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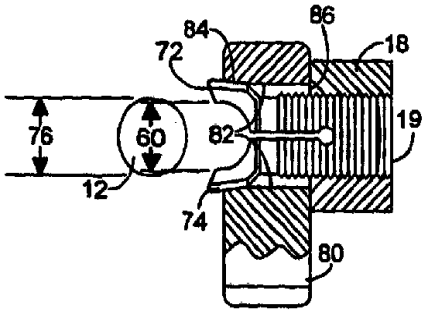
(57) Abstract

A spinal fixation implant system for correction and fixation of the human spine to facilitate an anatomically correct fusion. The spinal fixation system may include a connector, a spinal rod, a spinal fixation component, a sleeve, and a fastener. The spinal fixation component preferably includes a fixation device such as a hook or screw for securing the spinal rod to vertebrae of the thoracic or lumbar spine. The spinal fixation component preferably includes a threaded end on its top that is adapted to receive the fastener. The fixation component may include a body having a tapered cavity for engaging the receiving end of the connector. Tightening of the fastener preferably downwardly translates the sleeve over the fixation component body to force the connector through the tapered cavity, which compresses the receiving end about the spinal rod to fixation connect the spinal rod and the spinal fixation component. In an alternate embodiment, assembly pliers may be used to move the connector into the tapered cavity. The fixation component may also include a rotatable fixation member.



METHOD AND APPARATUS FOR SPINAL FIXATION

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention generally relates to spinal fixation systems and the like. More particularly, an embodiment of the invention relates to a spinal implant system for correction, fixation, and stabilization of the human spine to allow the development of a solid spinal fusion.

2. Description of the Related Art

Spinal fixation, such as lumbar sacral fusion and the correction of spinal deformities such as scoliotic curves, is a well known and frequently used medical procedure. Pedicle, lateral, and oblique mounting devices may be used to secure corrective spinal instrumentation to a portion of the spine that has been selected to be fused by arthrodesis.

A spinal fixation system typically includes corrective spinal instrumentation that is attached to selected vertebrae of the spine by screws, hooks, and clamps. The corrective spinal instrumentation includes spinal rods or plates that are generally parallel to the patient's back. The corrective spinal instrumentation may also include transverse connecting rods that extend between neighboring spinal rods. Spinal fixation systems are used to correct problems in the lumbar and thoracic portions of the spine, and are often installed posterior to the spine on opposite sides of the spinous process and adjacent to the transverse process.

Various types of screws, hooks, and clamps have been used for attaching corrective spinal instrumentation to selected portions of the patient's spine. Examples of pedicle screws and other types of attachments are illustrated in U.S. Patent Nos. 4,763,644; 4,805,602; 4,887,596; 4,950,269; and 5,129,388. Each of these patents is incorporated by reference as if fully set forth herein.

An eyebolt assembly of the TSRH® spinal system sold by Danek Medical Inc. is illustrated in Figure 1. The eyebolt assembly 2 encircles spinal rod 4 such that assembly mass completely surrounds the spinal rod. The spinal rod must be inserted through the eyebolt, which rests within the yoke of spinal hook 8. The spinal hook attaches the spinal rod to a bony element of the spine. A nut 6 is threaded onto a post of the eyebolt assembly to fixably secure the rod within the yoke. The nut is tightened so that the assembly resists axial, torsional, and shear forces to inhibit motion of the spinal rod relative to the assembly in the directions indicated by the arrows in Figure 1. Further details of the TSRH® spinal system are provided in the TSRH® Spinal Implant System Surgical Technique Manual and the TSRH® Crosslink Surgical Technique Manual. Both of these publications are available from Danek Medical Inc. and are incorporated by reference as if fully set forth herein.

Manual insertion of a spinal rod through the bores of a number of spaced-apart eyebolts within a surgical wound tends to be difficult. The bore axis of each eyebolt must be properly aligned along a common axis, which is difficult since the corrective procedure requires that the spinal rod initially be placed under

stress to resist deforming forces of the spine. Therefore, the use of systems such as the TSRH (Registered Trade Mark) spinal system may require that a predetermined number of screws or hooks be pre-loaded onto the spinal rod in a particular order and spacing prior to the insertion of the spinal rod into the surgical wound. After insertion of the spinal system into the surgical wound, however, it is often necessary to add, delete, or reposition one or more hooks or screws. Before such modifications can be made, the spinal system typically must be removed from the surgical wound and at least partially disassembled.

To overcome such problems, some spinal fixation systems include "open back" hooks or screws to allow a spinal rod to be dropped into the open back of the hook or screw and secured within the open back by a separate component and a set screw. Such a system is illustrated in U.S. Patent No. 5,102,412 to Rogozinski, which is incorporated by reference as if fully set forth herein. Such systems tend to be susceptible to fatigue stress failure and require assembly within the surgical wound. In addition, adding a hook or screw to the construct tends to require that the spinal rod first be repositioned. A further disadvantage of this approach is that component mass completely surrounds the spinal rod, resulting in an increase in the profile width of the device and greater impingement of the device upon the fusion mass. A low profile width is generally desired to minimize sinus formation and soft tissue irritation from hardware prominence.

U.S. Patent No. 5,242,445 to Ashman relates to a "split eyebolt" assembly for adding eyebolts to an assembled spinal fixation construction. Attaching the split eyebolt to a spinal rod requires a special crimping tool to crimp the split eyebolt over the rod. The crimping tool tends to be difficult to operate within the surgical wound. Furthermore, the threads of the opposing sides of the split eyebolt are often misaligned after crimping, making it difficult or impossible to thread a nut onto the split eyebolt. The split eyebolt also completely encircles the spinal rod thereby increasing the impingement of the construct upon the fusion mass.

It is therefore desirable that an improved spinal fixation system be derived that facilitates assembly and surgical implantation by allowing the spinal rod to be positioned within the surgical wound (a) after the fixation components (e.g., screws, hooks) have been implanted, (b) without modifying the fixation components, and (c) whereby fixation components may be subsequently added, deleted, and/or repositioned without disassembling the system.

SUMMARY OF THE INVENTION

In accordance with the present invention, a spinal fixation system is provided that largely eliminates or reduces the aforementioned disadvantages of conventional spinal fixation constructions. An embodiment of the invention relates to an implant system for fixation of the human spine that includes a spinal rod, a fixation component, a connector, and a fastener.

In accordance with a first aspect of the present invention, therefore, there is provided an implant system for fixation of the human spine, said system including: a connector including a threaded end, a receiving end opposite said threaded end, said receiving end terminating in a first arm and a second arm that together form a substantially U-shaped borehole, said first arm including a first tip and said second arm including a second tip, and wherein an opening is formed between said first tip and said second tip; a spinal rod axially positionable through said opening into said borehole during use; a fixation component including a body, said body including a cavity configured to receive said receiving end of said connector, wherein said connector is adapted to be at least partially disposed within said cavity such that the inner surface of said cavity engages and exerts a compressive force onto said receiving end of said connector during use; and a fastener adapted to engage said threaded end of said connector.

In accordance with another aspect of the invention there is provided a connector for connecting spinal fixation components to a spinal rod, said connector including: a threaded end; a receiving end opposite said threaded end, said receiving end terminating in a first arm and second arm that together form a substantially U-shaped borehole for receiving said spinal rod, said first arm including a first tip and said second arm including a second tip, and wherein said borehole includes an open end having a width defined by said first tip and said second tip; and a slot extending between said threaded end and said receiving end, wherein said arms are deflectable to cause narrowing or widening of a portion of said slot and variation of the width of the open end to allow a spinal rod to be snapped into said borehole through the open end to form a fixable engagement between a spinal rod and said receiving end.

The connector may be used to connect the spinal rod to the fixation component and preferably includes a receiving end and a fastening end. The receiving end may contain a first arm and a second arm that together form a substantially

U-shaped borehole into which the spinal rod may be axially positioned. The receiving end preferably surrounds only part of the spinal rod such that the unsurrounded portion of the spinal rod is exposed from the borehole. The exposed portion of the spinal rod may extend out of an open end of the U-shaped borehole. The spinal rod may be circular and preferably includes a cross-section having a

circumferential portion. The receiving end of the connector preferably surrounds and engages greater than about π radians and less than about 2π radians of the circumferential portion.

The receiving end of the connector preferably acts as a "pinch clamp" by exerting a clamping force on opposing sides of the spinal rod to secure the spinal rod within the borehole. The connector preferably contains a slot between the receiving end and the fastening end that enables the first arm and the second arm to be deflected relative to one another. The deflection of the arms allows the distance between a tip of the first arm and a tip of the second arm to be changed so that the spinal rod may be inserted through an open end of the U-shaped borehole that is defined between the tips of the arms.

The fixation component preferably includes a fixation device such as a bone screw or hook for engaging vertebrae of the thoracic or lumbar spine. The fixation component also preferably includes a body containing a cavity with an inner surface. The cavity is preferably sized to receive a portion of the connector. The connector is preferably partially disposed within the cavity such that at least a portion of the fastening end extends from the cavity, whereby the inner surface of the cavity engages an outer surface of the receiving end. The cavity of the body is preferably a tapered cavity that narrows in a direction from a first end of the cavity to a second end of the cavity. The tapered cavity preferably surrounds a portion of the receiving end and imparts a compressive force against the receiving end to secure the spinal rod within the borehole.

The fastener preferably engages both the body and the portion of the fastening end that extends from the cavity. The fastener may secure the connector and the fixation component together. The fastener is preferably a nut adapted to be threaded upon the fastening end. The fastener may be selectively tightened to allow an engagement between the connector and the spinal rod that may be overcome by the application of a distraction force to the connector. Rotation of the nut in a tightening direction about the fastening end preferably draws a portion of the receiving end through the tapered cavity, causing the inner surface of the cavity to compress the arms of the receiving end. In turn, the arms may exert a compressive force against the spinal rod to clamp it within the borehole. The magnitude of the compressive force against the spinal rod preferably varies as a function of the degree to which the nut is tightened. The open end of the U-shaped borehole preferably has a width that can be adjusted by tightening the fastener.

The fixation component may include a spacer located between the fastener and the spinal rod for laterally offsetting the fixation device a selected lateral distance from the spinal rod. The spacer may include a surface having a plurality of radially-spaced teeth. The fixation component may comprise a plurality of radially-spaced protrusions adapted to fit adjacent to the teeth on the surface of the spacer. The tightening of the nut preferably causes the spacer and the fixation component to become pressed together such that a complementary engagement between the teeth of the spacer and the protrusions of the fixation device is formed to inhibit rotation of the fixation device about the spacer.

The body may include a U-shaped yoke formed between a top section and a bottom section that each have an edge adjacent to the yoke. The tapered cavity preferably is formed between the top section and the bottom section and extends in a perpendicular direction relative to the U-shaped yoke. The fixation component is preferably adapted to pivot about the spinal rod in a substantially vertical plane. The edges of the top and bottom sections preferably contact the spinal rod during the pivoting of the fixation component to define the

range of pivotal motion of the fixation component about the spinal rod. The edges are preferably curved in a direction away from the spinal rod to increase the range of pivotal motion of the fixation component.

The fixation component may include a transverse connector to maintain a fixed distance between the spinal rod and a neighboring spinal rod. The transverse connector may include a reduced section that has a width less than that of the body, allowing the reduced section to be more easily bent. The reduced section may be bent to shorten the lateral distance between the spinal rod and an adjacent spinal rod. The transverse connector may contain a beveled section between the body and the reduced section.

In an embodiment, the connector includes a receiving end forming a substantially U-shaped borehole and a capped end opposite the receiving end. The connector may be forced into the cavity of a fixation component body with an instrument such as a pair of assembly pliers. The instrument preferably includes a first elongated member and a second elongated member. The elongated members may be moved relative to one another to exert a compressive force against the connector and the fixation component to move the connector within the cavity of the fixation component body. The first elongated member preferably includes a curvate indention for engaging the spinal rod. The second elongated member preferably includes a borehole for receiving an end of the connector.

In an embodiment, the fixation component includes a fastening end. The fastening end preferably is adapted to receive a fastener (e.g., threaded nut). Downward translation of the fastener preferably moves a sleeve downwardly over the body of the fixation component. The sleeve preferably contains a substantially U-shaped opening having a angled locking surface for engaging the spinal rod. During assembly, the fastener is preferably tightened to move the sleeve downwardly, thereby imparting a force on the spinal rod that causes the connector to move through the tapered cavity.

In an embodiment, the fixation component may include a pivotable fixation device. The fixation device is preferably adapted to pivot about the body of the fixation component along the longitudinal axis of the body. The body of the fixation component may be adapted to inhibit the lateral motion of the fixation device. The body of the fixation component may be adapted to engage a portion of the connector.

In an embodiment the connector may include an opening adapted to completely surround the circumferential portion of the spinal rod. The connector may include a slot running through the center of the connector, communicating with the opening. The slot may be adapted to allow the circumference of the opening to vary. Insertion of a spinal rod preferably causes the slot to widen such that the circumference of the opening increases. The connector may be placed within the fixation component such that the slot is narrowed to secure a spinal rod to the connector.

An advantage of the present invention relates to a fixation component that may be added to or deleted from a spinal fixation construct in a surgical wound without disassembling the construct.

Another advantage of the present invention relates to a spinal fixation system requiring minimal assembly within the surgical wound.

Yet another advantage of the present invention relates to a spinal fixation system having a relatively narrow profile width to reduce impingement upon the fusion mass.

BRIEF DESCRIPTION OF THE DRAWINGS

Further advantages of the present invention will become apparent to those skilled in the art with the benefit of the following detailed description of the preferred embodiments and upon reference to the accompanying drawings in which:

Figure 1 depicts a TSRH® spinal system eyebolt assembly;

Figure 2 depicts a side view of an embodiment of a spinal fixation system connected to a vertebra;

Figure 3 depicts a top view of the spinal fixation system of Figure 1;

Figure 4 depicts a side view of a tapered connector constructed in accordance with the present invention;

Figure 5 depicts a side view of a tapered connector prior to assembly with a fixation component body and a spinal rod;

Figure 6 depicts a side view of a tapered connector assembled with a spinal fixation component and a spinal rod;

Figure 7 depicts a side view of a transverse connector disposed between a pair of spinal rods in accordance with the present invention;

Figure 8 depicts a front view and side view partially in section of a bone screw constructed according to teachings of the present invention;

Figure 9 depicts a front view and side view partially in section of a bone screw having radially-spaced protrusions in accordance with the present invention;

Figure 10 depicts a front view and a side view partially in section of a reversible fixation component constructed according to teachings or the present invention;

Figure 11 depicts a side view partially in section of a spacer disposed between a spinal rod and a fastener in accordance with the present invention;

Figure 12 depicts a side view partially in section of a spinal fixation system prior to assembly;

Figure 13 depicts a side view partially in section of a spinal fixation system assembled with an instrument;

Figure 14 depicts a side view partially in section of a spinal fixation system that includes a set screw engaging a connector;

Figure 15 depicts a spinal fixation system that includes a locking sleeve;

Figure 16 depicts a side view of the spinal fixation system of Figure 15 after assembly;

Figure 17 depicts a side view partially in section of the system of Figure 15 after assembly;

Figure 18 depicts a side view of a spinal fixation system that includes a rotatable fixation device;

Figure 19 depicts a top view of a fixation component that includes a rotatable fixation device;

Figure 20 depicts a cross sectional view of the side of a spinal fixation system that includes a rotatable fixation device;

Figure 21 depicts a side view of a tapered connector adapted to completely surround a portion of a spinal rod;

Figure 22 depicts a cross sectional view of the side of a spinal fixation system that includes a rotatable fixation device and a connector adapted to completely surround a portion of a spinal rod;

Figure 23 depicts a rear view of a spinal fixation system adapted to completely surround a portion of a spinal rod; and

Figure 24 depicts a cross sectional view of the side of a spinal fixation system adapted to completely surround a portion of a spinal rod.

While the invention is susceptible to various modifications and alternative forms, specific embodiments thereof are shown by way of example in the drawings and will herein be described in detail. It should be understood, however, that the drawings and detailed description thereto are not intended to limit the invention to the particular form disclosed, but on the contrary, the intention is to cover all modifications, equivalents and alternatives falling within the spirit and scope of the present invention as defined by the appended claims.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Figure 2 depicts a spinal fixation system 10 constructed according to teachings of the present invention. In an embodiment of the invention, spinal fixation system 10 includes a spinal rod 12 generally aligned parallel with a portion of the spine. Connector 16 secures spinal fixation components to the spinal rod via fastener 18. The fixation components may include various fixation devices including bone screw 14, transverse connector 20, and spinal hooks 22 and 24.

Spinal rod 12 is preferably constructed of stainless steel or another relatively rigid material. The spinal rod preferably has a substantially circular cross-section (although other cross-sectional geometries may be employed) and a diameter between about 1/8 of an inch and about 1/4 of an inch. The spinal rod may have a shot-peened surface to increase its resistance to fatigue failure. The spinal rod may impart forces against the spine to maintain a portion of the spine in a fixed position to correct a spinal deformity or injury. The spinal rod may be contoured to a selected shape prior to or after surgical implantation.

Bone screw 14 is preferably inserted within the main body of a vertebra 26 and may contain threads 28 to create a fixable engagement with the vertebra. Alternatively, the bone screw may have a substantially smooth shank containing no threading. The stress imparted to spinal fixation systems resulting from a spinal deformity may cause fatigue failure of a threaded bone screw if a solid spinal fusion does not develop after a period of time. Threaded screws having relatively long shanks tend to fail at a location adjacent to the screw head. A substantially smooth, unthreaded shank tends to remove the stress concentration on the screw shank from a location adjacent to the screw head where failure of the screw often occurs. The bone screw may also include a tap relief 30 to facilitate its insertion into vertebra 26. The angle of the bone screw relative to the spinal rod is preferably adjustable. The bone screw may be angled to correct the angle 32 of a vertebra relative to other vertebrae in the spine. The angle between the bone screw and spinal rod is preferably fixable by tightening fastener 18. Furthermore, the height of the vertebra 26 may be adjusted by applying a distraction force in the directions indicated by arrow 34 between a pair of fixation devices such as bone screw 14 and spinal hook 24 prior to tightening fasteners 18. The distraction force may be applied with the use of a tool in a manner well known to those skilled in the art.

The spinal hooks 22 and 24 may be any of a number of types of hooks well known to those skilled in the art including large laminar, small laminar, thoracic laminar, and pedicle hooks. Each spinal hook may be positioned in the caudal direction (illustrated by hook 24 in Figure 2) or in the cranial direction (illustrated by hook 22 in Figure 2). Spinal hooks may be positioned on opposing sides of the spinal rod as shown in Figure 2.

Figure 3 depicts a top view of an embodiment of spinal fixation system 10 that includes a pair of spinal rods 12 in spaced relation on each side of the vertical axis 40 of the spine. Spinal hooks 22 and 24 are preferably positioned for attachment to bony elements of the posterior human spine. One or more transverse connectors 20 may be used to rigidly link the rods to improve the strength of the assembly. Each of the fixation components may be attached to the spinal rod using a fastener 18 that engages connector 16 and the fixation component.

Transverse connector 20 may connect neighboring rods to increase the rigidity of the construct and to prevent the movement of the rods relative to one another. The transverse connector may be attached to the spinal rod using crosslinking plates that are well known to those skilled in the art and described in the TSRH® Crosslink Surgical Technique Manual, which is incorporated by reference herein. It is preferred that neighboring rods be connected by two transverse connectors that may be aligned parallel and in spaced relation from one another. If the spinal rod is bent, transverse connector 20 is preferably attached to the spinal rod at a location other than the "peak" of the curved section of the rod so that additional stress is not placed at that location.

An embodiment of connector 16 is illustrated in Figure 4. The connector preferably includes a fastening end 50 and a receiving end 54 opposite the fastening end. The fastening end may be a threaded end containing male machine threads 52 that are adapted to engage a fastener. The fastener is preferably a nut. The receiving end preferably includes a first arm 56 and a second arm 58 that together form a U-shaped borehole 62. The first arm has a tip 72 and the second arm has a tip 74 (each labeled in Figure 5), and an opening 60 or open end is preferably defined by the tips of the first and second arm. A slot 64 preferably extends between the receiving end and the fastening end. The slot may extend from borehole 62 proximate the receiving end to a location proximate the fastening end. The slot may terminate in an enlarged opening 66 within the receiving end. The borehole is preferably adapted to receive a spinal rod 12 such that the first and second arms of the receiving end surround more than about half of a circumferential portion of the spinal rod.

The connector preferably does not completely surround the perimeter of the spinal rod. The unsurrounded portion of the spinal rod is preferably exposed from the open end 60 of the U-shaped borehole and may extend from the borehole through the open end. It is preferred that component mass be placed around only slightly greater than one-half of the circumference of the spinal rod to minimize the profile width of the construct. In this manner, the impingement of the construct upon the fusion mass is lessened, thereby reducing irritation of the surrounding tissue and facilitating the development of a correct spinal fusion in a minimal amount of time. Conventional assemblies tend to completely surround the spinal rod with component mass, causing a relatively greater impingement upon the fusion mass, which may interfere with fusion development.

The angle 68 in Figure 4 is defined by the circumferential portion of a spinal rod that is surrounded by the first arm, second arm, and the end of slot 64. The angle 68 is preferably less than about 2π radians (e.g., 360° around the cross-section of the spinal rod) and greater than about π radians (e.g., 180° around the cross-section of the spinal rod). It is preferred that more than about half of the circumferential portion the spinal rod be surrounded by a portion of the receiving end (e.g., first arm, second arm, end of slot 64) to allow the spinal rod to be adequately secured within the borehole. If less than half of the circumferential portion of the spinal rod were surrounded by the receiving end, forces resulting from spinal deformations might tend to pull the spinal rod from within borehole 62. First arm 58 and second arm 68 preferably engage the surface of greater than about half of the circumferential portion of the spinal rod.

The first arm and the second arm preferably each have an outside surface that is slightly tapered such that the distance between the outside surfaces of the arms narrows in a direction from tips 72 and 74 to the fastening end 50. The taper of the outside surfaces of the arms preferably defines a locking angle 70. Locking angle 70 is preferably a conical angle, although it may be formed within a substantially flat wedge instead.

Locking angle 70 is preferably less than about 30°, more preferably less than about 25°, and more preferably still between about 1° and about 20°.

Figures 5 and 6 illustrate the insertion of spinal rod 12 within borehole 62 in an embodiment of the invention. The spinal rod is preferably axially positioned within the borehole by passing the spinal rod through opening 60. Slot 64 preferably enables deflection of the first arm and the second arm relative to one another to allow the width of opening 60 to be altered. In the absence of an external force of a selected magnitude against the first or second arms, the width of opening 60 is preferably less than the outside diameter 76 of the spinal rod. Receiving end 54 is preferably adapted to form a "snap-fit" engagement with the spinal rod that may be realized by forcing the spinal rod into the inner surfaces of tips 72 and 74 of the first and second arms, respectively. The force against the inner surfaces of the tips 72 and 74 preferably causes the arms to slightly deflect in opposite directions, resulting in a slight widening of at least a portion of the slot. In this manner, the width of opening 60 may be increased by an amount sufficient to allow the insertion of the spinal rod through opening 60 and into the borehole. Once the spinal rod is fully inserted within the borehole (as shown in Figure 6), the arms preferably move back toward one another, causing the slot to narrow to its initial, unstressed width. If the diameter of the spinal rod is slightly greater than that of the borehole, the arms may remain slightly deflected and the slot may remain slightly widened after the spinal rod is snapped into the borehole. It is generally preferred that the diameter of the spinal rod and the diameter of the borehole be equal.

In an embodiment of the invention, connector 16 connects the spinal rod to a fixation component that engages a portion of the spine. The fixation component preferably includes a fixation device such as a bone screw, hook, transverse connector, or similar device. The fixation component preferably includes a body 80 having a tapered cavity into which connector 16 may be inserted. The tapered cavity preferably tapers in a direction that is substantially perpendicular to the longitudinal axis of the fixation component. The tapered cavity preferably has a first end 84, a second end 86, and an inside surface 82. The inside surface 82 is preferably tapered at an angle that corresponds to locking angle 70. The tapered cavity preferably narrows in a direction from first end 84 to second end 86. The tapered cavity is preferably sized so that fastening end 50 and a portion of receiving end 54 may be inserted within the tapered cavity through an aperture proximate the first end. The outer width of the receiving end proximate tips 72 and 74 is preferably slightly greater than the width of the aperture proximate the first end, thereby inhibiting the complete insertion of the receiving end into the tapered cavity.

Fastener 18 may be a hex nut and preferably contains female threading 19, which is sized to fit the male machine threads of the fastening end 50. The nut preferably engages fastening end 50 and body 80 whereby rotating the fastener in a tightening direction creates a tensile force in the connector in direction 88. Tightening of the fastener preferably moves the connector within the tapered cavity in a direction from first end 84 to second end 86, thereby creating an interference fit between the arms of the receiving end and inside surface 82. As the fastener is tightened, the arms are preferably deflected toward one another such that the slot is narrowed and the arms of the receiving end exert a compressive force against the spinal rod disposed within the borehole.

The magnitude of the compressive force exerted by the receiving end on the spinal rod is preferably variable as a function of the degree to which the fastener is tightened. The fastener may be selectively

tightened so that the connector is "loosely" engaged to the spinal rod. The "loose" engagement preferably fixes the position of the connector on the rod in the absence of a selected force against the connector, while allowing the connector to slide over the surface of the rod upon receiving a distraction force. For instance, the fastener may be partially tightened to loosely attach a connector and fixation device onto the rod at a selected location. A distraction force may be applied to the connector to move the connector to a selected location on the rod, and the fastener may then be fully tightened to maintain the connector at the selected location.

The arms 56 and 58 preferably exert a clamping force onto "opposite sides" of the rod (i.e., sections of the outer surface of the spinal rod that are separated by about 180°). The engagement between the arms 56 and 58 and the "opposite sides" of the spinal rod preferably "centers" the rod within the borehole as shown in Figure 6 so that substantially no gaps exist between the inner surface of the arms and the spinal rod. The rod may be constrained on opposing sides in this manner to provide further resistance to forces that might otherwise result in axial movement of the rod. When the arms 56 and 58 are deflected to engage the spinal rod, the receiving end preferably forms a "locking taper" engagement with the spinal rod. A "locking taper" engagement is taken to mean a largely irreversible deflection of the receiving end. That is, if the fastener becomes loose after the receiving end has been compressed about the spinal rod, the clamping force exerted by the receiving end will be maintained to fixably hold the spinal rod within the borehole.

In an embodiment of the invention depicted in Figure 7, a transverse connector 20 is disposed between a pair of spinal rods in spaced relation to secure the rods at a fixed distance 90. The spinal rods are fixed within the borehole of a connector in the manner depicted in Figures 5 and 6 and described above. The transverse connector may include a beveled surface between body 80 and a reduced section 92. Reduced section 92 preferably has a smaller width or diameter than body 80 to allow the reduced section to be bent more easily. Slight variations in distance 39 may be achieved by bending transverse connector 20 proximate reduced section 92. The bending of the transverse connector may be accomplished using a rod bender and a method well known to those skilled in the art. Alternately, the transverse connector may have a substantially constant width or diameter such that the width of section 92 and the width of body 80 are approximately equal.

The fixation component may include a bone screw that is used to correct the angle 32 between vertebrae. It is preferred that the bone screw be adapted to pivot about the spinal rod to form an oblique angle between the longitudinal axis of the spinal rod and the shank of the bone screw. The bone screw preferably can be pivoted in either direction 96 or direction 98 such that an oblique angle between about 90° and about 60° is formed between the shank and the longitudinal axis of the spinal rod. Other fixation devices (e.g., hooks) may be pivoted with respect the spinal rod in the same manner. As illustrated in Figure 8, the tapered cavity may contain an engaging side 100 adapted to contact flat 102 of connector 16 to limit the pivoting of a fixation device (e.g., bone screw) about the spinal rod within a selected range, thereby preventing a gross misalignment that might complicate the assembly of the construct during a surgical procedure.

Body 80 preferably includes a top section 104 and a bottom section 106 that together form a U-shaped yoke 112 that is substantially perpendicular to inside surface 82 of the tapered cavity. The fixation component may pivot about the spinal rod. The edges of top section 104 and/or bottom section 106 may contact the spinal rod to prevent the pivoting of the fixation component about the spinal rod beyond a selected degree. Top section 104 preferably contains a curved edge 108, and bottom section 106 preferably contains a curved edge

110. Curved edges 108 and 110 preferably increase the degree that the fixation component can pivot and allow a fixation device (e.g., bone screw 14) to form an angle within a selected range that is perpendicular with or oblique to the spinal rod.

In an embodiment of the invention, body 80 is laterally offset from the spinal rod. Body 80 may contain a spacer 114 that extends laterally to offset a fixation component from the spinal rod. Offsetting a fixation component from the spinal rod may reduce the degree that the spinal rod must be contoured for proper positioning of bone screws (e.g., pedicle screws) in regions of the spine such as the lower lumbar region. The offset between the fixation component and the spinal rod may be equal to the width of the spacer. The offset is preferably less than about 15 mm, more preferably less than about 10 mm, and more preferably still between about 3 mm and about 9 mm.

The spacer may contain a tapered cavity for receiving connector 16 as illustrated in Figure 9. In an embodiment, the spacer contains a first plurality of protrusions or teeth that are adapted to form an engagement with a second plurality of protrusions or teeth 120 disposed on a surface of a fixation device. The teeth of the spacer and the teeth of the fixation device preferably are radially spaced at a fixed spacing 118. The teeth of the spacer and the protrusions of the fixation device preferably form a complementary fit such that adjacent, opposing teeth contact one another over interface length 116 when fastener 18 is tightened. The complementary engagement of the teeth preferably inhibits and/or prevents the fixation device from rotating about spacer 114, thereby fixing the angle formed between the fixation device and the spinal rod.

An embodiment including a reversible fixation device is illustrated in Figure 10. The body 80 of the hook preferably includes a first U-shaped yoke 137 disposed on a first side 134 of the body and a second U-shaped yoke 138 disposed on a second side 136 of the body. A cavity 132 preferably extends through the body from the first side 134 to the second side 136. The cavity preferably contains a pair of tapered inner surfaces 133 and 135 that taper in opposite directions such that the cavity narrows in a direction from the first side 134 to the middle of the cavity and narrows in a direction from the second side 136 to the middle of the cavity. The tapered inner surfaces preferably each terminate in an engaging portion 130 disposed in the middle of the cavity. Connector 16 may be positioned within the cavity so that the receiving end extends from either first side 134 as shown in Figure 10B or from second side 136 as shown in Figure 10C. Thus, the reversible hook may be mounted so that either first side 134 or second side 136 is proximate the spinal rod, with the hook directed toward either the caudal or cranial direction in each case. The fixation component may contain a slot 109 through which the fastening end of the connector may be inserted during assembly of the construct. The engaging portion 130 preferably engages the outer surface of the receiving end to limit the extent to which the receiving end may be inserted into cavity 132. Fastener 18 preferably engages body 80 proximate the engaging portion.

An alternate embodiment including a spacer 114 is illustrated in Figure 11. The spacer preferably surrounds a portion of connector 16 and contains a tapered surface 140 corresponding to the outside surface of the arms of the receiving end. As fastener 18 is tightened, the connector is preferably drawn within the spacer whereby surface 140 engages and exerts a clamping force against the outer surface of the receiving end. A tensile force created by the tightening of fastener 18 preferably maintains the spacer in a fixed position between body 80 and the spinal rod. The tapered surface 140 may terminate in an engaging surface 142 that engages

the receiving end, thereby limiting the extent to which the receiving end may be drawn within the spacer. The receiving end preferably forms a "pinch clamp" about the spinal rod, wherein the tips 72 and 74 of the arms terminate slightly beyond a vertical axis 144, which extends through the center of the spinal rod. The fastener may be fully tightened to create a selected offset length 145 that is preferably between about 2 mm and about 10 mm.

To surgically install spinal fixation system 10, the threaded end of connector 16 is preferably inserted through the tapered cavity of a spinal fixation component and fastener 18 is loosely threaded onto the threaded end. The spinal fixation component is then attached to the spine via a hook or screw in a selected location. A plurality of spinal fixation components may be attached to the spine in like manner. Spinal rod 11 may be contoured to match the desired curvature of the spine and placed into the surgical opening. The spinal rod is preferably snapped within the borehole of the connector of each spinal fixation component. The spine is preferably manipulated such that each of the vertebra is at a selected angle and height relative to neighboring vertebrae and then each fastener 18 is fully tightened to fixably secure the spinal rod into the borehole of each connector and to secure each of the spinal fixation devices at a selected angle relative to the spinal rod. It is generally preferred that the only assembly of system components that occurs within the surgical wound is (a) the snapping of the spinal rod within one or more connectors and (b) the final tightening of one or more fasteners that have already been engaged with the fastening end. Each of the fasteners is preferably tightened with a torque of at least 150 lb-in. One or more transverse connectors may be added across neighboring spinal rods for support to increase the strength of the overall construct and maintain the spinal rods at a fixed distance from one another.

In an alternate embodiment, each connector and spinal fixation component can be pre-assembled on the spinal rod prior to the implantation of the rod into the surgical wound. A connector may first be snapped onto the spinal rod. A fixation component may be added onto the connector such that the fastening end of the connector extends through the tapered cavity and the arms of the receiving end contact the inner surface of the tapered cavity. The fastener is preferably positioned on the fastening end and partially tightened to maintain the connector and fixation component engaged with the spinal rod. The fastener is preferably loosely secured on the fastening end to allow the connector and fixation component to slide along the length of the rod when a selected force is applied to the connector. The spinal rod may be contoured as necessary, and the pre-assembled system may be inserted within the surgical wound. The location of the spinal fixation components may be adjusted along the length of the rod as necessary, and the construct may be connected to the spine via fixation devices. Once a fixation component is placed at a selected location, its corresponding fastener may be fully tightened to fix its location. Fixation components may be added to or deleted from the construct as necessary without altering the position of the spinal rod or other fixation components.

In an alternate embodiment, the system may be partially pre-assembled such that a number of connectors are initially snapped onto the spinal rod. Fixation components may be inserted within the surgical wound and connected to the spine at selected locations via fixation devices. The rod may be selectively contoured and inserted within the surgical wound and aligned proximate the spine. A connector is preferably slid along the rod to a selected location proximate a fixation component on the spine, and the fastening end of the connector is inserted through the tapered cavity of the fixation component. A fastener may be placed on

the fastening end to clamp the connector onto the spinal rod and to secure the fixation component therebetween. Additional connectors and fixation components may be secured to the spinal rod in like manner.

After the rod is implanted into the surgical wound, it may be necessary to add or delete a fixation component. Conventional systems tend to require that the spinal rod be removed from the surgical wound to allow a fixation component to be threaded onto or removed from the rod. In addition, fixation components of conventional systems may have to be removed from the construct to slide the added fixation component to a selected position. Connector 16 is preferably snapped onto the spinal rod at a selected location. Thus, a connector and any fixation device (e.g., screw, hook, transverse connector) may be added to the spinal rod without removing fixation components from the spinal rod or removing the spinal rod from the surgical wound. In the same manner, a connector and fixation device may be removed from the spinal rod without altering the position of the spinal rod or adjacent connectors. The fastener 18 may be loosened and a tool may be used to unclamp the receiving end of the connector from the spinal rod, thereby eliminating the need to slide the component off the end of the spinal rod as in some conventional systems.

FURTHER IMPROVEMENTS

The following embodiments may be used in combination with any of the features of the above-described embodiments.

An embodiment of a spinal fixation system that is assembled with a threadless wedge is depicted in Figure 12 and Figure 13. Figure 12 depicts the spinal fixation system prior to assembly. The spinal fixation system preferably includes connector 216 for attaching spinal rod 12 to fixation component body 80. Connector 216 preferably includes a receiving end that includes a pair of deflectable arms forming a substantially U-shaped borehole for receiving the spinal rod as in the above described embodiments. The outer surface of the receiving end may be tapered to complement the tapered inner surface of the cavity disposed within the fixation component. The outer surface of the receiving end and the tapered inner surface may be substantially flat. It is to be understood that the outer surface of the connector may be untapered while the inner surface of the cavity is tapered, or alternatively, the outer surface of the connector may be tapered while the inner surface of the cavity is untapered. The end of the connector opposite the receiving end may be capped as shown in Figure 12.

An instrument 200 is preferably used to move the connector through the cavity to cause the arms of the connector to clamp against the spinal rod to secure it within the borehole. The instrument is preferably a pair of assembly pliers that includes a first member 202 and a second member 204. Members 202 and 204 are preferably substantially elongated and capable of moving relative to one another to apply a compressive force onto components of the spinal fixation system to assemble the components. The members are preferably connected together via hinge 206. The hinge may include a pivotal connector (e.g., bolt) about which the members can pivot relative to one another.

One of the members preferably includes an indention 210 for engaging the spinal rod. The indention preferably has a curvate shape that conforms to the shape of the spinal rod. The other member preferably includes a bore 208 that is sized to receive the end of the connector. Bore 208 preferably has a width that is

greater than that of the end of the connector such that the end is capable of passing into or through the bore. Member 204 preferably includes contacting sections 214 that surround bore 208 for engaging the fixation component. Figure 13 depicts the spinal fixation system after assembly. Member 202 preferably engages the spinal rod at indention 210, while member 204 engages the fixation component with contacting sections 214. The handles of instrument 200 are preferably squeezed together to decrease the distance between members 202 and 204, thereby forcing the connector to move within the cavity of the fixation component. The end of the connector preferably moves through the cavity and into bore 208 whereby second member 204 does not inhibit the movement of the connector through the cavity. A locking taper engagement between the connector and the spinal rod is preferably formed, and then instrument 200 may be removed from the assembly. In an alternate embodiment, member 202 engages the tips of the arms of the connector rather than the spinal rod.

In an embodiment depicted in Figure 14, the fixation component includes a bore 222 through its top surface that communicates with the fixation component cavity. A locking element 220 is preferably inserted into bore 222 to inhibit movement of the connector within the fixation component cavity after the connector has been secured therein. Locking element 220 is preferably a set screw. Bore 222 is preferably threaded for engaging threads on the set screw. The locking element may engage the connector proximate indention 218 disposed on the outer surface of the connector.

In an embodiment depicted in Figure 15, fixation component 230 preferably includes a tapered cavity for receiving connector 216 as in the above described embodiments. The fixation system preferably includes a sleeve 234 that is adapted to fit about the body of the fixation component. The sleeve is preferably substantially cylindrical and may substantially surround the fixation component body. The sleeve preferably includes a substantially U-shaped opening 236 sized to permit spinal rod 12 to pass therethrough. The U-shaped opening is preferably substantially offset from the center of the sleeve as shown in Figure 15. Opening 236 may include an angled interior locking surface 237 for engaging the spinal rod. Fixation component 230 preferably includes a fastening end 232 on its top. Fastening end 232 preferably includes threading. A fastener 238 is preferably securable to the fastening end. Fastener 238 is preferably a nut that includes threading that complements the threading on the fastening end.

Figure 16 depicts a side view of the spinal fixation system after assembly, and Figure 17 depicts a cross sectional view of the assembled spinal fixation system. To assemble the system, the spinal rod is preferably snapped into the borehole of connector 216. A circumferential portion of the spinal rod preferably extends from the opening in the connector. The connector having the spinal rod disposed therein is then preferably positioned within the cavity of the fixation component. Sleeve 234 is preferably slid over fastening end 232 and around the body of the fixation component until locking surface 237 contacts the spinal rod. Fastener 238 may be threaded onto the fastening end such that the bottom surface of the fastener contacts the top of sleeve 234. Rotation of the fastener preferably downwardly translates the fastener along the fastening end and forces sleeve 234 down along the body of the fixation component. The angle 239 of locking surface 237 from a vertical axis allows the downward motion of the sleeve to impart a force on the spinal rod in a direction axially through the tapered cavity. Angle 239 preferably ranges from about 10 to 30 degrees. The distance that connector 216 moves within the tapered cavity is preferably a function of the degree to which

fastener 238 is tightened. It is preferred that a locking taper engagement is formed between the connector and the fixation body cavity after fastener 238 is tightened.

In an embodiment, depicted in Figure 18, fixation component 300 preferably includes a body 302 and a fixation device 304. The body 302 preferably includes a cavity 318 (shown in Figure 19) adapted to receive a connector 216. The body 302 may include a substantially U-shaped indentation 306 adapted to permit a portion of spinal rod 12 to rest within the indentation. The indentation 306 preferably runs along the bottom 312 of the body 302 in a direction substantially perpendicular to the longitudinal axis of the fixation device 304. The body 302 may include a bore (not shown) that communicates with the cavity 318. A locking element is preferably inserted into the bore to inhibit movement of the connector 216 within the body cavity 318 after the connector has been secured therein.

The body 302 is preferably adapted to hold a fixation device 304. The fixation device 304 preferably includes a head 310. The head 310 may be semi-spherical in shape. An opening (not shown) may extend through the central portion of the head 310, at a position equidistant from any position along the semi-spherical portion of the outside surface of the head. The fixation device may a bone screw (as shown), hook, traverse connector, or similar device. The body 302 may include a cavity 318 (shown in Figure 19) adapted to contain a portion of the head 310. A substantially cylindrical pin 308 is preferably positionable within the head 310 and the body 302 such that the fixation device 304 may be rotated about the pin 308 along the longitudinal axis of the body. The pin 308 may inhibit movement of the fixation device 304 in a direction perpendicular to the longitudinal axis of the body 302. The pin 308 may be a rivet or a screw. The pin 308 may be substantially hollow.

Figure 19 depicts a top view of the fixation component 300. The cavity 318 may be substantially U-shaped and include a front section 306 and a rear section 308. The front section 306 is preferably adapted to receive the fixation device 304. The front section 306 preferably includes at least two substantially flat arms 320 which extend out from the rear section 308. The arms 320 are preferably oriented on opposing sides of the body 302. The distance 322 between the two arms 320 may be substantially greater than the width of the head 310 of the fixation device 304. It is generally preferred that the distance 322 between the two arms 320 and the width of the head 310 be equal.

In another embodiment, the head 310 of the fixation device 304 may have at least two substantially flat edges 324. The distance 322 between the two arms 320 is preferably substantially the same as the width of the head 310 between the edges 324. The edges 324 are preferably oriented on opposing sides of the head 310. The fixation device 304 may be mounted within the cavity 318 such that the edges 324 are contained by the arms 320 of the body 302. The arms 320 may interact with the edges 324 such that movement in a direction perpendicular to the longitudinal axis of the body 302 is inhibited.

The rear section 308 of the cavity 318 is substantially rounded and adapted to receive a connector 216. Figure 20 depicts a cross sectional view of the fixation component 300, secured to a spinal rod 12, with a connector 216 oriented within the rear section of the cavity. Connector 216 preferably includes a receiving end that includes a pair of deflectable arms forming a substantially U-shaped borehole for receiving the spinal rod, as described in previous embodiments. The width of the body 302 between the rear side 328 and the interior surface 326 of the cavity 318 is preferably variable. The distance between the rear side 328 and the interior

surface 326 of the body 302 preferably becomes narrower in a direction from the top 314 toward the bottom 312. The interior surface 326 of the body 302 may be substantially flat.

The head 310 of the fixation device 304 is preferably located within the body 302 in a position such a portion of the connector 216 may be inserted between the head and the interior surface 326. Movement of the connector 216 through the bottom 312 of the body 302, in a direction toward the top 314, may allow the outer edges 330 of the connector to engage the interior surface 326 of the body and the head 310 of the fixation device 304. As the connector 216 is moved further toward the top 314 of the body 302, a compressive force may be exerted by the interior surface 326 and the head 341 upon the connector. The magnitude of the compressive force may be varied as the position of the connector 216 is varied within the cavity. The compressive force preferably secures spinal rod 12 within the U-shaped borehole of the connector 216. The compressive force may inhibit rotation of the fixation device 304. Instrument 200 (not shown) may be used to position the connector 216 within the body 302 in a position which preferably secures the spinal rod to the connector. The connector 216 may be positioned within the body 302 such that the spinal rod 12 is secured within the connector, and the rotation of the fixation device 304 is inhibited.

Figure 18 depicts a view of an assembled spinal fixation assembly. To assemble the system the spinal rod 12 is snapped into the borehole of connector 216. A circumferential portion of the spinal rod 12 preferably extends from the borehole in the connector 216. The connector 216 having the spinal rod 12 disposed therein is then preferably positioned within the body 302. The fixation device 304 may be rotated about the pin 308 until the desired angle between the body 302 and the fixation device is achieved. The angle may be varied in a direction toward the top 314 through an arc of at least 90 degrees or toward the bottom 312 through an arc of at least 90 degrees. The connector 216 may then be moved further within the body 302. As the connector 216 is moved, the head 310 and the interior surface 326 of the body 302 may impart a force upon the connector (as shown in Figure 20) causing the arms of the borehole to compress. In this manner the connector 216 may be secured onto the spinal rod 12. The force may also inhibit further rotation of the fixation device 304. The magnitude of the force is preferably a function of the distance that the connector 216 is placed within the body 302. Instrument 200 may be used to position the connector 216 within the body 302.

An embodiment of a connector 350 is depicted in Figure 21. The connector 350 is adapted to secure fixation components to a spinal rod. The substantially conical connector 350 includes a receiving section 352 and an upper section 354. The receiving section 352 preferably includes a substantially circular opening 356. The opening 356 is preferably adapted to receive a spinal rod (not shown) such that the receiving section 352 of the connector 350 substantially surrounds the circumferential portion of the spinal rod. The upper section 354 preferably includes a slot 358 extending longitudinally through the center of the upper section. The slot 358 may extend from the top of the connector to the opening 356, the slot communicating with the opening.

A spinal rod is preferably axially positioned within the opening 356 by passing the spinal rod through opening. Slot 358 preferably enables the circumference of opening 356 to be altered. Insertion of the spinal rod into opening 356 results in a slight widening of at least a portion of the slot 358. In this manner, the circumference of opening 356 may be increased by an amount sufficient to allow the insertion of the spinal rod through opening 356. If the diameter of the spinal rod is slightly greater than that of the opening 356, the slot

358 may remain slightly widened after the spinal rod is inserted into the opening. It is generally preferred that the diameter of the spinal rod and the diameter of the opening 356 be equal.

Figure 22 depicts a cross sectional view of an assembled spinal fixation assembly including a connector 350 and a fixation component 300. Movement of the connector 350 through the bottom 312 of the body 302, in a direction toward the top 314, may allow the outer edges 360 of the connector to engage the interior surface 326 of the body and the head 310 of the fixation device 304. As the connector 350 is moved further toward the top 314 of the body 302, a compressive force may be exerted by the interior surface 326 and the head 310 upon the connector. The magnitude of the compressive force may be varied as the position of the connector 350 is varied within the cavity. The compressive force preferably forces slot 358 to narrow, thereby securing spinal rod 12 within the opening 356 of the connector 350. The compressive force may inhibit rotation of the fixation device 304. Instrument 200 (not shown) may be used to position the connector 350 within the body 302 in a position which preferably secures the spinal rod 12 within the connector. The connector 350 may be positioned within the body 302 such that the spinal rod 12 is secured within the connector, and the rotation of the fixation device 304 is inhibited.

To assemble the system depicted in Figure 22 the spinal rod 12 is inserted into the opening 356 of connector 350. A circumferential portion of the spinal rod 12 preferably is completely surrounded by the connector 350. The connector 350 having the spinal rod 12 disposed therein is then preferably positioned within the body 302. The fixation device 304 may be rotated about the pin 308 until the desired angle between the body 302 and the fixation device is achieved. The connector 350 may then be moved further within the body 302. As the connector 350 is moved, the head 310 and the interior surface 326 of the body 302 may impart a force upon the connector causing the slot 358 of the connector to narrow. In this manner the connector 350 may be secured onto the spinal rod 12. The force may also inhibit further rotation of the fixation device 304. The magnitude of the force is preferably a function of the distance that the connector 350 is placed within the body 302. Instrument 200 may be used to position the connector 350 within the body 302.

In an embodiment depicted in Figure 23, fixation component 230 may be adapted to receive connector 350. Connector 350 preferably includes an opening 356 for receiving the spinal rod 12 and a slot 358 (shown in Figure 24) as in the above described embodiments. The fixation component 230 preferably can be pivoted in either direction 362 or direction 364 such that an oblique angle between 90° and about 60° is formed between the fixation component and the longitudinal axis of the spinal rod 12 as in the above described embodiments. The fixation component 230 preferably comprises a bone screw (as shown), hook, traverse connector, or similar device.

To assemble the system, depicted in a cross section view in Figure 24, the spinal rod 12 is preferably inserted into the opening 356 of connector 350. The connector 350 having the spinal rod 12 disposed therein is then preferably positioned within the cavity of the fixation component 230. The fixation component 230 may be rotated until the desired angle between the fixation component and the longitudinal axis of the spinal rod is achieved. The connector 350 may then be moved further within the fixation component 230. As the connector 350 is moved, the interior surfaces 366 of the fixation component may impart a force upon the connector causing the slot 358 of the connector to narrow. In this manner the connector 350 may be secured onto the spinal rod 12. The force may also inhibit further rotation of the fixation component 230. The

magnitude of the force is preferably a function of the distance that the connector 350 is placed within the body 302. Instrument 200 (not shown) may be used to position the connector 350 within the body 302.

Further modifications and alternative embodiments of various aspects of the invention will be apparent to those skilled in the art in view of this description. Accordingly, this description is to be construed as illustrative only and is for the purpose of teaching those skilled in the art the general manner of carrying out the invention. It is to be understood that the forms of the invention shown and described herein are to be taken as the presently preferred embodiments. Elements and materials may be substituted for those illustrated and described herein, parts and processes may be reversed, and certain features of the invention may be utilized independently, all as would be apparent to one skilled in the art after having the benefit of this description of the invention. Changes may be made in the elements described herein without departing from the spirit and scope of the invention as described in the following claims.

Where the terms "comprise", "comprises", "comprised" or "comprising" are used in this specification, they are to be interpreted as specifying the presence of the stated features, integers, steps or components referred to, but not to preclude the presence or addition of one or more other feature, integer, step, component or group thereof.

The claims defining the invention are as follows:

1. An implant system for fixation of the human spine, said system including: a connector including a threaded end, a receiving end opposite said threaded end, said receiving end terminating in a first arm and a second arm that together form a substantially U-shaped borehole, said first arm including a first tip and said second arm including a second tip, and wherein an opening is formed between said first tip and said second tip; a spinal rod axially positionable through said opening into said borehole during use; a fixation component including a body, said body including a cavity configured to receive said receiving end of said connector, wherein said connector is adapted to be at least partially disposed within said cavity such that the inner surface of said cavity engages and exerts a compressive force onto said receiving end of said connector during use; and a fastener adapted to engage said threaded end of said connector.

2. A connector for connecting spinal fixation components to a spinal rod, said connector including: a threaded end; a receiving end opposite said threaded end, said receiving end terminating in a first arm and a second arm that together form a substantially U-shaped borehole for receiving said spinal rod, said first arm including a first tip and said second arm including a second tip, and wherein said borehole includes an open end having a width defined by said first tip and said second tip; and a slot extending between said threaded end and said receiving end, wherein said arms are deflectable to cause narrowing or widening of a portion of said slot and variation of the width of the open end to allow a spinal rod to be snapped into said borehole through the open end to form a fixable engagement between a spinal rod and said receiving end.

3. The implant system as claimed in Claim 1, wherein said receiving end is deflectable.

4. The implant system as claimed in Claim 1 or Claim 3, wherein said connector includes a slot extending from said U-shaped borehole into at least a portion of said fastening end.

5. The implant system as claimed in any one of Claims 1, 3 and 4, further including a sleeve including a cavity configured to receive said receiving end of said connector, and said sleeve further being configured to be received in said cavity in said fixation component, wherein said fastener is adapted to move said connector into said cavity in said sleeve such that the inner surface of said cavity of said sleeve

engages and exerts a compressive force onto said receiving end of said connector during use.

6. The implant system as claimed in any one of Claims 1 and 3 to 5, wherein said fastener is further adapted to engage said body of said fixation component, and wherein said fastener is adapted to being tightened to cause movement of said receiving end within said cavity of said fixation component and deflection of said first and second arms such that said first and second arms exert a compressive force against said spinal rod to maintain said spinal rod within said borehole during use.

7. The implant system as claimed in any one of Claims 1 and 3 to 6, wherein said fixation component further includes a fixation device, said fixation device includes a head, said body includes a cavity configured to receive at least a portion of said head such that said fixation device is rotatable about said head along a longitudinal axis of said body, wherein a portion of said body and said head engage and exert a compressive force onto said receiving end to maintain said spinal rod within said borehole, and wherein said compressive force inhibits further rotation of said fixation device during use.

8. An implant system as claimed in any one of Claims 1 and 3 to 7, further including an instrument for assembling a spinal fixation system, including a first member adapted to engage said spinal rod during use, and a second member in spaced relation from said first member, said second member including a bore and a contacting section, said bore being sized to receive an end of a fixation connector that is disposed within a fixation component during use, said contacting section being adjacent to said bore and adapted to engage said fixation component during use, and wherein said first member is adapted to move relative to said second member to exert a compressive force on said spinal fixation system during use.

9. The implant system as claimed in any one of Claims 1 and 3 to 8, wherein said cavity of said fixation component is tapered.

10. The implant system as claimed in any one of Claims 1 and 3 to 9, wherein said fixation component further includes a bone screw having a shank.

11. The implant system as claimed in any one of Claims 1 and 3 to 10 , wherein said fixation component further includes a hook for engaging a bone.

12. The implant system as claimed in any one of Claims 1 and 3 to 11, wherein said fixation component further includes a transverse connector for connecting said spinal rod to a neighboring spinal rod at a fixed distance.

13. The implant system as claimed in any one of Claims 1 and 3 to 12, wherein said body includes a substantially U-shaped yoke having an axial length, said yoke being formed between a top section and a bottom section, said top section including a first edge, said bottom section including a second edge, said first and second edges defining a width of said yoke, and wherein said first and second edges are curved such that the width of said yoke varies across the axial length of said yoke.

14. The implant system as claimed in any one of Claims 1 and 3 to 13, wherein said fixation component further includes a fixation device and a spacer adapted to fit between said connector and said fixation component to laterally offset said fixation device from said spinal rod.

15. The implant system as claimed in any one of Claims 1 and 3 to 14, wherein said component further includes a fixation device and a spacer, said spacer being adapted to fit between said connector and said fixation component, said fixation device including protrusions, said spacer being adapted to offset said fixation device from said spinal rod and including teeth adapted to form a complementary engagement with said protrusions to inhibit rotation of said fixation device about said spacer.

16. The implant system as claimed in any one of Claims 1 and 3 to 15, wherein said fixation component further includes a fixation device and a spacer, fixation device extending from said body, said spacer having a width between 1mm and 10mm and being adapted to fit between a connector and a fixation component to laterally offset said fixation device from a spinal rod during use.

17. The implant system as claimed in any one of Claims 1 and 3 to 16, wherein said body further includes a top section and a bottom section, said cavity of said fixation component being formed in between said top section and said bottom section, said top section and said bottom section each including edges that are curved in a direction away from said spinal rod.

18. The implant system as claimed in any one of Claims 1 and 3 to 17, wherein said fixation component further includes a bore, and further including a locking element adapted to extend through said bore and contact said connector to inhibit movement of said connector within said cavity of said fixation component.

19. The implant system as claimed in any one of Claims 12 to 18, wherein said transverse connector includes a reduced section and a bevelled section, said reduced section having a width less than a width of said body, said bevelled section connecting said reduced section to said body.

20. The implant system as claimed in any one of Claims 12 to 18, wherein said transverse connector includes a reduced section and a bevelled section, said reduced section having a width less than a width of said body, said bevelled section extending between said body and said reduced section, and wherein said reduced section includes a bend to shorten a lateral distance between said spinal rod and a neighboring spinal rod.

21. The implant system as claimed in any one of Claims 1 and 3 to 20, wherein said receiving end includes a tapered outer surface that narrows in a direction away from said receiving end.

22. The implant system as claimed in any one of Claims 1 and 3 to 21, wherein said fixation component includes a threaded bore, and further including a screw adapted to extend through said bore and contact said connector to inhibit movement of said connector within said cavity of said fixation component during use.

23. The implant system as claimed in any one of Claims 1 and 3 to 22, wherein said fastener is a threaded nut.

24. The implant system as claimed in any one of Claims 1 and 3 to 22, wherein said receiving end includes a threaded surface.

25. The implant system as claimed in any one of Claims 5 to 23, wherein said sleeve is substantially cylindrical and adapted to substantially surround said body of said fixation component during use.

26. The implant system as claimed in any one of Claims 5 to 25, wherein said U-shaped opening is substantially offset from a center of said sleeve.

27. The implant system as claimed in any one of Claims 5 to 26, wherein said sleeve includes an angled interior locking surface adapted to impart a force onto said spinal rod to move said connector within said tapered cavity of said fixation component during use.

28. The implant system as claimed in any one of Claims 5 to 26, wherein said sleeve includes an interior surface that is adapted to impart a force onto a spinal rod when said sleeve is downwardly translated along said body, said force causing said connector to move into said tapered cavity during use.

29. The implant system as claimed in any one of Claims 8 to 28, wherein said first member of said instrument includes a substantially curvate indentation sized and shaped to engage said spinal rod during use.

30. The implant system as claimed in any one of Claims 8 to 29, wherein said first and second members of said instrument are substantially elongated.

31. The implant system as claimed in any one of Claims 8 to 30, wherein said instrument further includes a hinge between said first and second members to allow said first member to move relative to said second member during use.

32. The implant system as claimed in any one of Claims 8 to 30, wherein said instrument further includes a pivotal connector connecting said first member with said second member, said first member being adapted to pivot with respect to said second member about said pivotal connector during use.

33. The implant system as claimed in any one of Claims 7 to 32, wherein said cavity includes a rear section, said rear section including a tapered interior surface, and wherein said outer surface of said receiving end has a taper that complements that of said tapered interior surface, and wherein said receiving end is adapted to be moved within said cavity such that said tapered interior surface of said cavity and said fixation member together exert a compressive force against said outer surface of said receiving end to clamp said spinal rod within said borehole, said compressive force having a magnitude that is a function of a distance that said receiving end is moved into said cavity of said fixation component.

34. The implant system as claimed in any one of Claims 7 to 33, wherein said fixation component further includes a substantially U-shaped indentation along a bottom portion of said body oriented substantially perpendicular to a longitudinal axis of said body, and wherein said indentation is adapted to receive a portion of said rod.

35. The implant system as claimed in any one of Claims 7 to 34, wherein said cavity includes a front section and a rear section, and wherein said connector is positionable within said front section, and wherein said fixation device is positionable within said rear section.

36. The implant system as claimed in any one of Claims 7 to 35, wherein said head is positioned within said cavity of said fixation component such that said fixation device is rotatable along a longitudinal axis of said body.

37. The implant system as claimed in any one of Claims 7 to 36, wherein said fixation device is adapted to be rotatable within said body along a longitudinal axis of said body, and wherein said connector is positionable within said cavity such that rotation of said fixation device is inhibited.

38. The implant system as claimed in any one of Claims 7 to 37, wherein said fixation component further includes a pin, wherein said head is semi-spherical, wherein said head includes a borehole positioned equidistant from any position along an outer surface of said head, wherein said pin is positionable within said borehole

and said body such that said fixation device is rotatable about said pin along a longitudinal axis of said body, and wherein said pin is adapted to inhibit said fixation device from rotating along an axis perpendicular to a longitudinal axis of said body.

39. The implant system as claimed in any one of Claims 7 to 37, wherein said fixation component further includes a pin, wherein said head is semi-spherical, wherein said head includes at least two flat edges oriented on substantially opposing sides of said head, wherein said head includes a borehole positioned equidistant from any position along an outer surface of said head, wherein said pin is positionable within said borehole and said body such that said fixation device is rotatable about said pin along a longitudinal axis of said body, and wherein said flat edges of said head are positioned within said body such that said flat edges inhibit rotation of said fixation device along an axis perpendicular to said longitudinal axis of said body.

40. The connector as claimed in Claim 2, adapted to fixably hold said spinal rod within said borehole such that a portion of said spinal rod is exposed from said receiving end.

41. The connector as claimed in Claim 2 or Claim 40, wherein said receiving end is adapted to engage greater than about π radians and less than about 2π radians of the circumferential portion of a spinal rod including a circumferential portion of 2π radians.

42. The connector as claimed in any one of Claims 2, 40 and 41,wherein said first and second arms are deflectable to form a locking taper engagement with a spinal rod during use.

43. The connector as claimed in any one of Claims 2 and 40 to 42, wherein said first and second arms each have a tapered outer surface that is angled toward said threaded end.

44. An implant system for fixation of the human spine, substantially as described herein with reference to the accompanying drawings.

45. A connector for connecting spinal fixation components to a spinal rod, substantially as described herein with reference to the accompanying drawings.

DATED this 14th day of June 2000.

SPINAL CONCEPTS, INC.
By their Patent Attorneys
CALLINAN LAWRIE

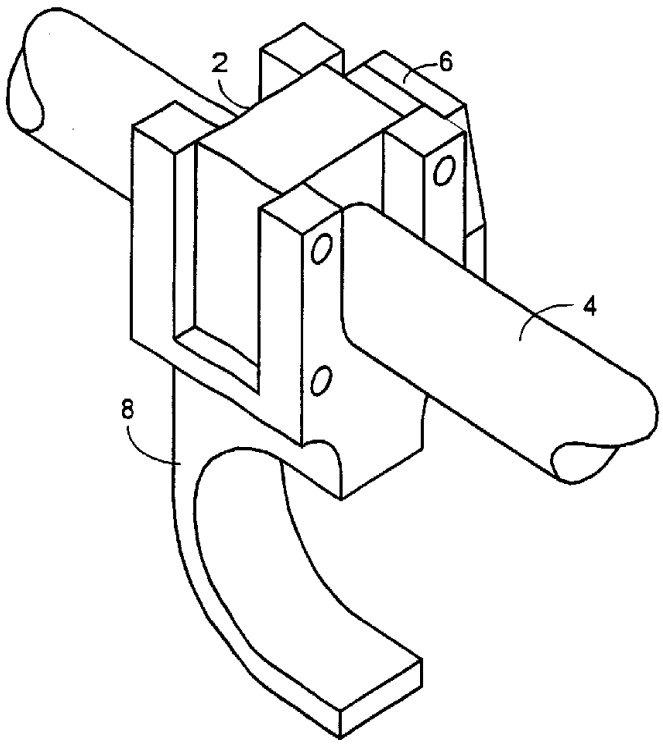


FIG. 1

(PRIOR ART)

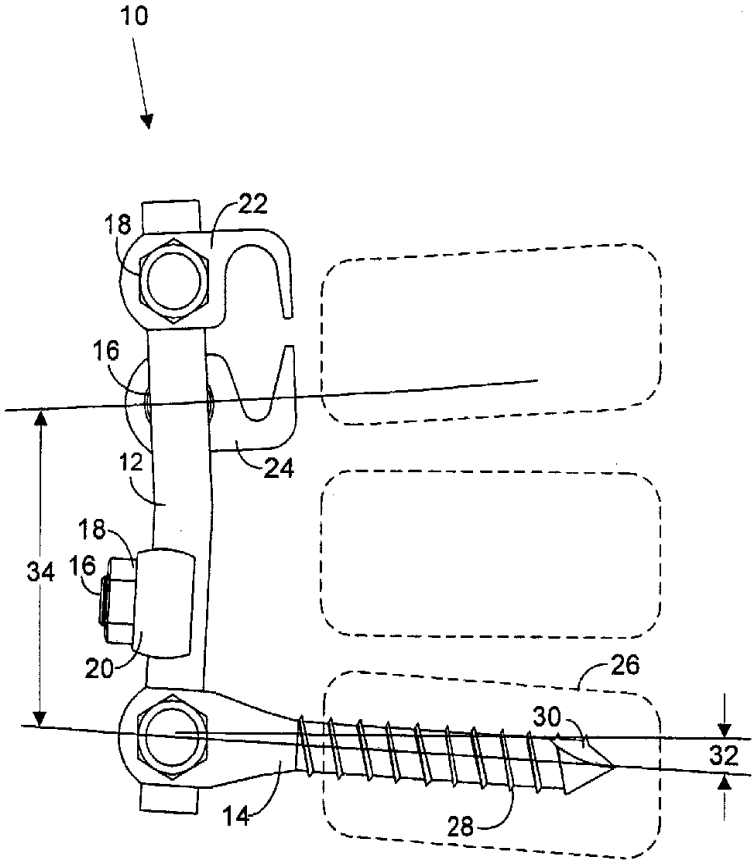


FIG. 2

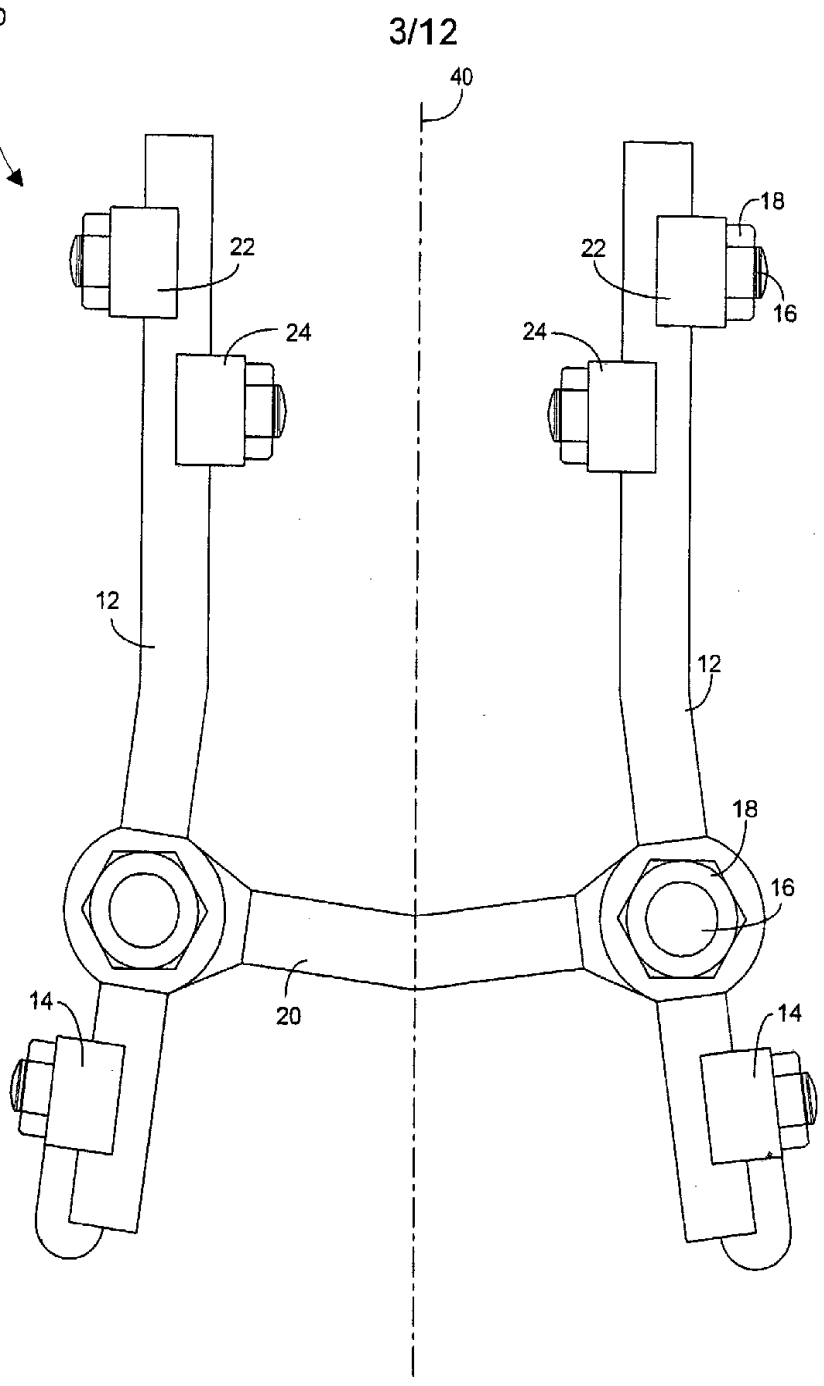


FIG. 3

SUBSTITUTE SHEET (RULE 26)

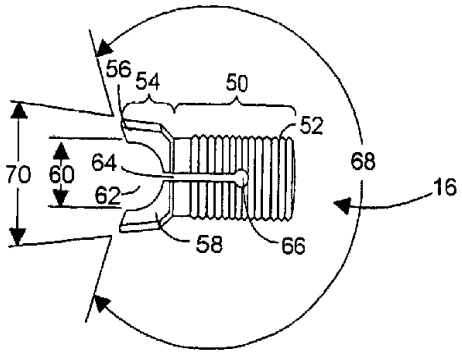


FIG. 4

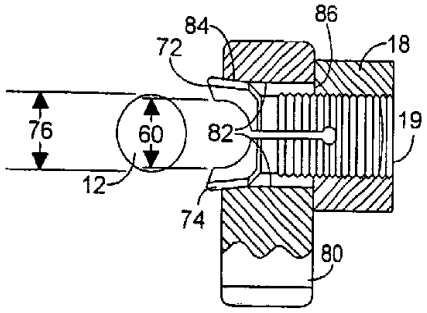


FIG. 5

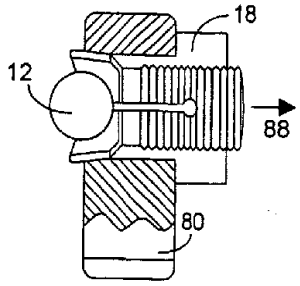
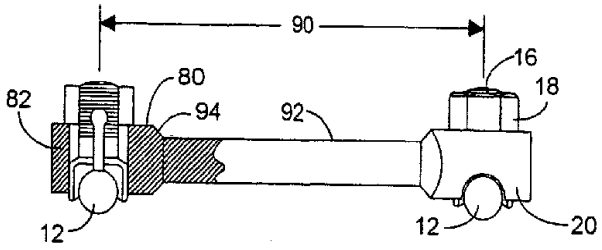


FIG. 6



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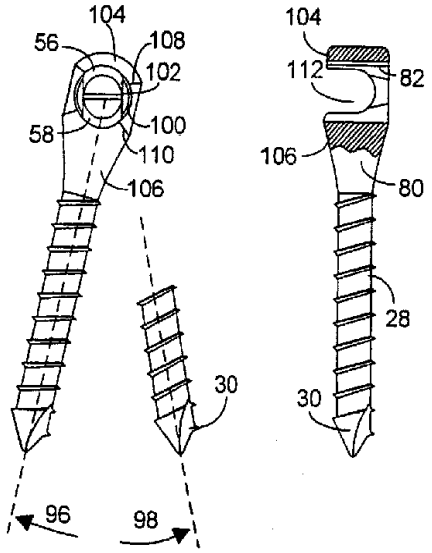


FIG. 8

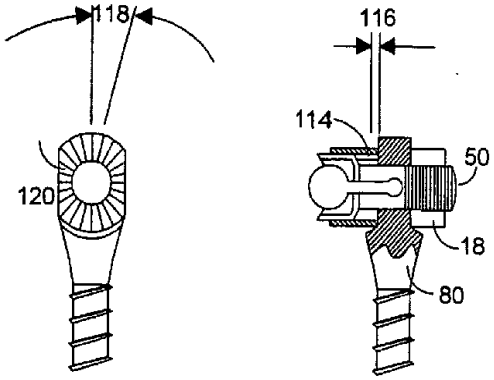


FIG. 9

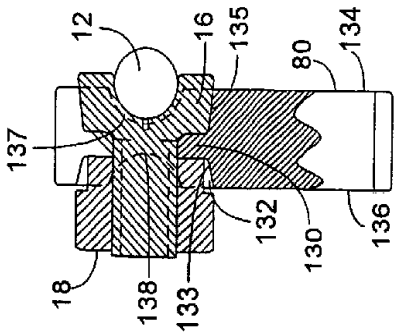


FIG. 10C

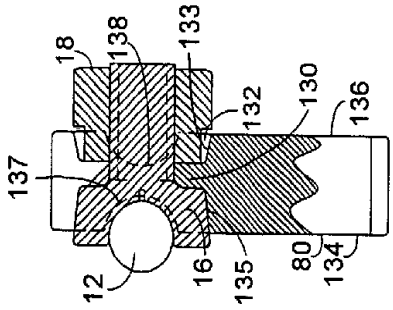


FIG. 10B

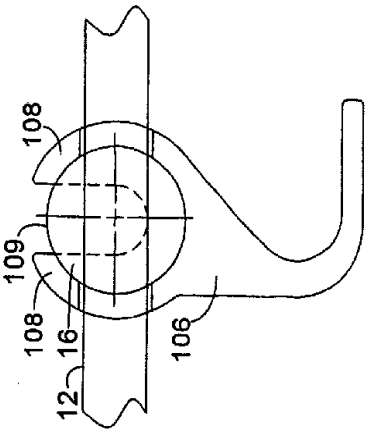


FIG. 10A

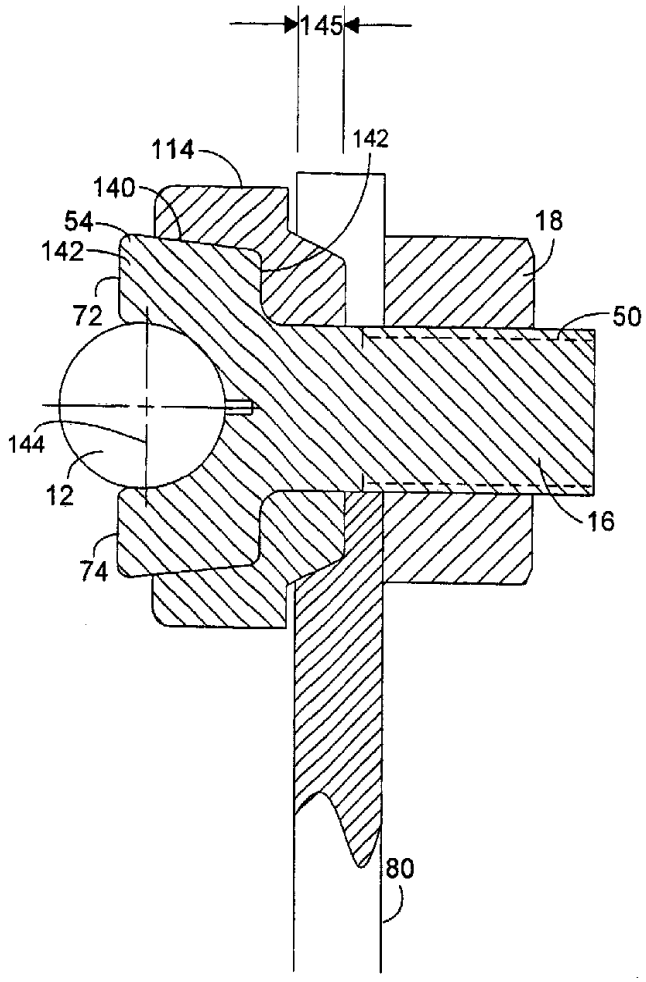


FIG. 11

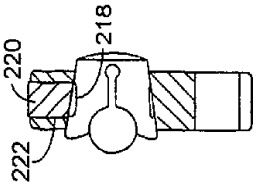


FIG. 14

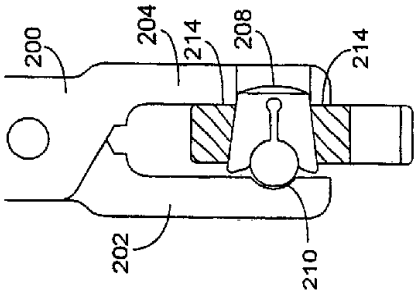


FIG. 13

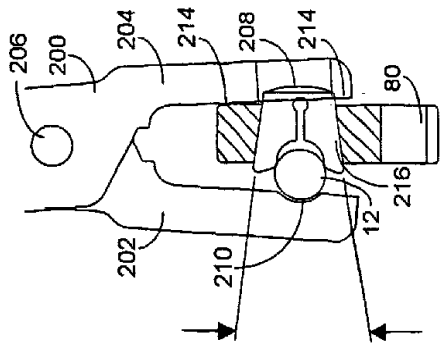


FIG. 12

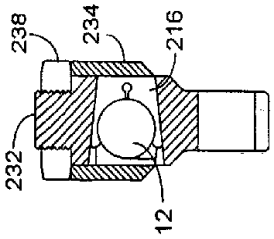


FIG. 17

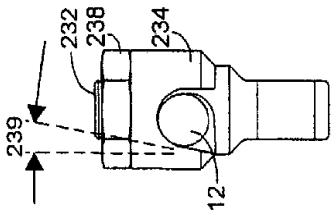


FIG. 16

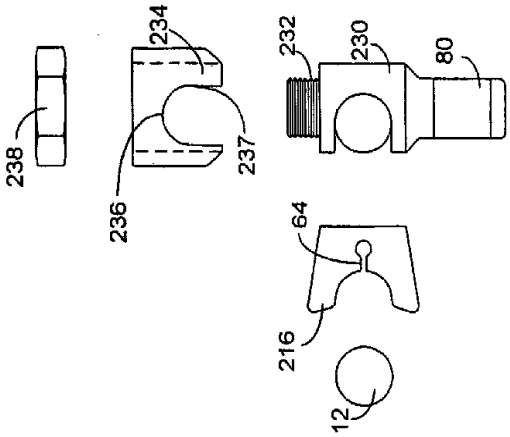


FIG. 15

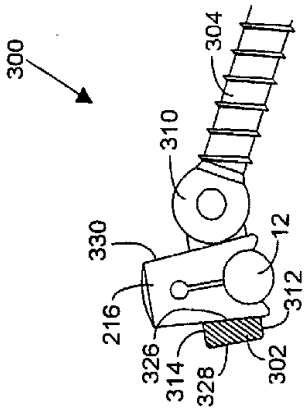
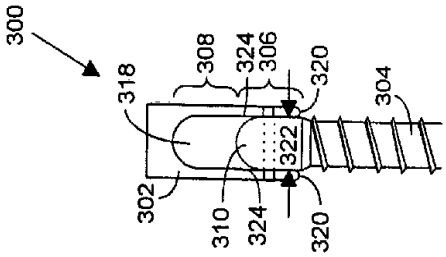


FIG. 20



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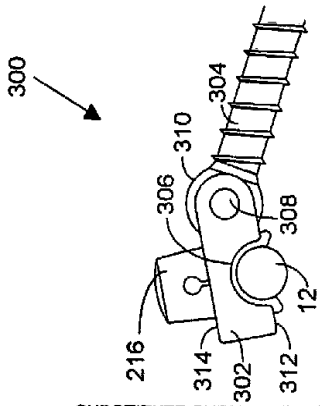

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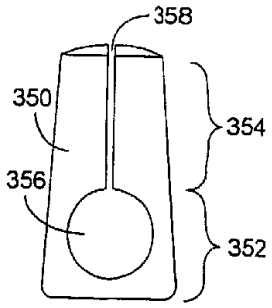
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FIG. 21

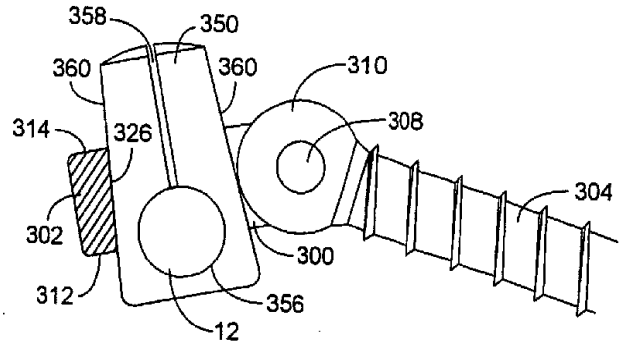
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FIG. 22

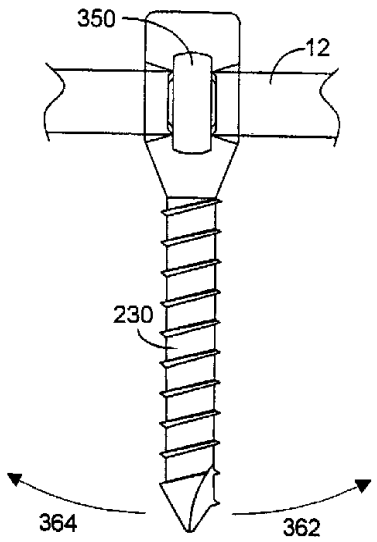

FIG. 23

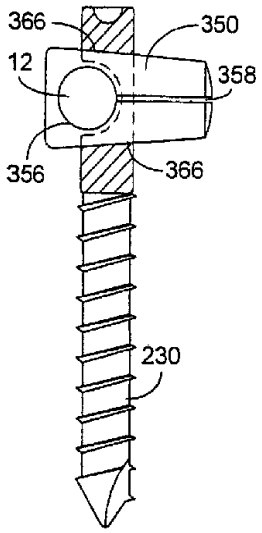

FIG. 24