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Pedicle screw systems and methods

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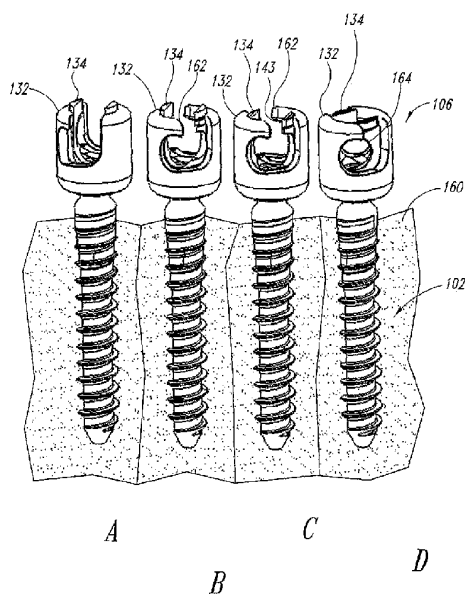
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(54) Title: PEDICLE SCREW SYSTEMS AND METHODS



(57) Abstract: The pedicle screw system may be used for fixation of spinal segments and may be advantageous when minimally invasive surgery (MIS) techniques are employed. The pedicle screw system includes a tulip assembly comprising of a tulip body, an inner member, and an expansion member. Installation of the pedicle screw system into pedicles of the spine, for example, includes inserting the pedicle screw into a portion of the spine and then coupling the tulip assembly to the pedicle screw. The tulip assembly may be locked onto the pedicle screw before a distraction rod is placed in the tulip assembly. After the rod is placed in the tulip assembly, the tulip body and the inner member can be rotated relative to one another to lock the rod into the tulip assembly. In addition, the relative rotation may also provide additional locking of the tulip assembly to the pedicle screw.

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PEDICLE SCREW SYSTEMS AND METHODS OF ASSEMBLING/INSTALLING THE SAME

CROSS-REFERENCES TO RELATED APPLICATIONS

This application claims the benefit of U.S. Provisional Patent Application Nos.
5 60/622,107 filed October 25, 2004; 60/622,180 filed October 25, 2004; 60/629,785 filed
November 19, 2004; 60/663,092 filed March 18, 2005; and 60/684,697 filed May 25,
2005, where these provisional applications are incorporated herein by reference in their
entireties.

BACKGROUND OF THE INVENTION

Field of the Invention

10 The present invention relates generally to bone fixation devices, and in particular
to a screw assembly for the internal fixation of vertebral bodies.

Description of the Related Art

Various devices for internal fixation of bone segments in the human or animal
15 body are known in the art. One type of system is a pedicle screw system, which is
sometimes used as an adjunct to spinal fusion surgery, and which provides a means of
gripping a spinal segment. A conventional pedicle screw system comprises a pedicle
screw and a rod-receiving device. The pedicle screw includes an externally threaded stem
and a head portion. The rod-receiving device couples to the head portion of the pedicle
20 screw and receives a rod (commonly referred to as a distraction rod). Two such systems
are inserted into respective vertebrae and adjusted to distract and/or stabilize a spinal
column, for instance during an operation to correct a herniated disk. The pedicle screw
does not, by itself, fixate the spinal segment, but instead operates as an anchor point to
receive the rod-receiving device, which in turn

receives the rod. One goal of such a system is to substantially reduce and/or prevent relative motion between the spinal segments that are being fused.

Although conventional prior art pedicle screw systems exist, they lack features that enhance and/or benefit newer, minimally invasive surgery (MIS) techniques that are more commonly being used for spinal surgeries. It has been suggested that one possible advantage of an MIS approach is that it can decrease a patient's recovery time.

Conventional pedicle screw systems and even more recently designed pedicle screw systems have several drawbacks. Some of these pedicle screw systems are rather large and bulky, which may result in more tissue damage in and around the surgical site when the pedicle screw system is installed during surgery. The prior art pedicle screw systems have a rod-receiving device that is pre-operatively coupled or attached to the pedicle screw. In addition, some of the prior art pedicle screw systems include numerous components that must all be carefully assembled together. For example, one type of pedicle screw system that may require up to nine (9) different components is disclosed in U.S. Published Patent Application Nos. 2005/0203516 and 2005/0216003 to Biedermann et al.

One drawback that is common among many prior art pedicle screw systems is that a threaded component is used to lock down the rod in the rod-receiving device. Examples of these types of systems can be found in U.S. Published Patent Application Nos. 2005/0192571 to Abdelgany; 2005/0192573 to Abdelgany et al.; the Biedermann et al. applications; 2005/0187548 to Butler et al.; 2005/0203515 to Doherty et al.; and 2004/0172022 to Landry et al. Each of these pedicle screw systems have an externally threaded fastening element either directly or indirectly coupled to the vertically extending walls of the rod-receiving device (e.g., referred to as a bone fixator, a receiving part, a coupling construct, etc.).

One problem associated with the above-identified pedicle screw systems is that cross-threading may occur when the fastening element is installed. Cross-threading may cause the fastening element to jam and/or may

result in an improper construct where some components may not be in the correct position. Due to the dynamic nature of spinal movement, a cross-threaded pedicle screw system may be more prone to post-operative failure.

Another problem with the above-identified pedicle screw systems is that the coupling between the fastening element and the rod-receiving device when subjected to dynamic, post-operative loading may result in the walls of the rod-receiving device splaying apart. In the above-identified pedicle screw systems, the walls of the rod-receiving device are unsupported. Post-operative tulip splaying, as it is commonly called, may result in the dislodgment of the fastening element and the rod. In short, the pedicle screw system may become post-operatively disassembled and no longer function according to its intended purpose.

Other prior art pedicle screw systems have attempted to address some of the aforementioned drawbacks. For example, U.S. Patent Nos. 5,609,593, 5,647,873, 5,667,508, 5,669,911, and 5,690,630, all to Errico et al., disclose a threaded, outer cap that extends over and couples to the walls of the rod-receiving device. However, the risk and/or potential for cross-threading is still present when the threaded, outer cap is coupled with the rod-receiving device.

Other pedicle screw systems such as U.S. Patent Nos. 5,882,350 to Ralph et al.; 6,132,432 to Richelsoph; 4,950,269 to Gaines, Jr.; 6,626,908 to Cooper et al.; 6,402,752 to Schäffler-Wachter et al.; and 6,843,791 to Serhan may address some of the aforementioned drawbacks, but each of these pedicle screw systems are pre-operatively assembled, which makes these systems more difficult to install and maneuver in a spinal operation where MIS techniques are used.

OBJECT OF THE INVENTION

It is the object of the present invention to substantially overcome or at least ameliorate one or more of the disadvantages of the prior art, or to provide a useful alternative.

SUMMARY OF THE INVENTION

In a first aspect the present invention relates to a tulip assembly comprising:
a pedicle screw having a threaded portion and a head portion;
a first device elastically expandable to receive said head portion of said pedicle screw; and

a second device having an engagement portion, the engagement portion in contact with said first device to fix the tulip assembly to the head portion of the pedicle screw;

at least a portion of the tulip assembly having generally opposing channels for receiving a rod; said at least a portion of said tulip assembly being adapted to receive said rod and rotate about the rod to capture the rod and cause the rod to become locked in the tulip assembly after said engagement portion contacts said first device to fix the tulip assembly to the head portion;

each of said generally opposing channels being defined by a first surface and a generally opposing second surface, said first and second surfaces also cooperating to define a first channel portion and a second channel portion that is in communication with said first channel portion, said first channel portion defining a rod-receiving opening that opens upwardly and away from an end of said tulip assembly from which said pedicle screw extends, said first channel portion extending away from said rod-receiving opening and toward said end in a first direction that is generally parallel to an axis of said tulip assembly, said second channel portion extending in a second direction that is not colinear with said first direction and that is not generally parallel to said axis;

said first channel portion being adapted to receive said rod after said rod is received in said rod-receiving opening and guide said rod to said second channel portion so that said second channel portion can receive and lock said rod in said tulip assembly in response to said tulip assembly being rotated.

In a second aspect the present invention relates to a pedicle screw system comprising:

a pedicle screw having a threaded portion and a head portion;

a tulip assembly comprising a first device and a second device, the first device being elastically expandable to receive the head portion of the pedicle screw, and the second device having an engagement portion, the engagement portion engageable with the first device to fix the tulip assembly to the head portion of the pedicle screw; and

at least a portion of the tulip assembly having generally opposing channels for receiving a rod; said at least a portion of said tulip assembly being adapted to receive said rod and rotate about the rod to capture the rod and cause the rod to become locked in the tulip assembly after said engagement portion engages said first device to fix the tulip assembly to the head portion;

each of said generally opposing channels being defined by a first surface and a generally opposing second surface, said first and second surfaces also cooperating to define a first channel portion and a second channel portion that is in communication with said first channel portion, said first channel portion defining a rod-receiving opening that opens upwardly and away an end of said tulip; assembly from which said pedicle screw extends, said first channel portion extending away from said rod-receiving opening and toward said end in a first direction that is generally parallel to an axis of said tulip assembly,

said second channel portion extending in a second direction that is generally normal to said first direction and that is not generally parallel to said axis;

said first channel portion being adapted to receive said rod after said rod is received in said rod-receiving opening and guide said rod to said second channel portion so that said second channel portion can receive and lock said rod in said tulip assembly in response to said tulip assembly being rotated.

In a third aspect the present invention relates to a pedicle screw system comprising:

a pedicle screw having a threaded portion and a spherical head portion;

a poly-axial tulip assembly having a bore for accommodating the passage of the spherical head portion of the pedicle screw therethrough, said poly-axial tulip assembly having an inner component, an outer component and a fastener assembly, said poly-axial tulip assembly positioned on the spherical head portion of the pedicle screw;

wherein the fastener assembly is tapered along an edge, wherein an inner bore of the inner component is reciprocally tapered such that the fastener assembly mates with the inner component to allow said poly-axial tulip assembly to be locked onto the spherical head portion of the pedicle screw while allowing said poly-axial tulip assembly to move poly-axially in relation to the pedicle screw; and

wherein the outer component is adapted to receive the inner component in an engaged position, wherein the inner component is received in a retained position and locks an orientation of the poly-axial tulip assembly relative to the pedicle screw and the inner component comprising at least one first channel and the outer component comprising at least one second channel adapted to receive a rod, the inner component and the outer component being rotatable relative to each other and said at least one first channel and said at least one second channel cooperate to capture the rod and lock the rod in said poly-axial tulip assembly;

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each of said at least one first channel and said at least one second channel being defined by a first surface and a generally opposing second surface, said first and second surfaces cooperating to define a first channel portion and a second channel portion that is in communication with said first channel portion, said first channel portion defining a
5 rod-receiving opening that opens upwardly and away from an end of said poly-axial tulip assembly from which said pedicle screw extends, said first channel portion extending away from said rod-receiving opening and toward said end in a first direction that is generally parallel to an axis of said poly-axial tulip assembly, said second channel portion extending in a second direction about at least a portion of said axis and that is not parallel
10 to said axis;

said first channel portion being adapted to receive said rod after said rod is received in said rod-receiving opening and guide said rod to said second channel portion so that said second channel portion can receive and lock said rod in said poly-axial tulip assembly in response to said relative rotation of said inner component or said outer
15 component.

The present invention at least in a preferred embodiment relates to a bone fixation assembly, such as a pedicle screw system for the internal fixation of vertebral bodies. The pedicle screw system may be used for fixation of spinal segments and may be preferable when minimally invasive surgery (MIS) techniques are employed. The
20 pedicle screw system includes a tulip assembly comprising a tulip body, an inner member, and an expansion member. Installation of the pedicle screw system into pedicles of the spine, for example, includes inserting the pedicle screw into a portion of the spine and then coupling the tulip assembly to the pedicle screw. The tulip assembly may be locked onto the pedicle screw before a distraction rod is placed in the tulip assembly, after the
25 distraction rod has been placed in the tulip assembly, but not yet locked therewith, or after the distraction rod has been placed in the tulip assembly and locked therewith. The tulip body and the inner member can be rotated relative to one another to lock the rod into the tulip assembly. In addition, the relative rotation may also provide additional locking of the tulip assembly to the pedicle screw.

30 In another aspect, a tulip assembly is coupled to a pedicle screw that has a threaded portion and a head portion. The tulip assembly includes a first device elastically expandable to receive the head portion of the pedicle screw; and a second device having a rod-receiving portion and an engagement portion, the engagement portion engageable with the first device to fix the tulip assembly to the head portion of the pedicle screw.

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5 In another aspect, a pedicle screw system includes a pedicle screw having a threaded portion and a head portion; and a tulip assembly comprising a first device and a second device, the first device elastically expandable to receive the head portion of the pedicle screw, and the second device having a rod-receiving portion and an engagement portion, the engagement portion engageable with the first device to fix the tulip assembly to the head portion of the pedicle screw.

10 In yet another aspect, a method of fixing a tulip assembly to a pedicle screw includes inserting the pedicle screw into bone, where the pedicle screw includes a head portion with a maximum diameter section; expanding a first device over and past the maximum diameter section of the pedicle screw after the pedicle screw is inserted into the bone; seating an inner surface of the

first device against the head portion of the pedicle screw; and urging a portion of a second device into contact with a portion of the first device to fix the tulip assembly to the pedicle screw.

In still yet another aspect, a method of fixing a rod to a pedicle screw system, where the system includes a tulip assembly and a pedicle screw, includes inserting the pedicle screw into bone, the pedicle screw having a head portion that includes a maximum diameter section; coupling the tulip assembly to the pedicle screw by expanding a first device over and past the maximum diameter section of the pedicle screw, seating an inner surface of the first device against the head portion of the pedicle screw, and then urging a portion of a second device into contact with a portion of the first device to fix the tulip assembly to the pedicle screw; inserting a rod into the tulip assembly; and positioning a third device relative to the second device to fix at least a portion of the rod in the tulip assembly.

In still yet another aspect, a pedicle screw system includes a pedicle screw having a threaded portion and a spherical head portion; a poly-axial tulip assembly having a bore for accommodating the passage of the spherical head portion of the screw therethrough, the tulip assembly having an inner component, an outer component and a fastener assembly, the tulip assembly positioned on the head portion of the screw; wherein the fastener assembly is tapered along a top and a bottom edge, wherein an inner bore of the inner component is reciprocally tapered such that the fastener assembly mates with the inner component to allow the tulip assembly to be locked onto the head portion of the screw while allowing the tulip assembly to move poly-axially in relation to the screw; and wherein the outer component includes a retaining member along a top edge for receiveably retaining the inner component in an engaged position, wherein the inner component lowered into a retained position locks an orientation of the tulip assembly relative to the screw.

In yet another aspect, a pedicle screw system includes a pedicle screw having a threaded portion and a spherical head portion; a poly-axial housing positioned on the head portion of the screw, the housing having an

inner component, an outer component and a fastener assembly; wherein the fastener assembly is tapered along a top and a bottom edge and wherein an inner bore of the inner component is reciprocally tapered such that the fastener assembly mates with the inner component to allow the housing to be locked
5 onto the head portion of the screw while allowing the housing to move poly-axially in relation to the screw; and wherein the fastener assembly includes pockets along an edge adjacent to the inner component, an edge of the inner component adjacent to the fastener assembly having reciprocal inclined planes for receivably retaining the inner component in an engaged position, wherein
10 partially rotating the inner component provides a provisional rotational lock of the housing to the screw.

In another aspect, a pedicle screw includes a screw having threads and a head; a tulip coupled to the screw; a fastener internal to the tulip and positioned to couple the tulip to the screw; and an inner component of the
15 tulip, the inner component of the tulip longitudinally moveable to engage the screw to provide a poly-axial lock between the tulip and the screw.

In yet another aspect, a method of connecting a rod to a pedicle screw system includes threading a screw having a head into bone of a patient; attaching a tulip assembly to the head of the screw; depressing a tulip inner
20 component to lock the tulip to the screw; placing a rod into a channel of the tulip; and rotating the tulip inner component to capture the rod.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S)

In the drawings, identical reference numbers identify similar elements or acts. The sizes and relative positions of elements in the drawings
25 are not necessarily drawn to scale. For example, the shapes of various elements and angles are not drawn to scale, and some of these elements are arbitrarily enlarged and positioned to improve drawing legibility. Further, the particular shapes of the elements as drawn, are not intended to convey any information regarding the actual shape of the particular elements, and have

been solely selected for ease of recognition in the drawings. In addition, identical reference numbers identify similar elements or acts.

Figure 1 is an isometric view of a pedicle screw system, according to one illustrated embodiment.

5 Figure 2 is a side elevational view of a pedicle screw having a variable minor diameter, according to one illustrated embodiment.

Figure 3 is an isometric view of a tulip assembly of the pedicle screw system of Figure 1.

10 Figure 4 is an isometric, exploded view of the tulip assembly of Figure 3.

Figure 5 is partial, cross-sectional view of a split ring and tulip body of the tulip assembly of Figure 3.

Figure 6 is an isometric view of an inner member of the tulip assembly of Figure 3.

15 Figures 7A-7D are isometric views of a method of installing a pedicle screw system into bone, according to the illustrated embodiments.

Figure 8 is a side elevational view of a pedicle screw system, according to another illustrated embodiment.

20 Figure 9 is an isometric, exploded view of a tulip assembly of the pedicle screw system Figure 8.

Figure 10 is a side elevational view of a pedicle screw system, according to another illustrated embodiment.

Figure 11 is an isometric, exploded view of a tulip assembly and a pedicle screw of the pedicle screw system Figure 10.

25 DETAILED DESCRIPTION OF THE INVENTION

By way of example, pedicle screw systems may be fixed in the spine in a posterior lumbar fusion process via minimally invasive surgery (MIS) techniques. The systems are inserted into the pedicles of the spine and then interconnected with rods to manipulate (e.g., correct the curvature, compress or

30 expand, and/or structurally reinforce) at least portions of the spine. Using the

MIS approach to spinal fixation and/or correction surgery has been shown to decrease a patient's recovery time and reduce the risks of follow-up surgeries.

The ability to efficiently perform spinal fixation and/or correction surgeries using MIS techniques is enhanced by the use of pedicle screw systems provided in accordance with the present invention, which systems provide many advantages over conventional systems. For example, a pedicle screw system in accordance with one embodiment provides the advantage that the pedicle screw may be inserted into the bone without being pre-operatively coupled with the rod-coupling assembly (hereinafter referred to as a tulip assembly). This is advantageous because the surgeon often needs to do other inter-body work after inserting the pedicle screw, but before attaching the larger and bulkier tulip assembly. Such an advantageous pedicle screw system may be even more crucial when using MIS techniques because the inter-body spatial boundaries in which the surgeon must work may be quite limited.

In addition, pedicle screw systems in accordance with the present invention advantageously allow a user to initially fix (e.g., lock) the tulip assembly to the pedicle screw at a desired angle before inserting and/or capturing the rod. Initially locking the tulip assembly to the pedicle screw means that at least one of the components of the tulip assembly is manipulated to grip and/or clamp onto the pedicle screw to reduce, if not prevent any translational and/or rotational movement of the tulip assembly relative to the pedicle screw. The ability to initially lock the tulip assembly to the pedicle screw may facilitate the surgeon in performing compression and/or distraction of various spinal and/or bone sections.

The term "distraction," when used in a medical sense, generally relates to joint surfaces and suggests that the joint surfaces move perpendicular to one another. However when "traction" and/or "distraction" is performed, for example on spinal sections, the spinal sections may move relative to one another through a combination of distraction and gliding, and/or other degrees of freedom.

Another advantageous feature of at least one embodiment of a pedicle screw system is to have an all-inclusive tulip assembly that can be coupled to the head portion of the pedicle screw intra-operatively. This advantageous tulip assembly may include the aspects or features that enable the tulip assembly to be initially locked onto the head portion of the pedicle screw and then to further receive, capture, and finally lock the rod into the tulip assembly. In one embodiment, the tulip assembly is initially locked onto the head portion of the pedicle screw after the rod has been received in the tulip assembly. This advantageous tulip assembly may decrease the complexity of the pedicle screw system installation by reducing the installation to essentially a three-step process, which is inserting the pedicle screw into bone, initially locking the tulip assembly onto the pedicle screw, which may be accomplished with or without the rod in the tulip assembly, and then capturing and locking the rod into the tulip assembly.

In addition to accommodating the new MIS approach to spinal correction and/or fusion, at least one pedicle screw system described herein may include features to prevent, or at least reduce, the problems of cross-threading and/or post-operative tulip splaying, which is when the amount of stress/strain in rod, which may be caused by post-operative back flexion, forces open the tulip assembly and eventually leads to the disassembly and/or the failure of the pedicle screw system.

Pedicle Screw System

Figure 1 generally shows a pedicle screw system 100 comprising a pedicle screw 102, a rod 104, and a coupling assembly 106, hereinafter referred to as a tulip assembly 106. The placement and/or number of pedicle screw systems 100 for a patient may be pre-operatively determined based on a pre-operative examination of the patient's spinal system using non-invasive imaging techniques known in the art, such as x-ray imaging, magnetic resonance imaging (MRI), and/or fluoroscopy imaging, for example. The tulip assembly 106 may be intra-operatively (*i.e.*, during surgery) coupled to the

pedicle screw 102 and maneuverable to achieve a desired placement, orientation, and/or angular position of the tulip assembly 106 relative to the pedicle screw 102. Once the tulip assembly 106 is at the desired position relative to the pedicle screw 102, the tulip assembly 106 can be fixed or locked
5 onto the pedicle screw 102. In one embodiment, the tulip assembly 106 is fixed onto the pedicle screw 102 before the rod is fixed or locked into the tulip assembly 102. In another embodiment, the tulip assembly 106 is fixed onto the pedicle screw 102 contemporaneously as the rod is fixed or locked into the tulip assembly 102.

10 It is understood that the relative, angular position 107 of a first tulip assembly 106 to a first pedicle screw 102 may be different from other pedicle screw systems 100 located elsewhere on a patient's spine. In general, the relative, angular position 107 of the tulip assembly 106 to the pedicle screw 102 allows the surgeon to selectively and independently orient and manipulate
15 the tulip assemblies 106 of each pedicle screw system 100 installed into the patient to achieve and/or optimize the goals of the surgical procedure, which may involve compressing, expanding, distracting, rotating, reinforcing, and/or otherwise correcting an alignment of at least a portion of a patient's spine.

Figure 2 shows the pedicle screw 102 having an elongated,
20 threaded portion 108 and a head portion 110. Although pedicle screws 102 are generally known in the art, the head portions 110 may be of varying configurations depending on what type of tulip assembly 106 is to be coupled to the pedicle screw 102. The head portion 110 of the pedicle screw 102 includes a driving feature 124 and a maximum diameter portion 126. The driving feature
25 124 permits the pedicle screw 102 to be inserted into a pedicle bone and/or other bone. The pedicle bone is a part of a vertebra that connects the lamina with a vertebral body. The driving feature 124 can be used to adjust the pedicle screw 102 even after the tulip assembly 106 is coupled to the pedicle screw 102. In the illustrated embodiment, the head portion 110 of the pedicle screw
30 102 is coupled to the threaded portion 108 and includes a generally spherical surface 127 with a truncated or flat top surface 128.

In one embodiment, the pedicle screw 102 is cannulated, which means a channel 130 (shown in dashed lines and extending axially through the pedicle screw 102) extends through the entire length of the pedicle screw 102. The channel 130 allows the pedicle screw 102 to be maneuvered over and
5 receive a Kirschner wire, commonly referred to as a K-wire. The K-wire is typically pre-positioned using imaging techniques, for example, fluoroscopy imaging.

Figures 3 and 4 show the tulip assembly 106 that includes a first member or tulip body 132, an inner member or inner member 134, and an
10 expansion/contraction member or split ring 136, according to one illustrated embodiment. The tulip body 132 includes a bore 138, an upper portion 140, a lower portion 142, and an internal lip 143. In one embodiment, the tulip body 132, the inner member 134, and the split ring 136 are pre-operatively assembled before being placed onto the head portion 110 of the pedicle screw
15 102. Both the inner member 134 and the split ring 136 may be inserted into the tulip body 132 through the bore 138 upward or through the lower portion 142 of the tulip body 132.

Figure 5 shows the split ring 136 inserted in the lower portion 142 of the tulip body 132. For purposes of clarity, the upper portion 140 of the tulip
20 body, the pedicle screw 102, and the inner member 134 are not shown. An inner surface 144 of the bore 138 through the lower portion 142 of the tulip body 132 is sized to allow the split ring 136 to float and/or translate upwards so that the split ring 136 can expand to receive the head portion 110 of the pedicle screw 102. The split ring 136 includes an outer surface 146 and an inner
25 surface 148. The outer surface 148 of the split ring 136 frictionally contacts the inner surface 144 of the bore 138 of the tulip body 132. The inner surface 148 of the split ring 136 frictionally engages the head portion 110 of the pedicle screw 102, as will be described in more detail below. In one embodiment, the split ring 136 is fabricated to be elastically expandable and contractible within
30 the range of operations described herein.

Figure 6 shows the inner member 134 having an outer diameter 150, a contoured channel 152 formed by extending arms 154, which includes a rod-support surface 156, and a bottom surface 158. The outer inner diameter 150 is sized to be received in the bore 138 of the tulip body 132 and then be rotatable within the tulip body 132, as will be described in more detail below. The contoured channel 152, along with the rod-support surface 156, operates in cooperation with the tulip body 132 to receive, capture, and eventually lock the rod 104 into the tulip assembly. The bottom surface 158 operates to engage the split ring 136 and force the split ring 136 down in the bore 138 of the tulip body 132, which results in contraction of the split ring 136 around the head portion 110 of the pedicle screw 102. It is understood that the forced contraction of the split ring 136 along with the radial constraint provided by the inner surface 144 of the tulip body 132 generates sufficient radial pressure on the head portion 110 of the pedicle screw 102 to lock the tulip body 132 onto the pedicle screw 102.

Pedicle Screw System Installation

Figures 7A-7C show various stages of assembly and/or installation of the tulip assembly 106 to the pedicle screw 102. In the illustrated embodiments, the pedicle screw 102 has already been inserted into bone material 160. In Figure 7A, the tulip assembly 106 is snapped onto the head portion 110 of the pedicle screw 102. The inner surface 148 of the split ring 136 mates with the head portion 110 of the pedicle screw 102. As the tulip assembly 136 is pushed onto the head portion 110 of the pedicle screw 102, the split ring 136 expands and snaps onto the head portion 110. The split ring 136 is initially pushed up into the bore 138 of the tulip body 132, as described above. The bore 138 in the lower portion 142 of the tulip body 132 permits the split ring 136 to float in the bore 138. Alternatively stated, as the split ring 136 is pushed upwards inside of the tulip body 132 by the head portion 110 of the pedicle screw, sufficient clearance is present for the split ring 136 to expand and snap around the head portion 110 of the screw 102. At this point, the tulip

assembly 106 is rotationally coupled to the head portion 110 of the pedicle screw 102. The tulip assembly 106 may be rotated to achieve a desired orientation with respect to the pedicle screw 102 and the initial coupling mechanisms just described reduce the likelihood that the tulip assembly 106
5 will be detached from the pedicle screw 102 during manipulation thereof.

Next, the mating tapered surfaces, which comprise the head portion 110 of the pedicle screw 102, the outer and inner surfaces 146, 148 of the split ring 136, and the inner surface 144 of the lower portion of the bore 138 of the tulip body 132, cooperate to lock the tulip assembly 106 onto the head
10 portion 110 of the pedicle screw. An upward force applied to the tulip body 132 tends to cause further compression and/or contraction of the split ring 136 because the split ring 136 is forced down further along the inner surface 144 of the bore 138 of the tulip body 132. Such additional compression and/or contraction of the split ring 136 substantially locks or fixes the tulip assembly
15 106 onto the pedicle screw 102, thus preventing additionally rotation, manipulation, loosening, and/or removal of the tulip assembly 106 with respect to the pedicle screw 102. In short, when the tulip assembly 106 is initially placed onto the head portion 110 of the pedicle screw 102, the tulip assembly 106 is free to move poly-axially in relation to the pedicle screw 102. Thus, the
20 tulip assembly 106 remains free to rotate on the pedicle screw 102 until it is locked onto the head portion 110 of the pedicle screw 102, where the locking will be described below. In addition, both the tulip body 132 and the inner member 134 are aligned to receive the rod 104. For purposes of clarity, however, the rod 104 is not shown so that the features of the tulip assembly
25 106 that capture and lock the rod 104 are more readily viewable.

Figure 7B shows that the tulip body 132 and the inner member 134 are rotated, about a common axis, to begin capturing the rod 104. In one embodiment, the inner member 134 is held while the tulip body 132 is rotated. In another embodiment, the tulip body 132 is held while the inner member 134
30 is rotated. In yet another embodiment, the inner member 134 and the tulip body 132 are rotated relative to one another, with both components being

rotated at the same time. The tulip body 132 includes extensions 162 that cooperate with the contoured channel 152 and arms 154 of the inner member 134 to begin the capture of the rod 104.

In addition, the inner member 134 may be rotated clockwise to
5 retain the rod 104 and/or the tulip body 132 rotated counterclockwise. Alternatively the inner member 134 may be rotated counterclockwise and/or the tulip body 132 may be rotated clockwise. The rod 104 is initially retained on the contoured surface 156 of the inner member 134, which includes a rod-capturing portion 164 (best shown in Figure 7D). The inner member 134 cooperates with
10 the bore 138 of the tulip body 132 to capture the rod 104. In addition, the inner member 134, after being rotated relative to the tulip body 132 to capture the rod 104, provides structural reinforcement to the tulip body 132 to prevent the tulip body 132 from splaying open under post-operative dynamic and static loading, for example.

As shown in Figures 7A and 7B, the arms 154 of the inner
15 member 134 are flexed inwards and protrude above the top surface of the tulip body 132. In Figure 7C, the inner member 134 is forced or pushed down into the tulip body 132 so that the top portion of the inner member 134 is approximately flush with the top portion of the tulip body 132. An additional or
20 continued downward force on the inner member 134 causes the inner member 134 to snap or engage under the lip 143 located in the upper portion 140 of the tulip body 132. Hence, the elasticity of the arms 154 of the inner member 134 permit the arms to flex inward when pushed down and then expand to become engaged under the lip 143 of the tulip body 132. This longitudinal engagement
25 to retain the inner member 134 within the tulip body 132 may be accomplished either before or after the rod 104 is placed in the tulip assembly 106. In one embodiment, forcing the inner member 134 down into the tulip body 132 may provide additional locking capacity of the tulip assembly 132 onto the pedicle screw 102 because the bottom surface 158 of the inner member 134 pushes
30 the split ring 136 even further down along the inner surface 144 of the bore 138

of the tulip body 132. As described above, this action clamps the tulip assembly 132 onto the head portion 110 of the pedicle screw.

In an alternate embodiment, forcing the inner member 134 down into the tulip body 132 may provide the initial locking of the tulip assembly 132 onto the pedicle screw 102. Depending on the configuration of the relative, interacting surfaces, and possibly other factors, the process of forcing the inner member 134 downward to be retained in tulip body 132 may, according to one embodiment, establish the initial lock of the tulip assembly 106 to the pedicle screw 102.

Figure 7D shows the tulip assembly 106 in a locked or closed position where the rod 104 is locked into the tulip assembly 106. As shown in the illustrated embodiment, a slight overlap occurs between the extensions 162 of the tulip body 132 and the arms 154 of the inner member 134. The additional amount of relative rotation illustrated from Figures 7C to 7D completes the rod-locking process to securely lock the rod 104 in the tulip assembly 106, according to the illustrated embodiment.

Figures 8 through 14 show alternative embodiments of pedicle screw systems. These alternative embodiments, and other alternatives described herein, are substantially similar to previously described embodiments. Structural aspects and/or features and assembly/installation steps that are common to the previously described embodiments are identified by like reference numbers. Only significant differences in operation and structure are described below.

Figures 8 and 9 show an alternative embodiment of a pedicle screw system 200, according to the illustrated embodiment. The pedicle screw system 200 includes the pedicle screw 102 with an alternative tulip assembly 202. The tulip assembly 202 comprises a tulip body 204, an inner member 206, and an expansion member or split ring 208. In the illustrated embodiment, the inner member 206 includes inclined planes 210 to provide a different method and structure for initially locking the angle of the tulip assembly 202 to the pedicle screw 102. The initial locking is achieved by rotating the inner member

206 partially through its allowable rotation. The inclined planes 210 of the inner member 206 engage with pockets 212 present in the expansion member 208. The inclined planes 210 operate as cam extensions on the inner member 206 to force the expansion member 208 downward and into a tight compression, thus locking the tulip assembly 202 onto the head portion 110 of the pedicle screw 102.

Figures 10 and 11 show a pedicle screw system 300 in accordance with yet another embodiment. Figure 11 is an exploded view of the pedicle screw system 300 of Figure 10. The pedicle screw system 300 includes a pedicle screw 302 and a tulip assembly 304. The pedicle screw 302 includes a dual diameter head portion 306. The tulip assembly 304 includes a tulip body 308, an inner member 310, and an expansion member or split ring 312.

According to aspects of the illustrated embodiment, the rod (not shown) is captured and then subsequently locked by rotating the inner member 310. An initial lock is achieved between the tulip assembly 304 and the pedicle screw 302 by pushing the inner member 310 down into the tulip body 308. Barbed surfaces 314 on the inner member 310 engage barbed surfaces in the tulip body 308 to retain the inner member 310 inside the tulip body 308. The inner member 310, in turn, pushes on the split ring 312 to lock the tulip assembly 304 onto the pedicle screw 302. In addition, inclined planes (not shown) may be located on the arms 316 of the inner member 310 to force the rod tightly against a first rod slot 318 in the inner member 310 and/or in a second rod slot 320 in the tulip body 308. Thus, the rotation of the inner member 310 relative to the tulip body 308 locks the rod in the tulip assembly 304.

In operation, the pedicle screw systems as described, but not limited to the embodiments herein, are designed for fixation of bone material and/or bone segments during a surgical procedure, such as fusing spinal segments in which MIS techniques are employed. For example, the pedicle screw system is inserted into the pedicles of the spine and then interconnected with rods to provide support to the spine to allow for post-operative fusion of the

spinal segments. While the pedicle screw can be inserted with the tulip assembly coupled with the pedicle screw, one embodiment for the installation of the pedicle screw system includes inserting the pedicle screw into the bone and subsequently coupling the tulip assembly to the pedicle screw, where such an approach has advantages over currently known pedicle screw system assemblies and/or installations.

In addition, various structural features of the pedicle screw systems as described, but not limited to the embodiments herein, may provide other advantages over existing pedicle screw systems. First, the pedicle screw may be inserted into the bone without the presence of the tulip assembly or rod, which permits the surgeon to place the screw and then perform subsequent inter-body work without having to work around the tulip assembly or the rod. Second, the tulip assembly includes a mechanism for capturing the rod that eliminates problems associated with conventional pedicle screws, such as cross-threading, because the pedicle screw systems disclosed herein do not use any threads to couple the tulip assembly to the pedicle screw or to capture and lock the rod into the tulip assembly. Third, the interface between the head portion of the pedicle screw and the tulip assembly provides an initial lock, which allows the angle of the tulip assembly to be set or fixed with respect to the pedicle screw before insertion of the rod and/or before the rod is captured in the tulip assembly. With this type of pedicle screw system, the surgeon has the ability to check and even double check the placement, angle, and/or orientation regarding aspects of the pedicle screw system to facilitate, and even optimize, the compression, distraction, and/or other manipulation of the spinal segments. Further, the pedicle screw systems accommodate the new MIS techniques being applied to spinal operations.

One possible post-operative advantage of the pedicle screw systems is that the cooperation and interaction of the inner member with the tulip body of the tulip assembly substantially reduces and most likely prevents the known problem of tulip splaying. Tulip splaying is generally regarded as a post-operative problem of when a stressed rod forces open portions of the tulip

body, which eventually leads to the disassembly and likely failure of the pedicle screw system within the patient. Yet another post-operative advantage of the pedicle screw systems is that unlike existing rod-coupling members or constructs, the tulip assemblies described herein have a smaller size envelope
5 (e.g., less bulky, lower profile, and/or more compact shape) and are easier to place onto the pedicle screw. The smaller size and ease of installation may reduce trauma to the soft-tissue regions in the vicinity of the surgical site, which in turn generally allows for a quicker recovery by the patient.

Yet another possible advantage of the pedicle screw systems
10 over existing systems is that all of the parts needed to lock the tulip assembly to the pedicle screw and to capture and lock the rod into the tulip assembly are included within the tulip assembly. Accordingly, once the tulip assembly is snapped or otherwise coupled to the pedicle screw, no additional locking cap or threaded fastener is needed to complete the assembly/installation of the pedicle
15 screw system. According to aspects described herein, and as appended by the claims, the inventive pedicle screw systems permit inserting the pedicle screw without the tulip assembly coupled thereto, locking the tulip assembly onto the pedicle screw, and subsequently capturing and locking the rod into the tulip assembly.

20 The various embodiments described above can be combined to provide further embodiments. All of the above U.S. patents, patent applications, provisional patent applications and publications referred to in this specification, to include, but not limited to U.S. Provisional Patent Application Nos. 60/622,107 filed October 25, 2004; 60/622,180 filed October 25, 2004;
25 60/629,785 filed November 19, 2004; 60/663,092 filed March 18, 2005; and 60/684,697 filed May 25, 2005 are incorporated herein by reference in their entirety. Aspects of the invention can be modified, if necessary, to employ various systems, devices and concepts of the various patents, applications and publications to provide yet further embodiments of the invention.

30 These and other changes can be made to the invention in light of the above-detailed description. In general, in the following claims, the terms

used should not be construed to limit the invention to the specific embodiments disclosed in the specification and the claims, but should be construed to include all bone fixation systems and methods that operate in accordance with the claims. Accordingly, the invention is not limited by the disclosure, but instead
5 its scope is to be determined entirely by the following claims.

The claims defining the invention are as follows:

1. A tulip assembly comprising:
 - a pedicle screw having a threaded portion and a head portion;
 - a first device elastically expandable to receive said head portion of said pedicle
 - 5 screw; and
 - a second device having an engagement portion, the engagement portion in contact with said first device to fix the tulip assembly to the head portion of the pedicle screw;
 - at least a portion of the tulip assembly having generally opposing channels for
 - 10 receiving a rod; said at least a portion of said tulip assembly being adapted to receive said rod and rotate about the rod to capture the rod and cause the rod to become locked in the tulip assembly after said engagement portion contacts said first device to fix the tulip assembly to the head portion;
 - each of said generally opposing channels being defined by a first surface and a
 - 15 generally opposing second surface, said first and second surfaces also cooperating to define a first channel portion and a second channel portion that is in communication with said first channel portion, said first channel portion defining a rod-receiving opening that opens upwardly and away from an end of said tulip assembly from which said pedicle screw extends, said first channel portion extending away from said rod-receiving opening
 - 20 and toward said end in a first direction that is generally parallel to an axis of said tulip assembly, said second channel portion extending in a second direction that is not colinear with said first direction and that is not generally parallel to said axis;
 - said first channel portion being adapted to receive said rod after said rod is received in said rod-receiving opening and guide said rod to said second channel portion
 - 25 so that said second channel portion can receive and lock said rod in said tulip assembly in response to said tulip assembly being rotated.
2. The tulip assembly of claim 1, further comprising:
 - a third device coupled to the second device, the second and third devices
 - working in cooperation to selectively fix at least a portion of a rod in the tulip assembly.
- 30 3. The tulip assembly of claim 1, wherein the tulip assembly is rotationally maneuverable on the head portion of the pedicle screw before the second device engages the first device.
4. The tulip assembly of claim 1, wherein the first device is a ring configured to be elastically, diametrically expandable and contractible.

5. The tulip assembly of claim 4, wherein the ring includes a split that permits a diameter of the ring to vary from a first, larger diameter to a second, smaller diameter.
6. The tulip assembly of claim 1, wherein the first device includes an inner
5 surface to seat against the head portion of the pedicle screw.
7. A pedicle screw system comprising:
a pedicle screw having a threaded portion and a head portion;
a tulip assembly comprising a first device and a second device, the first device being elastically expandable to receive the head portion of the pedicle screw, and the
10 second device having an engagement portion, the engagement portion engageable with the first device to fix the tulip assembly to the head portion of the pedicle screw; and
at least a portion of the tulip assembly having generally opposing channels for receiving a rod; said at least a portion of said tulip assembly being adapted to receive said rod and rotate about the rod to capture the rod and cause the rod to become locked in the
15 tulip assembly after said engagement portion engages said first device to fix the tulip assembly to the head portion;
each of said generally opposing channels being defined by a first surface and a generally opposing second surface, said first and second surfaces also cooperating to define a first channel portion and a second channel portion that is in communication with
20 said first channel portion, said first channel portion defining a rod-receiving opening that opens upwardly and away an end of said tulip; assembly from which said pedicle screw extends, said first channel portion extending away from said rod-receiving opening and toward said end in a first direction that is generally parallel to an axis of said tulip assembly,
25 said second channel portion extending in a second direction that is generally normal to said first direction and that is not generally parallel to said axis;
said first channel portion being adapted to receive said rod after said rod is received in said rod-receiving opening and guide said rod to said second channel portion so that said second channel portion can receive and lock said rod in said tulip assembly in
30 response to said tulip assembly being rotated.
8. The pedicle screw system of claim 7, further comprising:
a third device coupled to the second device, the second and third devices working in cooperation to selectively fix at least a portion of a rod in the tulip assembly.

9. The pedicle screw system of claim 7, wherein the tulip assembly is rotationally maneuverable on the head portion of the pedicle screw before the second device engages the first device.

10. The pedicle screw system of claim 7, wherein the first device is a compression ring that is expandable to be moved over the head portion of the pedicle screw.

11. The pedicle screw system of claim 10, wherein the compression ring includes a split that permits a diameter of the compression ring to vary from a first, larger diameter to a second, smaller diameter.

12. The pedicle screw system of claim 7, wherein the first device includes an inner surface to seat against the head portion of the pedicle screw.

13. A pedicle screw system comprising:

a pedicle screw having a threaded portion and a spherical head portion;

a poly-axial tulip assembly having a bore for accommodating the passage of the spherical head portion of the pedicle screw therethrough, said poly-axial tulip assembly having an inner component, an outer component and a fastener assembly, said poly-axial tulip assembly positioned on the spherical head portion of the pedicle screw;

wherein the fastener assembly is tapered along an edge, wherein an inner bore of the inner component is reciprocally tapered such that the fastener assembly mates with the inner component to allow said poly-axial tulip assembly to be locked onto the spherical head portion of the pedicle screw while allowing said poly-axial tulip assembly to move poly-axially in relation to the pedicle screw; and

wherein the outer component is adapted to receive the inner component in an engaged position, wherein the inner component is received in a retained position and locks an orientation of the poly-axial tulip assembly relative to the pedicle screw and the inner component comprising at least one first channel and the outer component comprising at least one second channel adapted to receive a rod, the inner component and the outer component being rotatable relative to each other and said at least one first channel and said at least one second channel cooperate to capture the rod and lock the rod in said poly-axial tulip assembly;

each of said at least one first channel and said at least one second channel being defined by a first surface and a generally opposing second surface, said first and second surfaces cooperating to define a first channel portion and a second channel portion that is in communication with said first channel portion, said first channel portion defining a

rod-receiving opening that opens upwardly and away from an end of said poly-axial tulip assembly from which said pedicle screw extends, said first channel portion extending away from said rod-receiving opening and toward said end in a first direction that is generally parallel to an axis of said poly-axial tulip assembly, said second channel portion
5 extending in a second direction about at least a portion of said axis and that is not parallel to said axis;

said first channel portion being adapted to receive said rod after said rod is received in said rod-receiving opening and guide said rod to said second channel portion so that said second channel portion can receive and lock said rod in said poly-axial tulip
10 assembly in response to said relative rotation of said inner component or said outer component.

14. The pedicle screw system of claim 13, wherein the fastener assembly includes a compression ring positioned around at least a part of the spherical head portion of the pedicle screw.

15 15. The pedicle screw system of claim 14, wherein the compression ring includes a split in the compression ring that permits the diameter of the compression ring to vary from a first, larger diameter to a second, smaller diameter.

16. The pedicle screw system of claim 13, wherein said poly-axial tulip assembly comprises a tulip assembly channel, the tulip assembly channel being shaped to
20 receive the rod.

17. The pedicle screw system of claim 16, wherein the tulip assembly channel is U-shaped.

18. The pedicle screw of claim 16, wherein the tulip assembly channel extends from a top region of the poly-axial tulip assembly to a lower region of the poly-
25 axial tulip assembly.

19. The pedicle screw system according to claim 13, wherein the inner component is rotatable from a first open position to a second closed position so that when the rod is placed in a recess of the poly-axial tulip assembly, said rod becomes retained in a locked position when said inner component is rotated relative to said outer component.

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20. The pedicle screw system according to claim 13, wherein the outer component has a lip.

Dated 1 September, 2010

X-spine Systems, Inc.

Patent Attorneys for the Applicant/Nominated Person

SPRUSON & FERGUSON

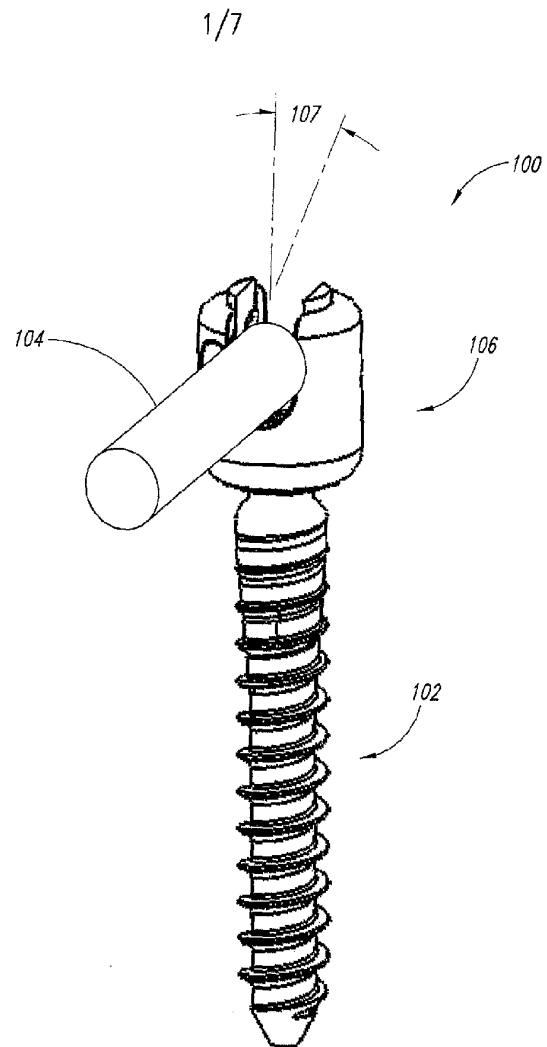


FIG. 1

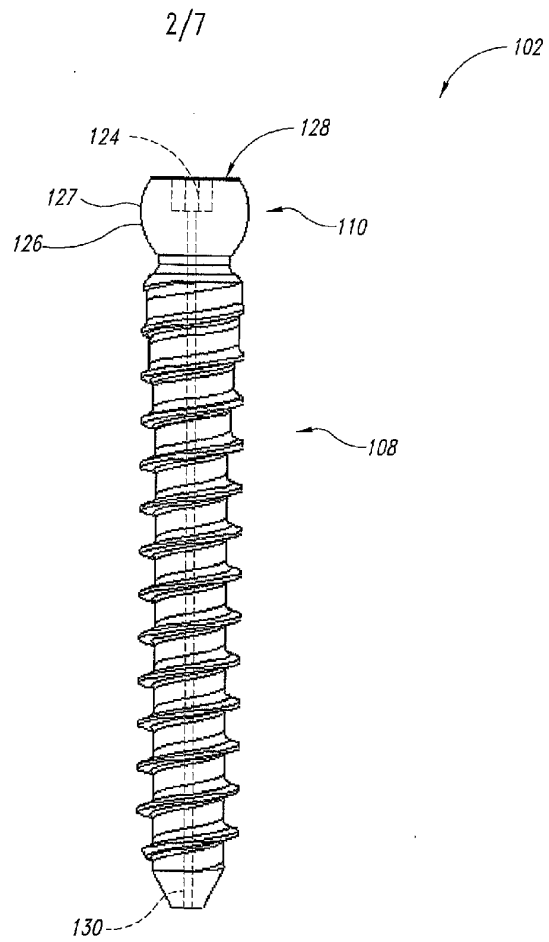


FIG. 2

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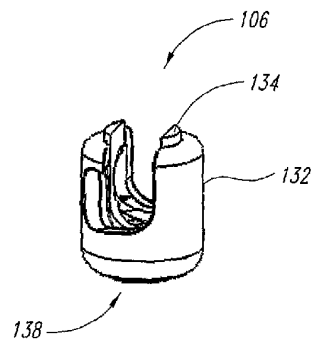


FIG. 3

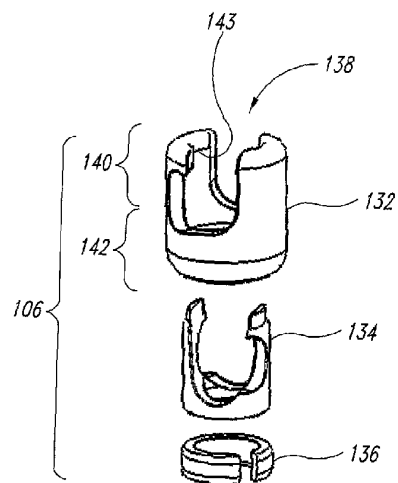


FIG. 4

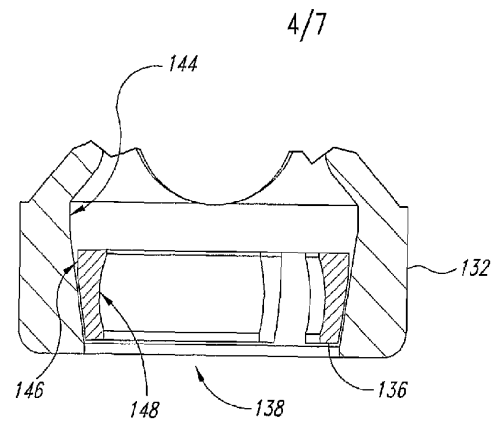


FIG. 5

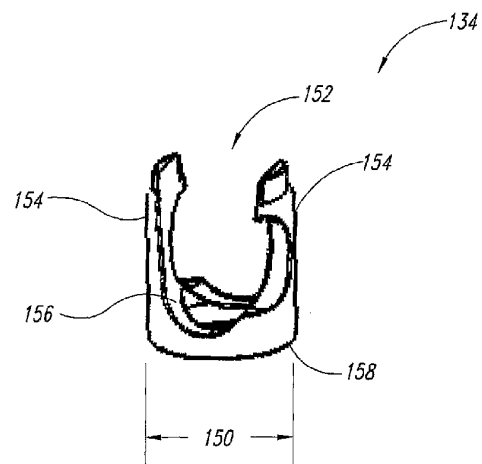


FIG. 6

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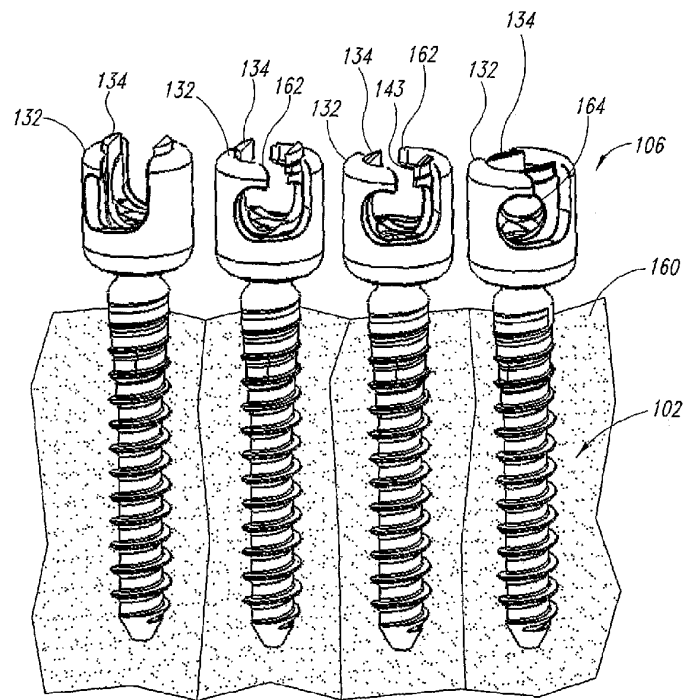


FIG. 7A

FIG. 7C

FIG. 7B

FIG. 7D

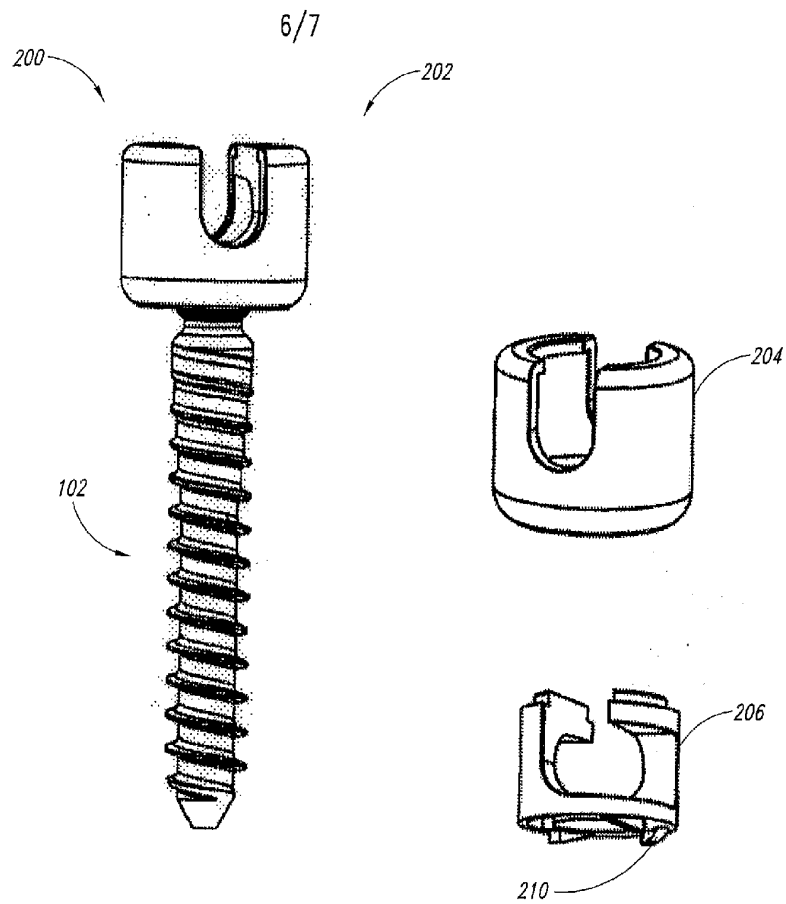


FIG. 8

FIG. 9

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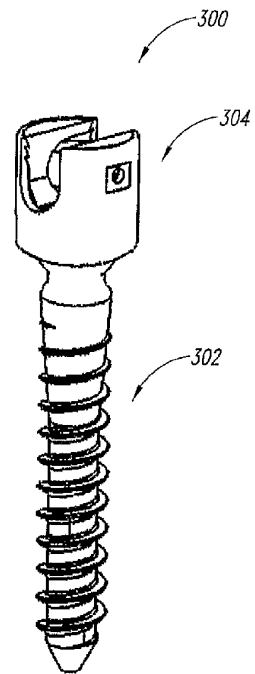


FIG. 10

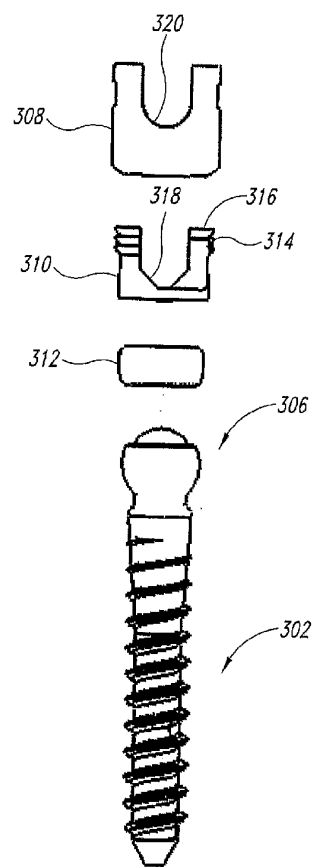


FIG. 11