, to prevent the projections **310** from spreading apart relative to one another. Rather, the compression nut **410** applies a radially inward (i.e., toward the axis A) force to the projections **310** as the compression nut **410** is screwed into the coupling element **115**. This keeps the projections **410** from spreading apart while the compression nut **410** is screwed into the coupling element **115**.

[0099] In addition, the threads are buttressed such that it requires less force to lower or tighten the compression nut **410** into the coupling element **115** and greater force to untighten or loosen the compression nut **410** relative to the coupling element **115**. In this manner, it is unlikely that the compression nut will inadvertently loosen from the coupling element over time. This is advantageous, as the assembly can often be mounted in a vertebra for an extended period of time (such as several years) and it is undesirable for the compression nut to inadvertently loosen from the coupling element.

[0100] Other advantageous embodiments of the compression nut are shown in FIGS. **15**A-**17**C. Bone fixation system shown in FIGS. **15**A-**15**C shows a compression nut **710** with an external thread **712** that has both a load flank **713** and a stab flank **714** that are tilted inwardly in a downward direction toward the distal or bottom end **718** of the compression nut **710** and away from the proximal or top end **717** of the compression nut **710**. Thread **712** has a load flank **713** that is sloped such that for a given cross-section of the thread through a longitudinal axis A of compression nut **710**, a point on load flank **713** at a root **711** of thread **710** is closer to the top end **717** of compression nut **710** than a point on load flank **713** at a crest **716** of thread **712**.

[0101] To define the angles of the thread surfaces, plane B normal to longitudinal axis A is also shown. Angle α represents the angle measured clockwise from thread root **711** at plane B to stab flank surface **714**. Load flank **713** is at a downward curved slope from thread root **711** to thread crest **716**. Stated somewhat differently, load flank **713** forms a concave shape from thread root **711** the thread crest **716** in which thread root **711** is closer to top end **717** of compression nut **710** than is thread crest **716**.

[0102] Coupling element **615** has an internal thread **612** that complements and mates with external thread **712** of compression nut **710**. When measured clockwise from normal plane B to clearance flank surface **614**, clearance flank **614** of internal thread **612** forms an angle that is of substantially the same magnitude as angle α. Stab flank **613** forms a convex shape from thread root **611** to thread crest **616**. Thus, thread **712** of compression nut **710** and thread **612** of coupling element **615** are engaged when compression nut **710** is threadedly engaged within internal bore **605** of coupling element **615**. Angle α can be between about $-1°$ and about $-40°$. In accordance with various embodiments, angle α can be about $-1°$, about $-5°$, about $-10°$, about $-15°$, about $-20°$, about $-25°$, about $-30°$, about $-35°$, or about $-40°$.

[0103] The thread configuration shown in FIGS. **15**A-**15**C causes the compression nut **710**, when screwed into the coupling element **615**, to prevent the projections **610** from spreading apart relative to one another. Rather, the compression nut **710** applies a radially inward (i.e., toward the axis A) force to the projections **610** as the compression nut **710** is screwed into the coupling element **615**. This keeps the projections **610** from spreading apart while the compression nut **710** is screwed into the coupling element **615**.

[0104] More specifically, the way in which the thread geometry of the embodiment shown in FIGS. **15**A-**15**C prevents splaying is based on the formation of a crest/root interference fit. Any outward, splaying force on the arms **610** of the coupling element **615** manifests itself in a force having two components: (1) a lateral component; and (2) an upward component. The upward component of the force causes crest **616** of thread **612** of coupling element **615** to arc up resulting in crest **616** getting lodged into root **711** of thread **712** of compression nut **710**. The lateral component causes clearance flank **614** of thread **612** of coupling element **615** to push laterally against stab flank **714** of thread **712** of compression nut **710**. Due to the angle of the stab flank **714**, this lateral force pulls thread **712** downward into an interference fit between crest **716** and root **611**. This dual-interference fit mechanism provides increased anti-splaying properties. Need to describe items **611** and **613** shown in FIGS. **15**A-**15**C.

[0105] FIG. **16** shows a compression nut **910** with threads **912** that are tilted inwardly in the same manner as those in FIG. **12**. Thread **912** of compression nut **410** is similar to thread **712** of compression nut **710**, except that load flank **913** of thread **912** is linear rather than curved or concave and thread crest **916** forms a point. As with the embodiment shown in FIGS. **15**A-**15**C, coupling element **815** has an internal thread **812** that complements and mates with external thread **912** of compression nut **10**. Stab flank **813** of thread **812** is also linear rather than curved or convex.

[0106] FIGS. **17**A-**17**C show another embodiment of a compression nut **1410** and corresponding coupling element **1315** with threads having a specific geometry. The internal threads **1312** of the coupling element include a forward-facing thread surface or load flank **1313** that is sloped so that, for a given cross-section of the thread **1312** through the longitudinal axis of the coupling element **1315**, a point on

the load flank surface **1313** at the crest **1316** of the thread **1312** is closer to the proximal or top of the coupling element **1315** than a point on the load flank surface **1313** at the root **1311** of the thread **1312**.

[**0107**] External threads **1412** of the compression nut **1410** have a specific geometry that complements the geometry of the threads **1312** of the coupling element **1315**. The rearward-facing or proximal facing thread surface (load flank surface **1413**) is sloped or angled so that, for a given cross-section of the thread **1412** through the longitudinal axis of the compression nut **1410**, a point on the load flank surface **1413** at the root **1411** of the thread **1412** is closer to the proximal end or top of the compression nut **1410** than a point on the load flank surface **1413** at the crest **1416** of the thread **1412**, resulting in an angle α measured clockwise from a normal plane, such as plane Z, to the load flank surface **1413**. Angle α can be between about −1° and about −40°. In accordance with various embodiments, angle α can be about −1, about −5°, about −10°, about −15°, about −20°, about −25°, about −30°, about −35°, about −37°, or about 40°. The forward-facing or distal facing thread surface (stab flank surface **1414**) is sloped or angled at an angle β measured clockwise from normal plane Z', to the stab flank surface **1414**. Plane Z' is parallel to plane Z. Angle β can be between about −1° and about −40°. In accordance with various embodiments, angle β can be about −1°, about −5°, about −10°, about −15°, about −20°, about −25°, about −30°, about −35°, about −37°, or about −40°.

[**0108**] The way in which the thread geometry shown in FIGS. **17**A-**17**C prevents splaying is based on the formation of a crest/root interference fit. Any outward, splaying force on the projections **1310** of the coupling element **1315** manifests itself in a force having two components: (1) a lateral component; and (2) an upward component. The upward component of the force causes the crest of the internal thread to arc up resulting in the crest of the internal thread getting lodged into the root of the external thread. The lateral component causes the rearward-facing or clearance flank of the internal thread to push laterally against the forward-facing or clearance flank of the external thread. Due to the angle of the clearance flank, this lateral force pulls the fastener thread downward into an interference fit between the crest of the external thread and the root of the internal thread. This dual-interference fit mechanism improves anti-splaying properties.

[**0109**] The thread geometry shown in FIGS. **17**A-**17**C is also directed to the issue of torque vs. rotational displacement of the compression nut **1410**. It can be desirable to stiffen the response of the fastener to torque in order to increase the amount of torque required to unscrew the compression nut. An improved response results from increasing the contact surface area, and consequently the frictional forces, between the internal threads **1312** of the coupling element **1315** and external threads **1412** of the compression nut **1410** in the manner shown in FIGS. **17**A-**17**C. Specifically, thread **1412** has three main sides: a proximal side **1466**, a lateral side **1467**, and a distal side **1468**. These three main sides of thread **1412** make contact with thread **1312**, which has a corresponding proximal side **1366**, lateral side **1367** and distal side **1368**. This results in an increase in contact surface area of approximately 20% over a buttress, v-shaped, or reverse-angle thread having only two main sides.

[**0110**] In one embodiment, the various components of the assembly are manufactured of an inert material, such as, for example, stainless steel or titanium.

[**0111**] The various embodiments of top saddles, compression nut threading geometries, and coupling element threading geometries are described herein with respect to polyaxial pedicle screws. However, it should be appreciated that they can be used with monoaxial pedicle screws as well.

[**0112**] Although embodiments of various methods and devices are described herein in detail with reference to certain versions, it should be appreciated that other versions, embodiments, methods of use, and combinations thereof are also possible. Therefore the spirit and scope of the appended claims should not be limited to the description of the embodiments contained herein.

What is claimed is:

1. A bone stabilizer assembly, comprising:

a fixation element adapted to engage a bone and having a head portion and shank portion;

a coupling element having an internal bore sized to receive the shank portion of the fixation element and a seat adapted to support the head portion of the fixation element, the coupling element further adapted to receive a stabilizer rod;

a saddle movably mounted in the coupling element below the stabilizer rod when the stabilizer rod is in the coupling element;

retention means for retaining the saddle in the coupling element in a floating configuration that permits a predetermined amount of movement between the saddle and the coupling element when the stabilizer rod is not forced down against the saddle; and

a compression nut engagable with the coupling element, the compression nut adapted to rotatingly move distally into the coupling element to translate a force to the head portion through the rod and the saddle such that the head portion is forced against the seat of the coupling element to prevent relative movement between the fixation element and the coupling element.

2. An assembly as defined in claim 1, wherein the retention means comprises one or more protrusions (spec uses projections) extending laterally from the saddle, said one or more protrusions mating with one or more corresponding channels bored into an inner surface of the coupling element, wherein the one or more protrusions are smaller than the one or more channels so that the one or more protrusions float within the one or more channels permitting the predetermined amount of movement between the saddle and coupling element when the stabilizer rod is not forced against the saddle.

3. An assembly as defined in claim 1, wherein the retention means comprises one or more protrusions extending laterally from the saddle, said one or more protrusions mating with one or more corresponding holes in a wall of the coupling element, said one or more holes extending along a central axis that is transverse to a central axis of the internal bore of the coupling element, wherein the one or more protrusions are smaller than the one or more holes so that the one or more protrusions float within the one or more holes permitting the predetermined amount of movement between

the saddle and coupling element when the stabilizer rod is not forced against the saddle.

4. An assembly as defined in claim 1, wherein the saddle has a first contact surface adapted for engaging the stabilizer rod and a second contact surface adapted for engaging the head portion of the fixation element, wherein the first and second contact surfaces are shaped to correspond to a shape of an outer surface of the stabilizer rod and head portion respectively in order to maximize contact area between the saddle and stabilizer rod and saddle and head portion of the fixation element.

5. An assembly as defined in claim 4, wherein the first and second contact surfaces are concave.

6. An assembly as defined in claim 1, wherein the coupling element includes a pair of opposed projections separated by a rod-receiving channel, and wherein inner surfaces of the opposed projections include inner threads, and wherein the compression nut includes outer threads adapted to engage the inner threads of the opposed projections.

7. An assembly as in claim 6, wherein the inner threads are buttressed.

8. An assembly as in claim 6, wherein the inner threads are tilted inwardly in order to prevent spreading of the projections as the compression nut moves downward into the coupling element.

9. An assembly as in claim 8, wherein the inner threads are tilted inwardly in an upward direction.

10. An assembly as in claim 8, wherein the inner threads are tilted inwardly in a downward direction.

11. A bone stabilizer assembly, comprising:

a fixation element adapted to engage a bone and having a head portion and shank portion;

a coupling element having an internal bore sized to receive the shank portion of the fixation element and a seat adapted to support the head portion of the fixation element, the coupling element further comprising a pair of opposed walls separated by a stabilizer rod-receiving channel, and wherein inner surfaces of the opposed walls include inner threads for mating with a compression nut and opposing indentations located below the inner threads; and

a saddle movably mounted in the coupling element below the stabilizer rod when the stabilizer rod is in the coupling element, the saddle comprising a pair of opposed walls separated by a rod-receiving region, wherein outer surfaces of the opposed walls include opposing protrusions that extend laterally from the walls, the protrusions adapted to engage the opposing indentations in the opposed walls of the coupling element so as to retain the saddle within the coupling element when the stabilizer rod is disengaged from the coupling element.

12. An assembly as in claim 11, wherein the opposing walls of the saddle are connected to one another by a flexible joint that permits the opposing walls to tilt toward one another in response to compression forces.

13. An assembly as in claim 12, wherein the opposing indentations each comprises a proximal region forming a ridge with a drop-off, a middle region distal the upper region that forms a ramp that is sloped inward toward a distal direction, wherein the proximal end of the ramp starts at the drop-off and a distal end of the ramp terminates in a distal region that joins the ramp to the inner surface of the wall of the coupling element.

14. An assembly as in claim 13, wherein when the opposing walls of the saddle are in a resting state, wherein a distance between outer edges of the opposing protrusions is less than a distance between the proximal ends of the ramps, and greater than a distance between the distal ends of the ramps, such that when the saddle is in the upper region of the opposing indentations it floats within the upper region and when the saddle is pushed distally toward the distal region of the opposing indentations the opposing protrusions make contact with the corresponding sloped ramps and are squeezed into frictional engagement with the sloped ramps.

15. An assembly as in claim 14, wherein the frictional engagement between the opposing protrusions and the distal region of the opposing indentations maintains the saddle in frictional engagement with the head portion of the fixation element to prevent relative movement between the fixation element and the coupling element when the stabilizer rod is disengaged from the saddle and the saddle engages the fixation element, the fixation element and the coupling element being manually movable relative to each other in opposition to the frictional engagement when the stabilizer rod is disengaged from the saddle.

16. An assembly as in claim 11, further comprising a compression nut engagable with the coupling element, the compression nut having external threads adapted to engage the inner threads of the opposed walls, the compression nut adapted to rotatingly move distally into the coupling element to translate a force to the head portion of the fixation element through the rod and the saddle such that the head portion is forced against the seat of the coupling element to prevent relative movement between the fixation element and the coupling element.

17. A bone stabilizer assembly, comprising:

a coupling element including a plurality of wall sections defining a longitudinal bore, the coupling element also including a transverse channel substantially perpendicular to the bore; and

a compression nut including a substantially cylindrical engagement portion having a longitudinal axis, and a thread formed on said engagement portion so that said engagement portion is adapted to be threadedly engaged within said bore to said wall sections;

wherein said thread has a profile comprising a rotation stiffening component and an anti-splay component, said rotation stiffening component and said anti-splay component being integrated.

18. An assembly as in claim 17, wherein said profile comprises a proximal facing surface, a lateral facing surface, and a distal facing surface, the proximal facing surface sloped in a distal direction from a root of the proximal facing surface to a proximal edge of the lateral facing surface.

19. An assembly as in claim 18, wherein the distal facing surface is sloped in a distal direction from a root of the distal facing surface to a distal edge of the lateral facing surface.

20. An assembly as in claim 18, wherein the proximal facing surface forms a slope of between about −1° and about −40°.

21. An assembly as in claim 18, wherein the proximal facing surface forms a slope of about −5°.

22. An assembly as in claim 19, wherein the distal facing surface forms a slope of between about −1° and about −40°.

23. An assembly as in claim 19, wherein the distal facing surface forms a slope of about −37°.

24. A bone stabilizer assembly, comprising:

a coupling element including a plurality of wall sections defining a longitudinal bore, the coupling element also including a transverse channel substantially perpendicular to the bore; and

a compression nut including a substantially cylindrical engagement portion having a longitudinal axis, and a thread formed on said engagement portion so that said engagement portion is adapted to be threadedly engaged within said bore to said wall sections;

wherein said thread is sloped in a distal direction from a root of the thread to a crest of the thread.

25. An assembly as in claim 24, wherein the thread forms a slope of between about −1° and about −40°.

26. An assembly as in claim 24, wherein the thread forms a slope of about −5°.

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