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Nilsson

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(54) **POLYAXIAL SPINAL STABILIZER CONNECTOR AND METHODS OF USE THEREOF**

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(52) **U.S. Cl.**
CPC **A61B 17/705** (2013.01); **A61B 17/7049** (2013.01); **A61B 17/7052** (2013.01)

(58) **Field of Classification Search**
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USPC 606/86 A, 246, 250-253, 264-279; 623/17.11-17.16

See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

5,207,678 A	5/1993	Harms et al.	
5,312,405 A *	5/1994	Korotko	A61B 17/7052 606/252
5,360,431 A	11/1994	Puno et al.	
5,466,237 A	11/1995	Byrd, III et al.	
5,474,555 A	12/1995	Puno et al.	
5,496,321 A	3/1996	Puno et al.	
5,536,268 A	7/1996	Griss	
5,624,442 A	4/1997	Mellinger et al.	

(Continued)

OTHER PUBLICATIONS

Aesculap, Inc., S4 Spinal System, Sales literature, 2004, Aesculap, printed in U.S.A., 4 pages.

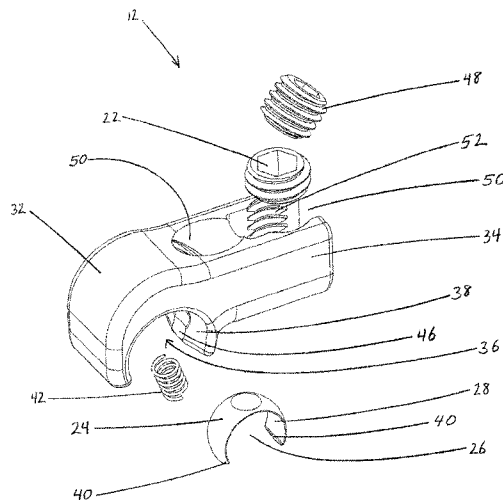
(Continued)

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(57) **ABSTRACT**

A connector device for a spinal stabilization apparatus comprises a first elongated portion adapted to engage a first spinal stabilizer rod proximal to the first end of the elongated member. The first end of the first elongated portion comprises a hook shape and a ferrule and may engage the first spinal stabilizer rod within about 20 degrees of perpendicular to the spinal stabilizer rod in any direction. The ferrule is adapted to be seated within the hook shape and is further adapted to engage the first spinal stabilizer rod. The connector device may also include a second elongated portion similar to the first adapted to engage a second spinal stabilizer. The first elongated portion and the second elongated portion may be directly attached. The connector device may be used in a method of treating a patient.

20 Claims, 13 Drawing Sheets



(56)

References Cited

U.S. PATENT DOCUMENTS

5,647,873 A	7/1997	Errico et al.		2004/0116928 A1*	6/2004	Young	A61B 17/7052
5,669,911 A	9/1997	Errico et al.					606/253
5,690,630 A	11/1997	Errico et al.		2004/0133203 A1*	7/2004	Young et al.	606/61
5,733,285 A	3/1998	Errico et al.		2004/0158247 A1	8/2004	Sitiso et al.	
5,733,286 A	3/1998	Errico et al.		2004/0193160 A1	9/2004	Richelsoph	
5,782,833 A	7/1998	Haider		2004/0215190 A1*	10/2004	Nguyen	A61B 17/1671
5,797,911 A	8/1998	Sherman et al.					606/86 A
5,879,350 A	3/1999	Sherman et al.		2004/0236330 A1	11/2004	Purcell et al.	
5,885,286 A	3/1999	Sherman et al.		2004/0249380 A1	12/2004	Glascott	
5,910,142 A*	6/1999	Tatar	606/272	2004/0267264 A1	12/2004	Konieczynski et al.	
5,947,967 A	9/1999	Barker		2005/0038430 A1	2/2005	McKinley	
5,964,760 A	10/1999	Richelsoph		2005/0049588 A1	3/2005	Jackson	
6,053,917 A	4/2000	Sherman et al.		2005/0055026 A1	3/2005	Biedermann et al.	
6,113,601 A	9/2000	Tatar		2005/0080415 A1	4/2005	Keyer et al.	
6,287,311 B1	9/2001	Sherman et al.		2005/0090821 A1	4/2005	Berrevoets et al.	
6,402,749 B1	6/2002	Ashman		2005/0187548 A1	8/2005	Butler et al.	
6,485,494 B1	11/2002	Haider		2005/0192571 A1	9/2005	Abdelgany	
6,540,748 B2	4/2003	Lombardo		2005/0192572 A1	9/2005	Abdelgany et al.	
6,565,567 B1	5/2003	Haider		2005/0192573 A1	9/2005	Abdelgany et al.	
6,626,908 B2	9/2003	Cooper et al.		2005/0261687 A1	11/2005	Garamszegi et al.	
6,709,434 B1	3/2004	Gournay et al.		2006/0036242 A1	2/2006	Nilsson et al.	
6,716,214 B1	4/2004	Jackson		2006/0036244 A1	2/2006	Spitler et al.	
6,733,502 B2	5/2004	Altarac et al.		2006/0036252 A1	2/2006	Baynham et al.	
6,740,086 B2	5/2004	Richelsoph		2006/0058787 A1	3/2006	David	
6,755,830 B2	6/2004	Minfelde et al.		2006/0058788 A1	3/2006	Hammer et al.	
6,869,433 B2	3/2005	Glascott		2006/0058880 A1	3/2006	Wysocki et al.	
6,974,460 B2	12/2005	Carbone et al.		2006/0084996 A1	4/2006	Metz-Stavenhagen	
RE39,089 E	5/2006	Ralph et al.		2006/0100622 A1	5/2006	Jackson	
7,708,736 B2*	5/2010	Mullaney	A61B 17/645 403/385	2006/0149241 A1	7/2006	Richelsoph et al.	
				2006/0149372 A1	7/2006	Paxson et al.	
				2006/0155278 A1	7/2006	Warnick	
				2006/0247626 A1	11/2006	Taylor et al.	
				2007/0233066 A1*	10/2007	Rezach	A61B 17/7037 606/252
2001/0023350 A1	9/2001	Choi					
2002/0010467 A1	1/2002	Cooper et al.					
2002/0035366 A1	3/2002	Walder et al.					
2002/0151900 A1	10/2002	Glascott					
2003/0028192 A1	2/2003	Schar et al.					
2003/0032957 A1	2/2003	McKinley					
2003/0199873 A1	10/2003	Richelsoph					
2004/0097933 A1	5/2004	Lourdel et al.					

OTHER PUBLICATIONS

Surgical Dynamics, Inc., Spiral Radius 90D, Sales literature, 2001, Surgical Dynamics, Inc., printed in U.S.A., 8 pages.

* cited by examiner

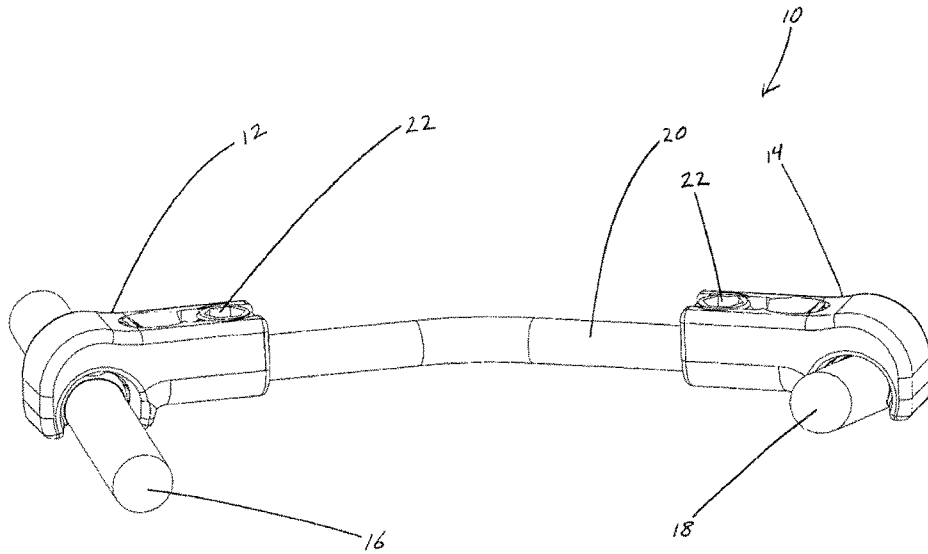


FIG. 1A

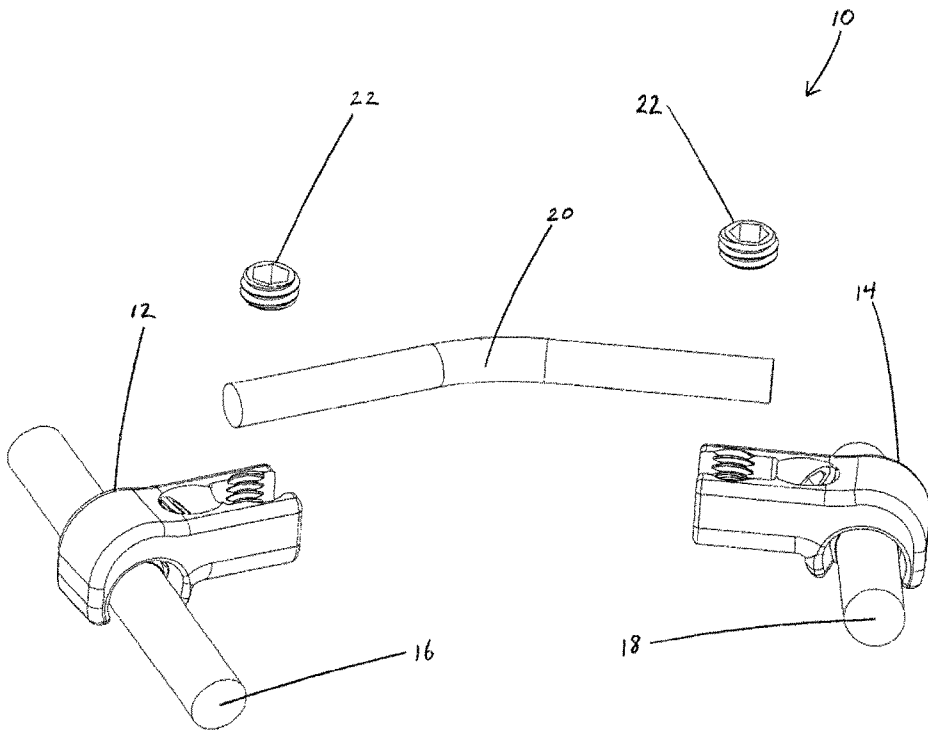


FIG. 1B

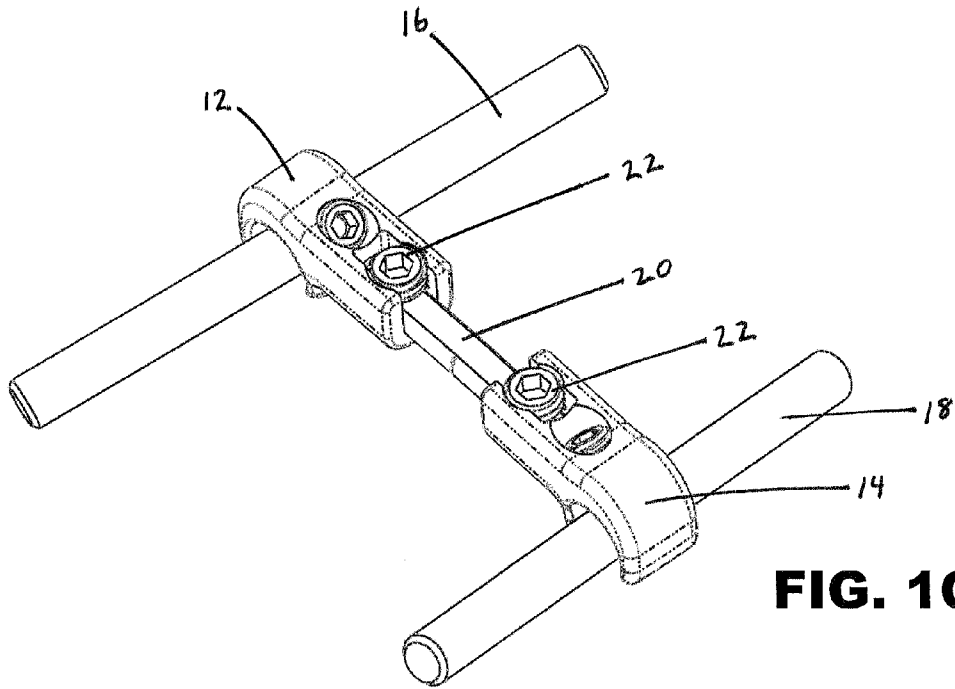


FIG. 1C

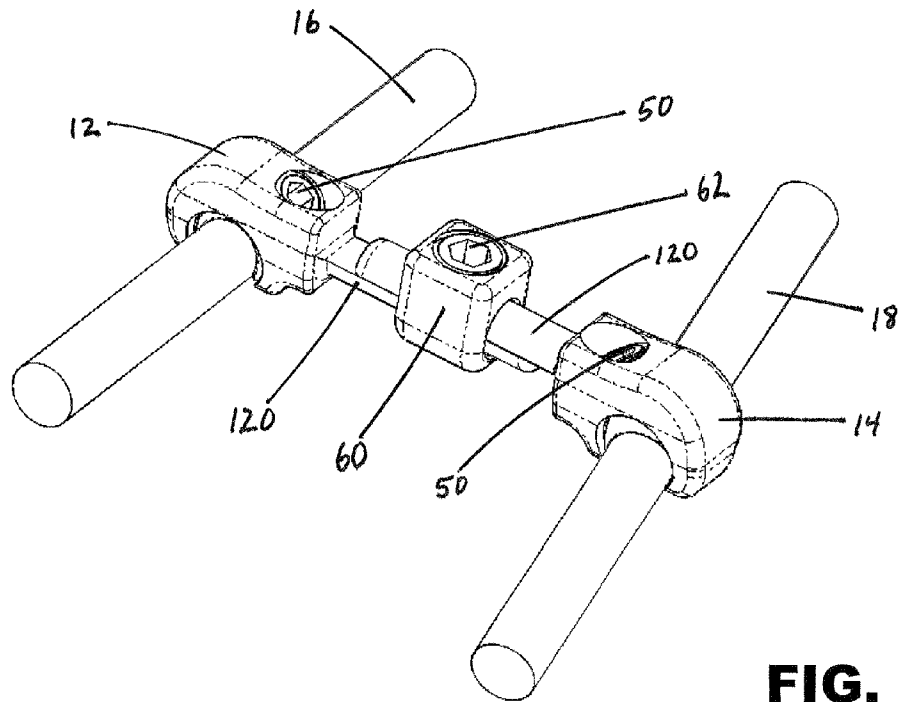


FIG. 1D

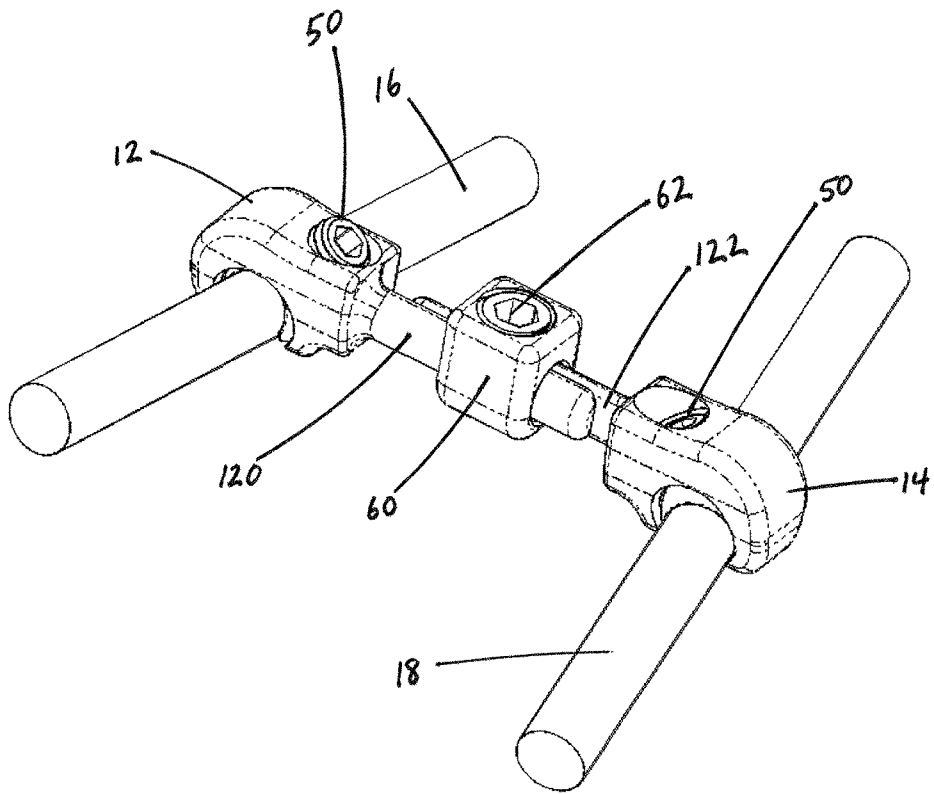


FIG. 1E

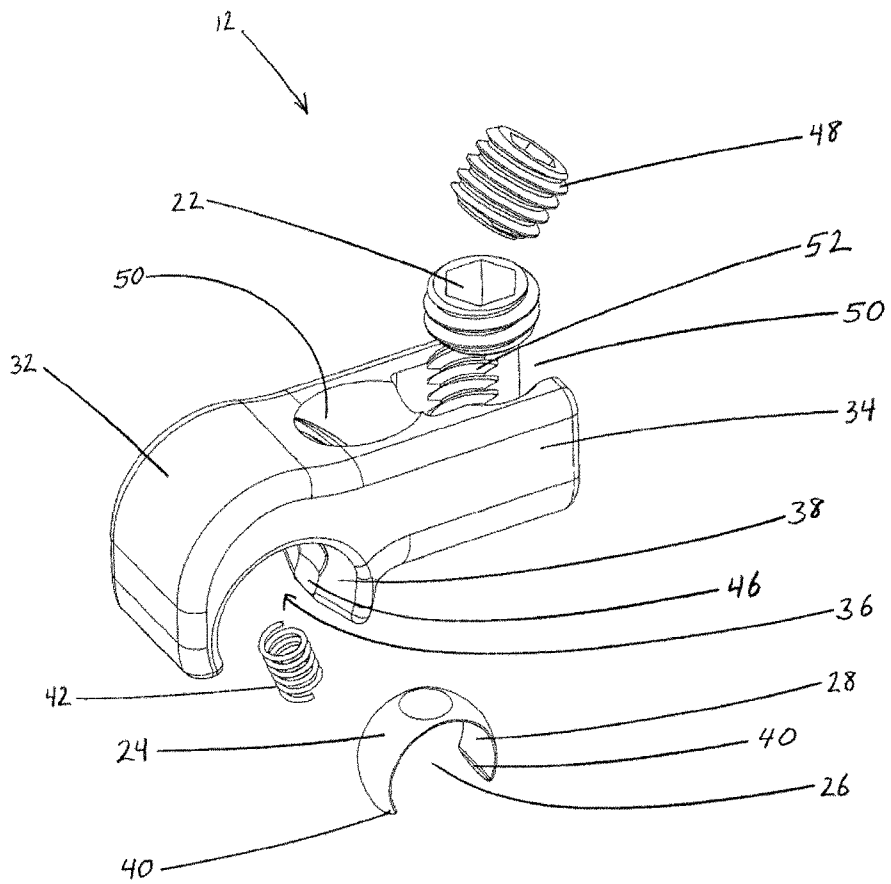


FIG. 2A

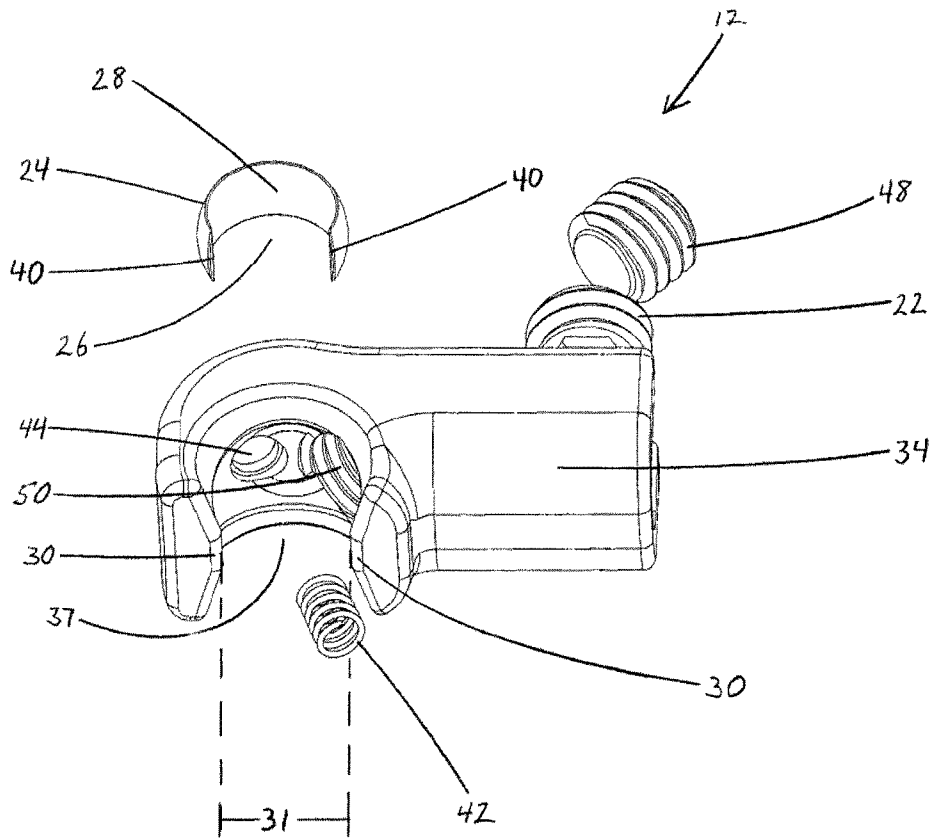


FIG. 2B

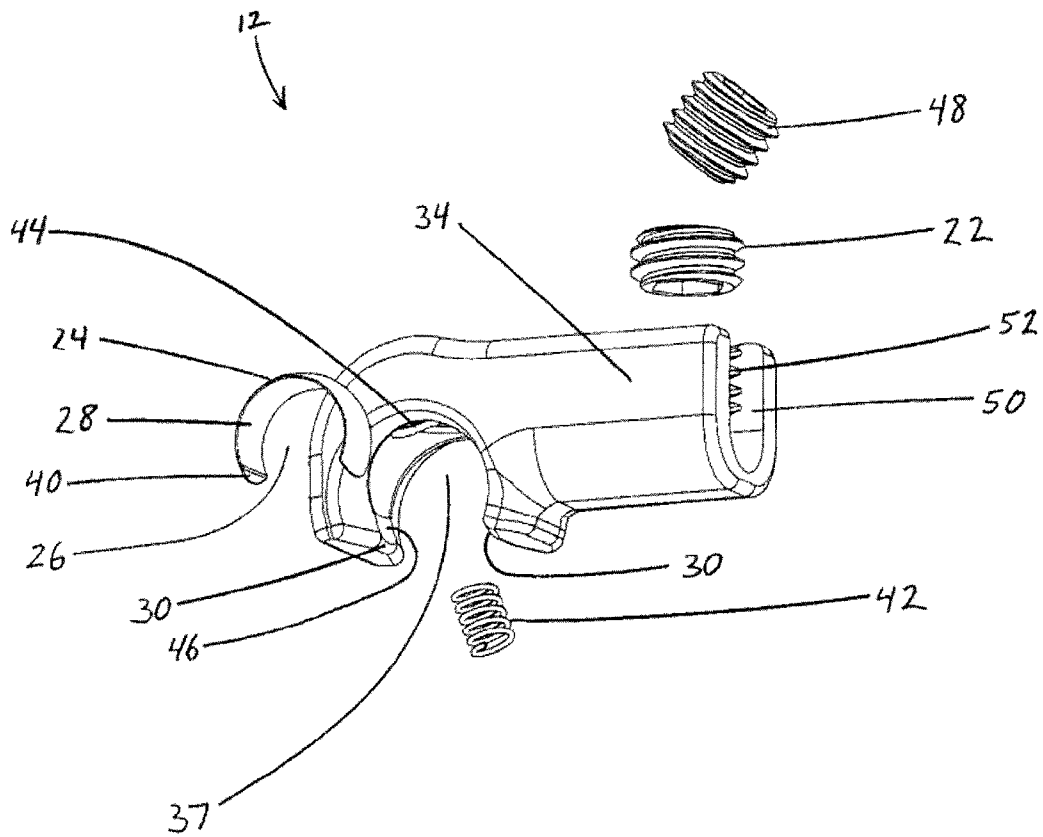
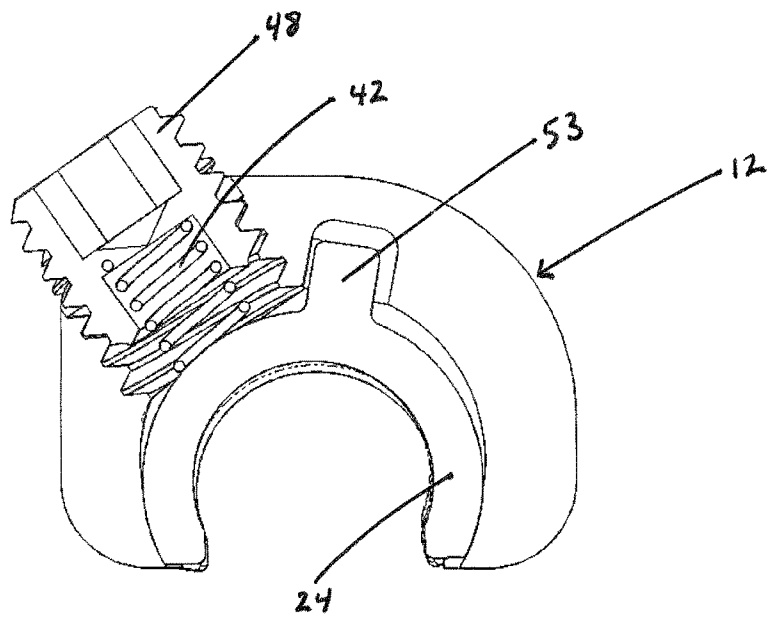
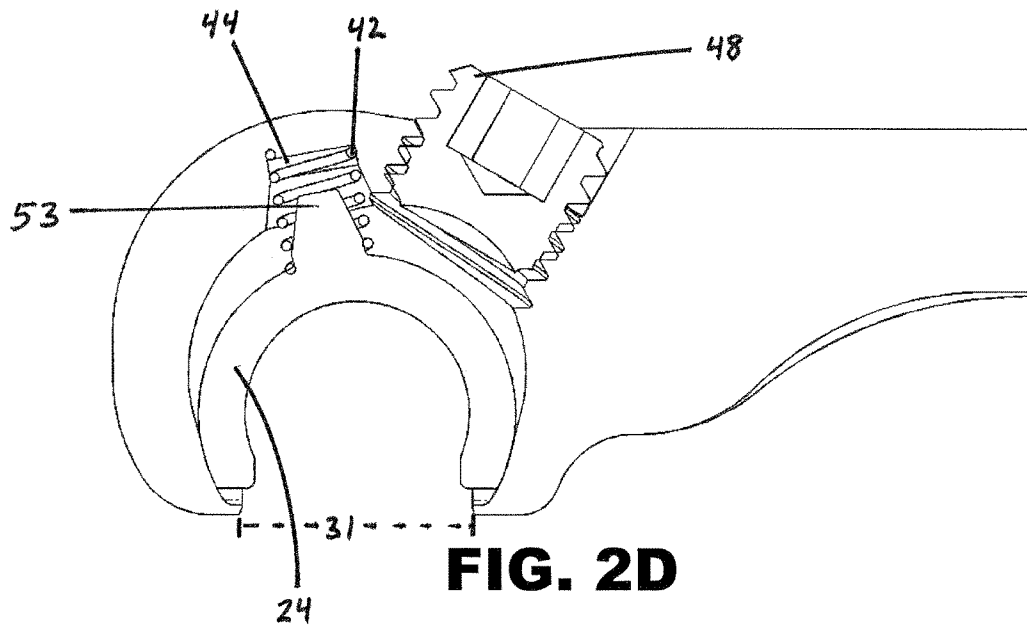


FIG. 2C



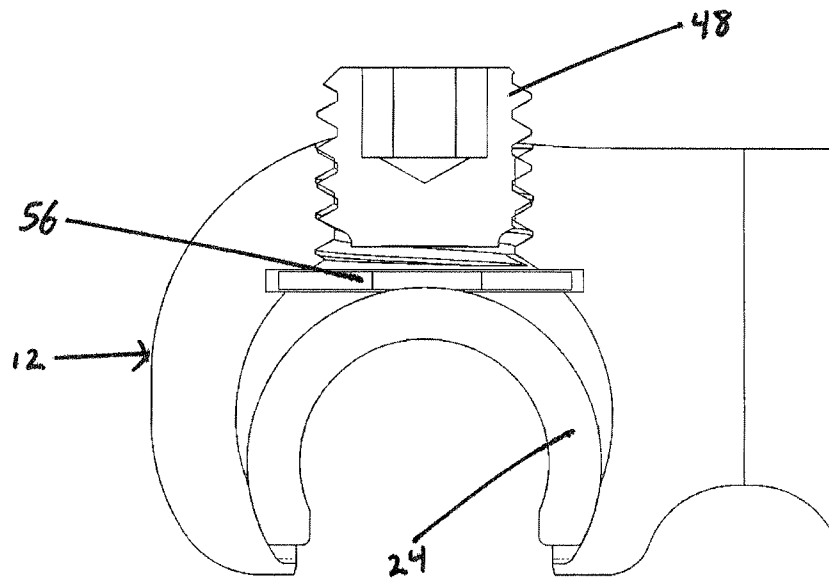


FIG. 2F

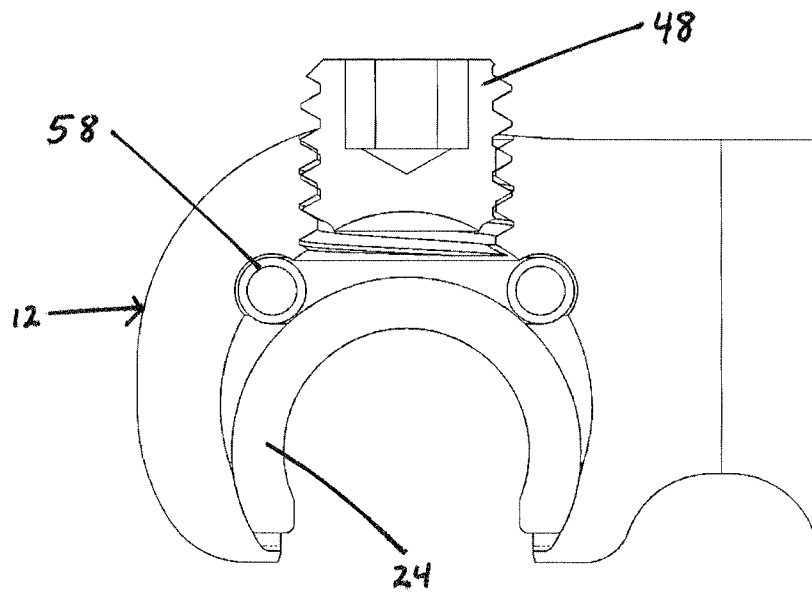


FIG. 2G

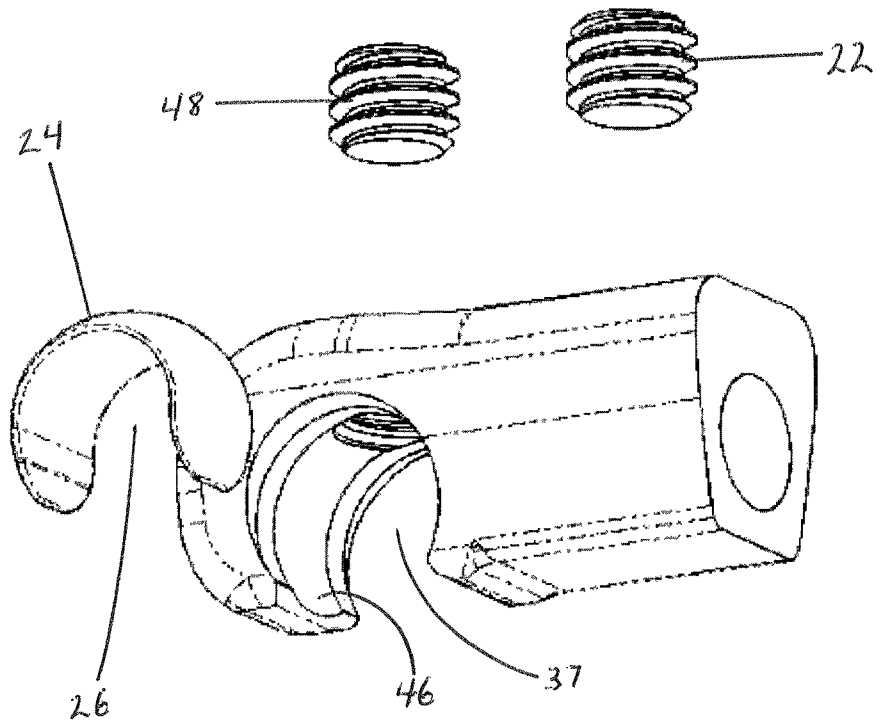


FIG. 2H

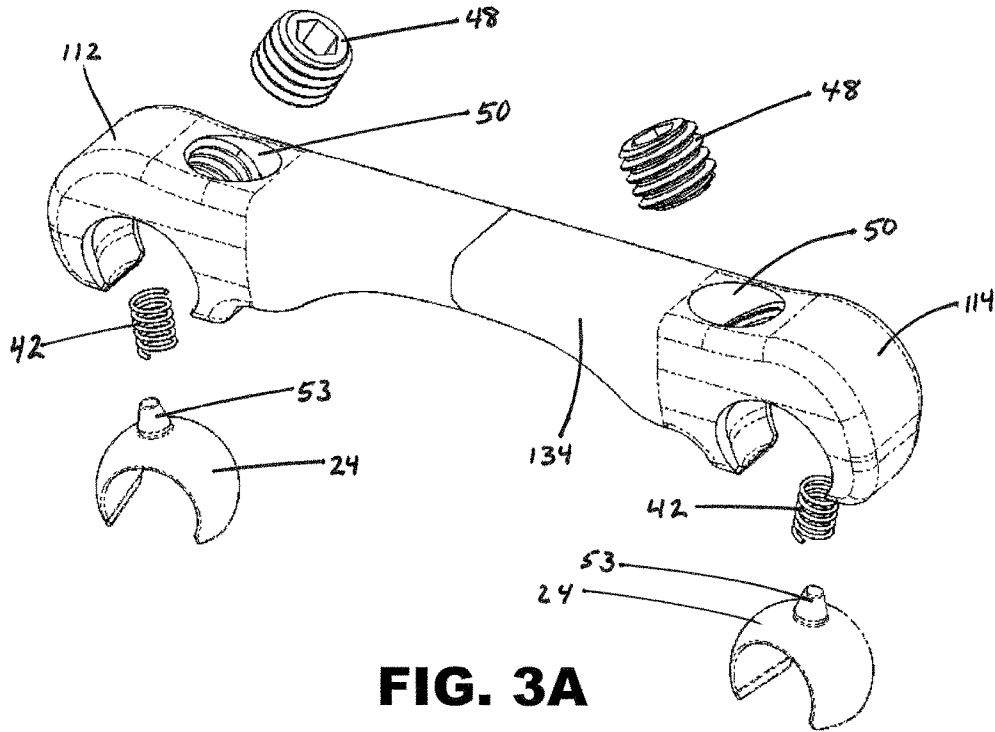


FIG. 3A

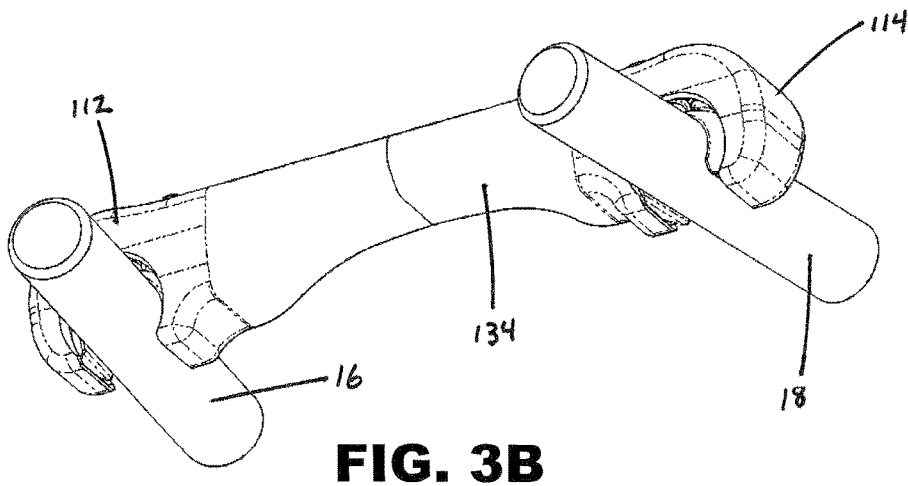


FIG. 3B

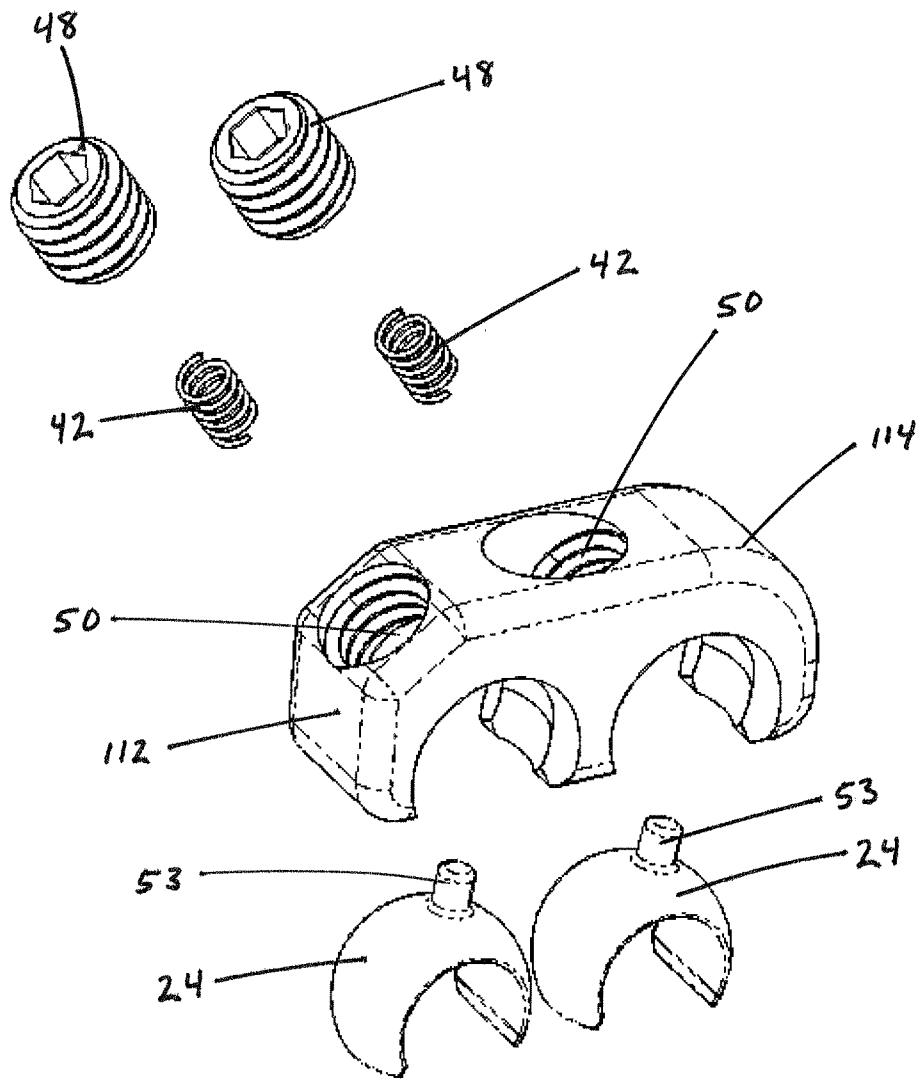


FIG. 4

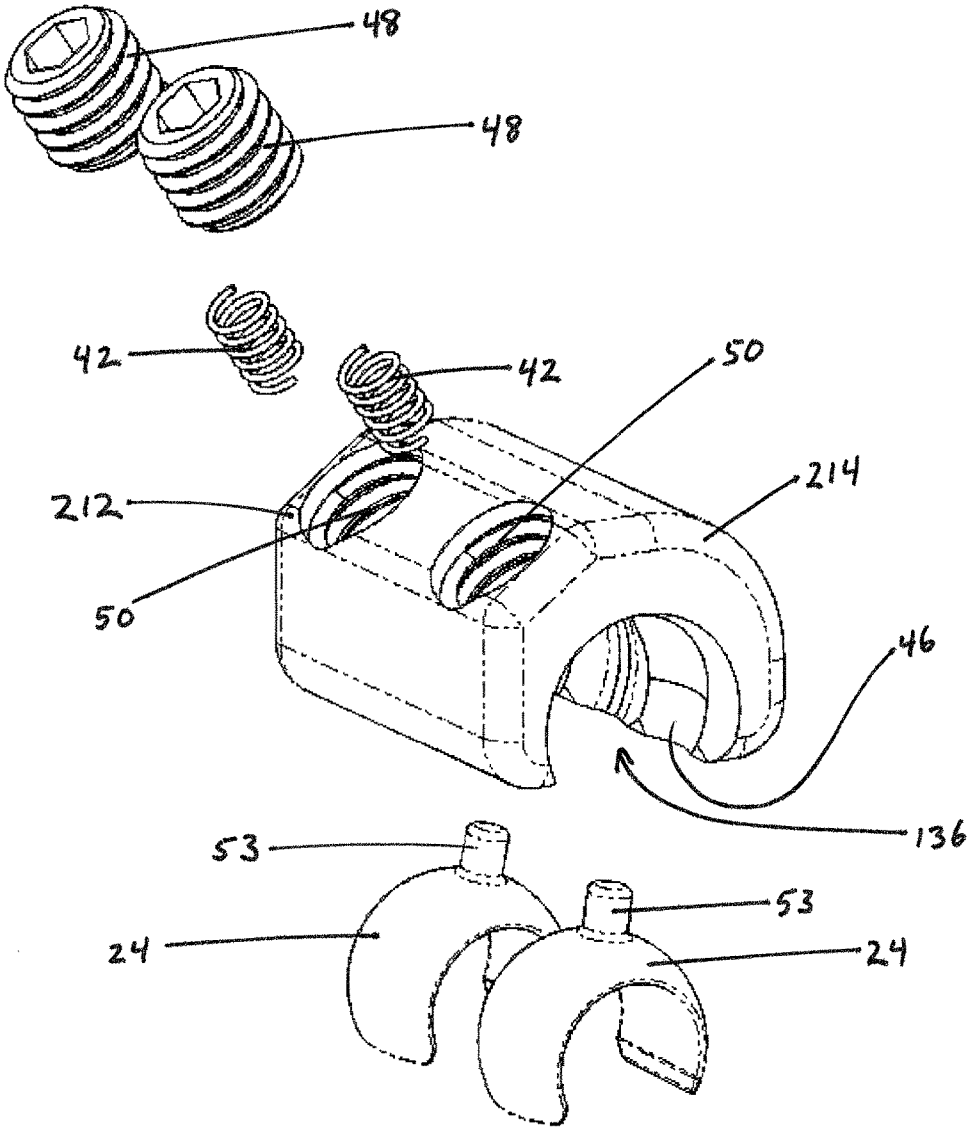


FIG. 5A

FIG. 5B

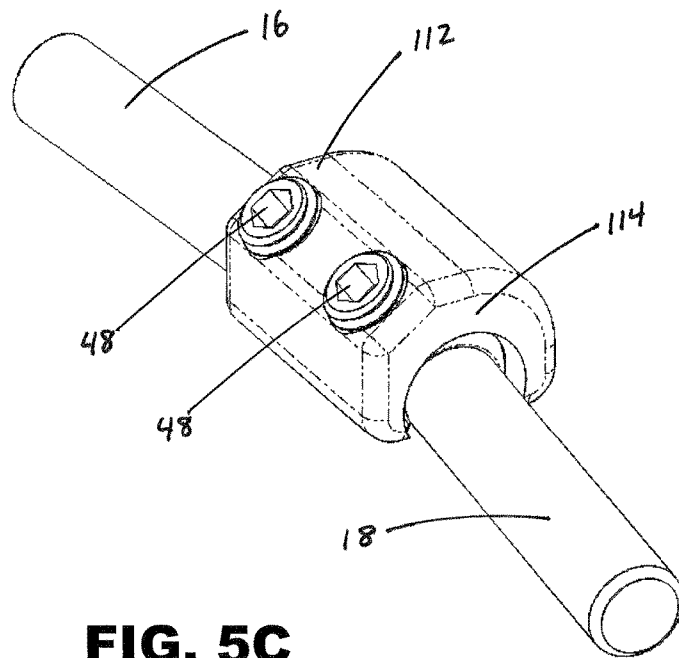
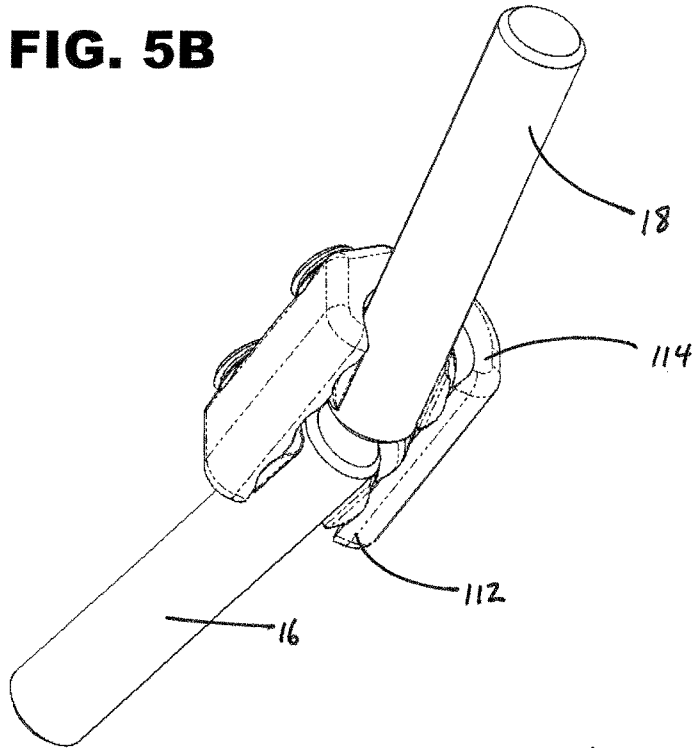


FIG. 5C

**POLYAXIAL SPINAL STABILIZER
CONNECTOR AND METHODS OF USE
THEREOF**

CROSS REFERENCE TO RELATED
APPLICATIONS

This application is a continuation-in-part of copending U.S. application Ser. No. 12/856,235, filed Aug. 13, 2010, which is incorporated by reference herein, and which is a continuation of U.S. application Ser. No. 11/623,180, filed Jan. 15, 2007, now U.S. Pat. No. 7,794,478, which is also incorporated by reference herein.

BACKGROUND OF THE INVENTION

This invention relates to fixation devices for the spinal column. More particularly, this invention relates to a connector for connecting spinal stabilization rods located on the same or opposing sides of the spinal column in a spinal fixation device and associated components. Specifically, this invention relates to a connector system that allows for connection of spinal stabilization rods even when the rods are oriented along axis that do not intersect.

The spine is formed of a series of bones called vertebrae. There are 33 vertebrae, which are grouped as cervical, thoracic, lumbar, sacral, and coccygeal vertebrae, according to the regions of the spine they occupy. A typical vertebra consists of two essential parts, an anterior segment or body, and a posterior part, or vertebral or neural arch. These two parts enclose a foramen, the vertebral foramen. Together, the vertebral foramen of the vertebrae form a canal for the protection of the spinal cord. The vertebral arch consists of a pair of pedicles and a pair of laminae.

The body is the largest part of a vertebra, and is more or less cylindrical in shape. Its upper and lower surfaces are flattened. In front, the body is convex from side to side and concave from above downward. Behind, it is flat from above downward and slightly concave from side to side. The pedicles are two short, thick processes, which project backward, one on either side, from the upper part of the body, at the junction of its posterior and lateral surfaces.

Over the years, various techniques and systems have been developed for correcting spinal injuries and/or degenerative spinal processes. Spinal correction frequently requires stabilizing a portion of the spine to facilitate fusing portions of the spine or other correction methodologies. Medical correction of this type is frequently employed for many spinal conditions, such as, for example, degenerative disc disease, scoliosis, spinal stenosis, or the like. Frequently, these corrections also require the use of implants, such as, bone grafts. Stabilizing the spine allows bone growth between vertebral bodies such that a portion of the spine is fused into a solitary unit.

Several techniques and systems have been developed for correcting and stabilizing the spine and facilitating fusion at various levels of the spine. In one type of system, a rod or more commonly, a pair of rods is disposed longitudinally, lateral to each side of the spine and adjacent along the length of the spine in the region of concern. The rod is arranged according to the anatomy and the correction desired. In this system, the rod is aligned along the spine and engages various vertebrae along its length. The rod or rods engage opposite sides of the spine using fixation elements, such as anchors, attached to vertebral bodies by a bone screw that is inserted into the pedicle and penetrates into the body of the vertebra.

Anatomy and correction frequently require aligning the rod and screw at various angles along the length of the portion of correction. In order to provide this alignment, polyaxial screws/anchors have been developed. Many variations of bone screw and rod fixation systems exist on the market today. However, prior systems have been limited in the amount of angulation permitted relative to the place of attachment to the spine. In extreme cases, even with polyaxial screws, the spinal stabilization rods may diverge in their orientation in not just one, but two or even three planes. Such divergence makes connection of the rods difficult. Stated another way, prior cross connector systems typically provided a connector rod that was attached to and extended from the spinal support rods perpendicularly. When the spinal support rods were non-parallel relative to each other, as is often the case, the cross connector system would typically require an additional mid-spine connector piece to join connector rods extending from opposing support rods approximately over the spine. Utilization of such a connector may require the excising of bone to prevent the spinous process of the spine from interfering with placement of the mid-spine connector. Additionally, such connection systems have required multiple components requiring multiple assembly steps during surgery. Also, prior systems have involved the securing of a screw assembly to a cross connector or spinal support rod by direct contact between a set screw and the rod. This contact causes subtle damage to the rod caused by plastic deformation of the rod by the set screw.

Therefore, there is a need for a spinal cross connector assembly that permits a wide range of angulation of spinal support rods relative to the spine and each other while providing an effective and secure lock of the cross connector and rod in the desired position. There is also a need for a mechanism of attachment of spinal stabilizer or support rods to each other that minimizes the possibility of damage by a set screw securing the cross connector to the support rods.

SUMMARY OF THE INVENTION

It is, therefore, an aspect of the present invention to provide a connector device for a spinal stabilization apparatus that provides an increased amount of allowable angulations between spinal stabilizer rods on opposing sides of the spine.

In addition, it is another aspect of the present invention to provide a spinal cross connector assembly that provides a mechanism of attachment of spinal stabilizers or support rods to each other without the spinal stabilizers or support rods sharing a plane of orientation along the axes of the rods.

It is still another aspect of the present invention to provide a cross connector system that utilizes attachment mechanisms that minimize the possibility of damage to the rod by a set screw securing the cross connector to the support rod.

It is still another aspect of the present invention to provide a cross connector that provides a simple method of attachment of opposing support rods located on either side of a spine.

In general, one embodiment of the present invention provides a connector device for a spinal stabilization apparatus that comprises a first elongated portion adapted to engage at least a first spinal stabilizer rod proximal to the first end of the elongated portion. The first end of the first elongated portion may comprise a hook shape and a first ferrule and may engage the first spinal stabilizer rod up to about 20 degrees from perpendicular to the first spinal stabilizer rod in any direction. The ferrule can be adapted to

be seated within the hook shape of the first elongated portion. The edges of the hook shape may also be chamfered to permit angulation of the spinal support rod. The connector device may also include a second elongated portion which may comprise a second hook shape and a second ferrule. The second elongated portion may engage a second spinal stabilizer rod up to about 20 degrees from perpendicular to the second spinal stabilizer rod in any direction. The edges of the second hook shape may be chamfered to permit angulation of the second spinal stabilizer.

The ferrule is adapted to be seated within the first and/or second hook shape and is further adapted to engage the first and/or second spinal stabilizer rod, respectively. The first and/or second hook shapes may comprise two opposed tabs separated by a first gap which forms an entrance into a channel of the hook shape. The ferrule may have an outside diameter that is greater than the width of the first gap. Optionally, the ferrule may additionally have an outward extension or lug which extends outwardly from the surface of the ferrule to engage a chamber or seat in a corresponding portion of the inner surface of the hook shape. The first and/or second elongated portion may additionally comprise a retainer, such as a spring, for maintaining the ferrule in contact with one or more side walls of the hook shape proximal to the first gap. The first and/or second elongated portion may additionally comprise an aperture, through which a set screw may be inserted to engage the ferrule and secure it in place.

A connector device for a spinal stabilization apparatus may additionally comprise an elongated cross connector member affixed to the first elongated portion on a first end of the cross connector member and affixed to the second elongated portion on a second end of the first elongated cross connector member. Alternatively, the first elongated portion may additionally comprise a first elongated cross connector member and the second elongated portion may additionally comprise a second elongated cross connector member. In such an embodiment, the connector device may additionally comprise a centerpiece adapted to connect the first elongated cross connector member and the second elongated cross connector member.

In some embodiments of the connector device, the first elongated portion and the second elongated portion are directly attached. In one such example, the first elongated portion and the second elongated portion are directly attached such that the first and second spinal stabilizer rods may be inserted into the connector device in an essentially parallel configuration relative to each other. In another example, the first elongated portion and the second elongated portion are directly attached such that the first gap and the second gap are contiguous.

The connector device described herein may be used in a method of treating a patient. The method may comprise attaching at least a first longitudinal spinal stabilizer and a second spinal stabilizer to the spine of a patient, and attaching a connector device as described to the spinal stabilizer. The first elongated member may have first and second ends, and the first spinal stabilizer is engaged to the first end of the first elongated member. The first and/or second end of the elongated member may be adapted to engage the first longitudinal spinal stabilizer within about 20 degrees of perpendicular to the first longitudinal spinal stabilizer in any direction. The first and/or second end of the first elongated member comprise a hook shape and a ferrule. The ferrule is adapted to engage a spinal stabilizer rod and to be seated within the hook shape.

The hook shape comprises two opposed tabs or extensions separated by a first gap which forms a lateral entrance into a channel of the hook shape. The ferrule may have an outside diameter that is greater than the first gap. A spring or other retainer may be present in the first end of the first elongated member for maintaining the ferrule in contact with one or more side walls of the hook shape proximal to the first gap.

In the method of treating a patient the second elongated portion of the connector device may be directly attached to the first elongated member. The first elongated portion and the second elongated portion may be directly attached such that the first and second spinal stabilizer rods may be inserted into the connector device in an essentially parallel configuration relative to each other. In another example of the method, the first elongated portion and the second elongated portion may be directly attached such that the first gap and the second gap are contiguous.

Additionally in the method, the second elongated portion may be similar to the first elongated member or may be separate and have first and second ends. The second elongated portion may be adapted to engage the second longitudinal spinal stabilizer within about 20 degrees of perpendicular to the second longitudinal spinal stabilizer in any direction. The first end of the second elongated member or second end of the first elongated member may also comprise a hook shape. The first end of the second elongated member or second end of the first elongated member may include a ferrule adapted to engage the second spinal stabilizer, with the ferrule being adapted to be seated within the hook shape. The hook shape may comprise two opposed tabs separated by a second gap which forms an entrance into a channel of the hook shape. The ferrule may have an outside diameter that is greater than the second gap. The first end of the second elongated member may additionally comprise a spring for maintaining the ferrule in contact with one or more side walls of the hook shape proximal to the second gap.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1A is a perspective view of one example of the polyaxial cross connector of the present invention;

FIG. 1B is a partially exploded view of the embodiment shown in FIG. 1A from an alternate elevation;

FIG. 1C is a perspective view of another example of the polyaxial cross connector of the present invention;

FIG. 1D is a perspective view of still another example of the polyaxial cross connector of the present invention;

FIG. 1E is a perspective view of a variation of the example of the polyaxial cross connector of the present invention shown in FIG. 1D;

FIG. 2A is an exploded, perspective view of a hook end member of the embodiment of FIG. 1, as assembled;

FIG. 2B is an exploded view of the embodiment shown in FIG. 2A from an alternate elevation;

FIG. 2C is an exploded view of the embodiment shown in FIGS. 2A and 2B from an alternate elevation;

FIG. 2D is a cross sectional view of an alternate embodiment of the polyaxial cross connector of the present invention;

FIG. 2E is a cross sectional view of a variation of the embodiment shown in FIG. 2D;

FIG. 2F is a cross sectional view of an alternate embodiment of the polyaxial cross connector of the present invention utilizing an alternate retainer;

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FIG. 2G is a cross sectional view of another alternate embodiment of the polyaxial cross connector of the present invention utilizing another alternate retainer;

FIG. 2H is an exploded, perspective view of a hook end member of an embodiment of the polyaxial cross connector which does not rely on the presence of a spring or other retainer;

FIG. 3A is an exploded view of an embodiment of the polyaxial cross connector of the present invention that utilizes a cross connector portion instead of a separate cross connector rod;

FIG. 3B is a perspective view of the embodiment shown in FIG. 3A;

FIG. 4 is an exploded view of an embodiment of the polyaxial cross connector of the present invention in which the first and second elongated members are directly attached;

FIG. 5A is an exploded view of an alternate embodiment of the polyaxial cross connector of the present invention in which the first and second elongated members are directly attached and form a single contiguous gap;

FIG. 5B is a perspective view of the embodiment shown in FIG. 5A;

FIG. 5C is a perspective view of the embodiment shown in FIGS. 5A and 5B shown from an alternate elevation.

DETAILED DESCRIPTION OF THE INVENTION

The present invention is directed toward a spinal stabilization apparatus for connecting and immobilizing spinal support rods located laterally on opposite sides of a section of a spine. In one embodiment, the apparatus includes first and second hook members. The first hook member is adapted to engage a first longitudinal spinal support stabilizer located laterally to a first side of a section of a spinal column, and the second hook member is adapted to engage a second longitudinal spinal support stabilizer located laterally to a second side of a section of a spinal column. Each of the first and second hook members may also be adapted to engage opposite ends of a cross connector rod. Alternatively, the first and second hook members may be attached to each other. That is, the first and second hook members are located on opposite ends of a single elongated member. First and second hook members may be further adapted to permit angulation of an attached spinal support rod relative to the hook end member. Stated another way, first and second hook end members may be adapted to attach to a spinal support rod at an angle of between about 70 and 90 degrees in any direction, i.e., through an arc of about 40 degrees in any direction centered on a perpendicular attachment to the spinal support rod.

In another embodiment, the first and second hook end members may be adapted to attach to a spinal support rod at an angle between about 75 and 90 degrees, that is, through an arc of about 30 degrees in any direction centered on a perpendicular attachment. In still another embodiment, the first and second hook end members may be adapted to attach to a spinal support rod at an angle between about 80 and 90 degrees, that is, through an arc of about 20 degrees in any direction centered on a perpendicular attachment.

The following examples should not be viewed as limiting the scope of the invention. The claims will serve to define the inventions. Additionally, it should be noted that elements of one example may be combined with elements of another example, except where the function of the components

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prohibits such combination. The following examples are non-limiting therefore in their arrangements and combinations of elements.

As shown in FIGS. 1A and 1B, a spinal stabilization apparatus 10 includes first 12 and second 14 hook members. First hook member 12 is adapted to engage a first longitudinal spinal support stabilizer rod 16 located laterally to a first side of a section of a spinal column, and the second hook member 14 is adapted to engage a second longitudinal spinal support stabilizer rod 18 located laterally to a second side of a section of a spinal column. Each of the first and second hook members 12, 14 are also adapted to engage opposite ends of a cross connector rod 20, which is secured in first and second hook members 12, 14 by set screws 22.

FIGS. 2A, 2B and 2C illustrate an arrangement of the first hook member 12. It should be understood, however, that similar or identical structures and components may also be present in second hook member 14. Hook member 12 is an elongated structure with a hook end 32 and cross connector end 34 on opposite ends of hook member 12. Hook end 32 may be generally described as hook shaped, comprising a hook end channel 36 passing through the hook shape and entering into a generally spherical cavity 37.

Hook member 12 (and also hook member 14) also includes a ferrule 24, which is C-shaped or generally spherical in shape with a generally cylindrical channel 26 located therethrough, creating an arcuate seat 28 in the walls of channel 26 for receiving a stabilizer such as a rod 16. As a result of the presence of channel 26 in ferrule 24, the open end of ferrule 24 includes two opposed tabs 40 located to each side of channel 26. Tabs 40 may be configured in such a way that tabs 40 have a minor amount of flexibility, allowing them to flex outwardly as rod 16 is inserted into and passes into channel 26 and is ultimately secured in seat 28. Alternatively, the open end of ferrule 24 may be configured such that rod 16 fits into channel 26 without requiring any movement of tabs 40. Channel 26 has a cross-sectional configuration that corresponds to the cross-sectional configuration of rod 16 (or rod 18) such that arcuate seat 28 maintains contact with at least half of the portion of rod 16 that lies within channel 26. In one embodiment, arcuate seat 28 maintains contact with more than half of the circumference of rod 16 that lies within channel 26. In another example, arcuate seat 28 maintains contact with about two thirds or more of the circumference of rod 16 that lies within channel 26. In this manner, any load to be transferred between rod 16 and hook end 32 is distributed as evenly as possible across the length and width of seat 28.

Ferrule 24 is adapted to be seated within cavity 37 in hook end 32 such that rods 16, 18 may be engaged in ferrule 24 and pass through channel 36. Channel 36 is generally cylindrical, with a gap 31 between hook tabs 30 forming a lateral entrance into channel 36 and forming the hook shape of hook end 32. Stated differently, channel 36 may be considered to be the center of C-shaped ferrule 24. Gap 31 is configured to allow rods 16, 18 to pass through gap 31 into channel 36, such that ferrule 24 makes contact with at least some portion of side wall 46 of hook member 12, 14. In some embodiments, gap 31 is essentially the same distance as the diameter of rods 16, 18. In other embodiments, gap 31 is up to 0.1 mm larger than the diameter of rods 16, 18. Ferrule 24 may be further configured to allow it to be inserted into cavity 37 through channel 36 but with an outside diameter that prevents it from passing through gap 31.

In another embodiment, as shown in FIG. 2D, ferrule 24 may have a lug 53 extending outwardly from the outer surface of ferrule 24. Lug 53 is adapted to engage or at least project into a corresponding seat 44 located in the inner surface of hook member 12, 14 created by cavity 37. Seat 44 may be larger than lug 53 to permit adjustment of the position of ferrule 24 and rod 16 inserted into ferrule 24. In one particular embodiment, lug 53 is a frustoconical projection from the outer surface of ferrule 24 (FIG. 2D). In another embodiment, lug 53 is generally rectangular in shape and may have rounded edges (FIG. 2E).

In one example, ferrule 24 has an outside diameter of about 6.5 mm, cavity 37 has a diameter of approximately 6.5 mm, gap 31 is about 5.5 mm wide and the diameter of rods 16, 18 is about 5.5 mm. This provides for the insertion of ferrule 24 into cavity 37 and for the insertion of rods 16, 18 into seat 28 of ferrule 24 through gap 31 but prevents ferrule 24 from passing through gap 31.

Channel 36 may be further adapted to permit rotation of ferrule 24 within channel 36 and thereby allow angulation of spinal support rod 16, 18 within channel 36. One possible adaptation is the presence of chamfered edges 38 surrounding channel 36, allowing ferrule 24 and rod 16, 18 to pivot within channel 36. In one embodiment, rod 16, 18 is capable of pivoting through an arc of approximately 40 degrees in any direction. Stated another way, hook members 12, 14 are adapted to attach to a spinal support rod at an angle of between about 70 and 90 degrees in any direction, i.e., through an arc of about 40 degrees in any direction centered on a perpendicular attachment to the spinal support rods. In another embodiment, hook members 12, 14 are adapted to attach to a spinal rod at an angle of between about 80 and 90 degrees in any direction, that is, through an arc of about 20 degrees in any direction centered on a perpendicular attachment. In still another embodiment, hook members 12, 14 are adapted to attach to a spinal rod at an angle of between about 85 and 90 degrees in any direction, that is, through an arc of about 10 degrees in any direction centered on a perpendicular attachment.

Hook end 32 may also include a retainer such as spring 42 for maintaining ferrule 24 in channel 36 by keeping ferrule 24 in contact with side wall 46 of cavity 37. As mentioned above, ferrule 24 may be configured such that it can not pass through gap 31. Spring 42 may be seated in a seat 44 within cavity 37 either in the absence (FIGS. 2A-2C) or in the presence (FIG. 2D) of lug 53. It should also be noted that when lug 53 is present, spring 42 is not required to be located over lug 53 as shown in FIG. 2D. It is also possible for spring 42 to be separate from lug 53. For example, spring 42 may be located within set screw 48, as shown in FIG. 2E.

It is also envisioned that other resilient components may be used in place of spring 42. For example, a retainer may take the form of a resilient, flexible tab projecting from the inner wall of cavity 37 (not shown). Alternatively, a Belleville washer (56, FIG. 2F) or a curled spring (58, FIG. 2G) may also be used as a retainer. Hook members 12 and 14 also each contain a set screw aperture 50, which passes through hook member 12 and accesses cavity 37, allowing set screw 48 to contact ferrule 24. Set screw 48 may have a flat surface where it contacts ferrule 24 or washer 56 (FIG. 2F) or it may have a concave surface which generally corresponds to the shape of ferrule 24 (FIG. 2G). It should also be noted that the

presence of a retainer is optional. An embodiment that does not rely on the use of spring or other retainer is provided in FIG. 2H.

Cross connector end 34 of hook members 12, 14 comprises a cavity 50 adapted to receive cross connector rod 20. As in the embodiment shown, cavity 50 may be enclosed on three sides to allow cross connector rod 20 to be inserted into cavity 50 and engage hook member 12 at cross connector end 34. Cavity 50 may also include threads 52 to engage a set screw 54. When cross connector rod 20 is inserted into cavity 50, set screw 54 contacts cross connector rod 20 and secures it in place in cross connector end 34.

It is envisioned that cross connector rod 20 may take any of a number of configurations. Cavity 50 may also be appropriately configured where necessary to accept rod 20. For example, cross connector rod 20 may not only be cylindrical, as shown in FIGS. 1A and 1B, but rod 20 may also have a flat upper surface as shown in FIG. 1C, to permit wider contact between rod 20 and set screws 22.

It is further envisioned that a cross connector rod may form a single unitary component with hook member 12, 14. For example, cross connector portion 120 of hook member 12 may be hemicylindrical in shape with a flat surface facing upward as shown in FIG. 1D. In such an embodiment, cross connector portion 122 of hook member 14 may be hemicylindrical in shape with a flat surface facing downward. Where cross connector portions 120 and 122 overlap, together they form a cylindrical structure, and which may be secured together at a centerpiece 60 which houses a set screw 62, by tightening set screw 62 and immobilizing each of cross connector portions 120 and 122 against each other and/or centerpiece 60. Portions 120 and 122 may also be oriented with complementing vertically oriented flat surfaces as shown in FIG. 1E.

As mentioned above, ferrule 24, cavity 37 and channel 36 are adapted to permit rod 16 to pivot within channel 36. In one embodiment, rod 16 is capable of rotating through an arc of approximately 40 degrees in any direction. Likewise, the identical structures in second hook member 14 permit rod 18 to be angulated through an arc of approximately 40 degrees in any direction, with the arc centered on a perpendicular attachment. Stated another way, rods 16, 18 may be angulated through hook members 12, 14 not only side-to-side, or up-and-down relative to the central axis of hook members 12, 14, but both side-to-side and up-and-down simultaneously. In this way, support rods 16 and 18 may be angled a total of up to 40 degrees from parallel in any direction while still directly connecting the first and second hook members 12, 14 with a substantially straight cross connector rod 20. In those situations where rods 16 and 18 are angled more than 40 degrees from parallel to each other, a connection may still be directly made between first and second hook members 12, 14 with a single cross connector rod 20. In such a case, cross connector rod 20 may be bent with an instrument for bending spinal rods, such as an instrument known in the art as a French Bender (not shown), to accommodate the greater angulation. Therefore, even in cases where there is greater than 40 degrees of angulation in any direction, relative to a parallel condition between the rods, the present invention provides an apparatus and method for spinal stabilization utilizing only a single cross connector rod without the need for an intervening connector piece located between the hook members, thereby directly connecting hook members 12 and 14 without an intervening connector. The absence of an additional connector other than those directly connected to the spinal support rods, i.e. hook members 12 and 14, permits spinal stabilization with a

decreased or even eliminated need for excision of bone, such as the spinous process, to permit installation of the stabilization system.

As mentioned above, a spinal stabilizer device may include a first hook end and a second hook end as described above, with the exception of the absence of a cross connector rod. That is, the device is of a fixed length. One such embodiment is shown in FIGS. 3A and 3B. The spinal stabilizer device 110 comprises first hook member 112 and second hook member 114, each of which is adapted to receive a C-shaped ferrule 24 with a lug 53 and a spring 42 as described above. First hook member 112 and second hook member 114 also each have a set screw aperture 50 adapted to receive a set screw 48, which can be secured in aperture 50 against ferrule 24, as also described above. In this embodiment, however, first hook member 112 and second hook member 114 are connected by cross connector member 134. This embodiment is otherwise similar to those embodiments described above.

One similar embodiment that may be particularly useful in the upper thoracic or lower lumbar regions eliminates cross connector member 134. As shown in FIG. 4, first hook member 112 and second hook member 114 are directly attached to each other. First and second hook members 112, 114 are each adapted to receive a C-shaped ferrule 24 optionally having a cylindrical lug 53, and additionally may have set screw apertures 50 adapted to receive set screws 48. First and second hook members 112, 114 may also comprise springs 42 for maintaining pressure on ferrules 24.

A further embodiment that may be used to secure two spinal stabilizer rods end-to-end is provided in FIGS. 5A-5C. As in previous embodiments, each of hook members 212, 214 may be generally described as hook shaped, comprising a hook end channel 136 passing through the hook shape and entering into a cavity 37. However, in the current embodiment, hook end channel 136 is common to both first hook end member 212 and second hook end member 214. In previously described embodiments, first hook member 12 and second hook member 14 are arranged such that stabilizer rods 16, 18 are capable of being inserted into hook members 12, 14 in an essentially parallel position. In contrast, in this embodiment, hook members 212, 214 are aligned such that channel 136 forms a common channel of first hook member 212 and second hook member 214 into which stabilizer rods 16, 18 are inserted. In this way, stabilizer rods 16, 18 are inserted into a stabilizer apparatus 210 in an end-to-end alignment. This may be particularly useful where a patient's physiology requires that stabilizer rods 16 and 18 be angled relative to each other, such as in the obtuse relationship shown in FIGS. 5B and 5C.

As with previous embodiments, hook members 212, 214 each include a ferrule 24, which is C-shaped or generally spherical in shape with a generally cylindrical channel 26 located therethrough, creating an arcuate seat 28 in the walls of channel 26 for receiving a stabilizer such as rods 16, 18. The open end of ferrule 24 again may include two opposed tabs 40 located to each side of channel 26. Tabs 40 may be configured in such a way that tabs 40 have a minor amount of flexibility, allowing them to flex outwardly as rods 16, 18 are inserted into and pass into channel 26 and are ultimately secured in seat 28. Alternatively, the open end of ferrules 24 may be configured such that rod 16 fits into channel 26 without requiring any movement of tabs 40. Channel 26 may have a cross-sectional configuration that corresponds to the cross-sectional configuration of rods 16, 18 such that arcuate seat 28 maintains contact with at least half of the portion of rod 16 that lies within channel 26. In one embodiment,

arcuate seat 28 maintains contact with more than half of the circumference of rod 16 that lies within channel 26. In another example, arcuate seat 28 maintains contact with about two thirds or more of the circumference of rod 16 that lies within channel 26. As with previous embodiments, any load to be transferred between rod 16 and hook end 32 is distributed as evenly as possible across the length and width of seat 28.

Ferrules 24 are adapted to be seated within hook members 212, 214 such that rods 16, 18 may be engaged in ferrules 24 and pass through channel 136. Channel 136 is generally cylindrical, with a gap 31 between hook tabs 30 forming a lateral entrance into channel 136 and forming the hook shape of hook members 212, 214. Gap 31 is configured to allow rods 16, 18 to pass through gap 31 into channel 36, allowing ferrules 24 to make contact with at least some portion of side wall 46 of hook member 212, 214. Alternatively, the open end of ferrules 24 may be configured such that rod 16 fits into channel 26 without requiring any movement of tabs 40. In some embodiments, gap 31 is essentially the same distance as the diameter of rods 16, 18. In other embodiments, gap 31 is up to 0.1 mm larger than the diameter of rods 16, 18. Ferrules 24 may optionally be further configured to have a lug 53 extending outwardly from the outer surface of ferrules 24. Lug 53 can be adapted to engage or at least project into a corresponding seat located in the inner surface of hook member 212, 214 as in previous embodiments. Seat 44 may be larger than lug 53 to permit adjustment of the position of ferrule 24 and rod 16 inserted into ferrule 24.

Springs 42 may also be present, again for maintaining ferrule 24 in channel 136 by keeping ferrule 24 in contact with side wall 46. Springs 42 may be positioned in association with lug 53 (as in a previous embodiment) or separate from lug 53. For example, spring 42 may be located within set screw 48 (FIG. 5A).

In use, the cross connector system of the present invention would be utilized after spinal stabilization rods 16, 18 have been secured to the spine using bone screws, such as pedicle screws. Hook members 12 and 14 (or 112, 114, or 212, 214) would typically be partially assembled prior to surgery, with ferrule 24 positioned within channel 36 and held in place by spring 42 or other similar structures, when present. Hook member 12 would be attached to rod 16 by sliding hook member 12 over rod 16 and positioning a portion of rod 16 within channel 26. As stated above, ferrule 24 is oriented in cavity 37 such that channel 26 cooperates with channel 36 of hook member 12 to permit alignment of rod 16 or rod 18 through both ferrule channel 26 and hook end channel 36. When rod 16 is passed through gap 31 and inserted into ferrule 24 in cavity 37, the resilience of spring 42 allows ferrule 24 to be temporarily and reversibly positioned upward into cavity 37, away from side wall 46. This allows tabs 40 to flex outward as rod 16, 18 passes into channel 26 becoming secured against arcuate seat 28. Once rod 16, 18 is secured in seat 28 and pressure against spring 42 is released, spring 42 again applies pressure to ferrule 24, forcing it into contact with side wall 46 and holding it in place there.

Once corresponding first and second hook members 12, 14 are attached to support rods 16, 18, cross connector rod 20 is then inserted into each cavity 50 of cross connector end 34 of hook members 12, 14. When a cross connector rod 20 is not present, as in the embodiments of FIGS. 3A-5C, this step may obviously be omitted. As mentioned above, the angulation of hook members 12, 14 relative to a perpendicular position on support rods 16, 18, allows the use of a

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single cross connector rod **20** between hook members **12** and **14** without resorting to an additional connector located between support rods **16**, **18**. This allows a surgeon to utilize fewer components in a spinal stabilization system than previously needed. A surgeon may simply select a cross connector rod of appropriate length to connect first and second hook members and bend it the appropriate amount if necessary. Once cross connector **20** is engaged in cavity **50**, a set screw **22** may be used to secure cross connector rod **20** in cavity **50**. Alternatively, the length of the cross connection between hook members **12** and **14** may be adjusted with the use of centerpiece **60**, as shown in FIGS. 1D and 1E.

After cross connector **20** (when present) is secured in cavities **50** of hook members **12**, **14**, any final adjustments to the angulation of rods **16** and **18** may be performed and ferrule **24** may be permanently secured into position with a set screw **48** that is inserted into a set screw aperture **50**. In contrast with spring **42**, set screw **48** keeps ferrule **24** in constant contact with side wall **46** and does not allow ferrule **24** to move upward into channel **36** away from side wall **46** even temporarily, thereby securing rod **16**, **18**. The engagement of set screw **48** against ferrule **24** results in ferrule **24** being locked in place with arcuate seat **28** at least partially surrounding rods **16**, **18**. Set screw **48** does not however, directly engage rods **16**, **18**. Instead, pressure from set screw **48** is distributed to ferrule **24** and locking pressure is exerted against a relatively large surface area of rods **16**, **18** by arcuate seat **28**. In this way, set screw **48** does not etch or otherwise deform or damage rods **16**, **18** and the possibility of damage to rods **16**, **18** during use is minimized or eliminated.

Although it is envisioned that ferrule **24** would ordinarily be permanently secured in place after cross connector **20** is secured in cavities **50**, such a sequence of assembly is not necessarily required. For example, in those situations where hook members **12** and **14** are attached to rods **16** and **18** in a substantially perpendicular position, set screw **48** could be utilized as described above to secure ferrule **24** in place before cross connector **20** is secured in place. The present spinal stabilization system may also be adjusted in place after set screws **48** and **22** have been secured in place by loosening one or more set screws, making the necessary adjustments and re-securing the set screws in place.

The present invention provides a self-adjusting spinal stabilization system. Ferrule **24** may rotate within cavity **37** to allow a particular angulation of hook members **12**, **14** (or **112**, **114**, or **212**, **214**) as dictated by the patient's anatomy until set screws **48** are fully engaged with ferrule **24**. This eliminates the need for separate adjustment of a connector in the mid-spine region as with prior systems, which only allow a hook member to attach to a spinal support rod perpendicularly.

Based upon the foregoing disclosure, it should now be apparent that the polyaxial cross connector assembly of the present invention will carry out the objects set forth hereinabove. It is, therefore, to be understood that any variations evident fall within the scope of the claimed invention and thus, the selection of specific component elements can be determined without departing from the spirit of the invention herein disclosed and described.

I claim:

1. A connector device for a spinal stabilization apparatus, the device comprising:

a first elongated portion adapted to engage a first spinal stabilizer rod proximal to a first end of the first elongated portion, the first end of the elongated portion comprising a first hook shape formed by two opposed tabs separated by a first gap which forms an entrance adapted to allow the first spinal stabilizer rod to pass

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laterally through the entrance into a first cavity of the hook shape, wherein the first cavity of the hook shape is generally spherical

a generally spherical first ferrule received in the generally spherical first cavity of the hook shape, and configured to be fixedly engaged with the first spinal stabilizer rod using a first set screw, and wherein the elongated portion is adapted to engage and to be fixed to the first spinal stabilizer rod up to about twenty degrees from perpendicular to the first spinal stabilizer rod in any direction; and

a second elongated portion for engaging with a second spine stabilizer rod in a fixed arrangement, the second elongated portion comprising a second hook shape formed by two opposed tabs separated by a second gap which forms an entrance adapted to allow the second spinal stabilizer rod to pass laterally through the entrance into a second cavity of the second hook shape, the second elongated portion engaging with the first elongated portion such that the first stabilizer rod and the second stabilizer rod are disposed in a fixed arrangement with respect to each other.

2. The connector device of claim 1, the second elongated portion comprising a second ferrule that is adapted to be seated within the hook shape and to engage the second spinal stabilizer rod.

3. The connector device of claim 2, wherein the first ferrule has an outside diameter that is greater than the width of the first gap.

4. The connector device of claim 1, the second elongated portion adapted to selectively engage and disengage with the first elongated portion.

5. The connector device of claim 1, the second elongated portion adapted to engage a second ferrule to be seated within the hook shape of the second elongated portion and is further adapted to engage the second spinal stabilizer rod.

6. The connector device of claim 5, wherein the second ferrule has an outside diameter that is greater than the width of the second gap.

7. The connector device of claim 1, wherein the first ferrule comprises an integral outward extension from the outer surface of the first ferrule, and the corresponding first elongated portion comprises a seat adapted to receive the outward extension of the first ferrule.

8. The connector device of claim 1, wherein the first elongated portion comprises a retainer adapted to maintain the first ferrule in contact with one or more side walls of the hook shape of the first elongated portion proximal to the first gap.

9. The connector device of claim 8, wherein the retainer comprises a spring.

10. The connector device of claim 1, the first set screw adapted to engage the first ferrule through an aperture in the first elongated portion.

11. The connector device of claim 1, wherein the connector device additionally comprises an elongated cross connector member affixed to the first elongated portion on a first end of the cross connector member and affixed to the second elongated portion on a second end of the first elongated cross connector member.

12. The connector device of claim 1, wherein the first elongated portion additionally comprises a first elongated cross connector member and wherein the second elongated portion additionally comprises a second elongated cross connector member.

13. The connector device of claim 12, additionally comprising a centerpiece adapted to connect the first elongated cross connector member and the second elongated cross connector member.

14. The connector device of claim 1, wherein the first elongated portion and the second elongated portion are directly attached.

15. The connector device of claim 14, wherein the first elongated portion and the second elongated portion are directly attached such that the first and second spinal stabilizer rods may be inserted into the connector device in an essentially parallel configuration relative to each other.

16. The connector device of claim 14, wherein the first elongated portion and the second elongated portion are directly attached such that the first gap and the second gap are disposed co-linear along a same axis.

17. A method of treating a patient, the method comprising: attaching at least a first longitudinal spinal stabilizer and a second longitudinal spinal stabilizer to the spine of a patient; and attaching a connector device according to claim 6 to the first and second spinal stabilizers.

18. The method of claim 17, wherein the first elongated portion and the second elongated portion of the connector device are directly attached.

19. The method of claim 18, wherein the first elongated portion and the second elongated portion are directly attached such that the first and second spinal stabilizer rods may be inserted into the connector device in an essentially parallel configuration relative to each other.

20. The method of claim 18, wherein the first elongated portion and the second elongated portion are directly attached such that the first gap and the second gap are disposed co-linear along a same axis.

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