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INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	
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(Use as many sheets as necessary)				First Named Inventor	Roger P. Jackson
				Art Unit	
				Examiner Name	
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Examiner Initials*	Cite No.[7]	Document Number Number-Kind Code [2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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				Examiner Name	
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U. S. PATENT DOCUMENTS					
Examiner Initials*	Cite No.[10]	Document Number Number-Kind Code [2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-2008/0161859	07/03/2008	Nilsson	
		US-2008/0161863	07/03/2008	Arnold, et al.	
		US-2008/0177321	07/24/2008	Drewry, et al.	
		US-2008/0177322	07/24/2008	Davis, et al.	
		US-2008/0183215	07/31/2008	Altarac, et al.	
		US-2008/0183223	07/31/2008	Jeon, et al.	
		US-2008/0195159	08/14/2008	Kloss, et al.	
		US-2008/0200956	08/21/2008	Beckwith, et al.	
		US-2008/0177332	07/24/2008	Reiley, et al.	
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		US-2008/0215095	09/04/2008	Biedermann, et al.	
		US-2008-0228229	09/18/2008	Walder, et al.	
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		US-2008/0234756	09/25/2008	Sutcliffe, et al.	
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		US-2010/0152788	06/17/2010	Warnick	
		US-2010/0160965	06/24/2010	Viker	
		US-2010/0160974	06/24/2010	Viker	
		US-2010/0160980	06/24/2010	Walsh, et al.	
		US-2010/0168796	07/01/2010	Eliasen, et al.	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	
				Filing Date	
(Use as many sheets as necessary)				First Named Inventor	Roger P. Jackson
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				Examiner Name	
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U. S. PATENT DOCUMENTS					
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		US-2008/0249570	10/09/2008	Carson, et al.	
		US-2008/0262548	10/23/2008	Lange, et al.	
		US-2008/0262556	10/23/2008	Jacofsky, et al.	
		US-2008/0269742	10/30/2008	Levy, et al.	
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		US-2008/0287994	11/20/2008	Perez-Cruet, et al.	
		US-2008/0288002	11/20/2008	Crall, et al.	
		US-2008/0306528	12/11/2008	Winslow, et al.	
		US-2008/0306533	12/11/2008	Winslow, et al.	
		US-2008/0306539	12/11/2008	Cain, et al.	
		US-2006/0166535	07/27/2006	Brumfield, et al.	
		US-2006/0276789	12/07/2006	Jackson	
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		US-2010/0168800	07/01/2010	Biedermann, et al.	
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		US-2010/0174322	07/08/2010	Abdelgany, et al.	
		US-2010/0179603	07/15/2010	Warnick	
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		US-5,683,392	11/04/1997	Richelsoph	
		US-7,604,655	10/20/2009	Warnick	

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(Use as many sheets as necessary)				First Named Inventor	Roger P. Jackson
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				Examiner Name	
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		US-7,695,498	04/13/2010	Rilland	
		US-7,695,497	04/13/2010	Cordaro, et al.	
		US-7,691,132	04/06/2010	Landry, et al.	
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		US-2010/0087865	04/08/2010	Biedermann, et al.	
		US-2010/0087861	04/08/2010	Lechmann, et al.	
		US-7,087,057	08/08/2006	Konieczynski, et al.	
		US-2006/0217716	09/28/2006	Baker, et al.	

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		US-2009/0082819	03/26/2009	Blain, et al.	
		US-2009/0076552	03/19/2009	Tornier	
		US-2010/0069969	03/18/2010	Ampuero, et al.	
		US-2010/0069963	03/18/2010	Eckman	
		US-2010/0063551	03/11/2010	Richelsoph	
		US-2010/0063550	03/11/2010	Felix, et al.	
		US-2010/0063546	03/11/2010	Miller, et al.	
		US-2010/0063545	03/11/2010	Richelsoph	
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		US-2010/0057125	03/04/2010	Viker	
		US-			
		US-			
		US-			

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				Examiner Name	
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U. S. PATENT DOCUMENTS

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		US-7,819,902	10/26/10	Abdelgany, et al.	
		US-7,811,310	10/12/10	Baker, et al.	
		US-7,811,288	10/12/10	Jones, et al.	
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		US-7,789,900	09/07/10	Levy, et al.	
		US-7,785,354	08/31/10	Biedermann, et al.	
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		US-7,780,706	08/24/10	Marino, et al.	
		US-7,766,945	08/03/10	Nilsson, et al.	
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		US-7,766,946	08/03/10	Bailly	
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				Examiner Name	
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		US-2010/0262196	10/14/10	Barrus, et al.	
		US-2010/0256682	10/07/10	Fallin, et al.	
		US-2010/0256681	10/07/10	Hammer, et al.	
		US-2010/0249856	09/30/10	Iott, et al.	
		US-2010/0249846	09/30/10	Simonson	
		US-2010/0241170	09/23/10	Cammisa, et al.	
		US-2010/0234891	09/16/10	Freeman, et al.	
		US-2010/0228293	09/09/10	Courtney, et al.	
		US-2010/0222822	09/02/10	Farris, et al.	
		US-2010/0204735	08/12/10	Gephart, et al.	
		US-2010/0198272	08/05/10	Keyer, et al.	
		US-2010/0198270	08/05/10	Barker, et al.	
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		US-2010/0185247	07/22/10	Richelsoph	
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		US-7,972,364	07/05/11	Biedermann, et al.	
		US-RE42,545	07/12/11	Ralph, et al.	
		US-7,985,242	07/26/11	Forton, et al.	
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	
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				Art Unit	
				Examiner Name	
	47	of	50	Attorney Docket Number	11,433

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Examiner Initials*	Cite No.[7]	Document Number Number-Kind Code [2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-2011/0178558	07/21/11	Barry	
		US-2011/0184471	07/28/11	Foley, et al.	
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		US-			

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		EBI Omega 21 Brochure, EBI Spine Systems, pub. 1999	
		Claris Instrumentation Brochure, G Med, pub. 1997	
		VLS System Variable Locking Screw Brochure, Interpore Cross International,1999	
		CD Horizon M8 Multi Axial Screw Spinal System Brochure, Medtronic Sofamor Danek, no publish date	
		Contour Spinal System Brochure, Ortho Development, no publish date	
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2012 年 7 月 5 日 (05.07.2012)

WIPO | PCT

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(71) 申请人 (对除美国外的所有指定国): **上海微创骨科医疗科技有限公司 (SHANGHAI MICROPORT ORTHOPEDICS CO., LTD.)** [CN/CN]; 中国上海市浦东新区天雄路 588 弄上海国际医学园区医谷现代商务园 23 号楼, Shanghai 201318 (CN)。

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[见续页]

(54) Title: DYNAMIC PEDICEL SCREW IMPLANT FOR VERTEBRAL ARCH

(54) 发明名称 : 动态椎弓根螺钉植入物

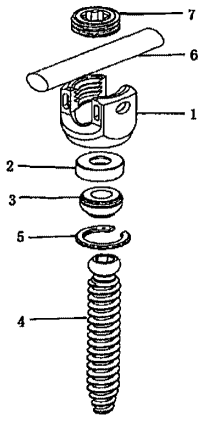


图2 / Fig.2

(57) Abstract: Disclosed is a dynamic pedicel screw implant for the vertebral arch, which comprises a screw base (1), a compression ring (2), a screw (4), a connecting bar (6) and a compression nut (7). The screw (4) includes a screw main body (16) and a connecting head (8), the connecting head (8) being accommodated in the screw base (1). The connecting bar (6) is arranged in an open slot of the screw base (1) and is located between the compression ring (2) and the compression nut (7). The compression nut (7) is used for screwing into the upper part of the screw base (1) so as to press the connecting bar (6) tightly. The dynamic pedicel screw implant for the vertebral arch is also provided with a screw bush (3) which is of a ball seat structure (13) on the inside. The connecting head (8) of the screw (4) has a spherical external structure, so that the ball seat structure (13) can fit the connecting head (8) of the screw (4). The dynamic pedicel screw implant for the vertebral arch of the present invention is able to provide not only the traditional multi-axial swinging, but also additional swinging angles after being locked, and it is able to ensure the stability of the spine.

[见续页]

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本国际公布:

— 包括国际检索报告(条约第 21 条(3))。

(57) **摘要**:

一种动态椎弓根螺钉植入物，包括：螺钉座（1），压环（2），螺钉（4），连接棒（6）以及压紧螺母（7）。螺钉（4）包括螺钉主体（16）和连接头（8），该连接头（8）容纳在螺钉座（1）内。连接棒（6）设置于螺钉座（1）的开槽中，并位于压环（2）和压紧螺母（7）之间。压紧螺母（7）用于被拧入螺钉座（1）的上部，从而压紧连接棒（6）。该动态椎弓根螺钉植入物还设置有螺钉头套（3），其内部为球窝结构（13）。螺钉（4）的连接头（8）具有球形外部结构，从而球窝结构（13）能够与螺钉（4）的连接头（8）相配合。本发明的动态椎弓根螺钉植入物既能够提供传统多轴向的摆动，还能在被锁紧之后提供额外的摆动角，并能够保证脊柱的稳定性。

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说 明 书

动态椎弓根螺钉植入物

技术领域

本发明涉及技术领域为骨科内植物技术领域，特别地涉及动态椎弓根螺钉植入物。

背景技术

当椎间盘退变或小关节滑脱或退变时，导致椎间高度丢失，后方结构不稳，从而导致椎间孔和椎孔狭窄，而这种狭窄会压迫脊神经或神经根，导致病人腰腿疼、麻木等症状，严重影响病人的生活质量。

在解决这一问题上已知的方法是医药保守治疗，这种方式旨在控制病症，即疼痛、麻木，而非矫正以解决问题。对于一些患者，这可能需要长期的治疗，而这可能需要长期使用止痛药，可能会引起病人的精神状态或其他不良副作用。

另一种已知的方法是椎间融合或棘突间融合，这样可以保持椎间高度，减少神经结构的压力。可以采用融合器，各种板状器件和椎弓根螺钉系统进行固定。然而，融合会使上下两个椎体生长成一个整体，使得病人丧失了活动能力，因为它阻止了脊柱在问题节段的任何方向的运动。而且更为严重的是它带来了新的问题，邻近脊柱节段的退变。

已知的是脊柱融合节段的相对固定会导致应力向邻近椎体集中，尤其加重了相邻椎体的负载。同时，融合节段的活动度丧失导致相邻节段的活动范围增大，以补偿融合节段的活动能力，从而引起邻近节段的生物力学环境异常，生物力学环境的改变最终导致了邻近节段退变。

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因此，脊柱外科医生和研究者研究发现，现有的椎弓根螺钉在植入后不能活动，虽然增加了腰椎的稳定性，但是改变了腰椎的生物力学环境，从而导致邻近节段退变的可能性。虽然现在已经有一些腰椎动态植入物出现，但是它们的治疗效果较差，会有棘突骨折、植入物松动等相关并发症，从而导致再次手术的可能性。另一方面，这些植入物不能或不适合治疗较为严重的腰椎退变症状，导致这些植入物的应用范围很窄。

专利文献CN200680020249公开了一种棘突间脊椎和腰骶稳定装置及使用方法，具体地，它公开了U 形的棘突柔性间隔体，以及构造成接合椎骨的棘突的一对侧向壁；可设置固定套以将椎骨的棘突固定至柔性间隔体；为了将柔性间隔体固定在腰椎骨与相邻椎骨之间，设置锚固组件；还提供了使用所述可植入装置来稳定患者脊柱的方法。

专利文献US 20100100137公开了一种植入物，它包括一个多轴向锚固件和连接件；锚固件具有一个柔性装置，能够提供关节活动，在多轴向锚固件固定后允许一定运动。但是该现有技术的结构不太稳定，且只能提供有限的动态活动度；另外，该现有技术的装配性能也不太好。

专利文献US 20050192571公开了一种椎弓根柔性组件和方法，该组件包括螺钉头具有公头隆起结构；骨固定结构具有母头凹陷的半球结构组成一个球窝关节；一个锁定固定销子固定螺钉头和骨固定结构；一个挡块，用于保证长轴向的稳定。

专利文献CN200480038132公开了一种骨锚定元件和包括这种类型的骨锚定元件的用于骨或脊椎骨的稳定装置，其中骨锚定元件包括一用于锚定在骨中的钉杆，所述杆具有一可锚定在骨中的第一部分和一弹性构成的第二部分；以及包括一钉头，所述钉头构造成用于连接一将至少两个骨锚定元件相连接的杆。该现有技术主要在普通椎弓根

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头端打下一沉孔直到螺钉颈部，在孔道的壁上切割出螺旋槽沟，此举会显著降低螺钉颈部强度，因而其实际可行性可能不高。

发明内容

鉴于现有技术的缺陷，本发明的目的在于开发一种动态椎弓根螺钉植入物，这种动态椎弓根螺钉植入物使得螺钉既能提供传统多轴向的摆动角，还能在锁紧后提供额外的角度摆动且保证脊柱的稳定性。

根据本发明的第一方面，提供了一种动态椎弓根螺钉植入物，包括：螺钉座；压环；螺钉；连接棒；以及压紧螺母，

其中，所述螺钉包括螺钉主体和连接头，该连接头容纳在所述螺钉座内；所述连接棒设置于所述螺钉座的开槽中，并且位于所述压环和所述压紧螺母之间；所述压紧螺母用于拧入所述螺钉座的上部，从而压紧所述连接棒，

其特征在于：

所述动态椎弓根螺钉植入物还设置有螺钉头套，该螺钉头套的内部为球窝结构，所述螺钉的连接头具有球形外部结构，从而该球窝结构能够与所述螺钉的连接头相配合。

根据上述的结构，提供了螺钉头套，该螺钉头套的主要作用是将螺钉的连接头包裹住，使得万向螺钉的螺钉头即使在固定后仍然可以在螺钉头套内做多轴向的微小角度摆动。因而，这种螺钉既有传统多轴向的摆动角，在锁紧后还能提供额外的角度摆动，并且能够保证脊柱的稳定性。额外的角度摆动可以防止邻近节段因坚强固定而导致的过度载荷，从而防止了邻近节段的退变。

优选的是，所述螺钉头套的下部具有唇结构，该唇结构与所述螺钉的颈部相配合，并布置成使得该唇结构的内侧能够限制螺钉的副摆动角，且该唇结构的外侧能够控制螺钉的主摆动角。

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根据上述的结构，螺钉头套的唇部与螺钉的颈部设计成可以限制螺钉摆动角度的范围。从而，本发明的结构可以增加螺钉的小角度摆动，可以改进邻近节段的应力分布，降低邻近节段退变可能性，维持脊柱生理活动范围，从而实现动态固定。

优选的是，所述压环的内部具有内凹面，所述内凹面为球形，以便与所述螺钉头套的球形外壁相配合。

根据上述的结构，压环的内球面与螺钉头套的外球面配合，使得在螺钉头套包住螺钉并装入螺钉座后具有多轴向的大角度摆动，从而实现传统万向螺钉，以方便医生从各个角度执行植入。由此，本发明既能提供植入过程中螺钉大角度的要求，也能提供植入后的小位移摆动。

优选的是，所述螺钉头套的球形外壁上具有台阶部，以使得所述压环的内凹面与所述螺钉头套的台阶部相接触。

根据上述的结构，所述压环的内凹面与所述螺钉头套的台阶部相接触并且传递压力，从而能够对螺钉的多轴向的大角度摆动进行更好的控制。

优选的是，所述压环的外周与所述螺钉座的内腔配合，从而所述压环能够沿所述螺钉座轴向运动。

根据上述的结构，所述压环能够沿所述螺钉座轴向运动，从而能够更好地实现本发明的动态椎弓根螺钉植入物的装配，并且通过压紧螺母从上部的拧入，可以将螺钉头套固定在螺钉座内，以利于对螺钉的多轴向的大角度摆动的控制。

优选的是，所述螺钉头套的外周具有多个条形开槽。

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根据上述的结构，条形开槽可以在螺钉的连接头插入螺钉头套时提供扩张的空间，以便于螺钉的插入。

优选的是，所述动态椎弓根螺钉植入物包括挡圈，所述挡圈用于嵌入到所述螺钉座的内腔的下部的凹槽中，同时与所述螺钉头套相接触。

根据上述的结构，可以将螺钉头套固定在螺钉座内，从而限制螺钉在轴向上的位移，以利于对螺钉的多轴向的大角度摆动的控制。

优选的是，所述挡圈中设置有开口。

根据上述的结构，挡圈设置有开口，从而可以方便挡圈的嵌入组装。

总之，根据本发明的技术方案，可以使得万向螺钉提供了动态固定的性能；并且，能够使得螺钉植入后可以自适应脊柱的弯曲中心；并且可以防止脊柱的邻近节段退变。从而，可以在恢复椎间高度、减少脊神经压力、提供脊柱稳定性的同时，保持脊柱的正常旋转中心，提供治疗后的微动，降低脊柱邻近节段退变的可能性。

从下面参考附图所描述的优选实施例中很容易理解本发明的上述特征和优点。

附图说明

图1是本发明的动态椎弓根螺钉植入物的整体透视图。

图2是本发明的动态椎弓根螺钉植入物的分解透视图。

图3是本发明的动态椎弓根螺钉植入物的横剖视图。

图4是本发明的动态椎弓根螺钉植入物的螺钉的示意图，其中图4

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（a）是螺钉的透视图，图4（b）是螺钉的横剖视图。

图5是本发明的动态椎弓根螺钉植入物的挡圈的透视图。

图6是本发明的动态椎弓根螺钉植入物的螺钉头套的示意图，其中图6（a）是螺钉头套的横剖视图，图6（b）是螺钉头套的透视图，图6（c）是螺钉头套的正视图，图6（d）是螺钉头套的顶视图。

图7是本发明的动态椎弓根螺钉植入物的压环的示意图，其中图7（a）是压环的透视图，图7（b）是压环的横剖视图。

图8是本发明的动态椎弓根螺钉植入物的螺钉座的示意图，其中图8（a）是螺钉座的透视图，图8（b）是螺钉座的横剖视图。

具体实施方式

以下参考附图来详细描述本发明的优选实施例。

图1是本发明的动态椎弓根螺钉植入物的整体透视图，图2是本发明的动态椎弓根螺钉植入物的分解透视图，图3是本发明的动态椎弓根螺钉植入物的横剖视图。

参看图1-3，本发明的用于植入在椎体之中的动态椎弓根螺钉植入物包括：螺钉座1；压环2；螺钉头套3；螺钉4；挡圈5；连接棒6；以及压紧螺母7。

图4是本发明的动态椎弓根螺钉植入物的螺钉4的示意图，其中图4（a）是螺钉的透视图，图4（b）是螺钉的横剖视图。从图4看看出，本发明的动态椎弓根螺钉植入物的螺钉包括螺钉主体16和连接头8。螺钉主体16具有用于骨固定、特别是用于椎骨固定的螺纹结构。连接头8大体具有球形的外形，并且位于螺钉主体16的一端且与螺钉主体16一体地相连。螺钉4的连接头8可以插入到螺钉头套3的球窝结构13中，从而与螺钉头套3相连接。连接头8的顶端设置有便于器械连接的接口9。

图5是本发明的动态椎弓根螺钉植入物的挡圈5的透视图。挡圈5

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可以嵌入到螺钉座1下部的凹槽17中，同时与螺钉头套3接触，因而它能限制螺钉4脱出，同时提供螺钉4的摆动角度。优选地，挡圈5设置有开口18，以便于挡圈5的嵌入组装。

图6是本发明的动态椎弓根螺钉植入物的螺钉头套3的示意图，其中图6（a）是螺钉头套3的横剖视图，图6（b）是螺钉头套3的透视图，图6（c）是螺钉头套3的正视图，图6（d）是螺钉头套3的顶视图。具体地，螺钉头套3整体上为大体空心球的结构。螺钉头套3在其上部具有上部通孔10，在其下部具有下部通孔11。上部通孔10方便上钉器械拧入，下部通孔11是用于插入螺钉4的插入孔。螺钉头套3的外周具有多个条形开槽12；优选地，在本实施例中，螺钉头套3的外周的上下两侧各有三个条形开槽12。这些条形开槽12可以在螺钉4的连接头8插入螺钉头套3时提供扩张的空间，以便于螺钉4的插入。

从图6可以看出，螺钉头套3的内部为球窝结构13，该球窝结构13用于配合螺钉4的连接头8，从而形成球窝关节。螺钉头套3的球形外壁上具有台阶部14，该台阶部14在螺钉头套3的高度方向上直径逐渐减小。该台阶部14可以与压环2的内凹面19配合，以传递压力载荷，以便锁定螺钉的主摆动角。螺钉头套3的下部具有唇结构15，该唇结构15的内侧可以限制螺钉的副摆动角，该唇结构15的外侧可以控制螺钉的主摆动角度。

图7是本发明的动态椎弓根螺钉植入物的压环2的示意图，其中图7（a）是压环2的透视图，图7（b）是压环2的横剖视图。压环2具有上钉器械插入孔20。压环2的外周与螺钉座1的内腔配合，从而压环2可以沿螺钉座1轴向运动。压环2的内部为球形的内凹面19，内凹面19与螺钉头套3的台阶部14相接触。压环2依靠设于上部的连接棒6向螺钉头套1提供压力。

图8是本发明的动态椎弓根螺钉植入物的螺钉座1的示意图，其中

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图8（a）是螺钉座1的透视图，图8（b）是螺钉座1的横剖视图。螺钉座1具有内腔21，所述内腔21包括带螺纹的上部部分和光滑的下部部分，所述内腔21可以容纳挡圈5、螺钉4的连接头8、螺钉头套3和压环2，并对压环2沿轴向移动提供导向作用。螺钉座1还具有U型开槽22，用于放置连接棒6。螺钉座1的上部的内侧面具有螺纹结构，以便于与压紧螺母7啮合连接。螺钉座1的内腔21的光滑的下部部分的下部周壁中沿着圆周方向设置有一凹槽17，挡圈5可以嵌入到螺钉座1的该凹槽17中，以用于固定挡圈17，从而限制螺钉4的向下位移。

连接棒6用于连接多个螺钉，连接棒6被设置于螺钉座1的U型开槽22中，并且位于压环2和压紧螺母7之间。

压紧螺母7可以拧入螺钉座1的上部的内侧面，从而与螺钉座1连接，用于压紧连接棒6。

从以上实施例可知，根据本发明的动态椎弓根螺钉植入物，在传统椎弓根螺钉的基础上进一步设置了螺钉头套装置并改进了螺钉结构。

如现有技术中已知的那样，传统椎弓根万向螺钉在固定后，螺钉头与螺钉座具有一定的角度且螺钉头不能再有任何摆动，属于坚强固定方式。但是，根据本发明，所述动态椎弓根螺钉植入物还设置有螺钉头套，该螺钉头套的内部为球窝结构，所述螺钉的连接头具有球形外部结构，从而该球窝结构能够与所述螺钉的连接头相配合。通过上述设置，本发明可以防止脊柱的邻近节段退变，保留脊柱活动度。即，本发明提供了螺钉头套，该螺钉头套的主要作用是将螺钉的连接头包裹住，使得万向螺钉的螺钉头即使在固定后仍然可以在螺钉头套内做多轴向的微小角度摆动。

而且，根据本发明，所述螺钉头套的下部具有唇结构，该唇结构

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与所述螺钉的颈部相配合，并布置成使得该唇结构的内侧能够限制螺钉的副摆动角，该唇结构的外侧能够控制螺钉的主摆动角。通过上述设置，螺钉头套的唇部与螺钉的颈部设计成可以限制螺钉摆动角度的范围。这种受限制的小角度摆动是本发明的一个重要方面，由此提供的优点是：可以增加螺钉的小角度摆动，可以改进邻近节段的应力分布，降低邻近节段退变可能性，维持脊柱生理活动范围，实现动态固定，更符合临床应用的要求，得到的临床效果更好。

另外，根据本发明，所述压环的内部具有内凹面，所述内凹面为球形，以便与所述螺钉头套的球形外壁相配合。从而，压环的内球面与螺钉头套的外球面配合，使得在螺钉头套包住螺钉并装入螺钉座后具有多轴向的大角度摆动（这点与传统万向螺钉的功能相似，但是实现的结构不同），从而实现传统万向螺钉，以方便医生从各个角度执行植入。即，本发明既能提供植入过程中螺钉大角度的要求，也能提供植入后的小位移摆动。

医生在植入操作过程中，根据实际需要可以调整螺钉头与钉座的角度范围，方便螺钉的植入。当植入到正确位置时，压紧压紧螺母使得压环与螺钉头套紧密配合，从而限制了螺钉头套的多轴向摆动，也就是锁定了螺钉的植入角度。这时，位于螺钉球套的螺钉还可以有微小角度的摆动，控制这种摆动的大小只与螺钉球套的唇部设计有关，而与螺钉是否锁紧没有关系。

另外，本发明的动态椎弓根螺钉植入物可以由钛合金、钴基合金、镍钛合金等金属材料制成；此外，本发明的植入物的部分结构也可以由聚醚醚酮、PCU、加强聚醚醚酮、超高分子量聚乙烯等高分子或复合材料制成。

对于本领域的普通技术人员而言，可以很容易对本发明的实施例的细节进行各种变型和改进。这些变型和改进都落在本发明的构思的范围之内。

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权 利 要 求 书

1. 一种动态椎弓根螺钉植入物，包括：螺钉座（1）；压环（2）；螺钉（4）；连接棒（6）；以及压紧螺母（7），

其中，所述螺钉（4）包括螺钉主体（16）和连接头（8），该连接头（8）容纳在所述螺钉座（1）内；所述连接棒（6）设置于所述螺钉座（1）的开槽（22）中，并且位于所述压环（2）和所述压紧螺母（7）之间；所述压紧螺母（7）用于拧入所述螺钉座（1）的上部，从而压紧所述连接棒（6），

其特征在于：

所述动态椎弓根螺钉植入物还设置有螺钉头套（3），该螺钉头套（3）的内部为球窝结构（13），所述螺钉（4）的连接头（8）具有球形外部结构，从而该球窝结构（13）能够与所述螺钉（4）的连接头（8）相配合。

2. 根据权利要求1所述的动态椎弓根螺钉植入物，其特征在于，所述螺钉头套（3）的下部具有唇结构（15），该唇结构（15）与所述螺钉的颈部相配合，并布置成使得该唇结构（15）的内侧能够限制螺钉的副摆动角，且该唇结构（15）的外侧能够控制螺钉的主摆动角。

3. 根据权利要求1或2所述的动态椎弓根螺钉植入物，其特征在于，所述压环（2）的内部具有内凹面（19），所述内凹面（19）为球形，以便与所述螺钉头套（3）的球形外壁相配合。

4. 根据权利要求3所述的动态椎弓根螺钉植入物，其特征在于，所述螺钉头套（3）的球形外壁上具有台阶部（14），以使得所述压环（2）的内凹面（19）与所述螺钉头套（3）的台阶部（14）相接触。

5. 根据权利要求1或2所述的动态椎弓根螺钉植入物，其特征在于，所述压环（2）的外周与所述螺钉座（1）的内腔配合，从而所述

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压环（2）能够沿所述螺钉座（1）轴向运动。

6. 根据权利要求1或2所述的动态椎弓根螺钉植入物，其特征在于，所述螺钉头套（3）的外周具有多个条形开槽（12）。

7. 根据权利要求1或2所述的动态椎弓根螺钉植入物，其特征在于，所述动态椎弓根螺钉植入物包括挡圈（5），所述挡圈（5）用于嵌入到所述螺钉座（1）的内腔（21）的下部的凹槽（17）中，同时与所述螺钉头套（3）相接触。

8. 根据权利要求 7 所述的动态椎弓根螺钉植入物，其特征在于，所述挡圈（5）中设置有开口（18）。

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说 明 书 附 图

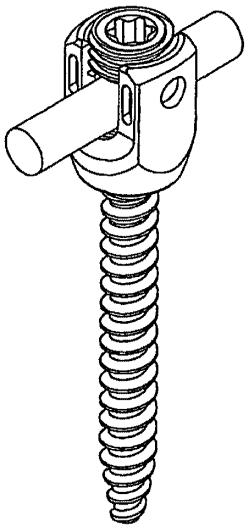


图1

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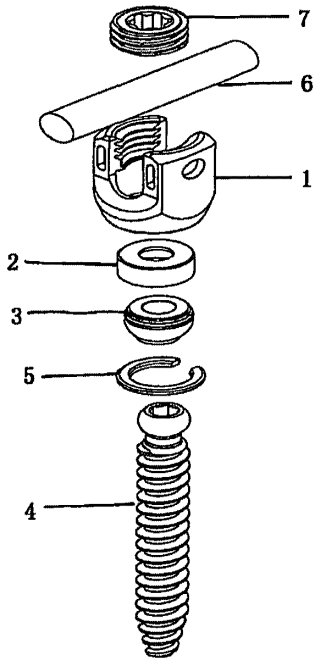


图2

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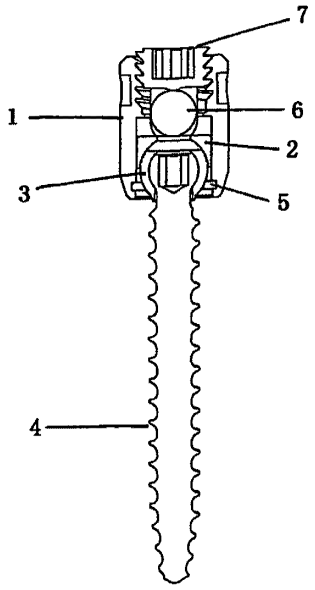


图3

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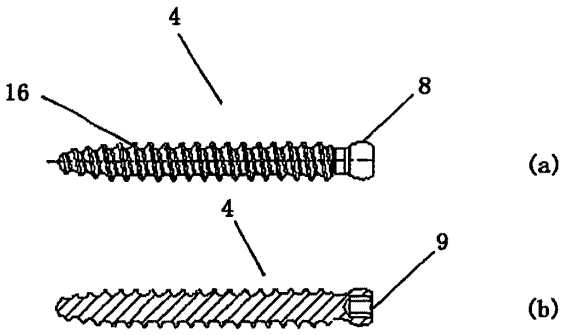


图4

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IPR2023-01433; Petitioners' EX1035
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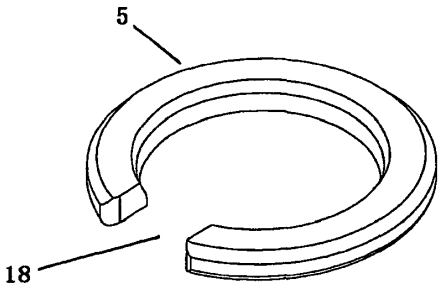


图5

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IPR2023-01433; Petitioners' EX1035
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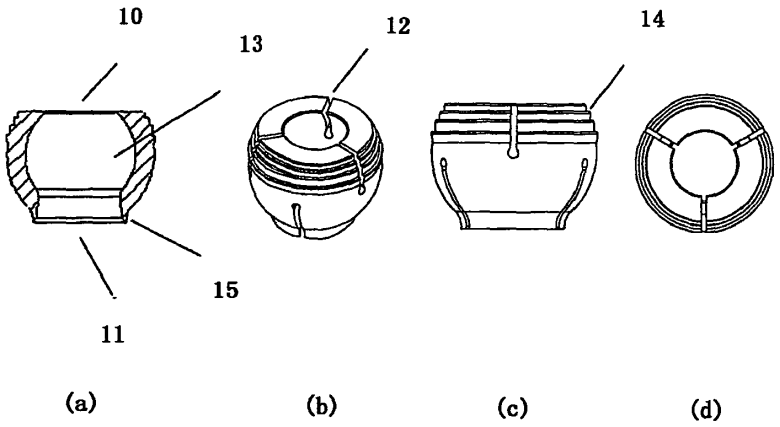


图6

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
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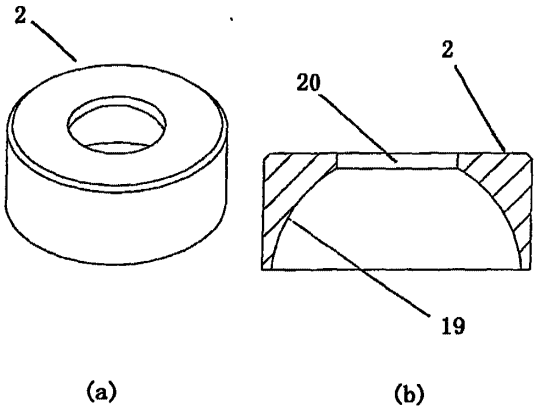


图7

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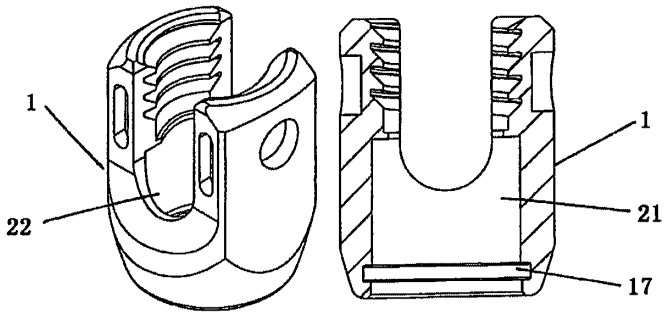


图8

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
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INTERNATIONAL SEARCH REPORT

International application No.
PCT/CN2011/078297

A. CLASSIFICATION OF SUBJECT MATTER

See extra sheet

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC: A61B17

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

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

CPRSABS, CNTXT, EPODOC, CNKI

head, screw, rod, shank

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	CN101677830A (CUI, Jiyun), 24 Mar. 2010(24.03.2010), page 5 line 14 to page 7 line 19 in the specification, figures 1-3.	1, 3, 5
Y		4, 6-8
Y	US2010137918A1 (WARSAW ORTHOPEDIC INC), 03 Jun. 2010(03.06.2010), paragraphs [0033], [0052] in the specification, figures 3-5.	4, 7, 8
Y	US2009143827A1 (LEVY MARK M et al), 04 Jun. 2009(04.06.2009), paragraphs [0014], [0021] in the specification, figures 2A-2C.	6
X	WO2009132110A1 (SYNTHES USA LLC et al), 29 Oct. 2009(29.10.2009), paragraphs [0032]-[0034] in the specification, figures 1-3.	1, 3, 5

☒ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&"document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
27 Oct. 2011(27.10.2011)	10 Nov. 2011(10.11.2011)
Name and mailing address of the ISA State Intellectual Property Office of the P. R. China No. 6, Xitucheng Road, Jimenqiao Haidian District, Beijing 100088, China Facsimile No. (86-10)62019451	Authorized officer ZHANG, Hongmei Telephone No. (86-10)62085626

Form PCT/ISA/210 (second sheet) (July 2009)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CN2011/078297

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P, X	CN102133132A (SHANGHAI MICROPORT ORTHOPEDICS CO LTD), 27 Jul. 2011(27.07.2011), claims 1-8.	1-8
A	US2008015597A1 (WHIPPLE DALE), 17 Jan. 2008 (17.01.2008), the whole document.	1-8
A	CN101810510A (BIEDERMANN MOTECH GMBH & CO KG), 25 Aug. 2010(25.08.2010), the whole document.	1-8

Form PCT/ISA /210 (continuation of second sheet) (July 2009)

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/CN2011/078297

Patent Documents referred in the Report	Publication Date	Patent Family	Publication Date
CN101677830A	24.03.2010	EP2095782 A1	02.09.2009
		WO2009107901 A1	03.09.2009
		US2009240290 A1	24.09.2009
		KR100895243B B1	30.04.2009
		JP2011512939 A	28.04.2011
US2010137918A1	03.06.2010	none	
US2009143827A1	04.06.2009	US7789900 B2	07.09.2010
		EP2224869 A1	08.09.2010
		EP2224869 B1	14.09.2011
		WO2009072125 A1	11.06.2009
		AT524123T T	15.09.2011
WO2009132110A1	29.10.2009	EP2265202 A1	29.12.2010
		US2011040335 A1	17.02.2011
		JP2011518030 A	23.06.2011
		CO6260039 A2	22.03.2011
		CN102006830 A	06.04.2011
		KR20110008033 A	25.01.2011
		CA2721584 A1	29.10.2009
CN102133132A	27.07.2011	none	
US2008015597A1	17.01.2008	none	
CN101810510A	25.08.2008	EP2221012 A1	25.08.2010
		EP2221013 A1	25.08.2010
		US2010234902 A1	16.09.2010
		JP2010194309 A	09.09.2010
		KR20100095373 A	30.08.2010

Form PCT/ISA/210 (patent family annex) (July 2009)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CN2011/078297

A. CLASSIFICATION OF SUBJECT MATTER(second sheet)

A61B17/70 (2006.01) i
A61B17/86 (2006.01) i

Form PCT/ISA /210 (extra sheet) (July 2009)

国际检索报告

国际申请号
PCT/CN2011/078297

A. 主题的分类

参见附加页

按照国际专利分类(IPC)或者同时按照国家分类和 IPC 两种分类

B. 检索领域

检索的最低限度文献(标明分类系统和分类号)

IPC: A61B17

包含在检索领域中的除最低限度文献以外的检索文献

在国际检索时查阅的电子数据库(数据库的名称，和使用的检索词（如使用）)

CPRSABS, CNTXT, EPODOC, CNKI

套，螺钉，头，head, screw, rod, shank

C. 相关文件

类 型*	引用文件，必要时，指明相关段落	相关的权利要求
X	CN101677830A (崔吉运), 24.3 月 2010(24.03.2010), 说明书第 5 页 14 行至第 7 页 19 行, 图 1-3.	1, 3, 5
Y		4, 6-8
Y	US2010137918A1 (WARSAW ORTHOPEDIC INC), 03.6 月 2010(03.06.2010), 说明书第[[0033], [0052]段, 图 3-5.	4, 7, 8
Y	US2009143827A1 (LEVY MARK M 等), 04.6 月 2009(04.06.2009), 说明书第[0014], [0021]段, 图 2A-2C.	6
X	WO2009132110A1 (SYNTHES USA LLC 等), 29.10 月 2009(29.10.2009), 说明书第[0032]-[0034]段, 图 1-3.	1, 3, 5
P, X	CN102133132A (上海微创骨科医疗科技有限公司), 27.7 月 2011(27.07.2011), 权利要求 1-8.	1-8
A	US2008015597A1 (WHIPPLE DALE), 17.1 月 2008 (17.01.2008), 全文.	1-8

☒ 其余文件在 C 栏的续页中列出。　　☒ 见同族专利附件。

* 引用文件的具体类型：

"A" 认为不特别相关的表示了现有技术一般状态的文件

"E" 在国际申请日的当天或之后公布的在先申请或专利

"L" 可能对优先权要求构成怀疑的文件，或为确定另一篇引用文件的公布日而引用的或者因其他特殊理由而引用的文件（如具体说明的）

"O" 涉及口头公开、使用、展览或其他方式公开的文件

"P" 公布日先于国际申请日但迟于所要求的优先权日的文件

"T" 在申请日或优先权日之后公布，与申请不相抵触，但为了理解发明之理论或原理的在后文件

"X" 特别相关的文件，单独考虑该文件，认定要求保护的发明不是新颖的或不具有创造性

"Y" 特别相关的文件，当该文件与另一篇或者多篇该类文件结合并且这种结合对于本领域技术人员为显而易见时，要求保护的发明不具有创造性

"&" 同族专利的文件

国际检索实际完成的日期	国际检索报告邮寄日期
27.10 月 2011(27.10.2011)	**10.11 月 2011 (10.11.2011)**
ISA/CN 的名称和邮寄地址： 中华人民共和国国家知识产权局 中国北京市海淀区蓟门桥西土城路 6 号 100088 传真号： (86-10)62019451	受权官员 张红梅 电话号码：(86-10) 62085626

PCT/ISA/210 表(第 2 页) (2009 年 7 月)

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C(续). 相关文件

类 型	引用文件，必要时，指明相关段落	相关的权利要求
A	CN101810510A (比德曼莫泰赫有限责任两合公司), 25.8月 2010(25.08.2010), 全文.	1-8

Zimvie_Zimmer Biomet v. Jackson
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国际检索报告
关于同族专利的信息

国际申请号
PCT/CN2011/078297

检索报告中引用的专利文件	公布日期	同族专利	公布日期
CN101677830A	24.03.2010	EP2095782 A1	02.09.2009
		WO2009107901 A1	03.09.2009
		US2009240290 A1	24.09.2009
		KR100895243B B1	30.04.2009
		JP2011512939 A	28.04.2011
US2010137918A1	03.06.2010	无	
US2009143827A1	04.06.2009	US7789900 B2	07.09.2010
		EP2224869 A1	08.09.2010
		EP2224869 B1	14.09.2011
		WO2009072125 A1	11.06.2009
		AT524123T T	15.09.2011
WO2009132110A1	29.10.2009	EP2265202 A1	29.12.2010
		US2011040335 A1	17.02.2011
		JP2011518030 A	23.06.2011
		CO6260039 A2	22.03.2011
		CN102006830 A	06.04.2011
		KR20110008033 A	25.01.2011
		CA2721584 A1	29.10.2009
CN102133132A	27.07.2011	无	
US2008015597A1	17.01.2008	无	
CN101810510A	25.08.2010	EP2221012 A1	25.08.2010
		EP2221013 A1	25.08.2010
		US2010234902 A1	16.09.2010
		JP2010194309 A	09.09.2010
		KR20100095373 A	30.08.2010

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国际检索报告

国际申请号
PCT/CN2011/078297

A. 主题的分类(第 2 页)

A61B17/70 (2006.01) i

A61B17/86 (2006.01) i

Zimvie_Zimmer Biomet v. Jackson
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(12) 按照专利合作条约所公布的国际申请

(19) 世界知识产权组织
国 际 局

(43) 国际公布日
2012 年 6 月 14 日 (14.06.2012)

WIPO | PCT

(10) 国际公布号
WO 2012/075827 A1

(51) 国际专利分类号:
A61B 17/70 (2006.01) *A61B 17/86* (2006.01)

(21) 国际申请号: PCT/CN2011/078277

(22) 国际申请日: 2011 年 8 月 11 日 (11.08.2011)

(25) 申请语言: 中文

(26) 公布语言: 中文

(30) 优先权:
201010584040.7 2010 年 12 月 10 日 (10.12.2010) CN

(71) 申请人 (对除美国外的所有指定国): **上海微创骨科医疗科技有限公司 (SHANGHAI MICROPORT ORTHOPEDICS CO., LTD.)** [CN/CN]; 中国上海市浦东新区天雄路 588 弄上海国际医学园区医谷现代商务园 23 号楼, Shanghai 201318 (CN)。

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(81) 指定国 (除另有指明, 要求每一种可提供的国家保护): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, QA, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW。

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(54) Title: POLYAXIAL PEDICLE SCREW

(54) 发明名称 : 一种万向椎弓根螺钉

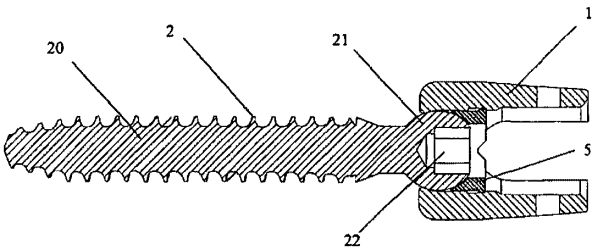


图 3/ Fig.3

(57) Abstract: A polyaxial pedicle screw comprises a screw base (1), a screw head (2), and a compression ring (5). The screw base (1) is tubular. Two U-shaped openings (11) are disposed on a side wall at one end of the screw base (1). A convex ridge (12) is disposed at an opening at the other end of the screw base (1). A snapping slot (13) is disposed on an inner wall of the screw base (1). The screw head (2) comprises a rod body (20) and a spherical structure (21) fixed at an end of the rod body (20). The spherical structure (21) is located in the screw base (1) and contacts an inner side of the convex ridge (12), and an outer diameter of the spherical structure (21) is greater than an inner diameter of the convex ridge (12). Two symmetrical bumps (51) are disposed on an outer wall at an end of the compression ring (5), and the compression ring (5) is disposed in the snapping slot (13). The compression ring (5) contacts the spherical structure (21), and an inner diameter of the compression ring (5) is greater than the outer diameter of the spherical structure (21), so that the spherical structure (21) is rotatablely fixed between the snapping slot (13) and the convex ridge (12). According to the polyaxial pedicle screw of the present invention, the convex ridge (12) on the screw base (1) snaps the spherical structure (21) of the screw head (2) in the screw base (1). As the screw base (1) is not elastically deformed, the problem caused by elastic snap strength in the polyaxial pedicle screw in the prior art is avoided.

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本国际公布:

— 包括国际检索报告(条约第 21 条(3))。

(57) **摘要**:

一种万向椎弓根螺钉，包括：螺钉座（1）、螺钉头（2）和压环（5）。螺钉座（1）为管状，其一端侧壁上设有两个U形开口（11），另一端开口处设有凸棱（12），在螺钉座（1）内壁上设有卡位槽（13）。螺钉头（2）包括棒体（20）和固定在棒体（20）一端的球状结构（21）。该球状结构（21）位于螺钉座（1）内，与凸棱（12）的内侧相接触，并且球状结构（21）的外径大于凸棱（12）的内径。压环（5）一端的外壁上设有两个相对称的凸块（51），该凸块（51）设在卡位槽（13）内。压环（5）与球状结构（21）相接触，且压环（5）的内径大于球状结构（21）的外径，使得球状结构（21）可转动地固定在卡位槽（13）与凸棱（12）之间。根据本发明的万向椎弓根螺钉，螺钉座（1）上的凸棱（12）将螺钉头（2）的球状结构（21）卡在螺钉座（1）内，由于螺钉座（1）不会发生弹性形变，避免了现有的万向椎弓根螺钉由于弹性卡圈强度的原因而导致的问题。

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说 明 书

一种万向椎弓根螺钉

技术领域

本申请涉及医疗器械领域，特别是涉及一种万向椎弓根螺钉。

背景技术

在临床通常采用脊柱内固定系统对脊柱损伤进行治疗，而在脊柱内固定系统中椎弓根螺钉嵌置固定在脊椎骨上，是脊柱内固定系统中不可或缺的部分。

目前常见的椎弓根螺钉根据螺钉头是否能够转动，主要分为两类：定向椎弓根螺钉和万向椎弓根螺钉。与定向椎弓根螺钉相比，万向椎弓根螺钉具有临床操作简单、可适用性强等优点，使用比较广泛。但由于椎弓根螺钉作为植入物，不适合采用焊接、铆接等手段实现万向功能，所以现有的万向椎弓根螺钉采用弹性卡圈的结构来实现万向功能。图 1 为现有万向椎弓根螺钉的结构示意图，图 2 为图 1 的爆炸图，如图 1 和图 2 所示，1 为螺钉座，2 为螺钉头，3 为弹性卡圈，4 为垫圈，在安装时，首先将垫圈 4 放置在螺钉座 1 内，再将螺钉头 2 的球状结构置于螺钉座 1 内，然后再用弹性卡圈 3 将球状结构固定在螺钉座 1 内，这样螺钉头 2 就可以以球状结构为固定点而转动，实现万向功能。

通过对现有技术的研究，申请人发现：采用的弹性卡圈对螺钉头的球状结构进行固定，其螺钉头拔出强度取决于弹性卡圈的弹性强度，受弹性卡圈的弹性强度的影响，在植入体内后，螺钉头常常会出现松动，影响脊柱内固定系统的稳定性。

发明内容

为解决上述技术问题，本申请实施例提供一种万向椎弓根螺钉，以解决由于弹性卡圈强度的原因，而导致螺钉头拔出强度低，进而导致螺钉头容易松动的问题，技术方案如下：

一种万向椎弓根螺钉，包括：螺钉座、螺钉头和压环，

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其中:

所述螺钉座为管状结构，其一端侧壁上设置有两个相对称 U 型开口，另一端开口处内壁上设置有凸棱，并且所述螺钉座内壁上设置有卡位槽;

所述螺钉头包括棒体和固定在所述棒体一端的球状结构，且所述棒体上设置有螺纹，所述球状结构位于所述螺钉座内，与所述凸棱的内侧相接触，并且其外径大于所述凸棱的内径，所述棒体位于所述螺钉座的外侧;

所述压环的一端外壁上设置有两个相对称的凸块，且所述凸块设置在所述卡位槽内，所述压环与所述球状结构相接触，且其内径大于所述螺钉头上球状结构的外径，将所述螺钉头上的球状结构可转动地固定在所述卡位槽与凸棱之间。

优选地，所述卡位槽设置在所述 U 型开口顶部与 U 型开口底部之间的螺钉座的内壁上。

优选地，所述压环与所述球状结构相接触一端的结构为弧形结构。

优选地，所述压环设置有凸块一端的端面上还设置有两个相对称的 V 型扩张槽。

优选地，所述两个 V 型扩张槽的轴线在一条直线上，且与所述两个凸块的连线相垂直。

优选地，所述螺钉头球状结构顶端设置有内六角形槽。

优选地，所述螺钉座上设置有凸棱的一端的断面上设置有多个万向槽。

由以上技术方案可见，本申请实施例提供的万向椎弓根螺钉，螺钉座的一端设置有凸棱、螺钉头的棒体从螺钉座的另一端穿入螺钉座，螺钉座上的凸棱将螺钉头上的球状结构卡在螺钉座内，压环设置在螺钉座内部的卡位槽内，并且压环在外界压力的作用下进行扩张，固定在卡位槽内并将螺钉头的球状结构固定在螺钉座内。该万向椎弓根螺钉中，当向外拔螺钉头时，螺钉座上的凸棱将螺钉头的球状结构卡在螺钉座内，由于螺钉座不会发生弹性形变，所以螺钉头的拔出强度大，避免了现有的万向椎弓根螺钉由于弹性卡圈强度的原因，而导致螺钉头拔出强度低，进而导致螺钉头容易松动的问题。

此外，弹性卡圈对材料弹性要相当的要求，而目前植入物螺钉通常采用

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的 Ti6Al4V 及 Ti6Al7Nb 等植入级别钛合金的弹性性能难以满足卡圈制作的弹性要求，而采用弹性较好的 Ti-Ni 合金制作卡圈的话，由于其材料与螺钉座及螺钉头的材料不相同，但当两种不同材料固定在一起作为植入物植入后，在人体体液的环境中，会由于材料不同而存在产生电腐蚀的可能性，影响椎弓根螺钉的质量及使用寿命。而本申请实施例提供的万向椎弓根螺钉中，压环是在外界压力的作用下扩张后，固定在螺钉座内的卡位槽内，所以压环的材料不需要弹性强度，可以选择与螺钉座及螺钉头相同的材料，因此还可以避免现有万向椎弓根螺钉植入体内后由于电腐蚀而影响椎弓根螺钉的质量及使用寿命的问题。

附图说明

为了更清楚地说明本申请实施例或现有技术中的技术方案，下面将对实施例或现有技术描述中所需要使用的附图作简单地介绍，显而易见地，下面描述中的附图仅仅是本申请中记载的一些实施例，对于本领域普通技术人员来讲，在不付出创造性劳动的前提下，还可以根据这些附图获得其他的附图。

图 1 为现有的万向椎弓根螺钉的结构示意图；

图 2 为图 1 的爆炸图；

图 3 为本申请实施例提供的万向椎弓根螺钉的剖视结构示意图；

图 4 为图 3 的爆炸图；

图 5 为本申请实施例提供的螺钉座的结构示意图；

图 6 为本申请实施例提供的螺钉座的剖视结构示意图；

图 7 为本申请实施例提供的压环的结构示意图；

图 8 为本申请实施例提供的压环的侧视图；

图 9 为图 8 的仰视图。

图 10 为本申请实施例提供的压环在组装时的结构示意图。

具体实施方式

为了使本技术领域的人员更好地理解本申请中的技术方案，下面将结合本申请实施例中的附图，对本申请实施例中的技术方案进行清楚、完整地描述，显然，所描述的实施例仅仅是本申请一部分实施例，而不是全部的实施

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例。基于本申请中的实施例，本领域普通技术人员在没有做出创造性劳动前提下所获得的所有其他实施例，都应当属于本申请保护的范围。

图 3 为本申请实施例提供的万向椎弓根螺钉的剖视结构示意图。图 4 为图 3 的爆炸图。

如图 3 和图 4 所示，该万向椎弓根螺钉包括：螺钉座 1、螺钉头 2 和压环 5，螺钉头 2 一端设置在螺钉座 1 内部，压环 5 位于在所述螺钉座 1 的内部。

图 5 为本申请实施例提供的螺钉座的结构示意图。图 6 为本申请实施例提供的螺钉座的剖视结构示意图。如图 5 所示，螺钉座 1 为管状结构，在其一端开口侧壁上设置有两个 U 型开口 11，并且两个 U 型开口 11 以管状结构的中心为对称中心对称分布，在螺钉座 1 的另一端开口处内壁上设置有凸棱 12，并且凸棱 12 的内径小于螺钉座 1 的内径。卡位槽 13 为环形卡位槽，设置在 U 型开口 11 顶部与 U 型开口 11 底部之间的螺钉座的内壁上，优选位置在 U 型开口 11 的底部位置处。本申请实施例中，螺钉座 1 的内径可以均匀一致，也可以为从设置有 U 型开口 11 的一端至设置有凸棱 12 一端直径逐渐减小。此外，如图 5 所示，在螺钉座 1 设置有凸棱 12 的一端的端面上还可以设置有多个万向槽 14。在本申请实施例中，万向槽 14 的个数为 3 个，通过设置万向槽 14，可以增加螺钉座 1 与螺钉头 2 之间的偏转角度，进而扩大万向转向范围。如图 4 所示，在两个 U 型开口 11 之间的压环 5 的壁上还可以设置有两个相对称的通孔 15。

如图 4 所示，螺钉头 2 包括棒体 20 和固定在棒体 20 一端的球状结构 21，，并且棒体 20 上还设置有螺纹，用于将球状结构 21 稳定的固定于人体脊椎上。螺钉头 2 的球状结构 21 的外径大于凸棱 12 的内径，球状结构 21 位于螺钉座 1 内，并且与凸棱 12 的内侧相接触。棒体 20 的另一端位于螺钉座 1 的外侧。球状结构 21 的外径还小于螺钉座 1 的内径，这样在安装时，棒体 20 的另一端由螺钉座 1 上设置有 U 型开口 11 的一端穿入，并使球状结构 21 与凸棱 12 相接触接触。本申请实施例中，如图 4 所示，螺钉头 2 的球状结构 21 顶端还设置有内六角形凹槽 22，用于通过工具将万向螺钉头植入人体脊椎。

图 7 为本申请实施例提供的压环的结构示意图。图 8 为本申请实施例提

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供的压环的侧视图。图 9 为图 8 的仰视图。

如图 7、图 8 和图 9 所示，压环 5 一端外壁上设置有两个相对称的凸块 51，并且压环 5 的外径小于螺钉座 1 的内径，两个相对称凸块的最远距离大于螺钉座 1 的内径且小于卡位槽 13 的内径。压环 5 上的凸块 51 位于卡位槽 13 内，并且远离凸块 51 的一端与螺钉头 2 的球状结构 21 相接触，将球状结构 21 可转动地固定在卡位槽 13 与凸棱 12 之间，并且压环 5 与球状结构 21 相接触一端的结构为弧形结构。

在本申请实施例中， 压环 5 上设置有凸块 51 一端的端面上还设置有两个相对称的 V 型扩张槽 52，两个 V 型扩张槽 52 的轴线在一条直线上，且与两个凸块 51 的连线相垂直，用于当压环 5 安装到位后，在外力作用下，将 V 型扩张槽 52 所在的一端扩张，使压环 5 固定在卡位槽 13 内。如图 10 所示，图中 6 为扩张工具，使用扩张工具 6 向两个 V 型扩张槽 52 进行施加压力 F，压力 F 会分成两个分力 F1 和 F2，并分别作用在 V 型扩张槽 52 的两个斜面上，将压环 5 上 V 型扩张槽 52 所在的一端扩张，使压环 5 固定在卡位槽 13 内。

下面结合该万向椎弓根螺钉的装配过程对其结构进行进一步描述。

装配该万向椎弓根螺钉时，首先将螺钉头 2 上的棒体 20，由螺钉座 1 上设有 U 型开口 11 的一端穿入，将螺钉头 2 上的球状结构 21 与凸棱 12 相接触。然后将压环 5 上两个凸块 51 分别卡在两个 U 型开口 11 中，并将压环 5 推到动与螺钉头 2 的球状结构 21 相接触，并且此时压环 5 上的两个凸块 51 到达卡位槽 13，再转动压环 5，使两个 V 型扩张槽 52 的轴线与两个 U 型开口 11 相平行。在外力作用下，将 V 型扩张槽 52 所在的一端扩张，使压环 5 固定在卡位槽 13 内，这样即可实现将螺钉头 2 的球状结构 21 可转动地固定在螺钉座 1 内。

由以上技术方案可见，本申请实施例提供的万向椎弓根螺钉，螺钉座的一端设置有凸棱、螺钉头的棒体从螺钉座的另一端穿入螺钉座，螺钉座上的凸棱将螺钉头上的球状结构卡在螺钉座内，压环设置在螺钉座内部的卡位槽内，并且压环在外界压力的作用下进行扩张，固定在卡位槽内并将螺钉头的

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球状结构固定在螺钉座内。该万向椎弓根螺钉中，当向外拔螺钉头时，螺钉座上的凸棱将螺钉头的球状结构卡在螺钉座内，由于螺钉座不会发生弹性形变，所以螺钉头的拔出强度大，避免了现有的万向椎弓根螺钉由于弹性卡圈强度的原因，而导致螺钉头拔出强度低，进而导致螺钉头容易松动的问题。

此外，弹性卡圈对材料弹性要相当的要求，而目前植入物螺钉通常采用的 Ti6Al4V 及 Ti6Al7Nb 等植入级别钛合金的弹性性能难以满足卡圈制作的弹性要求，而采用弹性较好的 Ti-Ni 合金制作卡圈的话，由于其材料与螺钉座及螺钉头的材料不相同，但当两种不同材料固定在一起作为植入物植入后，在人体体液的环境中，会由于材料不同而存在产生电腐蚀的可能性，影响椎弓根螺钉的质量及使用寿命。而本申请实施例提供的万向椎弓根螺钉中，压环是在外界压力的作用下扩张后，固定在螺钉座内的卡位槽内，所以压环的材料不需要弹性强度，可以选择与螺钉座及螺钉头相同的材料，因此可以避免现有万向椎弓根螺钉植入体内后由于电腐蚀而影响椎弓根螺钉的质量及使用寿命的问题。

以上所述仅是本申请的优选实施方式，使本领域技术人员能够理解或实现本申请。对这些实施例的多种修改对本领域的技术人员来说将是显而易见的，本文中所定义的一般原理可以在不脱离本申请的精神或范围的情况下，在其它实施例中实现。因此，本申请将不会被限制于本文所示的这些实施例，而是要符合与本文所公开的原理和新颖特点相一致的最宽的范围。

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1、一种万向椎弓根螺钉，其特征在于，包括：螺钉座、螺钉头和压环，其中：

所述螺钉座为管状结构，其一端侧壁上设置有两个相对称 U 型开口，另一端开口处内壁上设置有凸棱，并且所述螺钉座内壁上设置有卡位槽；

所述螺钉头包括棒体和固定在所述棒体一端的球状结构，且所述棒体上设置有螺纹，所述球状结构位于所述螺钉座内，与所述凸棱的内侧相接触，并且其外径大于所述凸棱的内径，所述棒体位于所述螺钉座的外侧；

所述压环的一端外壁上设置有两个相对称的凸块，且所述凸块设置在所述卡位槽内，所述压环与所述球状结构相接触，且其内径大于所述螺钉头上球状结构的外径，将所述螺钉头上的球状结构可转动地固定在所述卡位槽与凸棱之间。

2、根据权利要求 1 所述的万向椎弓根螺钉，其特征在于，所述卡位槽设置在所述 U 型开口顶部与 U 型开口底部之间的螺钉座的内壁上。

3、根据权利要求 1 所述的万向椎弓根螺钉，其特征在于，所述压环与所述球状结构相接触一端的结构为弧形结构。

4、根据权利要求 3 所述的万向椎弓根螺钉，其特征在于，所述压环设置有凸块一端的端面上还设置有两个相对称的 V 型扩张槽。

5、根据权利要求 4 所述的万向椎弓根螺钉，其特征在于，所述两个 V 型扩张槽的轴线在一条直线上，且与所述两个凸块的连线相垂直。

6、根据权利要求 1 所述的万向椎弓根螺钉，其特征在于，所述螺钉头球状结构顶端设置有内六角形槽。

7、根据权利要求 1 所述的万向椎弓根螺钉，其特征在于，所述螺钉座上设置有凸棱的一端的断面上设置有三个万向槽。

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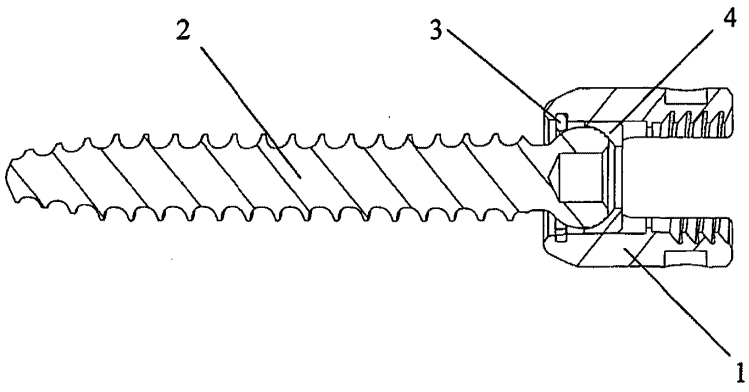


图 1

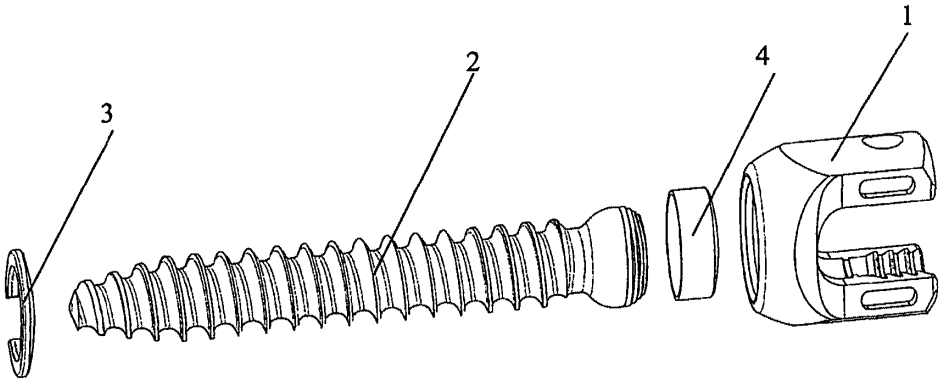


图 2

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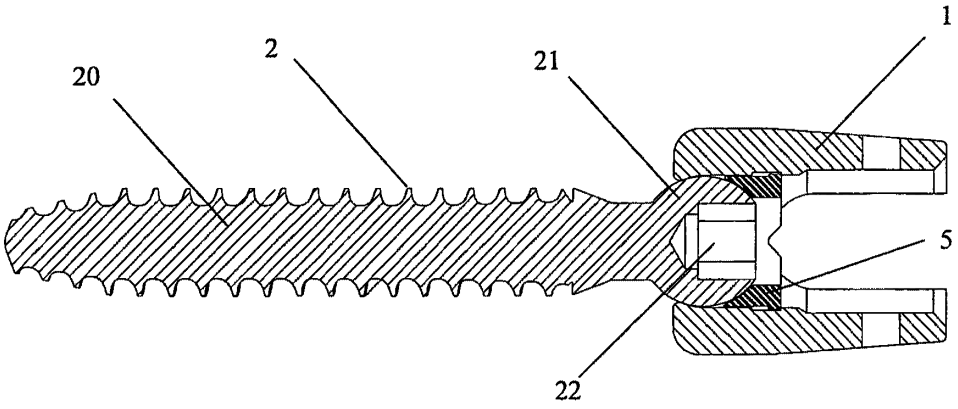


图 3

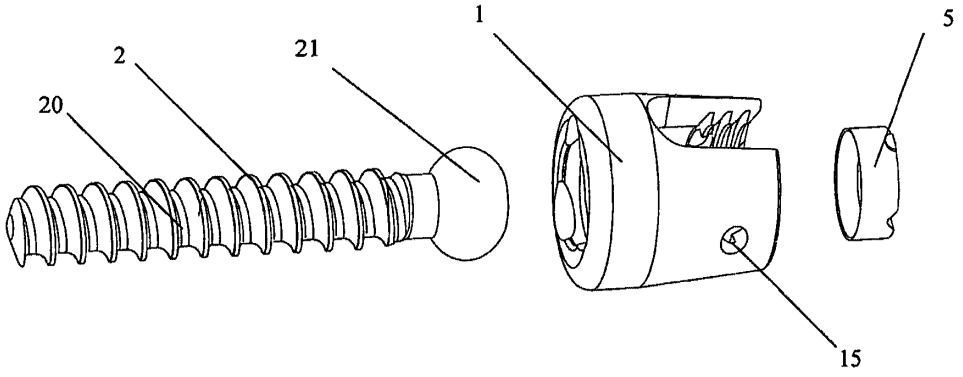


图 4

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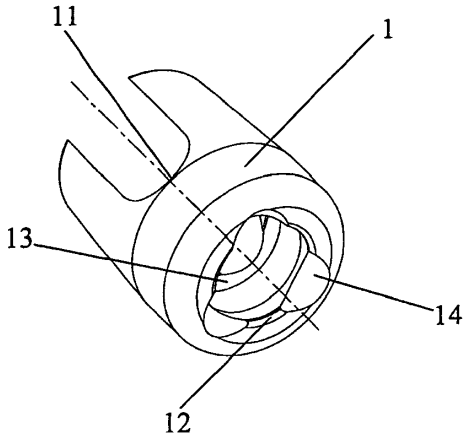


图 5

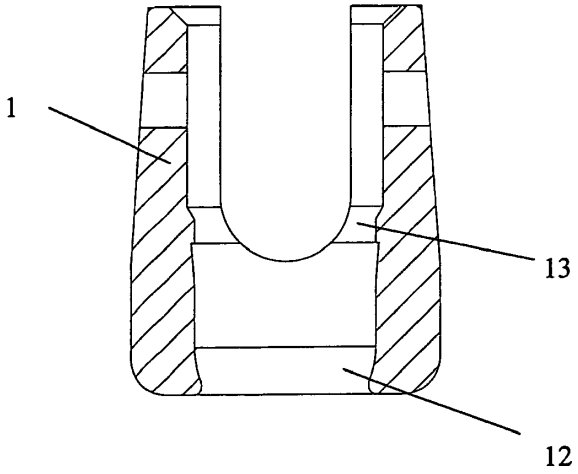


图 6

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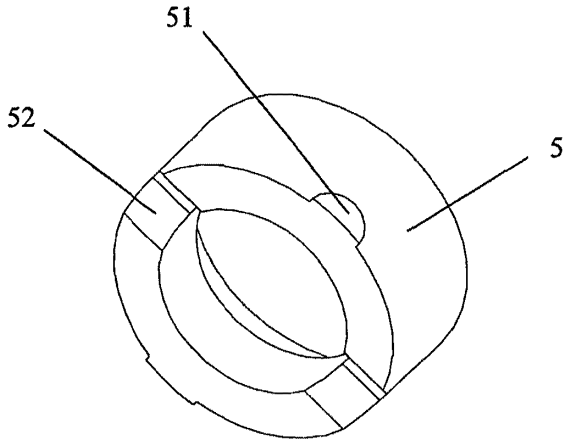


图 7

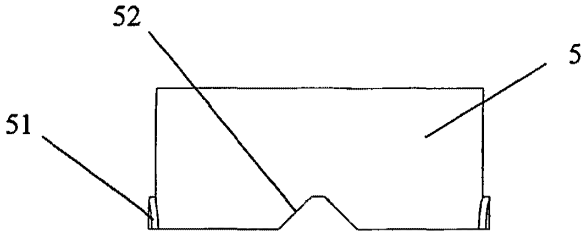


图 8

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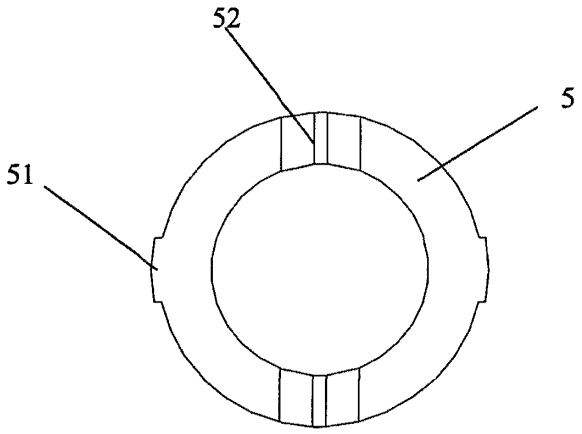


图 9

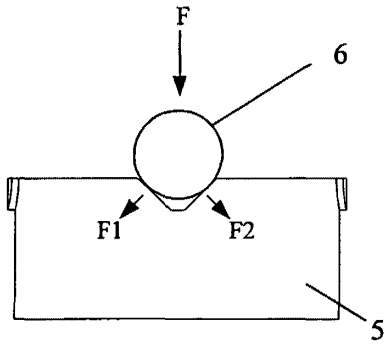


图 10

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/CN2011/078277

A. CLASSIFICATION OF SUBJECT MATTER

See the extra sheet

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC: A61B 17

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

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

EPODOC, CPRSABS, VEN, CNKI: universal, head, screw

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	CN 101389279 A (WARSAW ORTHOPEDIC INC.), 18 March 2009 (18.03.2009), description, page 3, line 19 to page 6, line 25, and figures 2-10	1-3, 6, 7
X	WO 2009124196 A2 (LIFE SPINE INC. et al.), 08 October 2009 (08.10.2009), description, page 5, line 22 to page 8, line 14, and figures 1 and 2	1-3, 6
A	US 2007088357 A1 (SDGI HOLDINGS INC.), 19 April 2007 (19.04.2007), the whole document	1-7
A	US 2004102781 A1 (U & I CORP.), 27 May 2004 (27.05.2004), the whole document	1-7
A	US 5443467 A (BIEDERMANN MOTECH GMBH), 22 August 1995 (22.08.1995), the whole document	1-7

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
24 October 2011 (24.10.2011)	**10 November 2011 (10.11.2011)**
Name and mailing address of the ISA: State Intellectual Property Office of the P. R. China No. 6, Xitucheng Road, Jimenqiao Haidian District, Beijing 100088, China Facsimile No.: (86-10) 62019451	Authorized officer **ZHANG, Hongmei** Telephone No.: (86-10) **62085626**

Form PCT/ISA/210 (second sheet) (July 2009)

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/CN2011/078277

Patent Documents referred in the Report	Publication Date	Patent Family	Publication Date
CN 101389279 A	18.03.2009	US 2005283157 A1	22.12.2005
		US 7264621 B2	04.09.2007
		EP 1768587 A1	04.04.2007
		WO 2006009753 A1	26.01.2006
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		CA 2572794 A1	26.01.2006
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		AU 2005265015 B2	23.09.2010
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WO 2009124196 A2	08.10.2009	US 2009254125 A1	08.10.2009
US 2007088357 A1	19.04.2007	EP 1945118 A2	23.07.2008
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		CA 2118562 C	05.05.1998
		KR 0128371 B1	01.04.1998
		ES 2089867 T3	01.10.1996

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/CN2011/078277

A. CLASSIFICATION OF SUBJECT MATTER (CONTINUATION OF SECOND SHEET)

A61B 17/70 (2006.01) i

A61B 17/86 (2006.01) i

Form PCT/ISA/210 (extra sheet) (July 2009)

国际检索报告

国际申请号
PCT/CN2011/078277

A. 主题的分类

参见附加页

按照国际专利分类(IPC)或者同时按照国家分类和 IPC 两种分类

B. 检索领域

检索的最低限度文献(标明分类系统和分类号)

IPC: A61B17

包含在检索领域中的除最低限度文献以外的检索文献

在国际检索时查阅的电子数据库(数据库的名称，和使用的检索词（如使用））

EPODOC, CPRSABS, VEN, CNKI

螺钉，万向，head, screw

C. 相关文件

类　型*	引用文件，必要时，指明相关段落	相关的权利要求
X	CN101389279A (华沙整形外科股份有限公司), 18.3 月 2009(18.03.2009), 说明书第 3 页 19 行至第 6 页 25 行, 图 2-10.	1-3，6，7
X	WO2009124196A2 (LIFE SPINE INC 等), 08.10 月 2009(08.10.2009), 说明书第 5 页 22 行至第 8 页 14 行, 图 1, 2.	1-3，6
A	US2007088357A1 (SDGI HOLDINGS INC), 19.4 月 2007 (19.04.2007), 全文.	1-7
A	US2004102781A1 (U & I CORP), 27.5 月 2004(27.05.2004), 全文.	1-7
A	US5443467A (BIEDERMANN MOTECH GMBH), 22.8 月 1995(22.08.1995), 全文.	1-7

☐ 其余文件在 C 栏的续页中列出。　　☒ 见同族专利附件。

* 引用文件的具体类型：

"A" 认为不特别相关的表示了现有技术一般状态的文件

"E" 在国际申请日的当天或之后公布的在先申请或专利

"L" 可能对优先权要求构成怀疑的文件，或为确定另一篇引用文件的公布日而引用的或者因其他特殊理由而引用的文件（如具体说明的）

"O" 涉及口头公开、使用、展览或其他方式公开的文件

"P" 公布日先于国际申请日但迟于所要求的优先权日的文件

"T" 在申请日或优先权日之后公布，与申请不相抵触，但为了理解发明之理论或原理的在后文件

"X" 特别相关的文件，单独考虑该文件，认定要求保护的发明不是新颖的或不具有创造性

"Y" 特别相关的文件，当该文件与另一篇或者多篇该类文件结合并且这种结合对于本领域技术人员为显而易见时，要求保护的发明不具有创造性

"&" 同族专利的文件

国际检索实际完成的日期	国际检索报告邮寄日期
24.10 月 2011(24.10.2011)	**10.11 月 2011 (10.11.2011)**
ISA/CN 的名称和邮寄地址： 中华人民共和国国家知识产权局 中国北京市海淀区蓟门桥西土城路 6 号 100088 传真号：　(86-10)62019451	受权官员 **张红梅** 电话号码：(86-10) **62085626**

PCT/ISA/210 表(第 2 页) (2009 年 7 月)

国际检索报告
关于同族专利的信息

国际申请号
PCT/CN2011/078277

检索报告中引用的专利文件	公布日期	同族专利	公布日期
CN101389279A	18.03.2009	US2005283157 A1	22.12.2005
		US7264621 B2	04.09.2007
		EP1768587 A1	04.04.2007
		WO2006009753 A1	26.01.2006
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		AU2005265015 B2	23.09.2010
		JP2008503260A	07.02.2008
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US2007088357A1	19.04.2007	EP1945118 A2	23.07.2008
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		KR100495876 B1	16.06.2005
US5443467A	22.08.1995	EP0614649 A1	14.09.1994
		EP0614649 B1	08.05.1996
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		CA2118562 C	05.05.1998
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		ES2089867 T3	01.10.1996

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国际检索报告

国际申请号
PCT/CN2011/078277

A. 主题的分类(第 2 页)

A61B17/70 (2006.01) i

A61B17/86 (2006.01) i

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(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 2 380 513 A1

(12) EUROPEAN PATENT APPLICATION

(43) Date of publication:
26.10.2011 Bulletin 2011/43

(51) Int Cl.:
A61B 17/70 *(2006.01)*

(21) Application number: **11174731.7**

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(84) Designated Contracting States:
CH DE ES FR GB IT LI

(62) Document number(s) of the earlier application(s) in accordance with Art. 76 EPC:
07019942.7 / 2 047 812

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  79367 Weiswell (DE)
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  76227 Karlsruhe (DE)

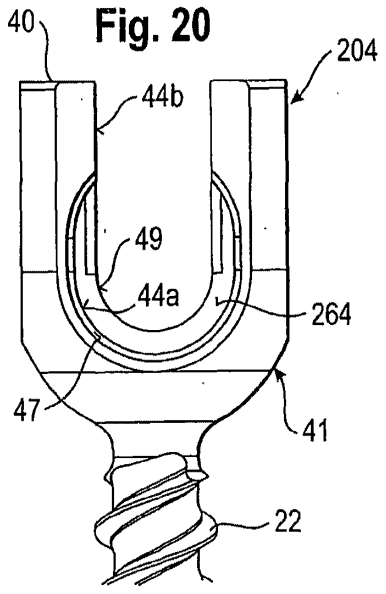
(74) Representative: **Prüfer & Partner GbR**
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Sohnckestraße 12
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Remarks:
This application was filed on 20-07-2011 as a divisional application to the application mentioned under INID code 62.

(54) Bone stabilization device

(57) A bone stabilization device (14), comprises: at least one bone anchoring device (14) comprising: (a) a receiving part (4) for receiving a rod-shaped implant element (16), the receiving part (4, 204) having: a first bore (42) coaxial with a longitudinal axis and extending from a first end (40) of the receiving part, and a recess (44) extending from the first end to accomplish insertion of the rod-shaped implant element (16); (b) a bone screw (2, 202) having a threaded section (22) for insertion into the bone; (c) a fixation element (8) provided to the first bore (42) to fixate a rigid section (161) of the rod-shaped implant element; the rod-shaped implant element (16), which further comprises (d) a rigid section (161) to be fixated by the fixation element (8) of bone anchoring device, wherein the rigid section (161) has a first width; (e) a stepped portion (162), having a thickness such as to be received by the bottom section (44a) of the recess (44) of the receiving part (4) of the bone anchoring device (14); wherein the recess(44) of the receiving part has a second width larger than the first width, such that the recess (44) may accommodate the stepped portion (162) of the rod-shaped implant element that has an increased thickness.

Fig. 20



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Description

[0001] The invention relates to a bone anchoring device comprising a receiving part for receiving a rod-shaped implant element, a bone screw having a thread section for insertion into a vertebral body of a spinal column, and a fixation element for fixating the rod-shaped implant element within the receiving part.

[0002] The rod-shaped implant element received by the above bone anchoring device may typically be connected to a further bone anchoring device that is similarly anchored in an adjacent vertebral bone in order to stabilize affected parts of the vertebral column.

[0003] One example of a bone stabilization device including two of such bone anchoring devices and a rod-shaped implant element (in the following also referred to as a "rod element") is described in document EP 1757243 A1, by the same applicant. Therein, a rod element is disclosed which is composed of a rigid section, a flexible section, a bore formed within the rod element and a core. The core is provided inside the bore and extends through parts of the rigid sections and through the flexible section.

[0004] The flexible section may be made of a cylindrical pipe, into which a helical opening extending from the inner bore to the outer surface is formed. The resultant flexible section is characterized by its axial compression or expansion stiffness. The stiffness is achieved by a combination of pitch, web thickness and used biocompatible material's elasticity.

[0005] The core may freely slide inside the bore in axial direction at least with regard to one of its ends. Thereby, the free end is guided in a rigid section adjacent to the flexible section. The bending stiffness of the core is bigger than of the flexible section itself. Hence, the bending characteristics of the rod element are determined mainly by the core.

[0006] According to EP 1757243 A1, due to the presence of a bore which accommodates the core, the diameter or width of the rod element increases as compared with a common rod element, in which flexible components are not utilized.

[0007] The one specific bone anchoring device designed to receive the end section of the rod element is provided with small openings instead of the recesses. The end section of the rod element can be introduced through the openings, whose widths correspond to the reduced width of the end section.

[0008] It is an object to provide an improved bone anchoring device, which provides an enhanced flexibility with regard to a stabilization device including a rod element. It is further an object to provide a reliable bone anchoring device which facilitates the implantation of stabilization devices in cases where distance requirements with regard to two adjacently placed bone anchoring devices become very strong. I.e., cases where the mutual distances of those devices are considerably reduced.

[0009] These and other objects are solved by a bone anchoring device for use in trauma or spinal surgery comprising the features according to claim 1. Further advantageous aspects and embodiments become apparent from the appended claims.

[0010] According to one aspect, there is provided a bone anchoring device having a receiving part for insertion of a rod-shaped implant element (in the following also referred to as a "rod element"). The recess extends from a first (upper) end of the receiving part towards a bottom section. At least in its bottom section, the recess attains a width (first width), which is larger than that of a section of the rod element (second width), which is to be fixated by the fixation element.

[0011] In another aspect, The receiving part is employed in conjunction with a rod element provided with a stepped portion. Therein, the rigid section intended to fixate the rod element by the fixation element has the first smaller width and the stepped portion substantially has the second larger width. Consequently, the stepped portion fits in the recess and the rigid portion fits to inner fixation or locking means provided within the receiving part.

[0012] Hence, there is no play and the reliability of the anchoring device and the fixation of the rod element is increased by a quasi form-fit connection. This kind of connection may even improve the behaviour of the device with regard to strong forces exerted on the rod element in axial direction, which might else act to slip the rod through the receiving part.

[0013] When using such a stepped rod element in the recess, the minimum distance between the bone anchoring device is reduced. As will be described in the embodiments below, the stepped portion may represent a flexible section of the rod element. Thereby, in order to maintain desired properties like bending, compression, expansion, torsion stiffness, etc., in combination with fatigue strength, a minimum length of the flexible section is needed.

[0014] In case the mutual distance of two adjacent bone anchoring device (more specifically: of two opposing surfaces of adjacent receiving parts) would decrease below that minimum length, a bone anchoring device as proposed herein may be utilized to increase the usable length for the flexible section by virtue of the recess being enlarged in width to receive portions of the flexible section.

[0015] According to another aspect related to a polyaxial anchoring device, a pressure element is provided which serves to transmit pressure exerted by the fixation element to a head section of the bone screw. The head section can be positioned in a bore at the bottom end of the receiving part. The pressure element has a cylindrical recess adapted to receive the rigid section of the rod element. The cylindrical recess has the first smaller width corresponding to the width of the rod element. The pressure element according to this aspect is further provided with a stop face. The stop face is designed to engage with an end face of the stepped portion of the rod element.

[0016] In an alternative aspect related to a monoaxial

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anchoring device, a cylindrical recess is provided at a bottom portion of a bore of the receiving part and is adapted to receive the rigid section of the rod element. Similar to the previous aspect, the cylindrical recess has the first smaller width corresponding to the width of the rod element. Further a stop face is oriented towards the recess having the larger width.

[0017] In one specific embodiment, the stop face is formed as a plane surface recessed from a generally cylindrically shaped surface of the pressure element.

[0018] According to this aspect, the pressure element may provide a form-fit connection with regard to the stepped rod element as well as with regard to a spherically or cylindrically shaped head section of the bone screw. Due to the recessed stop face, the stepped portion may reach into the inner space of the first bore formed in the receiving part, such that even more length can be reserved for the accommodating the flexible section of the rod element, i.e., the mutual distance of the anchoring devices can be further reduced.

[0019] The invention will be better understood with reference to specific embodiments of the invention when taken in conjunction with the accompanying drawings. Therein,

Fig. 1 shows an illustration of the spinal column;

Fig. 2 shows an explosion view of a bone anchoring device according to an embodiment of the invention;

Fig. 3 same as Fig. 2, but in an assembled state;

Fig. 4 shows in an enlarged perspective view a receiving part of the device according to Fig. 2;

Fig. 5 shows a top view of the receiving part of Fig. 4;

Fig. 6 shows a cross-sectional view of the receiving part according to Fig. 4;

Fig. 7 shows a side view of the receiving part according to Fig. 4;

Fig. 8 shows a front view of the receiving part according to Fig. 4;

Fig. 9 shows in an enlarged perspective view a pressure element of the device according to Fig. 2;

Fig. 10 shows a front view of the pressure element according to Fig. 9;

Fig. 11 shows a side view of the pressure element according to Fig. 9;

Fig. 12 shows a cross sectional profile of a bone stabilization device including the bone anchoring device of Fig. 2;

Fig. 13 shows an enlarged portion of Fig. 12;

Fig. 14 shows a first step of assembling the bone stabilization device of Fig. 12 in a side view;

Fig. 15 same as Fig 14, but with regard to a second (final) step of assembly;

Fig. 16 same as Fig. 14, but in a perspective view;

Fig. 17 same as Fig. 15, but in a perspective view,

Fig. 18 shows an exploded view of a bone anchoring device according to a second embodiment of the invention;

Fig. 19 same as Fig. 18, but in a perspective view with the fixation screw being screwed-in;

Fig. 20 shows in an enlarged front view a receiving part of the device according to Fig. 18;

Fig. 21 same as Fig. 20, but with regard to a sectional view of the receiving part;

Fig. 22 shows a sectional view of the bone stabilization device according to the second embodiment.

[0020] Fig. 1 shows a lower part of the spine anatomy in conjunction with variously positioned bone anchoring devices 14a - 14f. The bone anchoring devices each comprise a bone screw and a receiving part for receiving and fixing, e.g., a head section of the bone screw. Each of the bone anchoring devices 14a - 14f is anchored in one vertebrae of either the thoracic or lumbar spine.

[0021] As becomes apparent from Fig. 1, the interpedicular distance between two adjacent bone anchoring devices 14a and 14b in the high thoracic part decreases from 25 mm - 30 mm towards values of 10 - 15 mm for respective bone anchoring devices 14e and 14f in the lower lumbar part (which stabilize L5-S1). As noted above, a rod element 16 designed to furnish the stabilization by connecting adjacent ones of the anchoring devices 14a - 14f, and which is provided with flexibility and bending characteristics, must preserve a minimum length for a respective flexible section.

[0022] Hence, when considering the lower lumbar part, a flexible section requiring a length of, e.g., 15 mm cannot easily be positioned between respective receiving parts of conventional bone anchoring devices. It has to be noted that a typical receiving part may also contribute further 6-12 mm to the amount of needed distance.

[0023] Figs. 2 and 3 show an embodiment of a bone anchoring device 14 as proposed herein. Fig. 2 reveals an explosion view of the parts involved in a disassembled

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state, while Fig. 3 shows the device in an assembled state. First, the basic parts of the device which are partly known in the art will be described.

[0024] The bone anchoring device 14 comprises a bone screw 2, a receiving part 4, a pressure element 6 and a fixation element (screw) 8. The bone screw 2 has a thread section 22 for insertion into the bone e.g., a vertebral body (not shown), and a head section 24. In this embodiment, the bone screw 2 has a spherically shaped head section 24, but the invention shall not be limited to the specific shape and function of the head section 24 and/or the thread section 22. The materials selected for the components may be any biocompatible material or metals such as Titanium or Titanium alloy.

[0025] The receiving part 4 is of substantially symmetric form and has a first end 40 and a second end 41, which has a tapered profile. From the first end 40, there extends a first bore 42 to define an inner space of the receiving part 4, which also is of substantially cylindrical shape. At an upper portion of an inner wall of the bore 42, an inner thread 45 is formed which may engage with a corresponding outer thread 81 of the fixation element 8 (see also Figs. 4-8).

[0026] The pressure element 6 is positioned within the first bore 42 between the fixation element 8 and the head section 24 of the bone screw 2. The bone screw 2 is accommodated within a second bore 43 adjacent to the first bore 42 and is positioned at the second end 41 opposite to the first end 40 of the receiving part 4. The pressure element 6 is provided with a bottom surface 69 (not shown in detail), which in this specific embodiment is arranged to yield a form-fit connection with the spherically shaped surface of the head section 24 of the bone screw 2 (see also Figs. 9-11).

[0027] It may be noted herein that the specific type of connection of the bone screw 2 as described above refers to a polyaxial bone anchoring device. However, those who are skilled in the art will readily recognize that the function and effects of the invention to be explained are similarly applicable to monoaxial bone anchoring devices described below with regard to a second embodiment.

[0028] Upon screwing-in the fixation element 8 into the thread 45 of the receiving part 4, pressure is exerted onto the rod element 16 inserted into receiving part 4. The pressure is then transmitted further to the pressure element 6 in order to lock the bone screw 2 by means of frictional force.

[0029] Next, the details of a modification as proposed herein will be described with particular reference to Figs. 4-8, which show enlarged views of the receiving part 4.

[0030] The receiving part 4 is provided with two recesses 44 and 49, which extend from the first end 40. The recesses define two legs 46 of the receiving part 4 and serve to insert the rod element 16 into the receiving part 4. The first recess 44 has substantially the shape of a reversed keyhole. I.e., the first recess 44 has a bottom section 44a and an upper section 44b, wherein the bottom section has a larger width of 7,5 mm (diameter as measured in a direction perpendicular to the axis of the inserted rod element and perpendicular to the longitudinal axis of the receiving part 4), and the upper section has a smaller width of 5,5 mm.

[0031] The bottom section 44a has a substantially circular or oval shape (see Fig.8). It has an enlarged width in order to accommodate a stepped portion of the rod element 16. The second recess 49 on the back side in Figs. 4 and 8, or on the right side in Fig. 6 is of the conventional type having a U-shape. Its width amounts to 5,5 mm in its upper section as well as in its bottom section.

[0032] An edge 47 defined by an intersection of the an inner wall of the bottom section 44a of the first recess 44 with an outer surface of the receiving part 4 is chamfered in order to facilitate insertion of a stepped portion of the rod element 16 upon assembly as will be explained below.

[0033] Next, details of the pressure element 6 modified as proposed herein are explained with reference to Figs. 9-11. The pressure element 6 has two leg portions 62, separated by a cylindrical recess 61, and an annular base portion 65. The pressure lent further has a substantially cylindrical outer surface 63. The cylindrical recess 61 is designed to receive the rigid section 161 of the rod element 16 and therefore has a corresponding width of 5 mm in order to fit the same. The cylindrical recess has a longitudinal axis which upon insertion of the pressure element in the first bore 42 of the receiving part 4 is oriented perpendicular to the longitudinal axis of that bore 42.

[0034] The pressure element 6 further has a stop face 64, which is arranged as a plane surface recessed from the generally cylindrical outer surface 63. The stop face 64 is arranged to abut on the end face 163 of the stepped portion 162 of the rod element 16, or vice versa. The stop face 64 is accordingly shaped as an annular segment, which becomes apparent from the front view of Fig. 10. Preferably, the end face of the stepped portion is also represented by a plane surface perpendicular to the longitudinal axis of the rod, or of the cylindrical recess respectively.

[0035] It may be noted that the fixation element 8 in this embodiment has at its bottom end an extension 82. The extension 82 has a decreased diameter smaller than the threaded section. This decreased diameter allows the stepped portion 162 to be accommodated in the inner space of the first bore 42 of the receiving part 4. The length of the extension 82 along the longitudinal direction of the bore 42 is equal to or larger than the height of the step due to the stepped portion 162 of the rod element 16.

[0036] A bottom face of this extension 82 exerts pressure onto the rigid section 161 of the rod element 16, while an angular bottom face (not shown) of the threaded portion of the fixation element 8 may, for example, exert a pressure onto legs 62 of the pressure element 6.

[0037] Fig. 12 shows a cross-sectional view of a bone stabilization device 1 comprising two of the bone anchoring devices 14 as detailed above and a stepped rod element 16. Fig. 13 shows an enlarged detail of Fig. 12.

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The stepped portion 162 in this embodiment represents a flexible section of the rod element 16 comprising for example a helically opened pipe enclosing a bore in which a core being slidable at least at one end thereof with properties similar to EP '243 is disposed.

[0038] The stepped portion extends through respective first recesses 44 (due to the bottom section 44a) and into the internal spaces (due to the stop face 64) of the receiving parts 4 of the corresponding bone anchoring devices 14, for example devices 14e and 14f in Fig. 1. Amounts 100, 101 of length as schematically indicated in Fig. 12 may thus be saved to accommodate the stepped portion between the receiving parts 4. For example, the lengths 100, 101 amount each to 2-4 mm. The minimum length to accommodate the stepped portion is thus reduced to 9-11 mm, which may comply with the requirements applicable with regard to the L5-S1 stabilization (see Fig. 1).

[0039] Figs. 14 - 17 illustrate the assembly process of the bone stabilization device 1. Figs. 14, 15 show side views, while Figs. 16 and 17 show perspective views of respective steps. First, the bone screws 2 are inserted into the receiving parts 4 through the first and second bores 42, 43 followed by anchoring the screws 2 in the respective bones. Then, the stepped rod element 16 is inserted into recesses 44, 49 with respect to the rigid sections 161 having the smaller width of, e.g., 5 mm. The fixation elements 8 are then screwed in but are not yet fastened (Figs. 14, 16).

[0040] Next, the two receiving parts 4 are shifted towards each other to shorten the mutual distance (indicated by arrows in Fig. 14). The stepped portion 162 thereby enters each of the bottom sections 44a of the recesses 44 wherein the chamfered edges 47 of the recesses 4 help compensating for slight misalignments.

[0041] Finally, the end faces 163 of the stepped portions 162 abut on the stop faces 64 of the pressure elements 6 (Figs. 15, 17).

[0042] Another embodiment is illustrated with respect to Figs. 18-22. This embodiment relates to a monoaxial bone anchoring device 214. As compared with the first embodiment, similar components are denoted with the same numerals. In the following section only different features of the second embodiment are described.

[0043] In this embodiment, the bone screw part 202 is integrally formed with the receiving part 204. Thus the thread section 22 extends from the bottom end 41 of the receiving part in a fixed direction (i.e., not rotatable prior to fixation). Hence, contrary to the first embodiment, there is neither a pressure element nor second bore present in this anchoring device. Instead, the first bore 42 of the receiving part has a bottom end, at which is formed a cylindrical recess 261, which is similarly adopted to receive the rigid section 161 of the rod element 16.

[0044] Similar to the first embodiment, a plane stop face 264 is oriented towards a section 44a of the inverse key-shaped recess 44, which has the larger width to receive the stepped portion 162 of the rod element 16. The plane of the stop face 264 extends perpendicular to the longitudinal axis of the cylindrical recess 261 and - also similar to stop face 164 according the first embodiment - intersects the inner space of the first bore.

[0045] It will become apparent to the person skilled in the art, that the modifications proposed herein may be embodied with various other configurations while yielding similar effects without departing from the scope as set forth in the appended claims.

[0046] According to one aspect, a bone anchoring device 14 comprises: a receiving part 4 for receiving a rod-shaped implant element 16, the receiving part 4, 204 having: a first bore 42 coaxial with a longitudinal axis and extending from a first end 40 of the receiving part, and a recess 44 extending from the first end to accomplish insertion of the rod-shaped implant element; a bone screw 2, 202 having a threaded section 22 for insertion into the bone; a fixation element 8 provided to the first bore 42 to fixate a rigid section 161 of the rod-shaped implant element; wherein the rigid section 161 of the rod-shaped implant element has a first width, and the recess 44 of the receiving part has a second width, the second width being larger than the first width, such that the recess 44 may accommodate a stepped portion 162 of the rod-shaped implant element that has an increased thickness.

[0047] According to a second aspect, the bone anchoring device 14 according to the first aspect further comprises: a second bore 43 provided at a second end 41 of the receiving part 4 opposite to the first end 40, wherein the bone screw 2 has a head section 24 that can be positioned within the second bore 43; a pressure element 6, which is arranged between the head section 24 of the bone screw 2 and the fixation element 8 for transmitting pressure to the head section 24, wherein the pressure element has a cylindrical recess 61 adapted to receive the rigid section 161 of the rod-shaped implant element, the cylindrical recess 61 being arranged to have the first width.

[0048] According to a third aspect, in the bone anchoring device 14 according to the first aspect, the receiving part 4 is provided with a cylindrical recess 261 adapted to receive the rigid section 161 of the rod-shaped implant element, and being arranged to have the first width.

[0049] According to a fourth aspect, in the bone anchoring device 14 according to the second or third aspects, the pressure element 6 or the receiving part 204 further comprises a stop face 64, 264, on which the stepped portion 162 abuts when being received by the recess 44 of the receiving part 4, 204.

[0050] According to a fifth aspect, in the bone anchoring device 14 according to the fourth aspect, the stop face 64, 264 is oriented substantially perpendicular to a longitudinal axis of the cylindrical recess 61, 261.

[0051] According to a sixth aspect, in the bone anchoring device 14 according to any one of the fourth or fifth aspects, the pressure element 6 comprises a surface 63 having a substantially cylindrical shape adapted to fit with an inner wall of the first bore 42 of the receiving part 4,

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and the stop face 64 is formed as a plane recessed from the cylindrical surface 63 of the pressure element 6.

[0052] According to a seventh aspect, in the bone anchoring device 14 according to any one of the fourth to sixth aspects, the stop face 64, 264 is represented by a plane surface and has a shape of an annular segment.

[0053] According to an eighth aspect, in the bone anchoring device 14 according to any one of the preceding aspects, the recess 44 of the receiving part has a shape of a reversed keyhole, its bottom section 44a having the second width and its upper section 44b oriented towards the first end of the receiving part having the first width.

[0054] According to a ninth aspect, in the bone anchoring device 14 according to any one of the preceding aspects, the recess 44 of the receiving substantially U-shape including a substantially constant width from an upper section of the recess towards its bottom section.

[0055] According to a tenth aspect, in the bone anchoring device 14 according to any one of the preceding aspects, the receiving part has two recesses, the first recess 44 being provided with at least the bottom section 44a having the second width, and a second recess 49 formed with a substantial U-shape and being arranged with the first width.

[0056] According to an eleventh aspect, in the bone anchoring device 14 according to any one of the preceding aspects, the receiving part 4 has two recesses, the first and a second one of the recesses 44 being provided with at least the bottom section 44a having the second width, respectively.

[0057] According to a twelfth aspect, in the bone anchoring device 14 according to any one of the preceding aspects, the recess 44 of the receiving part 4 has an edge 47 that is chamfered at least in the bottom section 44a thereof.

Claims

1. A bone stabilization device (14), comprising:

   at least one bone anchoring device (14) comprising:

   (a) a receiving part (4) for receiving a rod-shaped implant element (16), the receiving part (4, 204) having:

   - a first bore (42) coaxial with a longitudinal axis and extending from a first end (40) of the receiving part, and
   - a recess (44) extending from the first end to accomplish insertion of the rod-shaped implant element (16);

   (b) a bone screw (2, 202) having a threaded section (22) for insertion into the bone;
   (c) a fixation element (8) provided to the first bore (42) to fixate a rigid section (161) of the rod-shaped implant element;

   the rod-shaped implant element (16), which further comprises

   (d) a rigid section (161) to be fixated by the fixation element (8) of bone anchoring device, wherein the rigid section (161) has a first width;
   (e) a stepped portion (162), having a thickness such as to be received by the bottom section (44a) of the recess (44) of the receiving part (4) of the bone anchoring device (14);

   wherein the recess(44) of the receiving part has a second width larger than the first width, such that the recess (44) may accommodate the stepped portion (162) of the rod-shaped implant element that has an increased thickness.

2. The bone stabilization device (1) according to claim 1,
   wherein the bone anchoring device (14) further comprises a pressure element (6) having a cylindrical recess (61) for receiving the rigid section (161) of the rod-shaped implant element and a stop face (64), wherein the stepped portion (162) of the rod-shaped implant element (16) has an end face (163) arranged to abut on the stop face (64) of the pressure element (6).

3. The bone stabilization device (1) according to claim 1,
   wherein the receiving part (4) is provided with a cylindrical recess (261) at a bottom end of the first bore (42), the cylindrical recess (261) being adapted to receive the rigid section (161) of the rod-shaped implant element (16), the bone screw (202) being integrally formed with the receiving part (4).

4. The bone stabilization device (1) according to claim 3,
   wherein the receiving part (204) further comprises a stop face (264), on which the stepped portion (162), or an end face (163) thereof, abuts when being received by the recess (44) of the receiving part (204).

5. The bone stabilization device (1) according to one of claims 2 or 4, wherein the stop face (64, 264) is oriented substantially perpendicular to a longitudinal axis of the cylindrical recess (61, 261).

6. The bone stabilization device (1) according to any one of claims 2 or 5, when referring back to claim 2, wherein
   the pressure element (6) comprises a surface (63)

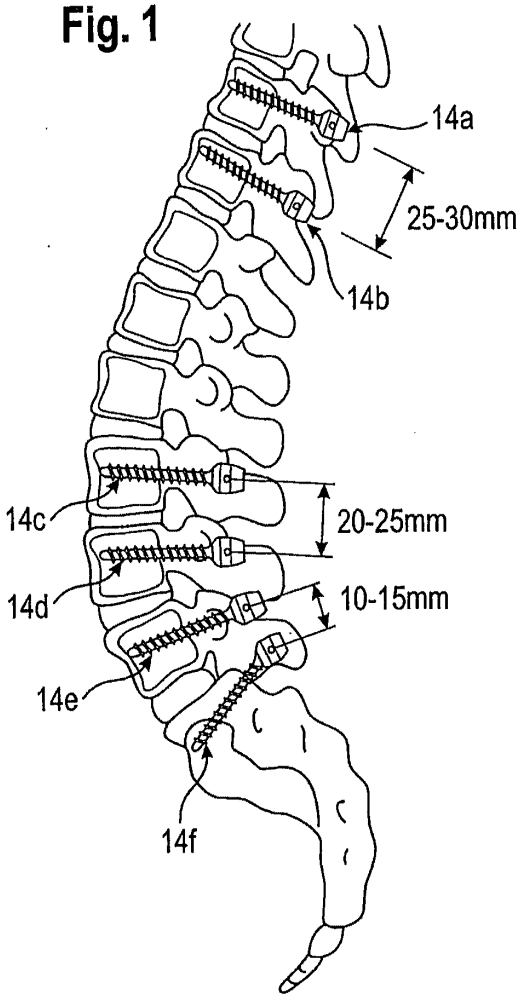
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having a substantially cylindrical shape adapted to fit with an inner wall of the first bore (42) of the receiving part (4), and
the stop face (64) is formed as a plane recessed from the cylindrical surface (63) of the pressure element (6).

7. The bone stabilization device (1) according to any one of claims 2, 5, when referring back to claim 2, or 6,
wherein a second bore (43) provided at a second end (41) of the receiving part (4) opposite to the first end (40), wherein the bone screw (2) has a head section (24) that can be positioned within the second bore (43); and
the pressure element (6) is arranged between the head section (24) of the bone screw (2) and the fixation element (8) for transmitting pressure to the head section (24).

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Fig. 1



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Fig. 2

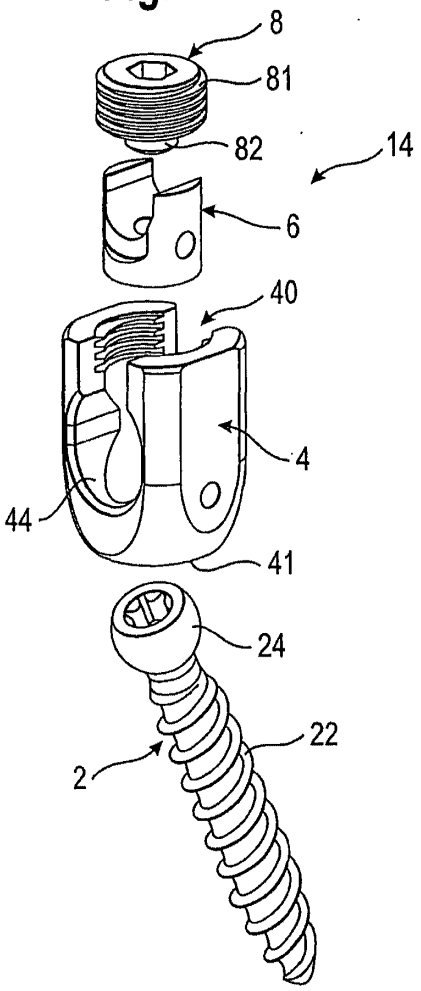
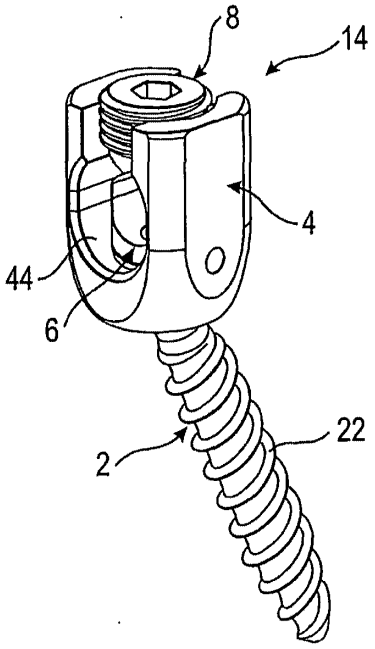


Fig. 3



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Fig. 4

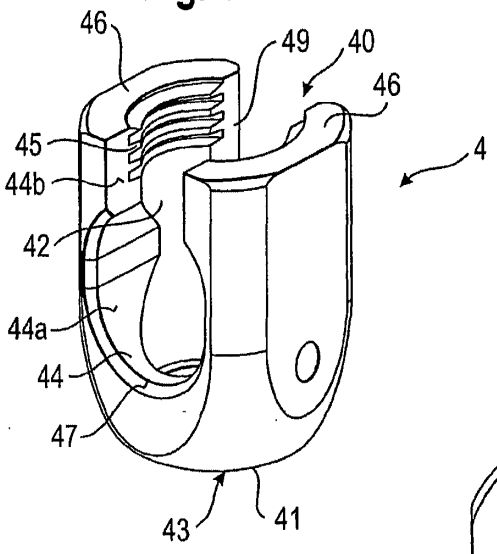


Fig. 5

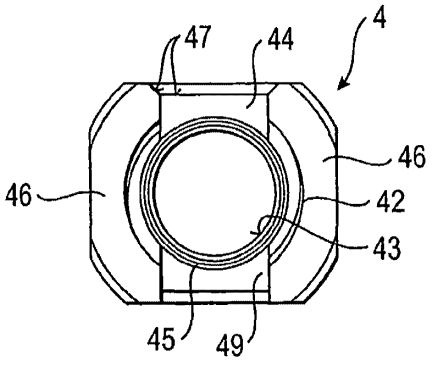
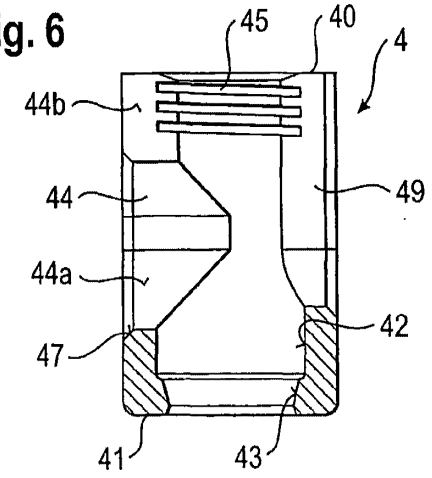


Fig. 6



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Fig. 7

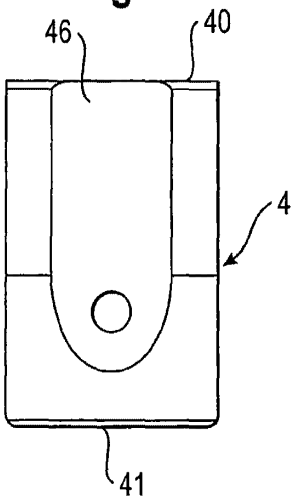


Fig. 8

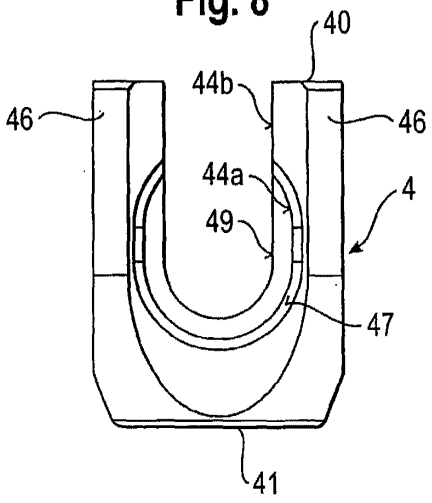


Fig. 9

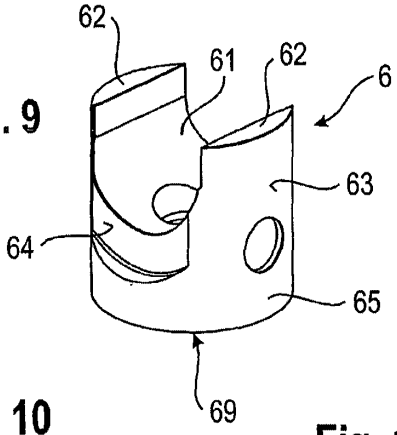


Fig. 10

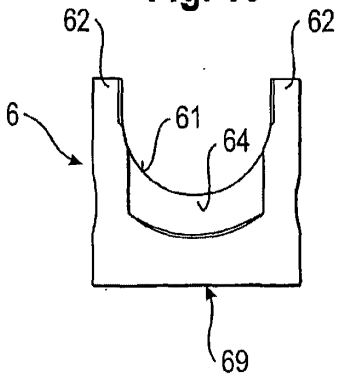
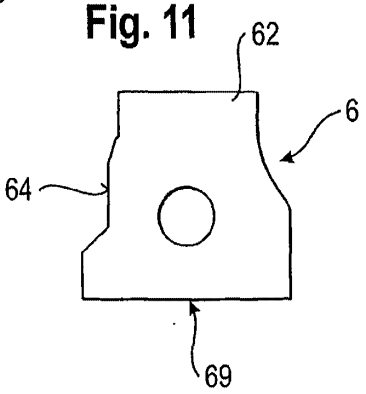


Fig. 11



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Fig. 13

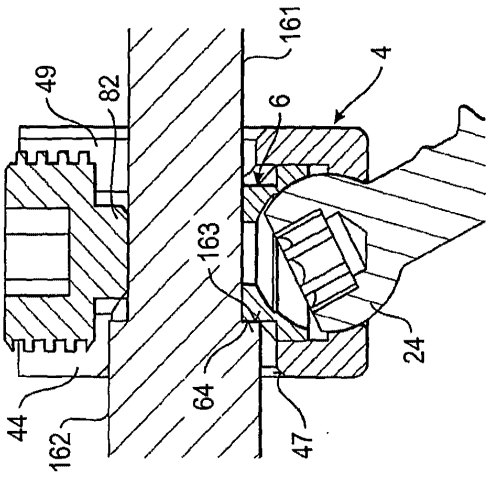
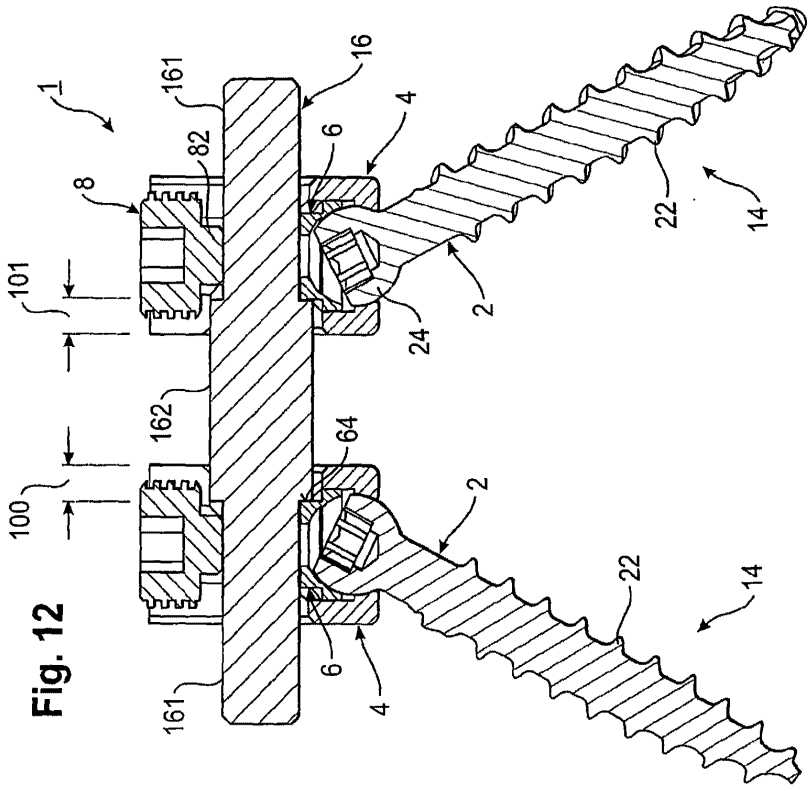


Fig. 12



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Fig. 14

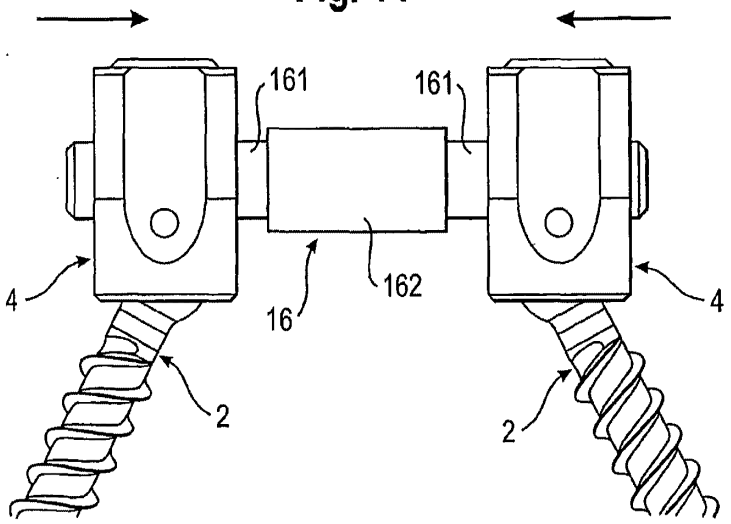
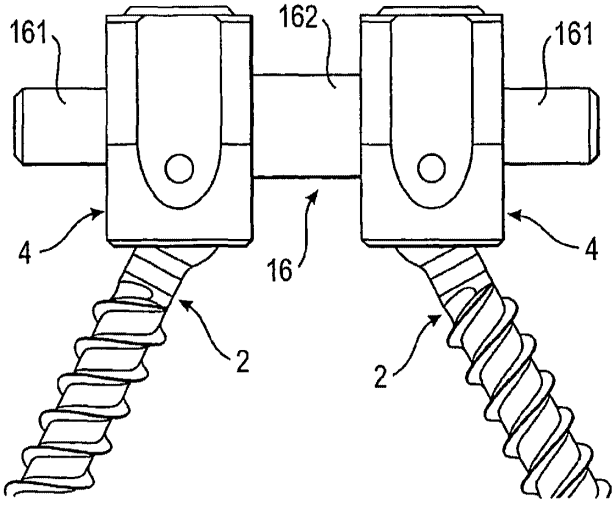


Fig. 15



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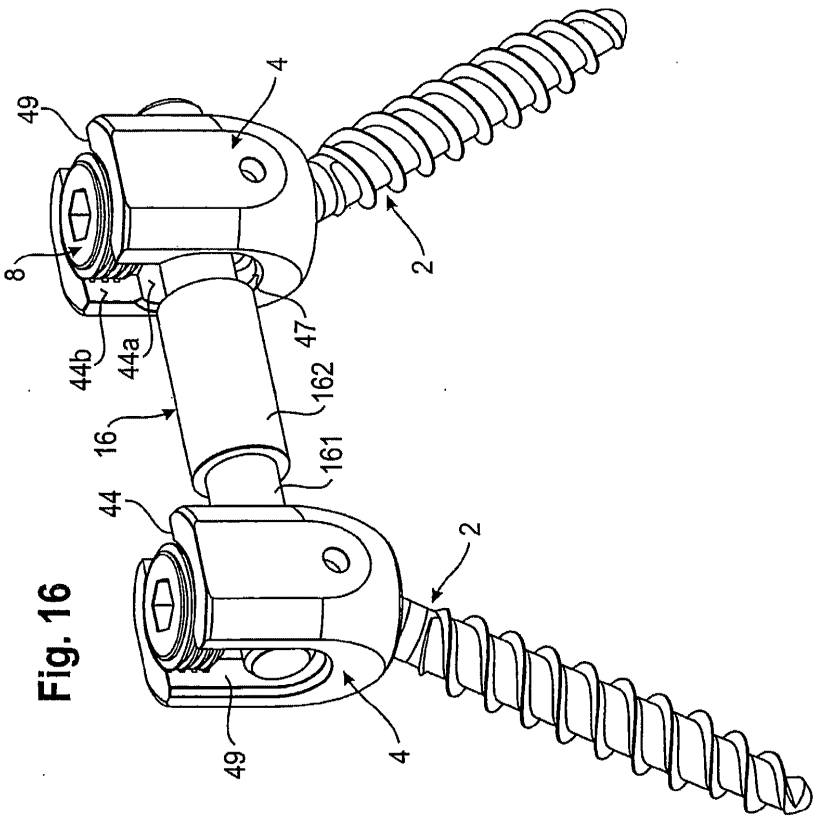


Fig. 16

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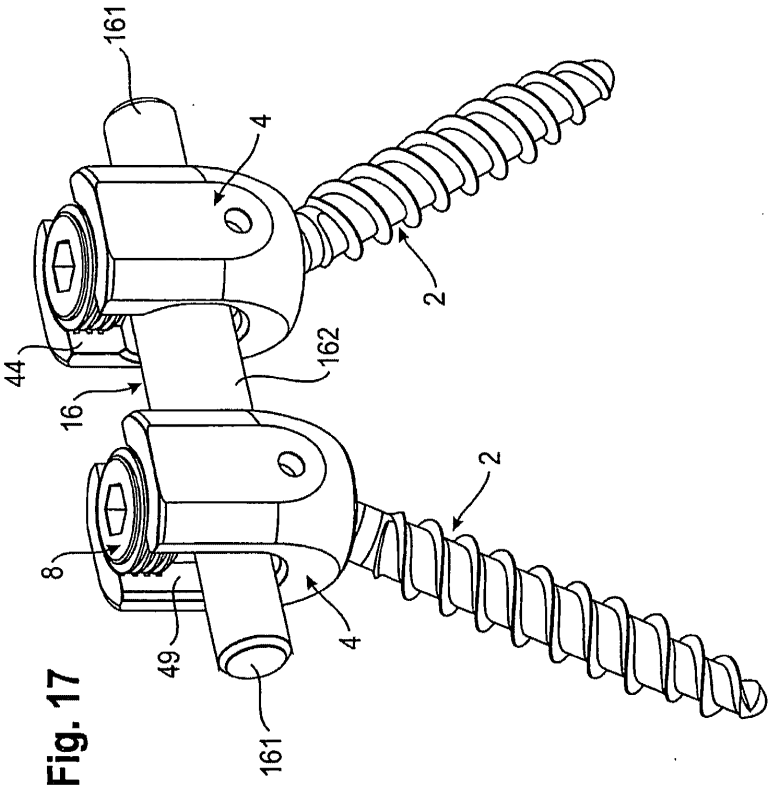


Fig. 17

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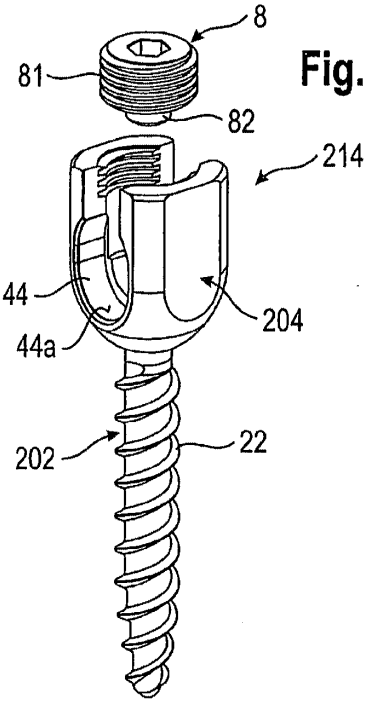
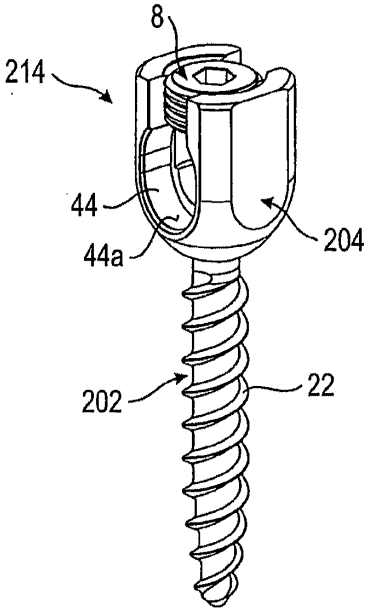


Fig. 18

Fig. 19



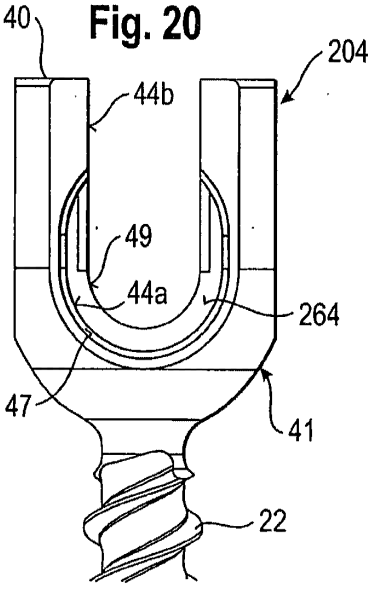


Fig. 20

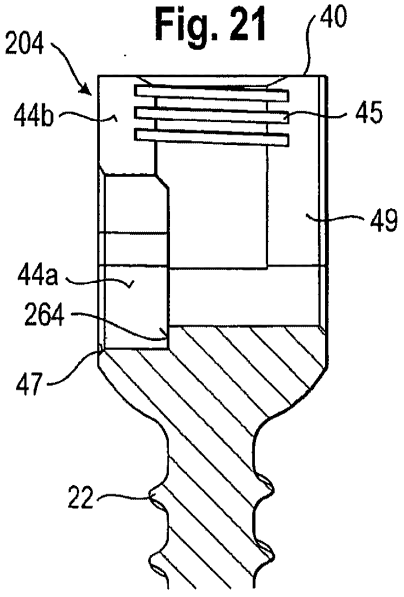
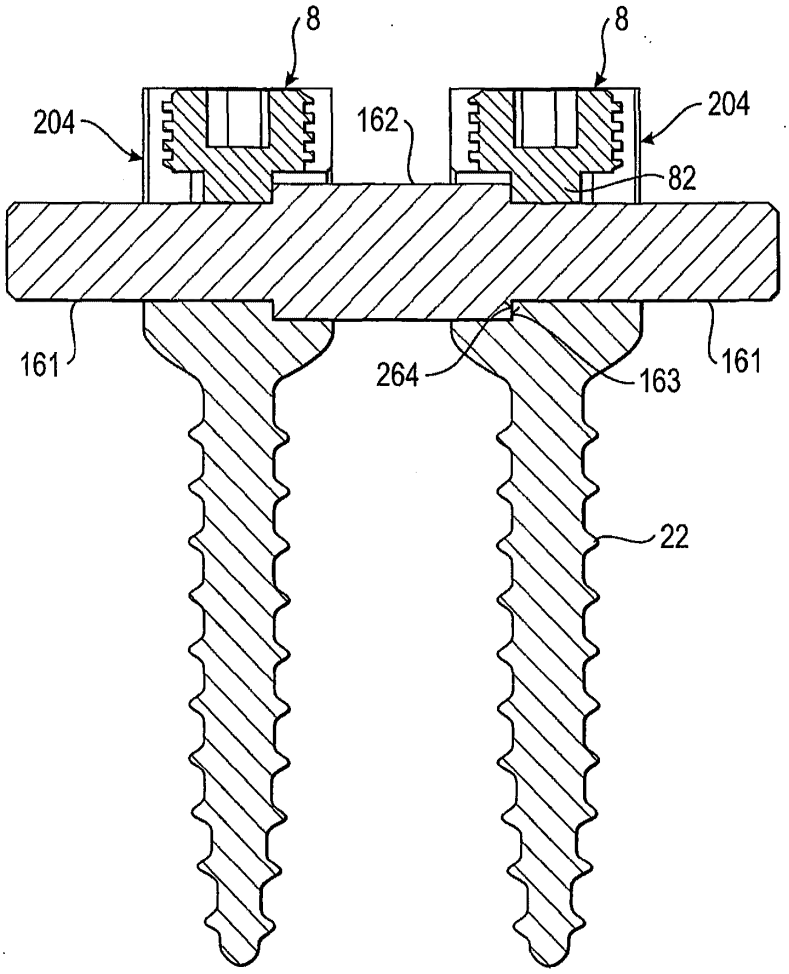


Fig. 21

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Fig. 22



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Europäisches Patentamt
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EUROPEAN SEARCH REPORT

Application Number
EP 11 17 4731

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
X	EP 1 815 812 A (SPINELAB AG [CH]) 8 August 2007 (2007-08-08) * figures 5a-8 *	1,3-5	INV. A61B17/70
X	WO 2006/066685 A (ZIMMER GMBH [CH]; EGLI THOMAS [CH]; ZYLBER EMMANUEL [FR]; LANCIAL MICH) 29 June 2006 (2006-06-29) * figures 14a-14c *	1,3	
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TECHNICAL FIELDS SEARCHED (IPC)
A61B

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
Munich	31 August 2011	Hamann, Joachim

CATEGORY OF CITED DOCUMENTS
X : particularly relevant if taken alone
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EPO FORM 1503 03.82 (P04C01)

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ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO. EP 11 17 4731

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31-08-2011

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For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

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REFERENCES CITED IN THE DESCRIPTION

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- EP 1757243 A1 **[0003] [0006]**

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[Continued on next page]

(54) Title: DYNAMIC PEDICLE SCREW

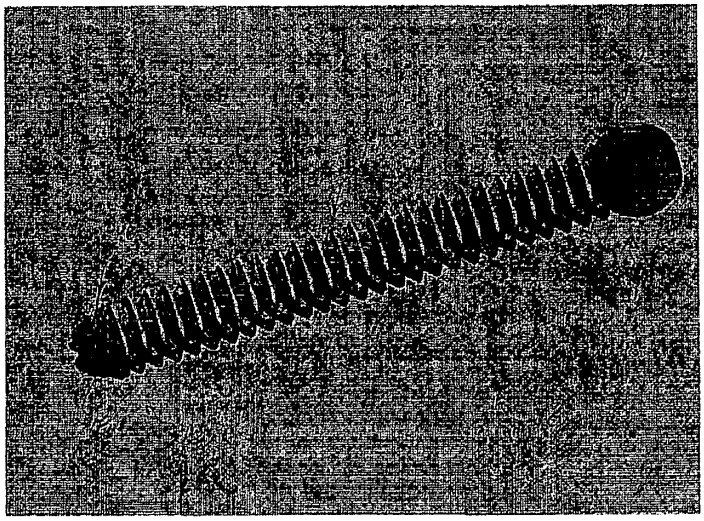


FIG. 3

(57) Abstract: A bone screw, such as a pedicle screw, comprises en elongate structure having a head, an anchoring portion or tip distal from the head, and an open, helical body extending there- between. In one embodiment, the invention provides a screw having an anchoring portion, which engages bone and which includes a means for engaging a driver or the like whereby the screw is driven into the bone by the anchoring portion. A method of driving a screw is also provided.

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TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

Published:

— *with international search report (Art. 21(3))*

DYNAMIC PEDICLE SCREW

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] The present application claims priority from US patent application number 61/189,184, filed on August 15, 2008, the entire contents of which are incorporated herein by reference.

FIELD OF THE INVENTION

[0002] The present invention relates to bone anchoring devices. In particular, the invention provides an improved pedicle screw for spinal fixation.

BACKGROUND OF THE INVENTION

[0003] Various devices and prostheses have been proposed to correct and/or stabilize spinal injuries or deformities. Such devices include artificial spinal discs, nuclei etc. Such devices serve to replace existing damaged or diseased portions of the spine. In some cases however, it is desired or necessary for fusing spinal vertebrae so as to prevent or reduce relative displacement there-between. Such fixation devices commonly utilize pedicle screws that are implanted into the pedicles of vertebrae and which serve as anchors for other prosthetic devices. Figures 1 and 2 illustrate a vertebral segment 1 and the pedicles 2a and 2b that extend from the vertebral body 3. Figure 2 illustrates the placement of pedicle screws 4 as known in the art. Such screws have a threaded portion 5 that is screwed into the pedicle and a head portion 6 that connects to other fixation devices such as a rod 7.

[0004] As shown in Figure 2, typical pedicle screw fixation systems are multi-component devices consisting of solid rods that are longitudinally interconnected and anchored to adjacent vertebrae using pedicle screws. The screws and other components are generally made of stainless steel, titanium or other acceptable implantable material. The surgeon selects from among these components to construct a system suitable for a patient's anatomical and physiological requirements. Pedicle screws are similar to the screws used in long bones.

[0005] During implantation, pedicle screws are inserted into channels that are drilled or otherwise formed through the cancellous central axis of each vertebral pedicle. The longitudinal connecting rods usually span and brace two or more vertebrae. Each vertebra typically receives a pedicle screw in both pedicles and, similarly, the connecting rods are provided in pairs each of the rods extending over one side of the spine.

[0006] Pedicle screw fixation systems have been used in providing spinal stabilization and in the promotion of spinal fusion in patients with a variety of conditions such as degenerative

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spondylolisthesis, isthmic spondylolisthesis, fusion after decompression, lumbar fractures, surgically repaired spinal pseudoarthroses. The advent of rigid pedicle screw/rod fixation devices has led to a dramatic increase in the rate of arthrodesis (i.e. the surgical fusion of a joint) particularly for the treatment of degenerative disc disease and spondylolisthesis. In addition to higher rates of arthrodesis, rigid instrumentation has enabled surgeons to maintain, improve, or fully reduce spondylolisthesis outright, and these devices have allowed for very aggressive strategies for decompression.

[0007] However, the use of such rigid instrumentation for the fusion of vertebrae has been associated with an increased prevalence of disc degeneration, new spondylolisthesis, disc herniation, or spinal canal stenosis at levels adjacent to the fused segments. Many surgeons suspect that the degree of stiffness of the instrumented levels relates directly to increased stress on adjacent discs and facet joints. These increased loads over time lead to segmental hypermobility, facet hypertrophy, osteophyte formation, and stenosis.

[0008] Another problem associated with current arthrodesis instrumentation is the failure of fixation of the bone screws. This problem is faced in cases of poor bone quality as in osteporotic patients. Fixation of a screw into bone is directly related to the amount of the contact area of the screw-bone interface and the quality of that contact. In other words the more direct contact there is between the bone and the surface of the screw the better the purchase or fixation. A long screw with a large diameter will provide better fixation than a short screw with a lesser diameter as a result of the larger surface contact area of the larger screw. Also the density of the bone determines the actual real contact surface between screw and bone, as bone with a high density will have more bone in direct contact with the available screw surface than bone with lower density. Thus, in patients with osteoporosis where the bone mineral density is low, there is less surface contact between the screw and bone than in patients with normal bone mineral density.

[0009] Apart from the above, other problems associated with current spine fusion instrumentation, or other orthopedic implants, relates to the loosening or breakage of the screws that are anchored into bone (Chao, C.K et al. *Increasing Bending Strength and Pullout Strength in Conical Pedicle Screws: Biomechanical Tests and Finite Element Analyses.* J. Spinal Disorders & Techniques. 2008. 21 (2): 130-138, 2008). Screw loosening generally occurs as a result of constant back and forth toggling forces acting on the screw such as would occur during regular flexion and extension motions of the spine. These forces result in the formation of a space between the bone and the screw and, eventually, displacement of the screw from the bone.

[0010] Shear stresses also are known to develop on pedicle screws after implantation. In these cases, once two adjacent vertebrae have been fused, they are often found to collapse or kyphose. In the result, the pedicle screws are subjected to shear stresses as the head portion of

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the screw is moved in a transverse direction away from the threaded portion. These stresses lead to breakage of the screws often at the connection point between the head and threaded portion.

[0011] Bone or pedicle screws currently known in the art are prone to the types of failure discussed above as they are not designed for flexibility but rather for rigidity. Examples of known pedicle screws are provided in, for example, US patent numbers 4,887,596 and 5,207,678. Some more recent screw and screw systems have been proposed to address some specific issues. For example, a cannulated pedicle screw is provided in US publication number 2007/0299450. In this reference, the pedicle screw is provided with a central cannula or canal having an opening at the distal tip of the screw. Once implanted, bone cement is injected into the cannula and into the joint between the screw and the bone.

[0012] US patent number 7,037,309 provides another cannulated pedicle screw having a self tapping distal tip. A screw of this type avoids the need for a boring hole to be provided for insertion of the screw.

[0013] US publication numbers 2005/0182409 and 2008/0015586 teach a device for dynamic stabilization of the spine and are directed to the problem of shear stresses on pedicle screws. In these references, the devices include pedicle screws that are provided with head that connects to moveable elements. In the course of regular motion, such elements are adapted to absorb compressive or expansive forces and to thereby reduce the amount of stresses translated to the screws. The moveable elements are often complicated devices as compared to the commonly known rods.

[0014] Although the above prior art examples provide improvements to specific issues, the screws taught therein all have a rigid structure. There is therefore a need for a pedicle or bone screw that would allow for the absorption and/or distribution of stresses.

SUMMARY OF THE INVENTION

[0015] In one aspect, the present invention provides a dynamic bone screw that is sufficiently flexible for absorbing forces applied thereto while providing the necessary anchoring function.

[0016] In another aspect, the screw of the invention includes a self tapping distal tip.

[0017] Thus, in one aspect, the invention provides a bone screw having a head portion, a tip portion and a helical body extending there-between.

[0018] In another aspect, the invention provides a bone screw comprising:

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- an elongate body having a first end, a second end and an open helical body portion extending there-between

- the first end being connected to a head and wherein the head is adapted for engaging elements of a prosthesis; and,

- the second end comprising an anchoring portion for entry into a bony structure.

[0019] In a further aspect, the invention provides a bone screw comprising:

- an elongate body having a first end, a second end and a body portion extending there-between;

- the body portion having an open helical structure, comprising at least one open helix, forming threads on the outer surface of the body portion, wherein spaces between the threads open into an axial bore extending through the body portion;

- the first end including a head; and,

- the second end including an anchoring portion adapted to engage bony material.

[0020] In another aspect, the invention provides a bone screw comprising:

- an elongate body having a first, proximal, end, a second, distal, end and a body portion extending there-between;

- the body portion comprising an externally threaded cylindrical rod with an axial bore extending longitudinally along at least a portion thereof;

- the first end including a head with an opening extending into the bore;

- the second end including an anchoring portion adapted to engage bony material; and,

- a first driver engaging element provided at the second end, the first driver engaging element being adapted to engage a driver for turning the bone screw.

[0021] In another aspect, the present invention provides pedicle screws.

[0022] In a further aspect, the invention provides a spinal stabilization system comprising one or more bone screws of the invention in combination with spinal stabilization prostheses, such as stabilizing rods and the like.

[0023] In a further aspect, the invention provides a method of implanting a bone screw comprising:

a) providing a bone screw having:

- an elongate body having a first, proximal, end, a second, distal, end and a body portion extending there-between;

- the body portion comprising: (i) an externally threaded cylindrical rod with an axial bore extending longitudinally along a portion of the body; or (ii) an open

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helix structure, wherein spaces between the threads open into an axial bore extending through the body portion;

the first end including a head with an opening extending into the hollow cavity;

the second end including an anchoring portion adapted to engage bony material; and,

the second end including a first driver engaging element;

b) providing a driver having a first end adapted to engage the first driver engaging element;

c) placing the second end of the screw against a bone structure;

d) rotating the driver thereby rotating the second end of the screw; and,

e) driving the screw into the bone structure.

BRIEF DESCRIPTION OF THE DRAWINGS

[0024] These and other features of the invention will become more apparent in the following detailed description in which reference is made to the appended drawings, which are described below. The drawings include reference numerals to identify like elements shown therein. In some cases, elements that are similar may be identified with the same reference numeral but with a letter suffix.

[0025] Figure 1 is a schematic plan view of a vertebra illustrating the pedicles.

[0026] Figure 2 is a cross sectional elevation of a spinal segment incorporating pedicle screws of the prior art.

[0027] Figure 3 is a side view of a pedicle screw according to one aspect of the invention.

[0028] Figure 4 is a side view of a pedicle screw in accordance with another aspect of the invention.

[0029] Figures 5 to 8 are partial side views of helical portions of the pedicle screw of the invention according to various aspects thereof.

[0030] Figure 9 is a side view of a screw of the invention (shown in phantom) in combination with a driver.

[0031] Figure 10a is an end perspective view taken from the distal end of the screw of Figure 3.

[0032] Figure 10b is a distal end view of the screw of Figure 3.

[0033] Figure 11a is a side view of screw of the invention according to another aspect comprised of multiple components in the assembled state.

[0034] Figure 11b is the screw of Figure 11a in the unassembled state.

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[0035] Figure 12 is a side view of the body portion of the screw of Figure 11a.

[0036] Figure 13 is a side perspective view of bone engaging element of the screw of Figure 11a.

[0037] Figures 14a to 14c are side perspective views of the head of the screw of Figure 11a.

[0038] Figure 15 is a top view illustrating the pedicle screw of Figure 3 implanted in a vertebra.

[0039] Figure 16a and 16c are side views of a pedicle screw and driver combination according to one aspect of the invention, shown in the assembled and unassembled states, respectively.

[0040] Figure 17 is a side view of a screw of the invention showing a helix with a variable pitch.

[0041] Figures 18 and 19 are side views of a screw of the invention showing a helix with a variable pitch and taper.

[0042] Figure 20 is a side perspective view of a bone engaging element according to one aspect.

[0043] Figure 21 is a proximal end perspective view of the bone engaging element of Figure 20.

[0044] Figure 22 is a distal end view of the bone engaging element of Figure 20.

[0045] Figure 23 is a side cross sectional view along the length of a bone screw according to another embodiment of the invention.

[0046] Figure 24 is a side view of the bone screw of Figure 23.

[0047] Figure 25 is a side cross sectional view of another embodiment of the head for use with the bone screw of Figure 23.

[0048] Figure 26 is a side view of the head of Figure 25.

[0049] Figure 27 is a side view of a combination of the bone screw of Figure 23 and the head of Figure 25.

[0050] Figure 28 is a side view of a combination of a bone screw according to another embodiment and the head of Figure 25.

DETAILED DESCRIPTION OF THE INVENTION

[0051] The invention will now be described with reference to various embodiments thereof. The following description will refer primarily to pedicle screws and to spinal stabilization.

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However, it will be understood by persons skilled in the art that the invention can be equally applied to any bone screw used in anchoring or fixation applications. Thus, the references herein to pedicle screws and/or to spinal fixation or fusion will be understood as being illustrative of a particular embodiment of aspect of the invention and are not intended to limit in any way the application of the invention in other areas of orthopedic surgery.

[0052] The invention can, for example, be used in applications involving various large bones such as the femur, tibia, fibula, ulna, etc. All references to "pedicle screws" as used herein will be understood as meaning bone screws of any type as known in the art, but adapted in the manner contemplated by the invention.

[0053] Further, unless otherwise indicated, the term "screw" will be understood to mean a unitary structure or a combination of structural units, such as a head, body and distal end, as described below.

[0054] It will be understood that the following description of the invention will be made with reference to the figures and elements shown therein and that such elements will be identified with one or more reference numerals. Unless indicated otherwise, the characteristics or features of any of the elements depicted in the figures will be understood to apply to all equivalent elements, indicted as being such, regardless of any difference in the reference numerals used to identify same. In the present disclosure, the terms "distal" and "proximal" are used to describe the screws of the invention. These terms are used for convenience only and are not intended to limit the invention in any way. As used herein, the term "distal" will be used in relation to that end of the screw of the invention that is inserted into bone. The term "proximal" will be used to refer to the opposite end of the screw that extends outside of the bone into which the screw is implanted. Thus, although these descriptive terms are used to describe the screws of the invention in reference to their placement in bone, it will be understood that the invention is not limited to screws solely when in use or solely when implanted or otherwise combined with bone.

[0055] In the present description, the terms "open helix" or "open helical structure" are used. These terms will be understood to refer to a hollow structure comprising one or more helically wound elements, resembling a "corkscrew". The helical structure forms a continuous thread to provide the screw functionality. The outer surface of such structure may include a cutting edge for assisting in the screw function. The spaces between the threads are open to a central bore.

[0056] Figure 3 illustrates a pedicle screw (or bone screw) of the invention in accordance with one aspect. As shown, the screw 10 generally comprises an elongate structure having a proximal end 11, an opposed distal end 13 and a body portion 14 extending there-between. Figure 15 illustrates the screw 10 when implanted through a pedicle in a vertebra. The proximal

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end 11 includes a head 12 of the screw, which extends outside of the bone once the screw is implanted. The head 12 may be provided with any one of a variety of configurations for use in connecting the screw to other elements of a spinal stabilization system. For example, the head 12 may be provided with a yoke for receiving a rod for spinal stabilization and a locking block for locking the rod within the yoke. Such a combination is shown, for example, in US patent number 4,887,596. Alternatively, the head 12 may be provided with any other known or desired configuration such as, for example, taught in the references mentioned above. It will also be understood that the head 12 may also be provided with a receiving means for engaging a driver or the like (i.e. a "driver engaging element") for rotating the screw during implantation as discussed further below. It will be understood that the invention is not limited to any specific design or configuration of the head 12.

[0057] The distal end 13 comprises the portion of the screw 10 that is inserted into the bone during implantation. The distal end is generally provided with an anchoring portion or tip 16 for engaging the bone into which the screw is to be implanted. It will be understood that although element 16 (and others as discussed below) is referred to as an "anchoring portion", this term is used simply for convenience. Persons skilled in the art would understand that, during implantation of the screw 10, the anchoring portion 16 is the simply the first portion of the screw to be inserted into the bone in question. Upon further implantation of the screw, it will be understood that other portions along the length thereof will engage bone and will, therefore, be "anchored" therein.

[0058] The body 14 of the screw 10 comprises, in a preferred embodiment, an open helical coil shape or a helical spring shape, thereby assuming a generally "corkscrew" structure. As can be seen in the figures, the body 14, comprises a single element or thread arranged in a helical manner. Outer surface of the body thereby forms the threads of the screw. In a preferred aspect, the outer edge of the helix includes a blade or sharpened portion for engaging the bony structure into which the screw is to be implanted. The "open" nature of the body results in a hollow core as well as openings between the threading extending into the core. The term "open helix" will be used herein to refer to the structure mentioned above.

[0059] Another embodiment of the screw of the invention is shown in Figure 4 wherein the screw 30 includes a head 32 at the proximal end 11, a body 34 and an anchoring portion 36, at the distal end 13, similar to those elements described above. However, unlike the embodiment shown in Figure 3 wherein the screw of the invention comprises a single helix, the embodiment shown in Figure 4 comprises a body 34 having two helical elements 35a and 35b, both coaxial with each other and both connected to a common head 32. By using a "double helix" structure for the body 34, the screw allows an even greater amount of surface area contact between the screw and the bone into which it is implanted. It will also be understood that the double helix

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structure also provides a screw that has greater stiffness than a single helix structure. It will be understood that, in other embodiments, a screw of the invention may comprise more than two helical elements.

[0060] The anchoring portions 16 or 36 of the screw serve to engage the bone at the site of implantation. For assisting this function, the anchoring portions may be provided with or may comprise a point for piercing and entering the bone. In another aspect of the invention the anchoring portion 16 may be provided with a bone engaging element 18 or other similar structure to assist in the implantation of the screw. In one aspect, the bone engaging element 18 may comprise a self-tapping device, such as that taught in US Patent number 7,037,309 or other similar structure that allows the screw to be self-boring into the bone upon being rotated. As will be understood, such a self-tapping or self-boring mechanism may obviate the need for separately boring a hole in the bone prior to implanting the screw. This aspect of the invention is discussed further below in relation to Figures 20 to 22.

[0061] In another aspect, as discussed further below with reference to Figure 9, the bone engaging element 18 may include a rotating means for engaging an end of a driver or the like (i.e. a "driver engaging element"). The driver may comprise any known mechanism used for implanting bone screws. In this configuration, and when the screw 10 is being implanted, the actuating end of a driver would be extended longitudinally through the center of the screw 10 and engage a cooperating structure provided by or in the rotating means of the bone engaging element 18. For example, such rotating means may comprise a hexagonal ring within the lumen of the bone engaging element 18 that is adapted to receive a cooperating hexagonal end of a driver. A driver having an actuating hexagonal head can then be inserted through the head 12 of the screw and longitudinally through the open helix of the screw. The head would then extend through and engage the hexagonal ring of the bone engaging element 18. Once engaged, rotation of the driver would serve to rotate the bone engaging element 18. Since the latter is fixedly connected to the body 14, the entire screw would thereby be rotated. It will be understood that with this arrangement, turning of the driver (not shown) will result in the screw 10 being "pulled" into the bone as opposed to being "pushed", as would be the case if the head 12 were engaged by the driver. It will be appreciated that in this version of the invention, the head 12 would preferably include a passage through which the driver would extend. Further, although the above description is provided with reference to a hexagonal nut/driver structure, any similarly functioning structure would also be usable in the invention.

[0062] As shown in Figure 9, a driver 40 is provided having a size capable of extending through an opening in the head 12. The distal end 42 of the driver 40 is extendable through substantially the entire length of the screw 10 and is adapted to engage, in one embodiment, the bone engaging element 18. In some cases, the distal end 42 of the driver may also extend

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through the bone engaging element 18. At least the distal end 42 of the driver 40 is provided with an outer surface having a geometry that functions as a drive shaft. As known in the art, the end of the driver 40 opposite to the distal end 42 may be provided with a handle or other similar structure (not shown) that facilitates rotation of the driver 40. As shown in Figures 10a and 10b, the bone engaging element 18 of the screw 10 includes an inner surface 44 having a geometry that is complementary to that of the distal end 42 of the driver. In the embodiment illustrated in Figures 9 and 10, the distal end 42 of the driver 40 and the inner surface of the bone engaging element 18 are provided with hexagonal cross section. Although such an arrangement provides an efficient means of imparting rotation force from the driver 40 to the screw 10, it will be understood that such geometry is not the sole means possible. Various other geometries will of course be known to persons skilled in the art for achieving the purpose of rotating and, thereby, driving the screw into the bone.

[0063] Although the above discussion has focused on the bone engaging element 18 being capable of engaging the driver 40, it will be understood that any similar driver engaging means or device may be provided within the body 14 of the screw 10 at either the distal end 11, the proximal end 13 or at any position there-between. Such driver engaging means may comprise an annular ring disposed co-axially within the lumen of the body 14. The outer surface of the annular ring would be secured to the inner surface of the body 14 (such as the helix portion). The inner surface of the annular ring would be provided with a geometry that is complementary to the outer surface of the driver. It will also be understood that one or more of such annular rings may be provided at various positions along the length of the body 14 or the screw 10 itself. Similarly, although reference in made to "annular rings" persons skilled in the art will understand this term to mean any type of driver engaging device. That is, a device that is capable of receiving and engaging a driver and imparting a rotational motion to the entire screw.

[0064] In a further aspect, the above described means of implanting a screw by rotation of the distal end may equally be applied to screws not having the aforementioned open helical structure. That is, the invention provides a pedicle or bone screw that comprises a solid screw similar to those known in the prior art. In this aspect, the invention provides a screw that is similar in structure to the screw 10 described above. That is, the screw would include a proximal end, with a head, an elongate body, and a distal end, preferably with an anchoring portion and/or a bone engaging element. Such screw comprises an elongate hollow or cannulated structure, wherein a central bore is provided extending through the substantial portion of the screw. The term "substantial" as used in this context refers to a bore that extends from the proximal end to at least distal end. In one case, the bore may extend through the distal end as well. The cannula of such screw is provided with a diameter that is sufficient to accommodate a driver such as that described above. The outer surface of the screw includes a thread for engaging bone upon

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being screwed into same. The distal end of the screw is provided with a driver engaging means as described above. In this manner, the screw can be implanted into a pedicle (or other bone structure) by rotating the driver and, thereby, "pulling" the screw into the bone. That is, the screw will be driven into the bone by rotation of the distal end as opposed to being "pushed" by rotating the proximal end.

[0065] In another embodiment, the screw may be rotated by applying the rotational force at the proximal end of the screw. For example, the head 12 of the screw may be adapted to be rotated as is commonly known in the art. In such an embodiment, any known means for rotating the head of known pedicle screws may be utilized in the invention. For example, the head 12 may be provided with any opening or structure to receive a cooperating driver. In one example, the head 12 may be provided with a female hexagonal opening, similar to that described above, into which a hexagonally shaped driver can be inserted or through which such driver can be extended. Rotation of the driver would then impart a rotational force to the head 12 and, thereby, to the screw 10. As indicated above, pedicle and other bone screws are commonly implanted using this approach of driving the screw via the head portion.

[0066] In yet a further embodiment, the screw of the invention may be driven by a single driver acting upon both the distal and proximal ends simultaneously. In this embodiment, the bone engaging element 18 and the head 12 may be provided with a rotating means to engage the same driver. For example, referring again to Figure 9, it can be seen that the driver 40 may be provided with a smaller outer dimension at the distal end thereof as compared to the proximal end. Thus, it is possible for both the distal 13 and proximal 11 ends of the screw 10 to be driven simultaneously by the same driver 40 if both the bone engaging element 18 and the head 12 are provided with an inner engagement means for cooperating with the outer surface of the driver. A bone engaging element 18 and head 12 that are adapted for this arrangement are illustrated in Figures 13 and 14c, respectively. In this aspect, the insertion of the driver 40 into the head 12 of the screw 10 would not impede the travel of the driver towards the distal end of the screw.

[0067] In another aspect of the above embodiment, the driver may be of a single size, adapted to engage the bone engaging element 18. The head 12 may also be provided with an engaging surface to be acted upon by the driver. However, the opening at the head 12 may be sized larger that the exterior surface of the driver. In order for the driver to actuate the head, a sizing collar having, for example, inner and outer hexagonal surfaces adapted to fit over the driver and within the opening of the head 12, may be slid over the driver and be trapped within the opening in the head. In this way, the driver may be used to initially rotate only the distal end of the screw and, later and/or when necessary, rotate both the distal and proximal ends. As will be understood, various other combinations of this feature may be used so as to drive the screw in a desired manner.

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[0068] A further embodiment of the invention is illustrated in Figure 16a, which shows, in combination, a screw 10, as described above, and an awl 60 that serves the function of the aforementioned driver. Figure 16b illustrate the combination when separated. As shown in Figures 16a and 16b, the awl 60 includes a handle 62 and at least a hexagonal outer portion 62 at its distal portion or its proximal (i.e. handle) portion. In this way, the awl 60 can engage a cooperating opening in the head 12, the bone engaging element 18, as described above, or a combination of the two. As shown in Figures 16a and 16b, the awl 60 further includes a distal tip 64 that extends beyond the bone engaging element 18 when the screw 10 is combined with the awl prior to implanting the screw 10. The distal tip 64 may be provided with a point and/or a cutting edge, thereby allowing the awl to function as a piercing tool to facilitate positioning of the screw during implantation. Alternatively, the distal tip 64 may serve as a drill bit or drilling mechanism, to provide a borehole drilling function during implantation of the screw 10. Thus, as will be understood, the combination of the awl and the screw, as shown and described, allows the surgeon to combine the screw 10 with the awl 60 and, by rotating the awl, to implant the screw 10 in one step. Once implanted, the awl may be extracted.

[0069] The screw of the invention may be manufactured as a unitary body or multiple, separate sections that are then assembled or connected to form the screw. In one embodiment, the screws of the invention may be machined from a hollow rod, such as a titanium rod (or a rod from any material acceptable for implantation).

[0070] In another embodiment, as shown in Figures 11a and 11b, the screw of the invention 10 may be formed of three separate elements namely, a body 14, a bone engaging element 18, located at the distal end 13, and a head 12, located at the proximal end 11. Figure 11a shows these components in the assembled state wherein they are joined to form the screw 10. Figure 11b shows these components in an unassembled or exploded form. The components forming the screw may be joined by various means as known in the art. For example, the components may be joined by welding (such as, for example, using a solid state or "cold welding" process, or a fusion welding process), by a friction fit or by any other metal connecting methods. In one aspect, the body 14 may be provided with reinforced terminal ends 44 and 46, for attaching the head 12 and the bone engaging element, respectively. In such case, the head 12 and the bone engaging element 18 would be provided with stems shown at 48 and 50, respectively, which are preferably insertable into respective reinforced terminal ends 44 and 46 of the body 14. This arrangement would provide a desired contact surface area for securing the components together. In one aspect, the respective reinforced end of the body and the stems 48 and 50 may be provided with cooperating threading on opposing surfaces so as to allow each of the head and the bone engaging element 18 to be screwed on to the body 14. It will be understood that this

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manner of assembly may be used with a body that comprises a threaded cylinder as opposed to an open helix.

[0071] Figure 13 illustrates the bone engaging element 18 as well as the preferred hexagonal lumen 51 for engaging the distal end of a driver. Figures 14a to 14c illustrate variations in the head 12. In figure 14a, for example, the head 12 is designed to receive the rod of a known spinal stabilizing structure. Figure 14c illustrates a head 12 having a hexagonal shaped lumen adapted to receive a correspondingly hexagonal shaped driver. As discussed above, this form of the head 12 may be used for screws that are driven exclusively or partially from the proximal end of the screw.

[0072] Figures 20 to 22 illustrate a further embodiment of the bone engaging element, identified as 80, that is adapted to provide a bone cutting function as well. In this case, the bone engaging element may be referred to as a bone cutting edge or element. As described above, such bone cutting function may serve, in one aspect, to allow the screw to be "self tapping" or "self boring". That is, rotation of the screw comprising such bone engaging element 80 would serve to drill the bone in contact therewith. This would allow the screw to be driven into the bone without the need for a borehole being provided. Alternatively, the bone engaging element 80 may equally be used with the provision of a borehole and wherein such element 80 serves to adapt the size of the borehole to accommodate the screw to which it is attached. In such cases, it will be understood that the borehole may serve as a "pilot hole" to assist in guiding the screw into the bone at or to a specific location. As shown in Figure 20, the bone engaging element 80 is provided with a distal end 82 and a proximal end 84. As will be understood, the terms "distal" and "proximal" will have the same meanings as provided above. The distal end 82 functions as a cutting edge by means of a plurality of cutting elements 86 extending generally axially away in the proximal to distal direction. The cutting elements 86 may comprise any shape or orientation sufficient to function in cutting bone. Various modifications of the cutting edge will be apparent to persons skilled in the art. In one example, as illustrated in Figure 20, the cutting edge may be formed by cutting notches, such as "V" shaped notches 88, into the distal end of the bone engaging element 80. To further assist in the cutting function of the element 80, longitudinally extending grooves 90 may be provided over the length of the element 80. As illustrated in Figure 20, the bone engaging element 80 is shown as a separate element from the body of the screw. However, it will be understood that the same cutting edge as shown may equally be provided on a screw having a unitary structure. Figure 20 illustrates the bone engaging element 80 having a stem 50, similar to that described above, which serves to attach such element 80 to a helical body portion when forming the screw of the invention.

[0073] Figures 21 and 22 illustrate an embodiment of the bone engaging element 80 having a lumen 51 for receiving a driver (not shown) as described above. In the embodiment illustrated,

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the lumen 51 is provided in a hexagonal shape, adapted to receive a complementary shaped driver and, thereby, function as a driver engaging means or device, as discussed previously. As described above, various other geometries would be possible for achieving the desired coupling between the screw and the driver. Figures 21 and 22 also illustrate the lumen 51 extending completely through the length of the element 80. Such a structure would, for example, be adapted to receive a driver completely there-through. In such example, the driver may comprise an awl as described above in reference to Figures 16a and 16b. As will be understood, the combination of an awl having a cutting tip, as described above, and a bone engaging element 80, having a cutting edge at its distal end 82, may allow the screw of the invention to be implanted into bone without the need for a borehole or pilot hole. That is, during implantation, the awl may be first coupled to a screw, having the bone engaging element 80, and can then be used to create an initial hole into the bone. The cutting edge of the bone engaging element 80 would then serve to increase the diameter of such hole to accommodate the body of the screw. As indicated above, the rotation of the awl will cause rotation of the screw as well due to the coupling between the driver and the screw.

[0074] Figures 20 to 22 illustrate the bone engaging element 80 having a lumen 51 adapted to function as a driver engaging means, that is, adapted to receive and be rotated by a driver. However, as discussed above, the driver engaging means can be provided at one or more other sections along the length of the screw.

[0075] As will be understood by persons skilled in the art upon reviewing the present description, the screw of the present invention offers a number of advantages. For example, it will be appreciated that the body 14 of the screw, due to its open helical structure, allows for an increased amount of screw surface area that contacts the adjacent bone. That is, as compared to known screws comprising a solid rod with a threaded outer surface, the screw of the invention allows a greater surface area of the "thread" to contact bone tissue. This therefore increases the total amount of the screw that contacts bone upon implantation. Further, the open helical structure of the invention also enables bone to grow through the body of the screw thereby increasing the degree of grip by which the screw is held within the bone. In another aspect, the interior of the screw may be filled with various compositions known in the art for promoting or enhancing bone in-growth and/or bone cementing compositions. For example, the interior may be filled with bone cementing or substitution substances, such as poly(methyl methacrylate) (PMMA), substances for inducing or enhancing bone growth, such as bone morphogenetic proteins (BMPs), or any combination(s) thereof. In such cases, it will be understood that the open nature of the screw of the invention facilitates the incorporation of such compositions.

[0076] In addition, the open helical structure also provides the screw with a degree of elasticity thereby allowing, for example, the head region of the screw to be laterally displaced or

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bent in relation to the body. As mentioned previously, studies of prior art pedicle screws have found that a high shear stress is developed at the junction of the head and the screw body post implantation. Thus, as discussed above, in cases where, after implantation, adjacent vertebral structures are displaced, the helical structure of the screw would be capable of withstanding the stresses applied thereto.

[0077] As discussed above in reference to Figure 4, the screw of the present invention may comprise one or more helixes combined together to form the body. Various figures of the present application depict a single helix structure while Figure 4 illustrates a double helix structure. As mentioned above, a multi-helix structure is also encompassed within the scope of the present invention. In a further aspect of the invention, a "hybrid" structure for the screw is contemplated though not shown in the figures. In such structure a portion of the length of the screw may comprise a solid cylinder that is typical of known bone screws, while the remaining portion comprises an open helical structure as taught herein. With this type of hybrid structure, the screw, where solid, would be provided with a stiffer portion as compared to the open helix portion. Thus, in one embodiment, the open helix portion may comprise only that portion of the screw that is implanted while the portion of the screw that is left outside of the bone or that comprises the proximal end comprises a solid screw. As will be understood, with such a structure, the portion that is implanted in bone will benefit from the advantages of an open helix structure as described above, while the portion of the screw that is external of bone, is provided with greater stiffness so as to improve its function, for example, in supporting the spinal stabilization system. Similarly, a portion of the proximal end of the screw may be formed as a solid but threaded section, while the body and distal portions are formed in the aforementioned open helical structure.

[0078] Figures 5 to 8 illustrate various different structures for the helix that forms the body of the screw. As will be noted, the screw of the invention may be provided with a threading of any type of profile configuration as will be apparent to persons skilled in the art. The term "profile configuration" is meant to describe various characteristics of screw threading as known in the art such as, *inter alia*, pitch, thread width, diameter (inner and outer), angular deflection of threading etc. It will also be appreciated that the invention is not limited to any one of the aspects described above and that any combination thereof may be used.

[0079] One example of the variability in the pitch of the thread forming the helical screw body is illustrated in Figure 17. As shown, in one aspect of the invention, a screw 10 comprises a proximal end 11, including a head 12, and a distal end 13 including a bone engaging element 18, similar to those described above. However, in this aspect of the invention, the body 70 is provided with an open helical structure that varies in "pitch", or the spacing of the threads comprising the helix as measured along the longitudinal axis of the screw. As will be understood,

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the pitch of the helix is deemed to be lower at a given point than another when the number of threads per unit length is higher at such point (i.e. the spacing between adjacent threads is lower). In the screw shown in Figure 17, it is noted that the pitch of the helix is lower towards the distal end 13 of the screw as compared to the proximal end 11. As will be understood by persons skilled in the art, a helix having a lower pitch would provide the helix with greater stiffness. Thus, in the example illustrated in Figure 17, the distal portion of the helix, by being provided with a lower pitch, would be stiffer than the proximal portion, which has a higher pitch. In addition, it will be understood that a single rotation of the screw shown in Figure 17 will result in a difference in screw surface to bone contact as between the distal and proximal ends. For example, in the case of the screw shown in Figure 17, with one rotation thereof, the portion of the helix at the distal end 13 will rotate to a greater degree than the portion at the proximal end 11 as a result of the difference in pitch. As will be understood, a screw according to the invention can be provided with the aforementioned pitch reversed, thereby resulting in the proximal portion of the screw being stiffer than the distal portion. It will also be understood that a number of variations in the pitch of the helix may be provided in order to provide the resulting screw with any desired variation in stiffness along its length or at certain discrete sections. The present invention is not limited to any one pitch or pitch design.

[0080] A further aspect of a screw according to the invention is illustrated in Figure 18 wherein a screw 10 is provided with a body 72 having a variable pitch helix as described above. That is, the pitch of the helix at a region of the distal end 13 is less than the pitch at a region of the proximal end 11. However, in this embodiment, the screw is also provided with a taper wherein the diameter of the screw at the distal end 13 is less than the diameter at the proximal end 11. Such variability in diameter along the longitudinal axis also serves to vary the stiffness characteristics of the screw. It will be understood that any degree of taper, or lack thereof, may be used with the screws of the invention. Figure 19 illustrates a variation of the screw 10 wherein the portion of the screw body 74 at the distal end 13 is provided with a greater diameter than the portion at the proximal end 11.

[0081] The screws and screw components of the present invention can be made of any material as will be known to persons skilled in the art. For example, the elements of the invention may be made of: metals or metal alloys such as stainless steel, titanium, titanium alloys, nickel-titanium alloys (such as Nitinol™), cobalt-chrome alloys; plastic and/or thermoplastic polymers (such as PEEK™); carbon fiber; or any other material, or combination of materials, commonly associated with bone screws. It will also be understood that the surface of the screws and screw components of the invention may optionally be coated with any known substances for improving their placement or adhesion within the bone. For example, in one embodiment, the outer surface of the screw, or at least that portion that will be in contact with

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bone after implantation, may be coated with hydroxyapatite to promote osseointegration of the screw and, thereby, inhibit or prevent screw pullout.

[0082] The open helical structure of the invention allows for the screw to be compressed or expanded prior to insertion into the bone. For example, as discussed above in reference to Figure 9, in one embodiment, the driver 40 is inserted axially into the lumen of the open helix screw 10, extending through the head 12, to engage the bone engaging element 18. In such embodiment, the proximal portion of the driver can engage the head 12 as well. In such orientation, rotation of the driver drives rotation of the screw at both the distal and proximal ends. However, in addition to such dual rotation, it is also possible to apply a distracting force through the driver 40 so as to slightly lengthen or stretch the helix of the screw along its longitudinal axis. In such state, when the distracted screw is placed into, for example, a fractured bone the release of the distracting force through the driver, and the resilient characteristic of the helix, will force the screw to return to its original state. This tendency will cause the screw to shorten in the bone thereby resulting in compression of the fractured fragments against each other. Such compressive state is known to enhance bone healing. It will be understood that, in a similar manner, the screw of the invention can be compressed prior to implantation, thereby serving to provide a distractive force on the bone when implanted.

[0083] In a further aspect, the driver 40 may be used to "unwind" or "wind-up" the helix of the screw to provide the aforementioned compressive of distractive forces. In this aspect, one end of the screw would be held stationary, preferably when loaded on the driver, while the opposite end is rotated. As will be understood, such rotation of one end results in a twisting or torquing of the screw. In the result, the screw will be pre-loaded with either a compressive or distractive force prior to implantation. When the driver is removed, after implantation of the screw into the bone, the helix will tend to resume its normal shape thereby imparting the desired forces between the distal and proximal ends of the screw. Various methods may be used to twist the screw. For example, in one aspect, the driver may be provided with a means to rotate the head of the screw in either direction while preventing rotation of the distal end. As discussed above, one aspect of the invention provides for the distal ends of the driver and the screw to be complementary in shape (e.g. hexagonal) and, in such arrangement, it will be understood that this would be one way of preventing rotation of the distal end of the screw.

[0084] A further aspect of the invention is illustrated in Figures 23 to 28 wherein a unique combination of separate screw and head is illustrated. In this aspect, the screw 100 is generally the same as that described previously. In particular the screw 100 includes a proximal end 102, a distal end 104 and a body portion 106 extending there-between. In one embodiment, the body portion 106 comprises a hollow structure having a central bore 108. In the embodiment shown in Figure 23, the body portion 106 comprises an open helical structure, as described above,

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composed of one or more helical elements arranged to form the threading of the screw. Again, by "open helical structure" or "open helix" it is meant that the spaces between each thread are open to a central bore 108 of the screw, similar to a "corkscrew". As described previously, the distal end 104 is adapted to engage bony material during the implantation step. For this purpose, the distal end 104 may be provided with a bone engaging element 110, such as described above. Alternatively, particularly in the case where the body portion 106 is an open helix, the distal end 104 may comprise a sharpened ends of the one or more helical elements.

[0085] In the embodiment of the invention as illustrated in Figures 23 and 24, the head 112 of the screw 100 comprises a generally cylindrical hollow body having a first, distal end 114 that cooperates with and engages proximal end 102 of the screw 100. For example, in the embodiment shown, the internal bore of the distal end 114 of the head 112 is provided with threads 116 that cooperate with the threads formed or provided at the proximal end 102 of the screw. In this manner, the head 112 can be threaded onto the proximal end 102 of the screw 100 and positioned at any location along the length thereof.

[0086] As shown in Figure 24, the head 112 of the illustrated embodiment may be preferably provided with a slot 118 extending there-through. The slot 118 is adapted to receive a rod 120 or other such apparatus typically used for spinal stabilization as known in the art. The internal bore of the second, or proximal end 115 of the head 112 would also preferably be provided with threads that are adapted to receive a locking nut 122. The locking nut 122 would typically have a bearing end 123 and a driving end 124. The bearing end 123 is adapted to bear against the outer surface of the rod 120 and thereby secure the head 112 to the rod 120 once the desired relative positioning has been established. The driving end 124 of the locking nut 122 may be adapted in any manner to receive a driving tool. For example, as shown in Figure 24, the driving end 124 may be provided with a hexagonal shape to receive a suitably shaped tool. It will be understood that the configuration of the driving end 124 is variable.

[0087] One advantage of the embodiment shown in Figures 23 to 28 lies in the adjustable positioning of the head 112 with respect to the screw 100. With known bone screws, such as pedicle screws and the like, the heads provided on such screws are generally fixed to the end of the screw shaft. Such design does not allow for adjustment of the head position. However, with the embodiment of Figures 23 to 28, the head 112 may be rotated or threaded to any position along the length of the screw 100. Once a desired position is reached, the head may be fixed to the screw 100 using a variety of methods. For example, the head may be secured or fixed to the screw 100 using a cold welding method or the head may be retained in position by a friction fit. Alternatively, any other means such as adhering etc. can be utilized for this purpose. Further, since the head 112 is threaded onto the screw 100, the amount of contact surface area between the head and the screw is large.

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[0088] The locking nut 122 also serves to "lock" the screw 100, head 112 and rod 120 together. More specifically, as will be understood, a screw-rod spinal stabilization construct is formed when a screw 100, which comprises the bone anchoring device, secured to one vertebra is connected to another screw secured to an adjacent vertebra by means of a link. In one aspect, the link comprises the rod 120. To provide for a stable construct the screw-rod connection should preferably be rigid and not allow for any movement once the construct is "locked". The head 112 serves to secure the screw 100 to the rod 120. As discussed above, this may be accomplished by a cold weld or a friction fit between the head 112 and screw 100 interface. A locking nut 122 may then be screwed onto the head 112 to secure the rod 120 to the head 112 and thereby to the screw 100. Such a "friction fit" may be accomplished by tightening of the locking nut 122. Such tightening increases the friction between the contact surfaces of the screw 100 and head 112. Further, since the rod 120 prevents further rotation of the head on the screw, the positioning of the head would be fixed. In addition, where the screw 100 comprises an open helix (i.e. a shaft-less screw) it is possible, according to the invention, to compress the portion of the screw thread contained within the slot 118 of the head 112. By compressing this portion of the screw thread, it will be understood that the head 112 is tightened against the screw 100. Furthermore, the force applied by tightening the locking nut 122 also serves to pull the head 112 against the rod 120. This therefore serves to essentially "lock down" the construct providing rigid fixation.

[0089] In another aspect, the sizing of the thread 116 provided on the head 112 can be tailored. For example, where the thread 116 closely or exactly corresponds to the threading provided on the screw 100, it will be understood that very little relative movement between the head 112 and the screw 100 is possible. Such an orientation results in a fixed angle screw. However, in some cases, it may be desired for the angle of the head to be adjusted along various axes. In such case, the thread 116 of the head 112 may be sized to allow a degree of relative movement between the head 112 and the screw 100. Such an orientation would be advantageous when considered against some known devices such as that taught in US patent no. 7,314,467 wherein a system comprising a plurality of head designs are required depending on the angle required to receive a spinal stabilization rod.

[0090] Figures 25 to 28 illustrate another embodiment of the head, identified as element 112a, which comprises a shorter distal end 114. That is, the amount of threading 116 provided on the head 112a to engage the screw 100 is less than that of the embodiment shown in Figures 23 and 24. In the result, the head 112a would be able to rotate more easily with respect to the screw 100 in a multiaxial manner. To further assist such movement, the threading 116 of the head 112a may also be rounded somewhat to allow a degree of relative mobility between the head 112a and the screw 100. In addition, the distal end of the slot 118 may also be provided

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with a curved surface such as that shown as element 128 in figures 25 and 26. These features, either individually or in combination, allow the head 112a to "wobble" with respect to the screw 100 until such time as it is locked in position as described previously. This therefore allows the head to be positioned as needed to receive the rod prior to being locked.

[0091] In the above description with respect to Figures 23 to 28, it will be understood that the body 106 and distal end 104 of the screw 100 may assume any of the aforementioned orientations. In a similar manner, although the above description has referred to the body of the screw being an open helix, it will be appreciated that the unique head 112 of the invention may be used with a solid screw as well. This feature is illustrated in Figures 27 and 28. As will be appreciated, the advantages offered by the head 112 or 112a, as described above, would apply equally to a screw having the aforementioned open helical shape (Figure 27), a solid screw (Figure 28) or a cannulated screw (not shown). As known in the art, a cannulated comprises screw shaft having a longitudinal bore.

[0092] As can be seen in comparing Figures 27 and 28, the manner in which the rod 120 is locked to the screw and head combination is generally the same.

[0093] As discussed above, a further advantage offered by the embodiment of Figures 23 to 28 is that the height of the head 112 could also be adjusted. This provides flexibility in instances where the anatomy might require it. This technique of fixation could be used for not only the open helix screws (or shaft-less screws) but also solid shaft or cannulated screws. As will be understood, in the latter case, the screw thread would not be compressible; however, the rod will still be compressed between the sold shaft of the screw and the locking nut 122. This technique would be useful for reducing spondylolisthesis.

[0094] In Figures 23 to 28, the head 112, 112a is shown as being "open" at the proximal end (which receives the locking nut 122). That is, the slot 118 is illustrated as extending completely through the proximal end. However, it will be understood that the invention is not restricted to such structure. It will be appreciated, for example, that the proximal end may be "closed" thereby providing the slot 118 with a desired finite length. The "open" proximal end would be understood to have the advantage of being able to receive a rod 120 axially into the slot 118. In the case of a "closed" proximal end, it will be understood that the rod 120 would need to be inserted or fed through the slot opening.

[0095] In another embodiment of the invention shown in Figures 23 to 28, the outer surface of the head 112, 112a may be provided with a threaded region 130 over which a screw cap (not shown) or other such element may be secured. In one aspect, the threaded region 130 may be provided only at the proximal end of the head so that the cap may be screwed over the outer surface of the head 112, 112a. As will be appreciated, including such a cap will serve to close

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and/or reinforce the proximal opening of the head and may also serve to prevent dislodging of the locking nut 122. It will be understood that the screw cap, or closure, can assume any shape to serve this purpose.

[0096] Although the invention has been described with reference to certain specific embodiments, various modifications thereof will be apparent to those skilled in the art without departing from the purpose and scope of the invention as outlined in the claims appended hereto. Any examples provided herein are included solely for the purpose of illustrating the invention and are not intended to limit the invention in any way. Any drawings provided herein are solely for the purpose of illustrating various aspects of the invention and are not intended to be drawn to scale or to limit the invention in any way. The disclosures of all prior art recited herein are incorporated herein by reference in their entirety.

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WE CLAIM:

1. A bone screw comprising:

- an elongate body having a first end, a second end and a body portion extending therebetween;

- the body portion having an open helical structure, comprising at least one open helix, forming threads on the outer surface of the body portion, wherein spaces between the threads open into an axial bore extending through the body portion;

- the first end including a head; and,

- the second end including an anchoring portion adapted to engage bony material.

2. The bone screw according to claim 1 further comprising a first driver engaging element provided at the second end, said first driver engaging element being adapted to engage a driver for turning the bone screw.

3. The bone screw according to claim 2 wherein the head includes an opening extending into the axial bore of the body portion.

4. The bone screw according to claim 3 further comprising a second driver engaging element provided within the head, said second driver engaging element being adapted to engage the driver for turning the bone screw.

5. The bone screw according to any one of claims 1 to 4 wherein said second end includes a bone cutting edge or element, for boring into bone during implantation.

6. The bone screw according to claim 5 wherein said second end includes a self-tapping element.

7. The bone screw according to any one of claim 1 to 6 wherein the body portion, the first end and the second end form a unitary structure.

8. The bone screw according to any one of claim 1 to 6 wherein said screw is formed of one or more sections comprising the body portion, the first end and the second end, and wherein such sections are adapted to be connected or joined together.

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9. The bone screw according to any one of claims 1 to 8 wherein a segment of the body portion adjacent at least one of the first or second ends comprises a solid, externally threaded cylinder, wherein spaces between the threads are closed.

10. The bone screw according to any one of claims 1 to 9 wherein the head includes an axial bore with an internal thread and wherein said internal thread cooperates with the threads of the body portion, whereby the head is adapted to be secured to the body portion.

11. The bone screw according to any one of claims 1 to 10 wherein the position of the head is adjustable axially along the length of the body portion.

12. The bone screw according to claim 11 wherein the head includes a threaded opening cooperating with the threading of the body portion.

13. The bone screw according to claim 12 further comprising a locking nut to lock the head in position with respect to the body portion.

14. The bone screw according to claim 13 wherein the head includes a cylindrical, threaded external surface adapted to receive a screw cap.

15. The bone screw according to claim 11 wherein the head is moveable along one or more axes with respect to the body portion.

16. The bone screw according to any one of claims 1 to 15 wherein said screw comprises a pedicle screw.

17. The bone screw according to claim 16 wherein said head is adapted to connect to a spinal stabilization prosthesis.

18. A bone screw comprising:

- an elongate body having a first, proximal, end, a second, distal, end and a body portion extending there-between;
- the body portion comprising an externally threaded cylindrical rod with an axial bore extending longitudinally along at least a portion thereof;
- the first end including a head with an opening extending into the bore;
- the second end including an anchoring portion adapted to engage bony material; and,

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- a first driver engaging element provided at the second end, said first driver engaging element being adapted to engage a driver for turning the bone screw.

19. The bone screw according to claim 18 further comprising a second driver engaging element provided within the head, said second driver engaging element being adapted to engage the driver for turning the bone screw.

20. The bone screw according to claim 18 or 19 wherein said second end includes a bone cutting edge or element, for boring into bone during implantation.

21. The bone screw according to claim 20 wherein said second end includes a self-tapping element.

22. The bone screw according to any one of claim 18 to 21 wherein the body portion, the first end and the second end form a unitary structure.

23. The bone screw according to any one of claim 18 to 21 wherein said screw is formed of one or more sections comprising the body portion, the first end and the second end, and wherein such sections are adapted to be connected or joined together.

24. The bone screw according to any one of claims 18 to 23 wherein the head includes an axial bore with an internal thread and wherein said internal thread cooperates with the threads of the body portion, whereby the head is adapted to be secured to the body portion.

25. The bone screw according to any one of claims 18 to 24 wherein said screw comprises a pedicle screw.

26. The bone screw according to claim 25 wherein said head is adapted to connect to a spinal stabilization prosthesis.

27. The bone screw according to any one of claims 18 to 26 wherein the position of the head is adjustable axially along the length of the body portion.

28. The bone screw according to claim 27 wherein the head includes a threaded opening cooperating with the threading of the body portion.

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29. The bone screw according to claim 28 further comprising a locking nut to lock the head in position with respect to the body portion.

30. The bone screw according to claim 29 wherein the head includes a cylindrical, threaded external surface adapted to receive a screw cap.

31. The bone screw according to claim 27 wherein the head is moveable along one or more axes with respect to the body portion.

32. The bone screw according to any one of claims 18 to 31 wherein said screw comprises a pedicle screw.

33. The bone screw according to claim 32 wherein said head is adapted to connect to a spinal stabilization prosthesis.

34. A spinal stabilization system comprising one or more bone screw according to any one of claims 1 to 33 and spinal stabilization prostheses adapted to be connected to said screws.

35. The system according to claim 34 wherein said bone screws are pedicle screws and wherein said prostheses are spinal stabilization rods.

36. A method of implanting a bone screw comprising:

a) providing a bone screw having:

- an elongate body having a first, proximal, end, a second, distal, end and a body portion extending there-between;
- the body portion comprising: (i) an externally threaded cylindrical rod with an axial bore extending longitudinally along a substantial portion of said body; or (ii) an open helix structure, wherein spaces between the threads open into an axial bore extending through the body portion;
- the first end including a head with an opening extending into the hollow cavity;
- the second end including an anchoring portion adapted to engage bony material; and,
- the second end including a first driver engaging element;

b) providing a driver having a first end adapted to engage the first driver engaging element;

c) placing the second end of the screw against a bone structure;

d) rotating the driver thereby rotating the second end of the screw; and,

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e) driving the screw into the bone structure.

37. The method according to claim 36 wherein the head includes a second driver engaging element for receiving said driver and wherein step (d) comprises rotating the first and second ends of the screw.

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FIG. 1

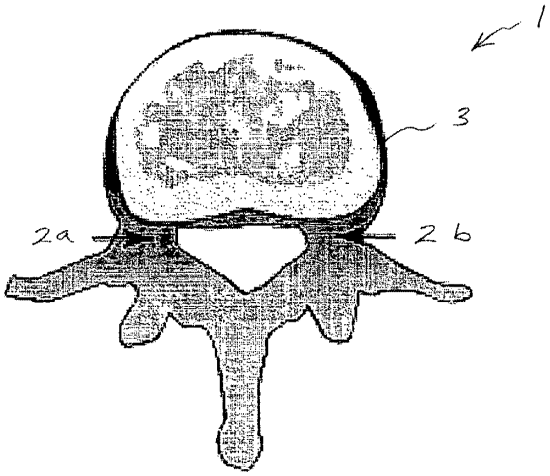
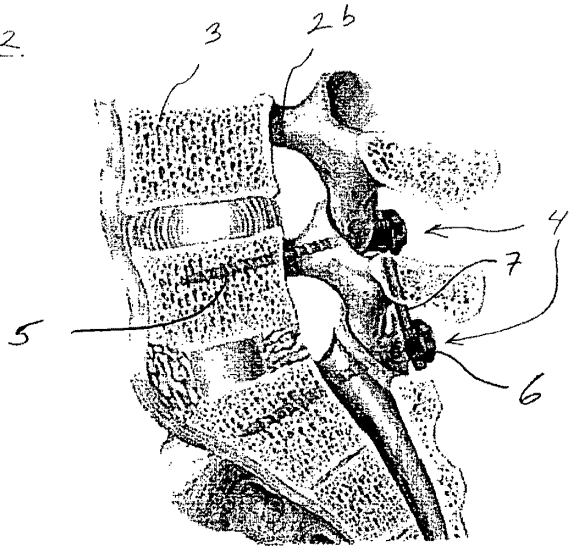


FIG. 2



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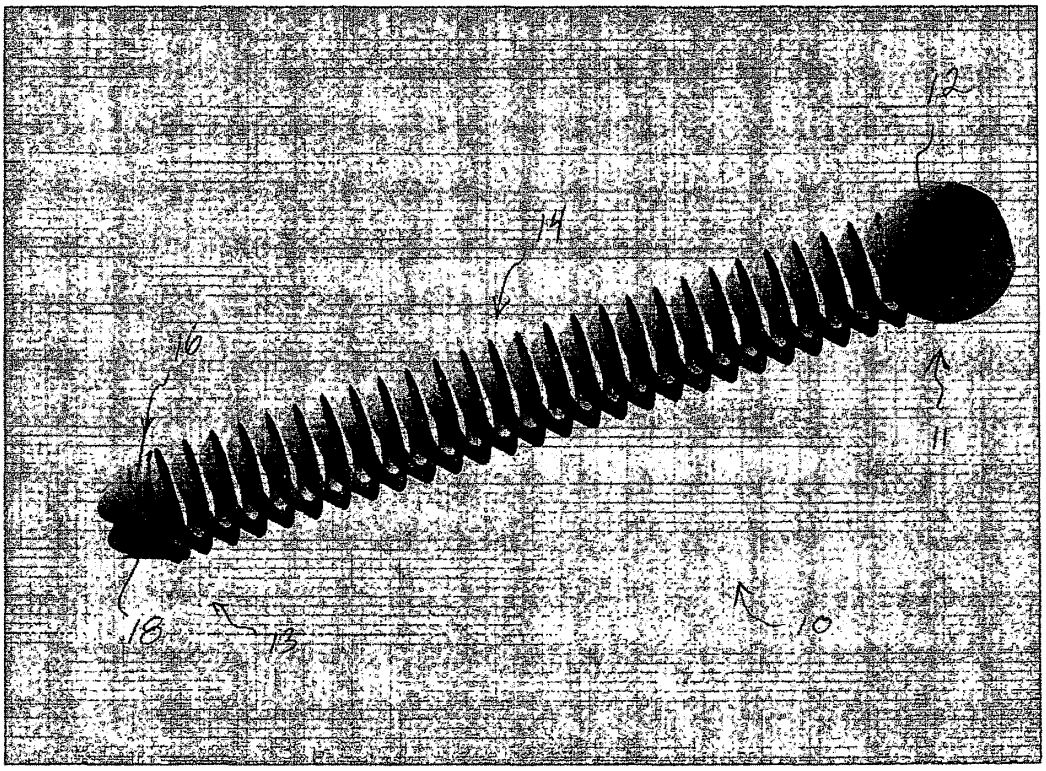


FIG. 3

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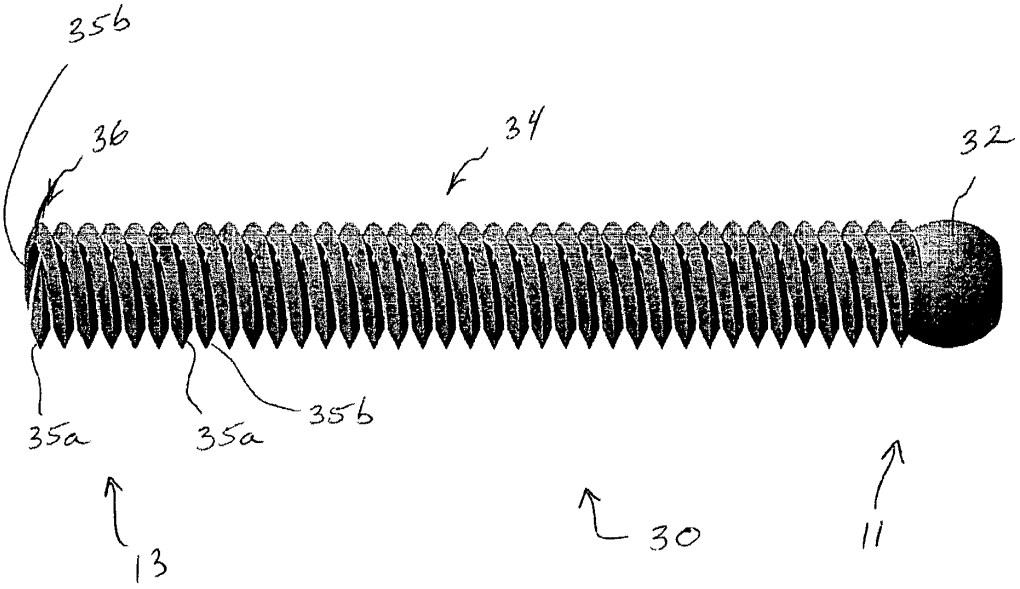


FIG. 4

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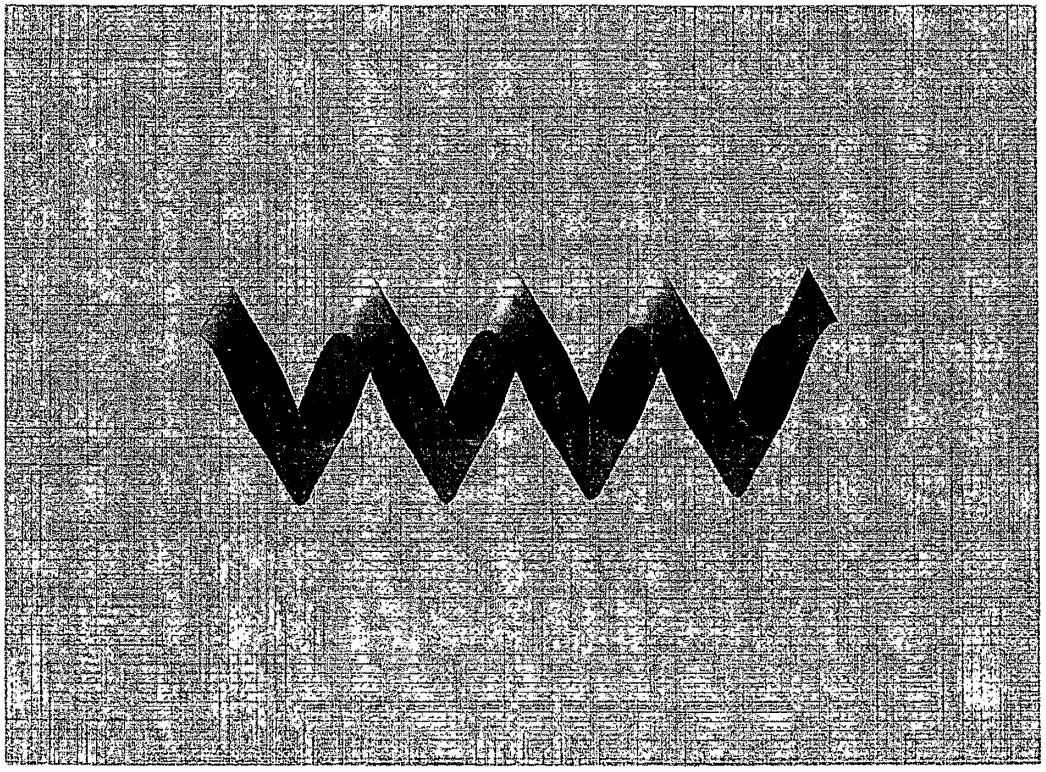


FIG. 5

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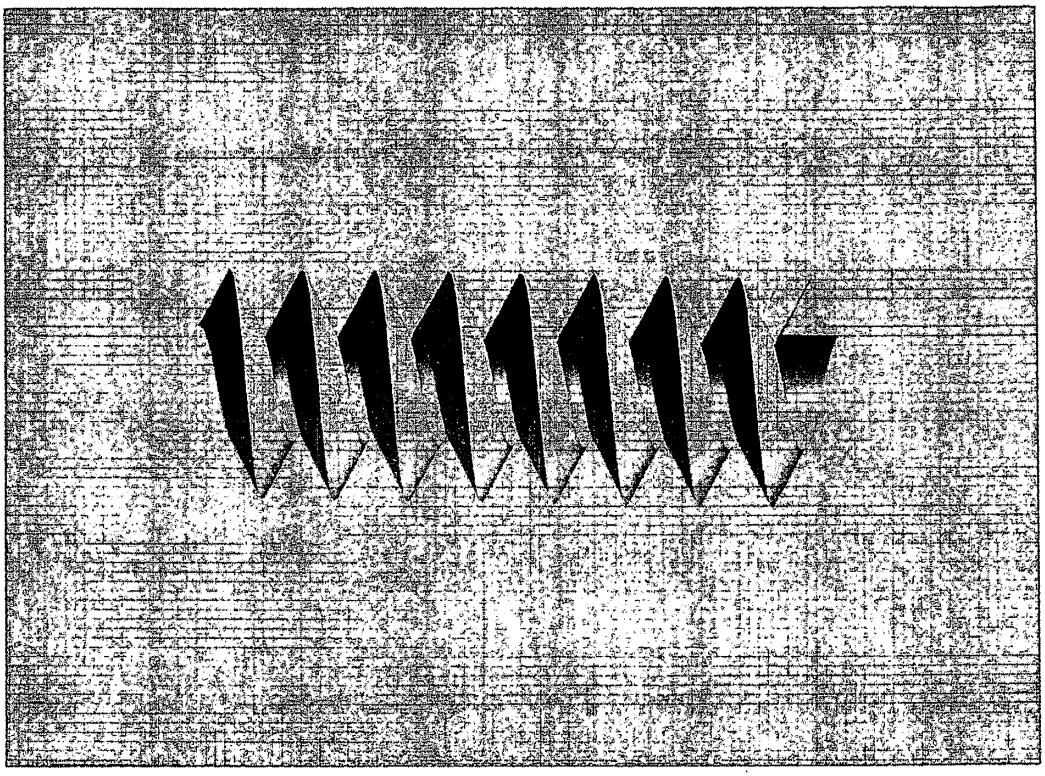


FIG. 6

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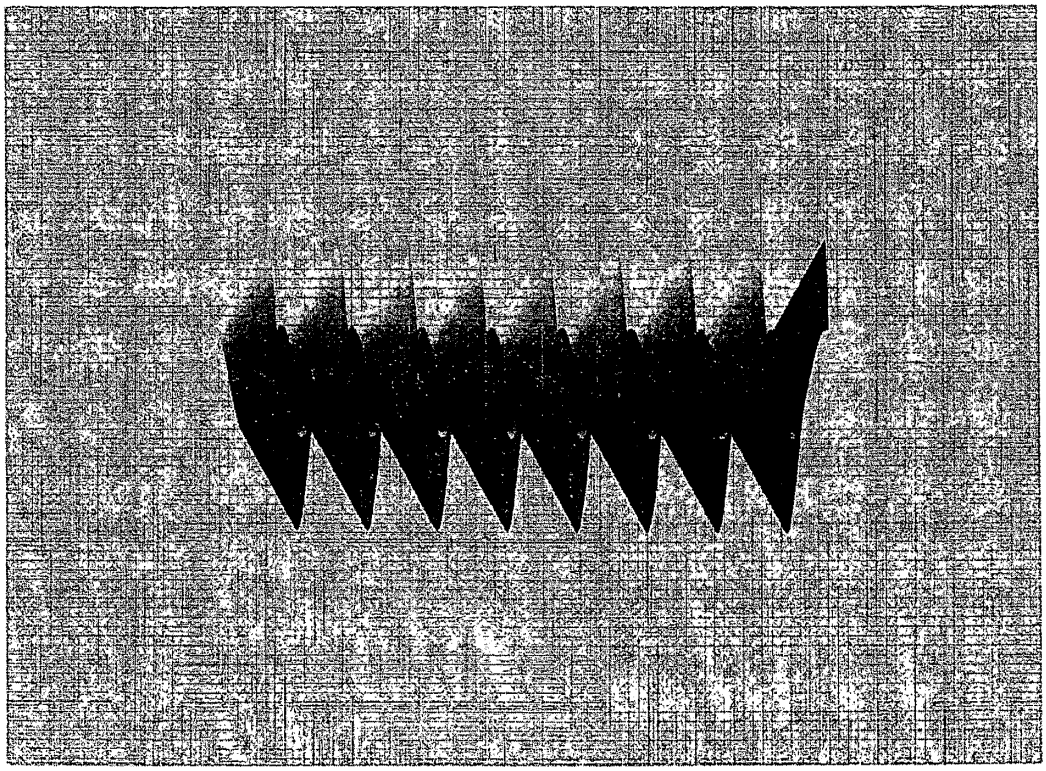


FIG. 7

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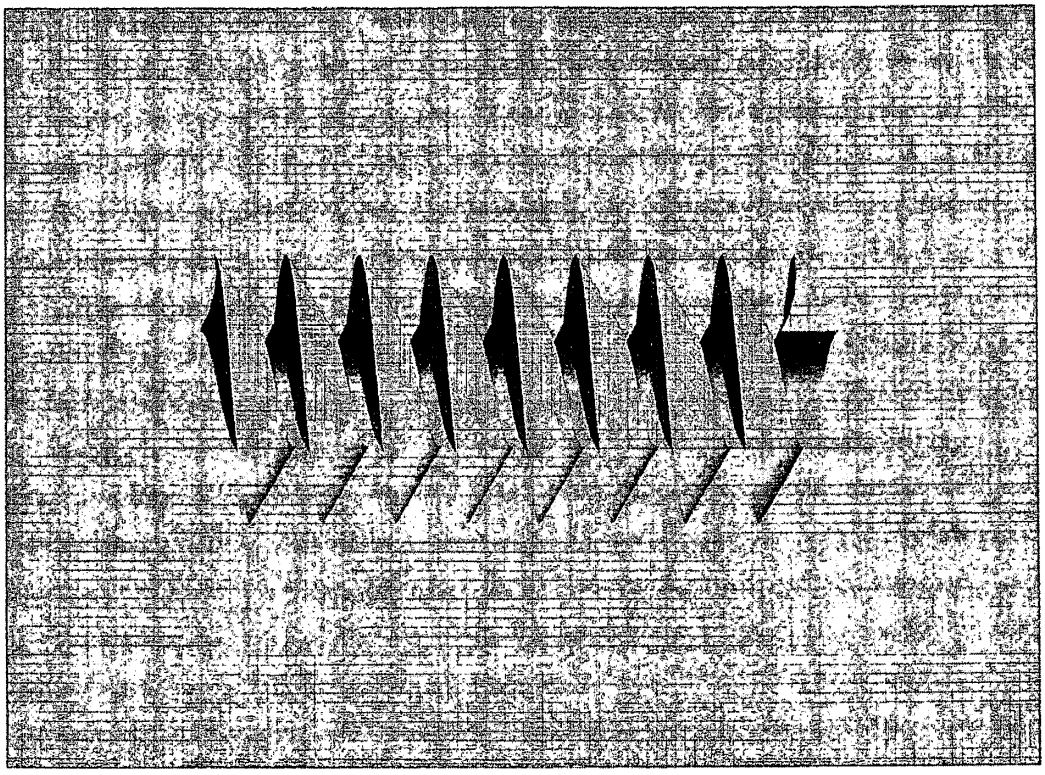


FIG. 8

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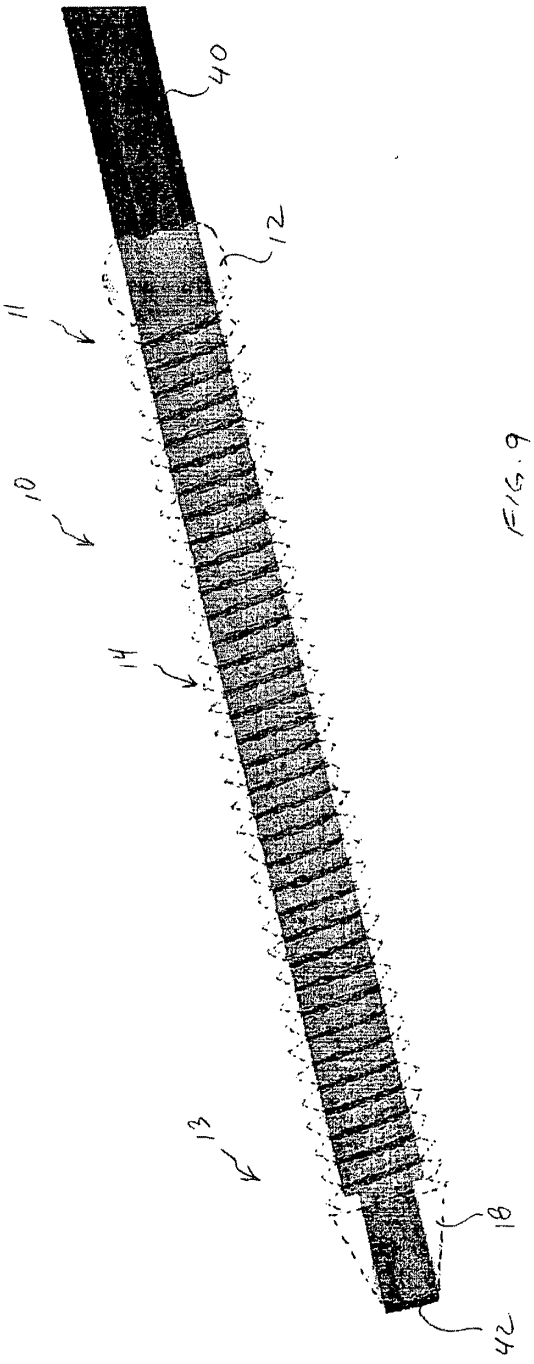


FIG. 9

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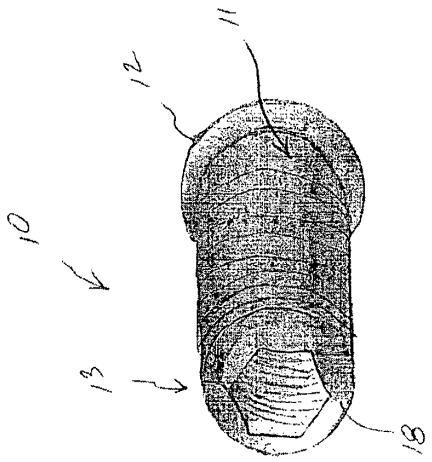


FIG. 10a

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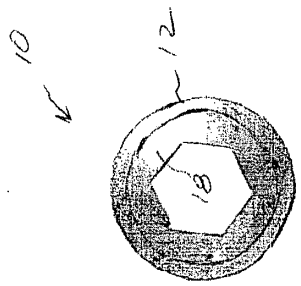
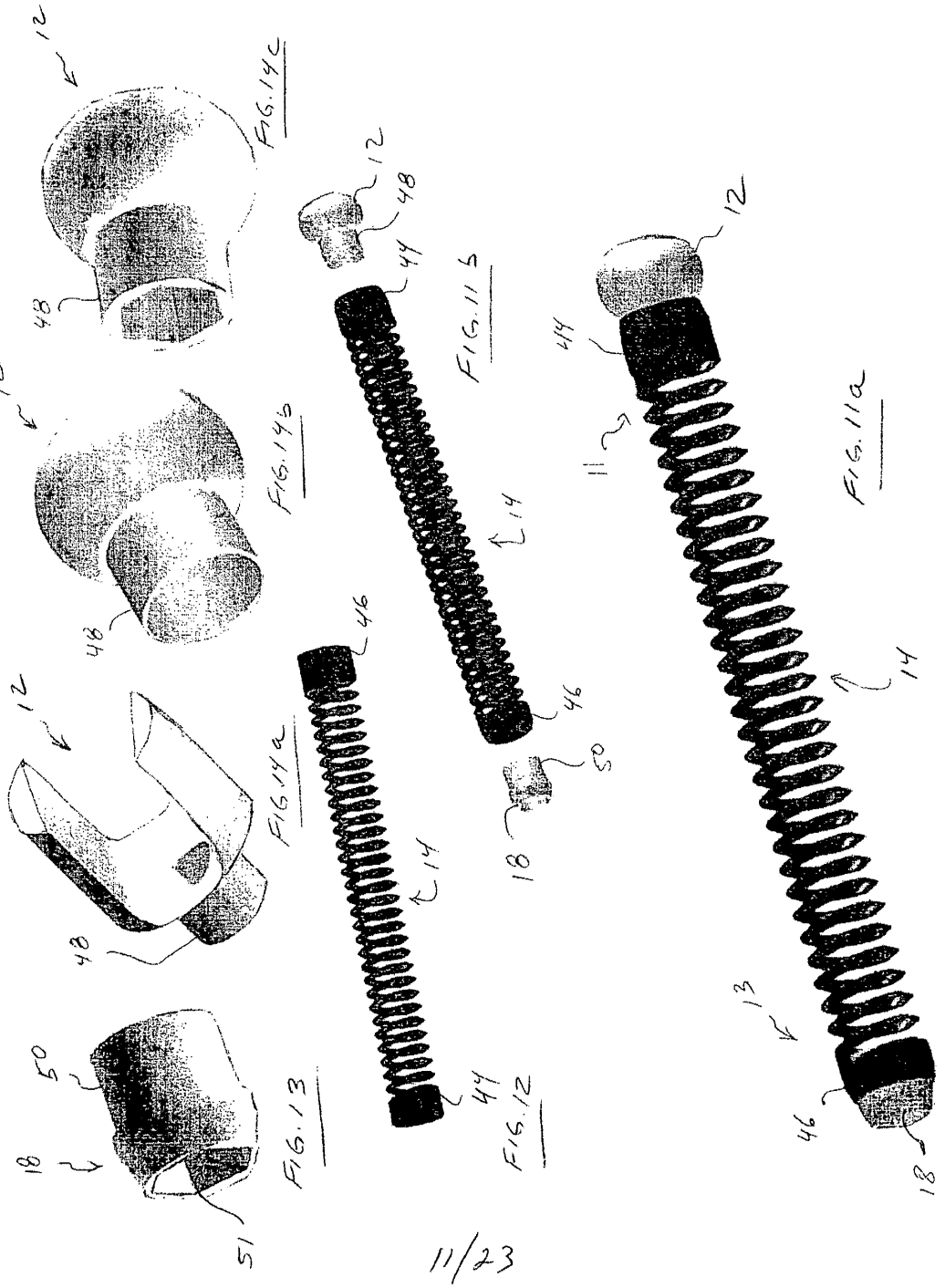


FIG. 10b

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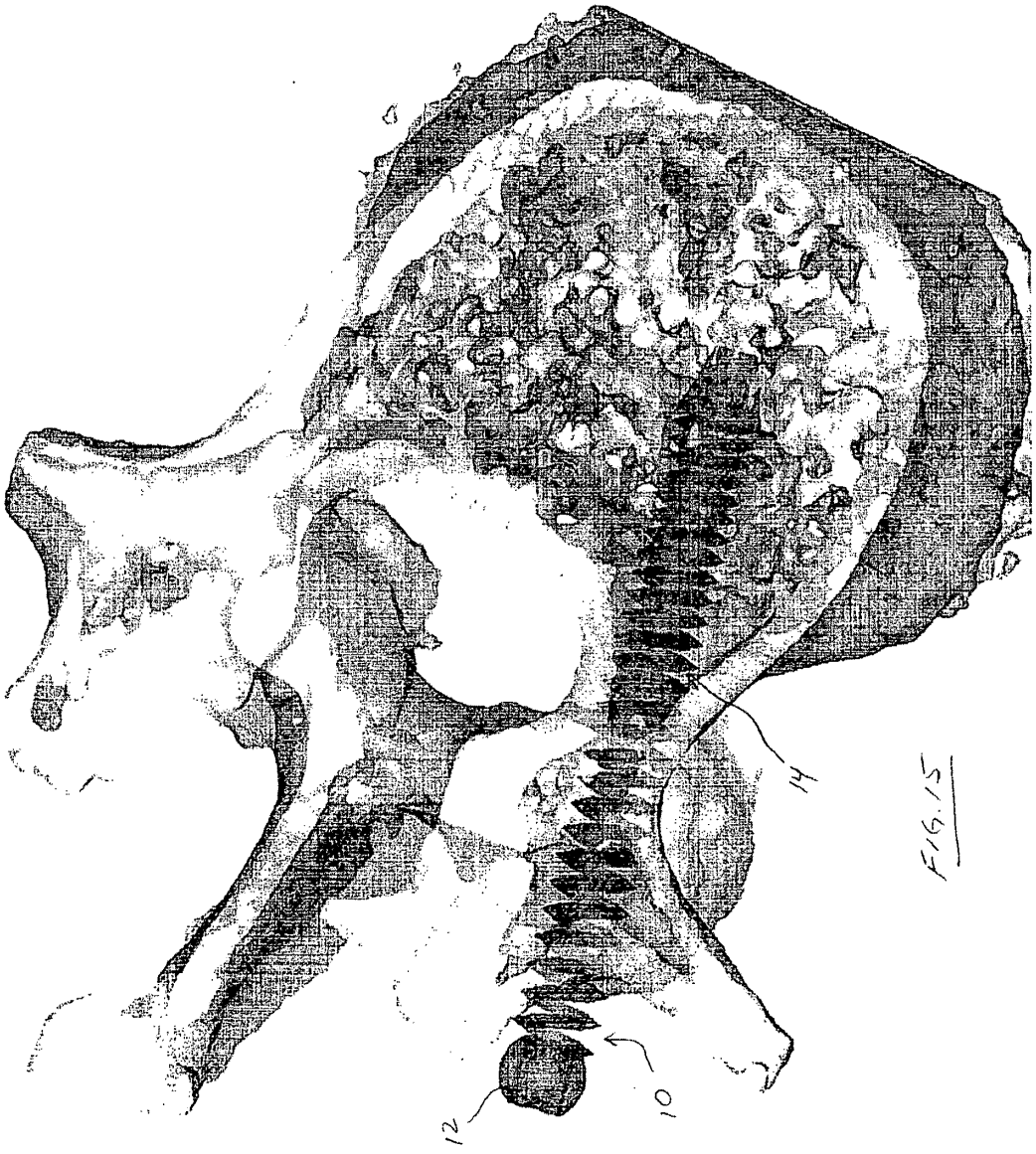


FIG. 15

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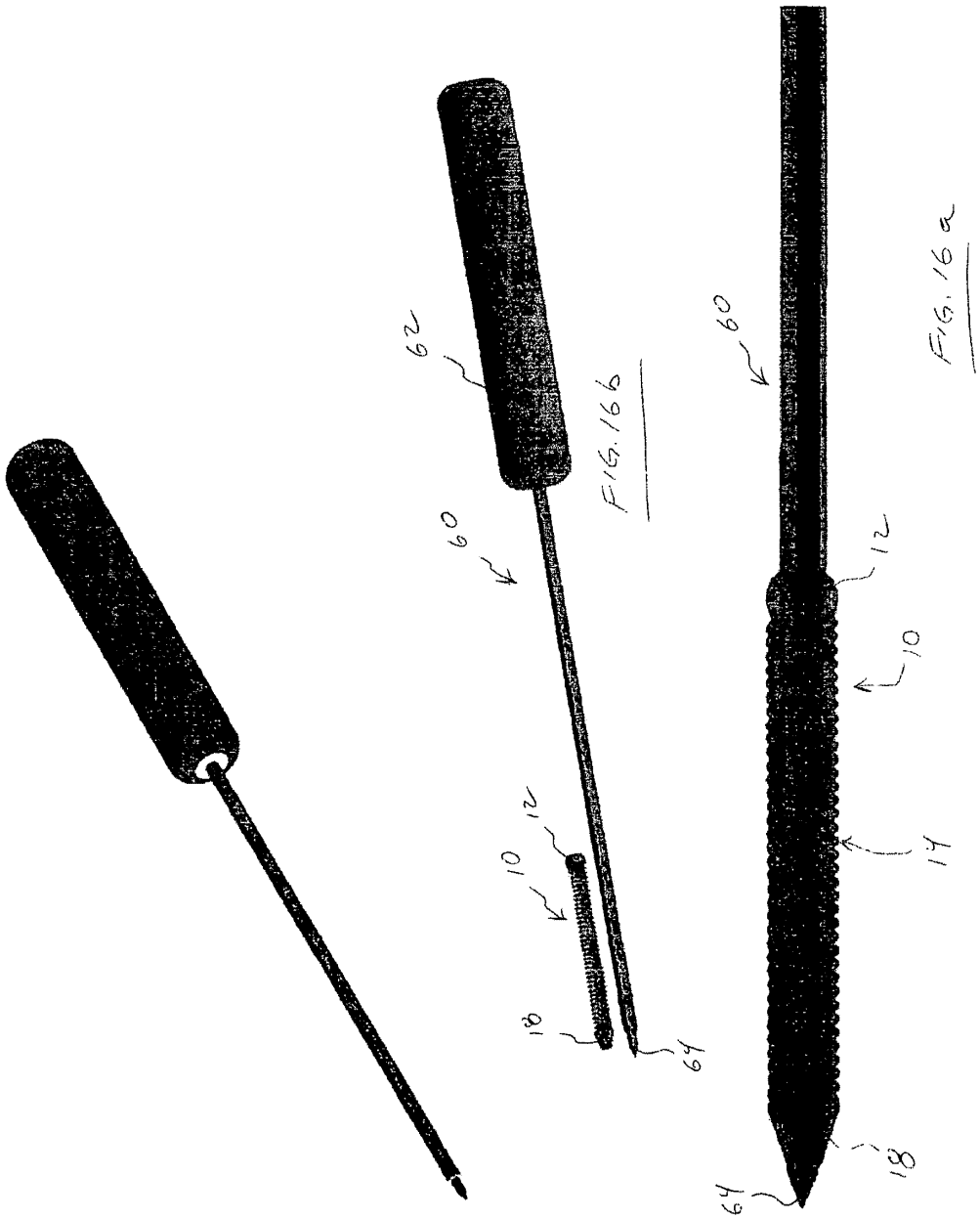


FIG. 16b

FIG. 16a

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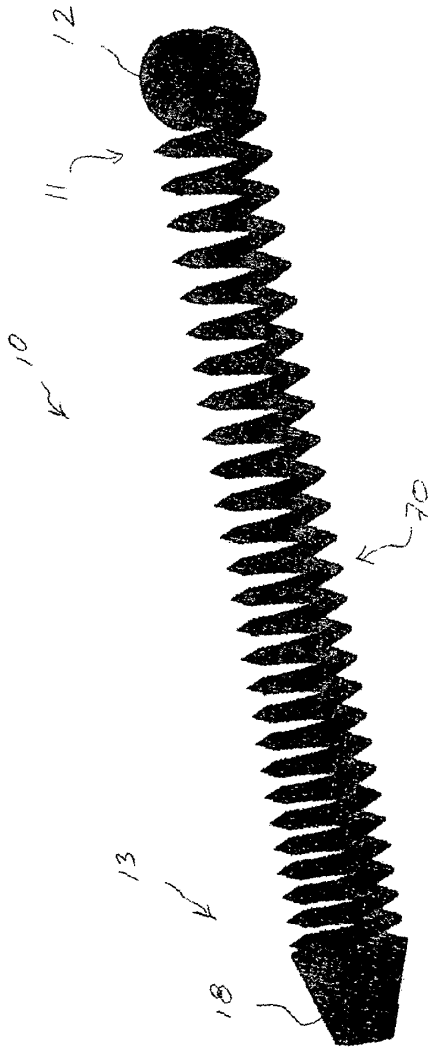


FIG. 17

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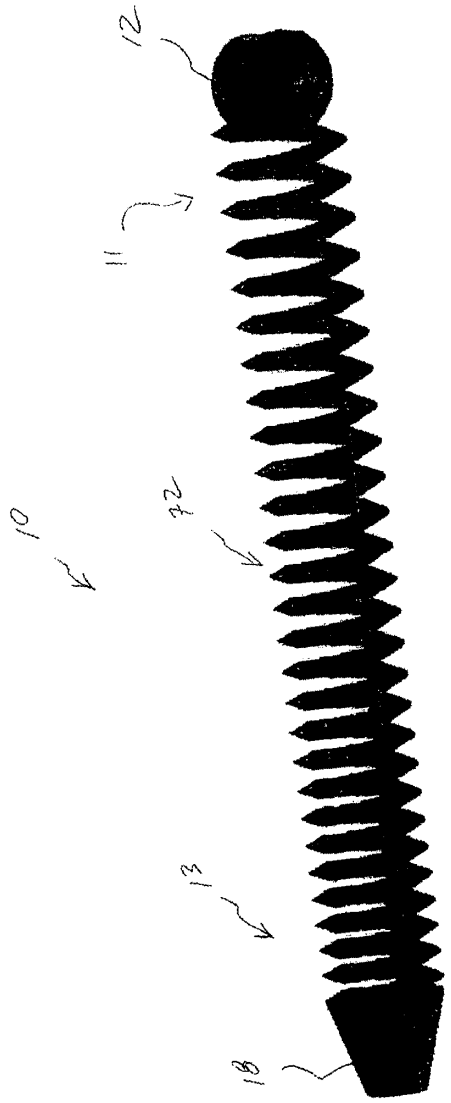


Fig. 1B

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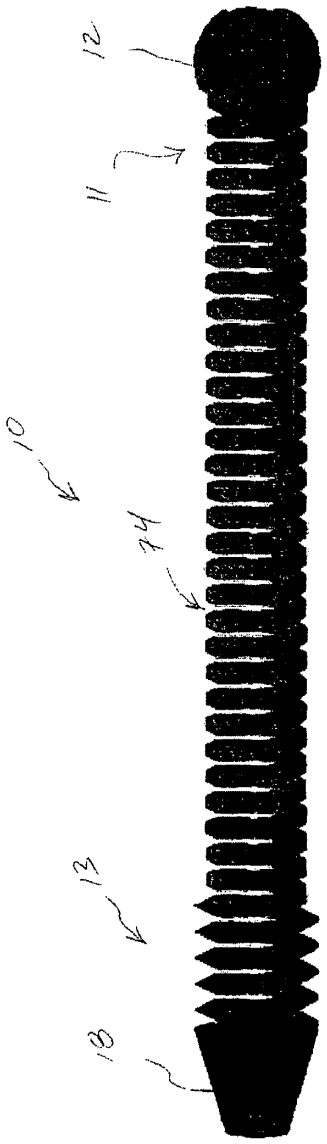


FIG. 1A

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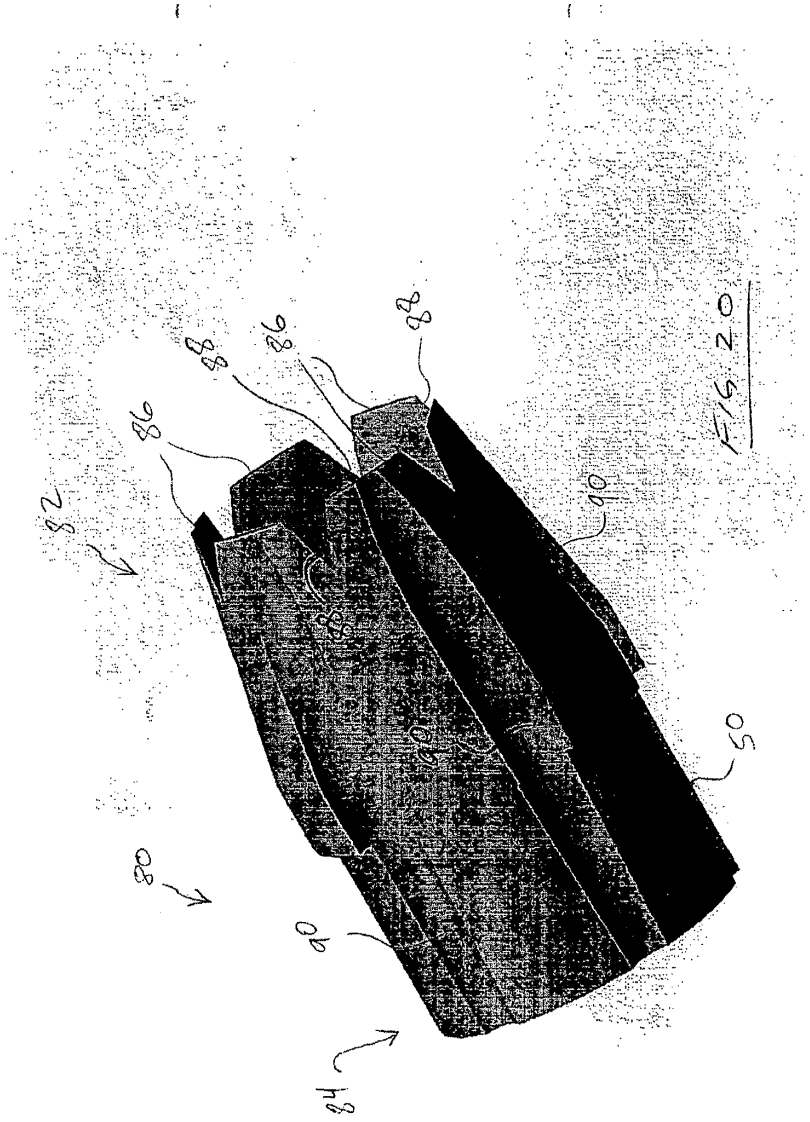


FIG. 20

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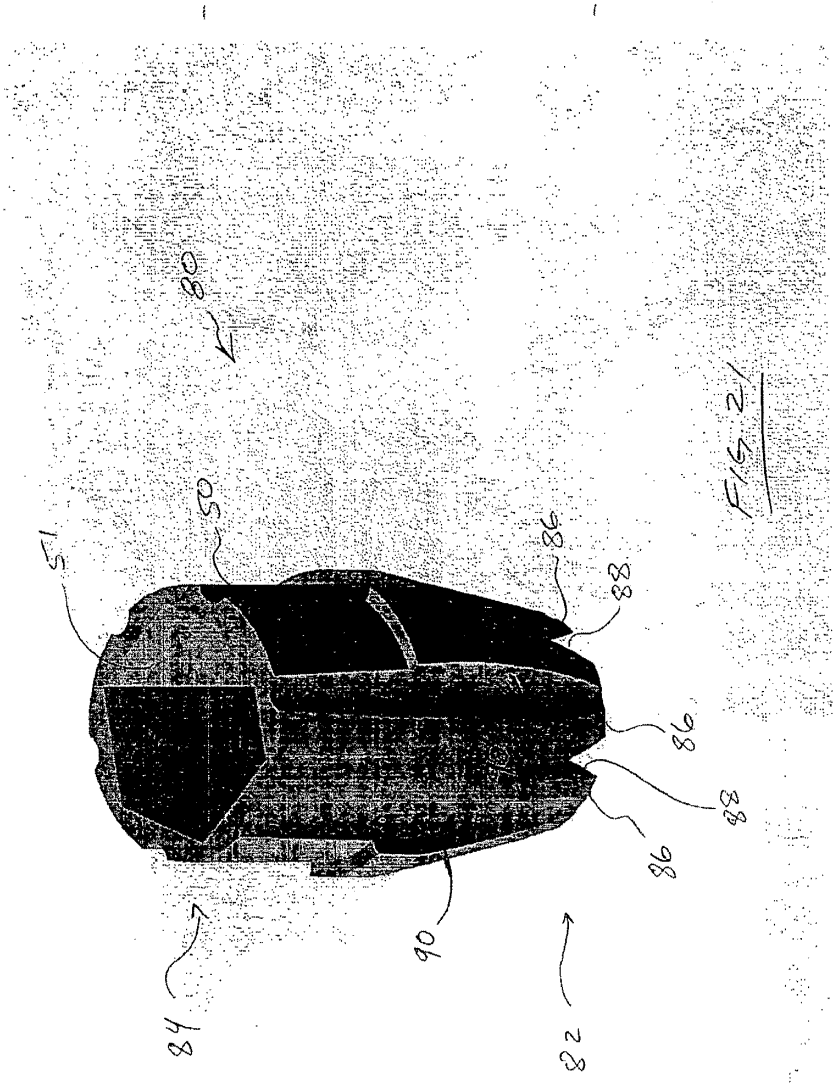


FIG. 21

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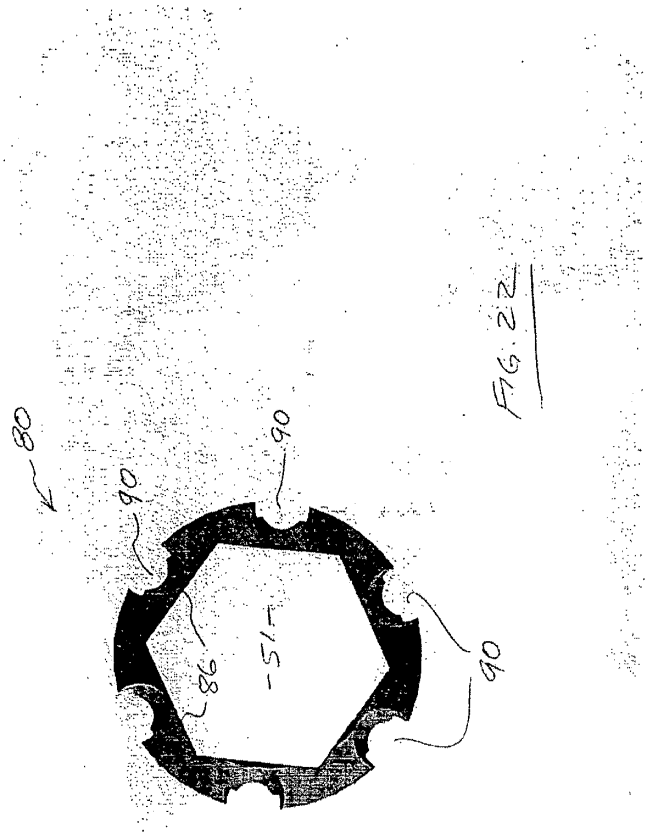


FIG. 22

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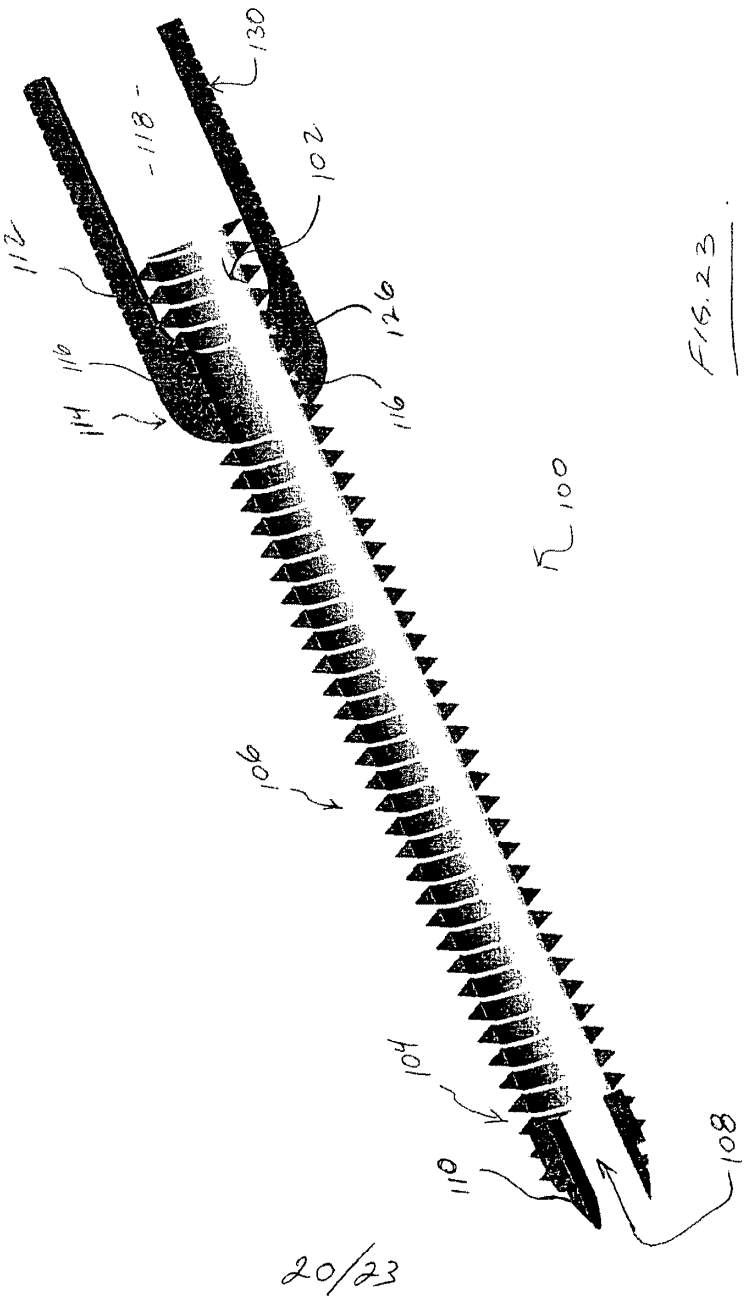


FIG. 23

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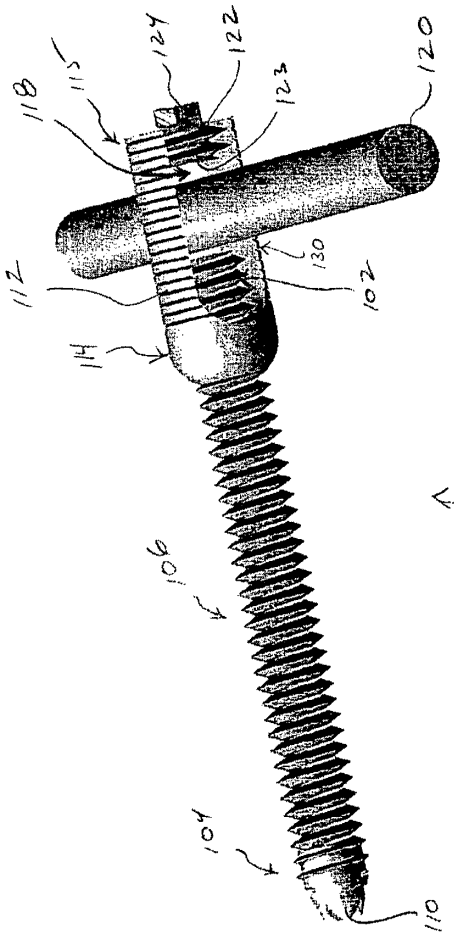


FIG. 24

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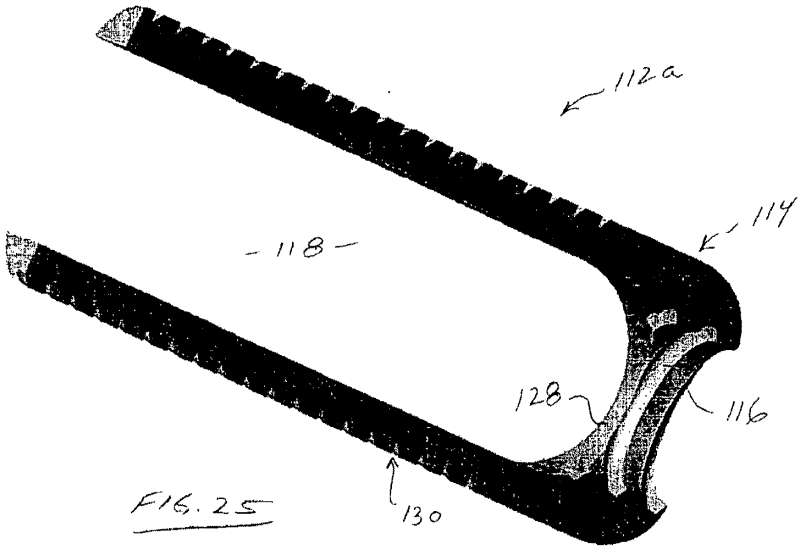


FIG. 25

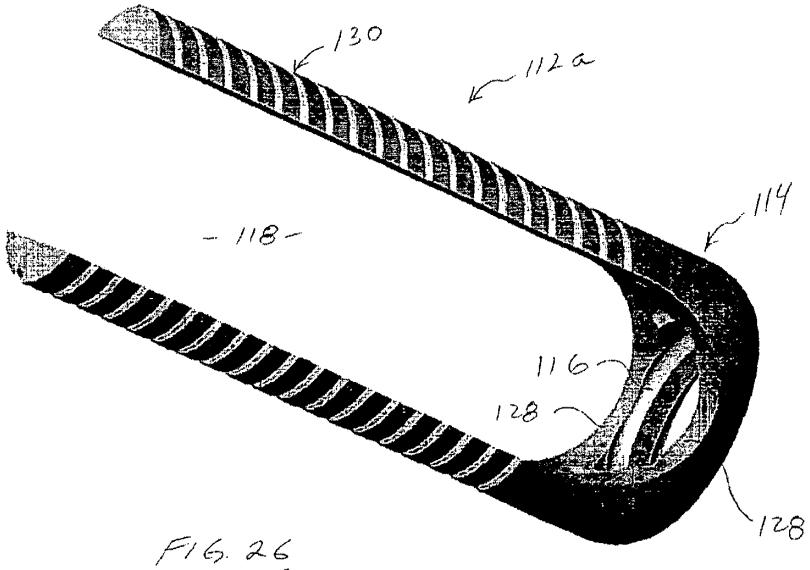


FIG. 26

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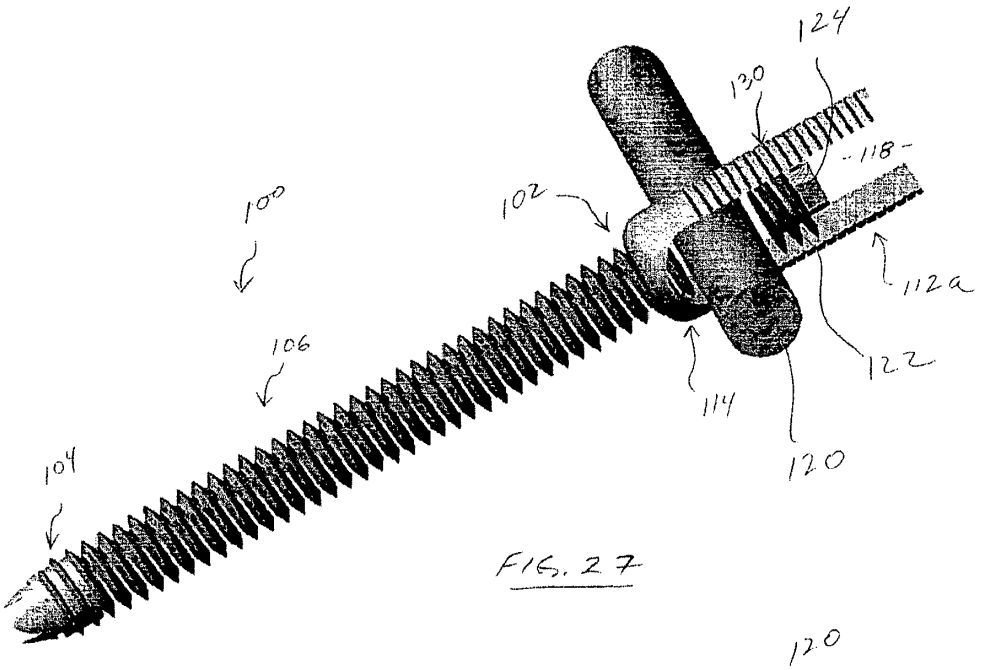


FIG. 27

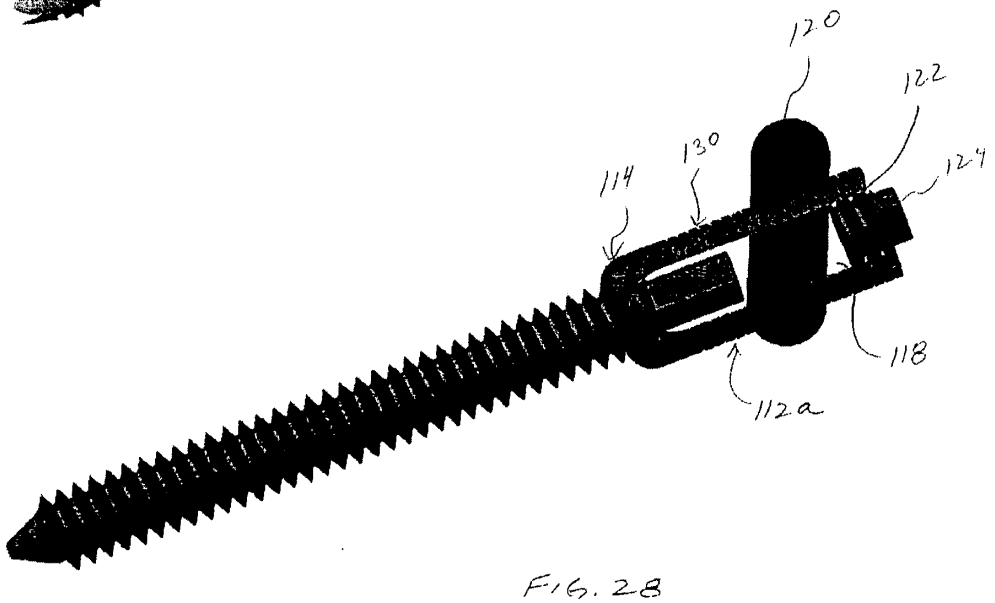


FIG. 28

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/CA2009/001122

A. CLASSIFICATION OF SUBJECT MATTER
IPC: ***A61B 17/88*** (2006.01) , ***A61B 17/86*** (2006.01) , *A61B 17/70* (2006.01)
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC (2006.01) A61B -17/86; A61B-17/88; A61B -17/70; USCL 606/73

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

Electronic database(s) consulted during the international search (name of database(s) and, where practicable, search terms used)
Canadian Patents Database; Delphion (Keywords: bone, pedicle, screw, head, spinal stabilization prosthesis, drive, distal, etc)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US20020055740 A1 (LIEBERMAN, I. H.) 9 May 2002 (09-05-2002) *Col. 4, par. [0076]; Fig. 1*	1-7, 9, 16-25
Y	US7175626 B2 (NEFF, J. R.) 13 February 2007 (13-02-2007) *Abstract; Col. 1. lines 46-59; Fig. 1*	1-7, 9, 16-25
Y	US4950270 A1 (BOWMAN, J. A. et al.) 21 August 1990 (21-08-1990) *Abstract; Figs. 2, 5	1-7, 9, 16-25

[ ] Further documents are listed in the continuation of Box C. [X] See patent family annex.

* Special categories of cited documents :
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
15 October 2009 (15-10-2009)	19 November 2009 (19-11-2009)
Name and mailing address of the ISA/CA Canadian Intellectual Property Office Place du Portage I, C114 - 1st Floor, Box PCT 50 Victoria Street Gatineau, Quebec K1A 0C9 Facsimile No.: 001-819-953-2476	Authorized officer Daniel Cormier (819) 997-2754

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/CA2009/001122

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of the first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons :

1. [X] Claim Nos. : 36-37

because they relate to subject matter not required to be searched by this Authority, namely :

Claims 36-37 are directed to a method of implanting a bone screw and therefore relate to a method of medical treatment. Claims 36-37 relate to subject matter that this authority is not required to search in view of PCT Rule 39.1. As no search has been performed on the subject matter of these claims, no comment is made regarding their novelty, inventive step and industrial

2. [ ] Claim Nos. :

because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically :

3. [ ] Claim Nos. :

because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows :

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claim Nos. :

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim Nos. :

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

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INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/CA2009/001122

Patent Document Cited in Search Report	Publication Date	Patent Family Member(s)	Publication Date
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(continued on page 5)

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(19) RÉPUBLIQUE FRANÇAISE

INSTITUT NATIONAL
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(30) **Priorité** :

(43) **Date de mise à la disposition du public de la demande** : 26.06.09 Bulletin 09/26.

(56) **Liste des documents cités dans le rapport de recherche préliminaire** : *Se reporter à la fin du présent fascicule*

(60) **Références à d'autres documents nationaux apparentés** :

(71) **Demandeur(s)** : *TIMOTEO MICHEL* — FR.

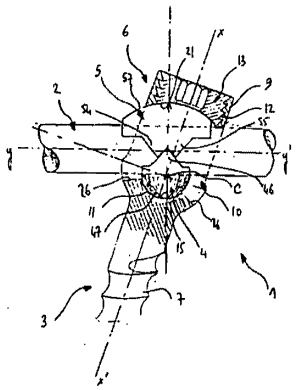
(72) **Inventeur(s)** : TIMOTEO MICHEL et LE HUEC JEAN CHARLES.

(73) **Titulaire(s)** :

(74) **Mandataire(s)** : GARIN ETIENNE.

(54) DISPOSITIF DE CONNEXION PIVOTANT POUR VIS D'OSTEOSYNTHESE RACHIDIENNE.

(57) Le dispositif de connexion pivotant pour vis d'ostéosynthèse rachidienne suivant la présente invention comprend deux éléments de liaison (4, 5) disposés à l'intérieur de la tête de connexion (6) de la vis rachidienne (3) et coopérant respectivement avec la tige de liaison (2), lesdits premiers et seconds éléments de liaison (4, 5) étant agencés l'un par rapport à l'autre au moyen d'une liaison à créneaux (46, 54, 55) pour pouvoir pivoter simultanément autour d'un même point C se trouvant sur l'axe principal xx' de la vis rachidienne (3) et en dessous de l'axe longitudinal yy' de la tige de liaison (2) et des moyens de serrage (13) coopérant d'une part avec la section filetée (12) de la tête de connexion (6) de la vis rachidienne (3) et d'autre part au moyen d'une liaison pivot glissant (22, 58) avec le second élément de liaison (5) pour l'immobilisation en rotation, en translation et dans une position angulaire déterminée la tige de liaison (2) à l'intérieur de la vis rachidienne (3).



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DISPOSITIF DE CONNEXION PIVOTANT POUR VIS D'OSTEOSYNTHESE RACHIDIENNE

La présente invention est relative à un dispositif de connexion pivotant pour vis d'ostéosynthèse rachidienne venant se fixer dans le corps osseux d'une vertèbre d'un segment rachidien à instrumenter d'une colonne vertébrale.

On connaît d'après le brevet français FR 2 659 546 un dispositif de connexion pour une vis pédiculaire comprenant une tête de connexion pourvue de deux branches délimitant une ouverture en forme de U et recevant entre elles une tige de liaison à immobiliser. Le dispositif de connexion comprend une bague fendue qui est enfilée sur la tige de liaison de manière à être interposée entre le fond de l'ouverture en forme de U de la vis pédiculaire et la vis de serrage venant coopérer avec une section filetée aménagée sur la partie interne et supérieure des branches verticales de la tête de connexion. Le dispositif de connexion est prévu pour assurer un certain débattement angulaire de la tige de liaison par rapport à l'axe de la vis pédiculaire.

Le dispositif de connexion pivotant suivant la présente invention a pour but d'optimiser le débattement angulaire de la tige de liaison par rapport à l'axe xx' de la vis rachidienne tout en assurant une stabilité et une immobilisation maximum de ladite tige à l'intérieur de la tête de connexion de ladite vis.

Le dispositif de connexion pivotant pour vis d'ostéosynthèse rachidienne suivant la présente invention comprend deux éléments de liaison disposés à l'intérieur de la tête de connexion de la vis rachidienne et coopérant respectivement avec la tige de liaison, lesdits premiers et seconds éléments de liaison étant agencés l'un par rapport à l'autre au moyen d'une liaison à créneaux pour pouvoir pivoter simultanément autour d'un même point C se trouvant sur l'axe principal xx' de la vis rachidienne et en dessous de l'axe longitudinal yy' de la tige de liaison et des moyens de serrage coopérant d'une part avec la section filetée de la tête de connexion de la vis rachidienne et d'autre part au moyen d'une liaison pivot glissant avec le second élément de liaison pour l'immobilisation en rotation, en translation et dans une position angulaire déterminée de la tige de liaison à l'intérieur de ladite vis rachidienne.

Le dispositif de connexion pivotant pour vis d'ostéosynthèse rachidienne suivant la présente invention montre un premier élément de connexion qui comporte un corps présentant une face externe à profil sphérique qui est complémentaire à celui interne d'une cuvette ménagée dans le fond de l'ouverture de la tête de connexion de la vis rachidienne.

Le dispositif de connexion pivotant pour vis d'ostéosynthèse rachidienne suivant la présente invention montre que le point C de pivotement du corps du premier

élément de liaison à l'intérieur de la tête de connexion est le centre de la face externe à profil sphérique dudit corps.

Le dispositif de connexion pivotant pour vis d'ostéosynthèse rachidienne suivant la présente invention montre que le corps comporte en son milieu et suivant une direction transversale une empreinte destinée à recevoir la tige de liaison, et de chaque coté de ladite empreinte une jupe latérale présentant chacune un profil en forme de pointe pourvu sur sa face externe d'un ergot permettant la retenue du premier élément de connexion à l'intérieur de la tête de connexion.

Le dispositif de connexion pivotant pour vis d'ostéosynthèse rachidienne suivant la présente invention montre que le second élément de liaison est constitué d'un corps comportant une face externe à profil sphérique bombé ou convexe et en son milieu suivant une direction transversale une empreinte permettant de recevoir la tige de liaison.

Le dispositif de connexion pivotant pour vis d'ostéosynthèse rachidienne suivant la présente invention montre que le corps comprend de chaque coté de l'empreinte une jupe latérale présentant chacune un profil en forme de créneau délimitant entre deux pointes un espace destiné à recevoir le profil en forme de pointe des jupes latérales du premier élément.

Le dispositif de connexion pivotant pour vis d'ostéosynthèse rachidienne suivant la présente invention montre que le corps comporte dans son épaisseur une rainure oblongue qui débouche d'une part sur la face externe et d'autre part au niveau de l'empreinte transversale.

Le dispositif de connexion pivotant pour vis d'ostéosynthèse rachidienne suivant la présente invention montre que la rainure oblongue comporte dans sa partie supérieure un épaulement délimitant une réduction de la dimension d'ouverture de ladite rainure oblongue au niveau de la face externe.

Le dispositif de connexion pivotant pour vis d'ostéosynthèse rachidienne suivant la présente invention montre que le corps comporte dans la partie supérieure de sa jupe latérale et à partir de cette dernière une autre rainure débouchant à l'intérieur de la rainure oblongue.

Le dispositif de connexion pivotant pour vis d'ostéosynthèse rachidienne suivant la présente invention montre que les moyens de serrage sont constitués d'un écrou comprenant un corps cylindrique comportant sur sa face externe un filetage venant coopérer avec la section filetée de la tête de connexion de la vis rachidienne, ledit corps cylindrique comprenant une face inférieure à profil sphérique concave présentant en son milieu un doigt cylindrique pourvu d'une tête.

Le dispositif de connexion pivotant pour vis d'ostéosynthèse rachidienne suivant la présente invention montre que l'empreinte présente un profil plan pourvu à

chaque extrémité d'au moins un ergot coopérant avec le profil cannelé de la tige de liaison.

Les dessins annexés, donnés à titre d'exemple, permettront de mieux comprendre l'invention, les caractéristiques qu'elle présente et les avantages qu'elle est susceptible de procurer :

Figure 1 est une vue en perspective éclatée illustrant les différents éléments constituant le dispositif de connexion pivotant pour vis d'ostéosynthèse rachidienne suivant la présente invention.

Figure 2 est une vue en perspective montrant les deux éléments formant la liaison pivotante du dispositif de connexion suivant la présente invention.

Figures 3 à 5 sont des vues représentant le premier élément dit « élément inférieur » de la liaison pivotante du dispositif de connexion suivant la présente invention.

Figures 6 à 10 sont des vues illustrant le second élément dit « élément supérieur » de la liaison pivotante du dispositif de connexion suivant la présente invention.

Figure 11 est une vue en perspective montrant l'agencement du second élément dit « élément supérieur » de la liaison pivotante avec un écrou de serrage pour l'immobilisation du dispositif de connexion suivant la présente invention.

Figures 12 à 14 sont de vues représentant en détail l'écrou de serrage du dispositif de connexion suivant la présente invention.

Figures 15 à 17 sont des vues illustrant l'assemblage des différents éléments constituant le dispositif de connexion pivotant dans le corps d'une vis d'ostéosynthèse rachidienne suivant la présente invention.

Figures 18 et 19 sont des vues représentant une variante du second élément dit « élément supérieur » de la liaison pivotante lorsque la tige de liaison est de type cannelé suivant la présente invention.

On a illustré en figure 1 un dispositif de connexion pivotant 1 permettant l'immobilisation en translation et en rotation d'une tige de liaison 2 dans le corps d'une vis rachidienne ou pédiculaire 3 destinée à être ancrée dans une vertèbre d'un segment rachidien à instrumenter d'une colonne vertébrale.

Le dispositif de connexion 1 est constitué de deux éléments de liaison 4 et 5 qui sont respectivement disposés dans la vis rachidienne 3 et plus particulièrement à l'intérieur d'une tête de connexion 6 en forme de U.

Ainsi, chaque vis rachidienne 3 est formée principalement d'une partie filetée 7 permettant son ancrage dans la partie osseuse de la vertèbre et d'une tête de connexion 6 se trouvant dans le prolongement de ladite partie filetée et permettant la mise en place et la retenue de la tige de liaison 2.

La tête de connexion 6 est constituée de deux branches verticales 8 et 9 délimitant une ouverture 10 en forme de U et dont le fond 11 comporte d'une part en son milieu une cuvette 15 présentant un profil interne en portion de sphère et d'autre part deux pans inclinés 26 bordant latéralement ladite cuvette.

La partie interne des branches verticales 8 et 9 de la tête de connexion 6 comporte au-dessus du fond 11 une section filetée 12 permettant le serrage d'un écrou de serrage 13 pour le blocage en translation et en rotation de la tige de liaison 2 dans chaque tête de connexion 6.

La vis rachidienne 3 peut présenter sur le pourtour de la face externe de la tête de connexion 6 et plus particulièrement dans la zone de raccordement des branches verticales 8 et 9 avec la partie filetée 7 une série de dents fraisées 14 destinées à pénétrer dans la partie osseuse de la vertèbre recevant ladite vis rachidienne 3.

On a montré en figures 2 à 10 les deux éléments de liaison 4 et 5 du dispositif de connexion 1 destinés à maintenir et à immobiliser la tige de liaison 2 à l'intérieur de la tête de connexion 6 de la vis rachidienne 3 correspondante.

Le premier élément de liaison 4 dit « élément inférieur » comporte un corps 40 présentant une face externe 47 à profil sphérique qui est complémentaire à celui interne de la cuvette 15 du fond 11 de la tête de connexion 6 de la vis rachidienne 3.

Le corps 40 comporte en son milieu et suivant une direction transversale une empreinte 41 à profil cylindrique qui est destinée à recevoir lors du montage du dispositif de connexion 1 la tige de liaison 2.

Le corps 40 comprend de chaque coté de l'empreinte 41 une jupe latérale 42, 43 élastiquement déformable et s'étendant verticalement au-dessus de ladite empreinte et présentant chacune un profil en forme de pointe 46.

L'extrémité pointue de chaque jupe latérale 42, 43 comporte sur sa face externe un ergot 44 coopérant avec un logement 16 de forme complémentaire ménagé au-dessus du fond 11 et sur chaque face interne de l'ouverture 10 en forme de U afin de permettre l'encliquetage et la retenue du corps 40 dans la cuvette 15 de la vis rachidienne 3 correspondante.

Le corps 40 est percé en son milieu et suivant une direction verticale à partir de son empreinte 41 d'un alésage débouchant 45 permettant la mise en place d'un outil adapté pour la manipulation et l'introduction du corps 40 dans la cuvette 15 de la vis rachidienne 3 correspondante.

Lorsque le corps 40 à profil sphérique est engagé dans la cuvette 15 de la vis rachidienne 3 ce dernier peut librement pivoter autour des ergots 44 de chaque jupe latérale 42, 43.

Le second élément de liaison 5 dit « élément supérieur » est constitué d'un corps 50 comportant une face externe 57 à profil sphérique bombé ou convexe et en son milieu suivant une direction transversale une empreinte 51 à profil cylindrique, complémentaire à celle 41 du premier élément 4, afin de recevoir lors du montage du dispositif de connexion 1 à l'intérieur de la vis rachidienne 3 la tige de liaison 2.

Le corps 50 comprend de chaque coté de l'empreinte 51 une jupe latérale 52, 53 s'étendant verticalement au-dessus de ladite empreinte et présentant chacune un profil en forme de créneau délimitant entre deux pointes 54, 55 un espace 56 destiné à recevoir lors du montage du dispositif de connexion 1 le profil en forme de pointe 46 des jupes latérales 42, 43 du premier élément 4.

Le corps 50 comporte dans son épaisseur une rainure oblongue 58 qui débouche d'une part sur la face externe 57 et d'autre part au niveau de l'empreinte transversale 51.

La rainure oblongue 58 comporte dans sa partie supérieure un épaulement 58a délimitant une réduction de la dimension d'ouverture de ladite rainure oblongue 58 au niveau de la face externe 57.

Le corps 50 comporte dans la partie supérieure de sa jupe latérale 52 et à partir de cette dernière une autre rainure 59 débouchant à l'intérieur de la rainure oblongue 58.

La rainure 59 est destinée à former une entrée qui débouche latéralement à l'intérieur de la rainure oblongue 58. La rainure 59 peut présenter un profil cylindrique se prolongeant vers l'extérieur et en direction de la face externe 57 par un profil rectiligne de dimension inférieure à celle du profil cylindrique.

Egalement, la rainure 59 peut être positionnée à l'une des extrémités de la rainure oblongue 58 et suivant une direction axiale qui est inclinée par rapport à l'axe vertical et principal du corps 50.

La rainure oblongue 58 et la rainure d'entrée 59 permettent la mise en place et la retenue de l'écrou de serrage 13 destiné à coopérer avec la section filetée 12 de la tête de connexion 6 de la vis rachidienne 3.

Le corps 50 du second élément de liaison 5 dit « élément supérieur » peut présenter une empreinte 51 à profil plan afin de permettre la mise en place et la retenue d'une tige de liaison 2 dont la face externe présente un profil cannelé obtenu par l'intermédiaire de dents longitudinales 2a (figures 18 et 19).

L'empreinte 51 comporte à chaque extrémité de son profil plan des ergots 51a destinés lors de l'assemblage du second élément de liaison 5 de coopérer et pénétrer entre les dents longitudinales 2a formant le profil cannelé de la tige de liaison 2 afin de bloquer en rotation et en translation cette dernière entre les premiers et seconds éléments de liaison 4, 5.

En ce qui concerne le premier élément de liaison 4 ce dernier présente la même empreinte 41 à profil cylindrique quel que soit le profil externe de la tige de liaison 2.

On a représenté en figures 11 à 14 l'écrou de serrage 13 qui comprend un corps cylindrique 17 comportant sur sa face externe un filetage 18 venant coopérer avec la section filetée 12 de la tête de connexion 6 de la vis rachidienne 3.

Le corps cylindrique 17 comporte une face supérieure plane 19 dans laquelle est ménagée au milieu dudit corps une empreinte 20 permettant la mise en place d'un outil, non représenté, pour l'entraînement en rotation de l'écrou de serrage 13 à l'intérieur de la tête de connexion 6. Le corps cylindrique 17 comporte à l'opposé de la face supérieure plane 19 une face inférieure 21 à profil sphérique concave présentant en son milieu un doigt cylindrique 22 pourvu d'une tête 23 dont le diamètre externe est supérieur à celui du doigt cylindrique 22.

Ainsi l'écrou de serrage 13 est assemblé avec le corps 50 du second élément de liaison 5 par l'intermédiaire du doigt cylindrique 22 qui est introduit à l'intérieur de la rainure oblongue 58 au moyen de la rainure d'entrée 59 dont le profil interne est complémentaire à celui dudit doigt.

L'écrou de serrage 13 et le corps 50 du second élément de liaison 5 peuvent se déplacer librement l'un par rapport à l'autre suivant le profil de la rainure oblong 58 pour permettre un ajustement axial dudit élément de liaison à l'intérieur de la tête de connexion 6 de la vis rachidienne 3 lors de l'assemblage de la tige de liaison 2 à l'intérieur de cette dernière.

Lors de l'assemblage de l'écrou de serrage 13 avec le corps 50 du second élément de liaison 5 la face inférieure 21 à profil sphérique concave dudit écrou 13 est positionnée au-dessus de la face externe 57 à profil sphérique bombé ou convexe dudit corps 50 pour venir en appui sur cette dernière lors du serrage de l'écrou dans la tête de connexion 6 de la vis rachidienne 3.

A cet effet, on a illustré en figures 15 à 17 l'assemblage et la fixation de la tige de liaison 2 d'un dispositif d'ostéosynthèse rachidienne à l'intérieur de la tête de connexion 6 de la vis rachidienne 3 au moyen du dispositif de connexion 1 suivant la présente invention.

La tête de connexion 6 reçoit en premier lieu le premier élément de liaison 4 du dispositif de connexion 1 de manière à ce que ce dernier coopère librement avec la cuvette 15 ménagée dans le fond 11 de l'ouverture 10.

Le premier élément de liaison 4 est d'une part retenu à l'intérieur de la tête de connexion 6 par l'intermédiaire des ergots 44 de chaque jupe latérale 42, 43 qui coopèrent avec les logements 16 prévus à cet effet et d'autre part libre en rotation autour desdits ergots 44 pour pouvoir pivoter par rapport à un centre C se trouvant en dessous de l'axe longitudinal yy' de la tige de liaison 2 et sur l'axe principal xx' passant par la partie filetée 7 de la vis rachidienne 3.

On note que le point C de pivotement du corps 40 du premier élément de liaison 4 à l'intérieur de la tête de connexion 6 est également le centre de la face externe 47 à profil sphérique dudit corps 40.

Enfin, on remarque que le point C est placé au milieu et sur la face de l'empreinte 41 recevant la tige de liaison 2 à immobiliser.

En fonction de la position d'ancrage de la vis rachidienne 3 dans le corps de la vertèbre à instrumenter et de la position axiale de la tige de liaison 2 par rapport à la position de ladite vis, la tige de liaison 2 est placée, après pivotement du premier élément de liaison 4 autour du point C, à l'intérieur de l'empreinte 41 du corps 40.

Ensuite, le second élément de liaison 5 est introduit dans la tête de connexion 6 de la vis rachidienne 3 au moyen de l'écrou de serrage 13 dont il est associé au moyen de la liaison pivot glissant 22, 58. L'écrou de serrage 13 coopère par l'intermédiaire de son filetage 18 avec la section filetée 12 prévue sur chaque branche verticale 8, 9 de la tête de connexion 6.

Le profil sphérique convexe de la face externe 57 du second élément de liaison 5 et le profil sphérique complémentaire concave de la face inférieure 21 de l'écrou 13 permettent au corps 50 dudit second élément de liaison 5 de basculer autour dudit écrou 13 maintenu entre les branches verticales 8, 9 afin de s'adapter à la position de la tige de liaison 2.

Lors de la mise en place de l'écrou serrage 13 entre les branches verticales 8, 9 de la tête de connexion 6 l'élément de liaison 5, et plus particulièrement l'espace 56 du profil en créneau 54, 55 des jupes latérales 52,53 reçoit le profil en forme de pointe 46 de chaque jupe latérale 42, 43 du premier élément de liaison 4.

La connexion par une liaison à créneaux 46, 54, 55 entre le premier élément de liaison 4 et le second élément de liaison 5 permet à ce dernier de se présenter dans le même plan d'inclinaison que celui dudit premier élément de liaison 4 assurant aux premiers et seconds éléments de liaison 4, 5 un pivotement autour du même point C.

Lors du serrage de l'écrou 13 dans la tête de connexion 6 la face inférieure 21 à profil sphérique concave vient en appui sur la face externe 57 à profil sphérique convexe du corps 50 du second élément de liaison 5 permettant d'immobiliser en rotation et translation la tige de liaison 2 à l'intérieur des empreintes 41, 51 du premier et second élément de liaison 4, 5.

On note que les surfaces de contact entre l'écrou de serrage 13 et le corps 50 de l'élément de liaison 5 et entre l'empreinte 51 et la tige de liaison 2 étant optimisées, ces dernières permettent d'assurer et augmenter l'efficacité du blocage de la tige de liaison 2 à l'intérieur de la tête de connexion 6 de la vis rachidienne 3.

On constate que le profil du dispositif de connexion 1 constitué des premiers et seconds éléments de liaison 4 et 5 et notamment du décalage du centre C de pivotement en dessous de l'axe yy' de la tige de liaison 2 ainsi que les pans inclinés 26 aménagés dans le fond de la tête de connexion 6 de la vis rachidienne 3 permettent une augmentation du pivotement angulaire de la tige de liaison 2 par rapport à la vis rachidienne 3 facilitant sa mise en place et son introduction dans ladite tête de connexion.

Il doit d'ailleurs être entendu que la description qui précède n'a été donnée qu'a titre d'exemple et qu'elle ne limite nullement le domaine de l'invention dont on ne sortirait pas en remplaçant les détails d'exécution décrits par tous autres équivalents.

REVENDICATIONS

1. Dispositif de connexion pivotant pour vis d'ostéosynthèse rachidienne (3) comprenant une tête de connexion (6) pourvue d'une ouverture (10) en forme de U permettant la mise en place d'une tige de liaison (2) et une partie filetée (7) permettant son ancrage dans la partie osseuse d'une vertèbre à instrumenter, **caractérisé en ce** qu'il comprend deux éléments de liaison (4, 5) disposés à l'intérieur de la tête de connexion (6) de la vis rachidienne (3) et coopérant respectivement avec la tige de liaison (2), lesdits premiers et seconds éléments de liaison (4, 5) étant agencés l'un par rapport à l'autre au moyen d'une liaison à créneaux (46, 54, 55) pour pouvoir pivoter simultanément autour d'un même point C se trouvant sur l'axe principal xx' de la vis rachidienne (3) et en dessous de l'axe longitudinal yy' de la tige de liaison (2) et des moyens de serrage (13) coopérant d'une part avec la section filetée (12) de la tête de connexion (6) de la vis rachidienne (3) et d'autre part au moyen d'une liaison pivot glissant (22, 58) avec le second élément de liaison (5) pour l'immobilisation en rotation, en translation et dans une position angulaire déterminée de la tige de liaison (2) à l'intérieur de ladite vis rachidienne (3).

2. Dispositif de connexion pivotant pour vis d'ostéosynthèse rachidienne suivant la revendication 1, **caractérisé en ce que** le premier élément de connexion (4) comporte un corps (40) présentant une face externe (47) à profil sphérique qui est complémentaire à celui interne d'une cuvette (15) ménagée dans le fond (11) de l'ouverture (10) de la tête de connexion (6) de la vis rachidienne (3).

3. Dispositif de connexion pivotant pour vis d'ostéosynthèse rachidienne suivant la revendication 1, **caractérisé en ce que** le point C de pivotement du corps (40) du premier élément de liaison (4) à l'intérieur de la tête de connexion (6) est le centre de la face externe (47) à profil sphérique dudit corps (40).

4. Dispositif de connexion pivotant pour vis d'ostéosynthèse rachidienne suivant la revendication 2, **caractérisé en ce que** le corps (40) comporte en son milieu et suivant une direction transversale une empreinte (41) destinée à recevoir la tige de liaison (2), et de chaque coté de ladite empreinte (41) une jupe latérale (42, 43) présentant chacune un profil en forme de pointe (46) pourvu sur sa face externe d'un ergot (44) permettant la retenue du premier élément de connexion (4) à l'intérieur de la tête de connexion (6).

5. Dispositif de connexion pivotant pour vis d'ostéosynthèse rachidienne suivant la revendication 1, **caractérisé en ce que** le second élément de liaison (5) est constitué d'un corps (50) comportant une face externe (57) à profil sphérique bombé ou convexe et en son milieu suivant une direction transversale une empreinte (51) permettant de recevoir la tige de liaison (2).

6. Dispositif de connexion pivotant pour vis d'ostéosynthèse rachidienne suivant la revendication 5, **caractérisé en ce que** le corps (50) comprend de chaque coté de l'empreinte (51) une jupe latérale (52, 53) présentant chacune un profil en forme de créneau délimitant entre deux pointes (54, 55) un espace (56) destiné à recevoir le profil en forme de pointe (46) des jupes latérales (42, 43) du premier élément (4).

7. Dispositif de connexion pivotant pour vis d'ostéosynthèse rachidienne suivant la revendication 5, **caractérisé en ce que** le corps (50) comporte dans son épaisseur une rainure oblongue (58) qui débouche d'une part sur la face externe (57) et d'autre part au niveau de l'empreinte transversale (51).

8. Dispositif de connexion pivotant pour vis d'ostéosynthèse rachidienne suivant la revendication 7, **caractérisé en ce que** la rainure oblongue (58) comporte dans sa partie supérieure un épaulement (58a) délimitant une réduction de la dimension d'ouverture de ladite rainure oblongue (58) au niveau de la face externe (57).

9. Dispositif de connexion pivotant pour vis d'ostéosynthèse rachidienne suivant la revendication 7, **caractérisé en ce que** le corps (50) comporte dans la partie supérieure de sa jupe latérale (52) et à partir de cette dernière une autre rainure (59) débouchant à l'intérieur de la rainure oblongue (58).

10. Dispositif de connexion pivotant pour vis d'ostéosynthèse rachidienne suivant la revendication 1, **caractérisé en ce que** les moyens de serrage (13) sont constitués d'un écrou comprenant un corps cylindrique (17) comportant sur sa face externe un filetage (18) venant coopérer avec la section filetée (12) de la tête de connexion (6) de la vis rachidienne (3), ledit corps cylindrique (17) comprenant une face inférieure (21) à profil sphérique concave présentant en son milieu un doigt cylindrique (22) pourvu d'une tête (23).

11. Dispositif de connexion pivotant pour vis d'ostéosynthèse rachidienne suivant la revendication 5, **caractérisé en ce que** l'empreinte (51) présente un profil plan pourvu à chaque extrémité d'au moins un ergot (51a) coopérant avec le profil cannelé de la tige de liaison (2).

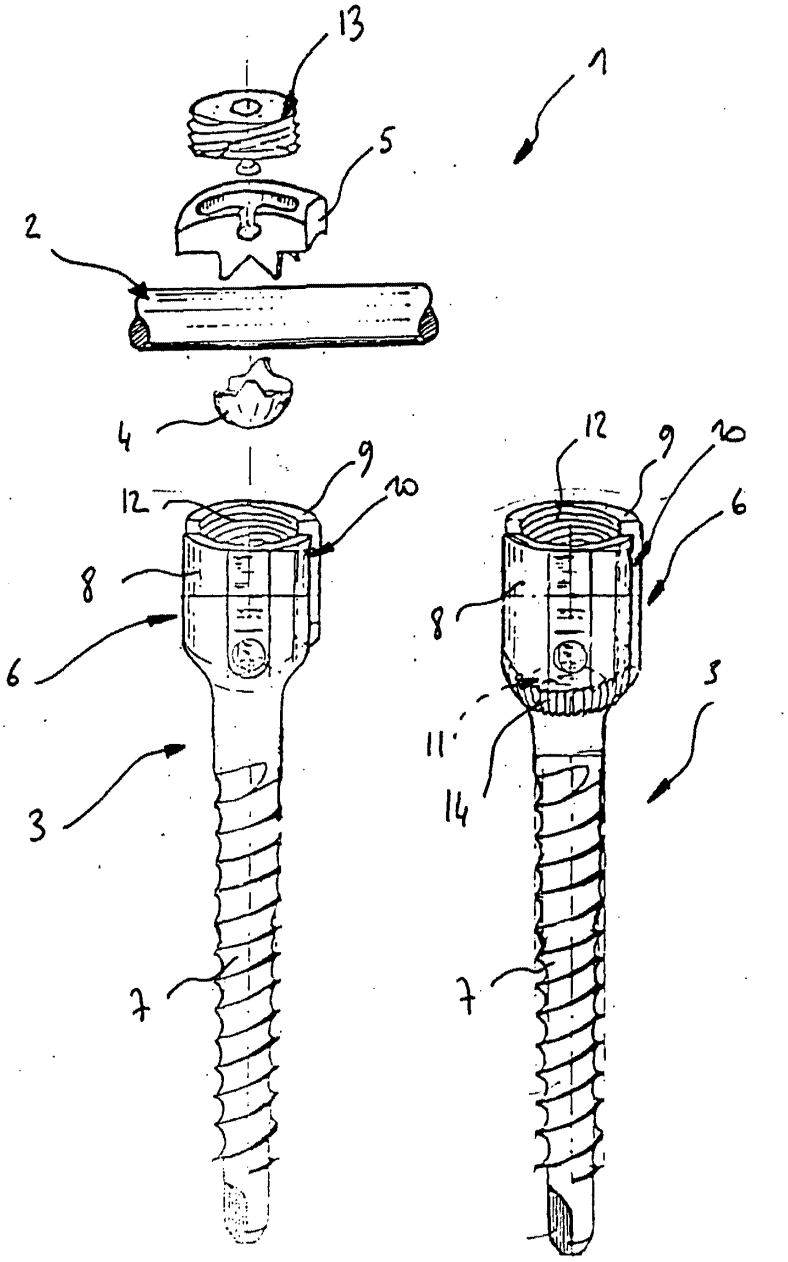


FIGURE 1

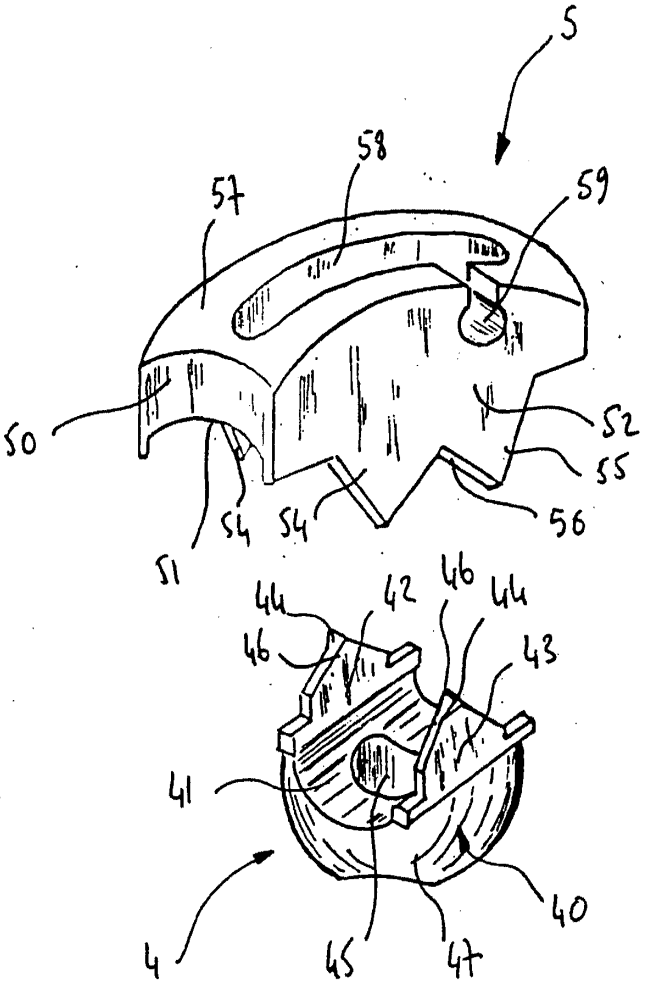


FIGURE 2

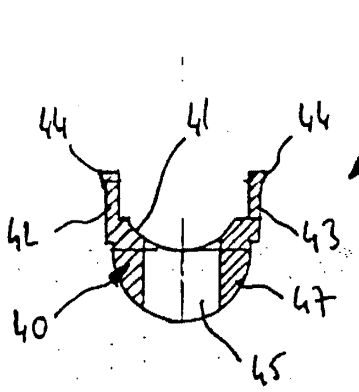


FIGURE 3

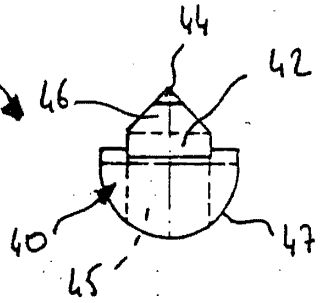


FIGURE 4

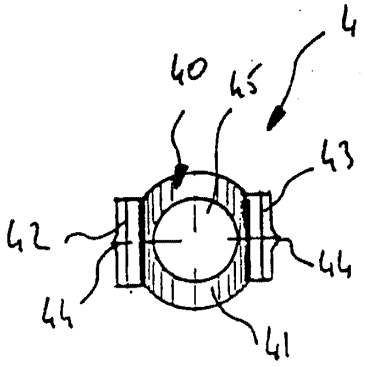


FIGURE 5

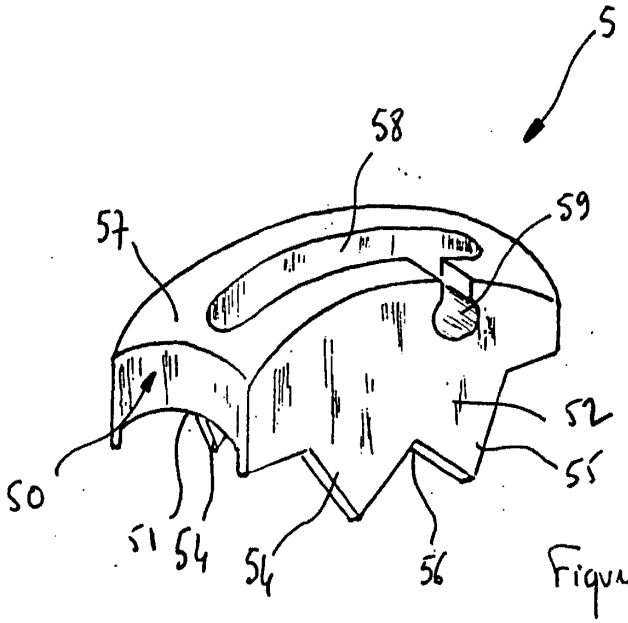


Figure 6

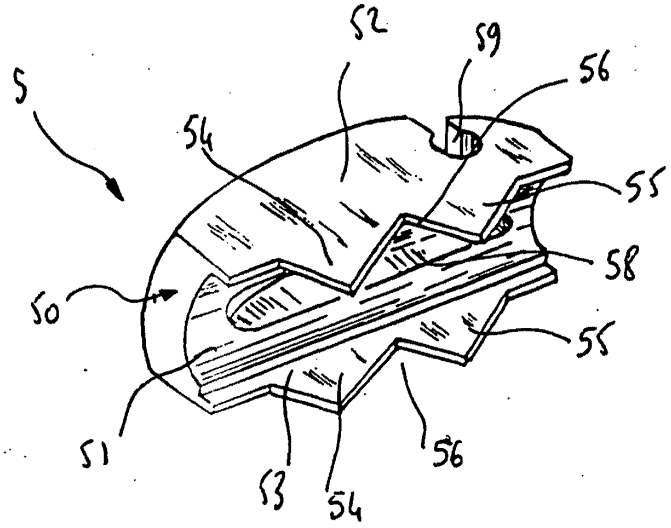


FIGURE 7

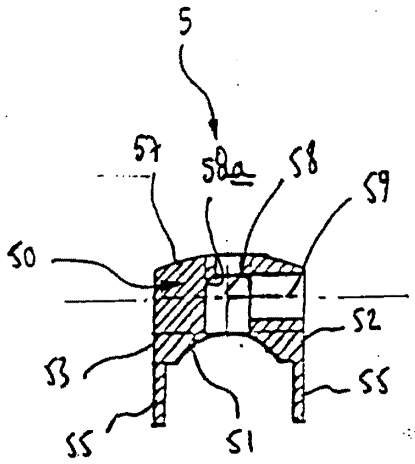


FIGURE 8

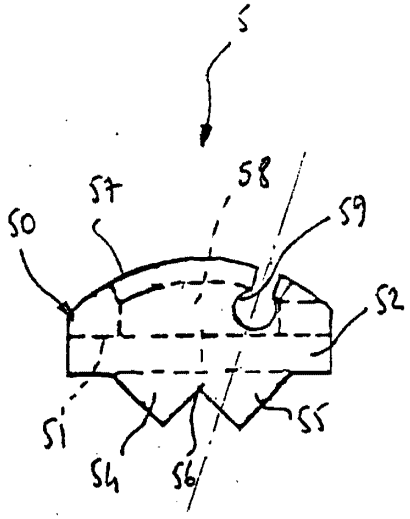


FIGURE 9

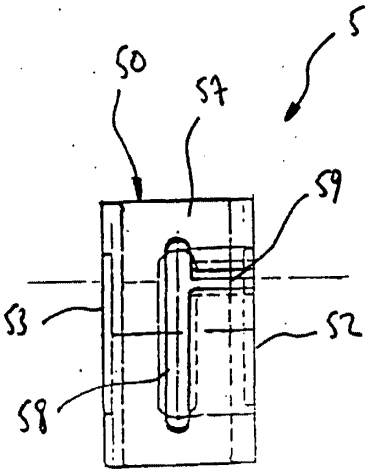


FIGURE 10

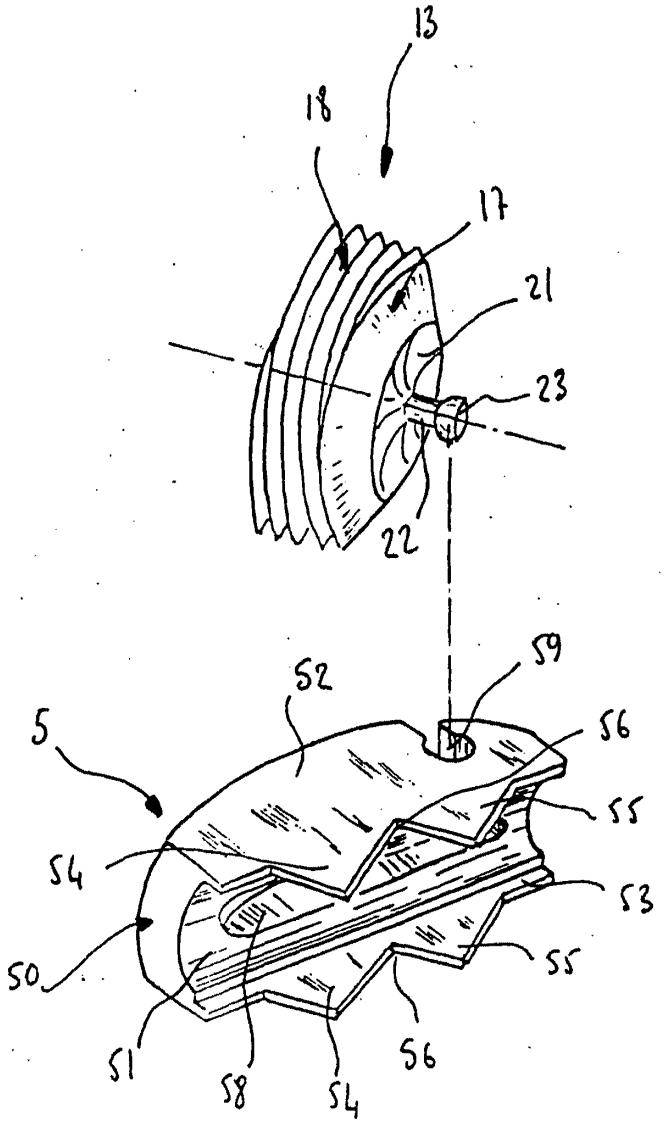


FIGURE 11

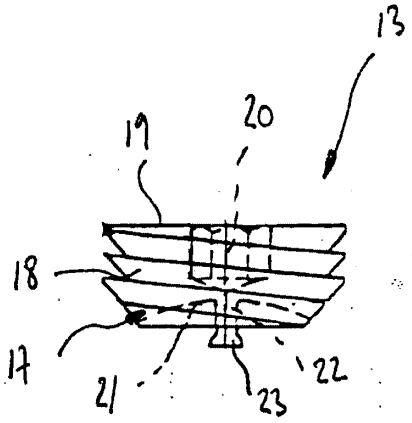


FIGURE 12

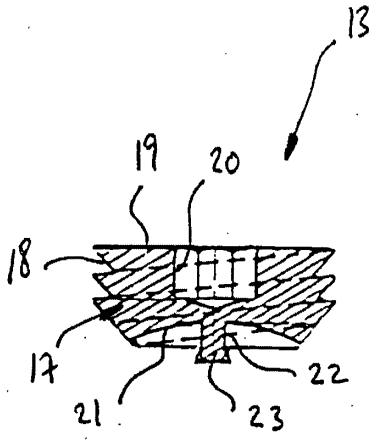


FIGURE 13

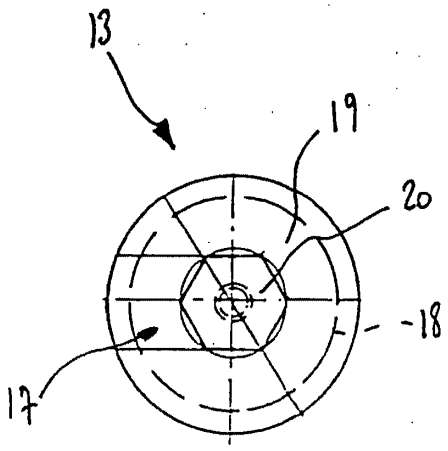


FIGURE 14

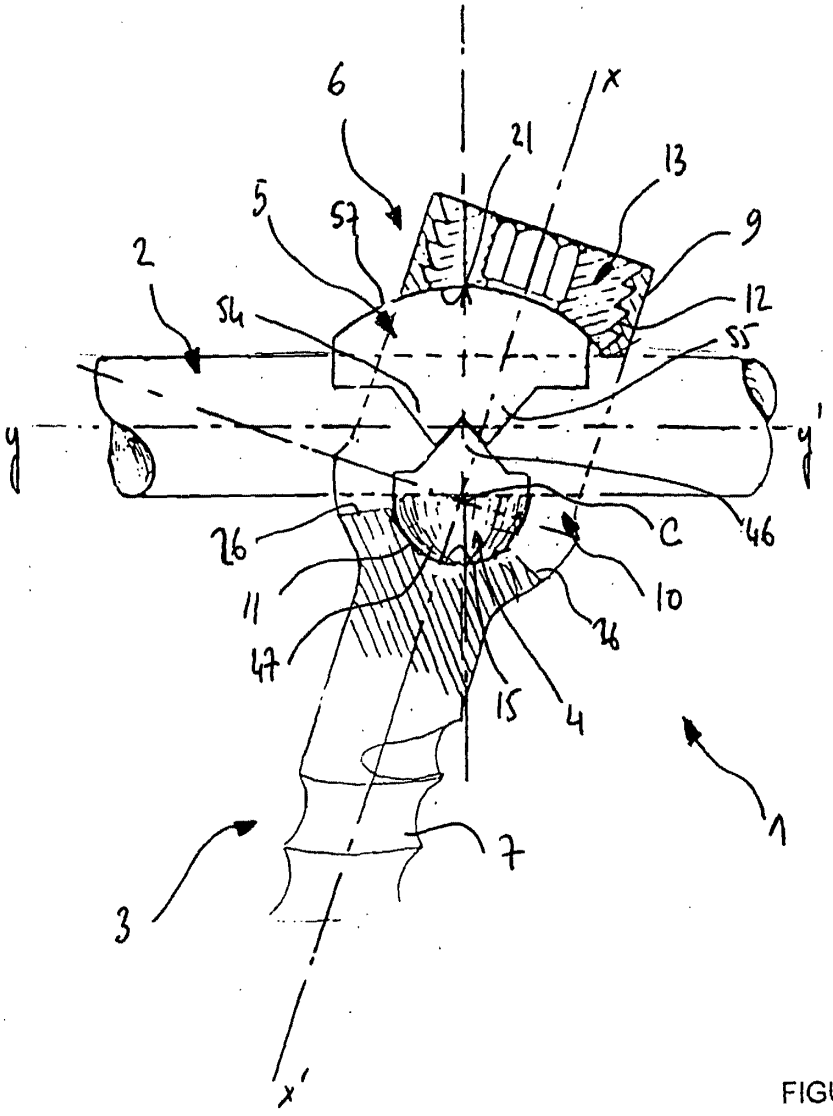


FIGURE 15

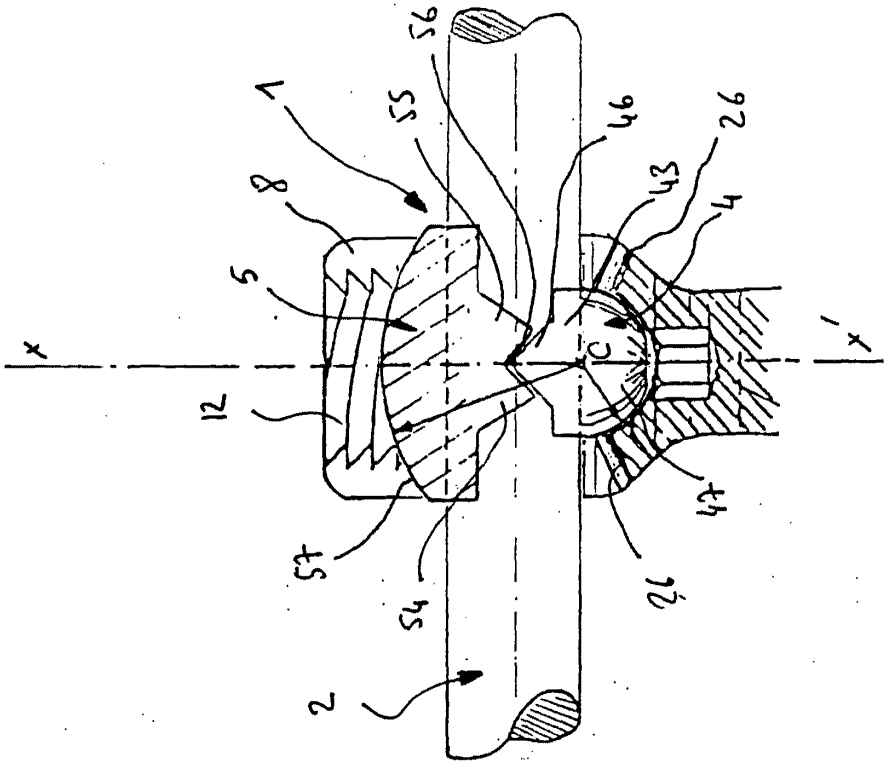


FIGURE 17

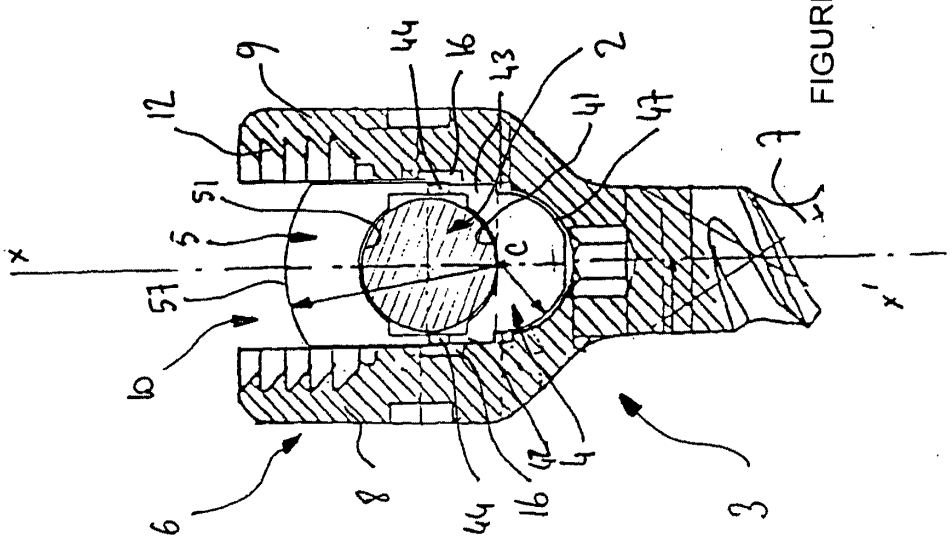


FIGURE 16

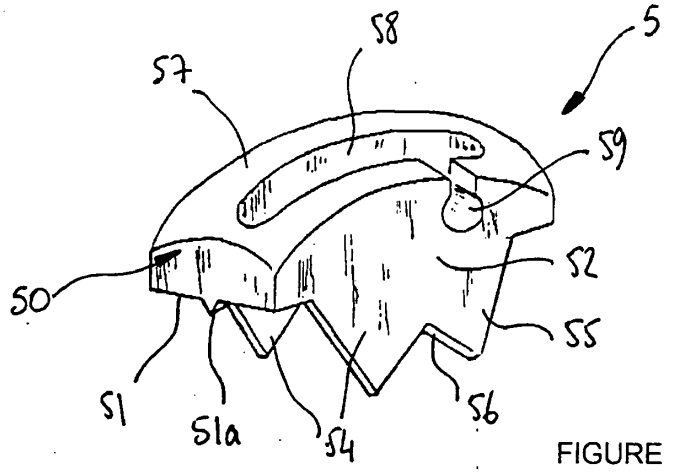


FIGURE 18

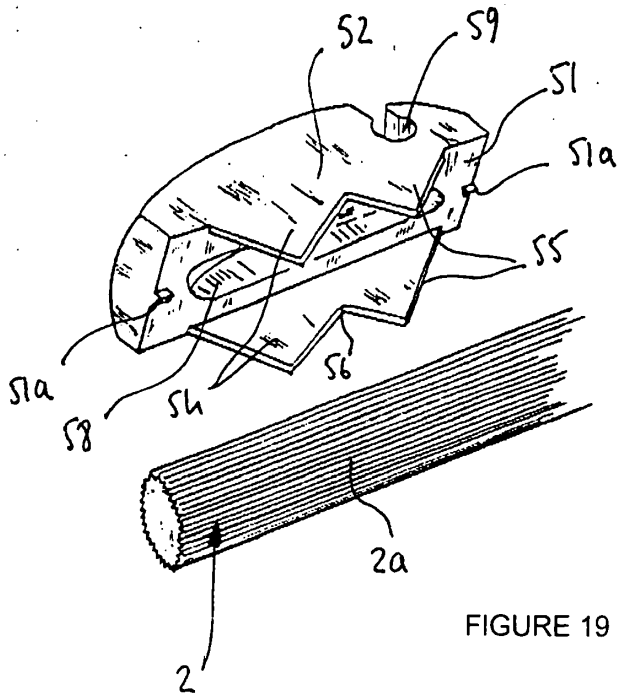


FIGURE 19

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INSTITUT NATIONAL DE LA PROPRIÉTÉ INDUSTRIELLE

RAPPORT DE RECHERCHE PRÉLIMINAIRE

établi sur la base des dernières revendications déposées avant le commencement de la recherche

N° d'enregistrement national

FA 702266
FR 0708975

DOCUMENTS CONSIDÉRÉS COMME PERTINENTS		Revendication(s) concernée(s)	Classement attribué à l'invention par l'INPI
Catégorie	Citation du document avec indication, en cas de besoin, des parties pertinentes		
D,A	FR 2 659 546 A (LAPRESLE PHILIPPE [FR]; MISSENARD GILLES [FR]; SACRISTE JEAN FRANCOIS) 20 septembre 1991 (1991-09-20) * abrégé; figures 1,2 *	1	A61B17/70
A	US 2007/270972 A1 (GORDON CHARLES R [US] ET AL) 22 novembre 2007 (2007-11-22) * alinéa [0119] - alinéa [0120]; figure 15 *	1	
A	US 2002/082601 A1 (TOYAMA YOSHIAKI [JP] ET AL) 27 juin 2002 (2002-06-27) * figures 1-3 *	1	
			DOMAINES TECHNIQUES RECHERCHÉS (IPC)
			A61B

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Date d'achèvement de la recherche	Examinateur
12 août 2008	Ducreau, Francis

CATÉGORIE DES DOCUMENTS CITÉS

X : particulièrement pertinent à lui seul
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EPO FORM 1503 12.99 (P04C14)

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RELATIF A LA DEMANDE DE BREVET FRANÇAIS NO. FR 0708975 FA 702266

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Document brevet cité au rapport de recherche	Date de publication	Membre(s) de la famille de brevet(s)	Date de publication
FR 2659546 A	20-09-1991	AUCUN	
US 2007270972 A1	22-11-2007	AUCUN	
US 2002082601 A1	27-06-2002	JP 2002200093 A	16-07-2002

EPO FORM P0465

Pour tout renseignement concernant cette annexe : voir Journal Officiel de l'Office européen des brevets, No.12/82

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(54) Title: POLYAXIAL BONE FIXATION ELEMENT

(57) Abstract: The present invention is directed a polyaxial bone fixation element for use in spinal fixation to interconnect a longitudinal spinal rod with a patient's vertebra. The polyaxial bone fixation element preferably includes a bone anchor, a collet, a body, and a locking cap. The polyaxial bone fixation element preferably enables in-situ assembly. That is, the polyaxial bone fixation element is preferably configured so that in use, the bone anchor may be secured to the patient's vertebra prior to being received within the body. Accordingly, the polyaxial bone fixation element enables a surgeon to implant the bone anchor without the body to maximize visibility and access around the anchoring site. Once the bone anchor has been secured to the patient's vertebra, the body can be snapped-onto the bone anchor. The bone anchor preferably also includes a second tool interface so that a surgical instrument can be directly coupled to the bone anchor.

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POLYAXIAL BONE FIXATION ELEMENT

CROSS REFERNCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Application No. 60/950,995, filed on July 20, 2007, entitled "TOP-LOADING POLYAXIAL PEDICLE SCREW," and the benefit of U.S. Provisional Application No. 60/988,584, filed on November 16, 2007, entitled "BONE SCREW WITH AN INSTRUMENT INTERFACE," the entire contents of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

[0002] It is often necessary due to various spinal disorders to surgically correct and stabilize spinal curvatures, or to facilitate spinal fusion. Numerous systems for treating spinal disorders have been disclosed.

[0003] One method involves a pair of elongated members, typically spinal rods, longitudinally placed on the posterior spine on either side of spinous processes of the vertebral column. Each rod is attached to various vertebrae along the length of the spine by way of pedicle screws. The pedicle screws each may include a body having a U-shaped rod-receiving channel for receiving a portion of the longitudinal spinal rod therein. Moreover, the body often interacts with a locking cap to clamp and secure the position of the spinal rod within the rod-receiving channel.

[0004] To facilitate insertion of the spinal rod into the rod-receiving channels and to provide additional flexibility in the positioning of the spinal rods and the pedicle screws, pedicle screws have been developed wherein the body is pivotable with respect to the bone anchor (commonly known as polyaxial pedicle screws).

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[0005] It is desirable to develop a pedicle screw that is simple for a surgeon to use, provides for polyaxial rotation and is able to securely mount the rod to the selected vertebra.

SUMMARY OF THE INVENTION

[0006] A preferred embodiment of the present invention is directed to a polyaxial bone fixation element for use in a spinal fixation procedure. The polyaxial bone fixation element preferably includes a bone anchor having an enlarged head portion (*e.g.*, a bone screw), a collet (*e.g.,* an insert member), a body having an axial bore for receiving the collet and the enlarged head portion of the bone anchor. The body also includes a rod-receiving channel and threads for threadably receiving a locking cap (*e.g.*, an externally threaded set screw). The polyaxial bone fixation element preferably enables in-situ assembly. That is, the polyaxial bone fixation element is preferably configured so that in use, the bone anchor may be secured to the patient's vertebra prior to being received within the body. Accordingly, the polyaxial bone fixation element preferably enables a surgeon to implant the bone anchor without the body and collet to maximize visibility and access around the anchoring site. Once the bone anchor has been secured to the patient's vertebra, the body can "pop-on" to the bone anchor. The bone anchor may also include an instrument interface so that a surgical instrument can be directly coupled to the bone anchor.

[0007] In one preferred embodiment, the polyaxial bone fixation element includes a bone anchor, a body, a collet and a locking cap. The bone anchor preferably includes an enlarged head portion. The head portion preferably includes a drive surface for engaging a first surgical instrument and an instrument interface for engaging a second surgical

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instrument. The body preferably includes a longitudinal axis, an upper end with an upper opening, a lower end with a lower opening, a bore extending between the upper opening and the lower opening wherein the bore has a first diameter, and a rod-receiving channel for receiving the spinal rod. The rod-receiving channel has a channel axis that is oriented substantially perpendicular to the longitudinal axis. The body preferably also includes a lower edge portion adjacent the lower opening. The lower edge portion has a second diameter smaller than the first diameter. The collet preferably includes a first end, a second end and one or more slots extending from the second end, wherein the slots define a plurality of flexible arms. The collet is preferably movably positioned within the bore of the body. The locking cap is preferably removably engageable with the body. The locking cap is movable from an unlocked position to a locked position, wherein movement of the locking cap from the unlocked position to the locked position urges the rod against the collet and the flexible arms against the lower edge portion to secure a position of the bone anchor relative to the body.

[0008] In another preferred embodiment, the polyaxial bone fixation element includes a body sized and configured to snap onto a head portion of an implanted bone anchor. The body preferably includes a longitudinal axis, an upper end with an upper opening, a lower end with a lower opening, a bore extending between the upper and lower openings wherein the bore has a first diameter, and a rod-receiving channel extending from the upper end toward the lower end and positioned on a channel axis that is oriented substantially perpendicular to the longitudinal axis. The bore preferably includes a lower edge portion terminating proximate the lower end and an enlarged diameter portion disposed adjacent to the lower edge portion and between the lower edge portion and the

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upper end. The lower edge portion preferably has a second diameter while the enlarged diameter portion has a third diameter, wherein the third diameter is preferably larger than the first diameter, which is larger than the second diameter. The collet preferably includes a first end, a second end and one or more slots extending from the second end, wherein the slots define a plurality of flexible arms. The flexible arms preferably each have a root end, a terminal end and a generally spherical, external surface proximate the terminal end. The flexible arms render the collet expandable to accept the head of the bone anchor and compressible to secure the head of the bone anchor relative to the collet. The flexible arms are preferably positioned proximate the enlarged diameter portion in a loading position and at least a portion of the external surface of the flexible arms contact the lower edge portion in a locked position.

[0009] In an alternate preferred embodiment, the polyaxial bone fixation element preferably includes a bone anchor, a body and a collet. The bone anchor preferably includes a head portion, wherein the head portion includes a drive surface for engaging a first surgical instrument and an instrument interface for engaging a second surgical instrument. The body preferably includes a longitudinal axis, an upper end with an upper opening, a lower end with a lower opening, a bore extending between the upper and lower openings, and a rod-receiving channel extending from the upper end toward the lower end and positioned on a channel axis that is oriented substantially perpendicular to the longitudinal axis. The bore preferably also includes a lower edge portion proximate the lower end and an enlarged diameter portion adjacent to the lower edge portion and between the lower edge portion and the upper end. The collet is preferably movably positioned within the bore of the body. The collet preferably includes a first end, a

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second end and one or more slots extending from the second end, wherein the slots define a plurality of flexible arms. The flexible arms preferably render the collet expandable to accept the head of the bone anchor and compressible to secure the head of the bone anchor relative to the collet. The collet preferably further includes a cavity extending from the second end. The flexible arms of the collet are preferably positioned in general vertical alignment with the enlarged diameter portion in a loading position so that the head of the bone anchor can be received in the cavity formed in the collet. At least a portion of the flexible arms preferably contact the lower edge portion in a locked position so that the head of the bone anchor is secured with respect to the collet. In the locked position, the contact is generally a line contact between the collet and the body.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

[0010] The foregoing summary, as well as the following detailed description of a preferred embodiment of the application, will be better understood when read in conjunction with the appended drawings. The preferred embodiment of the polyaxial bone fixation element is shown in the drawings for the purposes of illustration. It should be understood, however, that the application is not limited to the precise arrangements and instrumentalities shown. In the drawings:

[0011] Fig. 1 illustrates an exploded, perspective view of a preferred embodiment of a polyaxial bone fixation element;

[0012] Fig. 2A illustrates a front elevational view of a portion the polyaxial bone fixation element shown in Fig. 1, mounted in a patient's vertebra;

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[0013] Fig. 2B illustrates a side elevational view of the portion of the polyaxial bone fixation element shown in Fig. 1, mounted in the patient's vertebra;

[0014] Fig. 3 illustrates a partial, cross-sectional view of the polyaxial bone fixation element shown in Fig. 1, taken along line 3-3 of Fig. 2B;

[0015] Fig. 4A illustrates a magnified cross-sectional view of a head portion of a bone anchor used in connection with the polyaxial bone fixation element shown in Fig. 1;

[0016] Fig. 4B illustrates a top plan view of the bone anchor shown in Fig. 4A;

[0017] Fig. 5A illustrates a front elevational view of a collet used in connection with the polyaxial bone fixation element shown in Fig. 1;

[0018] Fig. 5B illustrates a side elevational view of the collet shown in Fig. 5A;

[0019] Fig. 5C illustrates a cross-sectional view of the collet shown in Fig. 5A, taken along line 5C-5C of Fig. 5B;

[0020] Fig. 6A illustrates a front elevational view of a first preferred embodiment of a body used in connection with the polyaxial bone fixation element shown in Fig. 1;

[0021] Fig. 6B illustrates a side elevational view of the body shown in Fig. 6A;

[0022] Fig. 6C illustrates a cross-sectional view of the body shown in Fig. 6A, taken along line 6C-6C of Fig. 6B;

[0023] Fig. 6D illustrates a magnified, cross-sectional view of a lower end of the body shown in Fig. 6A, taken from within circle 6D of Fig. 6C;

[0024] Fig. 6E illustrates a magnified, cross-sectional view of the lower end of the body shown in Fig. 6D and a collet and head of a bone anchor of the polyaxial bone fixation element shown in Fig. 1;

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[0025] Fig. 6F illustrates a magnified, cross-sectional view of a second preferred embodiment of a lower end of a body of the polyaxial bone fixation element shown in Fig. 1;

[0026] Fig. 6G illustrates a magnified, cross-sectional view of the lower end of the body shown in Fig. 6F;

[0027] Fig. 7A illustrates a top plan view of a locking cap used in connection with the polyaxial bone fixation element shown in Fig. 1;

[0028] Fig. 7B illustrates a cross-sectional view of the locking cap shown in Fig. 7A, taken along line 7B-7B of Fig. 7A;

[0029] Fig. 8A illustrates a side perspective view of a preferred embodiment of a screw driver and a sleeve coupled to a portion of the polyaxial bone fixation element of Fig. 1;

[0030] Fig. 8B illustrates a cross-sectional view of the screw driver and sleeve coupled to the portion of the polyaxial bone fixation element of Fig. 1, taken along line 8B-8B of Fig. 8A;

[0031] Fig. 9A illustrates a cross-sectional view of a syringe assembly and the sleeve coupled to a portion of the polyaxial bone fixation element of Fig. 1; and

[0032] Fig. 9B illustrates a magnified, cross-sectional view of the syringe assembly and sleeve shown in Fig. 9A, taken from within the circle 9B of Fig. 9A.

DETAILED DESCRIPTION OF THE INVENTION

[0033] Certain terminology is used in the following description for convenience only and is not limiting. The words "right", "left", "lower" and "upper" designate directions in the drawings to which reference is made. The words "inwardly" and "outwardly" refer

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to directions toward and away from, respectively, the geometric center of the polyaxial bone fixation element, the described instruments and designated parts thereof. The words, "anterior", "posterior", "superior", "inferior" and related words and/or phrases designate preferred positions and orientations in the human body to which reference is made and are not meant to be limiting. The terminology includes the above-listed words, derivatives thereof and words of similar import.

[0034] Certain exemplary embodiments of the invention will now be described with reference to the drawings. In general, such embodiments relate to a preferred polyaxial bone fixation element, and related instruments by way of non-limiting example and a polyaxial bone fixation element for use in spinal fixation to facilitate insertion of a longitudinal spinal rod in a rod-receiving channel formed in the body of the polyaxial bone fixation element. The invention may have other applications and uses and should not be limited to the structure or use described and illustrated.

[0035] Referring to Figs. 1-7B, a preferred polyaxial bone fixation element 10 includes a bone anchor 20 (shown as a bone screw), a collet 150, a body 200, and a locking cap 300 (shown as an externally threaded set screw). As will be described in greater detail below, the polyaxial bone fixation element 10 preferably enables in-situ assembly. That is, preferably, the polyaxial bone fixation element 10 is configured so that in use, the bone anchor 20 may be secured to a patient's vertebra 700 prior to being received within the body 200. The polyaxial bone fixation element 10 preferably enables a surgeon to implant the bone anchor 20 without the body 200 and collet 150 pre-assembled to the bone anchor 20. By enabling the surgeon to implant the bone anchor 20 only, the polyaxial bone fixation element 10 maximizes visibility and access around the

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anchoring site. Once the bone anchor 20 has been secured to the patient's vertebra 700, the body 200 and collet 150 may "pop-on" to the bone anchor 20. Accordingly, the preferred polyaxial bone fixation element 10 is typically considered a bottom loading device, because the bone anchor 20 enters the body 200 through a lower or bottom end 204. Alternatively, the polyaxial bone fixation element 10 may be provided pre-assembled using identical components as described herein or may be configured for top loading with minor modifications, as would be apparent to one having ordinary skill in the art. Further, the collet 150 and body 200 assembly may be popped-off of the bone anchor 20 in-situ by arranging the collet 150 relative to the body 200 in a loading position, after the fixation element 10 has been arranged in the locked position, and removing the assembly from the bone anchor 20, as will be described in greater detail below.

[0036] While the polyaxial bone fixation element 10 will be described as and may generally be used in the spine (for example, in the lumbar, thoracic or cervical regions), those skilled in the art will appreciate that the polyaxial bone fixation element 10 may be used for fixation of other parts of the body such as, for example, joints, long bones or bones in the hand, face, feet, extremities, cranium, *etc.*

[0037] As will be described in greater detail below, several polyaxial bone fixation elements 10 may be used to secure a longitudinal spinal rod 250 to several vertebrae 700. It should be understood that the spinal rod 250 may include, but is not limited to, a solid rod, a non-solid rod, a flexible or dynamic rod, *etc.* It should be understood that the polyaxial bone fixation element 10 is not limited in use to any particular type of spinal rod 250.

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[0038] Referring to Figs. 1-4B, the bone anchor 20 preferably is in the form of a bone screw 22. Alternatively, however, the bone anchor 20 may be, for example, a hook or other fastener such as, a clamp, an implant, *etc.*

[0039] The bone screw 22 preferably includes an enlarged, curvate head portion 24 and an externally threaded shaft portion 26 for engaging the patient's vertebra 700. The specific features of the shaft 26 including, for example, thread pitch, shaft diameter, shaft shape, *etc.* are interchangeable, and it would be apparent to one having ordinary skill in the art that the bone screw 22 is not limited to any particular type of shaft 26. The bone screw 22 may or may not be cannulated (See Figs. 9A and 9B). The bone screw 22 may also include a reduced diameter neck portion 28 between the head portion 24 and the shaft portion 26, which accommodates the polyaxial nature of the bone fixation element 10. The bone screw 22 may further be cannulated and fenestrated (not shown)such that openings extend outwardly from a central hollow channel in a cannulated screw to urge fluid out of the screw during injection or draw fluid into the central hollow channel from sides of the screw during extraction of material adjacent the screw.

[0040] Referring to Figs. 3-4B and 8A-9B, the enlarged curvate head portion 24 preferably has a curvate or semi-spherical shape to facilitate rotation with respect to the collet 150, as will be described in greater detail below. The head portion 24 also preferably includes a drive surface 30 for receiving a corresponding tip 501 formed on a drive tool, such as a screw driver 500 (Figs. 8A and 8B) for rotating the bone screw 22 into engagement with the patient's vertebra 700. The drive surface 30 may have any form now or hereafter known including, but not limited to, an external hexagon, a star drive pattern, a Phillips head pattern, a slot for a screw driver, a threading for a

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correspondingly threaded post, *etc.* Preferably, as shown, the drive surface 30 is comprised of a first tool interface or an internal recess 32, but is not so limited and may be comprised of an external drive feature that engages a female-type driver (not shown). The specific shape of the drive surface 30 or first tool interface 32 may be chosen to cooperate with the corresponding drive tool.

[0041] The head portion 24 may also include a second tool interface or a sleeve interface 40. The second tool interface 40 may be in any form now or hereafter known including, but not limited to, an internal or external thread, an external hexagon, a star drive pattern, a Phillips head pattern, a slot for a screw driver, a groove, a slot, *etc.* Preferably, however, the second tool interface 40 includes a plurality of threads 42 for threadably engaging a surgical instrument, such as a sleeve 600 (Figs. 8A-9B), bone augmentation instrumentation, aspiration instrumentation, reduction tool for sagittal reduction or other reduction, coronal rotation tool, soft tissue retraction tool, kyphosis and lordosis correction tool, *etc.* The second tool interface 40 of the preferred embodiment permits application of forces to the bone anchor 20 along a longitudinal axis of the bone anchor 20, as well as along or at angles to the axis. In the preferred embodiment, the sleeve 600 is adaptable for use in combination with at least the screw driver 500 and an injection assembly 650. The surgical instrument may alternatively be any surgical instrument now or hereafter used in connection with a spinal fixation procedure including, but not limited to, a compressor, a distractor, minimally invasive instrumentation, *etc.* By incorporating the second tool interface 40 into the head portion 24 of the bone anchor 20, the sleeve 600 is able to directly engage the bone anchor 20 thus eliminating the need for the sleeve 600 to engage the body 200 of the polyaxial bone

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fixation element 10 and thereby, limiting toggling between the sleeve 600, screw driver 500 and/or bone anchor 20 in a working configuration, as will be described in greater detail below. In addition, the preferred second tool interface 40 permits application of forces to the bone anchor 20 through the sleeve 600 or another tool that mates with the second tool interface 40 to manipulate the bone anchor 20 and potentially the bone that the bone anchor 20 is mounted in.

[0042] Referring to Figs. 3-4B, 8B and 9B, the second tool interface 40 and the first tool interface 32 are preferably formed in a head interface cavity 41 exposed from the top end of the head 24. Exposing both the second tool interface 40 and the first tool interface 32 at the top end of the head 24 permits simultaneous engagement of instruments with the second tool interface 40 and first tool interface 32 for manipulating the bone anchor 20. Both the second tool interface 40 and the first tool interface 32 may be engaged individually or simultaneously by an instrument prior to mounting the collet 150 and body 200 to the head 24 or after the collet 150 and body 200 are mounted to the head 24 (See Figs. 8B and 9B).

[0043] Referring to Figs. 3 and 5A-5C, the collet 150 preferably includes a first or upper end 152 sized and configured to contact at least a portion of the spinal rod 250 (schematically depicted in Fig. 5A) when the spinal rod 250 is received within a rod-receiving channel 208 formed in the body 200 and a second or lower end 154 sized and configured to contact at least a portion of the head portion 24 of the bone anchor 20. More preferably, the upper end 152 of the collet 150 includes a seat 160 sized and configured to receive at least a portion of the spinal rod 250 when the spinal rod 250 is received within the rod-receiving channel 208 of the body 200. The lower end 154 of the

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collet 150 preferably includes an interior cavity 165 for receiving and securing the head portion 24 of the bone anchor 20 so that, as will be generally appreciated by one of ordinary skill in the art, the bone anchor 20 can polyaxially rotate through a range of angles with respect to the collet 150 and hence with respect to the body 200. The cavity 165 formed in the collet 150 preferably has a curvate or semi-spherical shape for receiving the curvate or semi-spherical head portion 24 of the bone anchor 20 so that the bone anchor 20 can polyaxially rotate with respect to the collet 150 and hence with respect to the body 200. Furthermore, at least a portion of the outer surface of the collet 150 is comprised of a curvate or spherical, convex surface 151 having a radius of curvature r_5 for contacting the inner surface 211 of the body 200, preferably the lower edge portion 218, as will be described in greater detail below.

[0044] The collet 150 preferably also includes one or more slots 170 (shown as a plurality of slots) extending from the lower end 154 thereof so that at least a portion of the collet 150 is: (i) radially expandable so that the head portion 24 of the bone anchor 20 can be inserted through the lower end 154 and into the cavity 165 of the collet 150 and (ii) radially compressible to compress or crush-lock against the head portion 24 of the bone anchor 20, in accordance with the application of radial forces applied thereto. In the preferred embodiment, the slots 170 define a plurality of flexible arms 172. Preferably each flexible arm 172 includes a root end 173 and a terminal end 174. The outer surface of the flexible arms 172 preferably include the curvate or spherical convex surface 151 of the collet 150 for defining a line-contact with the inner surface 211 of the body 200, preferably the first undercut 218a, as will be described in greater detail below.

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[0045] The collet 150 may also include one or more grooves 175 formed on the outer surface thereof for engaging a projection or dimple 216a formed in the inner surface 211 of the body 200. As will be described in greater detail below, the collet 150 is permitted to float within the axial bore 206 formed in the body 200 between a loading position and a locked position. That is, the collet 150 is preferably movably positioned within the body 200 in an assembled configuration. Interaction between the one or more grooves 175 and the projection or dimples 216a prevents the collet 150 from moving out of the upper end 202 of the body 200 when in the loading position.

[0046] The collet 150 also includes a bore 156 extending from the upper end 152 to the lower end 154 with an upper opening at the upper end 152 so that, for example, a drive tool, such as, for example, a screw driver 500, can be inserted through the collet 150 and into engagement with the bone anchor 20 so that the bone anchor 20 may be rotated into engagement with the patient's vertebra 700. The upper opening at the upper end 152 of the collet 150 also permits simultaneous insertion of the screw driver 500 and a second tool, such as the sleeve 600, therethrough to engage the head 24 (Figs. 8B and 9B).

[0047] The collet 150 may also include one or more provisional rod-locking features so that the spinal rod 250 may be provisionally coupled to the collet 150, and hence with respect to the body 200. The provisional rod-locking features may be any mechanism now or hereafter developed for such purpose.

[0048] Referring to Fig. 5C, the collet 150 includes one or more inwardly projecting ledges 184, 186 disposed on an inner surface 161 of the seat 160 adjacent the upper end 152 of the collet 150. The ledges 184, 186 may be engaged by a tool (not shown) to

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apply a force between the collet 150 and the body 200 to move the collet 150 relative to the body 200. For example, the body 200 may be urged downwardly toward the bone anchor 20 relative to the collet 150 when the collet 150, body 200 and bone anchor 20 are in the locked position. Such application of a force may move the collet 150 from the locked position into the loading position, in situ, such that the flexible arms 172 are able to flex outwardly within an enlarged diameter portion 220 to permit the head 24 to move out of the cavity 165. Accordingly, the ledges 184, 186 may be utilized to disassemble the collet 150 and body 200 from the bone anchor 20 after the collet 150 and body 200 have been locked to the head 24.

[0049] Referring to Figs. 6A-6D and 7A-7B, the body 200 may generally be described as a cylindrical tubular body having a longitudinal axis 201, an upper end 202 having an upper opening 203, a lower end 204 having a lower opening 205, and an axial bore 206 substantially coaxial with the longitudinal axis 201 of the body 200. The axial bore 206 extends from the upper opening 203 to the lower opening 205. The axial bore 206 preferably has a first diameter portion D_1 proximate the upper end 202. The body 200 also includes a substantially transverse rod-receiving channel 208 (shown as a top loading U-shaped rod-receiving channel) defining a pair of spaced apart arms 209, 210. The inner surface 211 of the spaced apart arms 209, 210 preferably includes a plurality of threads 212 for engaging a locking cap 300. Alternatively, the body 200 and, in particular, the spaced apart arms 209, 210 may have nearly any mounting receiving structure for engaging the locking cap 300 including, but not limited to, external threads, cam-lock, quarter lock, clamps, *etc.* The outer surface 213 of the spaced apart arms 209, 210 may each include a recess 214 for engaging one or more surgical instruments such

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as, for example, rocker forceps, a compressor, a distractor, a sleeve, minimally invasive instrumentation, *etc.*

[0050] Referring to Figs. 5A-6E, the axial bore 206 preferably has the first diameter portion D_1 proximate the upper end 202. The inner surface 211 of the axial bore 206 preferably also includes a lower end portion 218 proximate the lower end 204 thereof. The lower end portion 218 defines a second diameter portion D_2, which is comprised of the smallest diameter portion of the axial bore 206. The second diameter portion D_2 is preferably defined by a first spherical undercut 218a adjacent the lower end 204 of the body 200. The first spherical undercut 218a preferably has a second radius of curvature r2 that is centered on the longitudinal axis 201 of the body 200. The second diameter portion D_2 is preferably smaller than the first diameter portion D_1 of the axial bore 206 such that the collet 150 may be inserted through the upper end 202 into the axial bore 206, but generally preventing the collet 150 from being inserted into the lower end 204 or from falling out of the lower end 204 once inserted into the axial bore 206.

[0051] The first spherical undercut 218a is preferably defined as a curvate or spherical concave surface for accommodating the outer curvate or spherical convex surface 151 of the collar 150. The first spherical undercut 218a and the spherical convex surface 151 preferably have a different radius of curvature such that line contact is defined between the surfaces 151, 218 when the collet 150 is positioned proximate the lower end 204. The second diameter portion D_2 is preferably sized and configured so that the enlarged head portion 24 of the bone anchor 20 may be passed through the lower opening 205 of the body 200, but is prevented from passing therethrough once the head

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portion 24 of the bone anchor 20 is received within the interior cavity 165 of the collar 150.

[0052] The inner surface 211 of the axial bore 206 preferably includes an enlarged portion 220 that is located toward the lower end 204 relative to the first diameter portion D_1. The enlarged portion 220 preferably defines a third diameter D_3 comprised of a curvate, preferably spherical, radially outwardly recessed portion. In the enlarged portion 220 of the axial bore 206, the third diameter D_3 is larger than the first diameter D_1 of the axial bore 206. In addition, the third diameter D_3 is larger than the second diameter D_2. In the preferred embodiment, the third diameter D_3 is defined by a second spherical undercut 220a.

[0053] The enlarged portion 220 is preferably located in between the upper end 202 and the lower end portion 218 and accommodates expansion of the flexible arm 172 therein when the head 24 is loaded into the collet 150, as will be described in greater detail below. The enlarged portion 220 is preferably in the form of a curvate or spherical concave surface having a third radius of curvature r3, which defines the third diameter D_3 at the largest diameter within the axial bore 206. The third radius of curvature r3 defines the spherical nature of the second spherical undercut 220a. The enlarged portion 220 is sized and configured so that when the collet 150 is placed in general alignment with the curvate or spherical concave surface of the enlarged portion 220, the flexible arms 172 of the collet 160 are permitted to radially expand within the axial bore 206 of the body 200 so that the head portion 24 of the bone anchor 20 can be inserted through the lower opening 205 formed in the body 200 and into the cavity 165 formed in the collet 150. More preferably, the enlarged portion 220 is sized and configured so that the outer

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curvate or spherical convex surface 151 of the collet 150 does not touch or contact the enlarged portion 220 of the body 200 when the head 24 is loaded into the collet 150. That is, the enlarged portion 220 formed in the body 200 is preferably sized and configured so that a gap remains between the outer curvate or spherical convex surface 151 of the collet 150 and the enlarged portion 220 of the body 200 even when the flexible arms 172 radially expand to accept the head portion 24 of the bone anchor 20. The enlarged portion 220 is not limited to constructions comprised of the preferred curvate or spherical undercut defined by the third radius of curvature r3 and may be constructed of nearly any undercut having nearly any shape that permits expansion of the collet 150 therein in the loading position to accept the head 24. For example, the enlarged portion 220 may be defined by a rectangular slot or groove on the inner surface 211 that results in the third diameter D_3 being larger than the first and second diameters D_1, D_2.

[0054] In the preferred embodiment, the second radius of curvature r2 of the first spherical undercut 218a is preferably different than an outer radius of curvature r5 of the outer curvate or spherical convex surface 151 of the collet 150 so a line contact results between the first spherical undercut 218a and the outer convex surface 151 when the collet 150 is positioned adjacent the lower end portion 218. That is, by providing non-matching radius of curvatures between the first spherical undercut 218a and the collet 150, only line contact occurs between the first spherical undercut 218a of the body 200 and the outer curvate or spherical convex surface 151 of the collet 150. The line contact between the body 200 and the collet 150 effectively pinches the lower ends of the flexible arms 172 onto the lower end of the head 24 below the greatest diameter of the head 24 to direct the lower end 154 beneath the largest diameter of the head 24, effectively locking

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the bone anchor 20 to the collet 150 in the locked position. In addition, the line contact between the collet 150 and body 200 permits disengagement of the collet 150 from the body 200 after the collet 150 and body 200 are engaged in the locked position or popping-off of the body 200 and collet 150 from the bone anchor 20, in situ.

[0055] Referring to Figs. 5A-5C, 6F and 6G, the second and third diameters D2, D3 may be formed by a single internal radius of curvature r4 that undercuts the body 200 in the axial bore 206. The single internal radius of curvature r4 preferably permits expansion of the collet 150 to accept the head 24, insertion of the collet 150 into the axial bore 206 from the upper end 202 but not the lower end 204 and line contact between the outer curvate or spherical convex surface 151 of the collet and the lower end portion 218 when the collet 150 is in facing engagement with the lower end portion 218. In this configuration, the second diameter portion D2 is smaller than the first diameter portion D1, which is smaller than the third diameter portion D3.

[0056] Referring to Figs. 1-3 and 5A-6C, the body 200 and collet 150 also preferably include a collet retention feature 50 so that once the collet 150 has been inserted into the bore 206 formed in the body 200 and, if necessary, the collet retention feature 50 has been engaged, the collet retention feature 50 inhibits the collet 150 from passing back through the upper opening 203 formed in the body 200, but permits some degree of vertical translation or floating of the collet 150 with respect to the body 200. That is, once inserted into the axial bore 206 of the body 200, the collet 150 is sized and configured to float or move within the axial bore 206 between a loading position and a locking position. The collet retention feature 50 preferably prevents the collet 150 from moving out of the upper opening 203 of the body 200. Preferably the collet retention

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feature 50 permits the flexible arms 172 to align with the enlarged portion 220 in the loading position when the lower edge of the grooves 175 come into contact with the dimples 216a. In addition, the collet 150 is preferably permitted to float between the loading position and the locking position prior to locking of the head 24 in the collet 150. Specifically, the collet 150 may float between the loading position where the dimples 216a are in contact with the lower edge of the grooves 175 and the locking position wherein the outer curvate or spherical convex surface 151 is in line contact with the lower end portion 218. The collet retention feature 50 preferably limits rotation of the collet 150 with respect to the body 200, because the dimples 216a slide within the grooves 175, so that the seat 160 formed in the collet 150 is aligned with the rod-receiving channel 208 formed in the body 200. However, the retention feature 50 is not limited to limiting rotation of the collet 150 with respect to the body 200 and may be configured to permit unlimited rotation of the collet 150 relative to the body 200 by eliminating the grooves 175 from the collet 150 and forming a shelf (not shown) around the collet 150 at the bottom end of the grooves 175 such that the dimples 216a engage the shelf to limit removal of the collet 150 out of the upper end 202 of the body 200, but permit unlimited rotation of the collet 150 relative to the body 200 in the assembled configuration.

[0057] The collet retention feature 50 may be any feature now or hereafter known for such purpose including, but not limited to, for example, an inwardly protruding shoulder or detent formed on the collet 150 for engaging corresponding indentations formed on the inner surface 211 of the body 200. In the preferred embodiment, the body 200 includes one or more partial passageways 216 formed therein so that once the collet 150 has been

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received within the axial bore 206 of the body 200, a force may be applied to the partial passageways 216 formed in the body 200 deforming the remaining portion of the partial passageway 217 into the dimple or projection 216a formed in the inner surface 211 of the body 200. That is, once the collet 150 has been received within the bore 206 of the body 200, an external force may be applied to the partial passageways 216 formed in the body 200 transforming the passageways 216 into the projections or dimples 216a that extend inwardly from the inner surface 211 of the spaced apart arms 209, 210 and into the bore 206 formed in the body 200. The dimples or projections 216a are preferably sized and configured to interact with the longitudinal groove 175 formed in the outer surface of the collet 150 so that the collet 150 is permitted to move with respect to the body 200 at least along the longitudinal axis 201, but inhibited from moving back through the upper opening 203 formed in the body 200. The collet 150 is also preferably partially inhibited from rotational movement with respect to the body 200. Movement of the collet 150 with respect to the body 200 toward the upper end 202 is preferably inhibited by the projections or dimples 216a contacting the bottom and/or lateral surfaces of the grooves 175. Limiting rotational movement of the collet 150 with respect to the body 200 permits alignment of the rod-receiving channel 208 and the seat 160 for receiving the rod 250, as will be described in greater detail below.

[0058] In use, positioning the collet 150 in general alignment with the curvate or spherical concave surface of the enlarged portion 220 in the loading position preferably enables the flexible arms 172 of the collet 150 to radially expand within the axial bore 206 of the body 200 so that the head portion 24 of the bone anchor 20 can be inserted through the lower opening 205 formed in the body 200 and into the cavity 165 formed in

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the collet 150. The enlarged portion 220 formed in the body 200 is preferably sized and configured so that a gap remains between the outer curvate or spherical convex surface 151 of the collet 150 and the enlarged portion 220 of the body 200 even when the flexible arms 172 radially expand to accept the head portion 24 of the bone anchor 20. Thereafter, movement of the collet 150 into general alignment and engagement with the first spherical undercut 218a of the lower end portion 218 causes a radial inward force to be applied to the flexible arms 172, which in turn causes the flexible arms 172 to compress against the head portion 24 of the bone anchor 20, thereby securing the position of the bone anchor 20 with respect to the collet 150 and hence with respect to the body 200. The lower end portion 218 and the outer curvate or spherical convex surface 151 of the collet 150 have non-matching radii of curvature r2, r4, r5 so that only line contact occurs between these components.

[0059] The head portion 24 of the bone anchor 20 and interaction of the dimples 216 with the grooves 175 preferably moves the collet 150 into alignment with the enlarged portion 220 as the head portion 24 is inserted through the lower opening 205 and into the axial bore 206. Moreover, the collet 150 is preferably moved into alignment and engagement with the lower edge portion 218 via engagement of the locking cap 300, as will be described in greater detail below.

[0060] Referring to Figs. 7A and 7B, the locking cap 300 is preferably an externally threaded set screw 302 for threadably engaging the threads 212 formed on the inner surface 211 of the body 200. The externally threaded set screw 302 generally provides flexibility when inserting a spinal rod 250 into the body 200 such that the spinal rod 250 does not have to be completely reduced or seated within the body 200 prior to

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engagement of the cap 300. Incorporation of a threaded set screw 302 also enables the set screw 302 to reduce the spinal rod 250 during tightening of the locking cap with respect to the body 200. The locking cap 300 may be any locking cap now or hereafter developed for such purpose including, but not limited to, an externally threaded cap, a quarter-turn or partial-turn locking cap, two-piece set screw, *etc.*

[0061] As shown, the externally threaded set screw 302 preferably includes a drive surface 304 for engaging a corresponding drive tool for securing (*e.g.*, threading) the set screw 302 onto the body 200. The drive surface 304 may take on any form now or hereafter developed for such purpose, including, but not limited to, an external hexagon, a star drive pattern, a Phillips head pattern, a slot for a screw driver, a threading for a correspondingly threaded post, *etc.* The drive surface 304 is preferably comprised of an internal recess. The specific shape of the internal recess may be chosen to cooperate with the corresponding drive tool. The drive surface 304 may also be configured to include the first and second tool interfaces 40, as were described above.

[0062] The externally threaded set screw 302 preferably also includes a saddle 310 operatively coupled thereto. The saddle 310 includes a transverse recess 312 formed therein for contacting at least a portion of the spinal rod 250. The rod-contacting surface of the recess 312 may include a surface finish (not shown) that adds roughness, such as, for example, a knurl, bead blasting, grooves, or other textured finish that increases surface roughness and enhances rod push through strength.

[0063] The saddle 310 may be coupled to the set screw 302 by any means now or hereafter developed for such purpose including, but not limited to, adhesion, mechanically fastening, *etc.* The set screw 302 preferably includes a bore 306 for

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receiving a stem 316 formed on a top surface 311 of the saddle 310. In use, the saddle 310 is preferably coupled to the set screw 302 but is free to rotate with respect to the set screw 302 so that the saddle 310 can self-align with the spinal rod 250 while the set screw 302 is being rotated with respect to the body 200.

[0064] In one particularly preferred embodiment, the threads formed on the externally threaded set screw 302 may incorporate inclined load flanks forming an angle with respect to the longitudinal axis 201 of the body 200. The load flanks may be converging so that the top surface of the thread and the bottom surface of the thread converge. The angle may be about five degrees (5°), although, as will be generally appreciated by one of ordinary skill in the art, the threads may take on any other form now or hereafter known for such purpose including, negative load threads, perpendicular threads flanks, buttress threads, *etc.*

[0065] Referring to Figs. 1-7B, the polyaxial bone fixation element 10 is preferably provided to the user in a kit including at least (1) bone anchors, (2) locking caps, and (3) pre-assembled collet/body subassemblies. The pre-assembled collet/body subassemblies are preferably assembled by inserting the collet 150 into the axial bore 206 formed in the body 200 through the upper opening 203 formed in the body 200. The flexible arms 172 may flex inwardly as the collet 150 is inserted into the axial bore 206, if the greatest diameter of the flexible arms 172 is larger than the first diameter D1. Such a configuration generally results in the collet 150 being retained within the axial bore 206, even before the collet retention feature 50 is engaged. Once the collet 150 is positioned within the axial bore 206 such that the flexible arms 172 are positioned proximate the enlarged portion 220, a force is applied to a distal end of the partial passageway 216

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formed in the body 200 so that a projection or dimple 216a is formed, which extends into the bore 206 of the body 200. The projection or dimple 216a is positioned within the longitudinal groove 175 formed in the collet 150 so that the collet 150 is free to vertically translate or float within the bore 206 with respect to the body 200, but generally prevented from passing back up through the upper opening 203 formed in the body 200 and limited in its ability to rotate relative to the body 200.

[0066] The kit is preferably shipped to the user for use in spinal surgery. During surgery, the surgeon preferably identifies a level of the spine where the surgery will take place, makes and incision to expose the selected area and implants the bone anchors 20 into the desired vertebrae 700. The body/collet subassemblies are preferably popped-on to the bone anchors 20 by urging the head 24 through the lower opening 205. Accordingly, the collet/body subassembly may be engaged with the head portion 24 of the bone anchor 20 in situ. Specifically, as the head 24 moves into the lower opening 205, the collet 150 is urged toward and into the loading position wherein the lower end of the longitudinal grooves 175 contact the dimples 216a. In the loading position, the outer curvate or spherical convex surface 151 of the collet 150 is in general vertical alignment with the enlarged curvate or spherical concave surface of the enlarged portion 220 formed in the axial bore 206 of the body 200. Alignment of the enlarged portion 220 with the collet 150 enables the collet 150 to radially or outwardly expand so that the head portion 24 of the bone anchor 20 can be received within the cavity 165 formed in the collet 150.

[0067] Once the head 24 is positioned in the cavity 165, the head portion 24 of the bone anchor 20 and the collet 150 are both preferably constrained within the body 200.

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The bone anchor 20 is preferably able to polyaxially rotate with respect to the collet 150 and the body 200 in this configuration. The spinal rod 250 is inserted into the rod-receiving channel 208 formed in the body 200 and onto the inner surface 161 of the seat 160. The spinal rod 250 is preferably positioned in facing engagement with the inner surface 161 of the seat 160. The set screw 302 is preferably threaded into engagement with the threads 212 formed in the body 200 to urge the spinal rod 250 and collet 150 toward the lower end 204.

[0068] Rotation of the set screw 302 causes the bottom surface of the set screw 300, preferably the saddle 310, to contact the top surface of the spinal rod 250, which in turn causes the spinal rod 250 and the collet 150 to move downwards with respect to the body 200. Downward movement of the collet 150 with respect to the body 200 causes line contact between the outer curvate or spherical convex surface 151 of the collet 150 and the first spherical undercut 218a of the lower end portion 218. Additional tightening of the set screw 300 and downward movement of the spinal rod 250 and collet 150 results in an inwardly directed compressive force to the flexible arms 172, causing the flexible arms 172 to pivot inwardly toward the head portion 24 at their terminal ends 174 about the root ends 173. In a locking position, the flexible arms 172 engage the head 24 of the bone anchor 20 securing the position of the bone anchor 20 with respect to the collet 150 and the body 200. Specifically, the flexible arms 172 of the collet 150 radially compress against the head portion 24 of the bone anchor 20, which secures the position of the bone anchor 20 with respect to the body 200. The line contact between the collet 150 and body 200 proximate the terminal ends 174 direct the radial inward force on the flexible arms 172 at a location preferably below the largest diameter of the head 24 to efficiently urge

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the terminal ends 174 beneath the curved outer surface of the head 24 in the locked position. In addition, the spinal rod 250 is sandwiched between the set screw 302 and the collet 150 in the locking position, thereby securing the position of the spinal rod 250 with respect to the body 200 and the bone anchor 20.

[0069] Referring to Figs. 3 and 5A-6E, the collet 150 and body 200 may be popped-off of the bone anchor 20, in situ, after the bone fixation element 10 is engaged in the locked configuration. Specifically, the set screw 300 may be removed from the body 200 and the spinal rod 250 may be extracted from the rod-receiving channel 208 and the seat 160. A tool (not shown) engages the ledges 184, 186 and the body 200 and applies a force between the collet 150 and the body 200 to move the body 200 downwardly toward the body anchor 20. The line contact between the body 200 and the collet 150 is released and the collet 150 is urged into the loading position. In the loading position, the flexible arms 172 flex outwardly within the enlarged portion 220 to permit popping-off of the body 200 and collet 150 from the head 24 of the bone anchor 20. The collet 150 and body 200 may then be popped back onto the bone anchor 20.

[0070] Referring to Figs. 4A, 4B and 8A-9B, the head portion 24 of the bone anchor 20 preferably includes a drive surface 30 in the form of an internal drive recess or a first tool interface 32 and a second tool interface 40. The second tool interface 40 preferably includes a plurality of threads 42 for threadably engaging the sleeve 600. The sleeve 600 preferably accommodates a variety of surgical instruments now or hereafter known including, but not limited to, the screw driver 500, a fluid delivery device such as the injection assembly 650, a compressor, a distractor, minimally invasive instrumentation, *etc*. By incorporating the second tool interface 40 into the head portion 24 of the bone

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anchor 20, the surgical instruments are able to directly engage the bone anchor 20, thus eliminating the need for the surgical instruments and/or the sleeve 600 to engage the body 200 or collet 150 of the polyaxial bone fixation element 10. In addition, once the sleeve 600 is engaged with the second tool interface 40, toggling between the screw driver 500 or another instrument inserted through an internal bore in the sleeve 600 and the bone anchor 20 is limited. In the preferred embodiment, the sleeve 600 is utilized to draw the screw driver 500 into the first tool interface 32 to limit toggling between the screw driver 500 and the bone anchor 20. The second tool interface 40 is described herein as interacting or engaging the sleeve 600, but is not so limited and may be configured to interact or engage with nearly any tool or instrument that preferably is utilized to positively engage the head 24 and apply forces to the bone anchor 20 for manipulating the bone anchor 20, vertebra 700 mounted to the bone anchor 20 or any other structure that is mounted to the bone anchor 20.

[0071] In order to facilitate implantation of the polyaxial bone fixation elements 10 and to perform, for example, one or more steps in a surgical procedure, it is advantageous to limit or remove "toggling" between the polyaxial bone fixation elements 10 and any surgical instruments that are utilized with the bone fixation elements 10. By incorporating the second tool interface 40 into the head portion 24 of the bone anchor 20, the sleeve 600 and, indirectly, the surgical instrument, for example, the screw driver 500, are directly connected to the bone anchor 20. The sleeve 600 includes a threaded distal portion 602 for threadably engaging the threads 42 of the second tool interface 40. In this manner, the sleeve 600 is directly coupled and secured to the bone anchor 20. Through this engagement, toggling is limited between the sleeve 600 and the bone anchor 20. In

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addition, having a close tolerance between in internal surface of the bore in the sleeve 600 and the screw driver 500 or other instrument significantly limits toggling between the screw driver 500 or other instrument and the bone anchor 20.

[0072] During the surgical procedure, the direct connection of the sleeve 600 with the bone anchor 20 facilitates protection of the polyaxial locking mechanism (the collet 150 and the body 200) of the polyaxial bone fixation element 10 and provides a more stable distraction, because the forces applied to the sleeve 600 are transferred directly to the bone anchor 20 via the second tool interface 40 and into the vertebra 700, as opposed to acting through these elements as well as the collet 150 and/or the body 200, which may distort some of the forces and cause toggling. In addition, instruments, such as the screw driver 500 or the injection assembly 650 may be securely positioned in engagement with the bone anchor 20 to drive the bone anchor 20 with the screw driver 500, inject bone cement or other fluid into and through the bone anchor 20 or otherwise conduct a procedure with the bone anchor 2, without operating through the body 200 and/or collet 150.

[0073] The second tool interface 40 preferably does not obstruct access to the drive recess 32, because the second tool interface 40 is preferably located above and radially outwardly relative to the drive recess 32. However, the second tool interface 40 is not limited to being located above and radially outwardly relative to the drive recess or first tool interface 32 and may be located below and radially inwardly relative to the first tool interface 32, as long as tools or instruments are able to engage the first and second tool interfaces 32, 40 simultaneously. Specifically, the second tool interface 40 may be comprised of a threaded recess in the bone anchor 20 having a smaller diameter and

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located below the first tool interface 32. Moreover, as best shown in Figs. 9A and 9B, the sleeve 600 preferably includes the longitudinal bore so that the screw driver 500, for example, may engage the drive recess 32 formed in the head portion 24 of the bone anchor 20. In this manner, the sleeve 600 engages the bone anchor 20 via the second tool interface 40 while the screw driver 500 simultaneously engages the drive recess 32.

[0074] Referring to Figs. 8A and 8B, the sleeve 600 is preferably associated with a slip sleeve 800 that surrounds the sleeve 600 in a working configuration. The sleeve 600 and the screw driver 500 are rotatable relative to the slip sleeve 800 such that a surgeon may grasp the slip sleeve 800 while turning a handle 502 on a distal end of the screw driver 500 to screw the bone anchor 20 into or out of the vertebra 700. When the surgeon rotates the handle 502, the sleeve 600, screw driver 500 and bone anchor 20 each rotate relative to the slip sleeve 800.

[0075] In an anchor driving position (Fig. 8B), external threads 602 on the sleeve 600 are fully threaded into the threads 42 of the second tool interface 40, thereby limiting any toggling between the sleeve 600 and bone anchor 20. The top 501 of the screw driver 500 is also fully engaged with the drive recess 32 of the bone anchor 20 in the anchor driving position. When a surgeon has completed manipulating the bone anchor 20 with the screw driver 500, the screw driver 500 may be removed from the sleeve 600 and another instrument may be utilized with the sleeve 600 to gain access to the bone anchor 20.

[0076] Referring to Figs. 9A and 9B, the injection assembly 650 may be utilized with the sleeve 600 to inject bone cement or other flowable materials into a cannulated bone anchor 20′. Once the bone anchor 20′ is mounted in the vertebra 700 and the sleeve 600

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is mounted on the bone anchor 20′, a cannula 652 of the injection assembly 650 is inserted into the sleeve 600. The cannula 652 is associated with a syringe 654 at a proximal end and includes a blunt tip 656 at a distal end. The cannula 652 preferably includes an engagement mechanism 656 proximate the proximal end to engage a proximal end of the sleeve 600 to secure the cannula 652 to the sleeve 600. In addition, the engagement mechanism 656 preferably urges the blunt tip 656 of the cannula 652 into engagement with a shelf 32a at the bottom of the first tool interface 32 such that a flow channel 34 of the cannula 652 is in communication with a flow channel 652a of the cannula and a seal is created between the blunt tip 656 and the shelf 32a. In the preferred embodiment, the engagement mechanism 656 is comprised of a threaded joint that may be tightened to secure the cannula 652 relative to the sleeve 600 and securely seal the blunt tip 656 to the shelf 32a, thereby generally preventing leakage of bone cement or other flowable fluid into the first tool interface 32. Bone cement is preferably injected into the flow channel 652a with the injection assembly 650 and into the vertebra 700 to securely mount the bone anchor 20′ to the vertebra 700, particularly in generally weak, brittle and/or osteoporotic bone. The bone anchor 20′ may also be fenestrated to inject bone cement toward the sides of the bone anchor 20′ or to generally directionally dispense the bone cement or other fluid. Further, the bone anchor 20′ may be utilized to extract material from the vertebra 700 or other bone that the bone anchor 20′ is engaged with by drawing the material into the flow channel 652a, by, for example, creating a vacuum in the flow channel 652a. For example, the bone anchor 20′ may be utilized to extract bone marrow from the bone. Further, the bone anchor 20′ may be utilized to aid in bone graft extension, as would be apparent to one having ordinary skill in the art.

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[0077] It should be understood that while the bone anchor 20 is being described herein as preferably including the second tool interface 40, the second tool interface 40 is optional. Furthermore, it should be understood that the bone anchor 20 including the second tool interface 40 may be used in any other type of bone screw application such as, for example, long bone fixation, fracture fixation, or in connection with securing a bone plate, vertebral spacer, dental implant, *etc.*

[0078] The polyaxial bone fixation element 10 including the bone anchor 20, the collet 150, the body 200 and the locking cap 300 may be made from any biocompatible material now or hereafter known including, but not limited to, metals such as, for example, titanium, titanium alloys, stainless steel, Nitinol, *etc.*

[0079] As will be appreciated by those skilled in the art, any or all of the components described herein may be provided in sets or kits so that the surgeon may select various combinations of components to perform a fixation procedure and create a fixation system which is configured specifically for the particular needs/anatomy of a patient. It should be noted that one or more of each component may be provided in a kit or set. In some kits or sets, the same device may be provided in different shapes and/or sizes.

[0080] While the foregoing description and drawings represent the preferred embodiment of the present invention, it will be understood that various additions, modifications, combinations and/or substitutions may be made therein without departing from the spirit and scope of the present invention as defined in the accompanying claims. In particular, it will be clear to those skilled in the art that the present invention may be embodied in other specific forms, structures, arrangements, proportions, and with other elements, materials, and components, without departing from the spirit or essential

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characteristics thereof. One skilled in the art will appreciate that the invention may be used with many modifications of structure, arrangement, proportions, materials, and components and otherwise, used in the practice of the invention, which are particularly adapted to specific environments and operative requirements without departing from the principles of the present invention. In addition, features described herein may be used singularly or in combination with other features. The presently disclosed embodiments are, therefore, to be considered in all respects as illustrative and not restrictive, the scope of the invention being indicated by the appended claims and not limited to the foregoing description.

[0081] It will be appreciated by those skilled in the art that changes could be made to the embodiments described above without departing from the broad inventive concept thereof. It is understood, therefore, that this invention is not limited to the particular embodiments disclosed, but it is intended to cover modifications within the spirit and scope of the present invention, as defined by the appended claims.

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CLAIMS

1. A polyaxial bone fixation element for coupling a longitudinal spinal rod to a vertebra, the bone fixation element comprising:

a bone anchor including an enlarged, curvate head portion, wherein the head portion includes a first tool interface for engaging a first surgical instrument and a second tool interface for engaging a second surgical instrument, the first and second tool interfaces positioned in a head interface cavity;

a body for interconnecting the bone anchor and the longitudinal spinal rod, the body having a longitudinal axis, an upper end with an upper opening, a lower end with a lower opening, a bore extending substantially between the upper opening and the lower opening, the bore having a first diameter D_1, a rod-receiving channel for receiving the spinal rod located at the upper end, the rod-receiving channel having a channel axis that is oriented substantially perpendicular to the longitudinal axis, the body further including a lower edge portion adjacent the lower opening, the lower edge portion defining a second diameter D_2 smaller than the first diameter D_1;

a collet including a first end, a second end and one or more slots extending from the second end, the slots defining a plurality of flexible arms, the collet movably positioned within the bore of the body; and

a locking cap removably engageable with the body, the locking cap being movable from an unlocked position to a locked position wherein movement of the locking cap from the unlocked position to the locked position urges the rod against the

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collet and the flexible arms against the lower edge portion to secure a position of the bone anchor relative to the body.

2. The polyaxial bone fixation element of claim 1, wherein the drive recess includes a drive surface which is an internal surface formed in the head portion of the bone anchor for receiving an external tip formed on the first surgical instrument and the second tool interface is a plurality of threads formed on the head portion for threadably engaging a portion of the second surgical instrument.

3. The polyaxial bone fixation element of claim 1, wherein the second tool interface is located proximal of the first tool interface so that the second tool interface does not obstruct access to the first tool interface.

4. The polyaxial bone fixation element of claim 1, wherein the second surgical instrument is selected from one of a compressor, a distractor, a screw driver, a sleeve, minimally invasive instrumentation, a bone augmentation tool, an aspiration tool, a reduction tool, a coronal rotation tool, a tissue retractor and a kyphosis or lordosis correction tool.

5. The polyaxial bone fixation element of claim 1, wherein the body further includes an enlarged diameter portion, the enlarged diameter portion being located between the lower edge portion and the upper end, the enlarged diameter portion defining a third diameter D_3, the third diameter D_3 being larger than the first diameter D_1 and the second diameter D_2.

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6. The polyaxial bone fixation element of claim 5, wherein the lower edge portion and the enlarged diameter portion each have a spherical concave surface.

7. The polyaxial bone fixation element of claim 6, wherein the collet is movably positioned within the bore of the body between a loading position wherein the collet is substantially aligned with the enlarged diameter portion so that the flexible arms of the collet can radially expand to receive the head portion of the bone anchor and a locked position wherein the collet is moved into contact with the lower edge portion so that the flexible arms compress against the head portion of the bone anchor to secure the position of the bone anchor with respect to the collet.

8. The polyaxial bone fixation element of claim 7, wherein the first spherical undercut has a radius of curvature r1 and the flexible arms have an outer spherical surface having a radius of curvature r2, wherein r1 is different than r2.

9. The polyaxial bone fixation element of claim 1 wherein the collet includes a pair of longitudinal grooves on an outer surface and the body includes a pair of dimples extending into the bore and into the longitudinal grooves in an assembled configuration.

10. A body assembly for snapping over a head portion of an implanted bone anchor and for interconnecting the bone anchor to an elongated spinal rod, the body assembly comprising:

a body including a longitudinal axis, an upper end with an upper opening, a lower end with a lower opening, a bore extending between the upper and lower openings along a longitudinal axis, the bore having a first diameter D_1 proximate the upper opening and a rod-receiving channel extending from the upper end toward the lower end, the rod-

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receiving channel positioned on a channel axis that is oriented substantially perpendicular to the longitudinal axis, the bore includes a lower edge portion having a first spherical undercut terminating proximate the lower end and an enlarged diameter portion having a second spherical undercut disposed adjacent to the first spherical undercut toward the upper end, the lower edge portion having a second diameter D_2 and the enlarged diameter portion having a third diameter D_3, the third diameter D_3 being larger than the first diameter D_1, which is larger than the second diameter D_2; and

a collet including a first end, a second end and at least two slots extending from the second end, the at least two slots defining flexible arms, the collet movably positioned within the bore of the body, wherein the flexible arms each have a root end, a terminal end and an outer curvate convex surface proximate the terminal end, the flexible arms rendering the collet expandable to accept the head of the bone anchor and compressible to secure the head of the bone anchor relative to the collet, wherein the flexible arms are positioned proximate the enlarged diameter portion in a loading position and at least a portion of the outer curvate convex surface of the flexible arms being in line contact with at least a portion of the first undercut in a locked position.

11. The body assembly of claim 10, further comprising a collet retention feature extending into the bore between the upper end and the second undercut that prevents the collet from passing through the upper opening in an assembled configuration.

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12. The body assembly of claim 11, wherein the collet retention feature contacts a bottom end of a groove in the collet in the loading position to align the flexible arms with the second spherical undercut.

13. The body assembly of claim 11, wherein the body includes one or more partial passageways formed therein so that once the collet has been received within the bore of the body, a force is applied to the one or more partial passageways, thereby deforming the one or more partial passageways into one or more dimples extending into the bore of the body, the one or more dimples comprising the collet retention feature.

14. The body assembly of claim 13, wherein the one or more dimples interact with the collet to inhibit the collet from moving back through the upper opening formed in the body.

15. A polyaxial bone fixation element for coupling a longitudinal spinal rod to a vertebra, the bone fixation element comprising:

a bone anchor including a head portion, wherein the head portion includes a first tool interface for engaging a first surgical instrument and second tool interface for engaging a second surgical instrument, the first and second tool interfaces positioned in a head interface cavity;

a body including a longitudinal axis, an upper end with an upper opening, a lower end with a lower opening, a bore extending between the upper and lower openings along a longitudinal axis, and a rod-receiving channel extending from the upper end toward the lower end and positioned on a channel axis that is oriented substantially perpendicular to

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the longitudinal axis, the bore includes a lower edge portion having a generally spherical diameter portion proximate the lower end and an enlarged diameter portion having a generally spherical diameter portion adjacent to the lower edge portion and between the lower edge portion and the upper end; and

a collet movably positioned within the bore of the body, the collet including a first end, a second end and at least two slots extending from the second end, the at least two slots defining a flexible arms, the flexible arms rendering the collet expandable to accept the head of the bone anchor and compressible to secure the head of the bone anchor relative to the collet, the collet further including a cavity extending from the second end, wherein the flexible arms of the collet are positioned in alignment with the enlarged diameter portion in a loading position so that the head of the bone anchor can be received in the cavity formed in the collet, wherein at least a portion of the flexible arms contact the lower edge portion in a locked position so that the head of the bone anchor is secured with respect to the collet.

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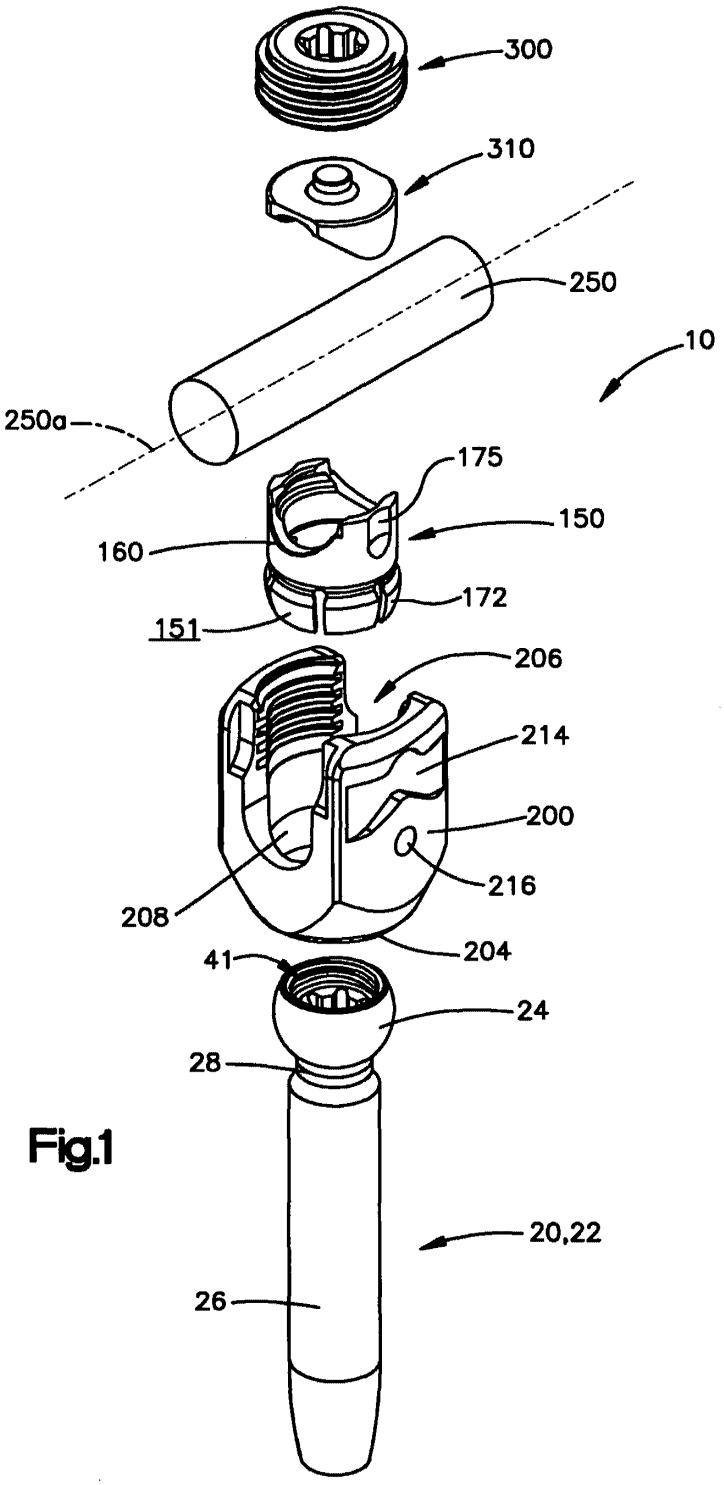

300
310
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20,22
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Fig.1

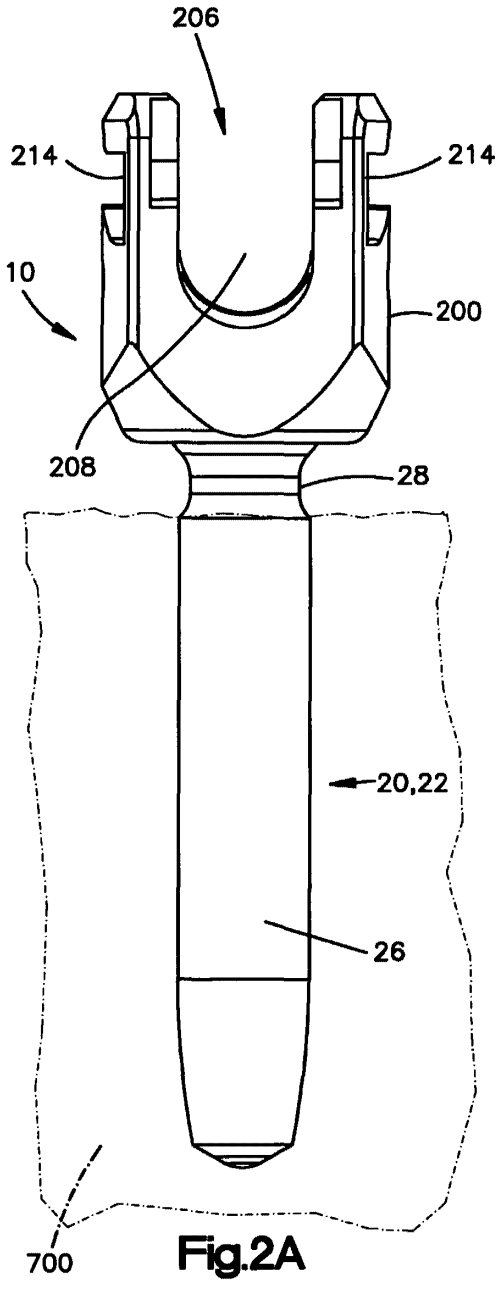

206
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Fig.2A

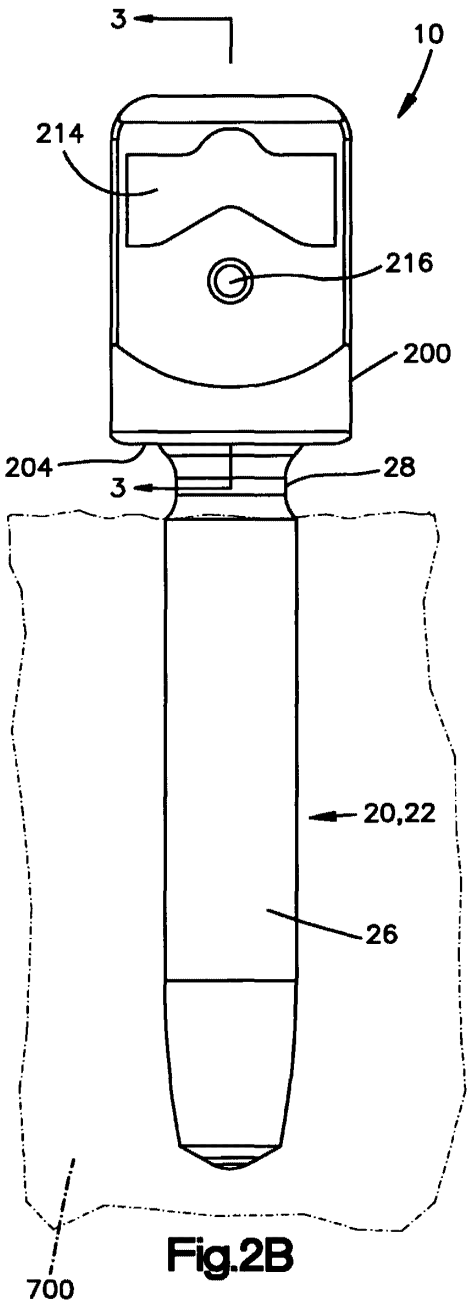

3
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Fig.2B

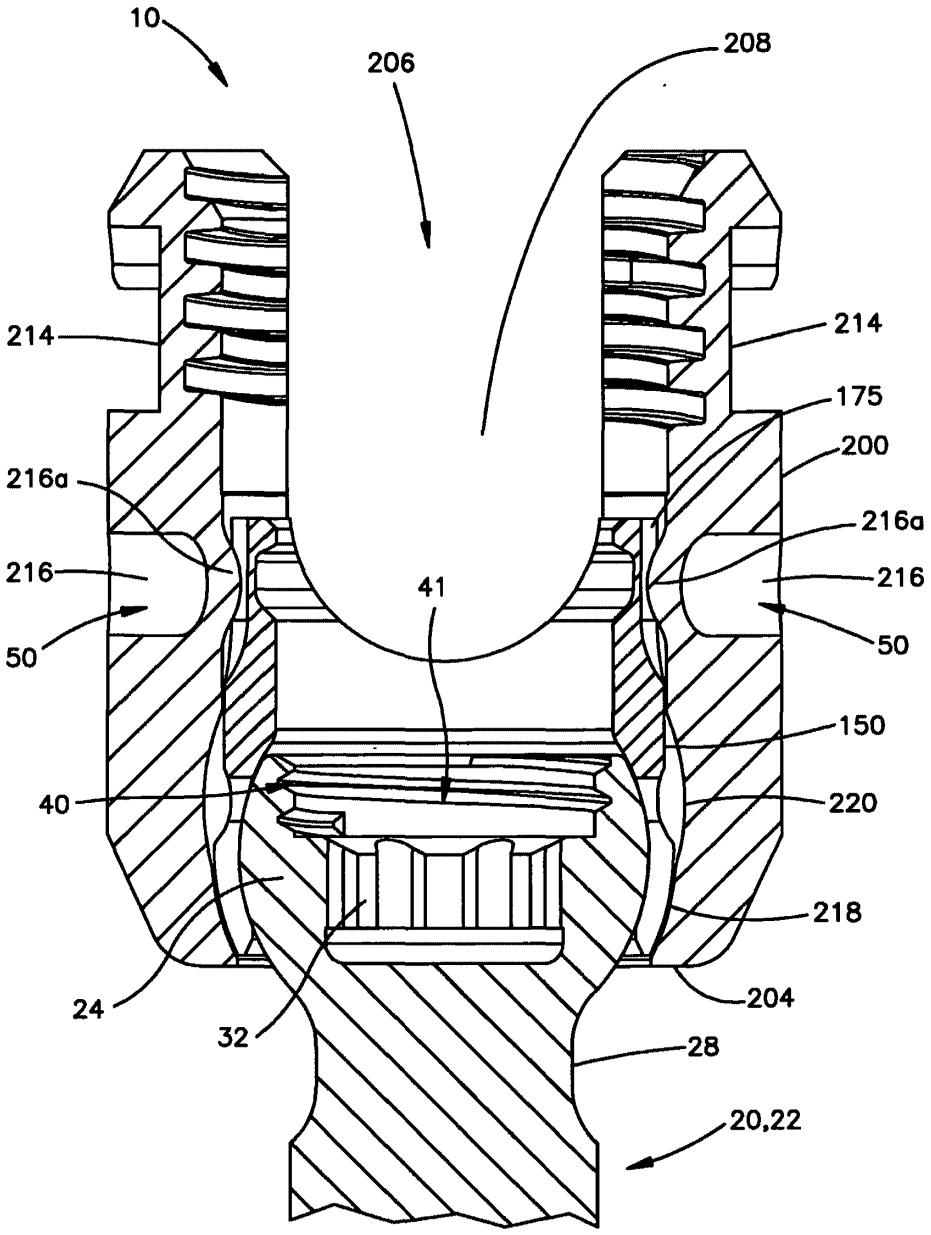

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Fig.3

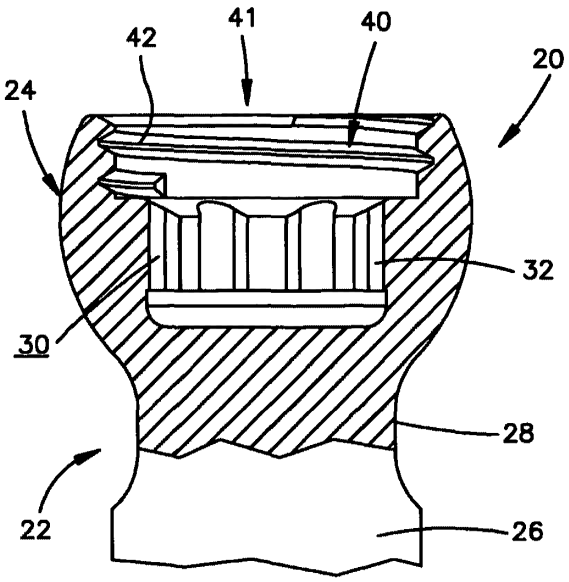


Fig.4A

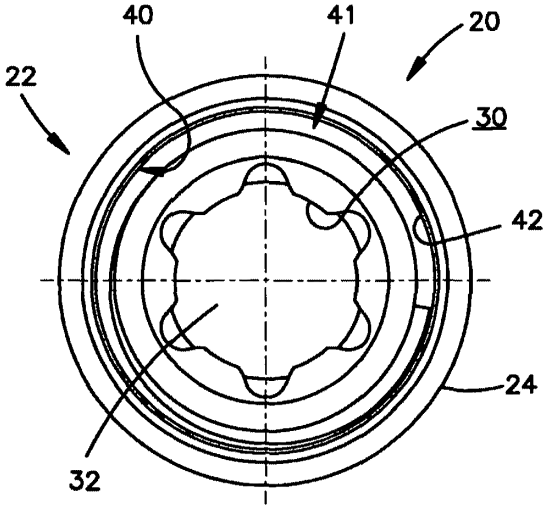


Fig.4B

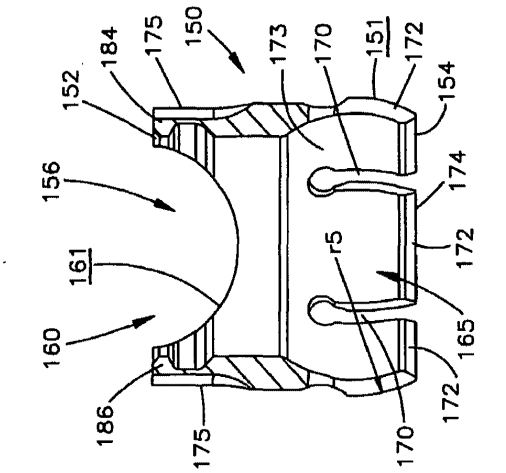


Fig.5C

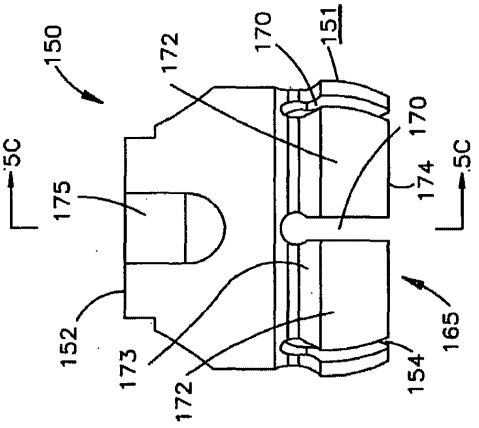


Fig.5B

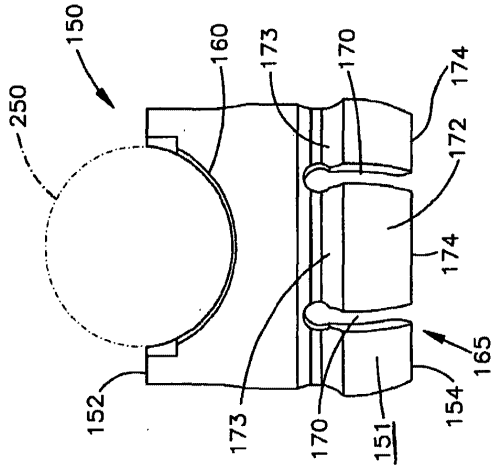


Fig.5A

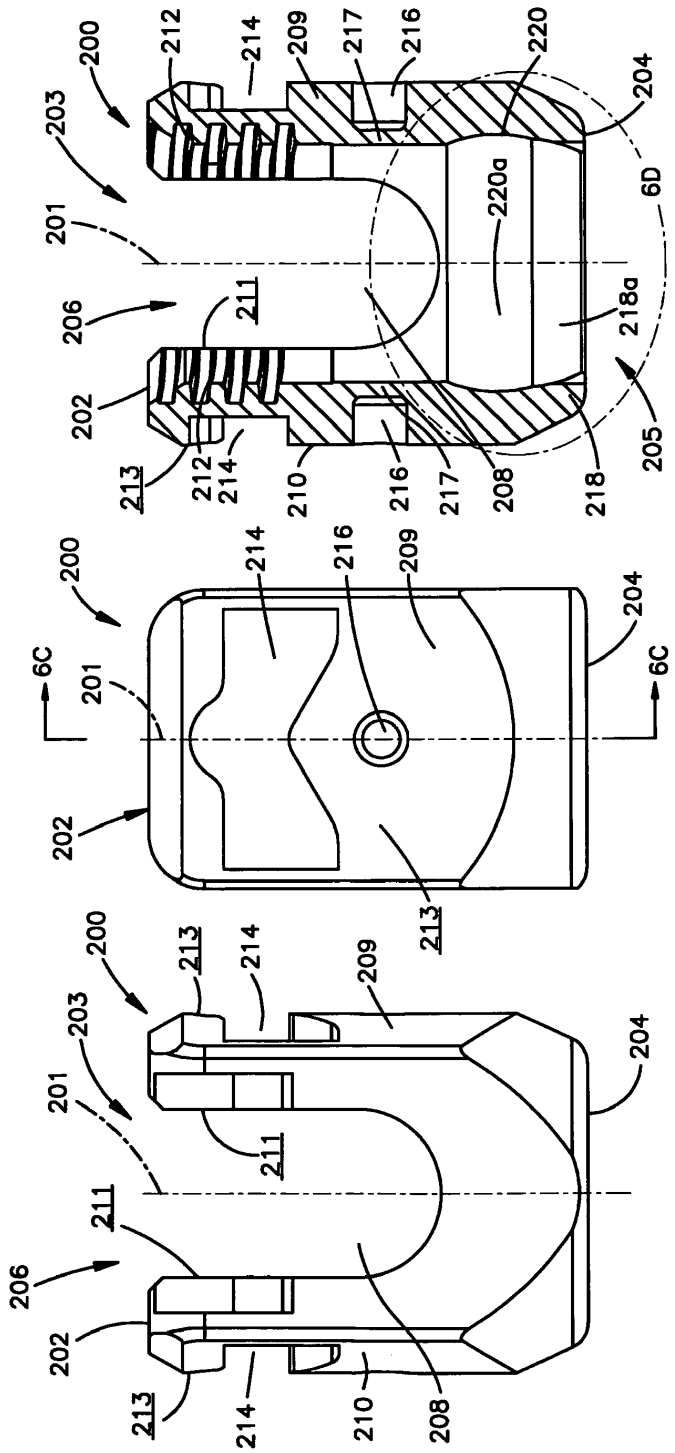


Fig.6C

Fig.6B

Fig.6A

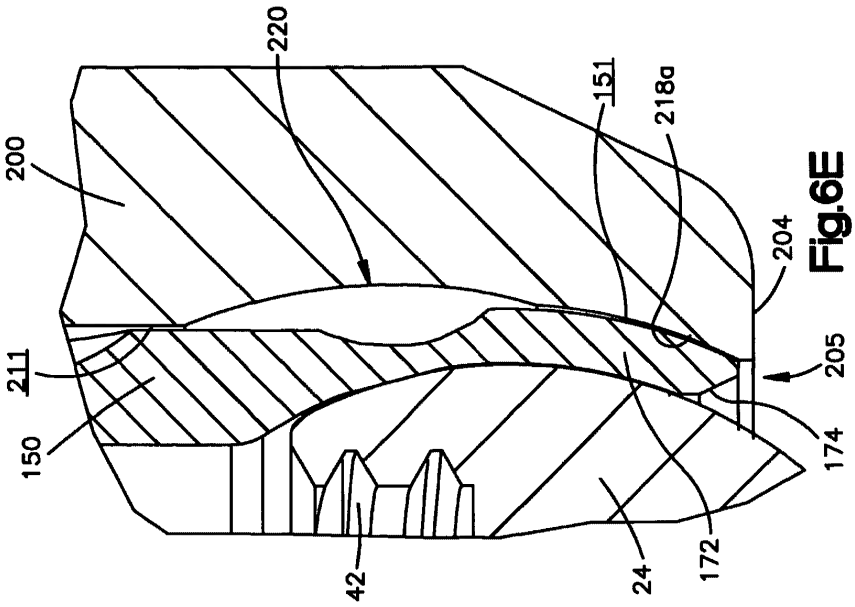

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Fig.6E

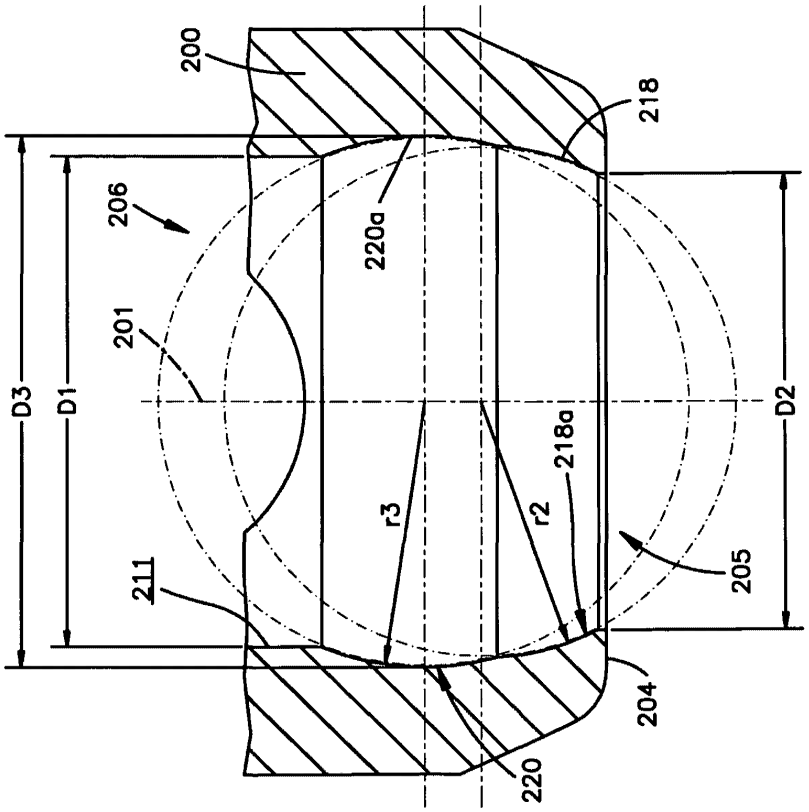

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D2
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220

Fig.6D

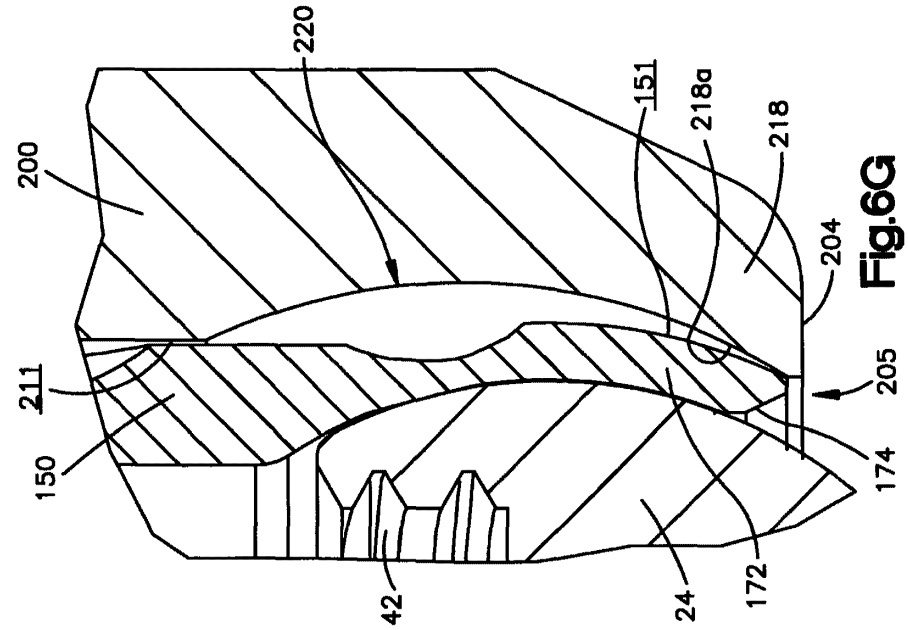

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Fig.6G

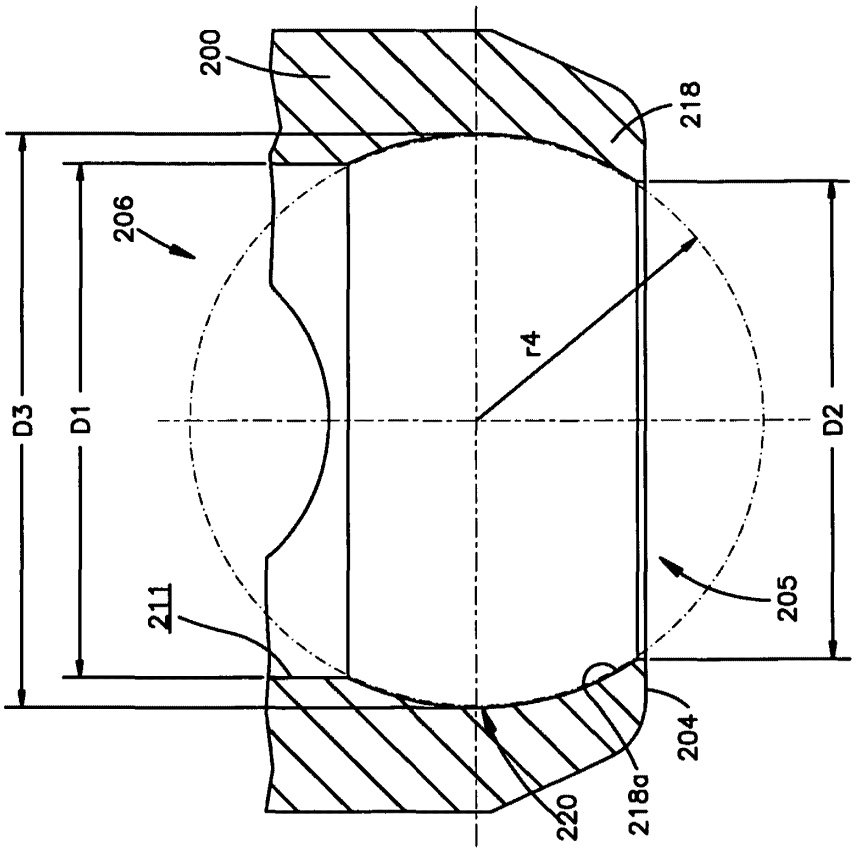

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r4
D3
D1
D2
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205
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Fig.6F

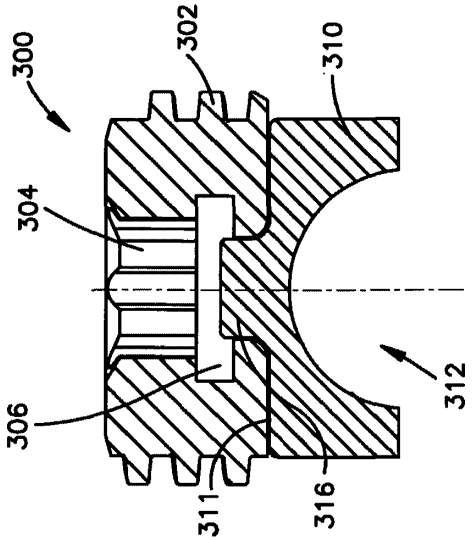


Fig.7B

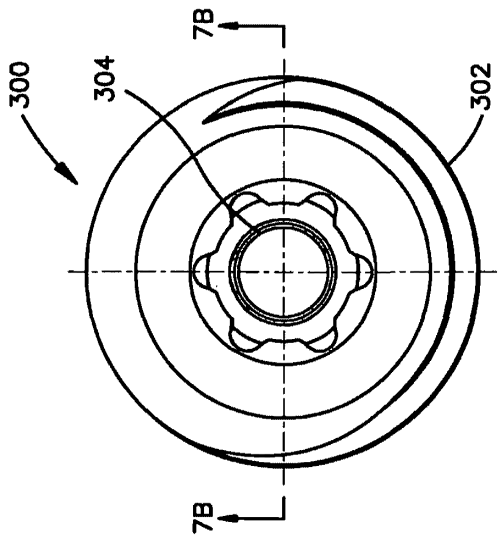


Fig.7A

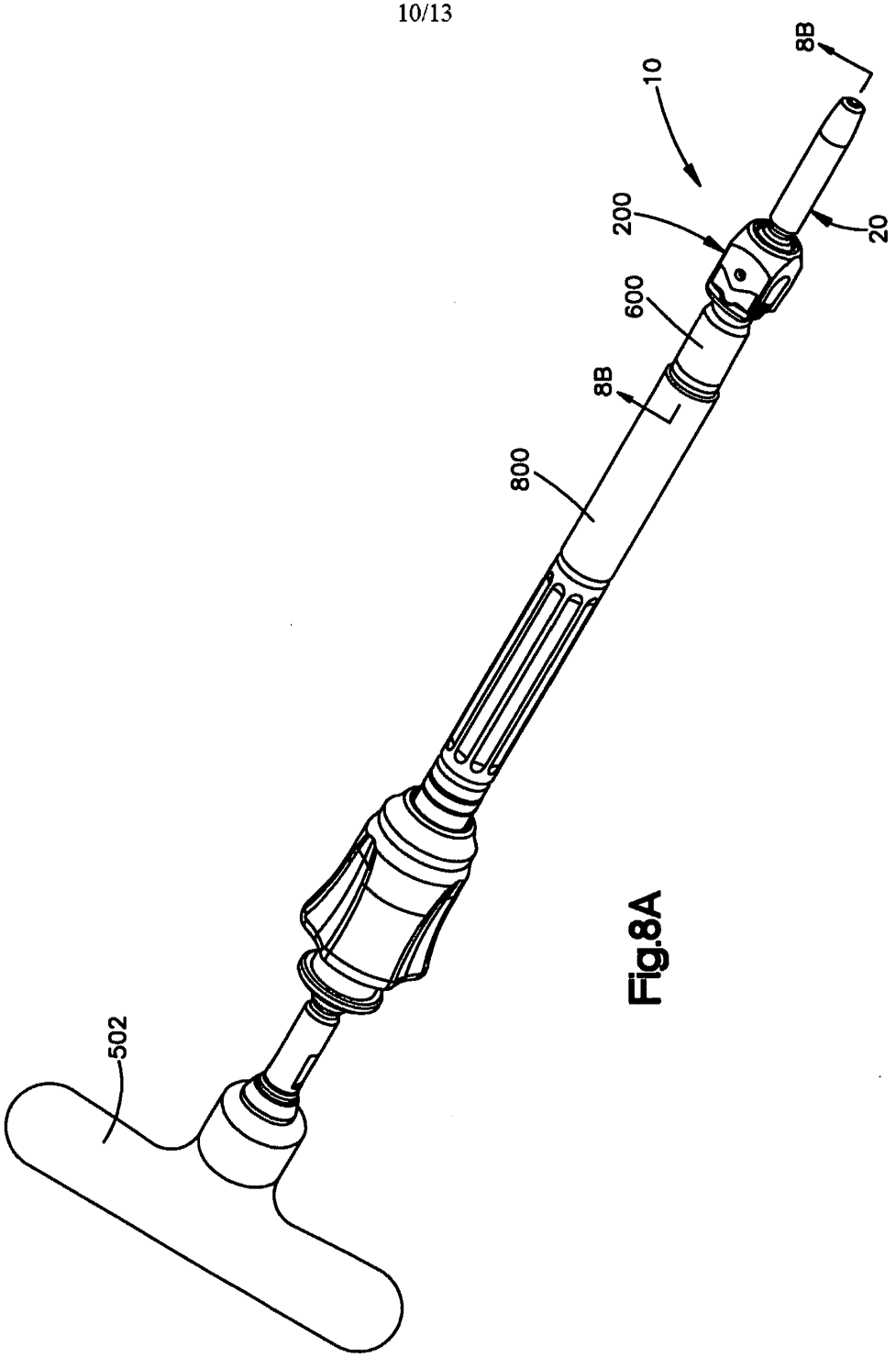


Fig.8A

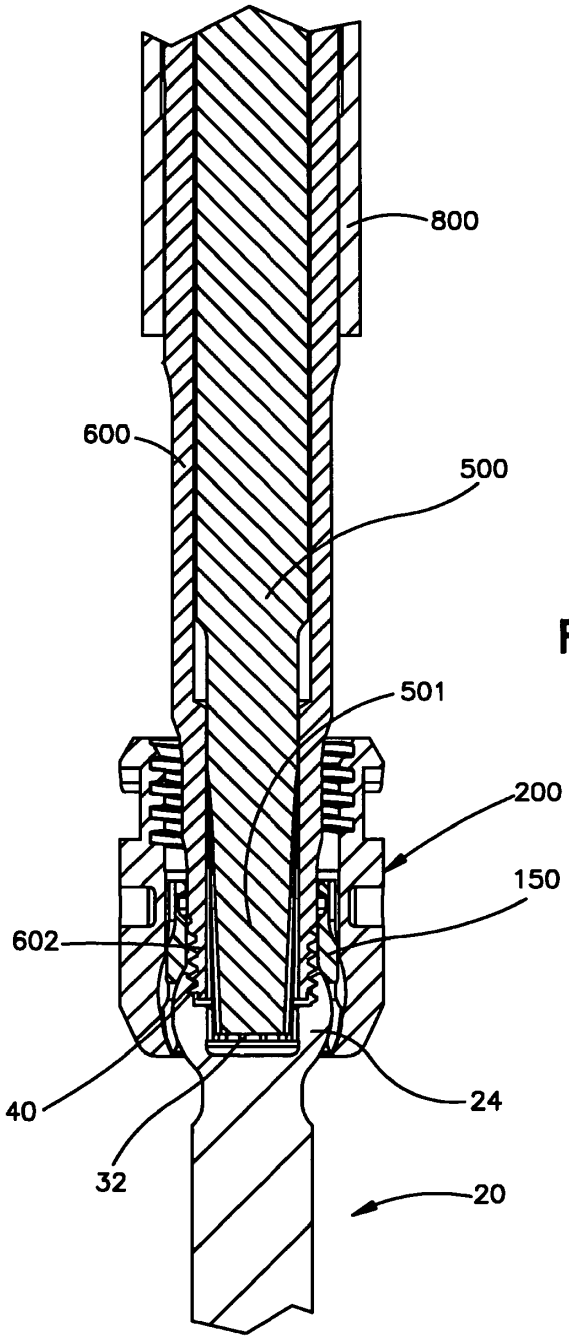


Fig.8B

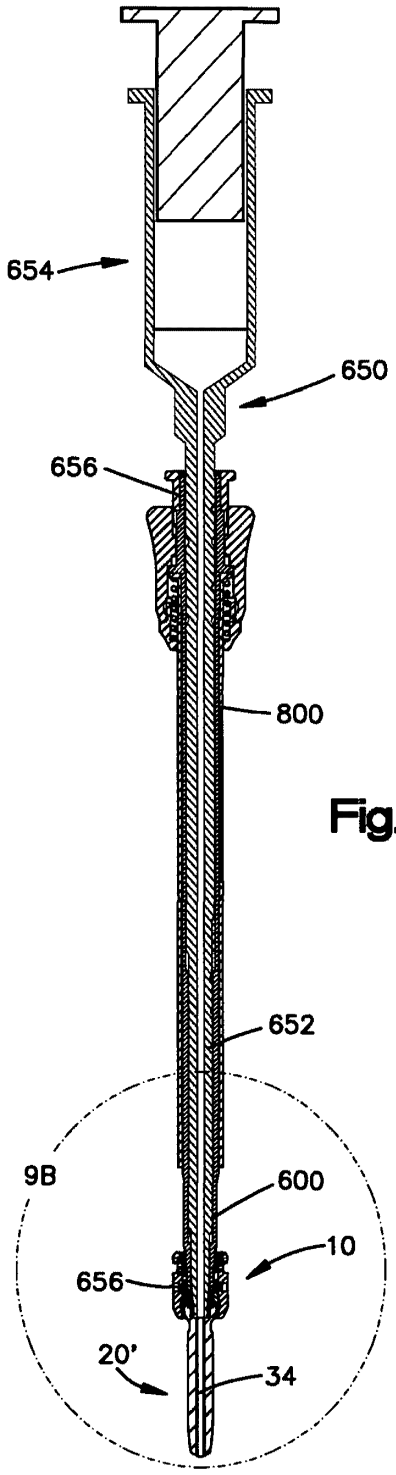


Fig.9A

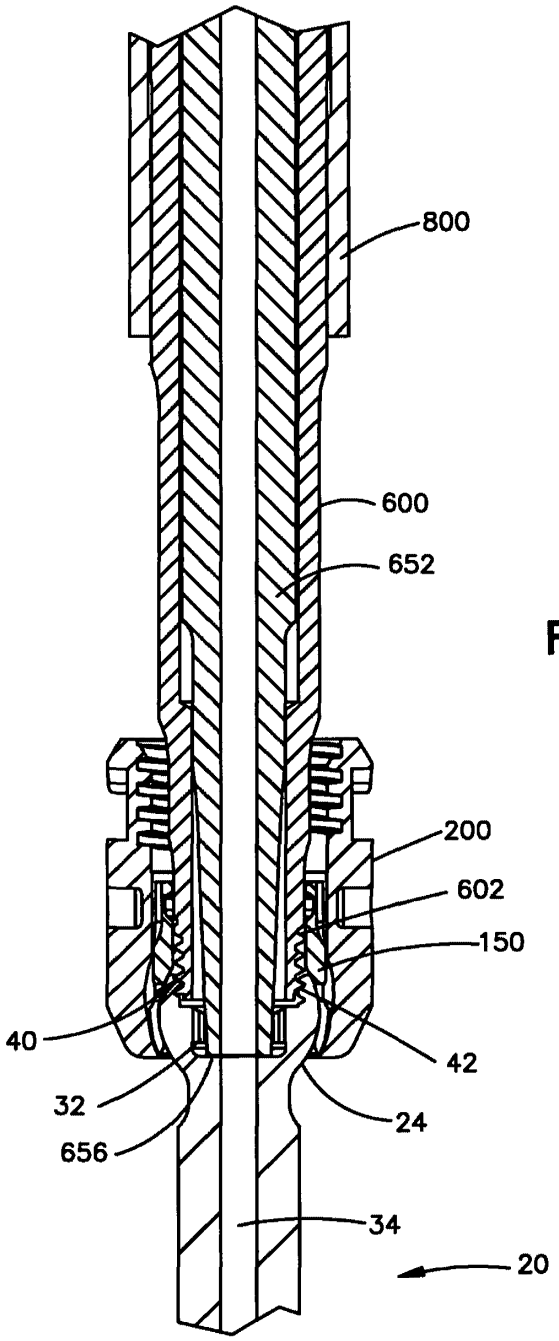


Fig.9B

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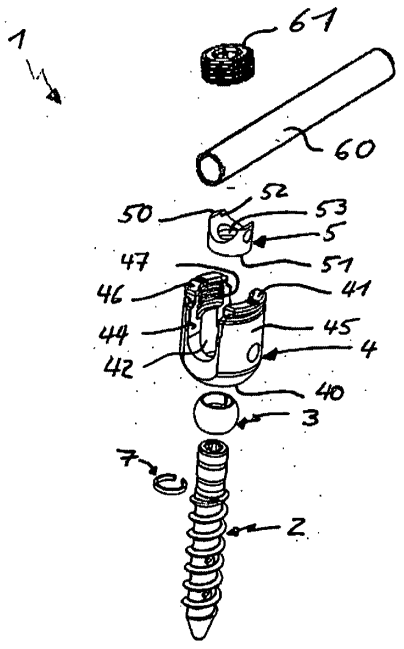
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(54) Bone anchoring device

(57) A bone anchoring device with a shank (2, 102, 202) to be anchored in a bone or vertebra, a head (3, 103, 203), and a receiving part (4) receiving the head (3, 103, 203) for connecting the shank (2, 102, 202) to a rod is provided. The shank (2, 102, 202) and the head (3, 103, 203) are separate parts. The head (3, 103, 203) has a bore (31, 131, 231) with a cylindrical inner surface, a ring-shaped groove (34, 134, 234) provided on the inner surface, and at least one slit (35, 135, 235) extending from the inner surface to the outer surface (30, 130, 230) of the head (3, 103, 203). The shank (2, 102, 202) has a first portion (21, 121, 221) for anchoring in the bone or vertebra and a second portion (23, 123, 223) with a cylindrical outer surface adjoining a free end (27, 127, 227). A projection (7, 107) is provided on the cylindrical outer surface which engages with the ring-shaped groove (34, 134, 234) of the head (3, 103, 203), when the cylindrical second portion (23, 123, 223) of the shank (2, 102, 202) is inserted in the bore (31, 131, 231) of the head.

Fig. 2



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Description

[0001] The present invention relates to a bone anchoring device, and more particularly to a polyaxial bone anchoring device comprising a shank and a head formed as separate parts.

[0002] US 6,835,196 B2 describes an anchoring element for connecting a screw to a rod. The shank of the screw and the head are formed as separate parts. The head is shaped as a segment of a sphere which is pivotably held in a receiving portion. In one example the end portion of the shank has a cylindrical shape and the head is provided with a slit and has a cylindrical bore into which the cylindrical end portion of the shank is inserted.

[0003] US 2005/0049588 A1 discloses a polyaxial bone screw for connection to a spinal fixation rod. At one end the shank of the bone screw has a frusto-conical capture structure diverging in diameter in a direction away from the threaded end of the shank. A retainer ring has a central bore with a conical shape which is compatible with the conical surface of the shank for receiving the shank. The angular orientation of the shank relative to a receiving part is fixed by the spinal fixation rod acting on an end portion of the shank.

[0004] US 2006/0036252 A1 discloses a polyaxial screw which has a threaded shaft for securing the screw to bone. One end of the shaft has a reverse tapered head tapering toward and away from the shaft from an enlarged median. A spherical shaped swivel, having an opening smaller than the median, is snapped over the head to rotatably engage the shaft.

[0005] It is the object of the invention to provide a bone anchoring device with a shank and a head formed as separate parts which allows convenient and reliable handling during assembly of the shank and the head and provides secure locking of the shank in the head after assembly. Further, a modular system having variability shall be provided.

[0006] The object is attained by a bone anchoring device according to claim 1.

[0007] Further developments of the invention are specified in the dependent claims.

[0008] Since the shank and the head are formed as separate parts, in use of the bone anchoring device, an appropriate shank can be selected depending on the application and can be connected to the head for forming the bone anchoring device. In particular, shanks of different lengths can be provided in combination with the head such that the costs for stock-keeping can be reduced.

[0009] The cylindrical shape of the end portion of the shank cooperating with the cylindrical bore in the head allows convenient and reliable insertion of the shank into the head. Easy insertion is further improved by at least one slit provided in the head which imparts a certain flexibility to the head. Engagement of a projection with a corresponding groove during assembly leads to the result that the shank is securely retained in the head in an assembled condition.

[0010] Further features and advantages of the invention will arise from the description of embodiments with reference to the enclosed figures, of which:

Fig. 1	is a perspective view of a bone anchoring device according to a first embodiment in an assembled condition;
Fig. 2	is an exploded view of the bone anchoring device of Fig. 1;
Fig. 3	is a sectional view of the bone anchoring device of Fig. 1;
Fig. 4a to 4c	are illustrations of the shank (Fig. 4a), the head (Fig. 4b), and a snap ring (Fig. 4c) of the first embodiment;
Fig. 5	is a perspective view for illustrating the assembly of the bone anchoring device according to the first embodiment;
Fig. 6	is a perspective view of the shank and the head of a second embodiment;
Fig. 7	is an exploded view of the embodiment of Fig. 6;
Fig. 8	is a sectional view of the upper part of the embodiment shown in Fig. 6 in an assembled state;
Fig. 9	is an exploded sectional view of the shank and the head of the second embodiment;
Fig. 10	is an exploded view of a third embodiment; and
Fig. 11	is a sectional view of the upper part of the third embodiment in an assembled state.

First Embodiment

[0011] A first embodiment will be described with reference to Figs. 1 to 4. As can be seen in the exploded view of Fig. 2, the bone anchoring element 1 of the first embodiment comprises a shank 2, a head 3 provided separately from the shank 2, a receiving part 4 and a pressure element 5. Further, in the first embodiment a ring 7 is provided which will be described in detail below.

[0012] As can be seen in Fig. 4a, the shank 2 comprises a tip 20, a first portion 21 which is provided with a bone thread 22, and a second portion 23 adjacent to the free end 27 opposite to the tip 20 which has a cylindrical surface. The second portion 23 has a substantially smooth surface. Further, a circumferential groove 24 is provided in the outer surface of the second portion 23. The free

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end 27 of the second portion 23 has a beveled shape such that the diameter tapers towards the free end 27.

[0013] As can be seen in Fig. 3, the shank 2 is further provided with a coaxial bore 25. The bore 25 is open at the free end 27 and extends to a predetermined distance from the tip 20. Lateral through-holes 26 can be provided in the first portion 21 which extend from the bore 25 to the outer surface of the first portion. The through-holes 26 can be arranged in the base of the bone thread 22 between the thread crests. The bore 25 and the through-holes 26 allow, for example, introduction of bone cement to enhance the fixation of the shank 2 in the bone. The free end 27 of the shank further comprises a recess for engagement with a screwing-in tool.

[0014] The head 3 has a substantially sleeve-like shape with a first end 32 and a second end 33. The outer surface 30 is shaped as a segment of a sphere. A cylindrical bore 31 is provided which extends through the head from the first end 32 to the second end 33. A circumferential groove 34 is provided approximately at the center of the cylindrical bore 31. As can be seen in Figs. 3 and 4b, the groove 34 has a substantially rectangular cross-section.

[0015] Further, a longitudinal slit 35 is provided in the head 3 which extends from the first end 32 to the second end 33. Although only one slit 35 which extends from the first end 32 to the second end 33 is shown in the embodiment, the slit does not have to extend continuously from the first end 32 to the second end 33. One slit extending from the first end 32 or the second end 33 to a predetermined distance from the respective other end may be provided. As an alternative, for example, several slits which alternately extend from the first end 32 to a predetermined distance from the second end 33 and from the second end 33 to a predetermined distance from the first end 32 may be provided. The slit in the head 3 serves to provide elasticity to the head 3 in order to allow insertion even of a slightly oversized shank, as will be described below, and to provide secure clamping after final locking with a securing element.

[0016] The ring 7 is provided as a snap ring which has a substantially annular shape with a clearance 70, as can be seen in Fig. 4c. The ring 7 has a substantially rectangular cross-section and is shaped such that it fits in the groove 24 on the second portion 23 of the shank 2 and in the groove 34 in the cylindrical bore 31 of the head 3. Due to the clearance 70 the ring 7 has certain flexibility, i.e. its diameter can be enlarged and decreased by a certain amount.

[0017] As can be seen in Figs. 2 and 3, the receiving part 4 has a substantially cylindrical shape with a first end 40 and a second end 41 and a longitudinal axis Z. A coaxial bore 42 extends through the receiving part 4 from the first end 40 to the second end 41. The shape of the longitudinal bore 42 tapers towards the first end 40 such that a seat 43 for accommodating the outer surface 30 of the head 3 is formed. The seat can have, for example, a spherical shape or a conical shape or another tapering shape. Further, a substantially U-shaped recess 44 is formed in the receiving part 4 adjacent to the second end 41 such that two free legs 45 and 46 are formed which form a channel extending substantially perpendicular to the bore 42 for receiving a rod 60. On the inner surface of the free legs 45, 46 adjacent to the second end 41 an inner thread 47 is provided for screwing-in a securing element 61 for securing the rod 60 in the U-shaped recess. In the embodiment the inner thread 47 is designed as a flat thread having the thread flanks arranged perpendicular to the longitudinal axis. However, the thread can have any other suited thread shape.

[0018] Further, as shown in Fig. 2 the pressure element 5 has a substantially cylindrical shape and is dimensioned such that it can be inserted in the coaxial bore 42 of the receiving part 4 and is slidably guided therein. On its upper side the pressure element 5 has a recess 52 shaped as a segment of a hollow cylinder the diameter of which substantially corresponds to the diameter of the bottom of the U-shaped recess 44 of the receiving part 4. On the lower side 51 of the pressure element 5 a recess (not shown) shaped as a segment of a hollow sphere is provided the diameter of which substantially corresponds to the outer diameter of the head 3. A bore 53 is provided in the pressure element 5 coaxially to its cylinder axis in order to allow guiding through of a screwing-in tool. In use, the pressure element 5 is placed in the longitudinal bore 42 such that the recess 52 shaped as a segment of a hollow cylinder is aligned with the U-shaped recess 44, as can be seen in Fig. 1.

[0019] The operation of the bone anchoring device 1 of the first embodiment will now be described with reference to Fig. 5.

[0020] In operation, first the shank 2 can be screwed into a bone or vertebra by engagement with a screwing-in tool.

[0021] The receiving part 4, the head 3, the ring 7 and the pressure element 5 can be provided in a preassembled state. In the pre-assembled state the ring 7 is inserted in the cylindrical bore 31 of the head 3 such that it rests in the ring-shaped groove 34. Further, the head 3 is placed in the longitudinal bore 42 of the receiving part 4 such that it rests on the seat 43 and remains pivotable with respect to the receiving part 4. The pressure element 5 is placed in the longitudinal bore 42 of the receiving part 4 such that the recess on the lower side 51 faces the outer surface 30 of the head 3 and such that the recess 52 shaped as a segment of a hollow cylinder is aligned with the U-shaped recess 44. In this assembled state, due to the flexibility provided by the clearance 70, the ring 7 can still be expanded such that its diameter is enlarged. Further, due to the slit 35, the head 3 can still be expanded such that its diameter is enlarged.

[0022] The assembly of receiving part 4, head 3, ring 7 and pressure element 5 can then be connected to the shank 2 by guiding the second portion 23 of the shank 2 into the cylindrical bore 31 of the head 3. The beveled shape of the upper free end 27 of the shank 2 facilitates

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insertion. During insertion the head 3 and the ring 7 are slightly expanded by the second portion 23 of the shank until the ring 7 snaps into the groove 24 of the second portion 23 of the shank. In this condition the ring 7 rests in the groove 24 of the end portion of the shank 2 and in the groove 34 of the head 3. As a result, the shank 2 is prevented from retracting again from the head 3 by form-locking engagement of the ring 7 in the groove 34 in the head 3.

[0023] The cylindrical shape of the second portion 23 of the shank 2 allows easy and convenient insertion of the shank 2 into the head 3. The projection formed by the ring 7 arranged in the groove 24 on the shank 2 allows secure fixation of the shank 2 to the head 3 by form-locking.

[0024] After insertion of the shank 2 in the head 3, the angular orientation of the shank 2 relative to the cylinder axis Z of the receiving part 4 can still be varied. In operation then a rod can be placed in the U-shaped recess 44 such that it rests in the recess 52 shaped as a segment of a hollow cylinder of the pressure element 5. A securing element can be screwed-in between the legs 45, 46 by cooperating with the inner thread 47. The securing element exerts pressure on the rod and the rod in turn exerts pressure on the pressure element 5. As a result, the pressure element 5 presses on the head 3 and the angular orientation of the head 3 relative to the receiving part 4 is thereby fixed. Further, since the head 3 is pressed against the seat 43 which is formed in a tapered shape, the head 3 is slightly compressed and the connection of the shank 2 to the head 3 is further strengthened.

[0025] The slit in the head 3 provides certain elasticity to the head 3. Thus, a shank 2 having a slightly over-dimensioned second portion 23 can be connected to the head 3. Further, this elasticity provides secure clamping of the shank 2 in the head 3, when the securing element is fastened.

[0026] It has been described above that the shank 2 is first screwed into the bone or vertebra before connecting it to the head 3. Alternatively the shank 2 can first be connected to the head 3 and the receiving part, such that the anchoring element is in a pre-assembled state, and thereafter the shank 2 can be screwed into the bone or vertebra by guiding a screwing-in tool through the longitudinal bore 42 of the receiving part 4 and through the bore 53 of the pressure element 5 into the structure in the longitudinal bore 25 of the shank 2. Thus, variability is ensured.

Second Embodiment

[0027] A second embodiment will be described with reference to Figs. 6 to 9. The second embodiment differs from the first embodiment in the structure of the shank and the head. The receiving part 4 and the pressure element 5 are identical to those of the first embodiment and will not be described again. The receiving part 4 and the pressure element 5 are omitted in Figs. 6 to 9.

[0028] The shank 102 according to the second embodiment comprises a first portion 121 which is provided with a bone thread 122 and a second portion 123 having a cylindrical outer surface with a first diameter wherein the surface is substantially smooth. As can be seen in Figs. 8 and 9, the shank 102 does not have a longitudinal bore as the shank in the first embodiment. A recess 126 for engagement with a screwing-in tool is provided at the free end 127. As in the first embodiment the free end 127 of the shank 102 has a beveled shape to facilitate insertion of the shank 102 into the head 103.

[0029] A circumferentially extending projection 107 is formed on the second portion 123. The projection 107 is formed integrally with the second portion 123.

[0030] Similar to the first embodiment, the head 103 has a substantially sleeve-like shape. The outer surface 130 is shaped as a segment of a sphere and cylindrical bore 131 is provided. A circumferential groove 134 is provided approximately at the center of the cylindrical bore 131.

[0031] Further, a plurality of longitudinal slits 135 are provided in the head 103 which alternately extend from the first end 132 to a predetermined distance from the second end 133 and from the second end 133 to a predetermined distance from the first end 132. This structure of the slits 135 provides a uniform flexibility to the head 103 in the region of the first end 132 and in the region of the second end 133.

[0032] Operation of the second embodiment is similar to the first embodiment. When the free end 127 of the shank 102 is inserted into the cylindrical bore 131 of the head 103, the diameter of the head 103 becomes enlarged by introduction of the circular projection 107. When the projection 107 reaches the ring-shaped groove 134 in the cylindrical bore 131, the head 103 elastically contracts and the projection 107 rests in the groove 134 such that the shank 102 is prevented from retracting from the cylindrical bore 131. After assembly of the complete bone anchoring device the pressure transmitted via the pressure element 5 further enhances the fixation of the shank 102 in the head 103 similar to the first embodiment.

[0033] According to the first embodiment, a projection projecting from the cylindrical outer surface of the second portion 23 of the shank 2 is formed by the ring 7 which is placed in a groove 24 in the shank 2. Similarly in the second embodiment a projection projecting from the cylindrical outer surface of the second portion 123 of the shank 102 is formed by the circular projection 107 which is integrally formed with the second portion 123. In both cases, easy and convenient insertion of the shank 2, 102 into the cylindrical bore 31, 131 of the head 3, 103 is allowed due to the cylindrical shape of the outer surface of the second portion 23, 123. Further, in both cases the shank 2, 102 is secured against unintended retraction by means of the projection 7, 107 projecting from the outer surface of the second portion 23, 123 engaging with the groove 34, 134 provided in the head 3, 103. The slits 35, 135 provide flexibility to the respective head 3, 103 which

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further facilitates insertion.

Third embodiment

[0034] A third embodiment is shown in Figs. 10 and 11. The third embodiment differs from the first and second embodiments in the structure of the head and the pressure element. The further structure is similar to that of the first and second embodiments and will not be described again.

[0035] The bone anchoring devices of the first and second embodiments provides a so-called polyaxial connection of the shank 2, 102 and the receiving part 4. In contrast, the bone anchoring device according to the third embodiment provides a monoaxial connection between a shank 202 and the receiving part 4. The shank 202 is constructed similar to the shank 2 in the first embodiment with a first portion 221, a cylindrical second portion 223 adjacent to a free end 227, and with a groove 224, but without a longitudinal bore and without through-holes.

[0036] As can be seen in Fig. 10, in the third embodiment the head and the pressure element are not constructed as separate parts but are formed in one piece as a head 203. The head 203 has a substantially cylindrical shape with a cylindrical outer surface 230 dimensioned such that it can be inserted in the longitudinal bore 42 of the receiving part 4. At a first end 203a the outer diameter of the head 203 tapers in a spherical shape. The opposite second end 203b is formed similar to the upper side 50 of the pressure element 5 in the first embodiment, i.e. a cylindrically-shaped recess 252 is formed at the second end 203b. A plurality of slits 235 extend from the first end 203a to a predetermined distance from the second end 203b. The slits 235 serve to provide flexibility to the head 203. Again, only one slit 235 may be provided alternatively.

[0037] The head 203 has a cylindrical bore 231 and a ring-shaped groove 234 similar to the head 3 in the first embodiment.

[0038] Assembly of the third embodiment is similar to the first embodiment. In operation, the head 203 is inserted in the longitudinal bore 42 of the receiving part 4. The snap ring 7 is placed in the groove 224 on the second portion 223. Then, the cylindrical second portion 223 of the shank 202 is inserted into the cylindrical bore 231 of the head 203 and the head 203 slightly widens due to the flexibility provided by the slits 235. The shank 202 is inserted until the snap ring 7 faces the ring-shaped groove 234 provided in the head 203 and then, due to the flexibility of the head 203, the snap ring 7 engages with the groove 234. As a result, the shank 202 is prevented from retracting again from the head 203.

[0039] After insertion of the rod 60 the securing element 61 is inserted for locking the rod 60 in the receiving part 4. During tightening of the securing element 61 pressure acts on the second end 203b of the head 203. The head 203 is pressed towards the first end 40 of the receiving part 4. Due to the tapering shape of the longitudinal bore 42 and to the slits 235 provided in the head 203, the head 203 is compressed and the shank 202 becomes securely locked in the head 203.

[0040] In an alternative way of operation the snap ring can first be placed in the ring-shaped groove 234 of the head 203 and thereafter the shank 202 can be inserted.

Further Modifications

[0041] In a further modification of the polyaxial bone anchoring device the shank is formed similarly to the shank 2 in the first embodiment with a groove 24 provided in the cylindrical outer surface of the second section 23. In contrast to the first embodiment the ring 7 is omitted and, instead of the ring-shaped groove 34 in the cylindrical bore 31 of the head 3, a ring-shaped projection with a reduced diameter as compared to the cylindrical bore 31 is integrally formed in the cylindrical bore 31. When the shank 2 is inserted in the cylindrical bore 31, this ring-shaped projection engages with the groove 24 of the shank 2.

[0042] As a result, a similar connection as that described with respect to the first and the second embodiments can be achieved. This structure can also be applied to the monoaxial connection shown in the third embodiment.

[0043] The ring 7 in the first and third embodiment can be considered to form a projection provided on the cylindrical inner surface of the bore 31, 231. The projection formed by the ring 7 engages with the groove 24, 224 provided on the shank 2, 202.

[0044] The structure of the projection 107 of the second embodiment cooperating with a groove provided in the head can be applied to the monoaxial connection of the third embodiment.

[0045] Although embodiments have been described in which locking of the rod and the angular orientation of the shank in the polyaxial bone anchoring device is performed by one single securing element, it is also possible to provide two securing elements for independently fixing the rod and the head. Alternatively, the securing element can be formed by an outer nut which is screwed on an outer thread provided on the free legs of the receiving part.

[0046] In the embodiments above the pressure element has a groove in the upper surface. However, it is also possible to provide a pressure element with a flat upper surface.

[0047] Further modifications are possible. For example the features of the head according to the second embodiment can be combined with the shank according to the first embodiment and vice versa.

[0048] Different types of shanks with or without coaxial bores and with different types of bone threads can be provided such that a modular system is formed. In such a system, also hooks may be provided. Further, different types of heads may be provided which can be combined with the shanks depending on the respective application.

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In this way, a modular system can be provided which offers variability in application.

Claims

1. A bone anchoring device with
a shank (2, 102, 202) to be anchored in a bone or vertebra, a head (3, 103, 203), and a receiving part (4) receiving the head (3, 103, 203) for connecting the shank (2, 102, 202) to a rod,
the shank (2, 102, 202) and the head (3, 103, 203) being separate parts,
the head (3, 103, 203) having a bore (31, 131) with a cylindrical inner surface, a ring-shaped groove (34, 134, 234) provided on the inner surface, and at least one slit (35, 135, 235) extending from the inner surface to the outer surface (30, 130, 230) of the head (3, 103, 203) and
the shank (2, 102, 202) having a first portion (21, 121, 221) for anchoring in the bone or vertebra and a second portion (23, 123, 223) with a cylindrical outer surface adjoining a free end (27, 127, 227), wherein a projection (7, 107) is provided on the cylindrical outer surface which engages with the ring-shaped groove (34, 134, 234) of the head (3, 103, 203), when the cylindrical second portion (23, 123, 223) of the shank (2, 102, 202) is inserted in the bore (31, 131, 231) of the head.

2. The bone anchoring device according to claim 1, wherein the projection (7, 107) on the cylindrical outer surface of the shank (2, 102, 202) is ring-shaped.

3. The bone anchoring device according to claim 1 or 2, wherein the projection (107) is formed in one piece with the cylindrical second portion (123) of the shank (2, 102, 202).

4. The bone anchoring device according to claim 1 or 2, wherein the projection (7) is formed by a ring arranged in a ring-shaped groove (24, 224) provided in the cylindrical outer surface of the second portion (23, 223).

5. A bone anchoring device with
a shank (2, 202) to be anchored in a bone or vertebra, a head (3, 103, 203), and a receiving part (4) receiving the head (3, 103, 203) for connecting the shank (2, 202) to a rod,
the shank (2, 202) and the head (3, 103, 203) being separate parts,
the head (3, 103, 203) having a bore (31, 131, 231) with a cylindrical inner surface, a projection (7) provided on the inner surface, and at least one slit (35, 135, 235) extending from the inner surface to the outer surface (30, 130, 230) of the head (3, 103, 203) and
the shank (2, 202) having a first portion (21, 221) for anchoring in the bone or vertebra and a second portion (23, 223) adjoining a free end (27, 227) with a cylindrical outer surface, wherein a ring-shaped groove (24, 224) is provided on the cylindrical outer surface which engages with the projection (7) of the head, when the cylindrical second portion (23, 223) of the shank (2, 202) is inserted in the bore (31, 131, 231) of the head (3, 103, 203) .

6. The bone anchoring device according to claim 5, wherein the projection (7) on the cylindrical inner surface of the head (3, 103, 203) is ring-shaped.

7. The bone anchoring device according to claim 5 or 6, wherein the projection is formed in one piece with the head.

8. The bone anchoring device according to claim 5 or 6, wherein the projection is formed by a ring (7) arranged in a ring-shaped groove (34, 134, 234) provided in the cylindrical inner surface of the bore (31, 131, 231) in the head.

9. The bone anchoring device according to one of claims 1 to 8, wherein the outer surface of the head (30, 130) is substantially shaped as a segment of a sphere.

10. The bone anchoring device according to one of claims 1 to 9, wherein the bore (31, 131, 231) penetrates the head (3, 103, 203) from a first end (32, 132, 203a) to a second end (33, 133, 203b).

11. The bone anchoring device according to one of claims 1 to 10, wherein the at least one slit (35, 135) extends from the first end (32, 132) to the second end (33, 133) of the head (3, 103).

12. The bone anchoring device according to one of claims 1 to 11, wherein several slits (135) are provided in the head (103) which alternately extend from the first end (132) to a predetermined distance from the second end (133) and from the second end (133) to a predetermined distance from the first end (132), respectively.

13. The bone anchoring device according to one of claims 1 to 12, wherein a longitudinal bore (42) passes through the receiving part from a first end (40) to a second end (41) and the longitudinal bore has a tapered shape adjacent to the second end (41) forming a seat (43) for accommodating the head (3, 103, 203).

14. The bone anchoring device according to one of claims 1 to 13, wherein a pressure element (5) is arranged in the longitudinal bore (42) for fixing the

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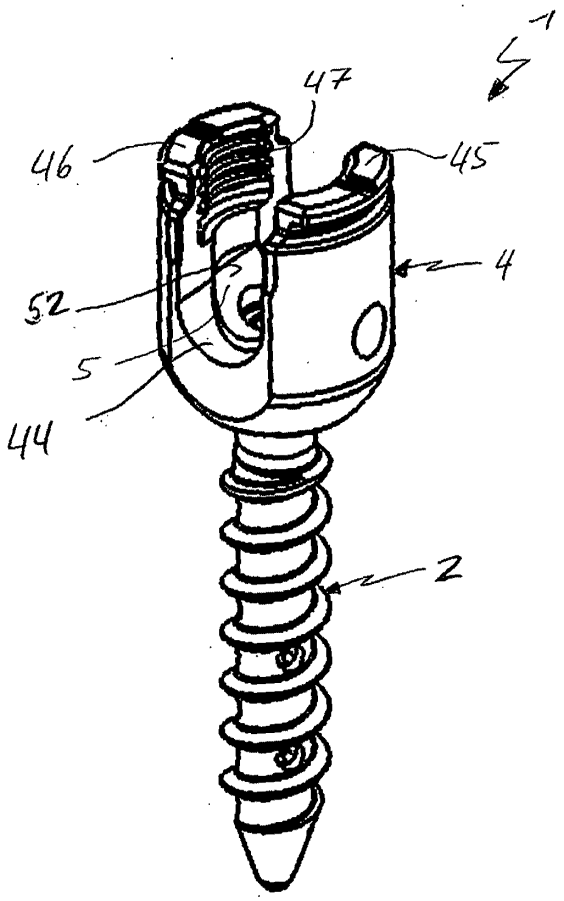
angular orientation of the shank (2) relative to the receiving part (4).

15. The bone anchoring device according to one of claims 1 to 14, wherein a U-shaped recess (44) is formed in the receiving part (4) adjacent to the first end (40) and extending substantially perpendicular to the longitudinal bore (42) such that two free legs (45, 46) are formed constituting a channel for receiving the rod.

16. Modular system comprising the bone anchoring device according to one of claims 1 to 15, wherein a plurality of different shanks (2, 102, 202) and/or a plurality of different heads (3, 103, 203) are provided.

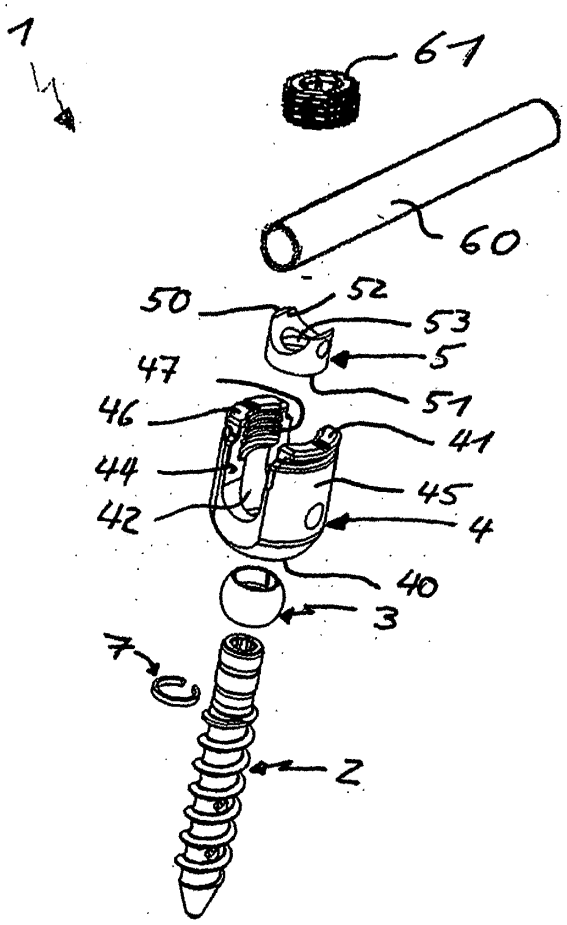
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Fig. 1



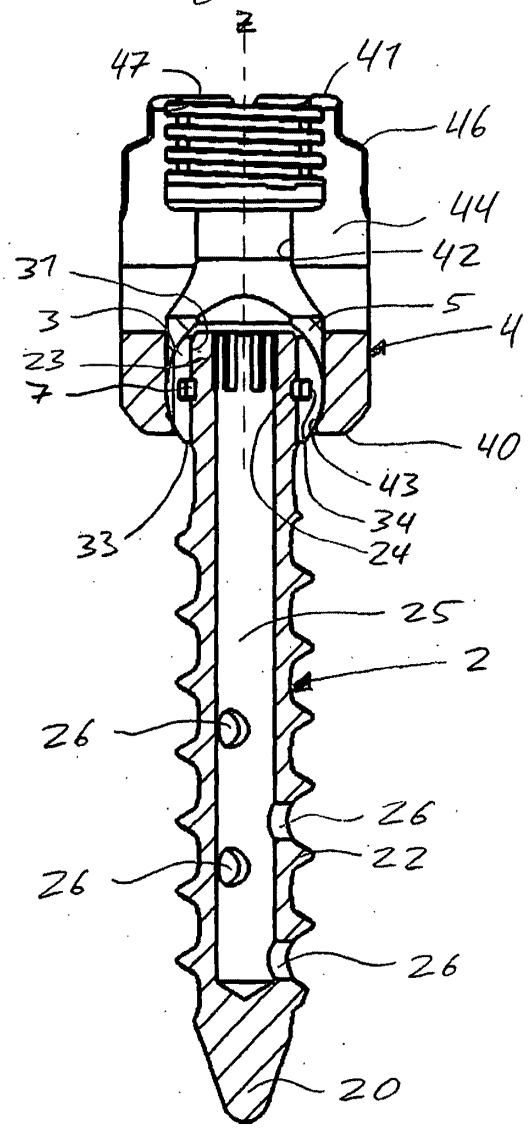
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Fig. 2



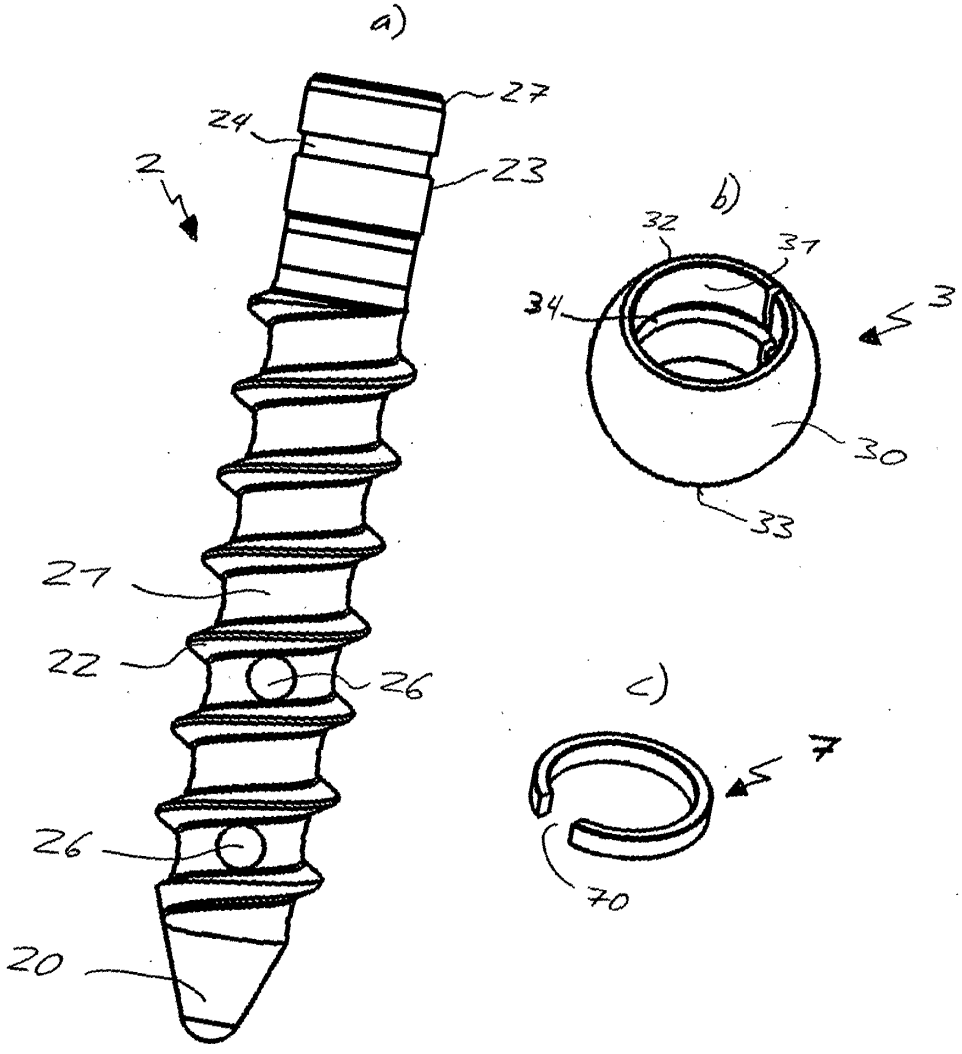
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Fig. 3



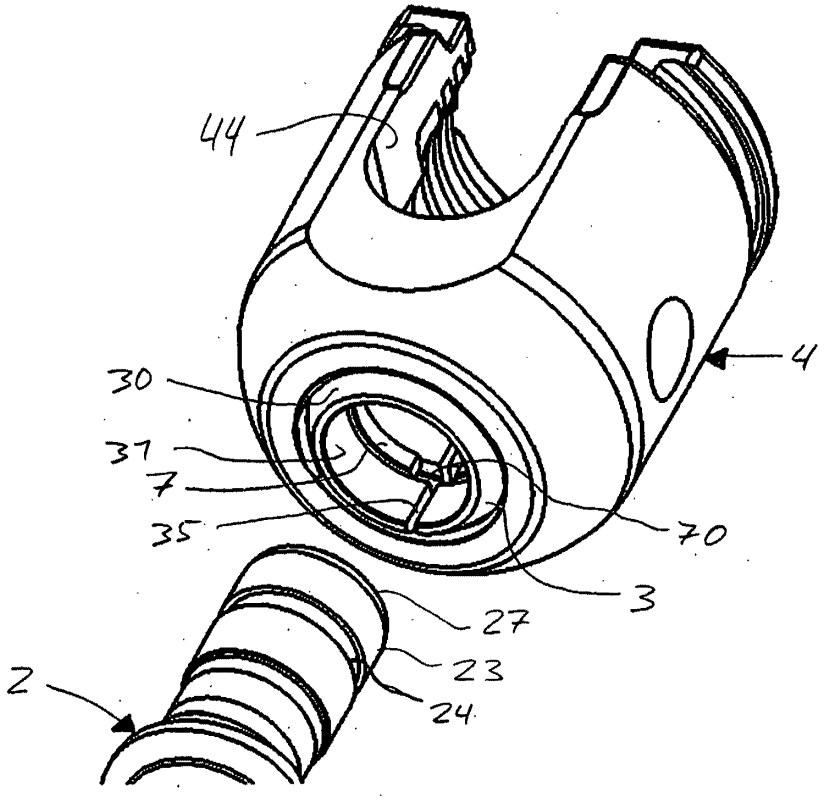
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Fig. 4



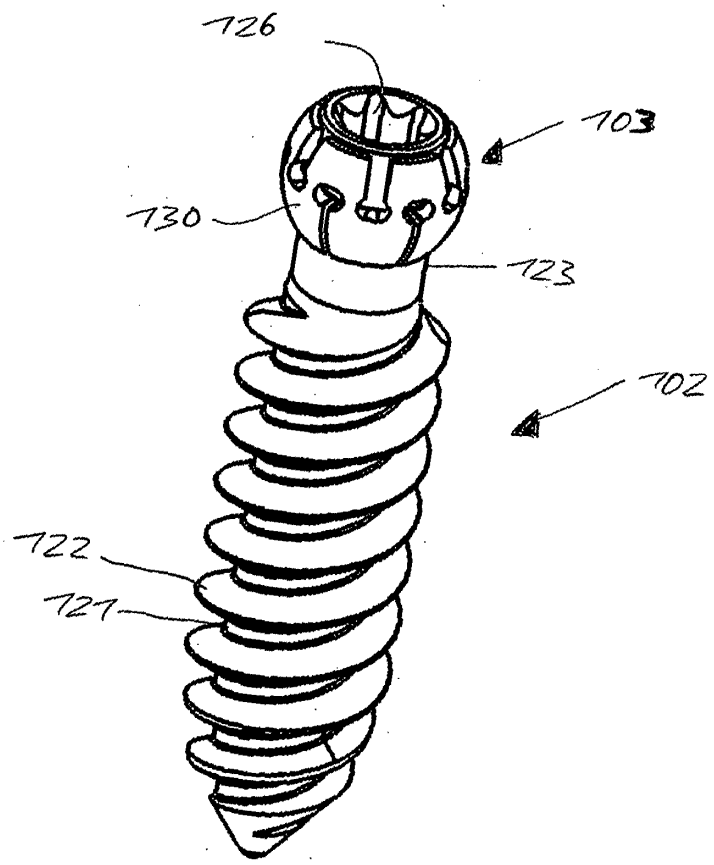
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Fig. 5



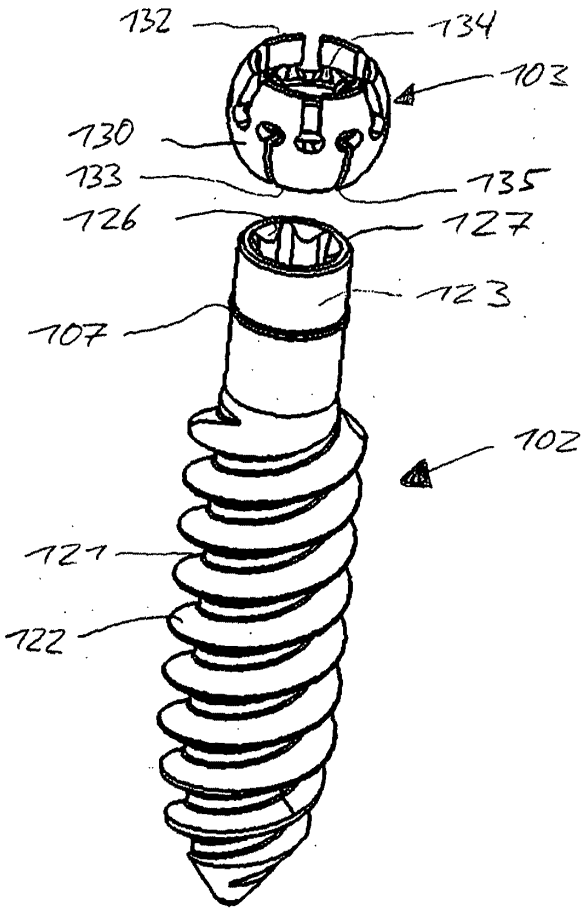
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Fig. 6



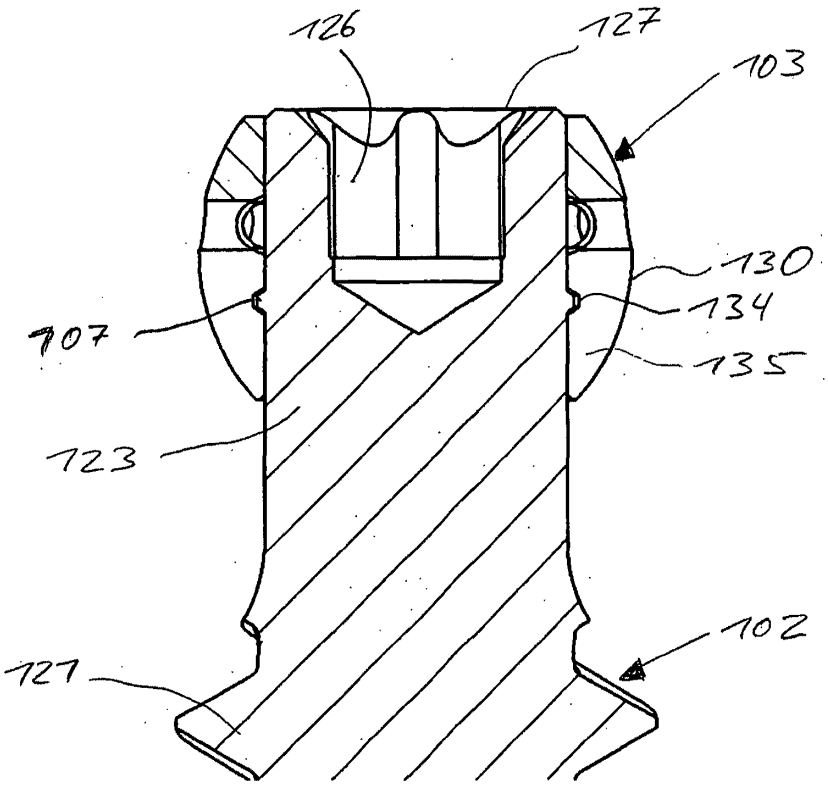
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Fig. 7



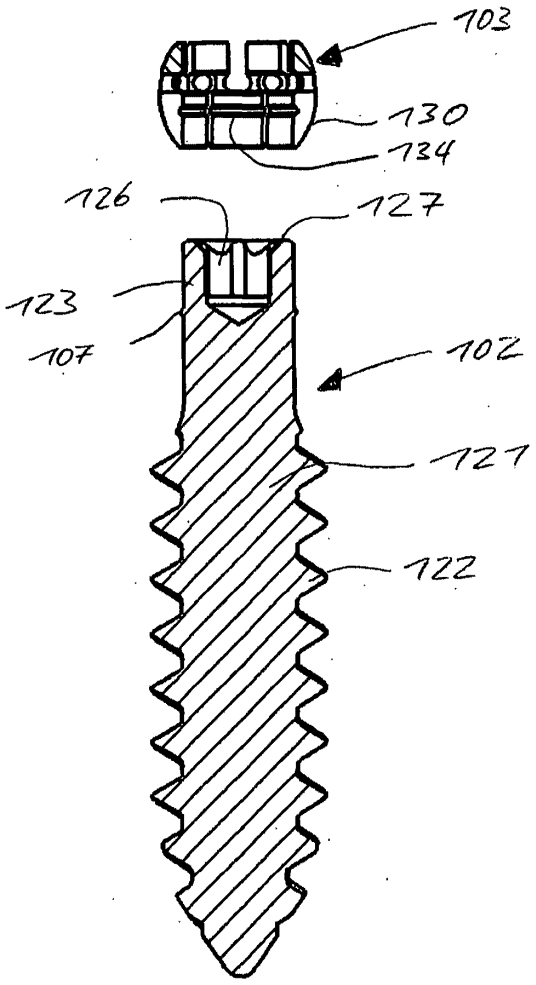
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Fig. 8



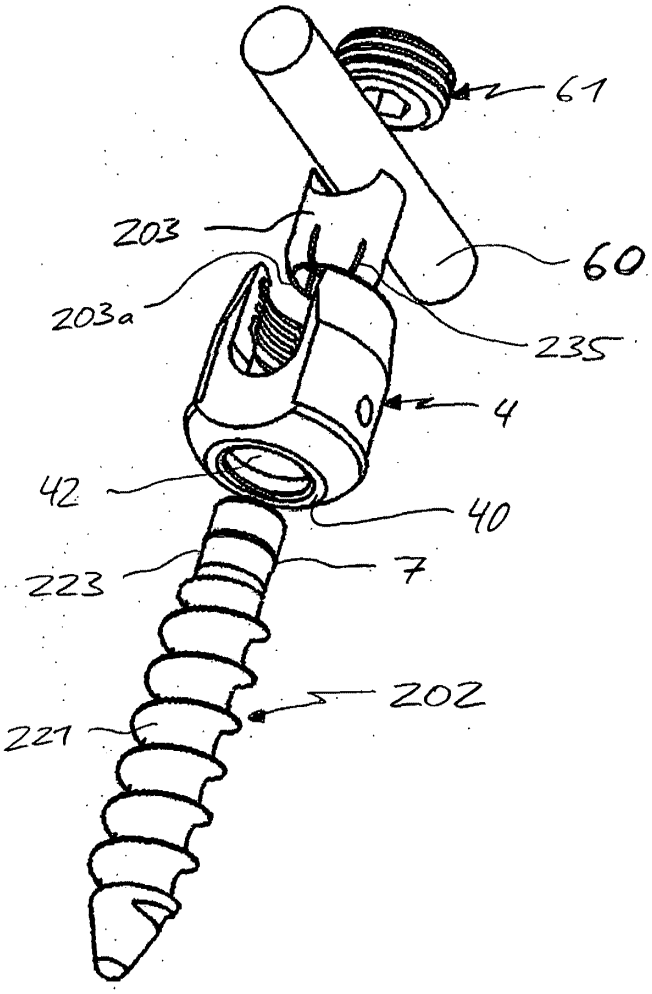
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Fig. 9



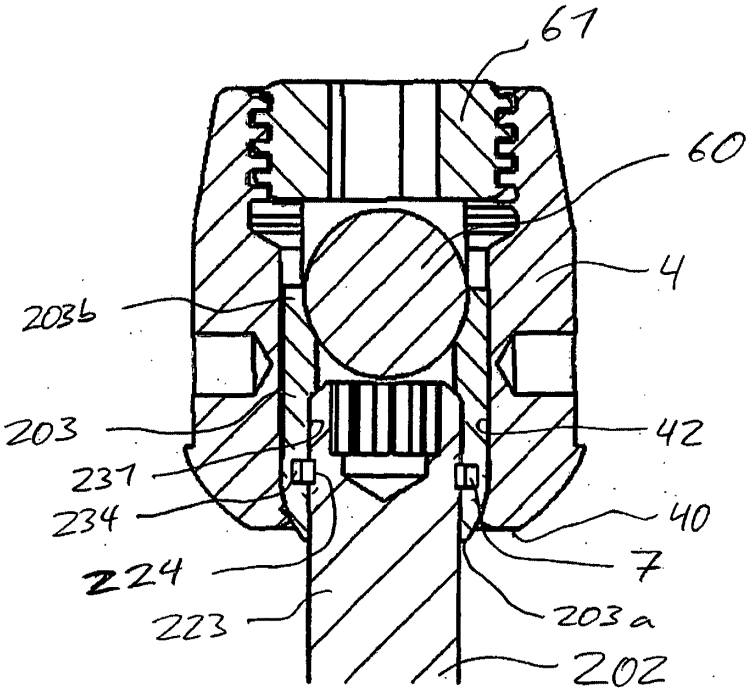
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Fig. 10



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Fig. 11



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EUROPEAN SEARCH REPORT

Application Number
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The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
Berlin	20 April 2007	Kakoullis, Marios

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EUROPEAN SEARCH REPORT

Application Number
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Place of search	Date of completion of the search	Examiner
Berlin	20 April 2007	Kakoullis, Marios

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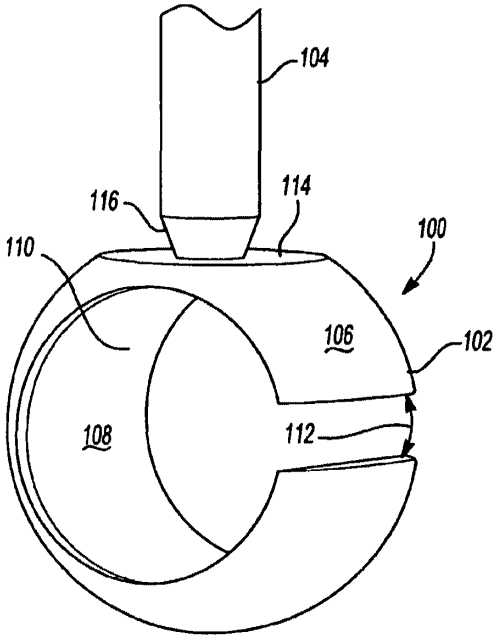
(74) Agents: **OLSON, Stephen, T.** et al.; Harness, Dickey & Pierce, P.L.C., P.O. Box 828, Bloomfield Hills, MI 48303 (US).

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[Continued on next page]

(54) Title: SPINAL FIXATION DEVICE



(57) Abstract: An enclosure device connecting a pedicle fixation device with an elongated spinal fixation member. The enclosure device can include an enclosure member and an elongated guide member affixed to the enclosure member and defining a fracture region for breaking off the guide member from the enclosure member. The enclosure member can have a spherical outer surface rotatably received within a receiver portion of the pedicle fixation device. The enclosure member can include an internal bore capable of slidably receiving the fixation member.

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Published:

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SPINAL FIXATION DEVICE

INTRODUCTION

[0001] Various spinal fixation or stabilization devices include pedicle screws having saddle-like receiver portions for receiving and guiding elongated connecting elements between vertebrae. Minimally invasive techniques can be used to reduce the size of incisions and associated trauma for implanting such spinal fixation devices.

[0002] The present teachings provide devices and methods of facilitating the insertion and manipulation of connecting elements to spinal fixation devices.

SUMMARY

[0003] The present teachings provide an enclosure device for connecting a pedicle fixation device with an elongated spinal fixation member. The enclosure device can include an enclosure member having an outer surface and an internal bore adapted for slidably receiving the spinal fixation member, and an elongated guide member affixed to a portion of the outer surface of the enclosure member. The guide member can have a fracture region for breaking off the guide member from the enclosure member.

[0004] The present teachings also provide a pedicle fixation device including a receiver portion defining a transverse opening for an elongated spinal fixation member. The pedicle fixation device can include a resilient enclosure member having an outer surface and an internal bore, and an elongated guide member affixed to a portion of the outer surface of the enclosure member. The enclosure member can be rotatably received within the receiver portion such that the internal bore is aligned with the transverse opening of the receiver portion. The internal bore of the enclosure member can slidably receive the spinal fixation member. The guide member can have a fracture region for breaking off the guide member from the enclosure member.

[0005] In another aspect, the present teachings provide a pedicle fixation device that can include a receiver portion defining a transverse opening

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for receiving an elongated spinal fixation member, an enclosure member having an outer surface, an internal bore and a gap, and an elongated guide member affixed to a portion of the outer surface of the enclosure member. The enclosure member can be rotatably received within the receiver portion such that the internal bore is aligned with the transverse opening of the receiver portion. The guide member can include a fracture region for breaking off the guide member from the enclosure member.

[0006] Further areas of applicability of the present invention will become apparent from the description provided hereinafter. It should be understood that the description and specific examples are intended for purposes of illustration only and are not intended to limit the scope of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0007] The present invention will become more fully understood from the detailed description and the accompanying drawings, wherein:

[0008] FIG. 1 is a perspective view of an enclosure device according to the present teachings;

[0009] FIG. 2 is a perspective view of an enclosure device according to the presents teachings, shown in a partially assembled pedicle fixation device;

[0010] FIG. 3A is a perspective view of an enclosure device according to the present teachings;

[0011] FIG. 3B is a perspective view of an enclosure device according to the present teachings;

[0012] FIG. 3C is a perspective view of an enclosure device according to the present teachings;

[0013] FIG. 4 is a top perspective view of an enclosure device according to the present teachings, shown in a pedicle fixation device;

[0014] FIG. 5 is a side perspective view of an enclosure device according to the present teachings, shown in a pedicle fixation device; and

[0015] FIG. 6 is a side perspective view of an enclosure device according to the present teachings, shown in a fully assembled pedicle fixation device.

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DESCRIPTION OF VARIOUS ASPECTS

[0016] The following description is merely exemplary in nature and is in no way intended to limit the invention, its application, or uses. For example, although the present teachings are illustrated for pedicle fixation in spinal surgery, the present teachings can be used for other orthopedic applications.

[0017] Referring to FIG. 1, an exemplary enclosure device 100 according to the present teachings includes an enclosure member 102 and a guide member 104. The enclosure device 100 can connect a pedicle fixation device 200 with an elongated spinal connecting rod or fixation member 208, as shown in FIG. 2. The pedicle fixation device 200 can be of a conventional type and can include a pedicle screw or fastener 202, and a receiver portion 204. The receiver portion 204 can include a longitudinal opening 220 along a longitudinal axis A, and a transverse opening along a transverse axis B defining a seat for the elongated fixation member 208. The receiver portion 204 can be U-shaped or saddle-shaped. The fastener 202 can be received through the longitudinal opening 220 and can have bone engaging threads or ridges 203.

[0018] The enclosure member 102 can be a substantially ball-shaped shell or sleeve having a substantially spherical outer surface 106 and an inner surface 108 defining a cylindrical inner bore 110. The inner bore 110 can be adapted to slidably receive the fixation member 208 when the enclosure device 100 is assembled in the pedicle fixation device 200, as shown in FIG. 2 and described below. The shape of the outer surface 106 can allow the enclosure member 102 to be rotatably received within the receiver portion 204 of the pedicle fixation device 200. The enclosure member 102 can be resilient, for example in the form of a split ring, such that the outer and inner surfaces 106, 108 of the enclosure member 102 are interrupted by a discontinuity or gap 112. The presence of the gap 112 can provide resiliency to the enclosure member 102 for facilitating insertion into the receiver portion 204 and for resiliently compressing the fixation member 208 within the inner bore 110, as described below.

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[0019] The guide member 104 can be an elongated small diameter element, such as wire. A titanium wire of about 2 mm diameter can be used, for example. The guide member 104 can be fixedly attached to an attachment surface 114 of the enclosure device 102 such that the guide member 104 can extend away from the enclosure device 100 and protrude from the surgical incision or portal. The guide member 104 can be used to install the enclosure device 100 into the pedicle fixation device 200 and control the orientation of the enclosure member 102 relative to the pedicle fixation device 200. The guide member 104 can include a break-off or fracture region 116 adjacent the attachment surface 114 of the enclosure member 102. The fracture region 116 can be a purposefully weakened region of the guide member 104 at or adjacent the transition of the guide member 104 to the attachment surface 114, such that twisting or applying a predetermined amount of torque to the guide member 104 can sever the guide member 104 from the enclosure member 102 at the fracture region 116. Accordingly, the guide member 104 can be removed after the installation and assembly of the enclosure device 100 and the fixation device 200 is completed.

[0020] The fracture region 116 can be generally formed as a region of reduced diameter or width of the guide member 104. For example, the fracture region 116 can be defined by a tapered transition to the attachment surface 114, as shown in FIG. 1. The fracture region 116 can also be in the form of a rounded groove or slot, as shown in FIG. 3A. The fracture region 116 can be in the form of a V-shaped or other sharp notch, as shown in FIG. 3B. FIG. 3C illustrates a fracture region 116 located at the connection of the distal end of the guide member 104 to the attachment surface 114. It will be appreciated that the fracture region 116 can have other features that contribute to weakening cross-section. For example, the fracture region 116 can be formed by any means that will produce localized reduction in fracture resistance, including, for example, means that locally weaken the cross-section of the guide member 104 or locally increase stress concentration. Further, weakening can be produced by mechanical means, such as local machining, or means of local chemical erosion, or use of weaker materials at the fracture region 116, and other means. The

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enclose device 100 can be generally made of polymeric or metal or other biocompatible materials.

[0021] Referring to FIGS. 2, 4 and 5, the enclosure device 100 can be guided and inserted in the pedicle fixation device 200 using the guide member 104. In one aspect, the enclosure device 100 can be assembled with the elongated fixation member 208, which can be slidably inserted through the cylindrical bore 110 of the enclosure member 102. The enclosure member 102 can be then guided with the guide member 104 into the receiver portion 204 and rotated such that the cylindrical bore 110 is aligned with the transverse opening 222 of the receiver portion 204 allowing the fixation member 208 to be oriented along the transverse axis B. This procedure can be done in connection with a minimally invasive surgical technique. Alternatively, the enclosure device 100 can be first inserted in the receiver portion 204 of the pedicle fixation device 200, the guide member 104 rotated to align the inner bore 110 with the transverse opening 222 of the receiver portion, and then the fixation member 208 can be slidably inserted into the inner bore 110 along the transverse axis B.

[0022] A cannulated locking member 206, such as a set screw, can be used to lock the pedicle fixation device 200 with the elongated fixation member 208. The locking member 206 can include a bore 224, such that the locking member 206 can be inserted over the guide member 104 into the receiver portion 204. The locking member 206 can include threading, ridges or other engagement formations 226 for engaging an inner surface 228 of the receiver portion 204 above the fixation member 208 and press down on the enclosure member 102. The enclosure member 104 can deform resiliently such that the gap 112 is reduced and the inner bore 110 tightens around the fixation member 110 securing the fixation member 110 in a locked position. The bore 224 of the locking member 206 can include a driver engagement portion 230 for engaging a driver or other tool that can be used to rotate the locking member 206 to secure the pedicle fixation device 200 with the fixation member 208 in a fixed or substantially rigid configuration, as shown in FIG. 5.

[0023] After the pedicle fixation device 200 is fixedly assembled as described above, the guide member 104 can be broken off the enclosure

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member 102 at the fracture region 116 by applying sufficient torque. The torque can be conveniently applied by using a tool to hold the guide member 104 and apply torsional moment to the guide member 104 relative to attachment surface 114. The fracture region 116 can be dimensioned such that when the guide member 104 breaks off at the fracture region 116, the portion of the guide member 104 that remains attached to the enclosure member 102 between the attachment surface 114 and the fracture region 116 is fully contained within the bore 224 of the locking member 206 and does not protrude above the locking member 206, as shown in FIG. 6

[0024] The foregoing discussion discloses and describes merely exemplary arrangements of the present invention. One skilled in the art will readily recognize from such discussion, and from the accompanying drawings and claims, that various changes, modifications and variations can be made therein without departing from the spirit and scope of the invention as defined in the following claims.

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CLAIMS

What is claimed is:

1. An enclosure device for connecting a pedicle fixation device with an elongated spinal fixation member, the enclosure device comprising:

an enclosure member having an outer surface and an internal bore adapted for slidably receiving the spinal fixation member; and

an elongated guide member affixed to a portion of the outer surface of the enclosure member, the guide member having a fracture region for breaking off the guide member from the enclosure member.

2. The enclosure device of claim 1, wherein the fracture region is a region of reduced cross-section of the guide member.

3. The enclosure device of claim 1, wherein the fracture region is a region of reduced fracture resistance in torsion of the guide member.

4. The enclosure device of claim 1, wherein the fracture region is a region of increased stress concentration in torsion of the guide member.

5. The enclosure device of claim 1, wherein the fracture region is defined by rounded groove in the guide member.

6. The enclosure device of claim 1, wherein the fracture region is defined by sharp notch in the guide member.

7. The enclosure device of claim 1, wherein the fracture region is adjacent to enclosure member.

8. The enclosure device of claim 1, wherein the outer surface of the enclosure member is substantially spherical.

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9. The enclosure device of claim 8, wherein the internal bore is cylindrical.

10. The enclosure device of claim 1, wherein the enclosure member is resilient and includes a gap.

11. A pedicle fixation device including a receiver portion defining a transverse opening for an elongated spinal fixation member, the pedicle fixation device comprising:

a resilient enclosure member having an outer surface and an internal bore, the enclosure member rotatably received within the receiver portion such that the internal bore is aligned with the transverse opening of the receiver portion, the internal bore slidably receiving the spinal fixation member; and

an elongated guide member affixed to a portion of the outer surface of the enclosure member, the guide member having a fracture region for breaking off the guide member from the enclosure member.

12. The pedicle fixation device of claim 11, wherein the outer surface of the enclosure member is substantially spherical and the internal bore of the enclosure member is cylindrical.

13. The pedicle fixation device of claim 12, wherein the fracture region is a V-shaped notch.

14. A pedicle fixation device comprising:

a receiver portion defining a transverse opening for receiving an elongated spinal fixation member;

an enclosure member having an outer surface, an internal bore and a gap, the enclosure member rotatably received within the receiver portion such that the internal bore is aligned with the transverse opening of the receiver portion; and

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an elongated guide member affixed to a portion of the outer surface of the enclosure member, the guide member comprising a fracture region for breaking off the guide member from the enclosure member.

15. The pedicle fixation device of claim 14, further comprising a cannulated locking member engageable with an inner surface of the receiver portion above the enclosure member, the locking member defining a bore, the guide member passable through the bore of the locking member.

16. The pedicle fixation device of claim 15, further comprising an elongated fixation member slidably received through the internal bore of the enclosure member and extending along the transverse opening of the receiver portion.

17. The pedicle fixation device of claim 14, wherein the outer surface of the enclosure member is substantially spherical.

18. The pedicle fixation device of claim 17, wherein the internal bore of the enclosure member is cylindrical.

19. The pedicle fixation device of claim 18, wherein the fracture region is a V-shaped notch.

20. The pedicle fixation device of claim 14, wherein the receiver portion defines and a longitudinal opening, and further comprising a pedicle fastener passing through the longitudinal opening.

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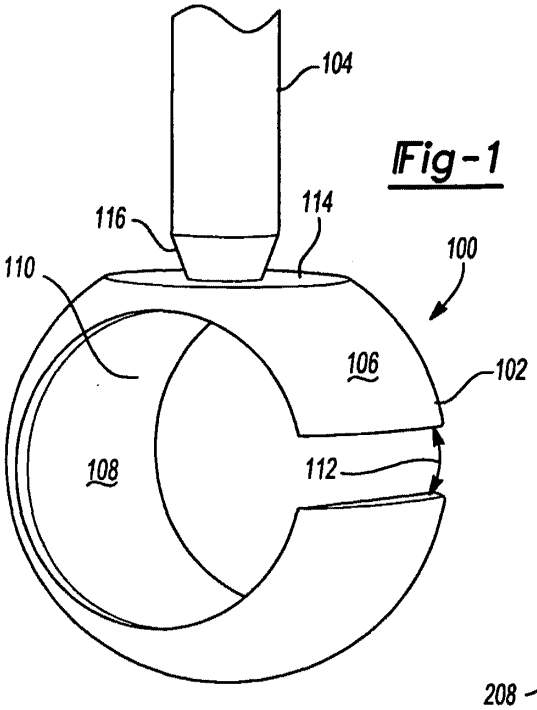

104
116
114
110
100
106
102
108
112

Fig-1

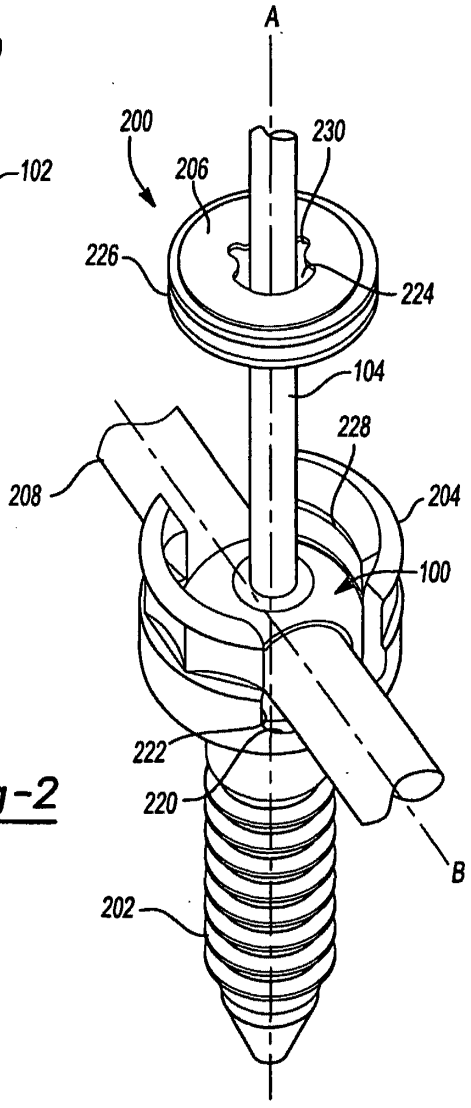

A
200
230
206
226
224
104
228
208
204
100
222
220
B
202

Fig-2

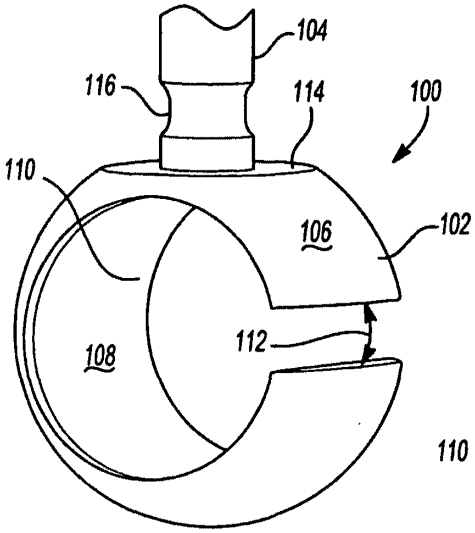


Fig-3A

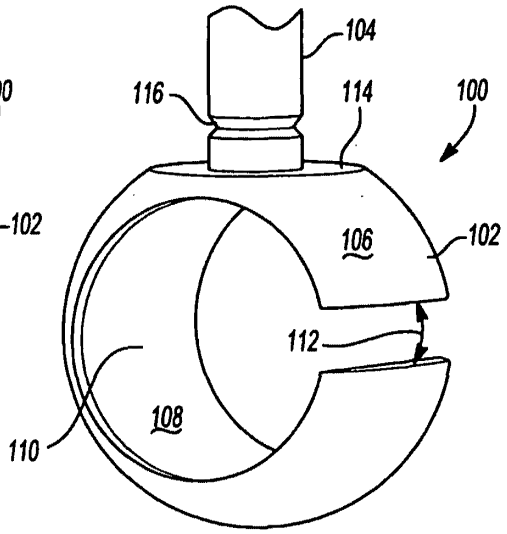


Fig-3B

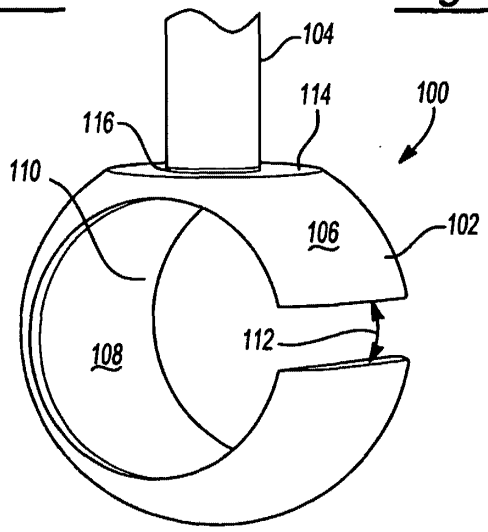


Fig-3C

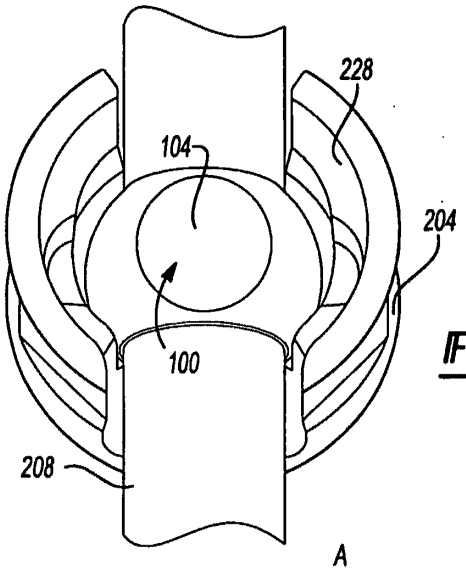


Fig-4

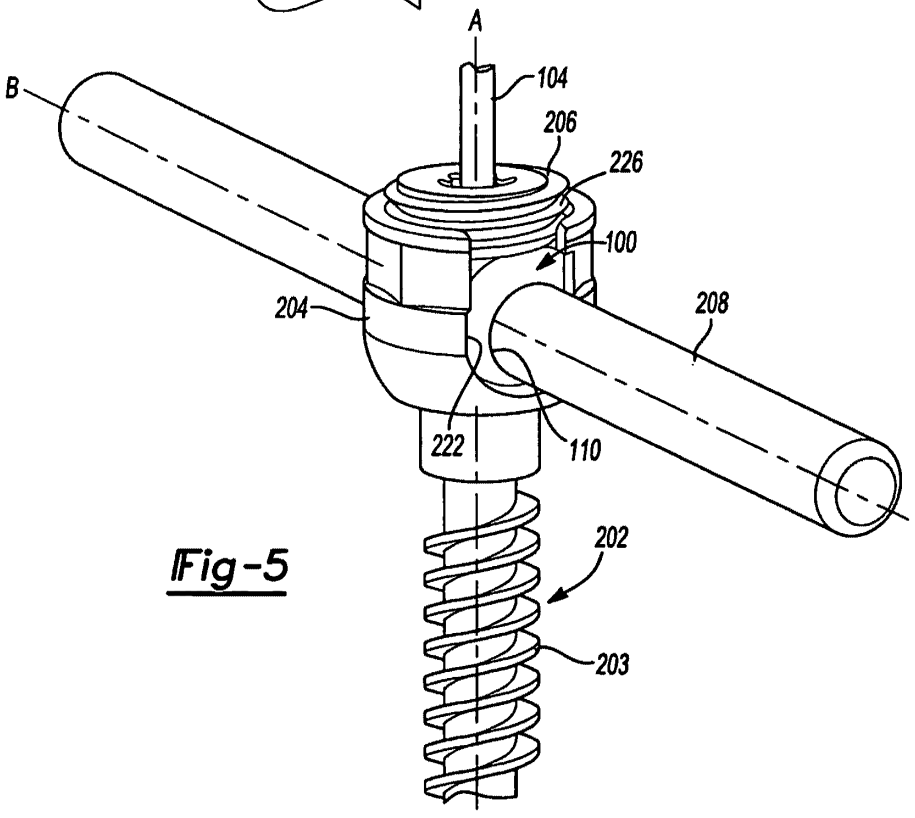


Fig-5

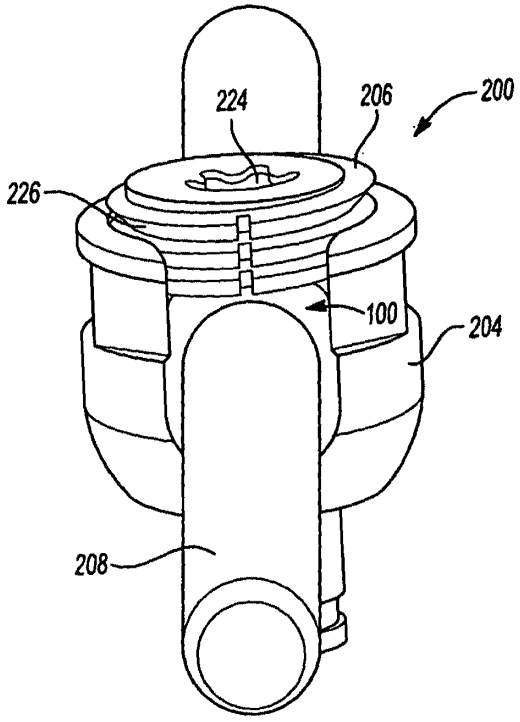


Fig-6

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2008/000389

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/70 A61B17/88

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

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

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2004/215190 A1 (NGUYEN THANH V [US] ET AL) 28 October 2004 (2004-10-28) paragraph [0053]; figure 1 paragraph [0054]; figure 2 paragraph [0057]; figure 3A paragraph [0061]; figure 3B	1,8-12, 14,17, 18,20
A	US 2006/241595 A1 (MOLZ FRED J IV [US] ET AL) 26 October 2006 (2006-10-26) paragraph [0014]; figure 3A	1
A	US 5 910 142 A (TATAR STEPHEN [US]) 8 June 1999 (1999-06-08) column 5, line 36 - line 51; figure 3 figure 5	1,8-12, 14,17, 18,20

-/--

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier document but published on or after the international filing date
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"O" document referring to an oral disclosure, use, exhibition or other means
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"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
2 June 2008	09/06/2008

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Ducreau, Francis

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INTERNATIONAL SEARCH REPORT

International application No
PCT/US2008/000389

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	FR 2 786 088 A (DIMSO SA [FR]) 26 May 2000 (2000-05-26) figures 1-3	1

Form PCT/ISA/210 (continuation of second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2008/000389

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		CA 2525491 A1	11-11-2004
		EP 1622525 A2	08-02-2006
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		WO 2004096080 A2	11-11-2004
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FR 2786088 A	26-05-2000	NONE	

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11/079,006	10 March 2005 (10.03.2005)	US
11/190,496	26 July 2005 (26.07.2005)	US

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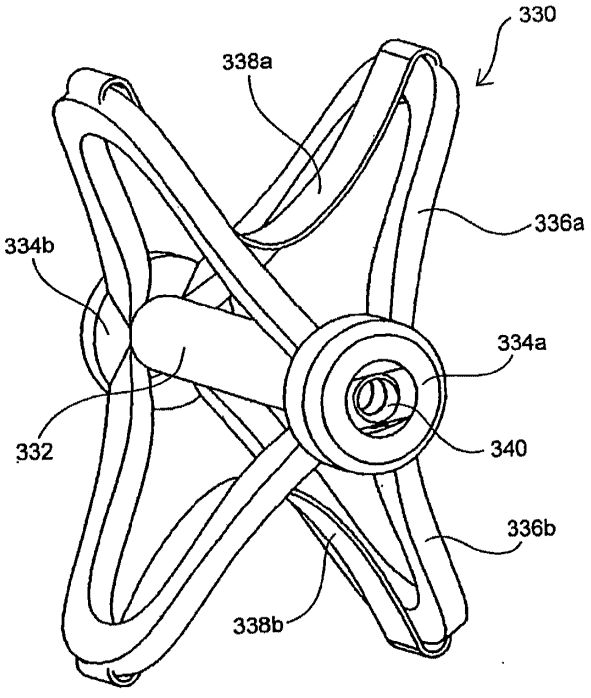
(74) Agent: **LASALLE, Carol M.**; Bozicevic, Field & Francis Llp, 1900 University Avenue, Suite 200, East Palo Alto, California 94303 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),

[Continued on next page]

(54) Title: SYSTEMS AND METHODS FOR POSTERIOR DYNAMIC STABILIZATION OF THE SPINE



(57) Abstract: Devices, systems and methods for dynamically stabilizing the spine are provided. The devices include an expandable spacer having an undeployed configuration and a deployed configuration, wherein the spacer has axial and radial dimensions for positioning between the spinous processes of adjacent vertebrae. The systems include one or more spacers and a mechanical actuation means for delivering and deploying the spacer. The methods involve the implantation of one or more spacers within the interspinous space.

WO 2006/045094 A2

European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *without international search report and to be republished upon receipt of that report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

SYSTEMS AND METHODS FOR POSTERIOR DYNAMIC STABILIZATION OF THE SPINE

Cross-Reference to Related Applications

[0001] This application claims priority to U.S. Patent Application No. 11/190,496, filed July 26, 2005, which is a continuation-in-part of U.S. Patent Application Serial No. 11/079,006, filed on March 10, 2005, which is a continuation-in-part of U.S. Patent Application Serial No. 11/052,002, filed on February 4, 2005, which is a continuation-in-part of U.S. Patent Application Serial No. 11/006,502, filed on December 6, 2004, which is a continuation-in-part of U.S. Patent Application Serial No. 10/970,843, filed on October 20, 2004, incorporated herein by reference in their entireties.

Field of the Invention

[0002] The present invention is directed towards the treatment of spinal disorders and pain. More particularly, the present invention is directed to systems and methods of treating the spine, which eliminate pain and enable spinal motion, which effectively mimics that of a normally functioning spine.

Background of the Invention

[0003] Fig. 1 illustrates a portion of the human spine having a superior vertebra 2 and an inferior vertebra 4, with an intervertebral disc 6 located in between the two vertebral bodies. The superior vertebra 2 has superior facet joints 8a and 8b, inferior facet joints 10a and 10b, and spinous process 18. Pedicles 3a and 3b interconnect the respective superior facet joints 8a, 8b to the vertebral body 2. Extending laterally from superior facet joints 8a, 8b are transverse processes 7a and 7b, respectively. Extending between each inferior facet joints 10a and 10b and the spinous process 18 are laminal zones 5a and 5b, respectively. Similarly, inferior vertebra 4 has superior facet joints 12a and 12b, superior pedicles 9a and 9b, transverse processes 11a and 11b, inferior facet joints 14a and 14b, laminal zones 15a and 15b, and spinous process 22.

[0004] The superior vertebra with its inferior facets, the inferior vertebra with its superior facet joints, the intervertebral disc, and seven spinal ligaments (not shown) extending between the superior and inferior vertebrae together comprise a spinal motion segment or functional spine unit. Each spinal motion segment enables motion along three orthogonal axes, both in rotation and in translation. The various spinal motions are illustrated in Figs. 2A-2C. In particular, Fig. 2A illustrates flexion and extension motions and axial loading, Fig. 2B illustrates lateral

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bending motion and Fig. 2C illustrated axial rotational motion. A normally functioning spinal motion segment provides physiological limits and stiffness in each rotational and translational direction to create a stable and strong column structure to support physiological loads.

[0005] Traumatic, inflammatory, metabolic, synovial, neoplastic and degenerative disorders of the spine can produce debilitating pain that can affect a spinal motion segment's ability to properly function. The specific location or source of spinal pain is most often an affected intervertebral disc or facet joint. Often, a disorder in one location or spinal component can lead to eventual deterioration or disorder, and ultimately, pain in the other.

[0006] Spine fusion (arthrodesis) is a procedure in which two or more adjacent vertebral bodies are fused together. It is one of the most common approaches to alleviating various types of spinal pain, particularly pain associated with one or more affected intervertebral discs. While spine fusion generally helps to eliminate certain types of pain, it has been shown to decrease function by limiting the range of motion for patients in flexion, extension, rotation and lateral bending. Furthermore, the fusion creates increased stresses on adjacent non-fused motion segments and accelerated degeneration of the motion segments. Additionally, pseudarthrosis (resulting from an incomplete or ineffective fusion) may not provide the expected pain-relief for the patient. Also, the device(s) used for fusion, whether artificial or biological, may migrate out of the fusion site creating significant new problems for the patient.

[0007] Various technologies and approaches have been developed to treat spinal pain without fusion in order to maintain or recreate the natural biomechanics of the spine. To this end, significant efforts are being made in the use of implantable artificial intervertebral discs. Artificial discs are intended to restore articulation between vertebral bodies so as to recreate the full range of motion normally allowed by the elastic properties of the natural disc. Unfortunately, the currently available artificial discs do not adequately address all of the mechanics of motion for the spinal column.

[0008] It has been found that the facet joints can also be a significant source of spinal disorders and debilitating pain. For example, a patient may suffer from arthritic facet joints, severe facet joint tropism, otherwise deformed facet joints, facet joint injuries, etc. These disorders lead to spinal stenosis, degenerative spondylolithesis, and/or isthmic spondylotlisthesis, pinching the nerves that extend between the affected vertebrae.

[0009] Current interventions for the treatment of facet joint disorders have not been found to provide completely successful results. Facetectomy (removal of the facet joints) may provide some pain relief; but as the facet joints help to support axial, torsional, and shear loads that act

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on the spinal column in addition to providing a sliding articulation and mechanism for load transmission, their removal inhibits natural spinal function. Laminectomy (removal of the lamina, including the spinal arch and the spinous process) may also provide pain relief associated with facet joint disorders; however, the spine is made less stable and subject to hypermobility. Problems with the facet joints can also complicate treatments associated with other portions of the spine. In fact, contraindications for disc replacement include arthritic facet joints, absent facet joints, severe facet joint tropism, or otherwise deformed facet joints due to the inability of the artificial disc (when used with compromised or missing facet joints) to properly restore the natural biomechanics of the spinal motion segment.

[0010] While various attempts have been made at facet joint replacement, they have been inadequate. This is due to the fact that prosthetic facet joints preserve existing bony structures and therefore do not address pathologies that affect facet joints themselves. Certain facet joint prostheses, such as those disclosed in U.S. Pat. No. 6,132,464, are intended to be supported on the lamina or the posterior arch. As the lamina is a very complex and highly variable anatomical structure, it is very difficult to design a prosthesis that provides reproducible positioning against the lamina to correctly locate the prosthetic facet joints. In addition, when facet joint replacement involves complete removal and replacement of the natural facet joint, as disclosed in U.S. Patent No. 6,579,319, the prosthesis is unlikely to endure the loads and cycling experienced by the vertebra. Thus, the facet joint replacement may be subject to long-term displacement. Furthermore, when facet joint disorders are accompanied by disease or trauma to other structures of a vertebra (such as the lamina, spinous process, and/or transverse processes) facet joint replacement is insufficient to treat the problem(s).

[0011] Most recently, surgical-based technologies, referred to as "dynamic posterior stabilization," have been developed to address spinal pain resulting from more than one disorder, when more than one structure of the spine have been compromised. An objective of such technologies is to provide the support of fusion-based implants while maximizing the natural biomechanics of the spine. Dynamic posterior stabilization systems typically fall into one of two general categories: posterior pedicle screw-based systems and interspinous spacers.

[0012] Examples of pedicle screw-based systems are disclosed in U.S. Patent Nos. 5,015,247, 5,484,437, 5,489,308, 5,609,636 and 5,658,337, 5,741,253, 6,080,155, 6,096,038, 6,264,656 and 6,270,498. These types of systems involve the use of screws that are positioned in the vertebral body through the pedicle. Certain types of these pedicle screw-based systems may be used to augment compromised facet joints, while others require removal of the spinous process

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and/or the facet joints for implantation. One such system, the Zimmer Spine Dynesys® employs a cord which is extended between the pedicle screws and a fairly rigid spacer which is passed over the cord and positioned between the screws. While this system is able to provide load sharing and restoration of disc height, because it is so rigid, it does not effective in preserving the natural motion of the spinal segment into which it is implanted. Other pedicle screw-based systems employ articulating joints between the pedicle screws. Because these types of systems require the use of pedicle screws, implantation of the systems are often more invasive to implant than interspinous spacers.

[0013] Where the level of disability or pain to the affected spinal motion segments is not that severe or where the condition, such as an injury, is not chronic, the use of interspinous spacers are preferred over pedicle based systems as they require a less invasive implantation approach and less dissection of the surrounding tissue and ligaments. Examples of interspinous spacers are disclosed in U.S. Patent Nos. Re. 36,211, 5,645,599, 6,149,642, 6,500178, 6,695,842, 6,716,245 and 6,761,720. The spacers, which are made of either a hard or compliant material, are placed in between adjacent spinous processes. The harder material spacers are fixed in place by means of the opposing force caused by distracting the affected spinal segment and/or by use of keels or screws that anchor into the spinous process. While slightly less invasive than the procedures required for implanting a pedicle screw-based dynamic stabilization system, implantation of hard or solid interspinous spacers still requires dissection of muscle tissue and of the supraspinous and interspinous ligaments. Additionally, these tend to facilitate spinal motion that is less analogous to the natural spinal motion than do the more compliant and flexible interspinous spacers. Another advantage of the compliant/flexible interspinous spacers is the ability to deliver them somewhat less invasively than those that are not compliant or flexible; however, their compliancy makes them more susceptible to displacement or migration over time. To obviate this risk, many of these spacers employ straps or the like that are wrapped around the spinous processes of the vertebrae above and below the level where the spacer is implanted. Of course, this requires some additional tissue and ligament dissection superior and inferior to the implant site, i.e., at least within the adjacent interspinous spaces.

[0014] With the limitations of current spine stabilization technologies, there is clearly a need for an improved means and method for dynamic posterior stabilization of the spine that address the drawbacks of prior devices. In particular, it would be highly beneficial to have a dynamic stabilization system that involves a minimally invasive implantation procedure, where the extent of distraction between the affected vertebrae is adjustable upon implantation and at a

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later time if necessary. It would be additionally advantageous if the system or device was also removable in a minimally invasive manner.

Summary of the Invention

[0015] The present invention provides devices, systems and methods for stabilizing at least one spinal motion segment. The stabilizing devices include an expandable spacer or member having an unexpanded configuration and an expanded configuration, wherein the expandable member in an expanded configuration has a size, volume, diameter, length, cross-section and/or shape configured for positioning between the spinous processes of adjacent vertebrae in order to distract the vertebrae relative to each other.

[0016] In certain embodiments, the expandable member is a balloon made of either non-compliant or compliant material which may be porous or non-porous, or may include a mesh material which may be coated or lined with a porous or non-porous material. The material may define a cavity which is fillable with an inflation and/or expansion medium for inflating and/or expanding the expandable member. The device may further include a port for coupling to a source of inflation/expansion medium. In certain embodiments, the port may be used to deflate or evacuate the expandable member.

[0017] In other embodiments, the expandable members are cages, struts, wires or solid objects having a first or unexpanded shape (having a lower profile) which facilitates delivery to the implant site and a second or expanded shape (having a larger profile) which facilitates distraction between vertebrae. The devices may have annular, spherical, cylindrical, cross, "X", star or elliptical shapes when in an expanded condition and/or unexpanded condition. The expandable members may be self-expanding or adjustably expandable depending on the extent of distraction required.

[0018] The stabilizing devices may be configured such that the transformation from the low-profile state to the high-profile state is immediate or gradual, where the extent of expansion is controllable. The transformation may occur in one-step or evolve in continuous fashion where at least one of volume, shape, size, diameter, length, etc. is continually changing until the desired expansion end point is achieved. This transformation may be reversible such that after implantation, the stabilizing device may be partially or completely unexpanded, collapsed, deflated or at least reduced in size, volume, etc. in order to facilitate removal of the member from the implant site or to facilitate adjustment or repositioning of the member in vivo.

[0019] The stabilizing devices may be configured to stay stationary in the implant site on their own (or "float") or may be further fixed or anchored to surrounding tissue, e.g., bone (e.g.,

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spinous processes, vertebrae), muscle, ligaments or other soft tissue, to ensure against migration of the implant. In their final deployed state, the stabilizing devices may be flexible to allow some degree of extension of the spine or may otherwise be rigid so as prevent extension altogether. Optionally, the devices may include one or more markers on a surface of the expandable member to facilitate fluoroscopic imaging.

[0020] The invention further includes systems for stabilizing at least one spinal motion segment which include one or more of the expandable members as described above. For spacers having a balloon configuration, the systems may further include an expansion medium for injection within or for filling the interior of the expandable member via the port. For expandable members which are expandable by mechanical means or actuation, the systems may further include delivery mechanisms to which the stabilizing spacers are attached which, when actuated or released from the stabilizing device, cause the device to expand. The subject systems may further include at least one means for anchoring or securing the expandable member to the spinal motion segment.

[0021] The invention further includes methods for stabilizing at least one spinal motion segment which involve the implantation of one or more devices or expandable spacers of the present invention, in which the expandable member is positioned between the spinous processes of adjacent vertebrae in an unexpanded or undeployed condition and then subsequently expanded or deployed to a size and/or shape for selectively distracting the adjacent vertebrae. The invention also contemplates the temporary implantation of the subject devices which may be subsequently removed from the patient once the intended treatment is complete. The methods may also include adjustment of the implants in vivo.

[0022] Many of the methods involve the percutaneous implantation of the subject devices from either an ipsolateral approach or a mid-line approach into the interspinous space. Certain methods involve the delivery of certain components by a lateral approach and other components by a mid-line approach. The implantation methods may involve the use of cannulas through which the stabilizing devices are delivered into an implant site, however, such may not be required, with the stabilizing devices be configured to pass directly through an incision.

[0023] These and other objects, advantages, and features of the invention will become apparent to those persons skilled in the art upon reading the details of the invention as more fully described below.

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Brief Description of the Drawings

[0024] The invention is best understood from the following detailed description when read in conjunction with the accompanying drawings. It is emphasized that, according to common practice, the various features of the drawings are not to-scale. On the contrary, the dimensions of the various features are arbitrarily expanded or reduced for clarity. Included in the drawings are the following figures:

[0025] Fig. 1 illustrated s perspective view of a portion of the human spine having two vertebral segments.

[0026] Figs. 2A, 2B and 2C illustrate left side, dorsal and top views, respectively, of the spinal segments of Fig. 1A under going various motions.

[0027] Fig. 3A illustrates an interspinous device of the present invention in an unexpanded or collapsed state coupled to a cannula of the delivery system of the present invention. Fig. 3B is an enlarged view of the interspinous device of Fig. 3A.

[0028] Fig. 4A illustrates an interspinous device of the present invention in an expanded state coupled to a cannula of the delivery system of the present invention. Fig. 4B is an enlarged view of the interspinous device of Fig. 4A.

[0029] Figs. 5A-5C illustrates top, dorsal and side views of an initial step of the method of the present invention in which a cannula is delivered to the target implant site.

[0030] Figs. 6A and 6B illustrate dorsal and side views of the step of dissecting an opening within the spinous ligament utilizing a cutting instrument of the system of Figs. 3 and 4. Fig. 6C is an enlarged view of the target area within the spinous ligament.

[0031] Figs. 7A and 7B illustrate dorsal aid side views of the step of inserting the interspinous device of Fig. 4A into the dissected opening of the spinous ligament. Figs. 7C and 7D are enlarged views of the target area in Figs. 7A and 7B, respectively.

[0032] Figs. 8A and 8B illustrate dorsal aid side views of the step of inflating or expanding the interspinous device of Fig. 4A within the implant site. Figs. 8C and 8D are enlarged views of the target area in Figs. 8C and 8D, respectively.

[0033] Fig. 9A illustrates a side view of the step of filling the interspinous device of Fig. 4A with an expansion medium. Fig. 9B is an enlarged view of the target area in Fig. 9A.

[0034] Fig. 10A illustrates a dorsal view of the step of further securing the interspinous device of Fig. 4A within the implant site. Fig. 10B is an enlarged view of the target area in Fig. 10A.

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[0035] Figs. 11A and 11B illustrate dorsal aid side views of the step of inserting another embodiment of an interspinous device into the dissected opening of the spinous ligament. Figs. 11C and 11D are enlarged views of the target area in Figs. 11A and 11B, respectively.

[0036] Figs. 12A and 12B illustrate dorsal aid side views of the step of expanding the interspinous device of Figs. 11A-11D within the implant site. Figs. 12C and 12D are enlarged views of the target area in Figs. 12A and 12B, respectively.

[0037] Fig. 13A illustrates a side view of the step of filling the interspinous device of Figs. 11A-11D with an expansion medium. Fig. 13B is an enlarged view of the target area in Fig. 13A.

[0038] Figs. 14A-14F illustrate dorsal views of another interspinous device of the present invention and a device for implanting the interspinous device where the implantation device is used initially distract the interspinous space prior to implanting the interspinous device.

[0039] Figs. 15A and 15B illustrate dorsal views of another interspinous device of the present invention implanted within an interspinous space.

[0040] Figs. 16A and 16B illustrate dorsal views of another interspinous device of the present invention implanted within an interspinous space. Fig. 16C is a side view of Fig. 16B.

[0041] Figs. 17A and 17B illustrate side views of another interspinous device of the present invention implanted within an interspinous space. Fig. 17C is a dorsal view of Fig. 17B.

[0042] Figs. 18A and 18B illustrate another interspinous device of the present invention in undeployed and deployed states, respectively.

[0043] Figs. 19A and 19B illustrate the device of Fig. 18 implanted within an interspinous space and operably coupled to a delivery device of the present invention.

[0044] Figs. 20A and 20B illustrate cut-away views of two embodiments of the handle portion of the delivery device of Figs. 19A and 19B.

[0045] Fig. 21 illustrates a cut-away view of a distal portion of the device of Fig. 18 operably positioned over the delivery device of Fig. 20B.

[0046] Figs. 22A-22C illustrate another interspinous spacer device of the present invention in undeployed, partially deployed and fully deployed states, respectively.

[0047] Figs. 23A-23C illustrate another interspinous spacer device of the present invention in undeployed, partially deployed and fully deployed states, respectively.

[0048] Figs. 24A-24C illustrate yet another interspinous spacer device of the present invention in undeployed, partially deployed and fully deployed states, respectively.

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[0049] Figs. 25A-25C illustrate another interspinous spacer device of the present invention in undeployed, partially deployed and fully deployed states, respectively.

[0050] Figs. 26A and 26B illustrate perspective and front views of another interspinous spacer device of the present invention in a deployed state.

[0051] Fig. 27 illustrates a front view of another interspinous spacer device of the present invention.

[0052] Fig. 28A illustrates a step in a method of implanting the interspinous spacer device of Figs. 26A and 26B. Figs. 28A' and 28A" illustrate side and front views of the interspinous spacer device in an undeployed state in the context of the step illustrated in Fig. 28A.

[0053] Fig. 28B illustrates a step in a method of implanting the interspinous spacer device of Figs. 26A and 26B. Figs. 28B' and 28B" illustrate side and front views of the interspinous spacer device in a partially deployed state in the context of the step illustrated in Fig. 28B.

[0054] Fig. 28C illustrates a step in a method of implanting the interspinous spacer device of Figs. 26A and 26B. Figs. 28C' and 28C" illustrate side and front views of the interspinous spacer device in a partially deployed state in the context of the step illustrated in Fig. 28C.

[0055] Fig. 28D illustrates a step in a method of implanting the interspinous spacer device of Figs. 26A and 26B in which the spacer is fully deployed and being released from a delivery device.

[0056] Fig. 28E illustrates the interspinous spacer device of Figs. 26A and 26B operatively implanted within an interspinous space.

[0057] Fig. 29A and 29A' illustrate perspective and front views of another interspinous spacer device of the present invention in an undeployed state.

[0058] Fig. 29B and 29B' illustrate perspective and front views of the interspinous spacer device of Fig. 29A in a partially deployed state.

[0059] Fig. 29C and 29C' illustrate perspective and front views of the interspinous spacer device of Fig. 29A in a partially deployed state but one which is more deployed than depicted in Fig. 29B.

[0060] Fig. 29D and 29D' illustrate perspective and front views of the interspinous spacer device of Fig. 29A in a fully deployed state.

[0061] Fig. 30A and 30A' illustrate perspective and front views of another interspinous spacer device of the present invention in a fully deployed state.

[0062] Fig. 30B and 30B' illustrate perspective and side views of the interspinous spacer device of Fig. 30A in an undeployed state.

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[0063] Fig. 30C and 30C' illustrate perspective and side views of the interspinous spacer device of Fig. 30A in a partially deployed state.

[0064] Figs. 31A and 31B illustrate perspective views of another stabilizing device of the present invention in partial and fully deployed states, respectively.

Detailed Description of the Invention

[0065] Before the subject devices, systems and methods are described, it is to be understood that this invention is not limited to particular embodiments described, as such may, of course, vary. It is also to be understood that the terminology used herein is for the purpose of describing particular embodiments only, and is not intended to be limiting, since the scope of the present invention will be limited only by the appended claims.

[0066] Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs.

[0067] It must be noted that as used herein and in the appended claims, the singular forms "a", "an", and "the" include plural referents unless the context clearly dictates otherwise. Thus, for example, reference to "a spinal segment" may include a plurality of such spinal segments and reference to "the screw" includes reference to one or more screw and equivalents thereof known to those skilled in the art, and so forth.

[0068] Where a range of values is provided, it is understood that each intervening value, to the tenth of the unit of the lower limit unless the context clearly dictates otherwise, between the upper and lower limits of that range is also specifically disclosed. Each smaller range between any stated value or intervening value in a stated range and any other stated or intervening value in that stated range is encompassed within the invention. The upper and lower limits of these smaller ranges may independently be included or excluded in the range, and each range where either, neither or both limits are included in the smaller ranges is also encompassed within the invention, subject to any specifically excluded limit in the stated range. Where the stated range includes one or both of the limits, ranges excluding either or both of those included limits are also included in the invention.

[0069] All publications mentioned herein are incorporated herein by reference to disclose and describe the methods and/or materials in connection with which the publications are cited. The publications discussed herein are provided solely for their disclosure prior to the filing date of the present application. Nothing herein is to be construed as an admission that the present invention is not entitled to antedate such publication by virtue of prior invention. Further, the

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dates of publication provided may be different from the actual publication dates which may need to be independently confirmed.

[0070] The present invention will now be described in greater detail by way of the following description of exemplary embodiments and variations of the devices and methods of the present invention. The invention generally includes an interspinous spacer device as well as instruments for the percutaneous implantation of the interspinous spacer. A key feature of the interspinous spacer device is that it is expandable from a low profile configuration to a higher profile or operative configuration. This design allows the device, when in the low profile condition, to be delivered by percutaneous means without requiring the removal of any portion of the spinal motion segment into which the device is implanted.

[0071] As mentioned above, certain of the devices include balloon embodiments or those having expandable cavities which are expandable by the introduction of an inflation or expansion medium therein. Many of these are illustrated in Figs. 3-14. Certain other devices include those which have a more mechanical structure which is self-expandable upon release from a confined condition or which is actively expandable by actuation of another instrument. These are illustrated in Figs. 15-31.

[0072] Referring now to the drawings and to Figs. 3 and 4 in particular, an exemplary interspinous spacer device 24 of the present invention is illustrated in collapsed and expanded configurations, respectively. Interspinous device 24 includes an expandable spacer body 4 that has a size and shape when in the expanded condition for operative positioning between the spinous processes of adjacent superior and inferior vertebrae of the spinal motion segment being treated. Expandable body 34 is made of an expandable or inflatable biocompatible material such as non-porous material, e.g., latex, acrylate or a metal mesh, e.g., a nitinol or titanium cage.

[0073] Those spacers made of an inflatable non-porous material, i.e., balloon type spacers (see Figs. 3-10), are inflated with an inflation or expansion medium, such as air, saline, another biologically compatible fluid, or a flowable solid material, such as polyurethane, or a gel, which thickens or hardens substantially upon injection into balloon 34. In one embodiment, balloon 34 is initially inflated with air to provide some structure or rigidity to it to facilitate its optimum positioning and alignment between the spinous processes. Once positioned as desired, balloon 34 is injected with a flowable solid material (the air therein being displaced possibly via a vent hole within port 32). In certain embodiments, the expandable body is made of a non-compliant or semi-compliant material so as to maintain a substantially fixed shape or configuration and

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ensure proper, long-term retention within the implant site. In other embodiments, the expandable member may be made of a compliant material. In any embodiment, the compressibility and flexibility of balloon 34 can be selected to address the indications being treated.

[0074] Other embodiments of the subject spacers are made of an expandable mesh or cage (see Figs. 11-12). The mesh or cage maybe made of a super-elastic memory material which is compressible for delivery through a cannula and which is self-expanding upon implantation. Upon expansion, the mesh or cage may be self-retaining whereby its struts, links or wires are sufficiently rigid by themselves to maintain the expanded condition and withstand the natural forces exerted on it by spine. The mesh or cage may have an exterior coating or an interior lining made of materials similar to or the same as that used for the balloon spacers, or may otherwise be embedded in such material. In certain embodiments, an expansion medium may be used to fill the interior of the cage or mesh structure, such as with a biologically compatible fluid or flowable solid material used with the balloon-type embodiments.

[0075] In certain embodiments of present invention, either during the implant procedure or in a subsequent procedure, the size or volume of the implanted expandable spacer may be selectively adjusted or varied. For example, after an initial assessment upon implant, it may be necessary to adjust, either reduce or increase, the size or volume of the spacer to optimize the intended treatment. Further, it may be intended to only temporarily implant the spacer for the purpose of treating a temporary condition, e.g., an injured or bulging or herniated disk. Once the repair is achieved or the treatment completed, the spacer may be removed, either with or without substantially reducing the size or volume of the spacer. In other embodiments, the spacer as well as the inflation/expansion material may be made of biodegradable materials wherein the spacer degrades after a time in which the injury is healed or the treatment completed.

[0076] When unexpanded or deflated, as shown in Figs. 3A and 3B (balloon type) and in Figs. 11C and 11D (mesh type) expandable body 34 has a low profile, such as a narrow, elongated shape, to be easily translated through a delivery cannula 70. The shape of expandable body 34, when in an expanded or inflated state, has larger profile which is generally H-shaped. Expandable body 34 has lateral or side portions 30, end portions 26 and apexes 28 defined between the side portions 30 and the end portions 26. End portions 26 are preferably recessed or contoured to provide a narrowed central portion along the height dimension or major axis of expandable body 34 to readily fit between and to conform to the spinous processes.

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Accordingly, expandable body 34 has an apex-to-apex dimension (i.e., height or major axis dimension) from about 3 to about 5 cm and a width dimension (minor axis dimension) from about 2 to about 4 cm

[0077] For those embodiments of expandable bodies which comprise a balloon configuration, balloon 34 has an inflation or injection port 32 at a sidewall 30 for coupling to a source of inflation or expansion material or medium. Port 32 may consist of a one-way valve which is self-sealing upon release from an inflation mechanism or tube 76. Port 32 is further configured to releasably engage from tube 76, where such engagement may be threaded or involve a releasable locking mechanism. Where the expandable body comprises a mesh or cage, port 32 simply acts as an exit port, however, where an expansion material is used, it also functions as an injection port for the expansion material.

[0078] Optionally, device 24 may include a pair of tabs 36 which may be positioned on one side of the device where the tabs 36 are preferably situated at the apexes 28 of expandable body 34. Pins or screws (not yet shown) may be used to secure the tabs against the spinous process to further ensure long-term retention of device 24 within the implant site. Tabs 36 are made of a biocompatible material, such as latex, acrylate, rubber, or a metal, and may be made of the same material used for the expandable member 34. Shown here attached to tabs 36 are tethers 38 which are used in part to manipulate the positioning of expandable body 34 upon implantation into the targeted spinal motion segment. The tethers may be made of any suitable material including but not limited to materials used to make conventional sutures. They may also be made of a biodegradable material. While two tabs and associated tethers are provided in the illustrated embodiment, one, three or more may be employed, where the respective tabs are located on the expandable body so as to be adjacent a bony structure of the vertebra suitable for anchoring thereto. In embodiments which do not employ securing tabs 36, tethers 38 may be attached directly to the expandable body itself.

[0079] Optionally still, device 24 may further include radiopaque markers 40 on the surface of expandable body 34 visible under fluoroscopic imaging to facilitate positioning of the expandable body. Any number of markers 40 may be employed anywhere on expandable body 34, however, as few as four markers, one at each apex, may be sufficient. With embodiments employing cage or mesh expandable bodies, the cage or mesh material itself may be radiopaque.

[0080] A system of the present invention includes a cannula device 70 having an outer sheath 72, a proximal hub 78 and preferably at least two interior lumens 74, 76 for the percutaneous

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delivery the device and other tools for implanting the device, which tools may include a cutting instrument 62 (see Fig. 6C), a device delivery instrument 76, an endoscope, etc., which tools will be further discussed in the context of the description of the subject methods with reference to Figs. 5-10.

[0081] In Figs. 5A-5C, the spinal motion segment of Fig. 1 is illustrated having spinal ligament 54 extending between the superior spinous process 18 and the inferior spinous process 22. A percutaenous puncture is made into the skin 30 adjacent the target spinal motion segment of a patient undergoing the implantation of the interspinous device of the present invention, and a cannula 70 is penetrated to the spinous ligament 54. The puncture and subsequent penetration may be made by way of a sharp distal tip of cannula 70 or by a trocar (not shown) delivered through a lumen of cannula 70.

[0082] As illustrated in Figs. 6A-6C, the spinous ligament 54 is then dissected and an opening 58 created therein by way of a cutting instrument 60, such as a simple scalpel, an electrosurgical device or the like, delivered through a lumen of cannula 70. Cutting instrument 60 may then be removed from cannula 70 and, as illustrated in Figs. 7A-7D (balloon type) and in Figs. 11A-11D (cage type), a delivery instrument 16 having interspinous device 24 operatively preloaded is delivered through cannula 70.

[0083] The preloading of device 24 to delivery instrument 76 involves providing expandable body 34 in an unexpanded or deflated state and releasably coupled, as described above, by way of inflation or injection port 32 of expandable body 34 to the distal end of delivery instrument 76. In addition to functioning as a pusher, instrument 76 may act as an inflation lumen for balloon type embodiments through which an inflation medium is transported to within expandable body 34.

[0084] Depending upon the material used to fabricate expandable body 34, the expandable body may have a degree of stiffness in an unexpanded or deflated state such that it may maintain an elongated configuration so as to be directly insertable and pushable through cannula 70. This may the case where the expandable member 34 is made of a cage or mesh material. Alternatively, a pusher or small diameter rod (not shown) may be inserted through inflation port 32 to within expandable body 34 to keep it in an elongated state so as to prevent expandable body 4 from bunching within cannula 70 and to provide some rigidity to more effectively position the expandable body in the target implant site. The rod is then removed from expandable body 34 and from delivery device 76 upon positioning the expandable body at the target implant site. In either case, expandable body 34 is folded or compressed about its

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minor axis with the side wall opposite the inflation port 32 defining a distal end 25 (see Fig. 3B) and the apexes 28 of the expandable body folded proximally of distal end 25 to provide a streamline, low profile configuration for delivery through cannula 70.

[0085] Once interspinous device 24 is preloaded to delivery device 76 as just described, device 24 is then inserted into a lumen of cannula 70 with tethers 38 pulled back and trail proximally so that the tether ends 38a extend from hub 78 of cannula 70. Expandable body member 34 is translated through cannula 70 to within opening 58 within spinous ligament 54 as best illustrated in Figs. 7C and 11C. For best results, expandable body 34 is centrally positioned within opening 58 so that the countered ends 26 of expandable body 34 readily engage with the opposed spinous processes 18, 22. Fluoroscopy may be employed to visualize markers 40 so as to ensure that expandable body 34 centrally straddles the spinous ligament opening 58, i.e., the markers on the distal side 25 of the expandable body are positioned on one side of the spine and the markers on the proximal side of the expandable body (the side on which port 32 is located) are positioned on the other side of the spine.

[0086] Once centrally positioned, expandable body 34 is inflated or expanded, as illustrated in Figs. 8A-8D and 12A-12D. For balloon spacers, inflation occurs by allowing an inflation or expansion medium, as discussed above, to enter into the interior of the expandable body via port 32. For expandable mesh spacers, the expandable body may be configured to expand automatically upon exiting cannula 70. The inflation or expansion of expandable body 34 may also be visualized under fluoroscopy whereby markers 40, as best shown in Fig. 8C, are observed and the position of expandable body 34 may be adjusted to ensure optimum positioning upon complete inflation. Adjustments of the expandable body's position may be accomplished by manually pulling on one or both tether ends 38a which in turn pulls on tabs 26 to which the tethers 38 are attached at their proximal ends. The tethers 38 are selectively pulled as necessary to center or optimally position interspinous expandable body 34 to achieve the desired treatment of the targeted spinal motion segment.

[0087] With embodiments in which the expandable body is initially inflated with air and then filled with a solid or fluid medium, the latter is preferably not delivered or injected into the interior of the expandable body until the position of the expandable body within the interspinous space has been verified and optimized. This is beneficial in situations where, upon inflation, it is found that the expandable body is misaligned within the interspinous space and requires repositioning. The expandable body may simply be deflated of air to the extent necessary and repositioned in a less inflated or deflated state. If necessary, for example where it

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is found that the maximum spacer or expandable body size is insufficient for the particular application at hand, expandable body 34 may be completely deflated and removed and replaced with a more suitably sized unit.

[0088] For balloon spacers and those mesh spacers which are not by themselves sufficiently self-retaining, once the position and extent of inflation or expansion of expandable body 34 are optimized, the expansion medium, e.g., polyurethane, is allowed to flow or injected into the interior of the expandable body via port 32. As illustrated in Figs. 9A and 9B, expandable body 34 is caused to expand to a selected volume and in so doing forces apart (see arrow 80) the spinous processes 18, 22 in between which it is situated. This selective distraction of the spinous processes also results in distraction of the vertebral bodies 2, 4 (see arrow 82) which in turn allows the disk, if bulging or distended, to retract to a more natural position (see arrow 84). Again, the extent of distraction or lordosis undergone by the subject vertebrae can be monitored by observing expandable body markers 40 under fluoroscopy.

[0089] The extent of possible distraction maybe limited by the capacity of expandable body 34 and the type of expandable body material employed. In certain embodiments, such as expandable bodies made of non-compliant or semi-compliant balloons, the requisite volume of the inflation medium may be substantially fixed whereby the balloon achieves its fully expanded configuration upon filling it with the fixed volume of medium. In other embodiments, such as with balloons made of a compliant material, the extent of expansion may be variable and selectable intraoperatively depending on the extent of lordosis or distraction to be achieved between the spinous processes in which balloon 34 is now interposed.

[0090] Upon achieving the desired distraction between the vertebrae, inflation/expansion lumen 76 is disengaged from expandable body port 32 which then becomes sealed by means of a one-way valve that is closed upon disengagement of lumen 76. Inflation/expansion lumen is then removed from cannula 70. While the opposing compressive force exerted on expandable body 34 by the distracted spinous processes 18, 22 may be sufficient to permanently retain expandable body 34 therebetween, the interspinous device may be further secured to the spinous processes 18, 22 to ensure that the expandable body does not slip or migrate from its implanted position. To this end, tabs 36 are anchored to the spinous processes as illustrated in Figs. 10A and 10B and in Figs. 13A and 13B. Any type of anchoring means, such as screws, tacks, staples, adhesive, etc. may be employed to anchor tabs 36. Here, cannulated screws 90 are used as anchors and are delivered to the target site releasably coupled to screw driving instrument 88. While various screw attachment and release mechanisms may be employed, a

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simple configuration involves providing the screws 90 with a threaded inner lumen which is threadably engagable with the threaded distal end of instrument 88.

[0091] To ensure accurate placement of screws 90, along with instrument 88, can be tracked and translated over respective tethers 38, which function as guide wires. By manipulating instrument 88, the screws are driven or screwed into the respective spinous process. Screwdriver 88 is then disengaged or unscrewed from screw 90. After both tabs 36 are securely anchored to the spinous processes, the screwdriver and the cannula may be removed from the patient's back.

[0092] Figs. 14A-14F illustrate an alternative method for implanting the expandable member. In particular, the method contemplates pre-inflating or pre-expanding the expandable member prior to positioning the expandable member within the interspinous space. To accomplish this, the vertebrae 2 and 4 may be distracted prior to insertion of the pre-expandable balloon implant. A temporary distraction mechanism, such as another balloon or a mechanically actuated device, is inserted into the interspinous space. When the desired amount of distraction is achieved, the permanent or implantable expandable member can then be placed within the interspinous space, and the temporary distraction member may then be removed from the space.

[0093] While certain of the expandable spacers are intended to be permanently implanted within a spine, certain others may be implanted only temporarily to facilitate the healing of an injury or the treatment of a reversible or non-chronic condition, such as a herniated disk. For such temporary treatments, the expansion material most likely is a fluid, such as saline, which may be easily aspirated through port 32 or may be allowed to drain out via a penetration or cut made in the expandable member. In those embodiments in which the expansion material is a flowable solid, which may or may not subsequently harden within the expandable member, the material may be one that is reconstitutable into a liquid form which may then be subsequently aspirated or evacuated from the expandable member. For percutaneous removal of the expandable member, a cannula such as cannula 70 may be used and an aspiration instrument delivered therethrough and coupled to port 32. After deflation and/or evacuation of the expandable member, and removal of the tacks, sutures, staples, etc. if such are used to secure tabs 36, the expandable member may be easily removed through cannula 70. With biodegradable spacers, removal of the spacer is obviated.

[0094] It should be noted that any of the above-described steps or procedures, including but not limited to cannulation of the target area, dissection of the spinous ligament, insertion of the expandable body within the dissected opening of the spinous ligament, inflation and/or

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expansion of the expandable body, adjustment or readjustment of the expandable body, and anchoring of the tabs, etc., may be facilitated by way of a scope 62 delivered through a lumen of cannula 70 to the open distal tip of cannula 70. Alternatively, a second cannula delivered through another percutaneous penetration may be employed for use of an endoscope and any other instruments needed to facilitate the procedure.

[0095] Fig. 14A illustrates an exemplary embodiment of a temporary distraction mechanism 100 having an expandable strut configuration. Mechanism 100 includes bilateral struts 102 which are hinged and foldable at hubs 104, respectively. Bridging the struts 102 at superior and inferior ends are spinous process engagement portions 106 which are preferably configured to conformingly engage with the spinous processes 18, 22. Extending centrally between hubs 104 is a distal portion of guide wire 108, which also extends proximally through proximal hub 104a. Guide wire 108 is in threaded engagement with both hub 104a whereby hub 104a can be translated both proximally and distally along guide wire 108. As such, expandable member 100 can be provided in a low profile, compressed state upon proximally translating hub 104a in a proximal direction. In such a low-profile state, distraction mechanism 100 is easily deliverable through cannula 70, as described above, to with the interspinous space. Upon proper positioning, distraction mechanism 100 is expandable to a higher profile or expanded state by translating hub 104a toward hub 104b in a distal direction along guide wire 108, as illustrated in Fig. 14A.

[0096] After the desired amount of distraction is achieved between vertebrae 2 and 4, an implantable expandable member 110 of the present invention is delivered adjacent the distracted spinal motion segment. Expandable member 110 may be delivered from the same incision and side as distraction mechanism 100 (ipsolateral approach) and as well as through the same working channel, or may be delivered through a different incision on the same or opposing side of the spinal motion segment being treated (bilateral approach) using two different working channels. In the illustrated embodiment, expandable member 110 is delivered from the same side of the spinous process as distraction mechanism 100. Expandable member 110 may delivered through a separate designated lumen in cannula 70 and translated distally of hub 104b of distraction mechanism 100.

[0097] As shown in Fig. 14B, after deployment, expandable member 110 is inflated or expanded as described above with respect to expandable member 34, for example, by way of an inflation lumen extending through guide wire 108. Tethers 112 may be provided on expandable member 110 to retract and manipulate it to within the interspinous space, as illustrated in Fig.

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14C. Once expandable member 110 is properly positioned within the interspinous space, distraction mechanism 100 may be removed from the interspinous space immediately or, if the expandable member has been filled with a curable expansion medium or one that involves setting or hardening, the distraction mechanism may be kept in the interspinous space until the desired consistency, curing or hardening has been achieved by the expansion medium. To remove distraction mechanism 100 from the interspinous space, its profile is reduced to a low profile state, as illustrated in Fig. 14D. As mentioned earlier, this is accomplished by translating proximal hub 104a proximally along guide wire 108. Distraction member 100 may be retracted out through a cannula or removed directly in this low profile state, leaving expandable member 100 alone within the implant site as illustrated in Fig. 14E. Tethers 112 may then be cut or secured in place. Optionally, a strap 116 or the like may be implanted to further secure expandable member 110 within the implant site and reduce the risk of migration. Here, bores or holes 114 have been formed through the thickness of the spinous processes 18, 22 and strap 116 threaded there through with its ends secured together by a securing means 120, such as a suture, staple or clip, as illustrated in Fig. 14F. Alternatively, strap 116 could be wrapped around the spinous processes 18, 22.

[0098] In addition to the expandable balloon spacers, the present invention further provides for mechanically expandable spacers such as those illustrated in Figs. 15-17. For example, expandable spacer 130 of Fig. 15A is a cage-like structure having spaced-apart, parallel strut members 132 extending between and fixed to hubs 134. Like the distraction mechanism of Figs. 14A-14F, spacer 130 may be provided on and deliverable by way of a guide wire 136 which is threadably engaged to and disengagable from proximal hub 134a. After placement of spacer 130 within the interspinous space, as illustrated in Fig. 15A, spacer 130 is expanded by advancing proximal hub 134a distally along guide wire 136 thereby forcing struts 132 radially outward and away from each other whereby the expanded configuration of spacer 130 is elliptical or, in a more advanced state of expansion, substantially spherical . Once the desired degree of distraction is achieved between vertebrae 2 and 4, guide wire 136 unthreaded from hub 134a and removed from the implant region.

[0099] Figs. 16A and 16B illustrate another embodiment of an expandable spacer 140 which is in the form of a coiled band 142 terminating at an outer end 144 having a configuration for receiving and locking onto inner end 146 upon full expansion or unwinding of the coil. The diameter of coil 142 in an unexpanded or fully wound state is small enough to allow easy insertion between spinous processes 18, 22. Upon proper positioning within the interspinous

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space, coil 142 is allowed to expand and unwind thereby distracting vertebrae 2 and 4 apart from each other. Once the desire level of distraction is achieved, inner end 146 is coupled to outer end 144. While the figures show band 142 inserted transversely to spinous processes 18, 22, it may alternatively be inserted in line or in the same plan defined by the spinous processes.

[00100] Figs. 17A-17C illustrate another interspinous spacer 150 having interlocked nested portions 152. Nested portions 152 are each shaped and configured to be received within one of its adjacent portions and to receive the other of the adjacent portions when in a low profile state, as illustrated in Fig. 17A. Upon expansion of spacer 150, which may be spring loaded or be expandable by way of an instrument (not shown) which may be inserted into the spacer's center and rotated to flare portions 152, vertebrae 2 and 4 are caused to distract from each other. Portions 152 may have a configuration or shape which allows them to bite or dig into the spinous process 18, 22 and become securely retained therein.

[00101] Figs. 18A and 18B illustrate another interspinous spacer 160 of the present invention in an undeployed or unexpanded state and a deployed or expanded state, respectively. Spacer 160 includes an expandable tubular member 162 having end portions 164a, 164b which are capped by hubs 166a, 166b, respectively. As is explained in greater detail below, one or both hubs may be provided fixed to tubular member 162 or may be releasably coupled thereto. A sleeve or retaining member 168 is circumferentially positioned about tubular between end portions 164a, 165a. Most typically, retaining member 168 is positioned substantially centrally (as shown) on tubular member 162, but may be positioned laterally towards one or the other end. Retaining member 168 has a length that covers about one third of the length of tubular member 162, but may be longer or shorter depending on the application. As is explained in greater detail below, interspinous spacer 160 may further include a core member (shown in Fig. 21) within the lumen of the tubular member and which may be provided integrated with spacer 160. Alternatively, the core member may be provided as a detachable component of the device used to deliver and implant the spacer (see Figs. 19A and 19B).

[00102] In the undeployed state, as illustrated in Fig. 18A, spacer 160 has an elongated tubular or cylindrical shape, and may have any suitable cross-sectional shape, e.g., circular, oval, starred, etc., where the more angular cross-sections may allow the device to bite or dig into the spinous processes and for better retention. In this undeployed or lengthened state, tubular member 162 has a length in the range from about 20 mm to about 80 mm, and more typically from about 30 mm to about 50 mm, and a diameter or average thickness in the range from about 4 mm to about 12 mm, and more typically from about 6 mm to about 9 mm. As such, spacer

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160 is deliverable to an implant site between adjacent spinous processes in a minimally invasive manner.

[00103] In the deployed state, as illustrated in Fig. 18B, spacer 160 has a dumbbell or H-shaped configuration, where the length of spacer 160 is less than and the diameter or height of spacer 160 is greater than the corresponding dimensions of the spacer when in an undeployed state. In particular, the length dimension of the end portions 164a, 164b of tubular member 162 has been reduced by about 25% to about 70% while the diameter of the end portions 164a, 164b has been increased by about 50% to about 600%, and the diameter of the central or sleeve-covered portion has been increased by about 200% to about 400%, where the diameter of the portions of the tubular member 164a, 164b not covered by retaining member 168 have a greater diameter than the portion of tubular member 162 which is covered by retaining member 168. The increased diameter of covered or central portion 168 distracts the adjacent vertebrae so as to provide pain relief. The diameter of hubs 166a, 166b may remain constant upon deployment of device 160. In this deployed state, tubular member 162 has a length in the range from about 15 mm to about 50 mm, and more typically from about 20 mm to about 40 mm, and an end portion diameter in the range from about 10 mm to about 60 mm, and more typically from about 15 mm to about 30 mm, and a central portion diameter in the range from about 5 mm to about 30 mm, and more typically from about 8 mm to about 15 mm. As such, when operatively placed and deployed within an interspinous space, the deployed spacer 160 fits snugly within the interspinous space and is held in place by the surrounding muscle, ligaments and tissue.

[00104] Any suitable materials may be used to provide a spacer 160 which is provided in a first state or configuration, e.g., the undeployed state illustrated in Fig. 18A, and which can be manipulated to achieve a second state or configuration, and back again if so desired. A polymer based material or any other material which allows for simultaneous axial shortening and radial expansion is suitable for use to form tubular member 162. The end portions 164a, 164b may be made of the same or a different material as that of the central or covered portion. A flexible or shaped memory material or any other material which also allows for simultaneous axial shortening and radial expansion, but which is less expandable, i.e., maintains a compressive force about tubular member 162, than the material employed for tubular member 162 may be used to form retaining member 168. As such, retaining member 168 limits the extent of radial expansion as well as axial shortening that the covered portion of tubular member 162 can undergo. Examples of suitable materials for the retaining member include but are not limited to Nitinol or polyethelene in a braided or mesh form. Further, the construct of retaining member

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168 may be such that the radial force applied to the portion of tubular member 162 that it covers is constant or consistent along its length so as to maintain a constant diameter along its length or, alternatively, may have a varying radial force so as to allow for selective shaping of the covered portion of tubular member when in a deployed state. Retaining member 168 may be constructed so as to resist bending or flexing upon forcible contact with the spinous processes and, as such, does not conform to the spinous processes. Conversely, the retaining member 168 may be constructed from a more flexible material that allows for some compression and, as such, may conform or be conformable to the spinous processes. Further, the physical properties and dimensions of the materials used for both the tubular member and the retaining may be selected to provide the desired amount of distraction between target vertebrae.

[00105] Referring now to Figs. 19A and 19B, spacer 160 is shown operatively employed within an interspinous space and coupled to delivery device 170. Delivery device 170 includes an outer shaft 172 and an inner shaft 178, movable relative (axially, rotationally or both) to outer shaft 172, both extending from a handle mechanism 174. For example, inner shaft 178 may be configured to be retracted proximally within outer shaft 172, or outer shaft 172 may be configured to be advanced distally over inner shaft 178, or both configurations may be employed together, i.e., while outer shaft 178 is advanced, inner shaft 178 is retracted. The relative movement may be accomplished in any suitable manner, for example by way of a screw configuration, i.e., where the shaft members engage by way of corresponding threads, as illustrated in Fig. 20A, or by way of a ratchet configuration, as illustrated in Fig. 20B. The relative movement is accomplished by manual actuation of actuator 176 coupled to handle 174. While only mechanical embodiments of the movement actuation are illustrated, the same can be achieved by electrically or pneumatically-driven devices or mechanisms.

[00106] As mentioned above, spacer 160 may be provided with an integrated core member or the core member may be detachably provided on the distal end 182 of inner shaft 178. In the first embodiment, distal end 182 of inner shaft 178 is configured to temporarily couple with a proximal end (i.e., the end closest to handle 174) of the core member. In the latter embodiment, the distal end 182 of inner shaft 178 is configured to be inserted into the lumen of tubular member 162, as illustrated in Fig. 21, connect to or engaged with distal hub 166b (i.e., the hub positioned furthest from handle 174) and be detachable at a proximal end 184 from inner shaft 178 to function as a core member. An advantage of the latter embodiment is that the end portion 182 of the inner shaft 178 functioning as the core member may have a length that is as short as the length of tubular member 172 when in a deployed state, with no extra length or

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remaining portion extending laterally of the implanted device. In the integrated embodiment, the core length may need to be as long as tubular member 172 when in the undeployed state. However, the core member may be segmented to allow for selective removal of one or more lengths or portions from the proximal side of the core member subsequent to implantation of the spacer so as not to have any excess length extending from the spacer.

[00107] With either embodiment, retraction of inner shaft 178, as described above, retracts distal hub 166b towards proximal hub 166a and/or advancement of outer shaft 172 advances proximal hub 166a towards distal hub 166b, thereby causing tubular member 162 to be compressed axially, and thus expanded radially, as shown in Fig. 19B. While distal hub 166b may be fixed to tubular member 162, proximal hub 166a may be provided as a separate component having a central bore which allows it to receive and axially translate over inner shaft 178. Proximal hub 166a may be configured to readily slide over inner shaft 178 in a distal direction (but possibly not in a proximal direction) or may be threaded in order to advance over inner shaft 178. The advancement of proximal hub 166a axially compresses tubular member 172 and causes it to radially expand. The axial compression or radial expansion may be continued until the desired extent of distraction occurs between vertebrae 2 and 4. When the desired level of distraction is achieved, proximal hub 166a is secured to either the proximal end of tubular member 162 and/or the proximal end of the core member 182, such as by a threaded or snap-fit engagement or by activating a lock mechanism (not shown). Inner shaft 178 may then be released from the core member (or distal end 182 of inner shaft 178 may be released from inner shaft 178 and left within tubular member 172 to function as the core member) which, along with the end hubs 166a and 166b, maintain the implanted spacer 160 in a deployed state so as to maintain distraction between the vertebrae.

[00108] The reconfiguration of spacer 160 may be further facilitated by selectively configuring the wall of tubular member 162. For example, the interior or luminal surface of tubular member 162 may be contoured or incorporated with divets or spaces 180 where, upon compression of tubular member 162, the walls of the uncovered portions 164a, 164b of tubular member 162 will more readily fold inward to provide the resulting configuration shown in Fig. 18B.

[00109] Figs. 22A-22C illustrate another interspinous spacer 190 of the present invention in an undeployed/unexpanded state, in an intermediate state during deployment and in a deployed/expanded state, respectively. Spacer 190 includes expandable end portions 192a, 192b which are capped by hubs 198a, 198b, respectively. As mentioned previously, one or both hubs may be provided fixed to the end members or may be releasably coupled thereto.

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Extending between end portions 192a, 192b is a central portion 194 including a plurality of blocks or wedges, such as side blocks 200 and end blocks 202, surrounded by a cover, sleeve or retaining member (not shown) which functions to hold the blocks in frictional engagement with each other. A core member or rod 196 extends centrally through end portions 192a, 192b and central portion 194 where end blocks 202 are coaxially positioned on core 196 and are slidably translatable thereon. Core member 196 or a portion thereof may be provided integrated with spacer 190 or may be provided as a detachable component of the device used to deliver and implant the spacer.

[00110] As with the previously described spacer, end portions 192a, 192b may be made of a polymer based material or any other material which allows for simultaneous axial shortening and radial expansion when compressed. Blocks 200, 202 have a more rigid configuration in order to distract the adjacent spinous processes which define the interspinous space into which spacer 190 is positioned without substantial compression of central portion 194. As such, the blocks may be made of a rigid polymer material, a metal, ceramics, plastics, or the like. In order to effect radial expansion and axial shortening of central portion 194, the blocks are selectively sized, shaped and arranged such that an inwardly compressive force on end blocks 202 along the longitudinal axis of the spacer forces end blocks 202 together which in turn forces side or lateral blocks 200 outward and away from each other, as illustrated in Fig. 22B. The inwardly tapered sides of the blocks enable slidable engagement between adjacent blocks. The covering (not shown) around the blocks is made of a stretchable material so as to accommodate the radial expansion of central portion 194. As such, the cover may be made of a polymer based material.

[00111] When in an undeployed state, as shown in Fig. 22A, the central and end portions of spacer 190 have tubular or cylindrical configurations, and may have any cross-sectional shape, length and or diameter as provided above with respect to spacer 160 of Figs. 18A and 18B. Deployment of spacer 190 within an interspinous space may be accomplished in the manner described above. In a fully deployed state, as illustrated in Fig. 22C, spacer 190 has a dumbbell or H-shaped configuration with a change in length and height dimensions as provided above. The increased diameter of central portion 194 when spacer 190 is the deployed configuration distracts the adjacent vertebrae so as to provide pain relief. While the respective dimensions of the spacers change from an undeployed to a deployed state, the spacers may be configured such that the overall size of volume occupied by the spacer does not change.

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[00112] Another interspinous spacer 210 of the present invention is illustrated in an undeployed/unexpanded state, in an intermediate state during deployment and in a deployed/expanded state in Figs. 23A-23C, respectively. Spacer 210 includes expandable end portions 212a, 212b capped by hubs 224a, 224b, respectively. As mentioned previously, one or both hubs may be provided fixed to the end members or may be releasably coupled thereto. Extending between end portions 212a, 212b is a central portion 214 including a plurality of linkages 216 and blocks 220, 222, which collectively provide opposing struts. Each linkage 216 has a length and is pivotally coupled to a side block 220 and an end block 222, where end blocks 222 are coaxially positioned on core 218 and are slidably translatable thereon. While the materials and configuration of end portions 212a, 212b may be as described above, linkages 216 are preferably made of a metal material. A core member or rod 218 extends centrally through end portions 212a, 212b and central portion 214. Core member 218 or a portion thereof may be provided integrated with spacer 210 or may be provided as a detachable component of the device used to deliver and implant the spacer.

[00113] In an undeployed state, as shown in Fig. 23A, the central and end portions of spacer 190 have tubular or cylindrical configurations, and may have any cross-sectional shape, length and or diameter as provided above. As such, side blocks 220 are close together and end blocks 222 are spaced apart with the lengths of linkages 216 aligned with the longitudinal axis of core member 218. When opposing, inwardly compressive forces are exerted on spacer 210 along its longitudinal axis, end portions 212a, 212b axially compress and radially expand as described above thereby forcing end blocks 222 together which in turn force side or lateral blocks 220 outward and away from each other, as illustrated in Fig. 23B. This action causes linkages 216 to spread apart, as shown in Fig. 23B, and move to positions where their lengths are transverse to the longitudinal axis of core 218, as illustrated in Fig. 23C.

[00114] Interspinous spacer 230 of Figs. 24A-24C employs the linkage arrangement of the central portion of spacer 190 of Figs. 23A-23C in both of its end portions 232a, 232b as well as its central portion 234. Specifically, end portions 232a, 232b employ linkages 236, which are longer than linkages 238 used for central portion 234, but which are arranged in similar engagement with side blocks 248 and end blocks 250. On each side of central portion 234 and in between the central portion and the end portions 232a, 232b, respectively, are dampening washers 244. A core member 240 extends between and through the end blocks 250 of distal end member 232a and the end blocks 252 of central portion 234 as well as the dampening washers 244 positioned therebetween, all of which, except the most distal end block, may

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slidably translatable along core member 240. Core member 240 is releasably attached at a proximal end to ratcheted drive rod 242 of a delivery device as discussed above with respect to Figs. 19-21 which rod 242 extends through the proximal end portion 232a and hub 246, as illustrated in Fig. 24B.

[00115] In an undeployed state, as shown in Fig. 24A, the central and end portions of spacer 230 have tubular or cylindrical configurations. As such, side blocks 248 and 252 of end portions 232a, 232b and central portion 234, respectively, are close together and end blocks 250 and 252 of end portions 232a, 232b and central portion 234, respectively, are spaced apart with the lengths of linkages 236, 238 aligned with the longitudinal axis of core member 240. When opposing, inwardly compressive forces are exerted on the distal block 250 and hub 246 of spacer 230 along its longitudinal axis, the end blocks are drawn together thereby forcing side or lateral blocks 220 outward and away from each other, as illustrated in Fig. 24B. This action causes the linkages of the end and central portions to spread apart, and move to positions where their lengths are transverse to the longitudinal axis of core 240, as illustrated in Fig. 24C, the fully deployed state of spacer 230.

[00116] The end portions and central portions of the compressible spacers described above may be used in any combination. For example, the polymer-based central portion of Figs. 18A and 18B and the linkage end portions of Figs. 24A-24C may be used together to form a spacer of the present invention. Such a spacer 260 is illustrated in Figs. 25A-25C. Spacer 260 includes linkage-block end portions 262a, 262b and a compressible central member 264 around which is positioned a circumferential retaining member 278 made of a braided mesh-like material. A core member 274 extends between and through the end blocks 270 of distal end member 262a and through central portion 264, all of which, except the most distal end block, may slidably translatable along core member 260. Core member 260 is releasably attached at a proximal end to ratcheted drive rod 272 of a delivery device as discussed above with respect to Figs. 19-21 which rod 272 extends through the proximal end portion 262a and hub 272, as illustrated in Fig. 25B.

[00117] In an undeployed state, as shown in Fig. 25A, the central and end portions of spacer 230 have tubular or cylindrical configurations. As such, side blocks 268 of end portions 262a, 262b are close together and end blocks 270 of end portions 262a, 262b are spaced apart with the lengths of linkages 266 aligned with the longitudinal axis of core member 274. When opposing, inwardly compressive forces are exerted on the distal block 270 and hub 272 of spacer 260 along its longitudinal axis, the end blocks are drawn together thereby causing

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linkages 266 of the end portions to spread apart thereby forcing side or lateral blocks 268 outward and away from each other, as illustrated in Fig. 25B, until linkages 266 move to positions where their lengths are transverse to the longitudinal axis of core 274, as illustrated in Fig. 25C, the fully deployed state of spacer 260.

[00118] Each of the expandable and or inflatable interspinous spacers described thus far is particularly configured to be delivered minimally invasively, even percutaneously, from a single incision located laterally to one side (left or right) of the spinal motion segment to be treated. However, the present invention also includes interspinous spacers which are deliverable through a mid-line incision made directly into the interspinous ligament. Examples of such spacers are now described.

[00119] Figs. 26A and 26B are perspective and front views, respectively, of interspinous spacer 280 which is configured for implantation by way of a percutaneous mid-line approach. Spacer 280, shown in a deployed state, includes a central member or portion 282 and four struts or legs 284 which are substantially radially expandable from central portion 282. Central portion 282 has a cylindrical configuration having a diameter sized for delivery through a small gauge cannula and a length that allows placement within an interspinous space. A lumen 285 extends at least partially through the center of central portion 282 and is configured, e.g., threaded, to be releasably engaged to a delivery tool.

[00120] Each strut 284 includes one or more blocks 288. Where more than one block 288 per strut is employed, such as with spacer 280 which employs two blocks 288 per strut 284 and spacer 290 of Fig. 27 which employs three blocks 288 per strut 284, the blocks are stacked and slidably interconnected to each other in a manner that allows the to translate linearly relative to each other along parallel axes. A tongue and groove configuration 292 is employed with the illustrated embodiment to interconnect stacked blocks, but any suitable interconnection which enables such relative motion between the blocks may be used. Such configuration may also be employed to interconnect the innermost block to central member 282 where outer ridges or tongues 296 on central member 282 slidably interface with a corresponding groove on inner end of the innermost block. As such, blocks 288 are slidable relative to central member 282 along an axis parallel to the longitudinal axis of central member 282. Depending on the application and the particular anatomy of the implant site, struts 284 may be evenly spaced apart about the circumference of central member 282. In other embodiments the distance between superior struts 284a and between inferior struts 284b may vary and/or the distance between each of those and between struts on the same side of the central member may vary.

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[00121] Spanning between each strut pair 284a and 284b is a strap 286a and 286b, respectively, affixed to the outermost blocks. Straps 286 may be made of any suitable material which is strong enough to maintain distraction between adjacent spinous processes and to endure any frictional wear which it may undergo due to natural spinal motion. The straps may be flexible such that they act as slings, or may be conformable to the spinous processes once in situ. Alternatively, the straps may be non-conforming and rigid with a planar or curved shape depending on the application at hand. Suitable strap materials include but are not limited to polyester, polyethylene, etc.

[00122] With reference to Figs. 28A-28E, various steps of a method according to the present invention for implanting spacer 280 as well as other spacers of the present invention configured for a mid-line implantation approach into a target spinal motion segment (defined by components of vertebral bodies 2 and 4) of a patient are described.

[00123] The initial steps of creating a percutaneous puncture and subsequent penetration into the skin 30 and the dissection of the spinous ligament 54 involve many of the same instruments (e.g., K-wire, trocar, cutting instrument, delivery cannula, etc.) and surgical techniques used in the ipsolateral implantation approach described above with respect to Figs. 5 and 6. Upon creating an opening within the interspinous space extending between the superior spinous process 18 and the inferior spinous process 22, a delivery instrument 300 having interspinous device 280 operatively preloaded in an undeployed state at a distal end is delivered to within the interspinous space. The delivery instrument 300 is provided with a mechanism for releasably connecting to spacer 380, such as by way of threaded screw 302 (see Fig. 28D) which is threadedly engaged with threaded lumens 285 of spacer 280.

[00124] As best illustrated in Figs. 28A' and 28A", when in an undeployed state, spacer 280 has a relatively low profile to facilitate entry into the interspinous space. Once properly positioned within the interspinous space, deployment of the spacer 280 is initiated, as illustrated in Fig. 28B, by manipulation of instrument 300 which simultaneously causes outward radial movement of the outermost blocks of strut pairs 284a, 284b and distal linear advancement of the proximal portion 304 of spacer 282 (see Figs. 28B' and 28B") resulting in radial expansion and axial shortening of spacer 280. Spacer 280 may be configured such that deployment of the struts is accomplished by either or both axial rotation of internally componentry or axial compression of central member 282.

[00125] As the struts are radially extended, straps 286a and 286b emerge and they become tauter as the slack in them is gradually reduced by the extension of the struts. Continued deployment

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of spacer 280 causes straps 286a, 286b to engage with opposing surfaces of spinous processes 18 and 22. The radial extension of the struts is continued, as illustrated in Figs. 28C, 28C' and 28C", until the desired amount of distraction between the vertebra is achieved. This selective distraction of the spinous processes also results in distraction of the vertebral bodies 2, 4 which in turn allows the disk, if bulging or distended, to retract to a more natural position. The extent of distraction or lordosis undergone by the subject vertebrae can be monitored by observing the spacer under fluoroscopy.

[00126] At this point, the delivery instrument 300 is released from spacer 280 by unscrewing threaded screw 302 from threaded lumen 285 and removing it from the implant site, as illustrated in Fig. 28D. Spacer 280 remains behind within the interspinous space, locked in a deployed state (see Fig. 28E).

[00127] Spacer 280 may configured such that the struts are not retractable without active manipulation of delivery instrument 300 to ensure that their extension, and thus the distraction on the spinal motion segment, is maintained. As configured, spacer 280 may be easily repositioned or removed by subsequent insertion of instrument 300 into the interspinous space and operative engagement with the spacer. Instrument 300 is then manipulated to cause retraction of the struts and the straps, reducing the spacer's profile to allow repositioning or removal of the spacer.

[00128] Figs. 29A-29D illustrate another spacer 310 of the present invention that is implantable through a mid-line approach to the interspinous space. Spacer 310 includes centrally opposed front and rear structures or blocks 312a, 32b which are pivotally interconnected on both sides to pairs of elongated linkages 314. The other end of each linkage 314 is pivotally connected to a lateral structure 318a or 318b. The resulting "X" configuration provides interconnected strut pairs on each side of spacer 310 which move and function similarly to the linkages described above with respect to the spacers illustrated in Figs. 23, 24 and 25, i.e., the lengths of linkages 314 extend parallel to the central axis of spacer 310 when in a fully undeployed state (Fig. 29A) and extend transverse to the central axis of spacer 310 in a fully deployed state (Fig. 29D). Extending between opposing superior lateral structures 318a and between opposing inferior structures 318b are straps 316a and 316b, respectively.

[00129] Spacer 310 is implantable and deployable by way of a mid-line approach similar to that described above with respect to the spacer of Figs. 28A-28E. Spacer 310 is preloaded to a delivery instrument shaft 320 which is insertable and axial translatable through a central opening within front block 312a. The distal end of shaft 320 is releasably attached to an axial

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member (not shown) of spacer 310. Axial member is fixed to rear block 312b and extends along the central axis of spacer 310, having a length which extends to front block 312a when spacer 210 is in a fully deployed state, as illustrated in Fig. 29D but which extends only a portion of the length of spacer 310 when it is in an undeployed state (Fig. 29A) or a partially undeployed (Figs. 29B and 29C) state.

[00130] After the necessary space is created within the interspinous space as described above, spacer 310, which is releasably connected to delivery shaft 320 as described above, is inserted into the space in a fully undeployed sate (see Figs. 29A and 29A'). Deployment of the spacer is accomplished by proximally pulling on shaft 320 which compresses rear block 312b towards front block 312a. This in turn causes the linkages 314 to pivot about their respective attachment points with superior and inferior lateral structures or blocks 318a and 318b forced away from each other, as illustrated in Figs. 29B and 29B'. Continued pulling of instrument 320 further expands linkages 314 in a direction transverse to the central axis of spacer 310 and extend straps 316a, 316b towards respective surfaces of the spinous processes. As front and rear blocks 312a and 312b are centrally tapered, defining a bowtie or hourglass configuration, the strut pairs define a centrally tapered profile as the align to their fully deployed position, as best shown in Figs. 29C' and 29D'. In the fully deployed state, the spacer's axial member is positioned within the opening of front block 312a and locked to it. Additionally, straps 316a and 316b are firmly engaged against the spinous processes and the contacted vertebra are distracted from each other. Delivery instrument 320 may then be released from spacer 310 and removed from the implant site.

[00131] Figs. 30A-30C illustrate yet another spacer 330 of the present invention having an "X" shape in an expanded condition and which is implantable through a mid-line approach to the interspinous space. As best illustrated in Figs. 30A and 30A', spacer 330 includes an elongated central member 332 extending between front and rear hubs 334a and 334b and a plurality of flexible or deformable struts 336 which also extend between hubs 334a, 334b. Struts 336 are configured to be deformable and to have a directional character to facilitate deployment of them radially outward from central member 332. Examples of suitable constructs of these struts include but are not limited to thin metal plates, e.g., flat springs, wire bundles or a polymer material. Extending between and affixed to each of strut pairs 336a and 336b are straps 338a and 338b, respectively.

[00132] The proximal end 342 of central member 332 is provided with ratcheted grooves which are releasably engaged within the distal end of 352 of delivery instrument 350 (see Fig. 30C').

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Front hub 334a is provided with an opening 340 which also has a grooved internal surface for engaging with the grooves of central member 332.

[00133] Spacer 330 is implantable and deployable by way of a mid-line approach similar to that described above with respect to the spacer of Figs. 29A-2D. Spacer 330 is preloaded in a fully undeployed state to delivery instrument shaft 350 as illustrated in Figs. 30B and 30B'. After the necessary space is created within the interspinous space as described above, spacer 330 is inserted into the interspinous space. Deployment of the spacer is accomplished by proximally pulling on shaft 350, by ratcheting as described above, which compresses rear hub 334b towards front hub 334a or distally pushing on front hub 334a towards rear hub 334b. This in turn causes struts 336a, 336b to flex or bend outward, as illustrated in Figs. 30C and 30C'. Continued pulling of instrument 350 (or pushing of hub 334a) further bends the struts such that they define an X-shaped structure with straps 338a and 338b forcably abutting against the interspinous processes. The pulling (or pushing) action advances the grooved proximal end 342 of central member 332 into grooved opening 340 of front hub 334a. The opposing grooves of the central member and the opening provide a ratchet relationship between the two whereby central member is readily translatable in a proximal direction but not in a distal direction, thereby locking spacer 330 in a deployed state. Upon achieving the desired amount of distraction between the vertebra, delivery instrument 350 is released from spacer 310 (such as by unscrewing) and removed from the implant site.

[00134] Figs. 31A and 31B illustrate a stabilizing spacer 360 similar to spacer 330 just described but which forms the expanded "X" configuration with solid linkages rather than struts. Spacer 360 includes an elongated central member 362 extending from and fixed to a rear hub 364a and slidably through a front hub 364b proximally to a delivery tool having a shaft 372. Also extending between the front and rear hubs are four linkage pairs, where each linkage pair 366a and 366b are interconnected to a respective hub by a hinge 368 and are interconnected to each other by a hinge 370. When in a fully unexpanded condition, each linkage pair extends parallel to central member 362, providing a low profile for delivery. When the front and rear hubs are caused to approach each other, each linkage pair 366a, 366b expands substantially radially outward from central member 362, as illustrated in Fig. 31A. The hubs are brought together to the extent desired to provide an expanded "X" configuration, as illustrated in Fig. 31B. Upon achieving the desired expansion, central member 362 is released or detached from delivery shaft 372. As with many of the "mechanical" type spacers discussed above, attachment and release of the spacer from the delivery device may be accomplished by various means, including but

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not limited to ratchet, threaded or quick-release configurations between the spacer and the delivery device.

[00135] Extending between and affixed to each of the top and bottom linkage pairs are brackets or saddles 374 for receiving the inner surfaces of opposing interspinous processes. Brackets 374 have a substantially rigid and flat central portion 374a and relatively flexible lateral portions 374b which are affixed to hinges 370. The rigid, flat central portion 374a facilitates engagement with the interspinous process. The flexible lateral portions 374b and their hinged connections to spacer 360 facilitate folding of the lateral portions 374b when in an undeployed state and allow for adjustment of spacer 360 once in a deployed state, where a least a portion of the adjustment may be self-adjustment by spacer 360 relative to interspinous space into which it is implanted.

[00136] The subject devices and systems may be provided in the form of a kit which includes at least one interspinous device of the present invention. A plurality of such devices may be provided where the devices have the same or varying sizes and shapes and are made of the same or varying biocompatible materials. Possible biocompatible materials include polymers, plastics, ceramic, metals, e.g., titanium, stainless steel, tantalum, chrome cobalt alloys, etc. The kits may further include instruments and tools for implanting the subject devices, including but not limited to, a cannula, a trocar, a scope, a device delivery/inflation/expansion lumen, a cutting instrument, a screw driver, etc., as well as a selection of screws or other devices for anchoring the spacer tabs to the spinous processes. The kits may also include a supply of the expandable body inflation and/or expansion medium. Instructions for implanting the interspinous spacers and using the above-described instrumentation may also be provided with the kits.

[00137] The preceding merely illustrates the principles of the invention. It will be appreciated that those skilled in the art will be able to devise various arrangements which, although not explicitly described or shown herein, embody the principles of the invention and are included within its spirit and scope. Furthermore, all examples and conditional language recited herein are principally intended to aid the reader in understanding the principles of the invention and the concepts contributed by the inventors to furthering the art, and are to be construed as being without limitation to such specifically recited examples and conditions. Moreover, all statements herein reciting principles, aspects, and embodiments of the invention as well as specific examples thereof, are intended to encompass both structural and functional equivalents thereof. Additionally, it is intended that such equivalents include both currently known

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equivalents and equivalents developed in the future, i.e., any elements developed that perform the same function, regardless of structure. The scope of the present invention, therefore, is not intended to be limited to the exemplary embodiments shown and described herein. Rather, the scope and spirit of present invention is embodied by the appended claims.

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CLAIMS

That which is claimed is:

1. A device for stabilizing at least one spinal motion segment comprising a first vertebra having a first spinous process and a second vertebra having a second spinous process, the device comprising:

an undeployed configuration having an axial dimension and a radial dimension substantially transverse to the axial dimension; and

a deployed configuration having an axial dimension and a radial dimension substantially transverse to the axial dimension;

wherein the radial dimension of the undeployed configuration is less than the radial dimension in the deployed configuration.

2. The device of claim 1, wherein the axial dimension of the undeployed configuration is greater than the axial dimension in the deployed configuration.

3. The interspinous device of claim 1, wherein the radial dimension is defined at least in part by a plurality of radially expanding members.

4. The device of claim 3, wherein the radially expanding members comprise deformable struts.

5. The device of claim 3, wherein the radially expanding members comprise linkages.

6. The device of claim 3, comprising a first bracket extending between a first pair of the radially expandable members and a second bracket extending between a second pair of the radially expandable members.

7. The device of claim 6, wherein the brackets each comprise a substantially rigid central portion and two substantially flexible lateral portions.

8. The device of claim 1, wherein the device in the undeployed has a cylindrical shape.

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9. The device of claim 1, wherein the device in the deployed has a "X" shape.

10. A system for stabilizing at least one spinal motion segment comprising a first vertebra having a first spinous process and a second vertebra having a second spinous process and an interspinous space defined between the first and second spinous processes, the system comprising:

the device of claim 1; and

a device for delivering the device in the undeployed configuration within the interspinous processes and for radially expanding the device from the undeployed configuration to the deployed configuration.

11. The system of claim 10, wherein the device is configured for delivery by the delivery device through a midline incision.

12. An interspinous device for stabilizing at least one spinal motion segment comprising a first vertebra having a first spinous process and a second vertebra having a second spinous process, the device comprising:

an axial dimension and a radial dimension substantially transverse to the axial dimension, wherein the axial dimension is greater when the device is in an undeployed configuration and the radially dimension is greater when the device is in a deployed configuration.

13. The interspinous device of claim 12, wherein the axial dimension is defined by a central member and the radial dimension is defined at least in part by a plurality of radially expandable members.

14. The interspinous device of claim 13, comprising a first strap extending between a first pair of the radially expandable members and a second strap extending between a second pair of the radially expandable members.

15. The interspinous device of claim 13, wherein the radially expandable members comprise linkages.

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16. The interspinous device of claim 13, wherein the radially expandable members comprise deformable struts.

17. The interspinous device of claim 13, wherein the radially expandable members comprise a compressible material.

18. A system for stabilizing at least one spinal motion segment comprising a first vertebra having a first spinous process and a second vertebra having a second spinous process and an interspinous space defined between the first and second spinous processes, the system comprising:

the interspinous device of claim 12; and

a device for delivering the interspinous device in the undeployed state within the interspinous processes and for axially reducing and radially expanding the device from the undeployed state to the deployed state.

19. The system of claim 18, wherein the interspinous device is configured for delivery by the delivery device through a midline incision.

20. An interspinous device for stabilizing at least one spinal motion segment comprising a first vertebra having a first spinous process and a second vertebra having a second spinous process, the device comprising:

a tubular member having a length and a diameter and being deployable from a first configuration to a second configuration, wherein one of the length and the diameter of the tubular member in the first configuration is changed when the tubular member is in the second configuration.

21. The device of claim 20 wherein the length of the tubular member in the first configuration is greater than the length of the tubular member in the second configuration.

22. The device of claim 20 wherein the diameter of the tubular member in the second configuration is greater than the diameter of the tubular member in the first configuration.

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23. The device of claim 20 further comprising a retaining member circumferentially positioned about a portion of the length of the tubular member, wherein the diameter of the retained portion of the tubular member is less than the diameter of the unretained portion of the tubular member when the tubular member is in the second configuration.

24. The device of claim 23, wherein the retaining member is positioned about a central portion of the tubular member.

25. The device of claim 20, further comprising

a core member positionable within the tubular member; and

first and second hubs configured for coupling with a first end of the core member and a second end of the core member, respectively.

26. The device of claim 25, wherein the at least one of the hubs is configured to translate axially over the core member.

27. The device of claim 20, wherein the tubular member comprises a polymer material.

28. The device of claim 20, wherein the retaining member comprises a braided or mesh material.

29. A system for stabilizing at least one spinal motion segment comprising a first vertebra having a first spinous process and a second vertebra having a second spinous process, the system comprising:

the interspinous device of claim 20; and

a device for delivering the interspinous device when in the first configuration between the first and second spinous process and for deploying the interspinous device in the second configuration.

30. The system of claim 29 wherein the delivery device comprises:

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an elongated shaft having a detachable distal end configured for insertion into the tubular member of the interspinous device; and

a handle mechanism for moving the elongated shaft wherein the movement causes the tubular member to be deployed from the first configuration to the second configuration.

31. An interspinous device for stabilizing at least one spinal motion segment comprising a first vertebra having a first spinous process and a second vertebra having a second spinous process, the device comprising:

an expandable member having an unexpanded configuration and an expanded configuration, wherein the expandable member in the unexpanded configuration has a size configured for positioning between the first and second spinous process and in the expanded configuration provides distraction of the first and second spinous processes, wherein the expandable member is mechanically actuatable from the unexpanded configuration to the expanded configuration.

32. The device of claim 31, wherein the expandable member comprises a plurality of parallel struts.

33. The device of claim 32, wherein the plurality of struts are affixed between two opposing hubs.

34. The device of claim 31, wherein the expandable member comprises a coiled band.

35. The device of claim 34, wherein the coiled band comprises inner and outer ends which are connectable to each other.

36. The device of claim 31, wherein the expandable member comprises a plurality of nested portions.

37. The device of claim 31, wherein the expandable member has a spherical configuration.

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38. The device of claim 1, wherein the expandable member has an elliptical configuration.

39. The device of claim 31, wherein the expandable member has a disk configuration.

40. The device of claim 31, wherein the expandable member is self-expanding.

41. A system for stabilizing at least one spinal motion segment comprising a first vertebra having a first spinous process and a second vertebra having a second spinous process, the system comprising:

an expandable member having an unexpanded configuration and an expanded configuration, wherein the expandable member in the unexpanded configuration has a size configured for positioning between the first and second spinous process and in the expanded configuration provides distraction of the first and second spinous processes, wherein the expandable member is mechanically actuatable from the unexpanded configuration to the expanded configuration.; and

means for mechanically actuating the expandable member.

42. The system of claim 41, wherein said mechanical actuation means is a guide wire.

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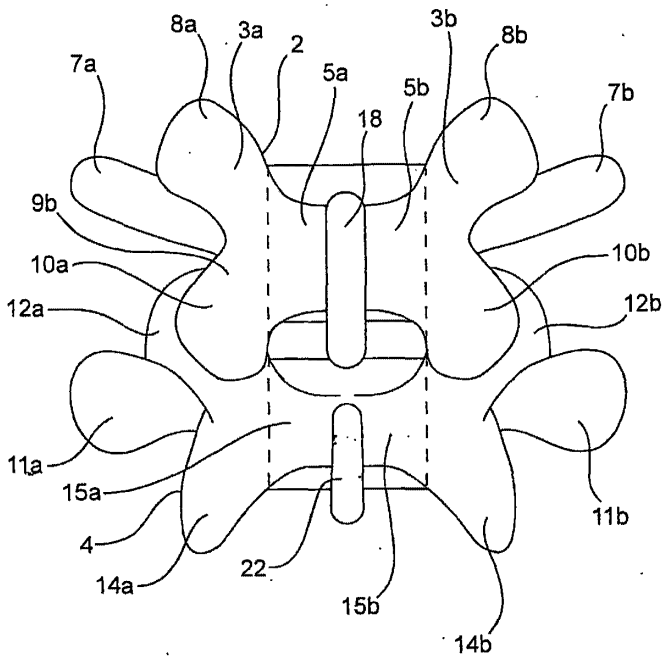

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3a
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3b
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FIG. 1

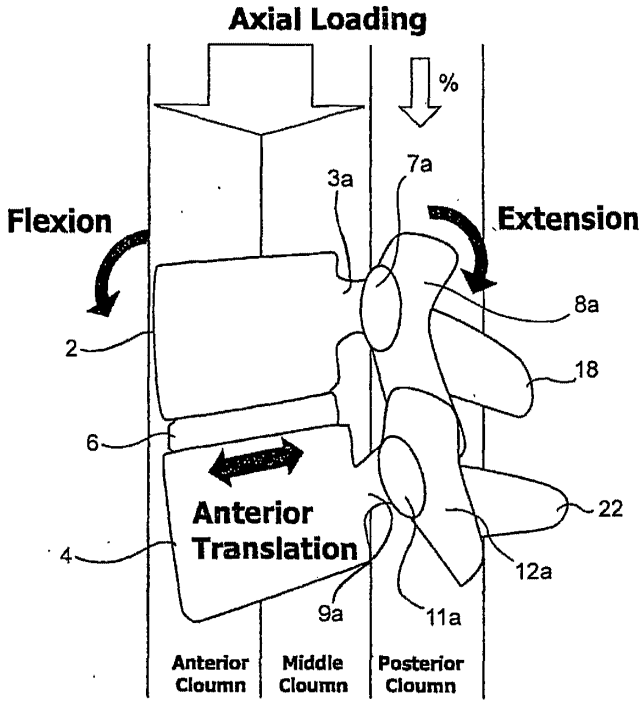

Axial Loading
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Flexion
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11a
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FIG. 2A

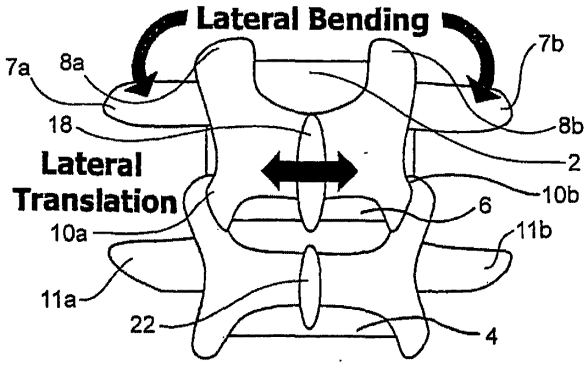

Lateral Bending
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Translation
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11b
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FIG. 2B

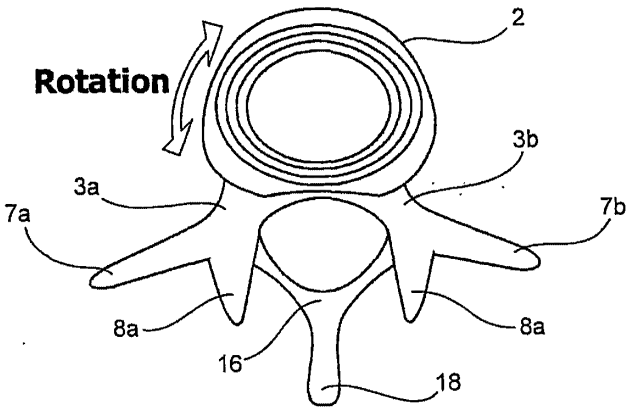


FIG. 2C

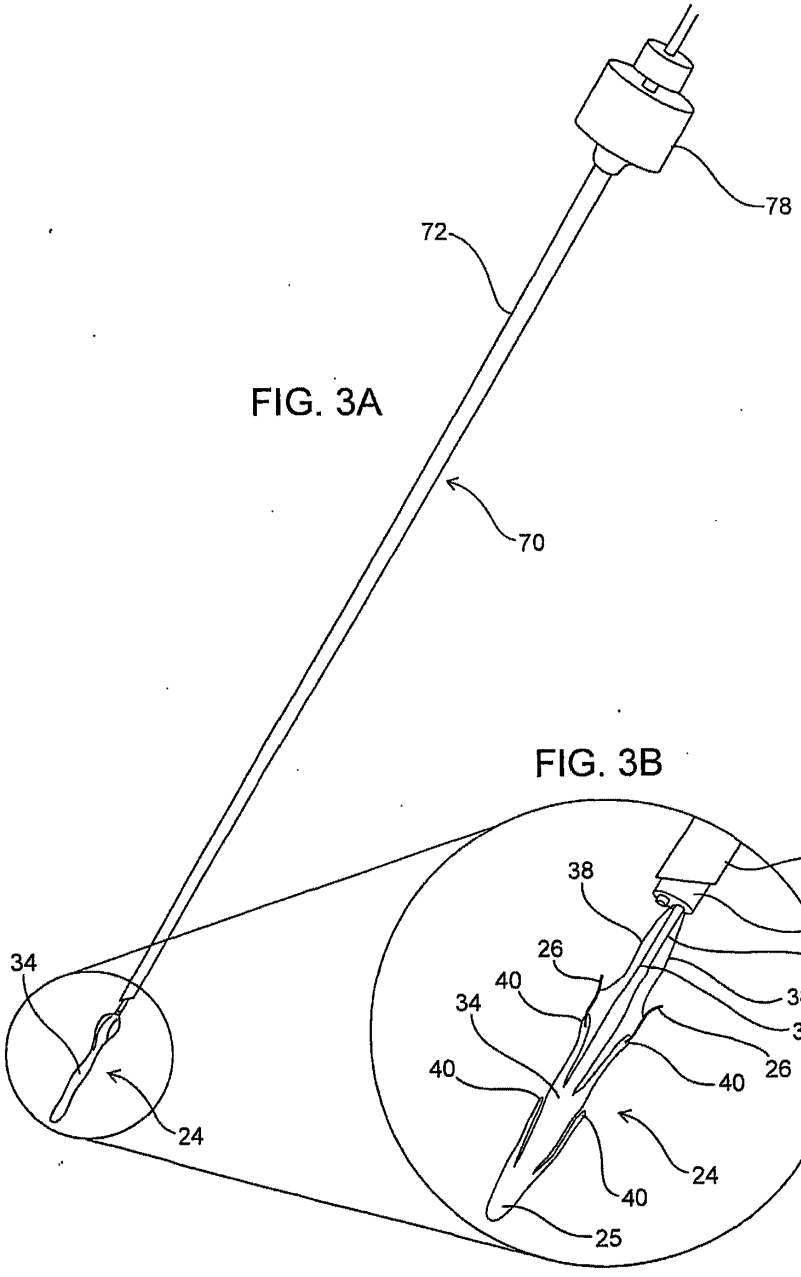


FIG. 3A

FIG. 3B

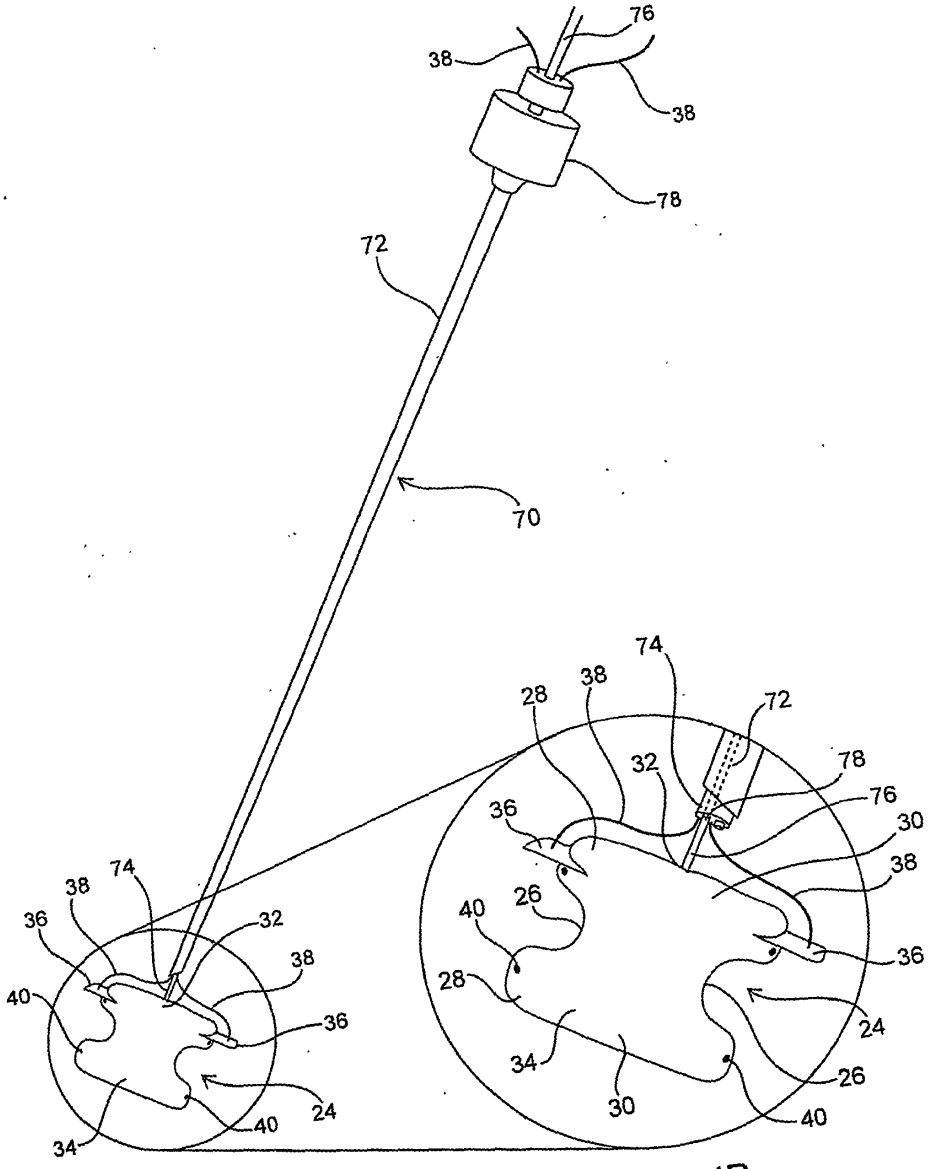

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FIG. 4A

FIG. 4B

FIG. 5A

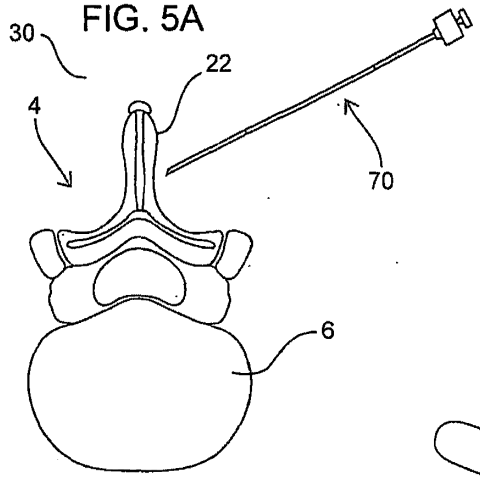


FIG. 5B

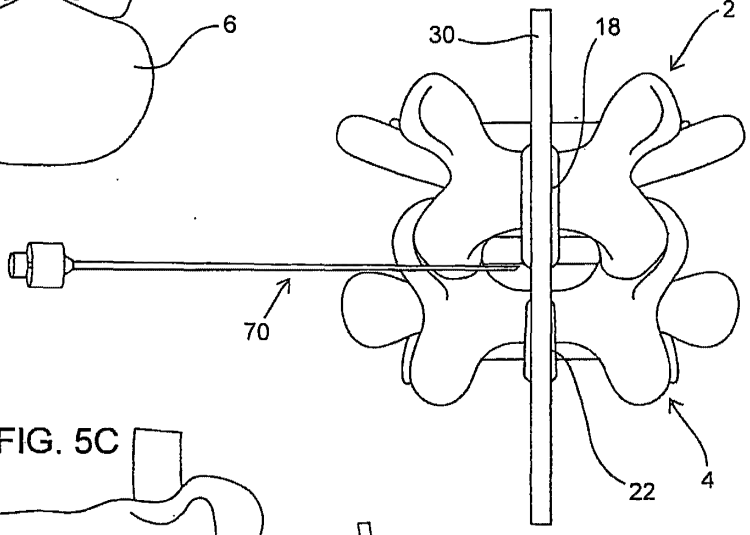
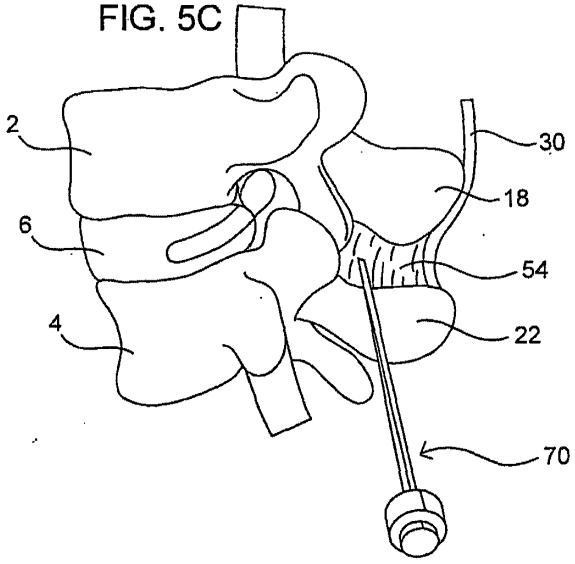


FIG. 5C



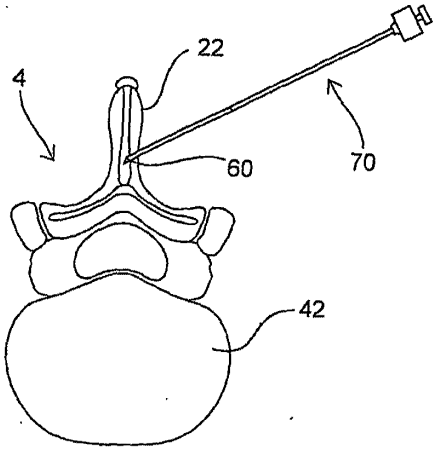


FIG. 6A

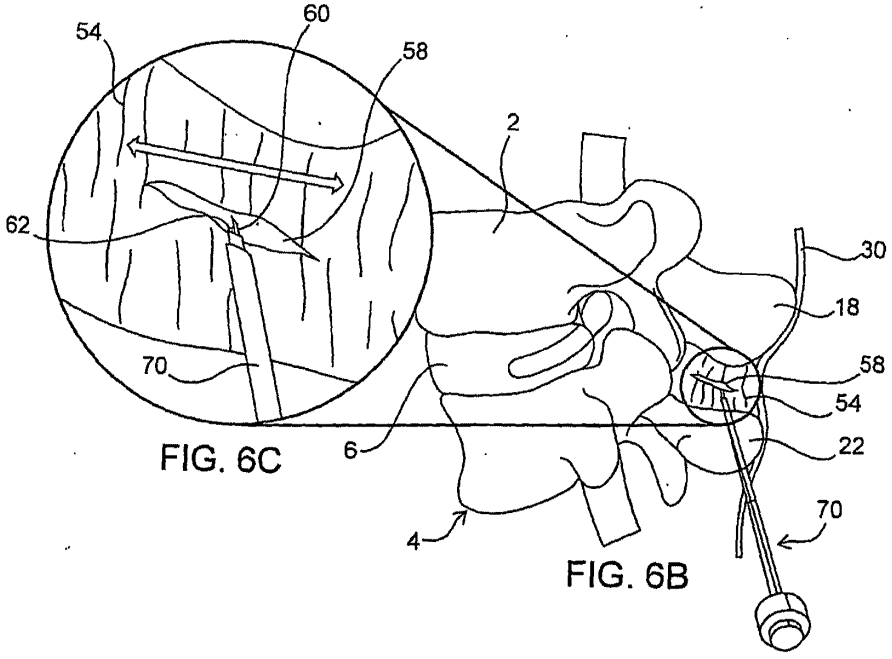


FIG. 6C

FIG. 6B

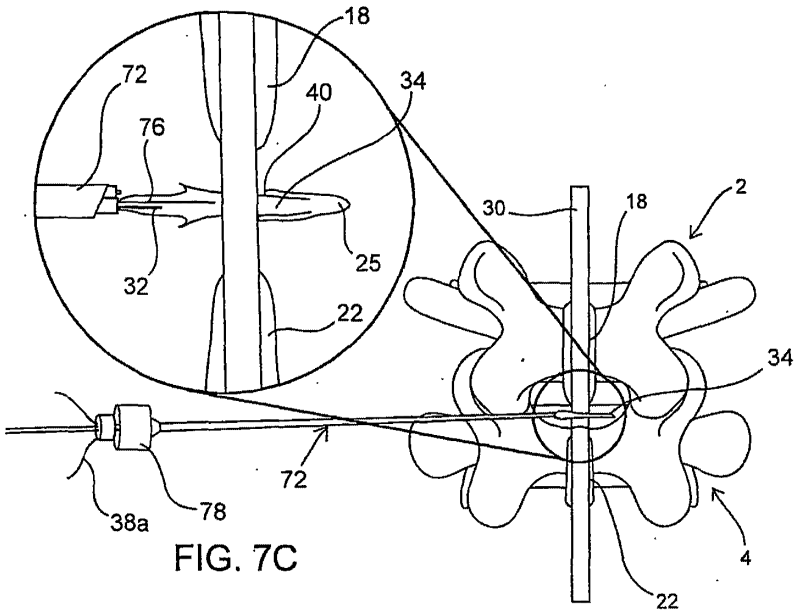


FIG. 7C

FIG. 7A

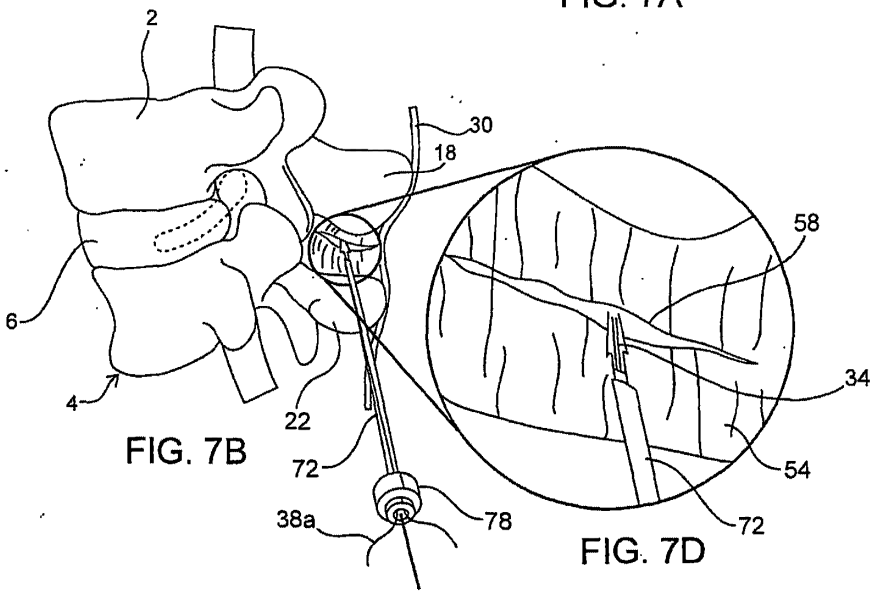


FIG. 7B

FIG. 7D

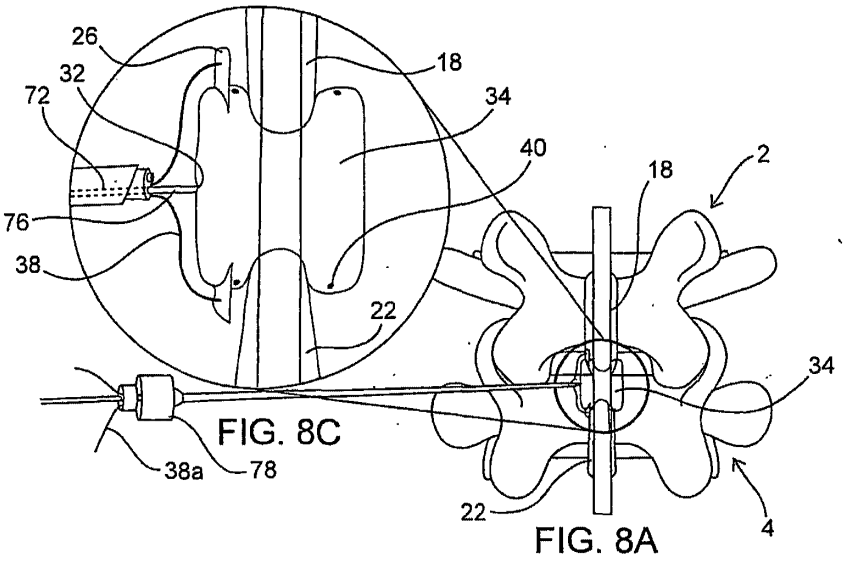


FIG. 8C

FIG. 8A

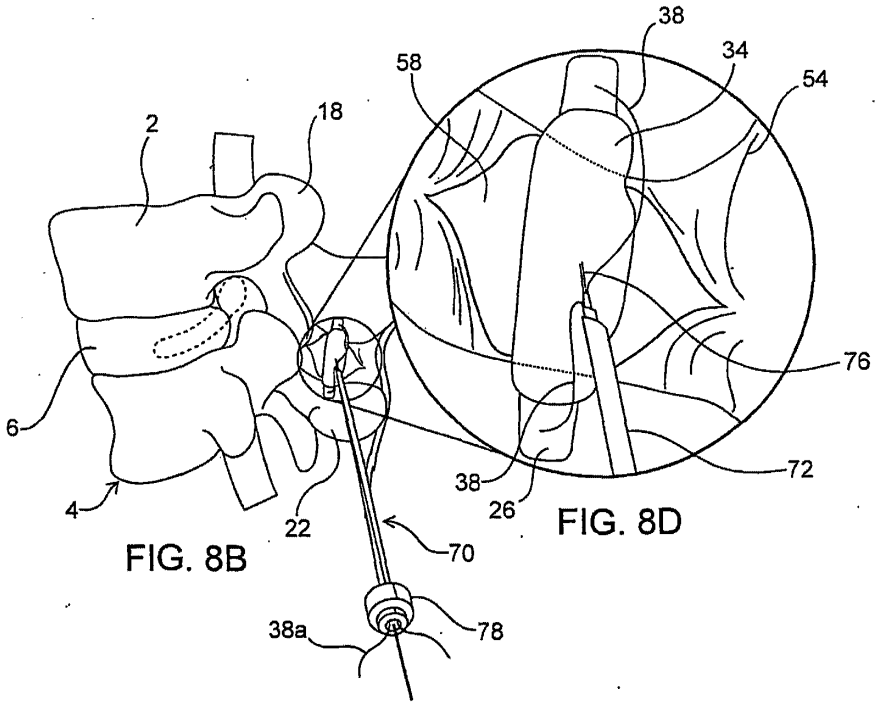


FIG. 8B

FIG. 8D

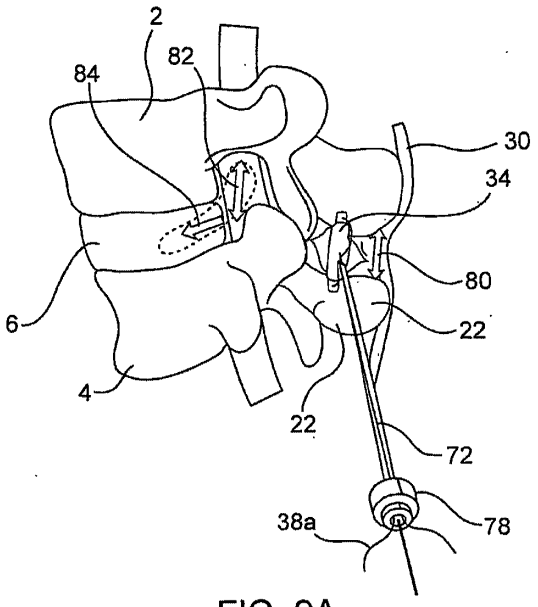


FIG. 9A

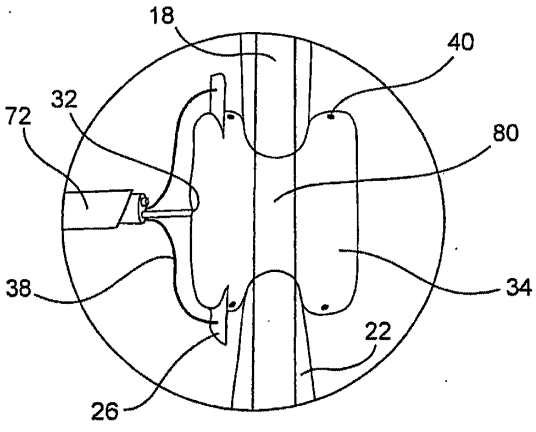


FIG. 9B

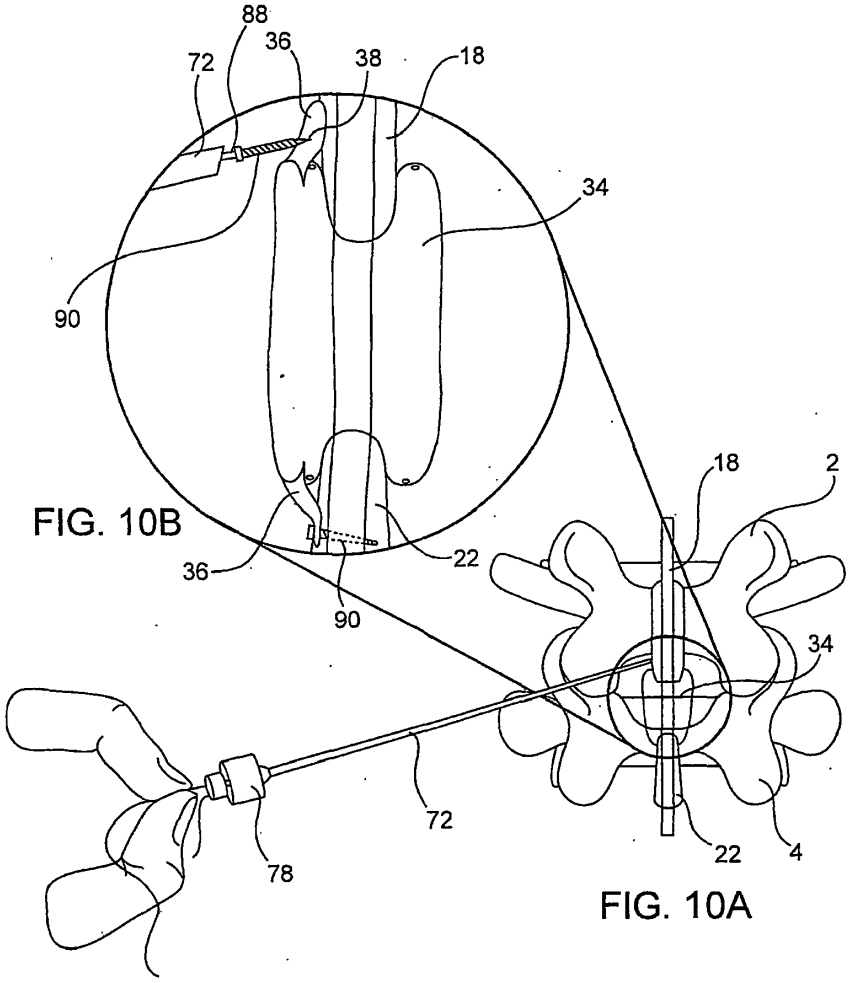


FIG. 10B

FIG. 10A

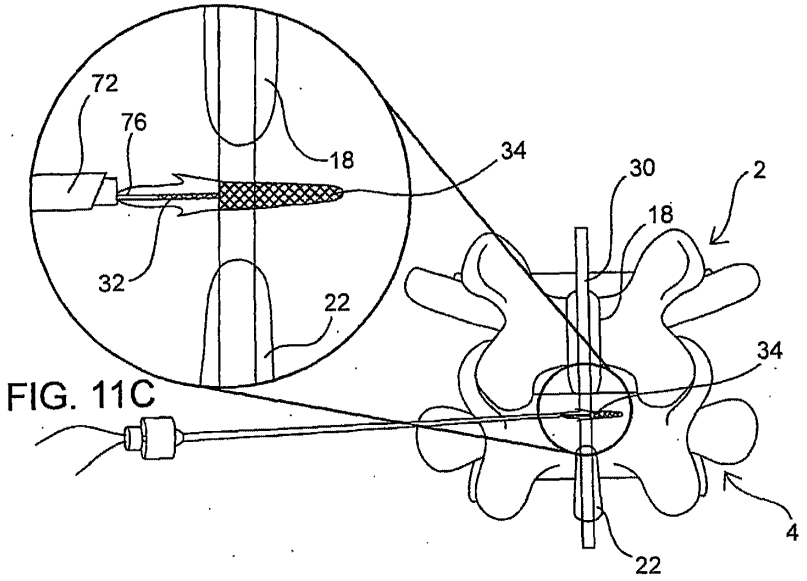


FIG. 11C

FIG. 11A

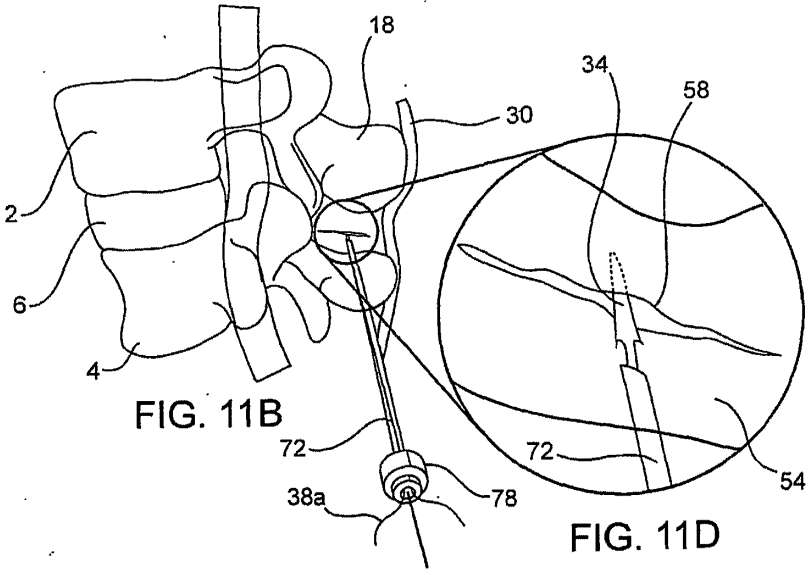


FIG. 11B

FIG. 11D

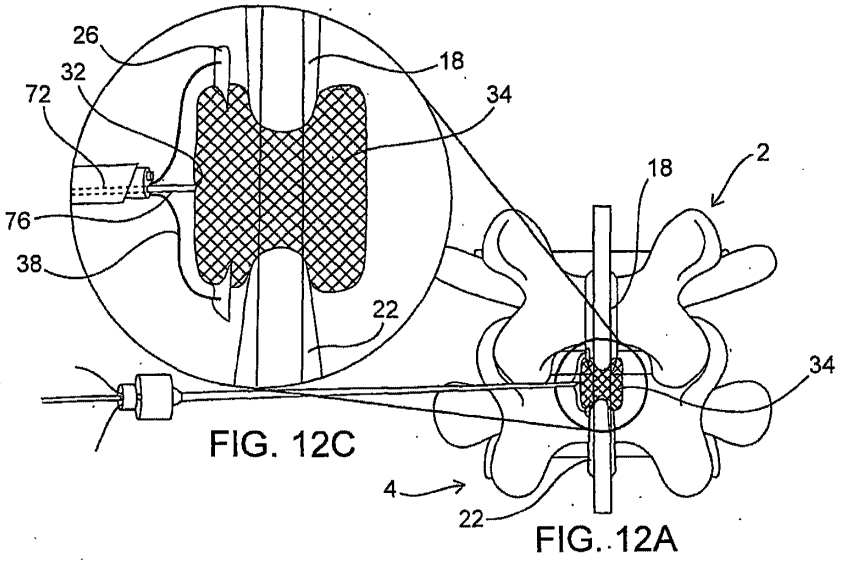


FIG. 12C

FIG. 12A

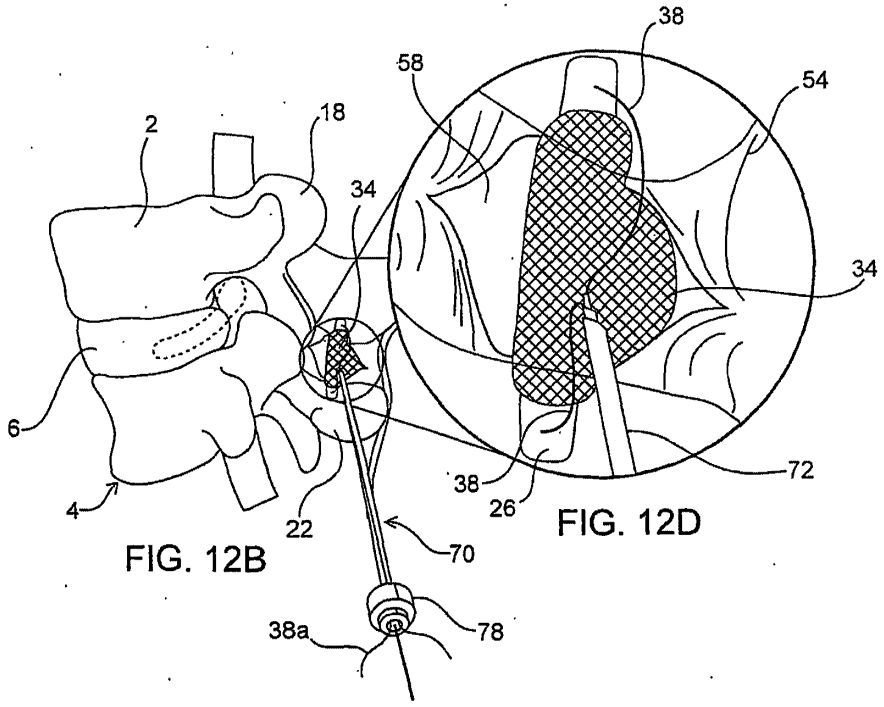


FIG. 12B

FIG. 12D

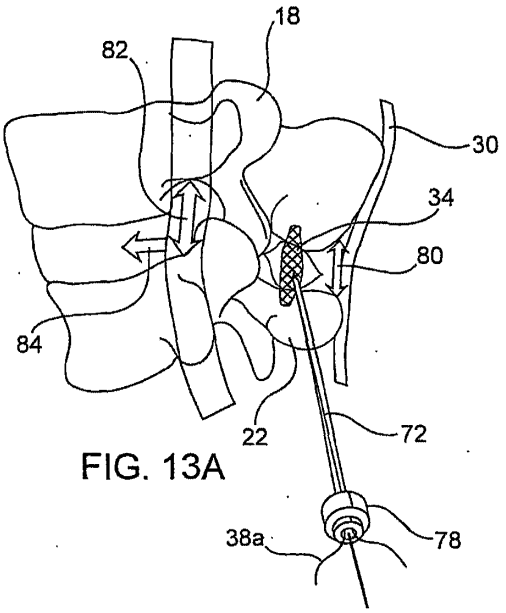


FIG. 13A

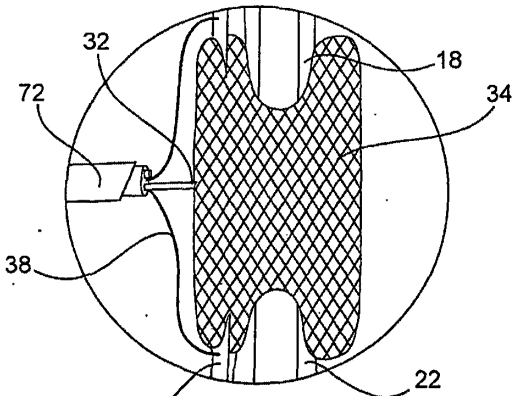


FIG. 13B

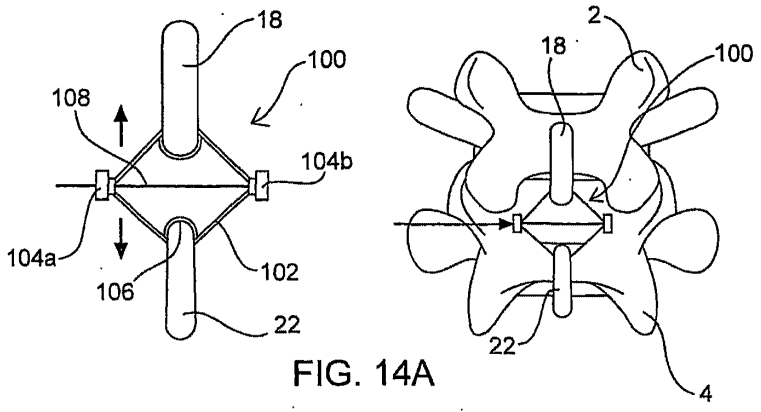


FIG. 14A

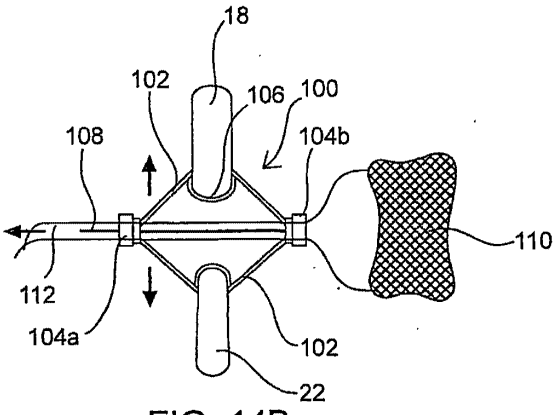


FIG. 14B

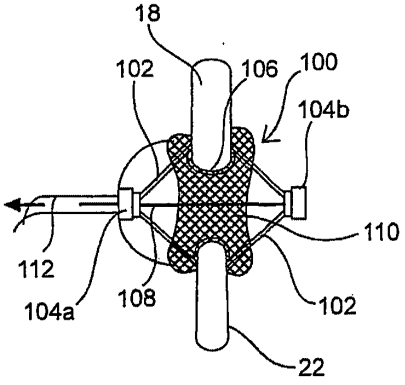


FIG. 14C

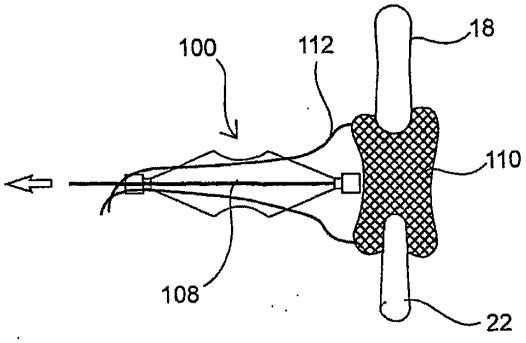


FIG. 14D

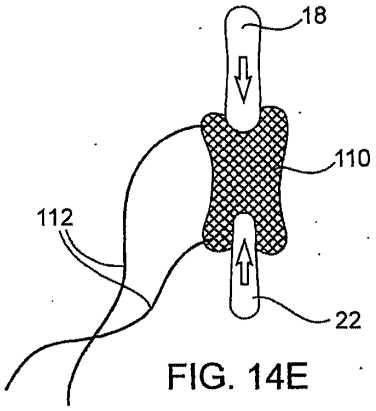


FIG. 14E

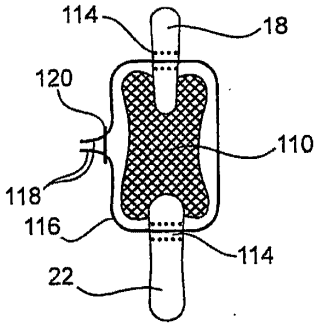


FIG. 14F

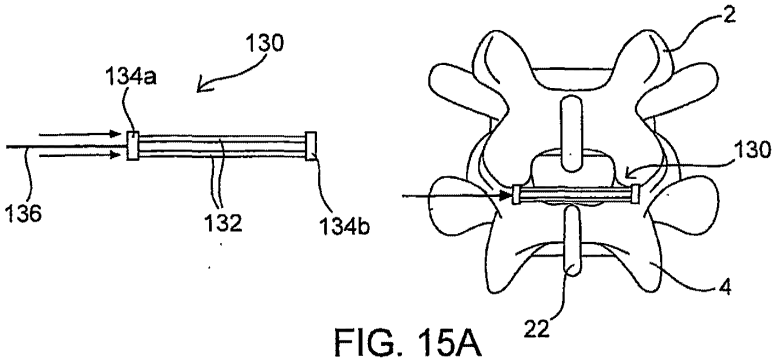


FIG. 15A

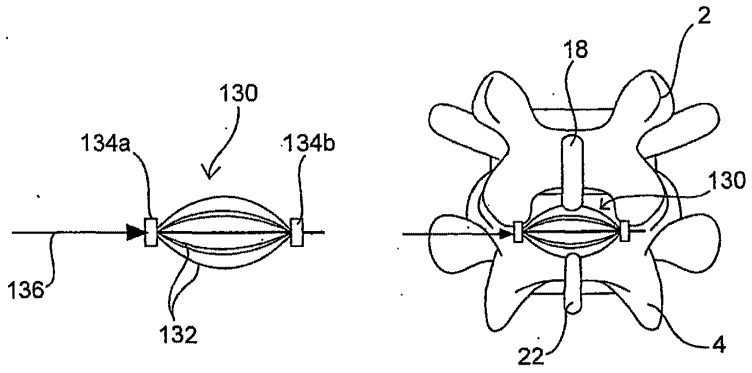


FIG. 15B

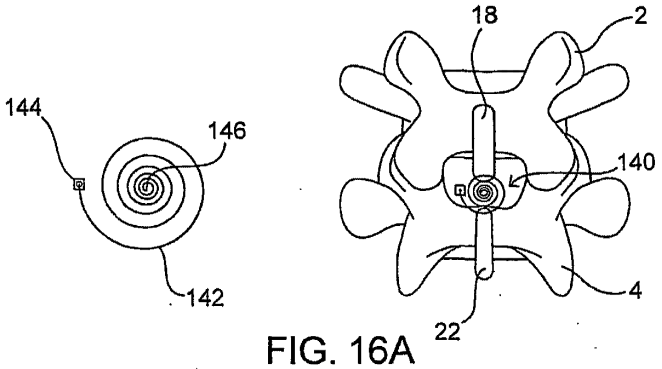


FIG. 16A

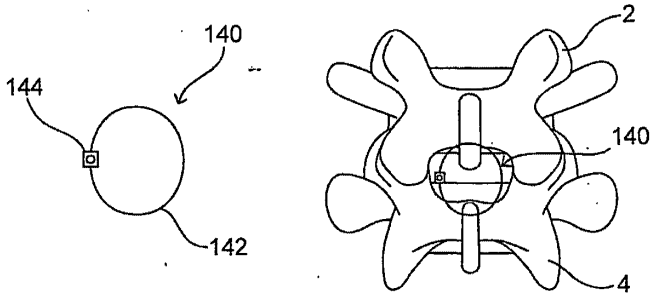


FIG. 16B

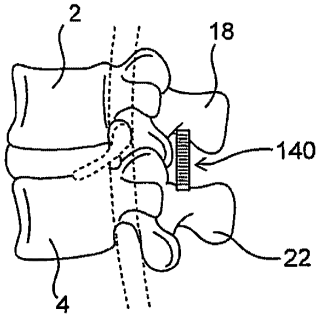


FIG. 16C

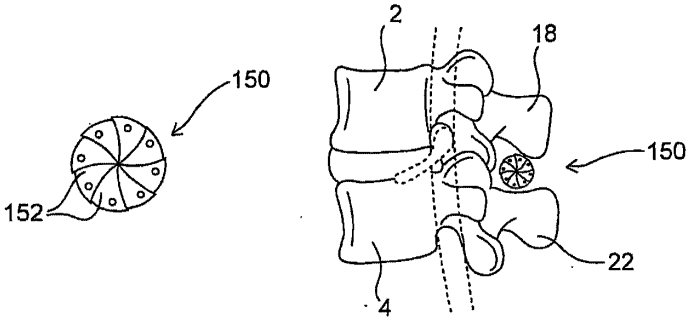


FIG. 17A

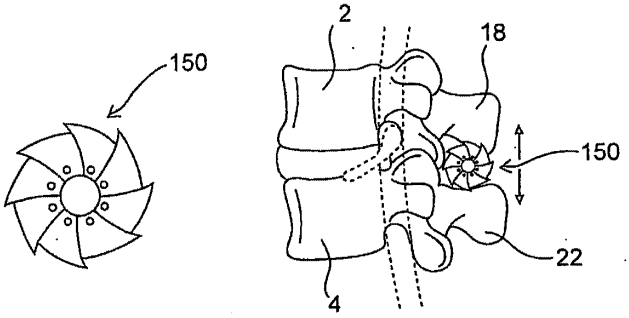


FIG. 17B

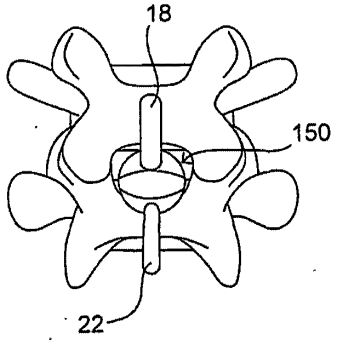


FIG. 17C

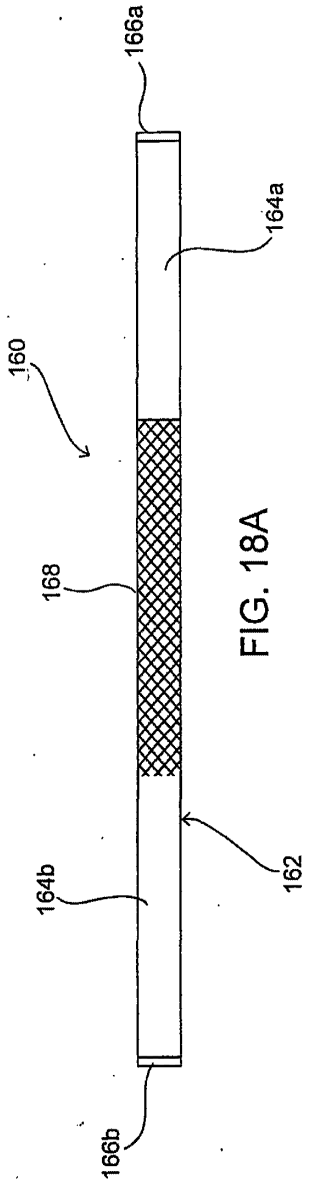


FIG. 18A

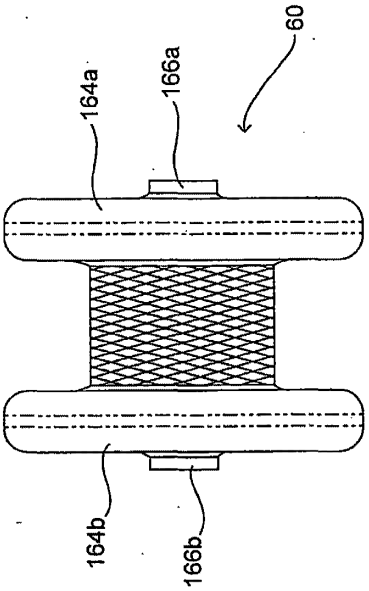


FIG. 18B

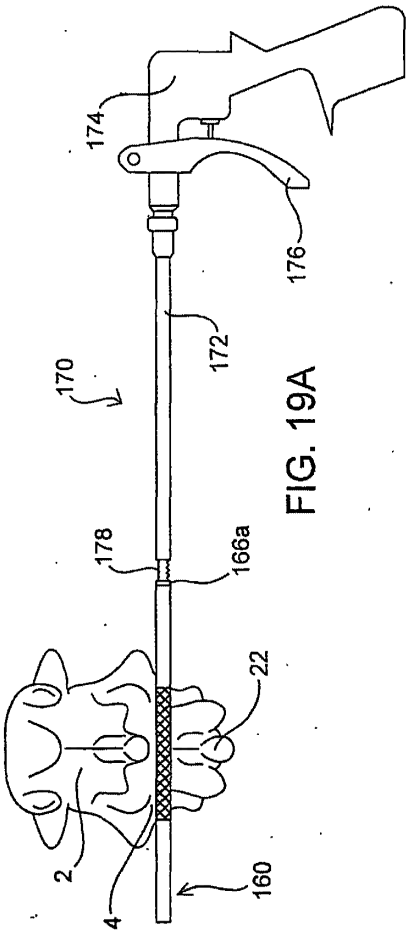


FIG. 19A

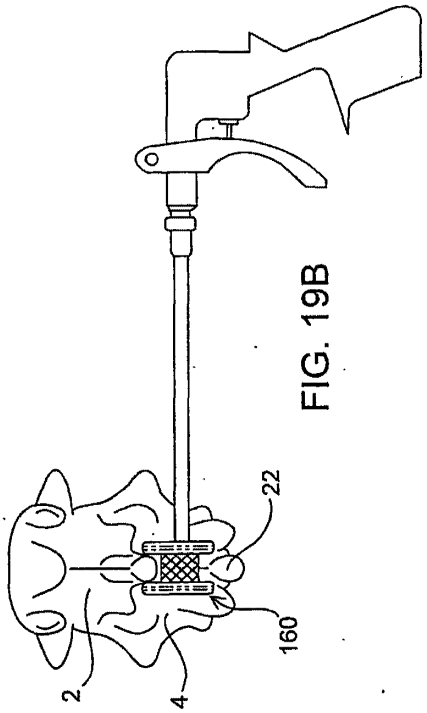


FIG. 19B

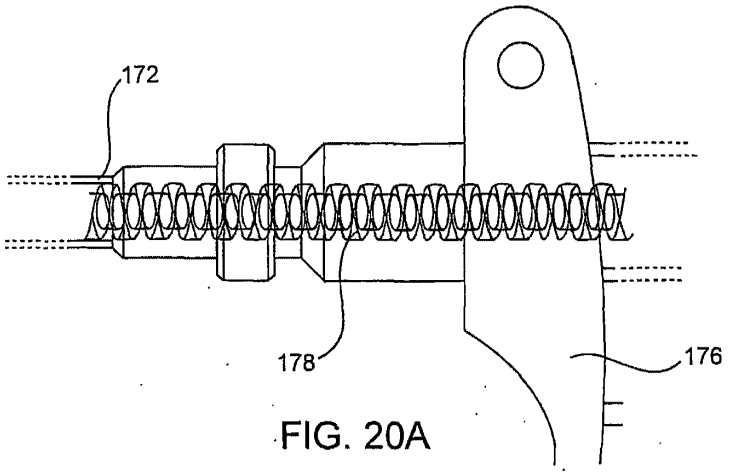


FIG. 20A

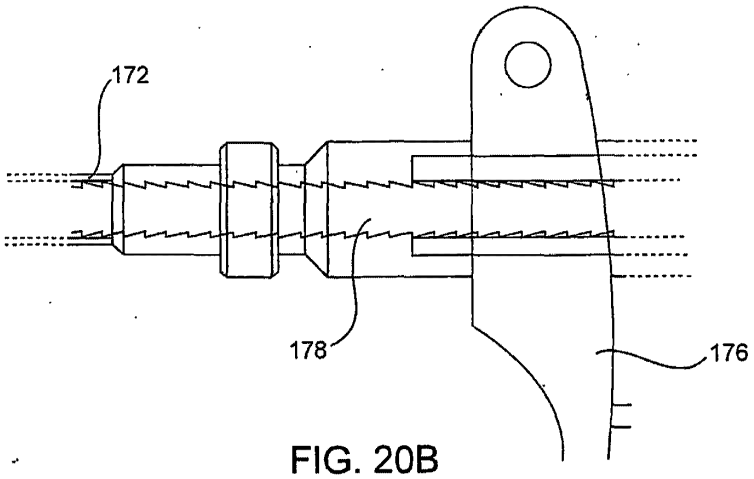


FIG. 20B

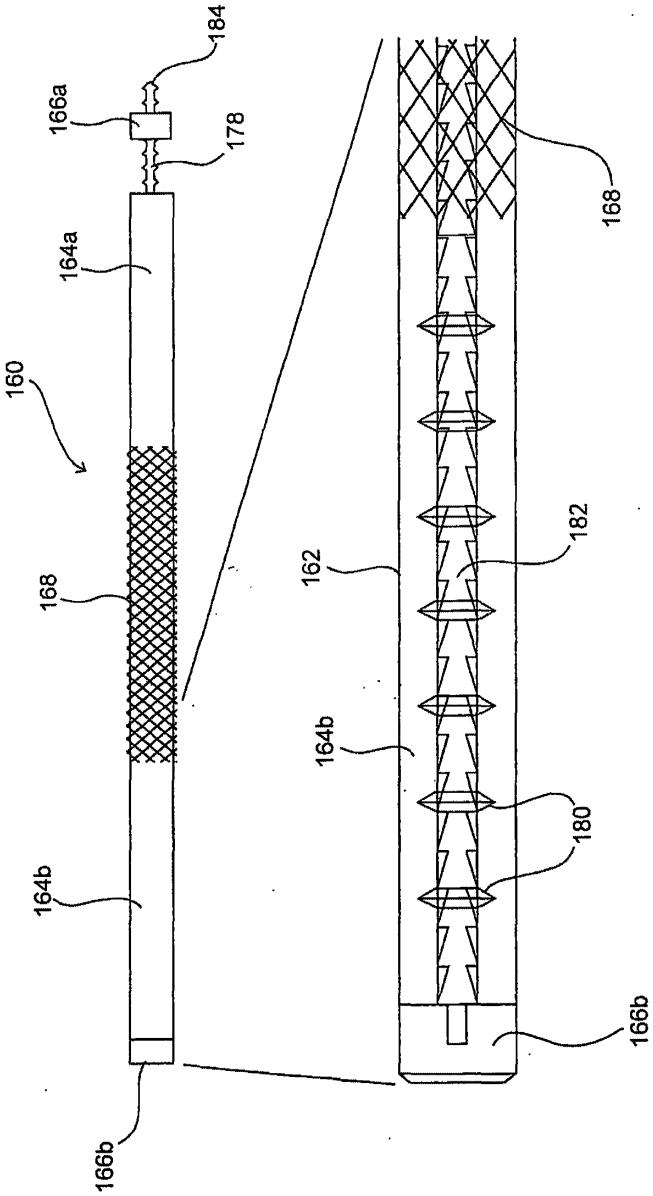


FIG. 21

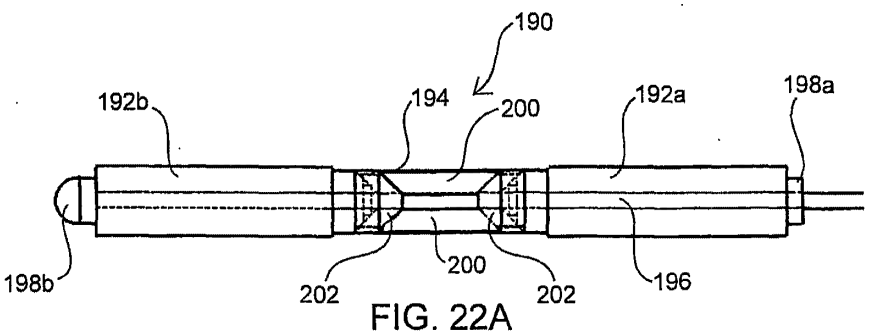


FIG. 22A

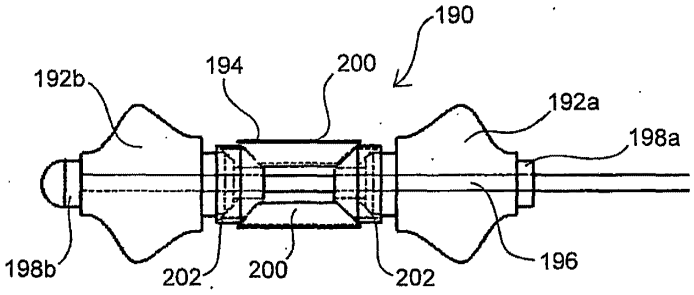


FIG. 22B

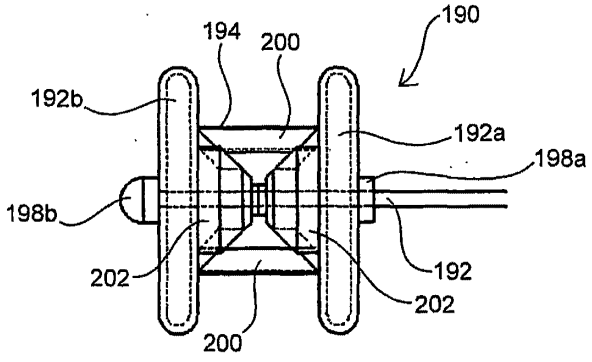


FIG. 22C

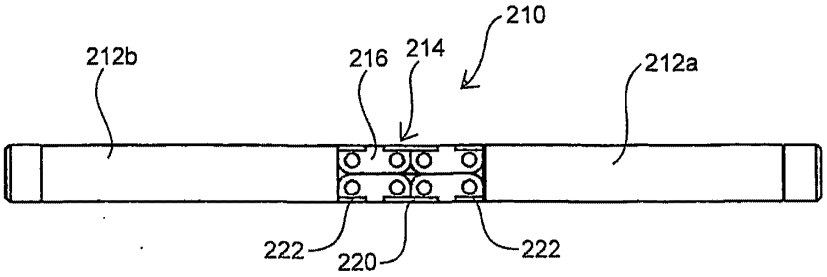


FIG. 23A

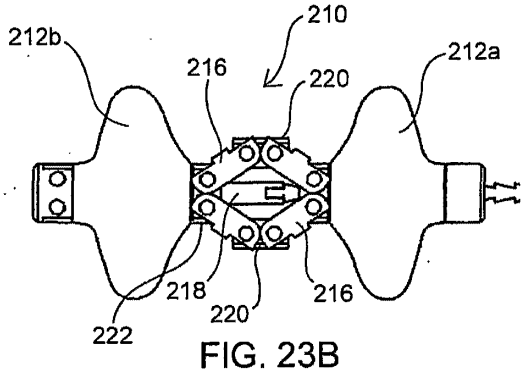


FIG. 23B

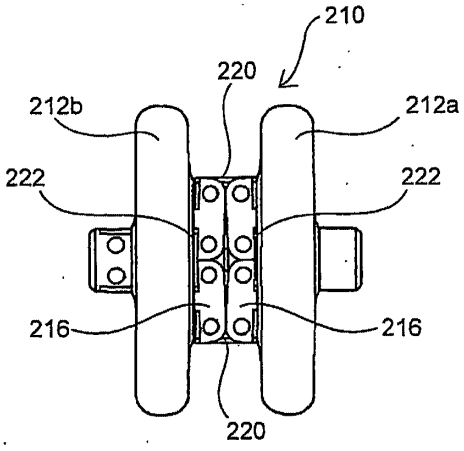


FIG. 23C

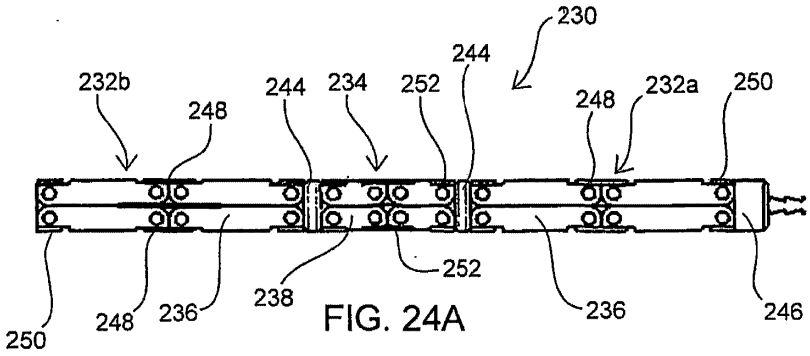


FIG. 24A

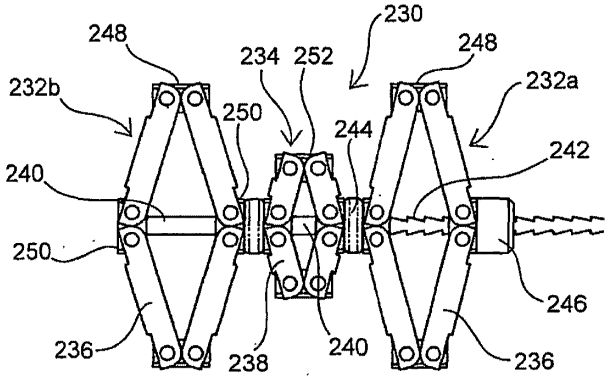


FIG. 24B

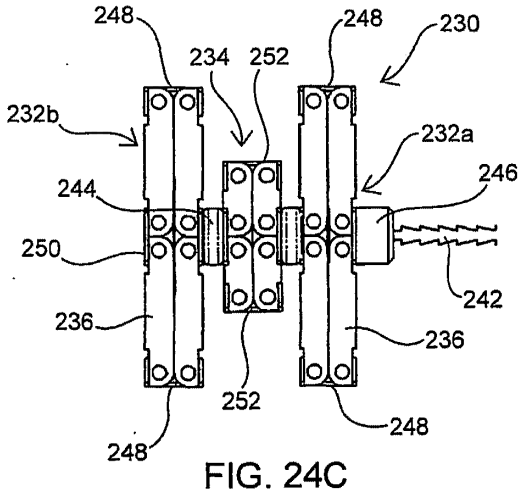


FIG. 24C

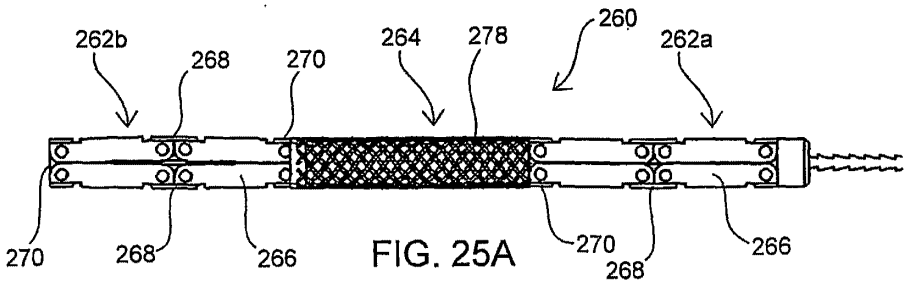


FIG. 25A

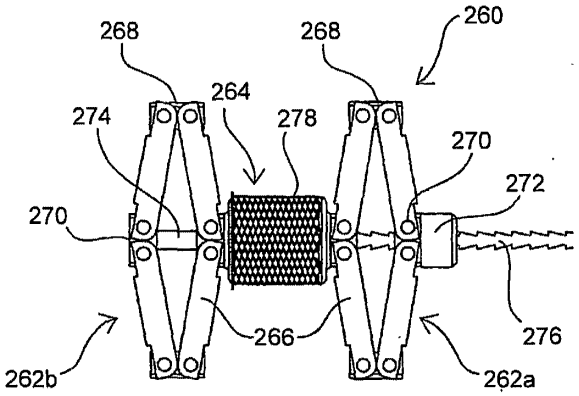


FIG. 25B

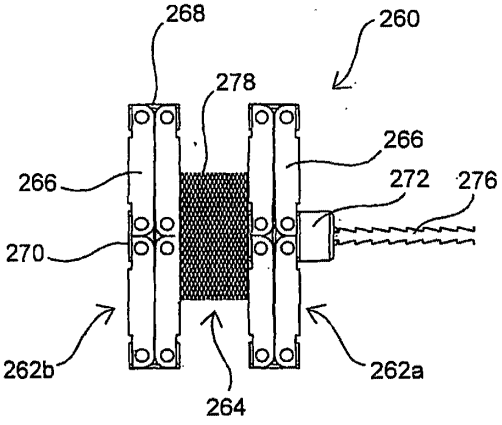


FIG. 25C

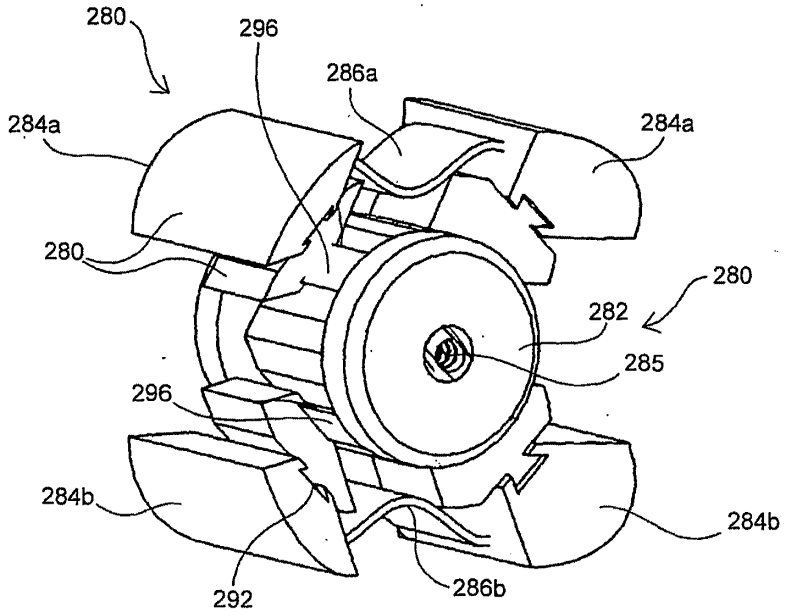


FIG. 26A

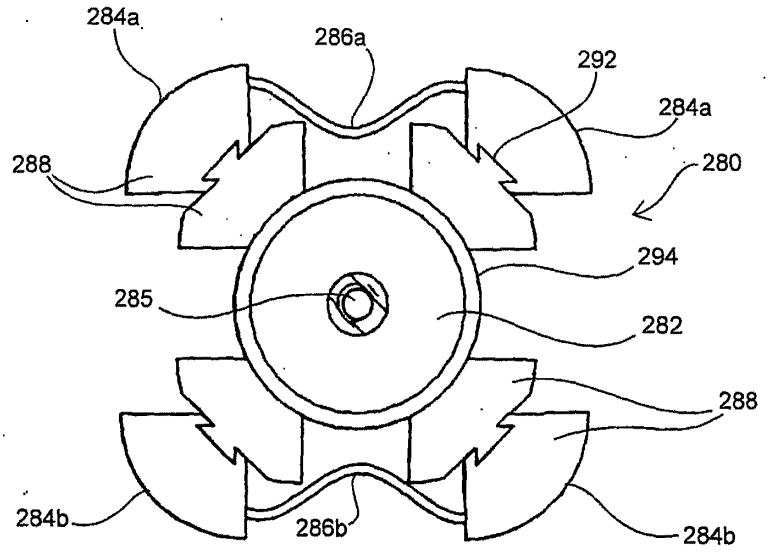


FIG. 26B

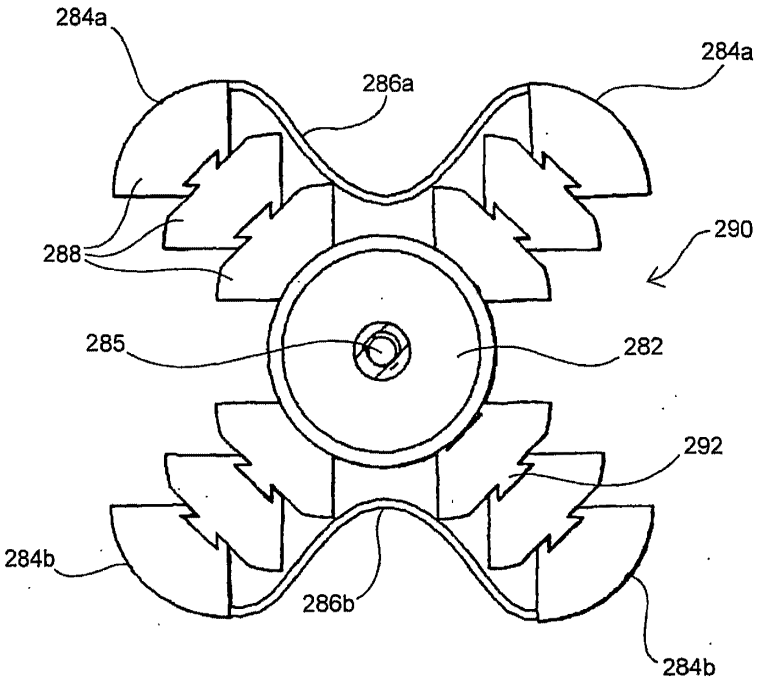


FIG. 27

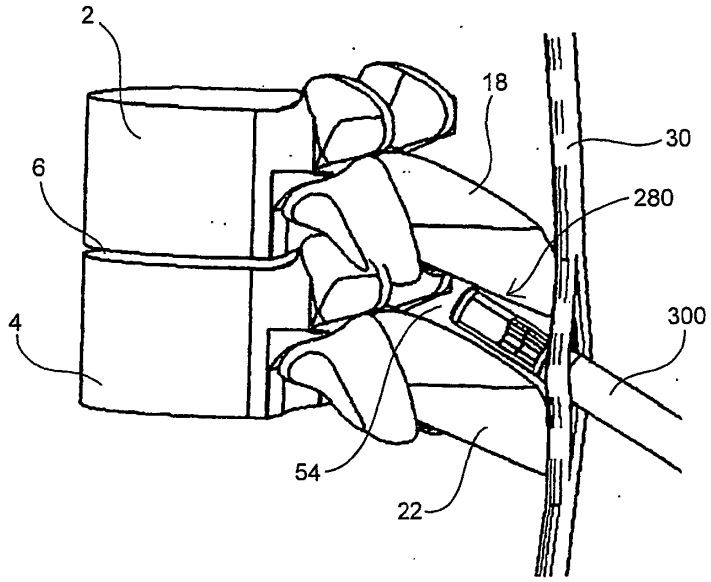


FIG. 28A

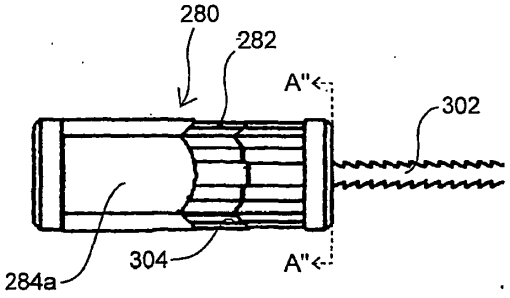


FIG. 28A'

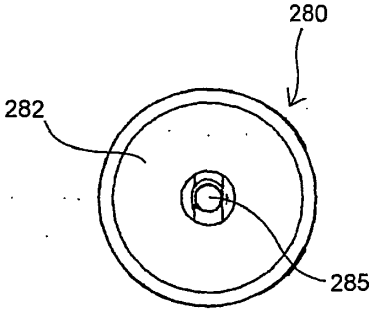


FIG. 28A"

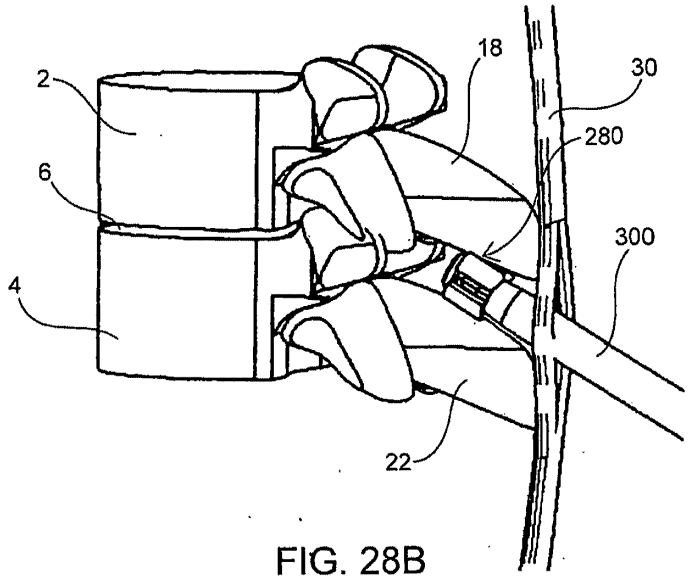


FIG. 28B

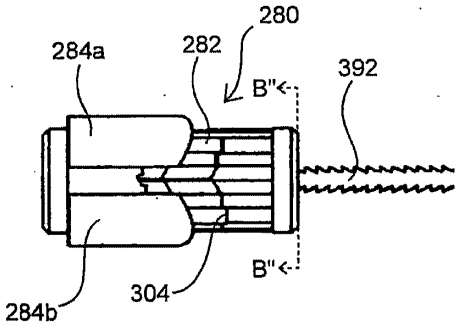


FIG. 28B'

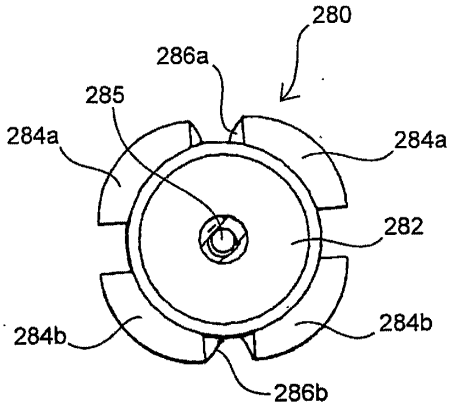


FIG. 28B"

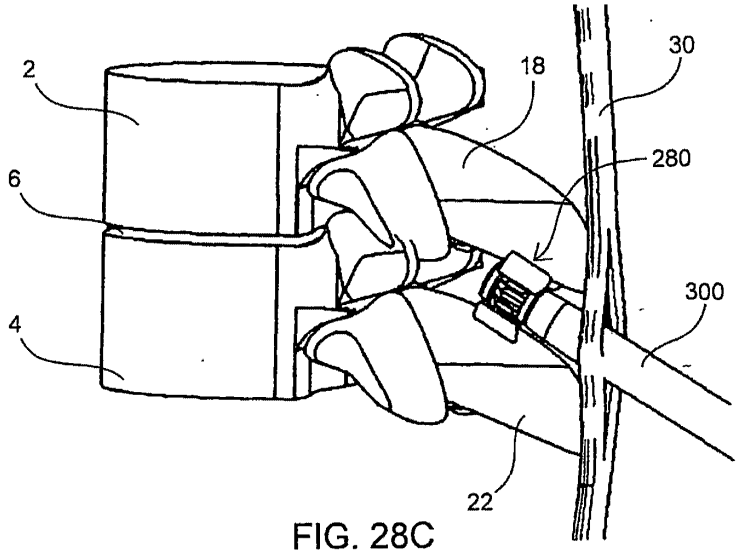


FIG. 28C

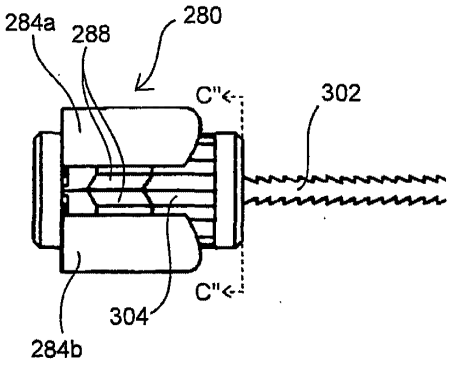


FIG. 28C'

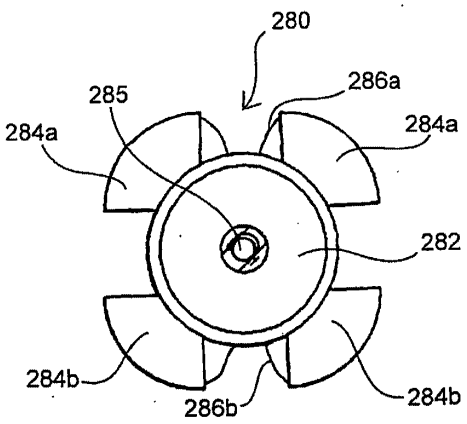


FIG. 28C"

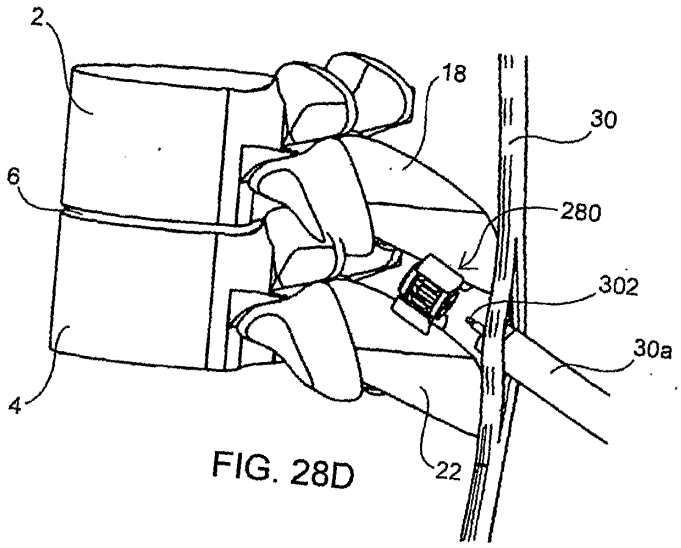


FIG. 28D

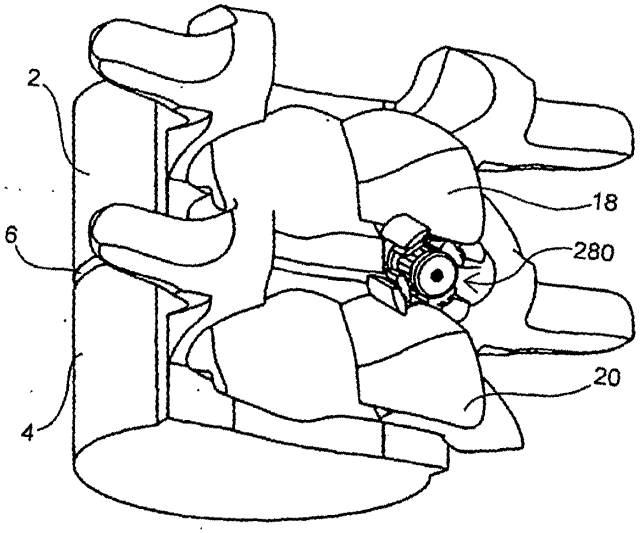


FIG. 28E

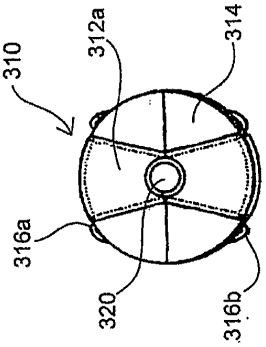


FIG. 29A'

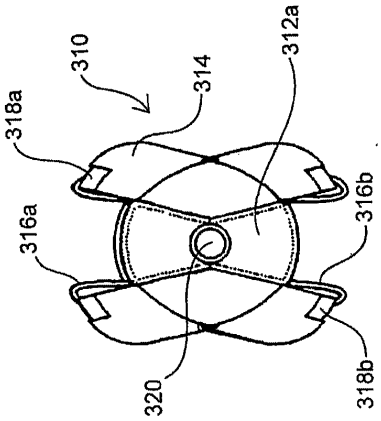


FIG. 29B'

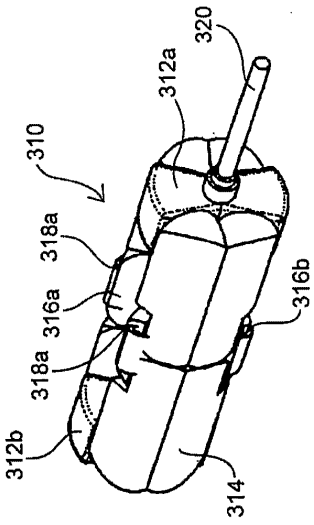


FIG. 29A

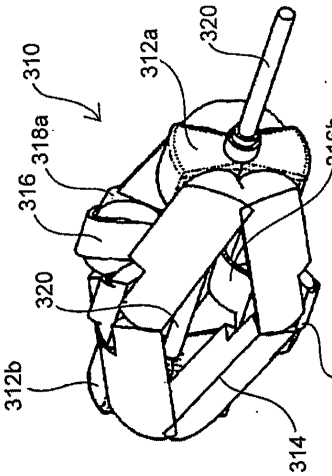


FIG. 29B

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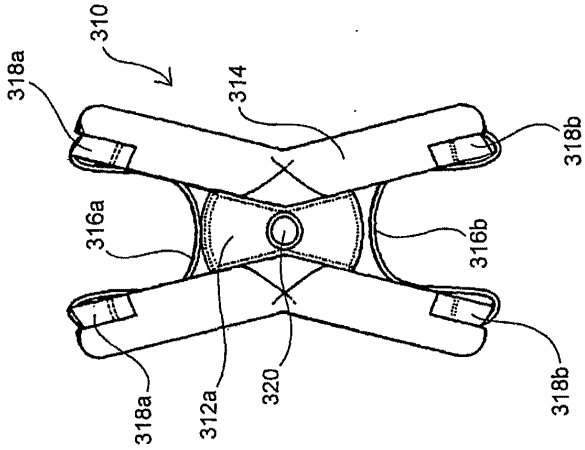


FIG. 29C'

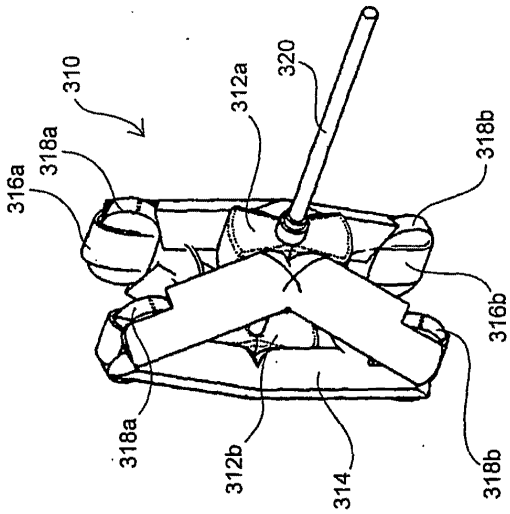


FIG. 29C

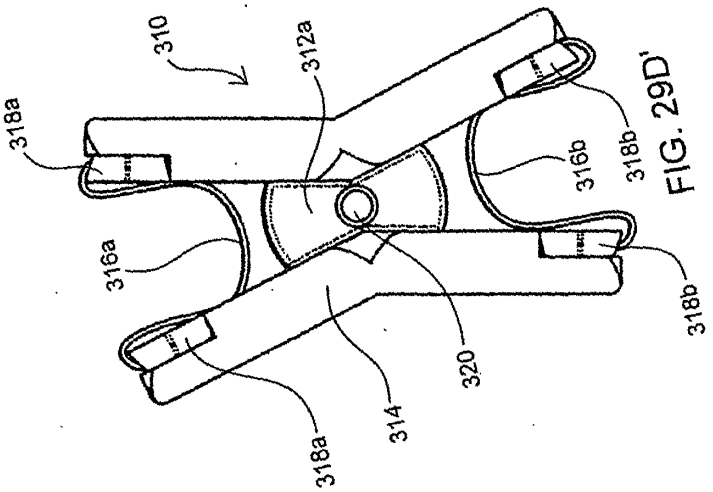


FIG. 29D'

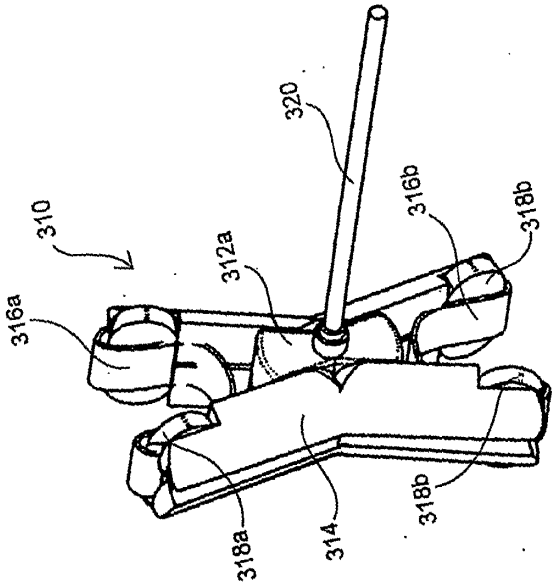


FIG. 29D

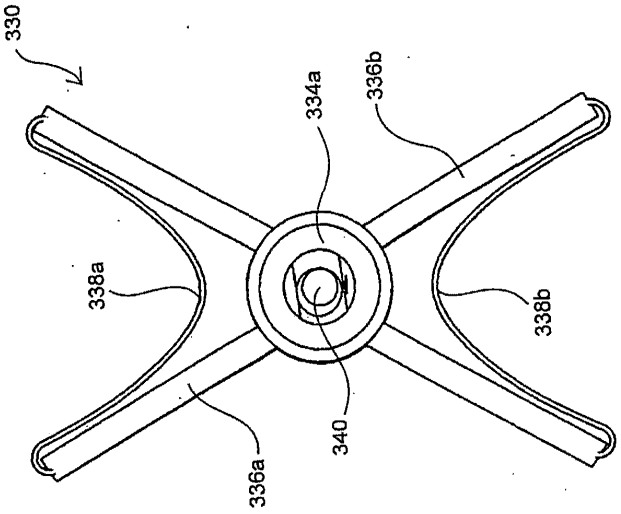


FIG. 30A'

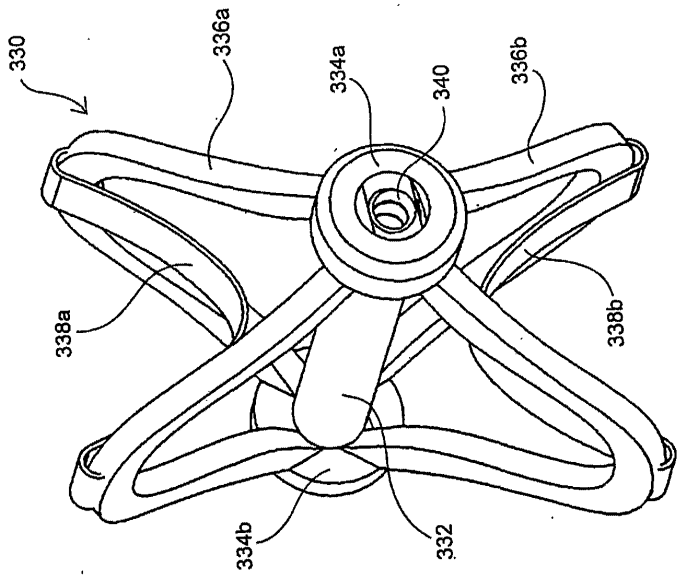


FIG. 30A

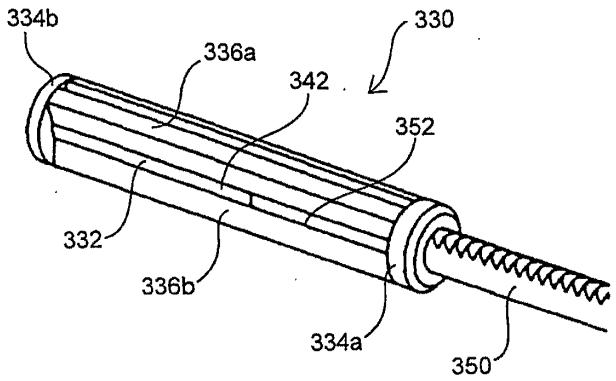


FIG. 30B

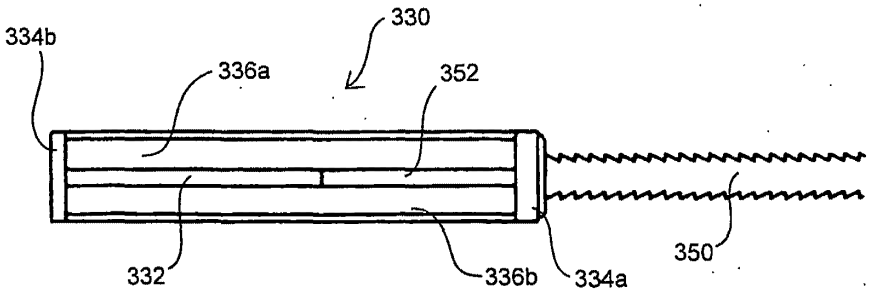


FIG. 30B'

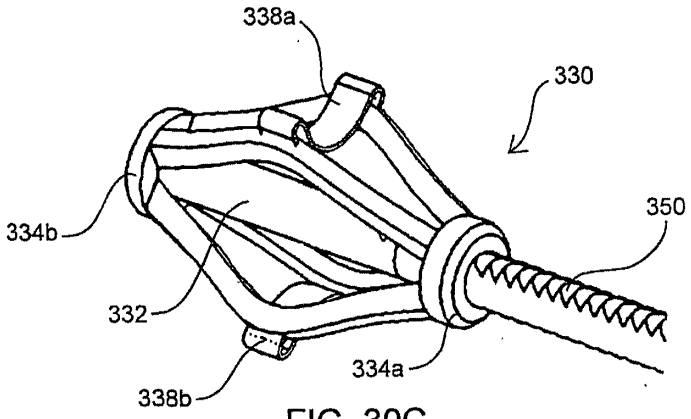


FIG. 30C

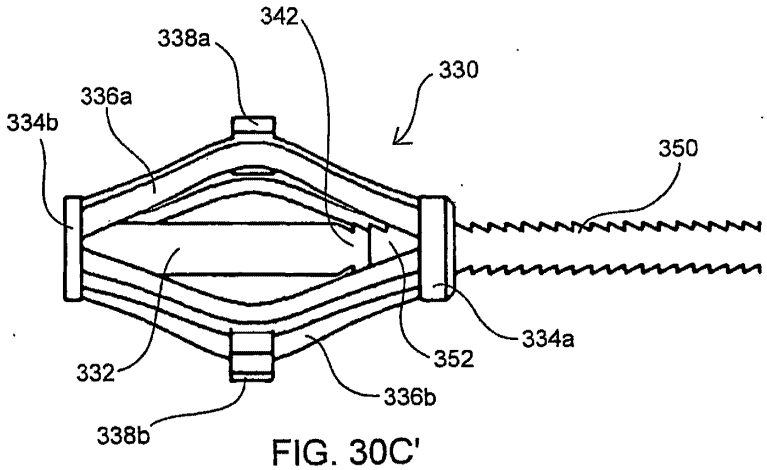


FIG. 30C'

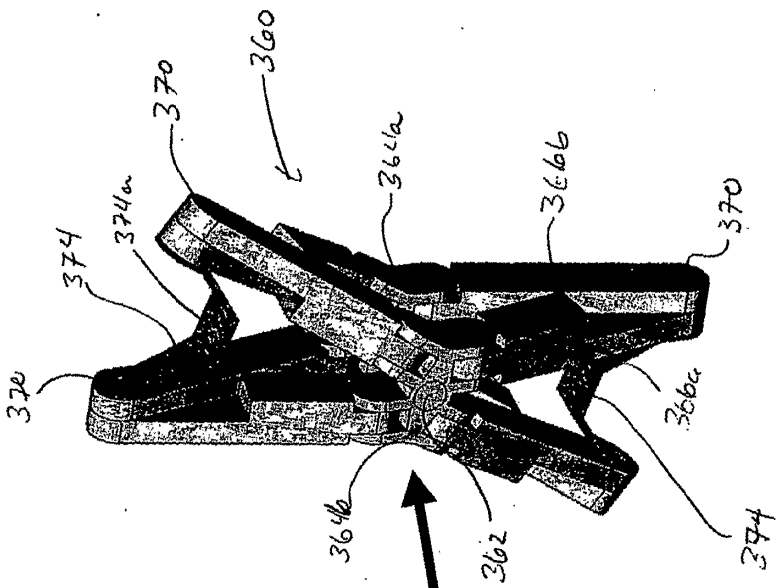


FIG. 31B

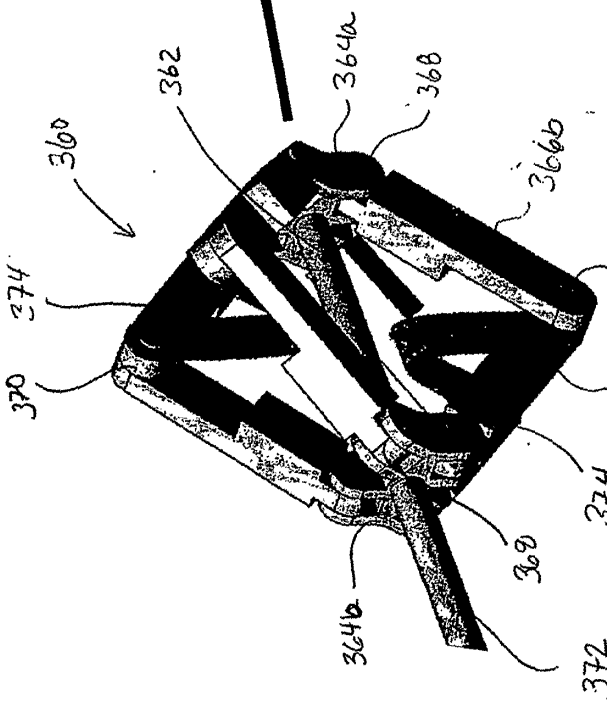


FIG. 31A

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(54) Title: CERVICAL PLATE WITH BACKOUT PROTECTION

(57) Abstract: The present invention provides a cervical plate with backout protection. In particular, a bushing residing in each of a plurality of through holes has a bottom edge that aligns with a protrusion on a screw head. The bottom edge aligning with the protrusion inhibits reverse threading or backing out of the bone screw.

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CERVICAL PLATE WITH BACKOUT PROTECTION

RELATED APPLICATIONS

This application is a continuation-in-part of United States Patent Application Serial Number 10/632,760, filed August 1, 2003, titled CERVICAL PLATE, which is a continuation in part of United States Patent Application Serial Number 10/178,371, filed June 24, 2002, titled CERVICAL PLATE, now U.S. Patent Number 6,602,257.

FIELD OF THE INVENTION

The present invention relates to implantable devices useful in bone fusion and, more particularly, to cervical plates having backout protection.

BACKGROUND OF THE INVENTION

The vertebrae of the human spine are arranged in a column with one vertebra on top of the next. Between each vertebra exists an intervertebral disc that transmits force between adjacent vertebrae and provides a cushion between the adjacent vertebrae.

Sometimes, back pain is caused by degeneration or other deformity of the intervertebral disk ("diseased disk"). Conventionally, surgeons treat diseased discs by surgically removing the diseased disc and inserting an implant in the space vacated by the diseased disk, which implant may be bone or other biocompatible implants. The adjacent vertebrae are then immobilized relative to one another. Eventually, the vertebrae grow into one solid piece of bone.

Currently, it is difficult to insert the bone graft into the vacated space and fuse the adjacent vertebrae. The current process of inserting a bone graft and fusing the adjacent vertebrae will be explained with referring to FIGS. 1 and 2. FIG. 1 shows two adjacent vertebrae 102 and 104. Located between vertebrae 102 and 104 is an intervertebral space 106 partially filled by an implant 108. When the implant 108 is first inserted into the intervertebral

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space 106, the adjacent vertebrae 102 and 104 are manually kept apart by the surgeon using, for example, a retracting device (not shown). As shown in FIG. 2, once the implant 108 is placed, the surgeon releases the adjacent vertebrae 102 and 104 allowing them to squeeze the implant 108 and hold the implant 108 in place.

To immobilize the vertebrae 102 and 104 with the implant 108 in place, the surgeon next applies a cervical plate 202 over the adjacent vertebrae 102 and 104. Cervical plate 202 may have a central viewing window 204 and one or more screw holes 206, in this example four screw holes 206a-206d are shown. Four bone screws (which will be identified by reference numerals 208a-208d) would be screwed into the vertebrae using the screw holes 206 to anchor the cervical plate to the vertebrae and immobilize the vertebrae with respect to one another.

The bone screws 208a-208d absent a locking mechanism tend to reverse thread, which is also known as backing out. Locking mechanisms have been developed to inhibit the bone screws from backing out. Some of the devices included caps or plates that extend over the screw holes 206to inhibit upwards movement of bone screws 208a-208d. Other devices include a frictional engagement between a bushing and the bone screws 208a-208d.

Although many devices exist that satisfactorily inhibit backout of the bone screws, it would be desirous to develop a device to inhibit the bone screws from backing out.

SUMMARY OF THE INVENTION

To attain the advantages and in accordance with the purpose of the invention, as embodied and broadly described herein, a cervical plate having backout protection is provided. The cervical plate comprises a plurality at through holes. Each through hole includes a channel in which a bushing resides. The bushing has a bottom edge that can align with a protrusion on a screw head that inhibits the screw from backing out.

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The foregoing and other features, utilities and advantages of the invention will be apparent from the following more particular description of a preferred embodiment of the invention as illustrated in the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWING

The accompanying drawings, which are incorporated in and constitute a part of this specification, illustrate embodiments of the present invention, and together with the description, serve to explain the principles thereof. Like items in the drawings are referred to using the same numerical reference.

FIG. 1 shows adjacent vertebrae with a bone graft;

FIG. 2 shows adjacent vertebrae with a bone graft and cervical plate;

FIG. 3 shows a perspective and cross-sectional view of a cervical plate with backout protection consistent with the present invention;

FIG. 4 shows a perspective view of a fixed angle bone screw;

FIG. 5 shows a perspective view of a variable angle bone screw;

FIG. 6 shows a perspective view of an embodiment of one possible bushing consistent with the present invention;

FIG. 7 shows a cross-sectional view of the bone screw and bushing as it would exist if the bone screw was threaded in the vertebral body; and

FIG. 8 shows a cross-section view similar to FIG. 7 but prior to complete engagement.

DETAILED DESCRIPTION

The present invention will be described with reference to FIGS. 3-8. Referring first to FIG. 3, a perspective and cross-sectional view of a cervical plate 300 illustrative of an embodiment of the present invention is shown. Cervical plate 300 is shown with a construct that could span two intervertebral spaces (a.k.a. a two level cervical plate); however, cervical plate 300 could be constructed to span more or less intervertebral spaces. Because plate 300 spans two intervertebral spaces, cervical plate 300 is shown with two viewing windows 302. More or less viewing windows 302

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could be provided. For example, for a construct that spanned one intervertebral space, only one viewing window may be used. Moreover, for a construct that spanned three intervertebral spaces, three viewing windows may be provided. Furthermore, for cervical plate 300, each viewing window 302 could be split into several smaller viewing windows as a matter of design choice.

Cervical plate 300 comprises a bone facing side 304, a top side 306 opposite bone facing side 304, and a plurality of through holes 308. Through holes 308 generally have a diameter d1, at least at bone facing side 304 and top side 306. Each of the plurality of through holes 308 has a channel 310 traversing a perimeter of through hole 308. Channel 310 resides between bone facing surface 304 and top side 306. Generally, channel 310 has a concave shape with a maximum diameter of diameter d2 greater than d1. While described separately, channel 310 may simply be a bowing or gradual increase in diameter along the sidewalls associated with through holes 308. A bushing 312 resides in channel 310, as will be explained further below. Bone screws 314 extend through through holes 308 such that bone screws 314 are threaded to vertebral bodies. A head 316 of bone screws 314 engage bushings 312, as will be explained further below, inhibiting bone screws 314 from reverse threading or backing out.

Referring to FIGS. 4 and 5, fixed angle bone screw 400 and variable angle bone screw 500 are shown. Note, bone screws 314 could be either fixed angle bone screws 400 or variable angle bone screws 500, and both are shown in FIG. 3. Fixed angle bone screws 400 and variable angle bone screws 500 are generally known in the art and will not be further explained herein. Head 316 will be explained further below with reference to FIG. 7.

Referring to FIG. 6, a perspective view of bushing 312 is shown in more detail. Bushing 312 comprises a top edge 602, which would be located proximate top side 304, and a bottom edge 604, which would be located proximate bone facing surface 306. Sidewall 606 extends between top edge 602 and bottom edge 604. Bushing 312 is shown generally cylindrical in shape but generally would have a shape consistent with channel 310 to allow

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cervical plate 300 and bone screws 314 to align properly during surgery. In this case, channel 310 has a concave shape to cooperatively engage a convex shape of an outer surface 608 of sidewall 606. Inner surface 610 has a shape consistent with heads 316. Outer surface 608 has a diameter d2 at its maximum. Bushing 312 is compressible such that bushing 312 can be compressed to fit within diameter d1. To assist with compression, bushing 312 may have a gap 610. Once the compressive force is removed, bushing 312 would expand such that outer surface 608 cooperatively engages channel 310.

At least a bottom portion 612 of bushing 312 comprises a flexible material that can expand outward when impinged by head 316, which will be explained further below. To facilitate the flexible movement, bottom portion 612 may comprises one or more slots 614. When not impinged by head 316, bottom edge 604 has a diameter d3.

Head 316 will be explained in more detail with reference to FIGS. 7 and 8. Head 316 has an internal matting surface 702. Internal matting surface 702 is designed to allow a surgical tool to drive bone screw 314 into a vertebral body. Head 316 has an external surface 704 that cooperatively engages inner surface 610 of bushing 312. In this case, inner surface 610 is concave and external surface 704 is convex. External surface 704 may extend over a portion or all of head 316, but terminates at a transition edge 706 where a protrusion 708, which may be a ledge or shoulder, extends. Transition edge 706 has a diameter d3 and protrusion 708 extends outward from transition edge 706 such that bottom edge 604 abuts protrusion 708. Thus, bushing 312 inhibits reverse threading of bone screw 314 because bottom edge 604 abutting protrusion 708 inhibits upward movement of bone screw 314. While bottom edge 604 could directly abut protrusion 708, washers or other devices could be implanted as well.

While FIG. 7 shows the implant after bone screw 314 has been threaded in the vertebral bodies, FIG. 8 shows the implant prior to completion of the threading operation. As bone screw 314 is threaded in the vertebral bodies, head 316 advances through bushing 312. A surface 802 on protrusion

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708 tends to impinge on bottom portion 612 as head 316 advances. The impingement causes bottom portion 612 to flex. Once protrusion 708 advances past bottom edge 604, bottom portion returns to it pre-flex position such that bottom edge 604 is aligned over protrusion 708.

While the invention has been particularly shown and described with reference to an embodiment thereof, it will be understood by those skilled in the art that various other changes in the form and details may be made without departing from the spirit and scope of the invention.

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We claim:

1. A device useful in bone fusion, comprising:

a cervical plate;

a plurality of through holes provided in the cervical plate;

each of the plurality of through holes comprising a channel;

a bushing residing in the channel;

the bushing comprising a shape that cooperatively engages the channel and a flexible bottom portion terminating in a bottom edge, whereby a head of a bone screw forces the flexible bottom portion outward as the bone screw is threaded until a protrusion on the head substantially aligns with the bottom edge and the bottom edge cooperatively engages the protrusion to inhibit the bone screw from reverse threading.

2. The device of claim 1, wherein the channel is formed by an increase in diameter of the through hole.

3. The device of claim 2, wherein the increase in diameter forms a concave shape.

4. The device of claim 3, wherein the shape of the bushing is convex to cooperatively engage the channel

5. The device of claim 1, wherein the bushing further comprises a gap, the gap allowing the bushing to be compressed between a first size where the bushing cooperatively engages the channel and a second size where the bushing is sufficiently compressed to fit in the through hole.

6. The device of claim 1, wherein the flexible bottom portion comprises at least one slot to facilitate the outward movement when the head impinges the bushing.

7. The device of claim 1, wherein the bushing cooperatively engages the channel allowing orientation of the bone screw.

8. A device useful in bone fusion, comprising:

a cervical plate;

a plurality of through holes provided in the cervical plate;

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a plurality of bone screws provided to be inserted through the plurality of through holes;

each of the plurality of through holes comprising a channel the channel comprising a channel shape;

a bushing residing in the channel;

the bushing comprising an outer shape that cooperatively engages the channel, an inner shape, and a flexible bottom portion terminating in a bottom edge;

at least one bone screw; and

the at least one bone screw having a head with a head shape that cooperatively engages the bushing and terminates at a protrusion;

whereby during threading of the at least one bone screw, the protrusion impinges on the flexible bottom portion such that the protrusion passes the bottom edge wherein the flexible bottom portion returns to an un-flexed position and the bottom edge substantially aligns with the protrusion to inhibit the bone screw from reverse threading.

9. The device of claim 8, wherein the at least one bone screw is a fixed angle bone screw.

10. The device of claim 8, wherein the at least one bone screw is a variable angle bone screw.

11. The device of claim 8, wherein the channel is formed by an increase in diameter of the through hole.

12. The device of claim 11, wherein the channel shape is concave and the outer shape is convex.

13. The device of claim 8, wherein the inner shape is concave and the head shape is convex.

14. The device of claim 12, wherein the inner shape is concave and the head shape is convex.

15. The device of claim 8, wherein the flexible bottom portion comprises at least one slot to facilitate the outward flexing of the flexible bottom portion when the head impinges on the flexible bottom portion.

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16. The device of claim 8, wherein the bushing has an uncompressed state and a compressed state, wherein when in the uncompressed state the bushing cooperatively engages the channel and in the compressed state the bushing fits in the through hole.

17. The device of claim 16, wherein the bushing comprises a gap to facilitate compression of the bushing.

18. The device of claim 8, wherein the bone screw further comprises a surface that facilitates the flexing of the flexible bottom portion.

19. A method for placing an implant useful in fusing bone, the method comprising the steps of:

compressing a bushing;

inserting the compressed bushing through a through hole;

aligning the bushing with a channel;

releasing the bushing such that the compressed bushing uncompresses and cooperatively engages the channel;

inserting a bone screw through the through hole;

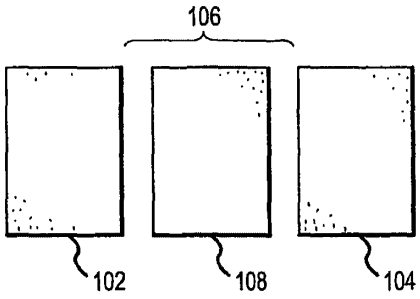
threading the bone screw through the through hole;

impinging a protrusion on the bushing causing the bushing to flex until the protrusion advances through the bushing; and

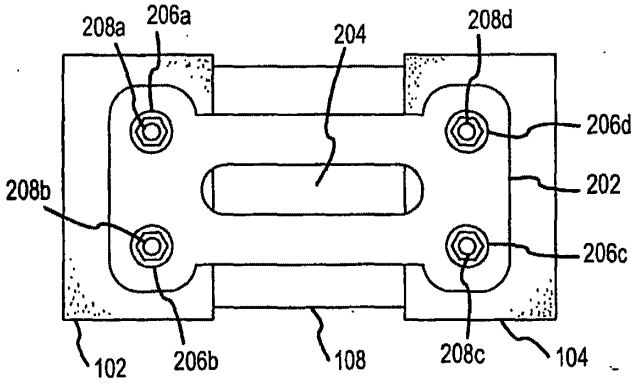
aligning the protrusion below a bottom edge of the bushing such that the reverse threading of the bone screw is inhibited.

20. The method of claim 19, further comprising the step of orienting the bushing in the channel prior to inserting the bone screw to facilitate threading the bone screw.

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(PRIOR ART)
FIG.1



(PRIOR ART)
FIG.2

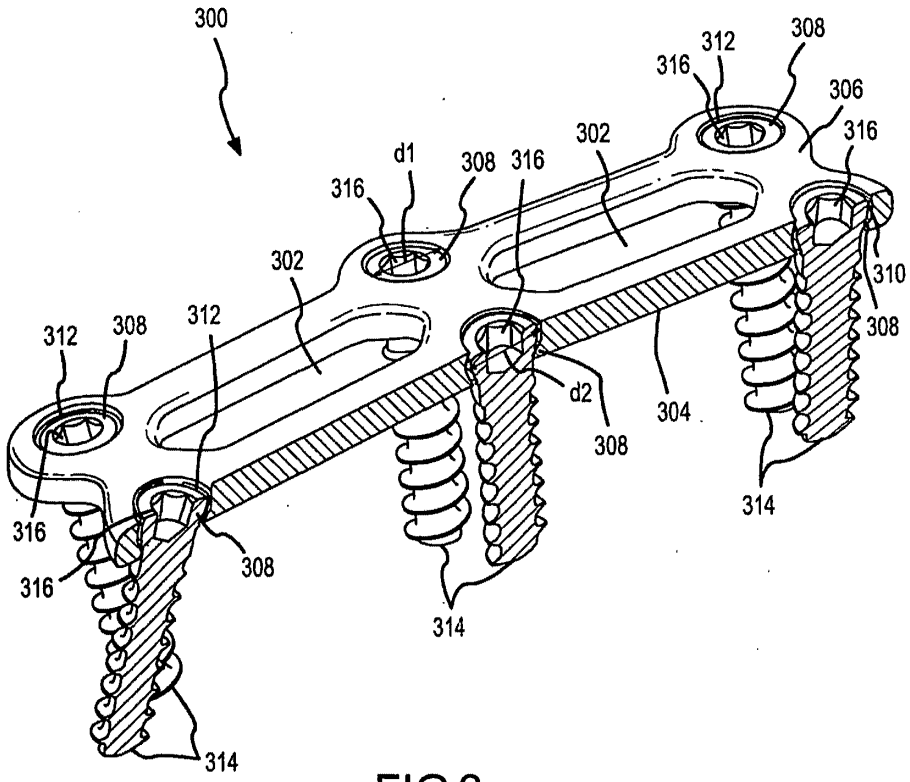

300
312
308
316
306
316
302
d1
308
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310
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312
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d2
304
316
316
308
314
314
314

FIG.3

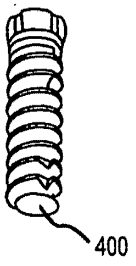


FIG.4

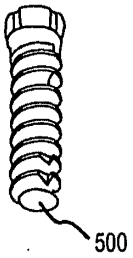


FIG.5

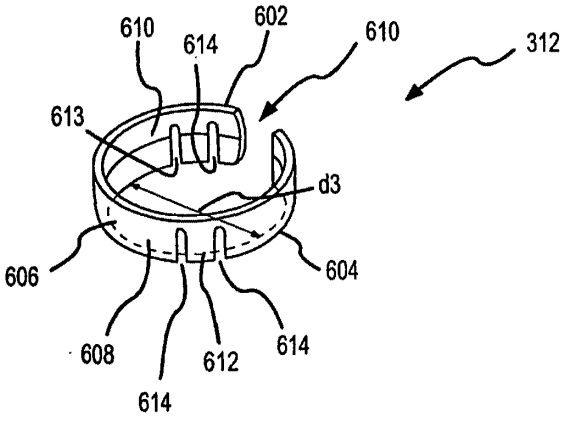


FIG.6

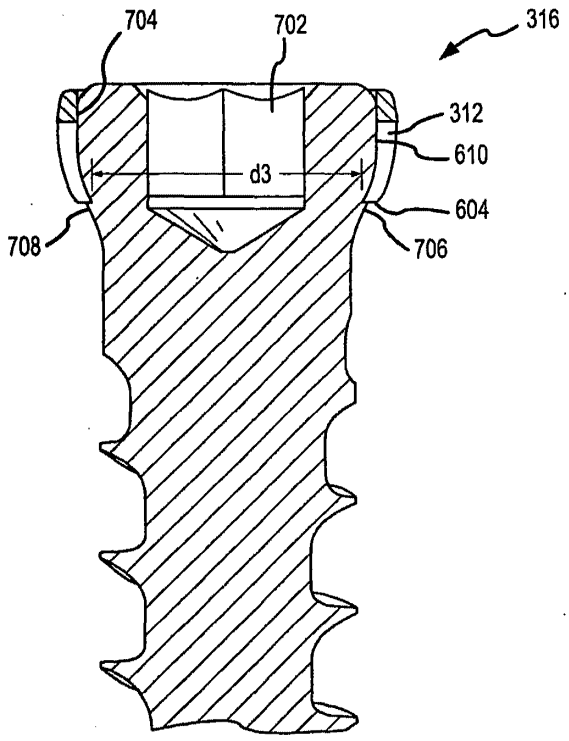


FIG.7

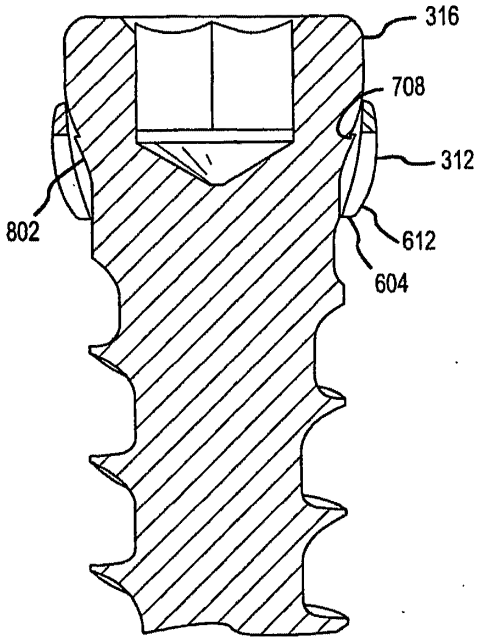


FIG.8

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(54) A modular polyaxial locking pedicle screw

(57) A modular polyaxial pedicle screw and orthopedic rod implant device includes a shaft portion (100, 300), a cuff (130, 350), a stem portion (120, 320), and a rod coupling sub-assembly (160, 360). The shaft portion (100, 300) is designed to be inserted into the pedicle, and in alternative embodiments includes a recess (108) and a convex semi-spherical bubble (308). In both embodiments, the shaft (100, 300) also includes a threading (110, 310) formed on the exterior surface. The stem portion (120, 320) is a threaded post and either an enlarged ball (124) or a recessed socket (324). The cuff (130, 350) is a cylindrical element that seats around the interface of the ball and socket combination initially so that the stem (120, 320) and shaft (100, 300) may polyaxially rotate and subsequently hold the stem and shaft in final securement.

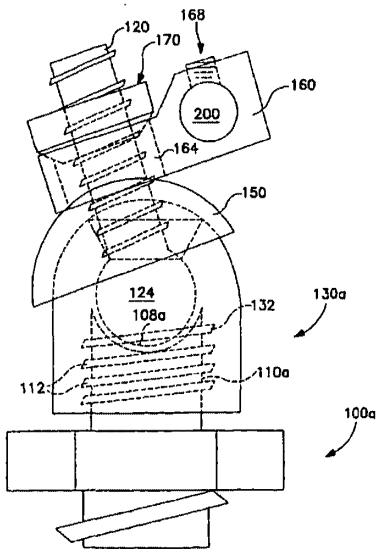


FIG. IOA

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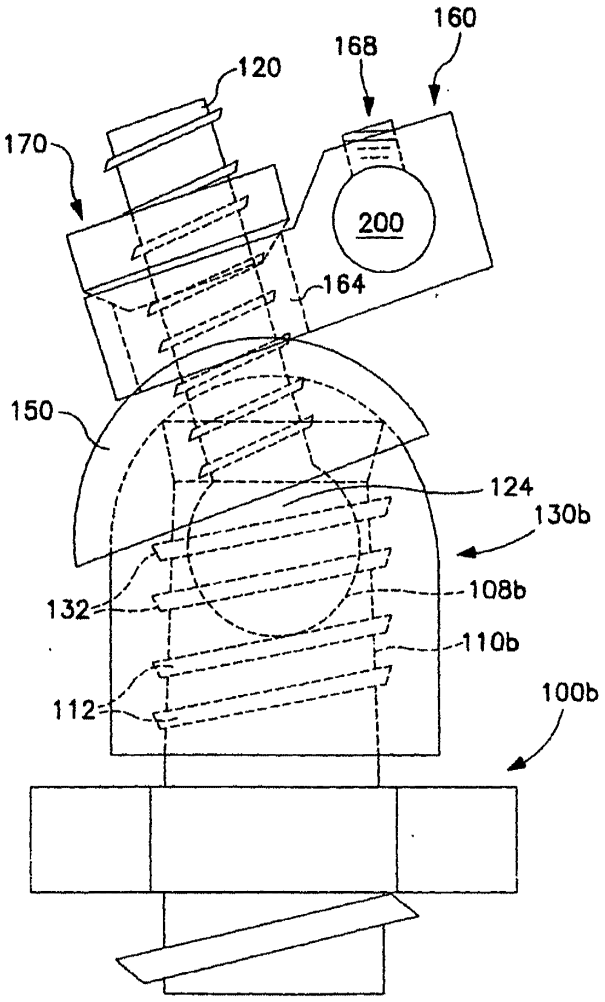


FIG. 10B

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Description

FIELD OF THE INVENTION

[0001] This invention relates generally to a polyaxial pedicle screw for use with orthopedic fixation systems having modular components. More particularly, the present invention relates to a screw for insertion into the vertebral bone having a shaft and a set of modular coupling elements which are polyaxially mounted thereto, via a stem member which is flexibly connected to the top portion of the shaft portion, therein enhancing the efficacy of the implant assembly by providing freedom of angulation among the rod, shaft and modular elements.

DESCRIPTION OF THE PRIOR ART

[0002] The bones and connective tissue of an adult human spinal column consists of more than 20 discrete bones coupled sequentially to one another by a tri-joint complex which consist of an anterior disc and the two posterior facet joints, the anterior discs of adjacent bones being cushioned by cartilage spacers referred to as intervertebral discs. Referring now to Figures 1, 2, and 3, top, side, and posterior views of a vertebral body, a pair of adjacent vertebral bodies, and a sequence of vertebral bodies are shown, respectively. The spinal cord is housed in the central canal 10, protected from the posterior side by a shell of bone called the lamina 12. The lamina 12 includes a rearwardly and downwardly extending portion called the spinous process 16, and laterally extending structures which are referred to as the transverse processes 14. The anterior portion of the spine comprises a set of generally cylindrically shaped bones which are stacked one on top of the other. These portions of the vertebrae arc referred to as the vertebral bodies 20, and are each separated from the other by the intervertebral discs 22. The pedicles 24 comprise bone bridges which couple the anterior vertebral body 20 to the corresponding lamina 12.

[0003] The spinal column of bones is highly complex in that it includes over twenty bones coupled to one another, housing and protecting critical elements of the nervous system having innumerable peripheral nerves and circulatory bodies in close proximity. In spite of these complexities, the spine is a highly flexible structure, capable of a high degree of curvature and twist in nearly every direction. Genetic or developmental irregularities, trauma, chronic stress, tumors, and disease, however, can result in spinal pathologies which either limit this range of motion and/or threaten the critical elements of the nervous system housed within the spinal column. A variety of systems have been disclosed in the art which achieve this immobilization by implanting artificial assemblies in or on the spinal column. These assemblies may be classified as anterior, posterior, or lateral implants. As the classifications suggest, lateral and anterior assemblies are coupled to the anterior portion of the spine, which is the sequence of vertebral bodies. Posterior implants generally comprise pairs of rods, which are aligned along the axis which the bones are to be disposed, and which are then attached to the spinal column by either hooks which couple to the lamina or attach to the transverse processes, or by screws which are inserted through the pedicles.

[0004] "Rod assemblies" generally comprise a plurality of such screws which are implanted through the posterior lateral surfaces of the laminae, through the pedicles, and into their respective vertebral bodies. These screws are typically provided with upper portions which comprise coupling means, for receiving and securing an elongate rod therethrough. The rod extends along the axis of the spine, coupling to the plurality of screws via their coupling means. The rigidity of the rod may be utilized to align the spine in conformance with a more healthful shape.

[0005] It has been identified, however, that a considerable difficulty is associated with inserting screws along a misaligned curvature and simultaneously exactly positioning the coupling elements such that the rod receiving portions thereof are aligned so that the rod can be passed therethrough without distorting the screws. Attempts at achieving proper alignment with fixed screws is understood to require increased operating time, which is known to enhance many complications associated with surgery. Often surgical efforts with such fixed axes devices cannot be achieved, thereby rendering such instrumentation attempts entirely unsucessful.

[0006] The art contains a variety of attempts at providing instrumentation which permit enhanced freedom for the surgeon with respect to aligning the screw and the rod, however, most are complex, inadequately reliable, and lack long-term durability. In addition, most generally lack the feature of being constructed to suit the specific anatomical requirements of every patient's spine. In particular, the Isola(TM) system, which is produced by Acromed, suffers from many of these failures in as much as it does not provide the surgeon to freely angulate the rod coupling means of the screw to meet the rod. More specifically, as illustrated in Figures 4 and 5, the Isola system consists of a shaft portion which is to be inserted into the patient's pedicle, the shaft having a threaded stem portion rigidly extending upwardly from the top of the shaft portion. (The interface of the shaft portion and the stem portion includes a hexagonally shaped annulus for engagement with a torque wrench to permit insertion.) Once the shaft and stem have been inserted, the surgeon threadably advances a number of spacer elements onto the stem portion (the spacer elements are threaded washers, some having a non-uniform thickness so as to provide an angular bias or tilt to the overall construct). Next the surgeon places the rod coupling means (which is slideably advanced axially onto the rod) onto the stem. The rod coupling means includes an elongated slot so that the specific position of the rod coupling means relative to the stem may be varied slightly. Once fully positioned, the surgeon secures the assembly together with

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a top locking nut.

[0007] While being modular so as to provide limited variability in the construct, the Isola system has very limited ability to angulate (the stem is rigidly connected to the shaft portion), and what limited ability to angulate that it has entails the use of a plethora of non-uniformly thick spacer elements which are tedious to use in a surgical environment.

[0008] It is, therefore, the principal object of the present invention to provide a pedicle screw and coupling element assembly which provides a polyaxial freedom of implantation angulation with respect to rod reception.

[0009] In addition, it is an object of the present invention to provide such an assembly which comprises a reduced number of elements, and which correspondingly provides for expeditious implantation.

[0010] Accordingly it is also an object of the present invention to provide an assembly which is reliable, durable, and provides long term fixation support.

[0011] Other objects of the present invention not explicitly stated will be set forth and will be more clearly understood in conjunction with the descriptions of the preferred embodiments disclosed hereafter.

SUMMARY OF THE INVENTION

[0012] The preceding objects of the invention are achieved by the present invention which is a polyaxial modular locking pedicle screw assembly for use with rod stabilization and immobilization systems in the spine. More particularly, the polyaxial screw assembly of the present invention comprises two alternative embodiments. The first embodiment includes a threaded shaft portion for insertion into the pedicle, the top of shaft portion including a bowl-shaped socket and a second threading; a stem portion having a threading, corresponding to the second threading, for receiving spacer elements and/or a rod coupling element thereon, the bottom of said stem portion including a ball (semi-spherical section); and a cylindrical locking cuff which is mounted about the top of the shaft and the bottom of the stem to secure the ball of the stem in the bowl-shaped socket of the shaft. The second embodiment includes a threaded shaft portion for insertion into the pedicle, the top of shaft portion including a convex top and a second threading; a stem portion having a threading, corresponding to the second threading, for receiving spacer elements and/or a rod coupling element thereon, the bottom of said stem portion including a bowl-shaped socket which is shaped to seat on and slide on the convex top of the shaft portion; and a cylindrical locking cuff which is mounted about the top of the shaft and the bottom of the stem to secure the bowl-shaped socket of the stem in the convex top of the shaft.

[0013] More particularly, with respect to the first embodiment, the shaft portion includes an elongate shank portion having the threading of a bone screw (standard or otherwise, but suited for proper purchase of the bone). The uppermost portion of the shaft comprises a bowl-shaped recess which forms a socket. This socket portion may be greater or less than a fully hemispherical recess. In an embodiment in which the socket is greater than a hemisphere, axial slots need to be provided so that the ball may be slipped into the socket. A small hexagonal bore may be disposed in the based of the bowl-shaped socket, coaxial with the shaft, so that a screw driving device (allen wrench, etc.) may be utilized to insert the shaft into the bone. Alternatively, a widened annular portion of the shaft, disposed between the two threadings may be hexagonal so as to permit the use of a torque wrench or other surgical tool. The axial surface of the shaft at the top (socket) end includes the second threading, for receiving and locking the cuff element thereto.

[0014] The stem comprises an elongate post portion having an enlarged ball (having a larger diameter than the post portion) formed at the bottom thereof; the enlarged ball having substantially the same radius of curvature as the bowl-shaped socket portion of the shaft. Therefore, when the ball is initially placed in the bowl-shaped socket, the stem may be positioned in a variety of different angulations relative to the axis of the shaft portion (through a polyaxial range of configurations from coaxial to substantially non-coaxial).

[0015] The securing cuff comprises a hollow cylindrical body, having a threading on the bottom half (halves being defined relative to the through axis) of the interior surface thereof. This threading is designed to mate with the threading on the uppermost portion of the shaft element. The upper half of the interior surface of the cuff may comprise a semi-spherical taper when used in conjunction with a shaft which has a socket which is less than hemispherical. This taper forms an open ended socket. In an alternative embodiment, to be used with a shaft having a socket which is greater than a hemisphere, the top end of the cuff need not be tapered on the inside. In either case, however, the inner diameter of the open end of the top of the cuff is larger than the diameter of the post portion of the stem, but more narrow than the diameter of the ball formed at the bottom end of the stem. During assembly, the stem and shaft portions are initially held coaxial, with the ball of the stem in the socket of the shaft portion, while the securing cuff is advanced down along the post portion of the stem until the threadings of the cuff and the uppermost exterior surface of the shaft engage. Prior to final tightening, the stem and shaft are thereby held together by the cuff, but each may be angulated relative to the other by virtue of the ball and socket interface. (The total range of angulation is established by the relative diameters of the ball, the post, and the opening at the top of the cuff.) Complete tightening of the cuff, however, causes the ball to be crushed into the socket of the shaft (and the tapered interior of the upper portion of the cuff), thereby preventing any further motion.

[0016] A portion of the exterior of the cuff comprises a hexagonally angled surface contour, such that the cuff

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may be easily engaged by a torque wrench. (It shall be understood that any one of a variety of such surface contours or other means may be employed equivalently.) The upper exterior of the cuff, however, is rounded (with a constant radius of curvature) so that it provides a curvate profile. This permits the secure engagement of similarly rounded spacer elements relative to the top of the cuff element independent of the angular orientation of the post portion of the stem relative to the cuff and shaft (the cuff and shaft remain coaxial).

[0017] More particularly, inasmuch as it is still desirable to permit variable positioning of the rod coupling means along the axis of the stem, in addition to the angular variability provided by the polyaxial shaft-stem-cuff assembly, spacer elements may also be utilized. The spacers are annular elements having a diameter which is equivalent to that of the post portion (and are preferrably threaded). The bottom surfaces of the spacer elements are concave, having a radius of curvature equal to that of the upper surface of the cuff. As stated above, this mutual contour permits the spacer to seat securely against the cuff independent of the angulation of the stem. The upper surface of the spacer element is convex, having an equivalent radius of curvature, such that multiple spacers may be nested.

[0018] It shall be understood that the advancing the spacer elements downwardly on the stem, and into contact with the cuff, and subsequent tightening, causes an increase in the total locking force applied to the ball in the socket (the ball is pulled into tighter contact with the socket-shaped interior of the cuff). In order to threadably advance the spacer elements easily, the outer lateral surface of the elements are contoured so as to be engageable by a torque wrench; e.g., having a hexagonal shape.

[0019] The rod coupling element of this assembly comprises a flat portion having an elongate hole therethrough for coupling to the stem, and a tubular portion which may be slideably advanced along the rod into the proper position Once in the proper position, the rod coupling means is locked to the rod by a set screw in order to prevent further movement relative to the rod. The elongate hole in the flat portion is elongate in nature so that distance from the rod to the stem may be varied. This element further includes the concave conformation on the underside thereof so that it may nest securely on the upper surface of either a spacer or directly on the cuff (in the case wherein no spacer is used).

[0020] With respect to the second embodiment, the shaft portion includes an elongate shank portion which is similar to that of the first embodiment insofar as it has the threading of a bone screw (standard or otherwise, but suited for proper purchase of the bone). The uppermost portion of this shaft, however, comprises a hemispherically curved convex bubble. This portion may he less than a full hemisphere, but a full hemisphere is preferred A small hexagonal bore may be disposed in the axial center of the hemisphere, coaxial with the shaft, so that a screw driving device (allen wrench, etc.) may be utilized to insert the shaft into the bone. Alternatively, a widened annular portion of the shaft, disposed between the two threadings may be hexagonal so as to permit the use of a torque wrench or other surgical tool. The lateral (circumferential) surface of the shaft at the top end includes the second threading, for receiving and locking the cuff element thereto.

[0021] The stem of the second embodiment comprises an elongate post portion having an enlarged lower portion which includes a spherically concave recess formed in the bottom thereof. The recess has substantially the same radius of curvature as the hemispherical upper portion of the shaft. Therefore, when the recess is initially permitted to nest on the hemisphere, the stem may be positioned in a variety of different angulations relative to the axis of the shaft portion (through a polyaxial range of configurations from coaxial to substantially non-coaxial).

[0022] The securing cuff comprises a hollow cylindrical body, having a threading on the bottom half (halves being defined relative to the through axis) of the interior surface thereof. This threading is designed to mate with the threading on the uppermost circumferential portion of the shaft element. The upper half of the interior surface of the cuff comprises a contour, preferably a semi-spherical taper which forms an open ended socket. The inner diameter of the open end of the top of the cuff is larger than the diameter of the post portion of the stem, but more narrow than the diameter of the lower socket portion formed at the bottom end of the stem. During assembly, the stem and shaft portions are initially held coaxial, with the recess of the stem on the hemispherical upper portion of the shaft portion, while the securing cuff is advanced down along the post portion of the stem until the threadings of the cuff and the uppermost exterior surface of the shaft engage. Prior to final tightening, the stem and shaft are thereby held together by the cuff, but each may be angulated relative to the other by virtue of the hemisphere and socket interface. (The total range of angulation is established by the relative diameters of the hemisphere, the post, and the opening at the top of the cuff.) Complete tightening of the cuff, however, causes the socket to be crushed on the hemispherical upper portion of the shaft (and the tapered interior of the upper portion of the cuff), thereby preventing any further motion.

[0023] A portion of the exterior of the cuff comprises a hexagonally angled surface contour, such that the cuff may be easily engaged by a torque wrench. (It shall be understood that any one of a variety of such surface contours or other means may be employed equivalently.) The upper exterior of the cuff, however, is rounded (with a constant radius of curvature) so that it provides a curvate profile. This permits the secure engagement of similarly rounded spacer elements relative to the top of the cuff element independent of the angular orientation of the post portion of the stem relative to the cuff and shaft (the cuff and shaft remain coaxial).

[0024] More particularly, inasmuch as it is still desirable to permit variable positioning of the rod coupling

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means along the axis of the stem, in addition to the angular variability provided by the polyaxial shaft-stem-cuff assembly, spacer elements may also be utilized. The spacers are annular elements having a diameter which is equivalent to that of the post portion (and are preferrably threaded). The bottom surfaces of the spacer elements are concave, having a radius of curvature equal to that of the upper surface of the cuff. As stated above, this mutual contour permits the spacer to seat securely against the cuff independent of the angulation of the stem. The upper surface of the spacer element is convex, having an equivalent radius of curvature, such that multiple spacers may be nested.

[0025] As with the first embodiment, it shall be understood that the advancing the spacer elements downwardly on the stem, and into contact with the cuff, and subsequent tightening, causes an increase in the total locking force applied to the socket on the hemisphere (the external surface of the lower socket portion of the stem is pulled more tightly into contact with the socket formed by the interior of the cuff). In order to threadably advance the spacer elements easily, the outer lateral surface of the elements are contoured so as to be engageable by a torque wrench; e.g., having a hexagonal shape.

[0026] The rod coupling element of this assembly comprises a flat portion having an elongate hole therethrough for coupling to the stem, and a tubular portion which may be slideably advanced along the rod into the proper position. Once in the proper position, the rod coupling means is locked to the rod by a set screw in order to prevent further movement relative to the rod. The elongate hole in the flat portion is elongate in nature so that distance from the rod to the stem may be varied. This element further includes the concave conformation on the underside thereof so that it may nest securely on the upper surface of either a spacer or directly on the cuff (in the case wherein no spacer is used)

[0027] The first step in the process of implanting this invention in either embodiment is to pre-drill the appropriate site in the pedicle to receive the shaft. The shaft is then driven into the vertebral body. The cuff is then advanced down the stem portion until it reaches the ball or socket portion. The ball and socket portions are then placed together such that they may rotate relative to one another, and the threadings on the top of the shaft and on the interior of the cuff are engaged. The stem is then angulated into the appropriate position, and the cuff is locked down, thereby securing the stem relative to the shaft. The rod coupling element is then slideably advanced along the rod into the appropriate position, and the stem placed in the elongate hole thereof. The set screw of the rod coupling element is engaged to lock thereto. (Spacers are threadably advanced onto the stem prior to the insertion of the stem through the elongate hole, if it is determined that they are necessary.) Once the assembly has been properly set, the top locking nut is advanced downwardly along the stem and into position against the top of the rod coupling element, thereby preventing any lateral or axial movement of the stem within the elongate hole.

[0028] Multiple screw and coupling element assemblies are generally necessary to complete the full array of anchoring sites for the rod immobilization system, however, the screw and coupling element assembly of the present invention is designed to be compatible with alternative rod systems so that, where necessary, the present invention may be employed to rectify the failures of other systems the implantation of which may have already begun.

BRIEF DESCRIPTION OF THE FIGURES

[0029]

Figure 1 is a top view of a human vertebra, which is representative of the type for which the present invention is useful for coupling thereto a rod apparatus;

Figure 2 is a side view of a pair of adjacent vertebrae of the type shown in Figure 1;

Figure 3 is a posterior view of a sequence of vertebrae of the type shown in Figures 1 and 2;

Figures 4a and 4b are side cross section views of alternative threaded shafts which are aspects of the present invention;

Figure 5 is a side view of a stem portion, having a ball formed at the bottom thereof, which is an aspect of the present invention;

Figures 6a and 6b are side cross section views of alternative cuffs of the present invention;

Figure 7 is a side cross section view of a spacer element which is an aspect of the present invention;

Figure 8 is a perspective view of a rod coupling element which is an aspect of the present invention;

Figure 9 is a side cross-sectional view of the top locking nut of the present invention;

Figures 10a and 10b are side views of two fully assembled modular polyaxial pedicle screws of the present invention;

Figure 11 is a side cross section view of a threaded shaft which is another aspect of the present invention;

Figure 12 is a side view of a stem portion, having a socket formed at the bottom thereof, which is an aspect of the present invention;

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Figure 13 is a side cross section views of a cuff element of the present invention;

Figure 14 is a side cross section view of a spacer element which is an aspect of the present invention;

Figure 15 is a perspective view of a rod coupling element which is an aspect of the present invention;

Figure 16 is a side cross-sectional view of the top locking nut of the present invention; and

Figure 17 is a side view of a fully assembled modular polyaxial pedicle screw of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODINIENT

[0030] While the present invention will be described more fully hereinafter with reference to the accompanying drawings, in which particular embodiments and methods of implantation are shown, it is to be understood at the outset that persons skilled in the art may modify the invention herein described while achieving the functions and results of this invention. Accordingly, the descriptions which follow are to be understood as illustrative and exemplary of specific structures, aspects and features within the broad scope of the present invention and not as limiting of such broad scope.

[0031] More particularly, referring now to Figures 4a and 4b, the alternative modular polyaxial pedicle screws of the present invention first comprises a threaded shaft portion 100a, 100b which is inserted into the pedicle. Both shafts 100a,100b include a lower shank portion 102 which include a bone screw threading 104. (This threading 104 may be standard or otherwise, but is in any case suited for necessary purchase of bone.) Specifically with respect to the illustration 4a, the top 106a of the shaft 100a comprises a bowl-shaped recess 108a which forms a socket. This socket 108a comprises less than a hemispherical section. Alternatively, as shown in Figure 4b, the top 106b of the shaft 100b may comprise a socket 108b which is greater than a hemispherical section. In such a socket 108b, the upper lip 109 thereof should include at least one axial slot 111 which extends below the maximum diameter A-A, and which may expand and contract in accordance with the application of a radial force on the upper lip 109.

[0032] In both alternatives, the axial surfaces of the upper ends 1 10a, 110b of the shafts 100a, 100b (around the sockets 108a, 108b) include a second threading 112. A widened hexagonal annulus 114, which is integrally formed with the shaft 100a,100b, and is disposed between the threaded shank 102 and upper portions 110a, 110b, is provided so that a suitable torque wrench may be employed to drive the shaft 100a, 100b into the vertebral body through the pedicle.

[0033] Referring now to Figure 5, a stem portion 120 is shown in a side view. More specifically, the stem 120 comprises an elongate threaded post portion 122 and an enlarged ball 124. The ball 124 has a larger diameter than the post 122. The ball 124 has substantially the same radius of curvature as the bowl-shaped socket 108 portion of the shaft 100. This mutual dimension permits the ball 124 to rotate freely in the socket 108 once the ball 124 is placed therein, thus permitting the stem 120 to be angulated relative to the shaft 100 (through a polyaxial range from coaxial to substantially non-coaxial).

[0034] Referring to Figures 6a and 6b, the mutual engagement of the shafts 100a, 100b with the stem 120 is provided by corresponding cuffs 130a, 130b, shown in side cross section views. The cuffs 130a, 130b are each hollow cylinders and have a threading 132 on the bottom half of the interior surface 134 thereof. This threading 132 is designed to mate with the threading 112 on the uppermost portion 110a, 110b of the shaft element 100a, 100b. With respect to the embodiment of the cuff 130a which is used in conjunction with the shaft 100a having a socket with a socket defining less than a hemisphere, the upper half of the interior surface 136 of the cuff 130a comprises a semi-spherical taper, which forms an open ended socket. Alternatively, the embodiment which is to be utilized with the shaft 100b having a socket 108b which defines greater than a hemisphere, has no internal taper at the upper end, however, the lower threaded portion may include a reverse taper, i.e. narrower at the top, in order to provide an inwardly directed radial force onto the upper lip 109. In each embodiment 130a, 130b, the inner diameter B-B of the open end 138 of the top of the cuff 130a, 130b is larger than the diameter of the threaded post portion 122 of the stem 120, but more narrow than the diameter of the ball 124.

[0035] During assembly, the stem 120 and shaft 100a, 100b portions are initially held coaxial, with the ball 124 of the stem 120 in the socket 108a, 108b of the shaft 100a, 100b (the ball 124 being snapped into the socket 108b by applying a downward force whereby the at least one slot 111 expands), while the securing cuff 130a, 103b is advanced down along the post portion of the stem until the threadings 132, 112 of the cuff 130a, 130b and the uppermost exterior surface 110a, 110b of the shaft, respectively, engage. Prior to final tightening, the stem 120 and shaft 100a, 100b are thereby loosely held together by the cuff 130a, 130b, respectively, but each may be angulated relative to the other by virtue of the ball 124 and socket 108a, 108b interface. The total range of angulation is established by the relative diameters of the ball 124, the post 122, (the upper lip 109 of the socket 108b), and the opening 138 at the top of the cuff. Complete tightening of the cuff 130a,130b, however, causes the ball 124 to be crushed into the socket 108a, 108b, thereby preventing any further motion.

[0036] A portion of the exterior 140 of the cuff 130a, 130b comprises a hexagonally angled surface contour, such that the cuff 130a, 130b may be easily engaged by

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a torque wrench. In addition, the upper exterior 142 of the cuff 130a, 130b, however, is rounded (with a constant radius of curvature) so that it provides a curvate profile. This permits the secure engagement of similarly rounded spacer elements (see Figure 7, and related description hereinbelow) relative to the top of the cuff 130a,130b independent of the angular orientation of the post 122 of the stem 120 relative to the cuff 130a, 130b and shaft 100a, 100b.

[0037] More particularly, with reference to Figure 7, inasmuch as it may be desirable to vary the axial position of the rod coupling means (see Figure 8, and related description hereinbelow) along the post 122, spacer elements 150 are provided. The spacers 150 are annular elements having an inner diameter C-C which is equivalent to that of the post 122. In the illustrated embodiment, the inner surface 152 includes a threading 154 which is engageable with the threading of the post 122. (It is not necessary for the spacers 150 to be threaded, however, such a threading may provide additional downward force on the cuff 130a, 130b to further secure the locking of the stem 120 and the shaft 100a, 100b.) The bottom surface of the spacer 150 is concave, having a radius of curvature equal to that of the tapered upper portion 142 of the cuff 130a, 130b. This mutual contour permits the spacer 150 to seat securely against the cuff 130a, 130b independent of the angulation of the stem 120. The upper surface 142 of the spacer 150 is convex, having an equivalent radius of curvature, such that multiple spacers 150 may be nested. In order that the threaded spacer 150 may be advanced easily along the threaded post 122, the outer lateral surface 156 is contoured so as to be engageable by a torque wrench; e.g., having a hexagonal shape.

[0038] Referring now to Figure 8, the rod coupling element 160 of this assembly comprises a flat portion 162 having an elongate hole 164 therethrough for coupling to the stem 120. The elongate hole 164 has a width equal to that of the post 122, but is elongated to permit variable lateral placement of the post 122 relative to the rod 200. The edge (not seen in this illustration) of the elongated hole 164, on the underside of the flat portion, is concavely tapered so as to ideally receive the curvate upper portion of the spacer 150 or the cuff 130a, 130b.

[0039] The rod coupling element 160 further includes a tubular portion 166, the axis of the tube is substantially perpendicular to the elongated axis of the hole 164. The rod coupling element 160 is positioned on the rod 200 by slideably advancing it therealong. Once in the proper position, the rod coupling element 160 is locked to the rod 200 by a set screw 168 in order to prevent further movement relative to the rod. In addition, this element 160 further includes a concave underside conformation 170 such that it may nest securely on the upper surface of either a spacer 150 or directly on the cuff 130a,130b (in the case wherein no spacer 150 is used).

[0040] Referring to Figure 9, a top locking nut 170 is utilized to lock the rod coupling element 160 onto the post 122. More particularly, the top locking nut 170 has a bottom surface 172 which is ideally suited to engage and hold the post 122 and the rod coupling element 160 from axial or lateral movement. Specifically, the top locking nut 170 is designed to apply a downward pressure which is sufficient to lock the cuff 130a, 130b into the tapered curvate edge of the elongate hole 164 such that the friction locking force of the spacer 150 or cuff 130a, 130b thereagainst is sufficient to hold the rod coupling element 160 from lateral, or axial, movement.

[0041] Referring now to Figures 10a and 10b, the steps of implanting this assembly is described. First, a hole is pre-drilled in the appropriate site in the pedicle in order to receive the shaft 100a, 100b. The shaft 100a,100b is then driven into the vertebral body. The cuff 130a,130b is then advanced down the stem 120 until it reaches the ball 124. The ball 124 is then placed (or snapped) into the socket 108a, 108b, and the threadings 112, 132 on the upper portion 110a, 110b of the shaft 100a, 100b and on the interior of the cuff 130a, 130b, respectively, are engaged. The post 122 is then angulated into the appropriate position, and the cuff 130a,130b is locked down, thereby securing the stem 120 relative to the shaft 130a, 130b. (The ball 124 is crush locked between the cuff 130a and the socket 108a. Alternatively, the ball 124 is crushed into the socket 108b by virtue of the socket itself being collapsed onto the ball 124.) If necessary, spacers 150 are positioned above the cuff 130a, 130b on the post 122. The rod coupling element 160 is then slideably advanced along the rod 200 into the appropriate position, and the post 122 is placed in the elongate hole 164 thereof. The set screw 168 of the rod coupling element 160 is engaged to lock it to the rod 200. Finally the top locking nut 180 is advanced downwardly along the post 122 and into position against the rod coupling element 160, thereby preventing any lateral or axial movement of the post 122 within the elongate hole 164.

[0042] A complete posterior rod implant system includes at least two, and generally four or more, screw assemblies. However, this assembly, as set forth above, may also be used in conjunction with other screw assemblies in the art wherein there is an immediate need for the beneficial properties of this assembly to correct deficiencies in the other assemblies. Therefore, it is anticipated that this modular polyaxial pedicle screw may be used individually, or in conjunction with others.

[0043] Referring now to Figure 11, and the second embodiment of the present invention wherein the stem portion includes the socket and the shaft includes the convex top, the modular polyaxial pedicle screw of the present invention first comprises a threaded shaft portion 300 which is inserted into the pedicle. The shaft 300 includes a lower shank portion 302 which include a bone screw threading 304. (This threading 304 may be standard or otherwise, but is in any case suited for necessary purchase of bone.) The top 306 of the shaft 300 comprises a hemispherical protuberance 308 which forms an upper rounded surface. The circumferentail surfaces of the up-

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per end 310 of the shaft 300 (around the hemisphere 308) includes a second threading 312. A widened hexagonal annulus 314, which is integrally formed with the shaft 300, and is disposed between the threaded shank 302 and upper portion 310, is provided so that a suitable torque wrench may be employed to drive the shaft 300 into the vertebral body through the pedicle.

[0044] Referring now to Figure 12, a stem portion 320 is shown in a side view. More specifically, the stem 320 comprises an elongate threaded post portion 322 and an enlarged lower socket portion 323. The lower portion 323 has a larger diameter than the post 322 and includes a spherical recess 324 formed in the bottom thereof. The recess 324 has substantially the same radius of curvature as the hemispherical upper portion 308 of the shaft 300. This mutual dimension permits the recess 324 to rotate freely over the hemispherical upper portion 308 once the socket 324 is nested thereon, thus permitting the stem 320 to be angulated relative to the shaft 300 (through a polyaxial range from coaxial to substantially non-coaxial).

[0045] Referring to Figure 13, the mutual engagement of the shaft 300 with the stem 320 is provided by a corresponding cuff 330, shown in side cross section views. The cuff 330 is a hollow cylinder and has a threading 332 on the bottom half of the interior surface 334 thereof. This threading 332 is designed to mate with the threading 312 on the uppermost portion 310 of the shaft element 300. The upper half of the interior surface 336 of the cuff 330 comprises a curvate taper, which is preferably semi-spherical and forms an open ended socket. The inner diameter of the open end 338 of the top of the cuff 330 is larger than the diameter of the threaded post portion 322 of the stem 320, but more narrow than the diameter of the lower socker portion 323.

[0046] During assembly, the stem 320 and shaft 300 portions are initially held coaxial, with the recess 324 of the stem 320 on the hemispherical upper portion 308 of the shaft3100, while the securing cuff 330 is advanced down along the post portion of the stem until the threadings 332,312 of the cuff 330 and the uppermost exterior surface 310 of the shaft engage. Prior to final tightening, the stem 320 and shaft 300 are thereby loosely held together by the cuff330, but each may be angulated relative to the other by virtue of the geometry of the recess 324 and hemispherical upper portion 308 interfacing. The total range of angulation is established by the relative diameters of the hemispherical upper portion 308, the lower socker portion of the stem, the post 322, and the opening 338 at the top of the cuff. Complete tightening of the cuff 330, however, causes the recess 324 to be crushed onto the hemispherical upper portion 308, thereby preventing any further motion.

[0047] A portion of the exterior 340 of the cuff 330 comprises a hexagonally angled surface contour, such that the cuff330 may be easily engaged by a torque wrench. In addition, the upper exterior 342 of the cuff 330, however, is rounded (with a constant radius of curvature) so that it provides a curvate profile. This permits the secure engagement of similarly rounded spacer elements (see Figure 14, and related description hereinbelow) relative to the top of the cuff 330 independent of the angular orientation of the post 322 of the stem 320 relative to the cuff 330 and shaft 300.

[0048] More particularly, with reference to Figure 14, inasmuch as it may be desirable to vary the axial position of the rod coupling means (see Figure 15, and related description hereinbelow) along the post 322, spacer elements 350 arc provided. The spacers 350 are annular elements having an inner diameter D-D which is equivalent to that of the post 322. In the illustrated embodiment, the inner surface 352 includes a threading 354 which is engageable with the threading of the post 322. (It is not necessary for the spacers 350 to be threaded, however, such a threading may provide additional downward force on the cuff 330 to further secure the locking of the stem 320 and the shaft 300.) The bottom surface of the spacer 350 is concave, having a radius of curvature equal to that of the tapered upper portion 342 of the cuff 330. This mutual contour permits the spacer 350 to seat securely against the cuff 330 independent of the angulation of the stem 320. The upper surface 342 of the spacer 350 is convex, having an equivalent radius of curvature, such that multiple spacers 350 may be nested. In order that the threaded spacer 350 may be advanced easily along the threaded post 322, the outer lateral surface 356 is contoured so as to be engageable by a torque wrench; e.g., having a hexagonal shape.

[0049] Referring now to Figure 15, the rod coupling element 360 of this assembly comprises a flat portion 362 having an elongate hole 364 therethrough for coupling to the stem 320. The elongate hole 364 has a width equal to that of the post 322, but is elongated to permit variable lateral placement of the post 322 relative to the rod 200. The edge (not seen in this illustration) of the elongated hole 364, on the underside of the flat portion, is concavely tapered so as to ideally receive the curvate upper portion of the spacer 350 or the cuff 330.

[0050] The rod coupling element 360 further includes a tubular portion 366, the axis of the tube is substantially perpendicular to the elongated axis of the hole 364. The rod coupling element 360 is positioned on the rod 200 by slideably advancing it therealong. Once in the proper position, the rod coupling element 360 is locked to the rod 200 by a set screw 368 in order to prevent further movement relative to the rod. In addition, this element 360 further includes a concave underside conformation 370 such that it may nest securely on the upper surface of either a spacer 350 or directly on the cuff 330 (in the case wherein no spacer 350 is used).

[0051] Referring to Figure 16, a top locking nut 370 is utilized to lock the rod coupling element 360 onto the post 322. More particularly, the top locking nut 370 has a bottom surface 372 which is ideally suited to engage and hold the post 322 and the rod coupling element 360 from axial or lateral movement. Specifically, the top locking

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nut 370 is designed to apply a downward pressure which is sufficient to lock the cuff 3 30 into the tapered curvate edge of the elongate hole 364 such that the friction locking force of the spacer 350 or cuff 330 thereagainst is sufficient to hold the rod coupling element 360 from lateral, or axial, movement.

[0052] Referring now to Figure 17, the steps of implanting this assembly is described. First, a hole is pre-drilled in the appropriate site in the pedicle in order to receive the shaft 300. The shaft 300 is then driven into the vertebral body. The cuff 330 is then advanced down the stem 320 until it reaches the lower socker portion 323. The recess 324 is then placed onto the hemispherical upper portion 308 of the shaft, and the threadings 312,332 on the upper portion 310 of the shaft 300 and on the interior of the cuff 330 are engaged. The post 322 is then angulated into the appropriate position, and the cuff 330 is locked down, thereby securing the stem 320 relative to the shaft 330. (The lower socket portion 323 is crush locked between the cuff 330 and the socket 308.) If necessary, spacers 350 are positioned above the cuff 3 30 on the post 322. The rod coupling element 360 is then slideably advanced along the rod 200 into the appropriate position, and the post 322 is placed in the elongate hole 364 thereof. The set screw 368 of the rod coupling element 360 is engaged to lock it to the rod 200. Finally the top locking nut 380 is advanced downwardly along the post 322 and into position against the rod coupling element 360, thereby preventing any lateral or axial movement of the post 322 within the elongate hole 364.

[0053] A complete posterior rod implant system includes at least two, and generally four or more, screw assemblies. However, this assembly, as set forth above, may also be used in conjunction with other screw assemblies in the art wherein there is an immediate need for the beneficial properties of this assembly to correct deficiencies in the other assemblies. Therefore, it is anticipated that this modular polyaxial pedicle screw may be used individually, or in conjunction with others.

[0054] While there has been described and illustrated embodiments of a modular polyaxial pedicle screw assembly for use with posterior spinal rod implantation apparatus, it will be apparent to those skilled in the art that variations and modifications are possible without deviating from the broad spirit and principle of the present invention. The present invention shall, therefore, be limited solely by the scope of the claims appended hereto.

Claims

1. A modular polyaxial pedicle screw assembly, comprising:

   a shaft having a curvate socket formed in the top thereof;
   a stem having an upper post portion and a lower ball portion, the ball portion having a larger diameter than the upper post portion, and said ball portion being shaped to nest and initially rotate in said curvate socket;
   a cuff having a hollow cylindrical body having an opening in a top thereof having a diameter greater than that of the upper post portion and less than that of the ball portion, such that prior to positioning the cuff on the shaft the stem may polyaxially rotate relative to the shaft through a range of orientations including coaxial and non-coaxial ones, and such that after positioning the cuff on the shaft the ball portion is crush locked in the curvate socket, thereby preventing further motion of the stem relative to the shaft;
   means for coupling said cuff on said shaft; and
   means for coupling a rod to the stem.

2. A modular polyaxial pedicle screw assembly, comprising:

   a shaft having a curvate socket formed in the top thereof and a threading disposed on the upper circumferential surface thereof;
   a stem having an upper post portion and a lower ball portion, the ball portion having a larger diameter than the upper post portion, and said ball portion being shaped to nest and initially rotate in said curvate socket;
   a cuff having a hollow cylindrical body and a threading on a lower interior surface thereof which threading is mateable with said threading on said upper circumferential surface of said shaft, and an opening in a top thereof having a diameter greater than that of the upper post portion and less than that of the ball portion, such that prior to complete securing of the cuff on the shaft the stem may polyaxially rotate relative to the shaft through a range of orientations including coaxial and non-coaxial ones, and such that by complete securing of the cuff on the shaft the ball portion is crush locked in the curvate socket, thereby preventing further motion of the stem relative to the shaft; and
   means for coupling a rod to the stem.

3. The assembly as set forth in claim 2, wherein the shaft includes a second threading disposed on a lower circumferential surface thereof.

4. The assembly as set forth in claim 2, wherein said socket formed in the top of said shaft is a recess having a constant radius of curvature.

5. The assembly as set forth in claim 4, wherein said recess defines a surface which is smaller in extent than a hemisphere.

6. The assembly as set forth in claim 4, wherein said

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recess defines a surface which is greater in extent than a hemisphere.

7. The assembly as set forth in claim 6, wherein the top of said shaft includes at least one axial slot formed therein, said slot extending axially downward from said top of said shaft to a position which is lower than the maximum diameter of said recess.

8. The assembly as set forth in claim 7, wherein the lower interior surface is tapered upwardly and radially inwardly.

9. The assembly as set forth in claim 2, wherein said shaft futher comprises an annulus portion integrally formed therewith which is positioned beneath the threaded upper circumferential portion, said annulus having a hexagonal outer conformation.

10. The assembly as set forth in claim 2, wherein said upper post portion comprises a surface threading.

11. The assembly as set forth in claim 2, wherein said cuff includes an external circumferential surface portion which defines a hexagonal conformation.

12. The assembly as set forth in claim 5, wherein said cuff includes an upper interior surface which is axially tapered so as to define a rounded interior cupping surface having the same radius of curvate as the recess.

13. The assembly as set forth in claim 2, wherein the cuff includes an upper exterior surface and a top exterior surface which are mutually axially tapered to exhibit a rounded conformation.

14. The assembly as set forth in claim 13, further comprising at least one spacer element disposed between the cuff and the means for coupling a rod to said stem.

15. The assembly as set forth in claim 14, wherein said at least one spacer element comprises a washer having a concave lower surface and a convex upper surface, said concavity and convexity of said upper and lower surfaces having the equivalent absolute curvature as said upper exterior and top surfaces of said cuff.

16. The assembly as set forth in claim 15, wherein said upper post portion of said stem includes an exterior surface threading and wherein said interior circumferential surface of said at least one spacer element also includes a threading.

17. The assembly as set forth in claim 16, wherein said at least one spacer element comprises an exterior circumferential conformation which defines a hexagonal shape.

18. The assembly as set forth in claim 2, wherein said means for coupling a rod to said stem comprises a rod counting element which is mountable on said upper post portion of said stem and top locking nut securable to said upper post portion, above said rod coupling element, thereby securing said rod coupling element between the top locking nut and said cuff.

19. An orthopaedic implant device for use in a spine, comprising:

at least one rod positioned in parallel with the elongate axis of the spine;
a plurality of pedicle screw assemblies for securely coupling said at least one rod to said spine, at least one of said pedicle screws being a modular polyaxial pedicle screw including:

a shaft having a curvate socket formed in the top thereof and a threading disposed on the upper circumferential surface thereof;
a stem having an upper post portion and a lower ball portion, the ball portion having a larger diameter than the upper post portion, and said ball portion being shaped to nest and initially rotate in said curvate socket;
a cuff having a hollow cylindrical body and a threading on a lower interior surface thereof which threading is mateable with said threading on said upper circumferential surface of said shaft, and an opening in a top thereof having a diameter greater than that of the upper post portion and less than that of the ball portion, such that prior to complete securing of the cuff on the shaft the stem may polyaxially rotate relative to the shaft through a range of orientations including coaxial and non-coaxial ones, and such that by complete securing of the cuff on the shaft the ball portion is crush locked in the curvate socket, thereby preventing further motion of the stem relative to the shaft; and
means for coupling a rod to the stem

20. A modular polyaxial pedicle screw assembly, comprising:

a bone screw having a shaft portion and an upper portion having a hemispherical upper portion which is coaxial with said shaft portion and a threading disposed on the upper circumferential surface of said upper portion disposed below said hemispherical upper portion;
a stem having an upper post portion and a lower portion, the lower portion having a wider diam-

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eter than the upper post portion, and forming a socket having the same radius of curvature as the hemispherical upper portion of the bone screw, said socket being shaped to nest and initially rotate on said hemispherical upper portion of said screw, and said exterior surface of said lower portion having a rounded conformation;
a cuff having a hollow cylindrical body having an opening in a top thereof having a diameter greater than that of the upper post portion and less than that of the ball portion, and a threading on a lower interior surface thereof, which threading is coaxial with said opening in said top and is mateable with said threading on said upper circumferential surface of said upper portion of said screw, and such that prior to complete securing of the cuff on the upper portion the stem may polyaxially rotate relative to the shaft with the post portion extending through the opening in the top of the cuff through a range of orientations including orientations which are coaxial and non-coaxial relative to the cuff and bone screw, and such that by complete securing of the cuff on the upper portion of the screw the curvate socket is crush locked in the hemispherical upper portion, thereby preventing further motion of the post relative to the shaft; and
means for coupling a rod to the stem.

21. A modular polyaxial pedicle screw assembly, comprising:

a shaft having a hemispherical upper portion and a threading disposed on the upper circumferential surface thereof and an annulus portion integrally formed therewith which is positioned beneath the threaded upper circumferential portion, said annulus having a hexagonal outer conformation;
a stem having an upper post portion and a lower socket portion, the lower socket portion having a wider diameter than the upper post portion, and said socket portion being shaped to nest and initially rotate on said hemispherical upper portion, said lower socket portion further including a curvate exterior surface;
a cuff having a hollow cylindrical body and a threading on a lower interior surface thereof which threading is mateable with said threading on said upper circumferential surface of said shaft, and an opening in a top thereof having a diameter greater than that of the upper post portion and less than that of the socket portion, such that prior to complete securing of the cuff on the shaft the stem may polyaxially rotate relative to the shaft through a range of orientations including coaxial and non-coaxial ones, and such that by complete securing of the cuff on the shaft the socket portion is crush locked on the hemispherical upper portion, thereby preventing further motion of the stem relative to the shaft; and
means for coupling a rod to the stem.

22. The assembly as set forth in claim 21, wherein said upper post portion comprises a surface threading.

23. The assembly as set forth in claim 21, wherein said cuff includes an external circumferential surface portion which defines a hexagonal conformation.

24. The assembly as set forth in claim 23, wherein said cuff includes an upper interior surface which is axially tapered so as to define a rounded interior cupping surface for cupping the curvate exterior surface of the lower socket portion.

25. A modular polyaxial pedicle screw assembly, comprising:

a shaft having a hemispherical upper portion formed in the top thereof and a threading disposed on the upper circumferential surface thereof;
a stem having an upper post portion and a lower socket portion, the socket portion having a wider diameter than the post portion, and said lower socket portion defining a curvate recess being shaped to nest and initially rotate on said hemispherical upper portion;
a cuff having a hollow cylindrical body and a threading on a lower interior surface thereof which threading is mateable with said threading on said upper circumferential surface of said shaft, and an opening in a top thereof having a diameter greater than that of the upper post portion and less than that of the lower socket portion, such that prior to complete securing of the cuff on the shaft the stem may polyaxially rotate relative to the shaft through a range of orientations including coaxial and non-coaxial ones, and such that by complete securing of the cuff on the shaft the lower socket portion is crush locked on the hemispherical upper portion, thereby preventing further motion of the stem relative to the shaft and an upper exterior surface and a top exterior surface which are mutually axially tapered to exhibit a rounded conformation;
means for coupling a rod to the stem; and
at least one spacer element disposed between the cuff and the means for coupling a rod to said stem, wherein said at least one spacer element comprises a washer having a concave lower surface and a convex upper surface, said concavity and convexity of said upper and lower surfaces having the equivalent absolute curvature as said

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upper exterior and top surfaces of said cuff.

26. The assembly as set forth in claim 25, wherein said upper post portion of said stem includes an exterior surface threading and wherein said interior circumferential surface of said at least one spacer element also includes a threading.

27. The assembly as set forth in claim 26, wherein said at least one spacer element comprises an exterior circumferential conformation which defines a hexagonal shape.

28. A modular polyaxial pedicle screw assembly, comprising:

a shaft having a hemispherical upper portion formed on the top thereof and a threading disposed on the upper circumferential surface thereof;
a stem having an upper post portion and a lower socket portion, the lower socket portion having a larger diameter than the upper post portion, the lower socket portion defining a curvate recess, and said curvate recess being shaped to nest and initially rotate on said hemispherical upper portion of said screw;
a cuff having a hollow cylindrical body and a threading on a lower interior surface thereof which threading is mateable with said threading on said upper circumferential surface of said shaft, and an opening in a top thereof having a diameter greater than that of the upper post portion and less than that of the lower socket portion, such that prior to complete securing of the cuff on the shaft the stem may polyaxially rotate relative to the shaft through a range of orientations including coaxial and non-coaxial ones, and such that by complete securing of the cuff on the shaft the lower socket portion is crush locked on the hemispherical upper portion, thereby preventing further motion of the stem relative to the shaft;
a rod coupling element which is mountable on said upper post portion of said stem, and
a top locking nut securable to said upper post portion, above said rod coupling element, thereby securing said rod coupling element between the top locking nut and said cuff.

29. An orthopaedic implant device for use in a spine, comprising:

at least one rod positioned in parallel with the elongate axis of the spine;
a plurality of pedicle screw assemblies for securely coupling said at least one rod to said spine, at least one of said pedicle screws being
a modular polyaxial pedicle screw including
a shaft having a hemispherical upper portion formed on the top thereof and a threading disposed on the upper circumferential surface thereof,
a stem having an upper post portion and a lower socket portion, the lower socket portion having a larger diameter than the upper post portion, the lower socket portion also defining a curvate recess, and said socket portion being shaped to nest and initially rotate on said hemispherical upper portion of said screw,
a cuff having a hollow cylindrical body and a threading on a lower interior surface thereof which threading is mateable with said threading on said upper circumferential surface of said shaft, and an opening in a top thereof having a diameter greater than that of the upper post portion and less than that of the lower socket portion, such that prior to complete securing of the cuff on the shaft the stem may polyaxially rotate relative to the shaft through a range of orientations including coaxial and non-coaxial ones, and such that by complete securing of the cuff on the shaft the lower socket portion is crush locked on the hemispherical upper portion, thereby preventing further motion of the stem relative to the shaft,
a rod coupling element which is mountable on said upper post portion of said stem, and
a top locking nut, securable to said upper post portion, above said rod coupling element, thereby securing said rod coupling element between the top locking nut and said cuff.

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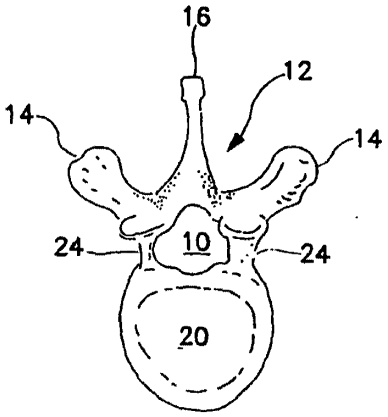


FIG. 1

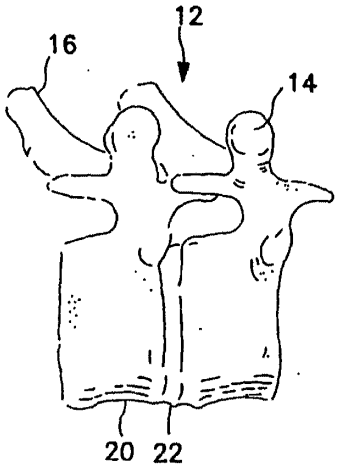


FIG. 2

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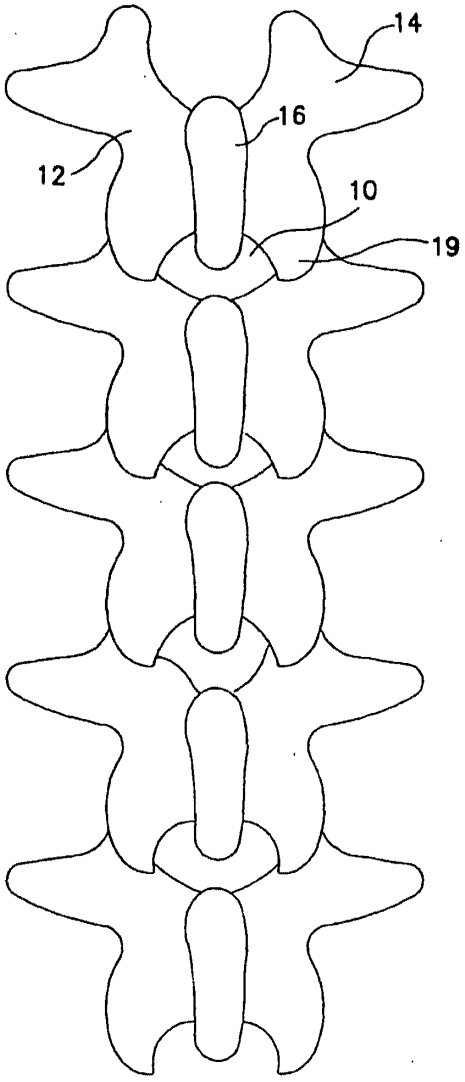


FIG. 3

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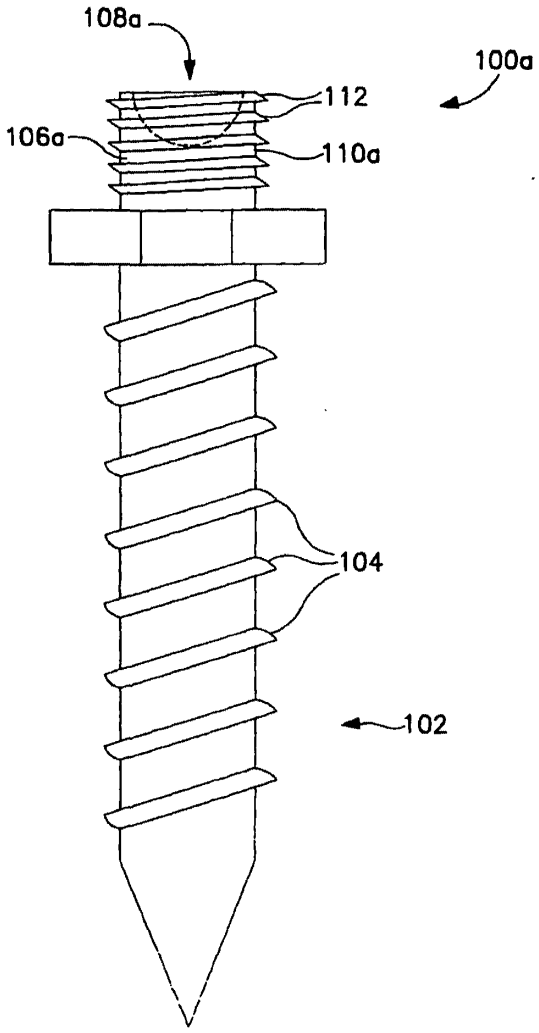


FIG. 4A

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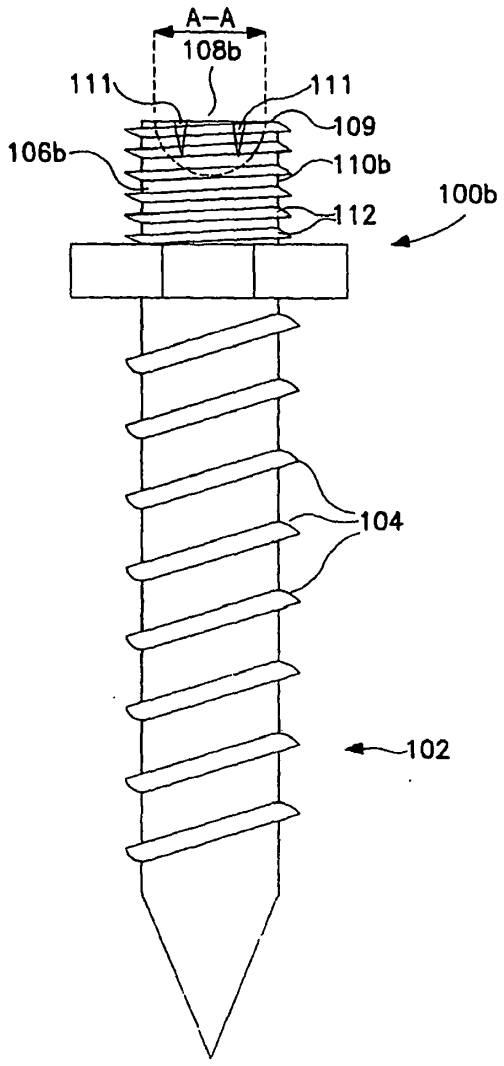


FIG. 4B

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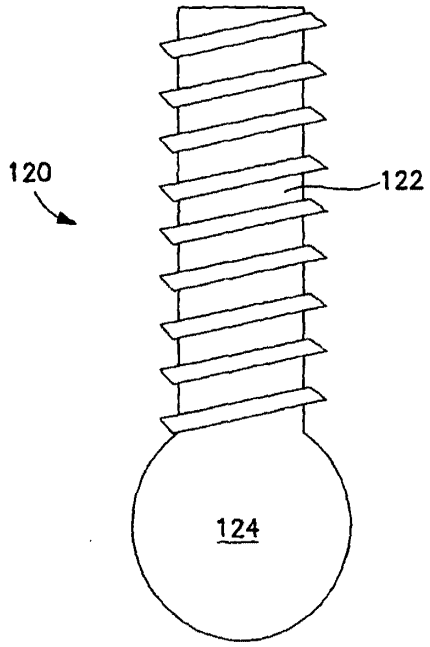


FIG. 5

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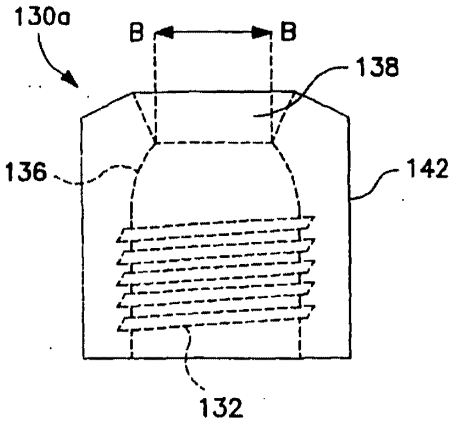


FIG. 6A

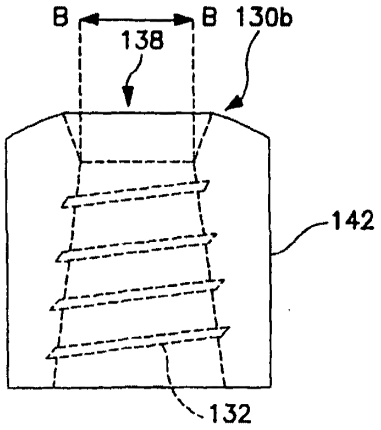


FIG. 6B

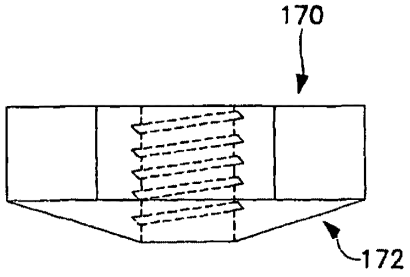


FIG. 9

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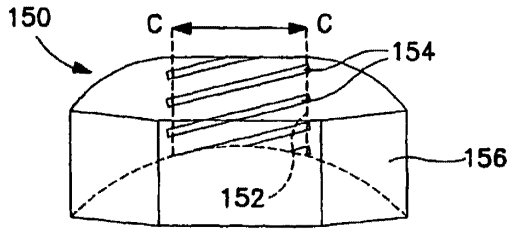


FIG. 7

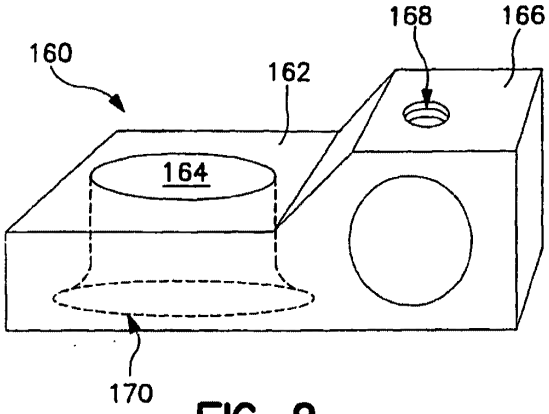


FIG. 8

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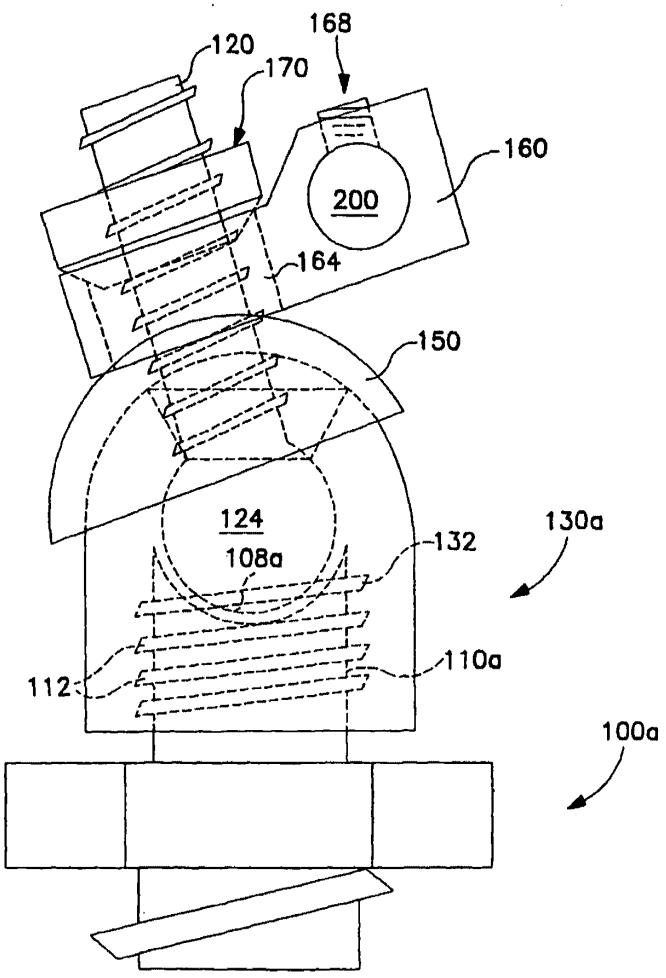


FIG. 10A

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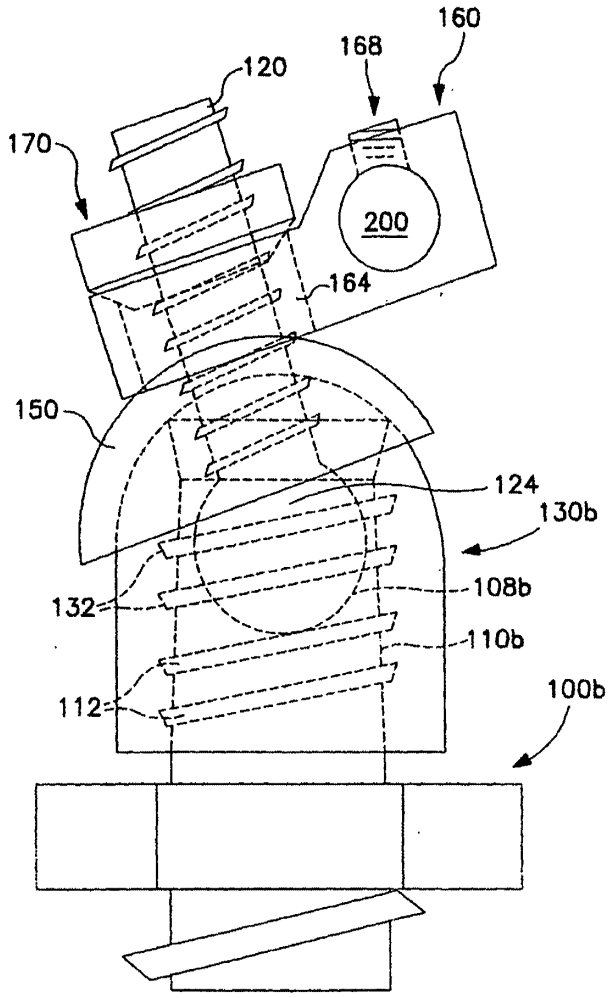


FIG. 10B

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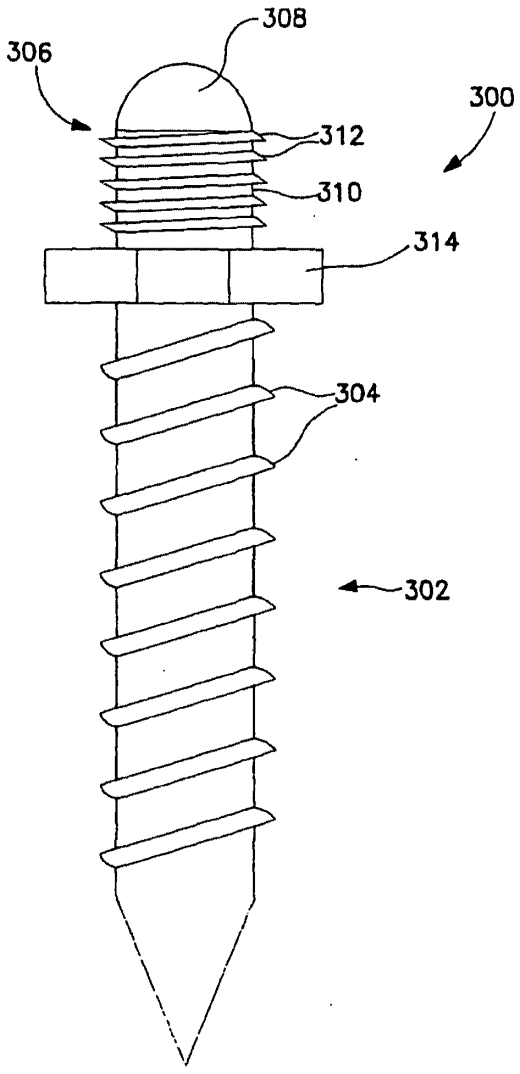


FIG. 11

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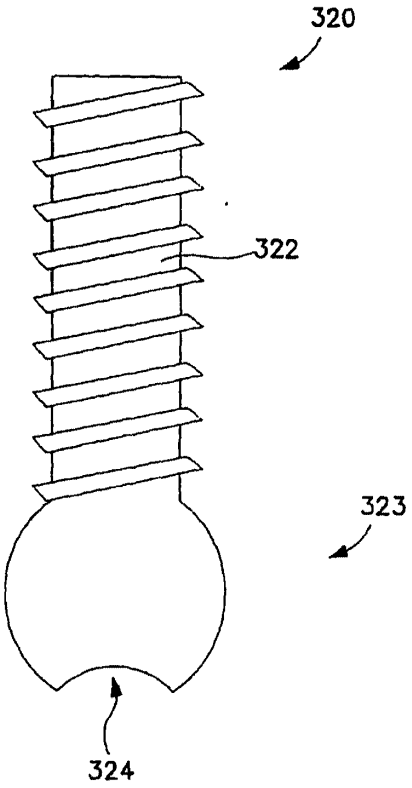


FIG. 12

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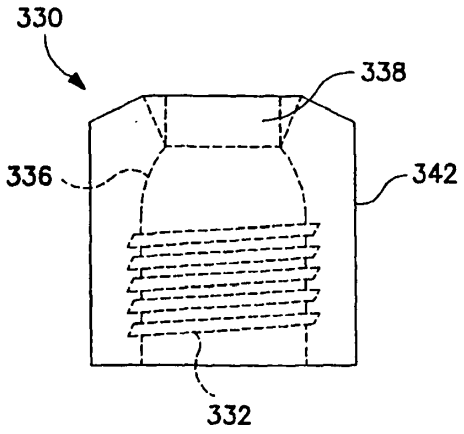


FIG. 13

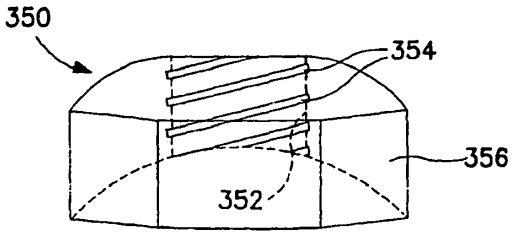


FIG. 14

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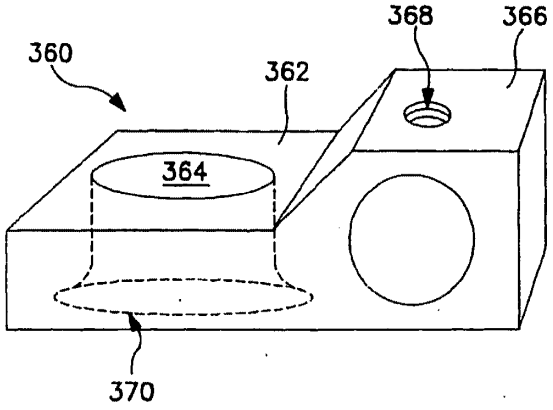


FIG. 15

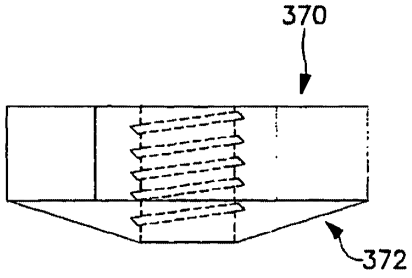


FIG. 16

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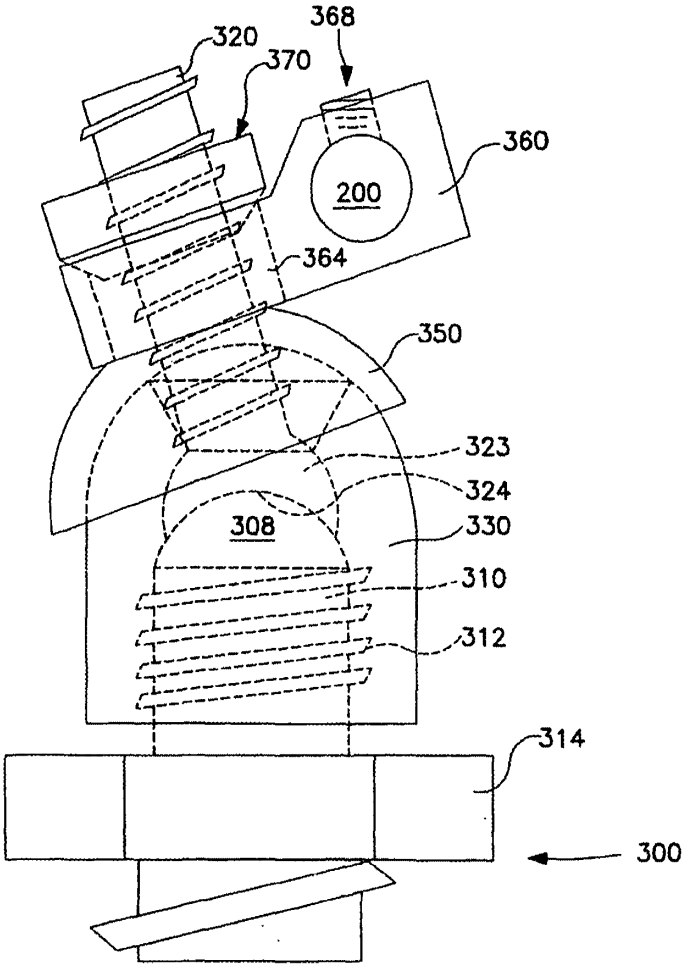


FIG. 17

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European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 05 07 7314

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.7)
X A	US 4 946 458 A (HARMS JUERGEN ET AL) 7 August 1990 (1990-08-07) * abstract; figures 1,3,4 * * column 2, line 19 - column 3, line 3 *	1-6,9, 11-14,19 20,21, 25,28,29	A61B17/70
X A	WO 96/29947 A (SMITH & NEPHEW RICHARDS INC) 3 October 1996 (1996-10-03) * abstract; figures 2-4 *	1-6,10, 13,14, 18,19 19-21, 25,28,29	
P,X	DE 195 12 709 A (REHDER GUENTHER) 10 October 1996 (1996-10-10) * abstract; figures 7,8,11,13 *	1,2,19	
A	US 5 501 684 A (HESS MARTIN ET AL) 26 March 1996 (1996-03-26) * abstract; figure 1 *	19-21, 25,28,29	
A	US 5 486 174 A (LUCET ALAIN ET AL) 23 January 1996 (1996-01-23) * abstract; figures 5,6 *	20,21, 25,28,29	TECHNICAL FIELDS SEARCHED (Int.Cl.7) A61B

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
The Hague	2 November 2005	Macaire, S

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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A : technological background
O : non-written disclosure
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T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

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EPO FORM 1503 03.82 (P04C01)

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ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO. EP 05 07 7314

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on
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For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

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10/912,532 5 August 2004 (05.08.2004) US

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(75) Inventors/Applicants *(for US only)*: **DOUBLER, Robert L.** [US/US]; 8530 Ida West Road, Ida, Michigan 48140 (US). **HAMMILL, SR., John E.** [US/US]; 290 Riverside, Rossford, Ohio 43460 (US).

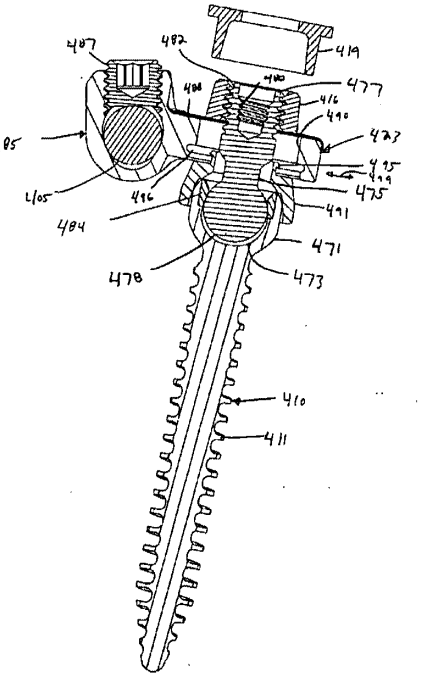
(74) Agents: **WU, Tong** et al.; 2200 Wells Fargo Center, 90 South Seventh Street, Minneapolis, Minnesota 55402-3901 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

[Continued on next page]

(54) Title: SPINAL FIXATION ASSEMBLY



(57) Abstract: This disclosure relates to spinal fixation assemblies (8, 108, 208, 308, 608) for use in spinal fixation constructs. The final fixation assemblies include fastening arrangements (16, 19; 16', 19'; 116, 119; 219; 316, 319; 419; 616, 619) for clamping components (23, 123, 223, 323, 423) of the assemblies at desired positions. The fastening arrangements are moved from pre-finally clamped orientations to finally clamped orientations through the use of linear force. An installation tool (90) can be used to inhibit linear force from being transferred to the patient.

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Published:
— *with international search report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

SPINAL FIXATION ASSEMBLY

Technical Field

The principles disclosed herein relate to bone stabilization systems. More specifically, the disclosure relates to intervertebral connection systems suited for stabilization of the spine.

Background

Chronic back problems cause pain and disability for a large segment of the population. In many cases, the chronic back problems are caused by intervertebral disc disease and deterioration and loss of stability of the intervertebral joint. Examples of these spinal conditions include degenerative disc disease, scoliosis, spondylolithesis, spinal stenosis, etc. Stabilization and/or arthrodesis of the intervertebral joint can reduce the pain associated with movement of a diseased or deteriorated intervertebral joint. In order to allow for development of a solid intervertebral fusion, the spine has to be stabilized.

Spinal stabilization systems have been developed to stabilize the vertebrae to allow for fusion or stabilization of diseased intervertebral joints. One type of spinal stabilization system includes connectors and rods that are used to stabilize the spine. Some examples of such spinal stabilization systems are disclosed in U.S. Patent Nos. 6,613,050 B1; 6,371,957 B1; 6,050,997; 5,879,350; 5,725,527; 5,628,740; 5,545,165, the entire disclosures of which are incorporated herein by reference. In these systems, connectors are anchored to the vertebral bodies desired to be stabilized by anchoring structures such as screws or hooks. One or more connecting rods are then secured to the connectors to form a connector/rod construct that stabilizes the vertebral bodies to which the connectors are secured.

In many known stabilization systems, threaded nuts are used to secure the rods to the connectors. The rods can be provisionally held in position by loosely tightening the nuts on the connectors. After desired adjustments are made with respect to the relative positioning of the bones desired to be stabilized, the nuts can be further tightened to finally secure the connector/rod construct. Typically, a torque wrench or similar device is used to achieve the required torques to finally secure the connector/rod construct. To prevent torque from being transferred to the patient while tightening the nut, an anti-torque device is frequently used in combination with the torque wrench. The effective use of the torque wrench and anti-torque device can be difficult and often is dependent upon the strength and experience of the surgeon. What are needed are alternative spine stabilization fastening techniques that do not require the use torque.

Summary

One inventive aspect of the disclosure relates to spine stabilization techniques and systems that do not require torque for final tightening.

A variety of additional inventive aspects will be set forth in the description that follows. The inventive aspects can relate to individual features and combinations of features. It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory only and are not restrictive of the broad inventive concepts upon which the embodiments disclosed herein are based.

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Brief Description of the Drawings

Figure 1 is a cross-sectional view illustrating a spinal fixation assembly having features that are examples of inventive aspects in accordance with the principles of the present disclosure, the assembly is shown in a non-finally clamped orientation;

Figure 1A is an enlarged detailed view of a portion of Figure 1;

Figure 2 is a cross-sectional view illustrating the spinal fixation assembly of Figure 1 in a finally clamped orientation;

Figure 2A is an enlarged detailed view of a portion of Figure 2;

Figure 3 is a perspective view of tool adapted for use in moving the spinal fixation assembly of Figures 1 and 2 from the non-finally clamped orientation to the finally clamped orientation;

Figure 4 is a perspective view of a bone anchor that is part of the spinal fixation assembly of Figures 1 and 2;

Figure 5 is a perspective view of a split ring that is part of the spinal fixation assembly of Figures 1 and 2;

Figure 6 is a perspective view of a compression ring that is part of the fixation assembly of Figures 1 and 2;

Figure 7 is a perspective view of a connector plate that is part of the fixation assembly of Figures 1 and 2;

Figure 8 is a plan view of a spinal stabilization construct incorporating fixation assemblies of the type depicted in Figures 1 and 2;

Figure 9 is a perspective view of an alternative compression ring adapted for use with the fixation assembly of Figures 1 and 2;

Figure 10 is a cross-sectional view illustrating a second embodiment of a spinal fixation assembly having features that are examples of inventive aspects in accordance with the principles of the present disclosure;

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Figure 11 is an exploded, perspective view illustrating a third embodiment of a spinal fixation assembly having features that are examples of inventive aspects in accordance with the principles of the present disclosure;

Figure 12 is a cross-sectional view of the spinal fixation assembly of Figure 11 showing the assembly in a non-finally clamped orientation;

Figure 13 is a cross-sectional view of the spinal fixation assembly of Figure 11 showing the assembly in a finally clamped orientation;

Figure 14 is a cross-sectional view illustrating a fourth embodiment of a spinal fixation assembly having features that are examples of inventive aspects in accordance with the principles of the present disclosure, the assembly is shown in a non-finally clamped orientation;

Figure 15 is a cross-sectional view showing the fixation assembly of Figure 14 in a finally clamped orientation;

Figure 16 is a perspective view of a bone stabilization construct including a fifth embodiment of a spinal fixation assembly having features that are examples of inventive aspects in accordance with the principles of the present disclosure;

Figure 17 is a perspective view of one of the spinal fixation assemblies of Figure 16 in isolation from the remainder of the construct;

Figure 18 is a cross-sectional view of the assembly of Figure 17 showing the assembly in a pre-finally clamped orientation;

Figure 19 is a cross-sectional view of the assembly of Figure 17 showing the assembly in a finally clamped orientation;

Figure 20 is a perspective view of a sixth embodiment of a spinal fixation assembly having features that are examples of inventive aspects in accordance with the principles of the present disclosure;

Figure 21 is a cross-section view taken along section line 21-21 of Figure 20 in which the spinal fixation assembly is shown in a finally clamped orientation;

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Figure 22 is a cross-section view of the spinal fixation assembly of Figure 21 in a non-finally clamped orientation;

Figure 23 is a perspective view of a split member of the spinal fixation assembly of Figure 21;

Figure 24 is a perspective view of an expansion plug of the spinal fixation assembly of Figure 21;

Figure 25 is an assembled, perspective view illustrating a seventh embodiment of a spinal fixation assembly having features that are examples of inventive aspects in accordance with the principles of the present disclosure;

Figure 26 is an exploded, perspective view of the spinal fixation assembly of Figure 25;

Figure 27 is an exploded, front view of the spinal fixation assembly of Figure 25;

Figure 28 is a cross-sectional view of the spinal fixation assembly of Figure 25 showing the assembly in a non-finally clamped orientation; and

Figure 29 is a cross-sectional view of the spinal fixation assembly of Figure 25 showing the assembly in a finally clamped orientation.

Detailed Description

Figures 1 and 2 show a bone fixation assembly 8 having features that are examples of inventive aspects in accordance with the principles of the present disclosure. The bone fixation assembly 8 includes a bone implant 10 adapted to be secured to a bone such as a vertebral body. The bone fixation assembly 8 also includes a connector 23 such as a plate, rod or other structure adapted for linking two or more bone implants together to form a stabilizing construct. The connector 23 is secured to the bone implant 10 by a split ring 16 or sleeve. A compression ring 19 or sleeve is adapted to be slid linearly over the exterior of the split ring 16 to compress the split ring 16 radially inwardly from a pre-clamped position (shown in Fig. 1) to a final clamped orientation (shown in Fig. 2). In the final clamped orientation, the connector 23 is compressed between the split ring 16

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and the bone implant 10 to limit or resist movement of the connector 23. An instrument 90 (shown in Fig. 3) can be used to minimize the amount of linear force that is applied to the patient when the compression ring 19 is slid over the split ring 16. The instrument 90 is capable of applying a downward force (see arrow b in Figure 1) to the compression ring 19 and simultaneously applying an opposite reactionary force (see arrow a in Figure 1) to the bone implant 10.

Referring now to Figure 4, the bone implant 10 of the assembly 8 includes a bone contacting element 11 (e.g., a pedicle screw, hook, anchor or other structure adapted to be secured to a bone), a collar 12 and a hollow shank 13. The hollow shank 13 includes interior threads 14 and exterior threads 15.

Referring to Figure 5, the split ring 16 of the assembly 8 includes internal threads 17 that allow the split ring 16 to be threaded over the external threads 15 of the hollow shank 13. An external surface 18 of the split ring 16 is tapered. For example, as shown in Figures 1 and 5, the split ring has a truncated conical shape with a first end 32 of the split ring 16 defining a minor exterior diameter and a second end 34 of the split ring 16 defining a major exterior diameter. The split ring 16 also defines a split or gap 31 that preferably extends completely through the split ring 16 from the first end 32 to the second end 34.

Referring to Figure 6, the compression ring 19 of the fixation assembly 8 has a tapered interior surface 20 that is complimentary to the exterior taper of the split ring 16. In one embodiment, the tapers can comprise Morse Tapers or other type of retaining tapers for retaining the compression ring 19 on the split ring 16 once the compression ring 19 has been inserted over the split ring 16. The compression ring 19 also has a flange 21 about the upper edge. The flange 21 has lugs 22 formed in a C-shape for engaging an extractor (not shown) used to remove, or disconnect the compression ring 19 from the split ring 16.

The connector 23 of the fixation assembly represents any ancillary apparatus, which would be held in place by the implant 10. As shown in Figure 7, the connector 23 has an aperture 24 that accommodates the shank 13 and secures the

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connector 23 to the implant 10. The connector 23 rests on the collar 12 of the implant 10. In certain embodiments, the connector could be a component of a set of spinal rods or spinal plates.

Referring to Figure 3, the driver instrument 90 is depicted having a pistol grip 93, a power source 94 and concentric pistons 91 and 92. Piston 92 is sized to grip a compression rod 25 (shown in Figure 1) having external threads 26 and an elongated extension 27. The external threads 26 are threaded within the internal threads 14 defined within the hollow shank 13 of the bone implant 10. Piston 91 is sized to seat on the compression ring 19. In use, piston 91 applies a downward force (indicated by arrow b in Figure 1) on the compression ring 19, while the piston 92 applies a reactionary force (indicated by arrow a in Figure 1) to the compression rod 25. The forces a and b are in opposite directions and are preferably balanced against one another such that minimal force is applied to the patient. The rod 25 can be configured to break at the limit of optimum pressure. Alternatively, the instrument 90 may have a gauge for setting the desired pressure.

Referring to Figure 1A, the interior threads 17 of the split ring 16 include ramp surfaces 17R that face upwardly and oppose corresponding ramp surfaces 15R defined by the exterior threads 15 of the shank 13. When the split ring 16 is hand-tightened down on the shank 13 into snug engagement with the connector 23, the split ring 16 is forced upwardly relative to the shank 13 such that the ramp surfaces 17R of the split ring 16 are moved into contact with the ramp surfaces 15R of the shank 13 as shown in Figure 1A. When the compression ring 19 is inserted over the split ring 16 while the split ring is in the hand-tightened orientation of Figure 1A, the relative tapers of the split ring 16 and the compression ring 19 cause the split ring 16 to be compressed radially inwardly. As the split ring 16 is compressed radially inwardly, the diameter of the split ring 16 reduces and a gap g between the exterior threads 15 of the shank 13 and the interior threads 17 of the split ring 16 closes. As the gap g closes, the ramp surfaces 15R of the shank 13 ride upwardly over the ramp surfaces 17R of the split ring 16 causing the shank 13 to be placed in tension (i.e., stretched) and the lower end 34 of the split ring 16 to be compressed securely against the connector 23. Figure 2A shows the fixation

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assembly after the compression ring 19 has been fully inserted over the split ring 16 and the gap g substantially closed. When in the final clamped position of Figures 2 and 2A, the split ring 16 applies an axial load to the connector 23, generated by the tension in the shank 13, which resists movement of the connector 23. Additionally, the compression ring 19 is in radial tension causing the split ring 16 to continue to apply a radial compressive load to the shank 13 which generates friction that resists back rotation of the split ring 16 that could cause loosening of the split ring 16. In other words, once the compression ring 19 is inserted over the split ring 16, the compression ring 19 is tensionally loaded so as to maintain an inwardly directed radial compressive force, resulting in a connection that is resistant to undesired loosening.

The fixation assembly preferably includes a first structure (e.g., the tapered interface between the interior of the compression ring 19 and the exterior of the split ring 16) that converts linear force from the linear driver 90 into radial force applied to the split ring 16. The fixation assembly also preferably includes a second structure (e.g., the engaging ramp surfaces that provide an interface between the interior of the split ring 16 and the exterior of the shank 13) that converts radial force back into linear/axial force that is used to clamp the connector 23 between the split ring 16 and the collar 12.

It will be appreciated that the bone implant 10, the connector 23, the compression sleeve 19 and the split ring 16 are preferably made of a biocompatible material. A preferred material includes a metal material such as titanium. Other example materials include nitinol, stainless steel, thermal plastic polymers, thermal set polymers as well as other materials.

It is preferred for the split ring 16 to apply an axial compressive load to the plate 23 that is sufficiently large to substantially resist movement of the connector 23 relative to the bone implant 10. In one embodiment, when the compression ring 19 is compressed over the split ring 16, the split ring generates an axial load on the connector 23 that is comparable to tightening the split ring 16 with at least 20 inch pounds of torque. In another embodiment, the split ring 16 generates a compressive load

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comparable to that generated by tightening the split ring 16 with at least 50 inch pounds of torque. In still another embodiment, the split ring 16 generates an axial load comparable to tightening the split ring 16 with at least 100 inch pounds of torque.

It will be appreciated that the compressive load generated by the split ring is dependent upon a number of factors. Example factors include the depth of the intermeshing threads and the distance of the gap g, the angles of the ramp surfaces, and the materials used to make the bone implant 10 and the split ring 16. In one non-limiting embodiment, the gap g is at least .005 inches. In another non-limiting embodiment, the gap g is at least .01 inches. In a further non-limiting embodiment, the gap is at least .015 inches. In still another non-limiting embodiment, the gap is at least .02 inches.

Figure 8 shows a spine stabilization construct incorporating a plurality of the bone implants 10. The construct is shown being used in a single level spinal stabilization procedure. In conducting the procedure, the bone implants 10 are secured to vertebral bodies 99a and 99b. Connectors 23 are then mounted to the bone implants 10. As shown in Figure 7, the connectors 23 are positioned on opposite sides of the patient's sagittal plane and extend across a space between the vertebral bodies 99a, 99b. After placement of the connectors 23, the surgeon can loosely thread the split rings 16 on the shanks 13 of the bone implants 10 such that the connectors 23 are provisionally retained in place. In one embodiment, the split rings 16 are finger tightened on the threaded shanks 13. In another embodiment, a torque wrench can be used to loosely tighten the split rings 16 to a provisionally tightened position. For example, in one embodiment, a torque wrench can be used to apply about 2 inch pounds of torque to the split ring 16.

After provisional tightening of the construct, the surgeon can adjust the relative positioning of the vertebral bodies 99a, 99b, to achieve a desired relative positioning. For example, the vertebral bodies 99a, 99b may be compressed together, distracted apart or moved laterally relative to one another. During distraction or compression, the connectors 23 can move relative to the anchors 10 to accommodate the adjustment and relative positioning of the vertebral bodies 99a, 99b. Once a desired spatial relationship between the vertebral bodies 99a, 99b is achieved, the connectors 23

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are finally locked or clamped relative the anchors 10 through the use of the compression rings 19. For example, the tool 90 can be used to force the compression rings 19 over the exterior of the split rings 16. When the split rings 16 are compressed by the compression rings 19, the split rings 16 are caused to finally clamp the connectors 23 in position relative to the anchors 10 by axially compressing the connectors 23 between the split rings 16 and the collars 12 of the implants 10. The use of the tool 90 to linearly slide the compression rings 19 over the split rings 16 allows the construct to be finally tightened without requiring torque and without having substantial amounts of linear force transferred to the patient. While Figure 8 shows a single level spinal stabilization procedure, it will be appreciated that constructs in accordance with the principles of the present disclosure can be used in multi-level procedures as well as other types of stabilization procedures.

In the event that the construct must be disassembled, removal instruments similar to the driver instrument 90 may be employed. The removal instrument would include a piston having a flange with flat lugs. The instrument would be placed over the compression ring and turned to engage the flat lugs. Once the flat lugs are engaged, an upward force can be applied to the compression ring to remove it from the split ring 16. Simultaneously, an inner piston would apply a downward force to the shank 13 of the bone anchor 10 such that minimal net force is transferred to the patient. Once the compression rings 19 are removed, the split rings 16 can be manually unthreaded from the shanks 13 to allow the construct to be disassembled.

Referring to Figure 9, an alternative split ring 16' adapted for use with the bone anchor 10 is depicted. The split ring 16' is internally threaded and includes an external surface that is conically tapered and defines a minor exterior diameter at a first end 32' and a major exterior diameter at a second end 34'. A radial flange 35 is provided at the second end 34'. The flange 35 may function as a flared base suitable to distribute clamping forces over a wide area or to provide a bearing surface for resisting relative rotation of adjacent components. The split ring 16' further includes a plurality of partial slots 37 that extend only partially through the split ring 16' between the first and second ends 32' and 34', and one full slot 31'.

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Figure 10 shows an alternative fixation assembly 108 having a bone anchor 110, a connector 123, a split ring 116 and a compression ring 119. The fixation assembly 108 has the same configuration as the fixation assembly 8, except the bone anchor 110 has been modified to provide a different interface for providing a connection with a linear driver tool. Specifically, rather than providing an internal bore within a shank 113 of the bone anchor 110, the bone anchor includes an enlarged tip 124 or projection constructed and arranged to be grasped by a linear driver tool 90'. The driver tool 90' includes an interior driver member 91' that grasps the tip 124 and an outer driver member 92' adapted to push downwardly on the compression sleeve 119. In use, the outer driver member 92' pushes downwardly on the compression sleeve 19 while the interior driver member 91' applies an opposite force to the shank of the bone implant 10 such that the net linear force transferred to the patient is minimal.

Figures 11-13 illustrate an alternative fixation assembly 208 having features that are examples of inventive aspects in accordance with the principles of the present disclosure. The fixation assembly 208 operates in a manner similar to the fixation assembly 8 of Figures 1 and 2, and includes a bone anchor 210, a connector 223, a split ring 216 and a compression ring 219. The assembly 208 is substantially the same as the fixation assembly 8, except the interface between the split ring 216 and the exterior surface of the shank 213 of the bone implant 210 has been modified. For example, rather than having intermating threads, the fixation assembly 208 includes non-threaded ramp surfaces that ramp against one another when the assembly is finally clamped.

Referring to Figure 12, the shank 213 of the bone implant 210 includes a downwardly facing ramp surface 215 located adjacent to a head 250 of the shank 213. The ramp surface 215 cooperates with an upwardly facing ramp surface 217 provided at the top end of the split ring 216. When the compression ring 219 is linearly slid axially over the exterior of the split ring 216, the split ring 216 is compressed radially inwardly (as shown in Figure 13) causing the ramp surface 215 of the shank to ride over the ramp surface 217 of the split sleeve 216. The interaction of the ramp surfaces converts radial force applied by the compression ring 219 into a linearly/axially directed force which causes the shank 213 to be placed in tension and the split ring 216 to be compressed

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firmly against the connector 223 such that the connector 223 is finally clamped in place relative to the bone implant 210. Figure 12 shows the fixation assembly prior to sliding the compression ring into the finally clamped orientation. Figure 13 shows the fixation assembly in the finally clamped orientation. A tool that limits or eliminates the linear force transferred to the patient can be used to force the compression ring 219 over the split sleeve 216.

Figures 14 and 15 show still another embodiment of a fixation assembly 308 having features that are examples of inventive aspects in accordance with the principles of the present disclosure. The fixation assembly 308 has the same basic components and operates under the same principles as the fixation assembly 8 of Figures 1 and 2. For example, similar to the fixation assembly of Figures 1 and 2, the fixation assembly includes a bone implant 310, a connector 323, a split ring 316 and a compression ring 319. The bone implant includes an anchor (e.g., a pedicle screw, hook, rivet, or other structure), a shoulder 312 and a shank 313 having internal and external threads. The split ring 316 has internal threads that mate with the external threads of the shank 313. However, the embodiment of Figs 14 and 15 has been modified to include a different interface between the interior surface of the compression ring 319 and the exterior surface of the split ring 316. For example, the split ring 316 includes a plurality of circumferential ribs 359 that project outwardly from the exterior of the split ring 316. The ribs 359 are separated by recesses 360. Upper and lower sides of the ribs 359 are ramped. The compression ring 319 has inwardly projecting ribs 361 separated by recesses 363. The top and bottom sides of the ribs 361 are also ramped.

Figure 14 shows the fixation assembly in a pre-clamped orientation. In this orientation, the ribs 361 of the compression ring 319 fit within the recesses 360 of the split ring 316. In this configuration, a gap exists between the interior threads of the split ring 316 and the exterior threads of the shank 313. When the compression ring 319 is forced down relative to the split ring 316 (e.g., with tool 90), the ribs 361 of the compression ring 319 ramp on to the ridges 359 of the split ring 316 causing the split ring to be compressed radially inwardly as shown in Figure 15. As the split ring 316 is compressed radially inwardly, the outer threads of the shank 313 ramp up on the inner

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threads of the split ring 316 causing the shank 313 to be tensioned and also causing the split ring 316 to be compressed axially against the connector 323 such that the connector is locked in a final position relative to the bone implant 310.

The rib configuration of Figures 14 and 15 allow the split ring 316 and the compression sleeve 319 to be interconnected when in the pre-clamped orientation to minimize the number of loose parts. Also, the ribs allow the amount of compression generated by the linear movement of the compression sleeve 319 relative to the split ring 316 to be precisely controlled by controlling the ramp angles of the ribs as well as the distance the ribs project outwardly from the split ring 316. This configuration allows a relatively large amount of compressive force to be generated in a relatively small range of linear movement.

Figure 16 illustrates a further spine stabilization construct having inventive aspects in accordance with the principles of the present disclosure. The construct includes a pair of rods 405 adapted to be positioned on opposite sides of a patient's sagittal plane. The rods are interconnected by a transverse connector 470. The construct also includes a plurality of vertebral implants 410. The vertebral implants 410 are linked to the rods 405 by connectors 423. The connectors 423 include first ends 425 clamped to the rods 405 and second ends 427 clamped to the vertebral implants 410. The connectors 423 are depicted as left offset connectors 423L, right offset connectors 423R, and straight connectors 423S. The vertebral implants 410 are clamped to the connectors 423 through the use of fasteners that utilize linear force for final tightening. Further details regarding the connectors 423 can be found in U.S. Patent No. 6,050,997, which is hereby incorporated by reference in its entirety.

Referring to Figures 17-19, one of the vertebral implants 410 and its corresponding connector 423 are shown in isolation from the remainder of the construct. The vertebral implant 410 is depicted including a pedicle screw 411 having a rounded head 471. A socket 473 is defined within the head 471. The implant 410 also includes a bolt 475 having a first end 477 positioned opposite from a second end 478. The first end 477 of the bolt 475 includes inner threads 480 and outer threads 482. The second end

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478 of the bolt 475 includes a rounded head that pivotally mounts within the socket 473 of the screw 411 to allow for polyaxial adjustment of the bone screw 411 relative to the bolt 475. The head of the bolt 475 is retained within the socket 473 by a retainer 484. Retainer 484 can be a ring fixedly connected to the head of the screw 411 by a conventional technique such as welding. Alternatively, the retainer 484 can be a split ring that is snap-fit within the socket 473, or can be threaded within the socket 473 or otherwise connected to the head 471 of the bone screw.

The connector 423 includes a rod coupler 485 including a receptacle 486 for receiving one of the rods 405. The rod 405 is clamped within the rod coupler 485 by a set screw 487. The connector 423 also includes an extension plate 488 that projects outwardly from the coupler 485. The extension plate 488 defines an elongated through-hole 490 through which the bolt 475 extends. A collar 491 is slidably mounted to the extension plate 488 adjacent the bottom side of the through-hole 490. The collar 491 includes an upper flange 495 that fits within a groove 496 located at the bottom of the through-hole 490. The groove 496 allows the position of the collar 491 to be adjusted along the length of the through-hole 490 in a direction indicated by arrow 499. The collar 491 has an interior surface that is curved to generally match the outer curvature of the head 471 of the screw 411. Prior to tightening of the toggle bolt 475, the bone screw 411 is free to pivot relative to the head of the toggle bolt 475, and also is free to pivot relative to the collar 491.

A fastener arrangement including a split ring 416 and a compression sleeve 419 is used to tighten the bolt 475 and clamp the screw 411 in position. When the split ring 416 and compression sleeve 419 are finally locked in place as shown in Figure 18, tension is applied to the bolt 475 causing the head 471 of the screw 411 to be securely clamped between the collar 491 and the head of the bolt 475 thereby resisting pivotal movement of the screw 411. The tensioned bolt 475 also functions to securely clamp the collar 491 against the underside of the extension plate 488 such that movement of the collar 491 along the length of the through-hole 490 is resisted. In one embodiment, the split ring 416 and the compression ring 419 can have the same general configuration as the split ring 16 and compression ring 19 of the embodiments of Figures 1 and 2.

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In use, the bone implants 410 are secured to vertebral bodies desired to be stabilized. The connectors 423 can then be secured to the bone implants 410 by inserting the threaded ends 471 of the bolts 475 through the through-holes 490 defined by the extension plates 488 of the connectors 423. Rods 405 can the be placed through the rod couplers 485 to link the various vertebral bodies together and form a stabilizing construct. When the desired spacing between the vertebral bodies has been established and the bone screws 411 are pivoted to desired polyaxial angles, the fasteners of the construct can be tightened down to lock the construct in a final position. For example, the set screws 487 are locked down by applying torque to the tight set screws such that the rods 405 are compressed within the rod couplers 485. The bone anchors 410 are fixed relative to the connectors 423 by first loosely threading the split rings 416 on the threaded ends 477 of the bolts 475. Preferably, the split rings 416 are finger tightened or tightened with minimal torque (e.g., 2 inch pounds) with a torque wrench so as to be placed in snug engagement with the top sides of the extension plates 488 (see Figure 18). Thereafter, the bone implants 410 are finally clamped in place relative to the connectors 423 by forcing the compression sleeves 419 over the exteriors of the split nuts 416 (see Figure 19). As the compression sleeves 419 are pushed downwardly, the split rings 416 compress radially inwardly causing their interior threads to ramp relative to the exterior threads of the bolt 475. This ramping action generates tension along the bolts 475, which causes the heads of the bone anchors 411 to be drawn tightly against the undersides of the collars 491, and the collars 491 to be compressed against the undersides of the extension plates 488. With the bolts 475 tensioned in this manner, a clamping effect is generated which resists pivotal movement of the bone screw 411 and also resists the sliding movement of the collar 491 relative to the connector 423. As described above with respect to the embodiment of Figures 1 and 2, a linear diver instrument 90 can be used to force the compression ring 419 downwardly without applying a substantial amount of linear force to the patient.

In certain embodiments, the set screw 487 of the rod coupler 485 can be replaced with a fastening arrangement that is placed in a finally locked orientation through the use of linear force. Figures 20-22 show a rod receiver/coupler 485' adapted

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for use with such a fastening arrangement. The rod coupler 485' has a main body 513 that defines a horizontal through-hole 501 for receiving a spinal stabilization rod, and a vertical fastener opening 502 that extends downwardly from a top side of the main body 513 to the horizontal through-hole 501. The fastener opening 502 includes internal threads.

The fastening arrangement includes a split member 516 (shown in Figure 23) that mounts within the fastener opening 502. The split member 516 includes external threads that mate with the internal threads of the fastener opening 502. The split member 516 is sized smaller than the fastener opening 502 such that, prior to expansion of the member 516, a gap is provided between the threads of the member 516 and the threads of the fastener opening 502. The split member 516 includes a top end 532 positioned opposite from a bottom end 534. A slit 531 extends completely through the split member 516 from the top end 532 to the bottom end 534. The split member 516 also defines an interior opening 517. Preferably, the interior opening 517 is tapered such that the interior opening 517 defines a maximum interior diameter adjacent the top end 532 of the split member 516 and a minor interior diameter located adjacent the bottom end 534 of the split member 516. The interior opening 517 can also define one or more tool engaging structures 581 adapted to interface with a tool (e.g., a wrench) for allowing torque to be applied to the split member 516.

The fastening arrangement also includes an expansion plug 519 (shown in Figure 24) adapted to fit within the interior opening 517 of the split member 516. The expansion plug 519 includes an enlarged head 583 and a tapered expansion portion 582 that projects axially outwardly from the head 583. In one embodiment, the tapered expansion portion 582 can have a taper angle that generally matches the taper angle of the interior of the split member 516.

In use of the rod coupler 485', a spinal stabilization rod is inserted through the horizontal through-hole 501. To lock the rod in place relative to the main body 513 of the rod coupler 485', the split member 516 is loosely threaded within the fastener opening 502 until the bottom end 34 of the member 516 is pressed snugly against the rod

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within the through-hole 501 as shown in Figure 22. For example, the split member 516 can be manually threaded or threaded with the assistance of a torque wrench inserted into the interior opening 517 of the split member 516. After loosely threading the split member 516 into the fastener opening 502, the assembly is locked in place by linearly inserting the expansion plug 519 into the interior of the split member 516 as shown in Figure 21. When the plug 519 is inserted into the split member 516, the split member 516 expands radially outwardly. As the split member 516 expands radially outwardly, upper ramp surfaces 516R (shown in Figure 22) defined by the threads of the split member 516 ride under lower ramp surfaces 502R (shown in Figure 22) defined by the threads within the fastener opening 502 of the main body 513 causing the split member 516 to be driven linearly downwardly against the rod.

In this embodiment, the main body 513 is tension loaded and the member 516 is compression loaded in the final clamped orientation. Preferably, the split member 516 is biased linearly downwardly with sufficient force to lock the rod relative to the main body 513 of the rod coupler 485'. An installation tool can be used to apply a downward linear force to the plug 519 and to simultaneously apply a substantially equal and opposite force to the body 513 to prevent force from being transferred to the patient as the assembly is moved to the finally clamped orientation.

Figures 25-29 illustrate another embodiment of a fixation assembly 608 for use in stabilization of the vertebrae. The embodiment shown in Figures 25-29 has a polyaxial screw locking arrangement having features similar to embodiments disclosed in U.S. Patent Nos. 5,863,293; 5,964,760; and 6,132,432, which are incorporated herein by reference in their entireties.

The embodiment of Figures 25-29 includes a receiver 613 having a rod receiving pocket 602 and an anchor receiving pocket 603. The rod receiving pocket 602 is defined between legs 605 of the receiver 613. The anchor receiving pocket 603 is adapted to house a retainer 606. A screw 611 is coupled to the retainer 606 within the pocket 603. The retainer 606 preferably includes a generally spherical cavity 670 that receives a generally spherical head 671 of the screw 611. The relative shapes of the head

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671 and the cavity 670 allow the head 671 to pivot/rotate within the retainer 606 to allow the orientation of the axis of the screw 611 to be angularly adjusted relative to the receiver 613 prior to final fixation.

The assembly also includes a final fastening arrangement including a split ring 616 and a compression ring 619. The final fastening arrangement is adapted for locking the screw 611 at a final axial position relative to the receiver 613, and for locking a rod within the rod receiving pocket 602. The retainer 606 includes flexible legs 673 that define the cavity 670. When the retainer 606 is mounted in the anchor receiving pocket 603, a top end 677 of the retainer 606 is exposed the rod receiving pocket 602 of the receiver 613. The anchor receiving pocket 603 of the receiver 613 includes a tapered internal surface 680 defining a diameter that reduces in size as the surface 680 extends downwardly away from the rod receiving pocket 602. The anchor receiving pocket 603 includes a lower opening 682 through which the retainer 606 and the head of the screw 611 can be bottom loaded into the receiver 613. To bottom load the screw 611 into the receiver 613, the retainer 606 is first inserted into the anchor receiving pocket 603 through the lower opening 682. After the retainer 606 has been inserted into the anchor receiving pocket 603, the head of the screw 611 is inserted through the lower opening 682 and snapped into the cavity 670 of the retainer 606. When the head of the screw 611 is inserted into the cavity 670, the retainer 606 expands thereby preventing the retainer 606 and the screw head from being removed from the pocket 603 without using a removal tool.

In use, the screws and receiver assemblies are anchored to bones desired to be stabilized. Rods are then inserted into the rod receiving pockets 602 of the receivers 613 to interconnect the anchored assemblies and thereby form a rod/implant construct. The rods can be provisionally retained within the pockets 602 by manually threading the split rings 616 about the exterior of the receiver 613. With the split rings 616 provisionally mounted on the legs, the polyaxial positions of the screws 611 can be adjusted relative to their corresponding receivers 613 to make final adjustments to the rod/connector construct. The positioning of the rods can also be adjusted. Once the final adjustments have been made, the split rings 616 can be further manually threaded onto

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the legs until a pre-final locking position is reached in which the rings 616 are snug against the rods (see Figure 28). Thereafter, the compression rings 619 is forced about the exteriors of the split rings 616 causing the spit rings to be forced radially inwardly (see Figure 29). As the split rings 616 are compressed radially inwardly, ramp surfaces provided by internal threads of the split rings 616 slide relative to corresponding ramp surfaces provided by external threads on the legs 605 thereby axially tensioning the legs causing the split rings 616 to be forced against the top sides of the rods to finally lock the rods in place.

When forces are applied to the top sides of the rods, the rods also press downwardly on the retainers 606 to lock the angular position of the bone screws 611. In other embodiments, rather than directly engaging the top sides of the rods, radial compression of the split ring may cause the legs 605 to be flexed together to clamp the rod in place and also to force the rod slightly downwardly to compress the retainer into the locked position.

The embodiments disclosed herein are all depicted including anchors in the form of screws. It will be appreciated that other anchors such as pins, hooks, rivets or other structures could also be used.

The embodiments disclosed herein include various components such as receivers, anchors, sleeves, split rings, compression rings, connectors and other components. It will be appreciated that these components can be manufactured from different types of materials. A preferred material includes titanium. Other example material include nitinol, stainless steel, thermal plastic polymers, thermal set polymers as well as other materials.

As used herein, the term "connector" is used to define members of a construct used to interconnect bone anchors. Example connectors include rods, plates or other members.

From the forgoing detailed description, it will be evident that modifications and variations can be made in the devices of the invention without departing from the spirit or scope of the invention. Therefore, it is intended that all

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modifications and variations not departing from the spirit of the invention come within the scope of the claims and their equivalents.

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We Claim:

1. A method for clamping a component of a spinal stabilization construct comprising:

applying a linear force to the construct;

converting the linear force to a radial force; and

converting the radial force back to a linear force which causes the component of the spinal stabilization construct to be clamped in position.

2. The method of claim 1, wherein the linear force is converted to a radial force by sliding tapered surfaces against one another.

3. The method of claim 1, wherein the radial force is converted back into a linear force by sliding ramp surfaces against one another.

4. The method of claim 1, wherein the ramp surfaces are defined by threads.

5. The method of claim 1, wherein the component is a spinal rod.

6. The method of claim 1, wherein the component is a spinal plate.

7. The method of claim 1, wherein the component is a connector.

8. The method of claim 1, wherein the spinal stabilization construct includes a compression sleeve, a tensioning structure and a split ring mounted on the tensioning

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structure, wherein the split ring and the tensioning structure include ramp surfaces, and wherein the initial linear force is applied to the compression sleeve, which radially compresses the split ring causing the ramp surfaces to engage one another such that the tensioning structure is placed in tension and the split ring is compressed against the component to clamp the component in position.

9. The method of claim 8, wherein the tensioning structure includes a shank, and the component comprises a plate.

10. The method of claim 9, wherein the split ring is internally threaded and the shank is externally threaded, and wherein the ramp surfaces are defined by the threads of the shank and the split ring.

11. The method of claim 9, wherein the ramp surfaces are defined by non-threaded ramps provided at an interface between the shank and the split ring.

12. The method of claim 8, wherein the tensioning structure includes legs of a rod receiver, and the component includes a rod received between the legs.

13. The method of claim 12, wherein the split ring is internally threaded and the legs are externally threaded, and wherein the ramp surfaces are defined by the threads of the legs and the split ring.

14. The method of claim 1, wherein the spinal stabilization construct includes an expansion member, a tensioning structure and a split member mounted within the tensioning structure, wherein the split member and the tensioning structure include ramp surfaces, and wherein the initial linear force is applied to the expansion member, which

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radially expands the split member causing the ramp surfaces to engage one another such that the tensioning structure is placed in tension and the split member is compressed against the component to clamp the component in position.

15. The method of claim 14, wherein the tensioning structure includes a rod receiver, and wherein the component includes a rod received within the rod receiver.

16. The method of claim 15, wherein the ramp surfaces are defined by threads located at an interface between the rod receiver and the split member.

17. The method of claim 1, further comprising applying an oppositely directed linear force to the construct to minimize a net linear force that is transferred to the patient.

18. A method for clamping a connector of a spinal stabilization assembly, the stabilization assembly including a bone anchor, a tensioning structure coupled to the bone anchor, a split ring that mounts over the tensioning structure with ramps provided at an interface between the split ring and the tensioning structure, and a compression ring, the method comprising:

securing the bone anchor to a vertebral body;

mounting the split ring over the tensioning structure with the connector positioned in a region located between the split ring and the bone anchor; and

linearly sliding the compression ring over the split ring causing the split ring to compress which in turn causes the ramps engage one another such that tension is applied to the tensioning structure, wherein the connector is clamped in position when the tensioning structure is tensioned.

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19. The method of claim 18, wherein the connector includes a plate.

20. The method of claim 18, wherein the connector includes a rod.

21. The method of claim 18, wherein the tensioning structure includes a shank.

22. The method of claim 18, wherein the tensioning structure includes legs of a rod receiver.

23. The method of claim 18, wherein the ramps are defined by threads.

24. A spinal fixation assembly comprising:

a connector including a rod coupler and an extension plate that projects outwardly from the rod coupler, the extension plate defining a through-hole;

a collar positioned at an underside of the extension plate;

a bone screw including a head defining a socket, the head of the bone screw being mounted at least partially within an underside of the collar;

a fastener including a head that mounts within the socket of the bone screw, and a shank that extends through the collar and the through-hole of the extension plate;

a split ring that mounts on the threaded shank; and

a compression ring that is linearly forced over the exterior of the split ring to compress the split ring relative to the shank.

25. The assembly of claim 24, wherein the shank is externally threaded and the split ring is internally threaded.

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26. The assembly of claim 24, wherein the split ring defines at least one slit that extends completely through the split ring.

27. The assembly of claim 24, wherein ramp structures are provided at an interface between the shank and the split ring.

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FIG. 1

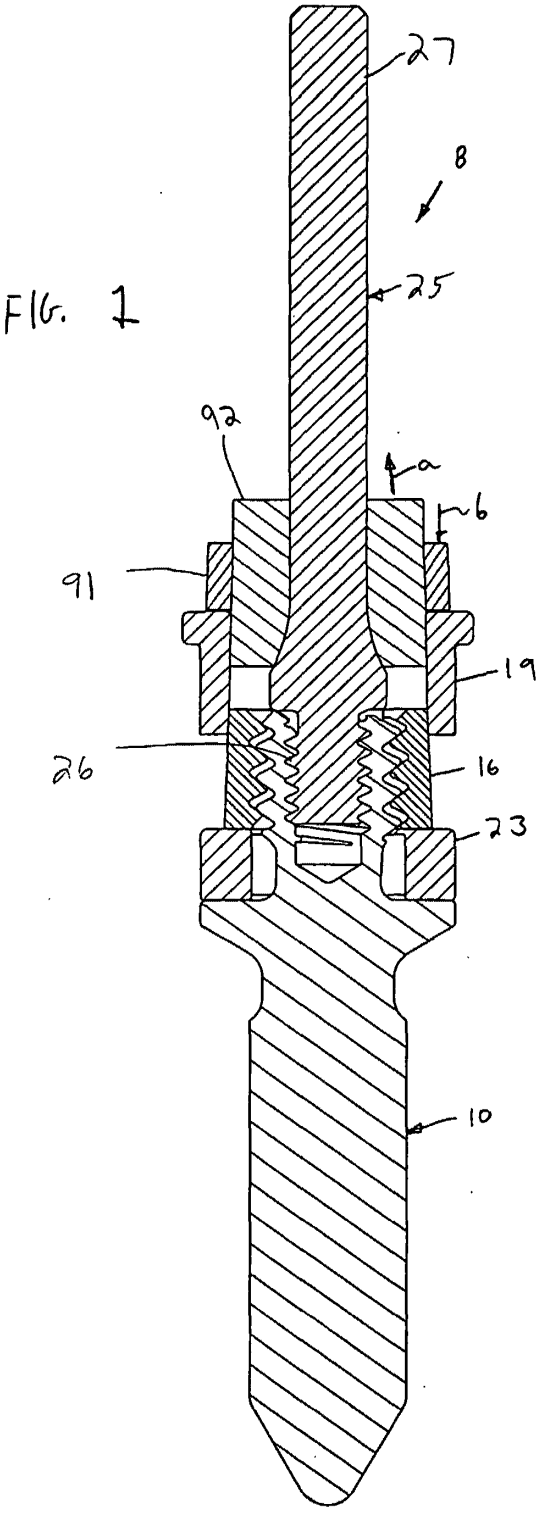


FIG. 2

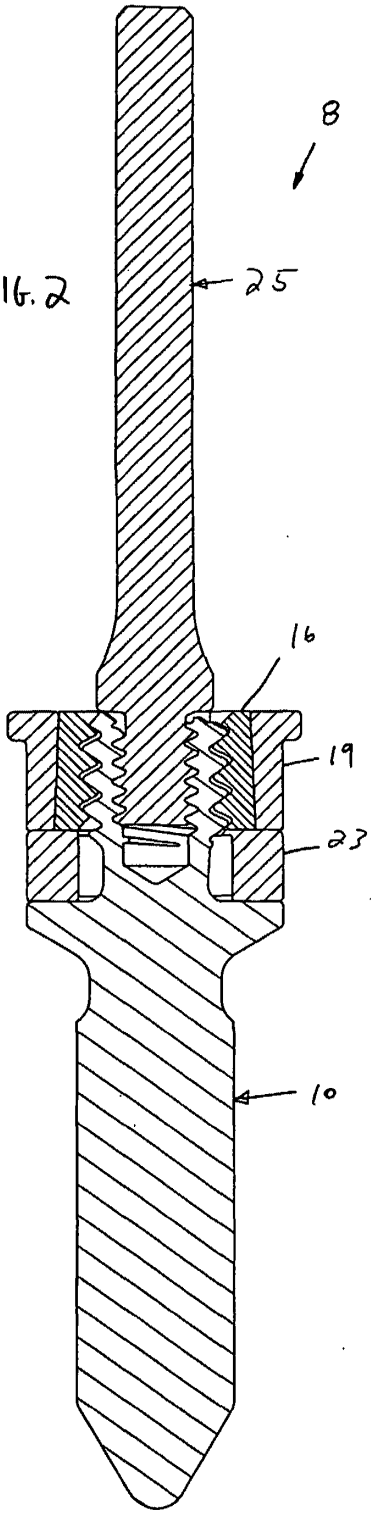


FIG. 1A

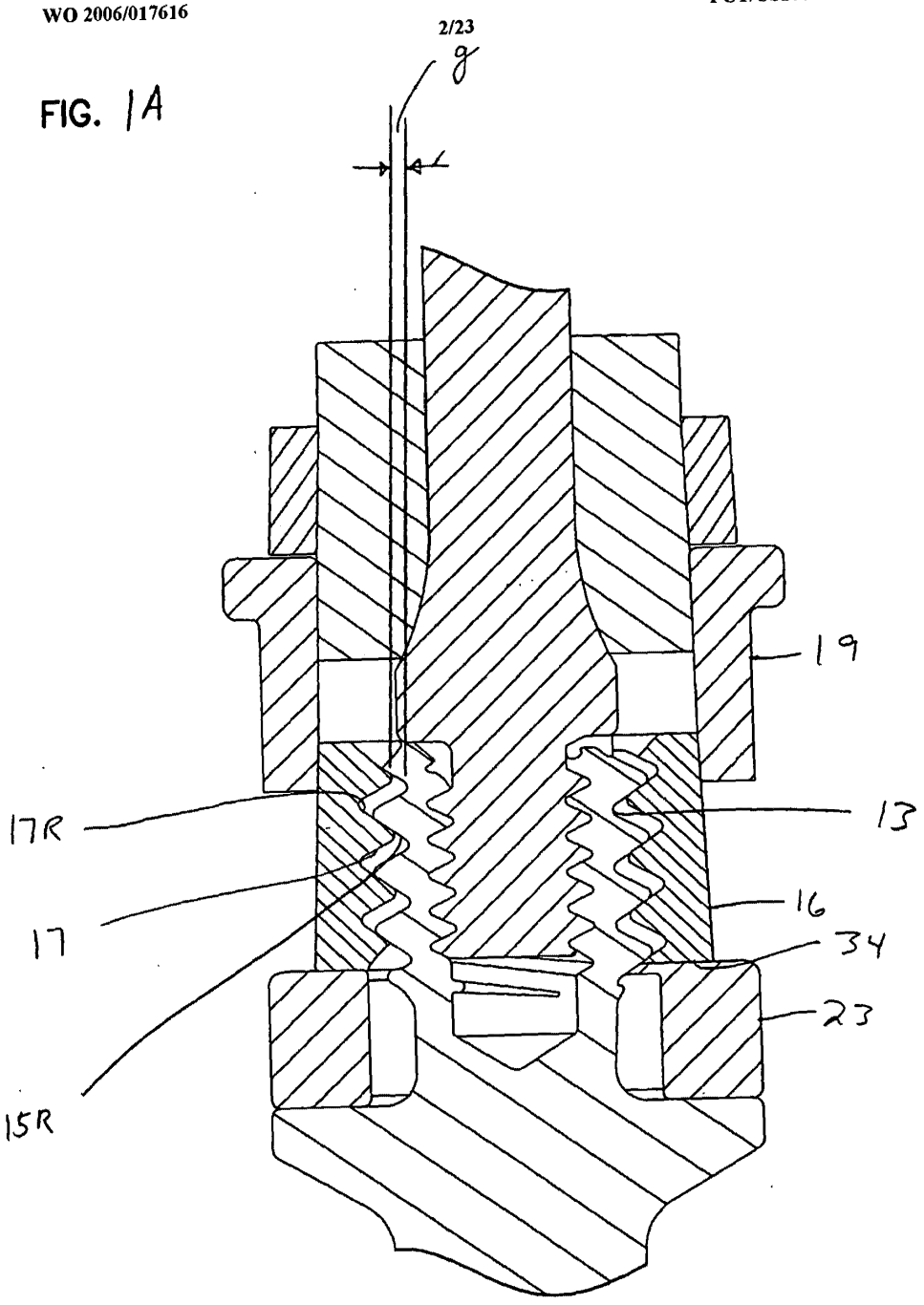
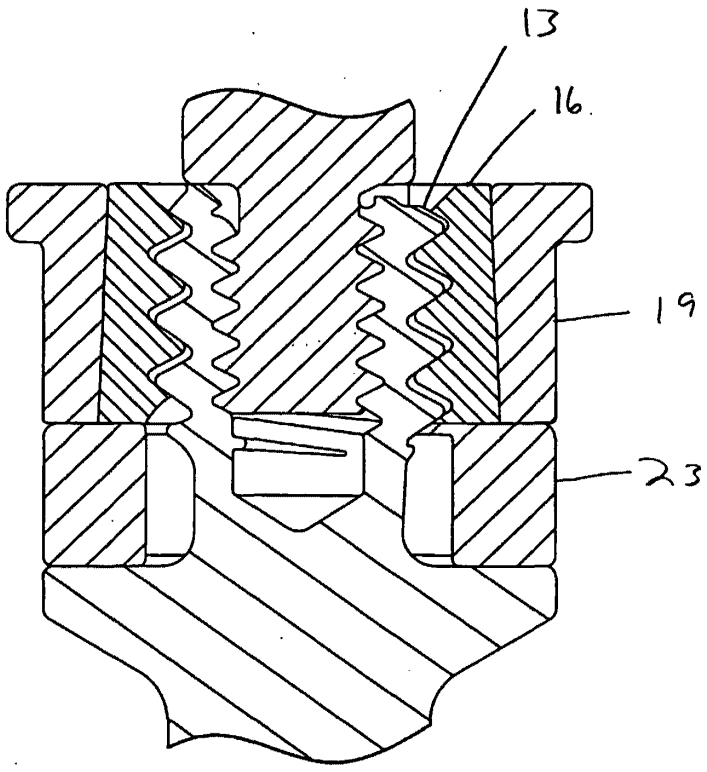


FIG. 2A



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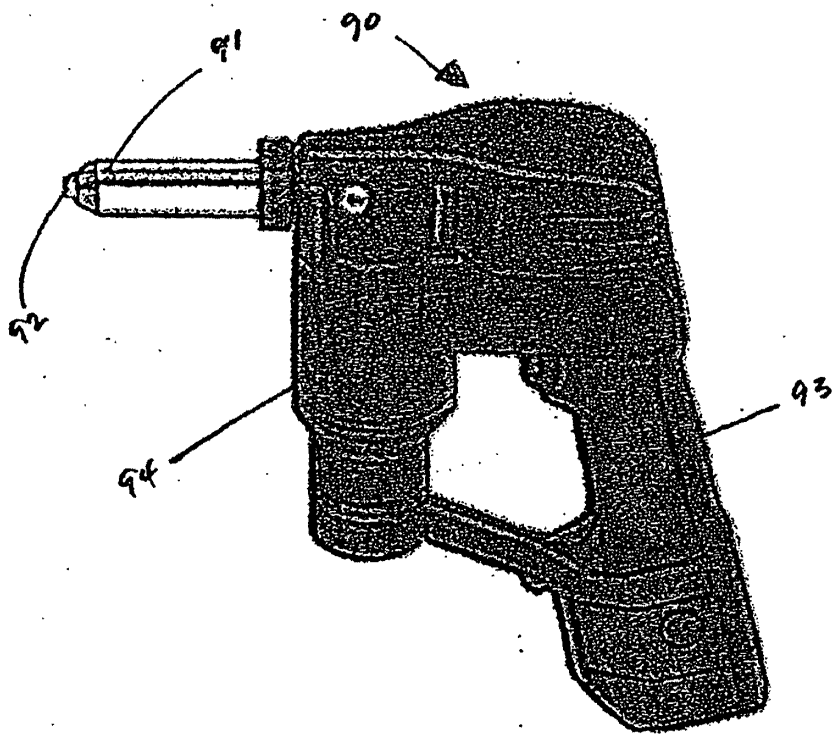


FIG. 3

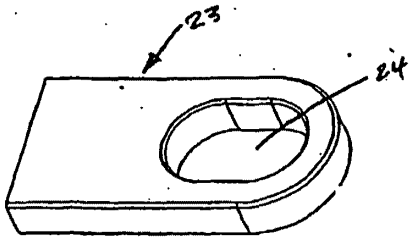


FIG. 7

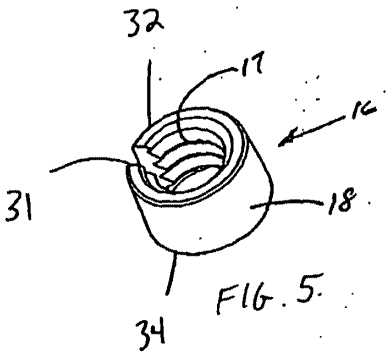


FIG. 5

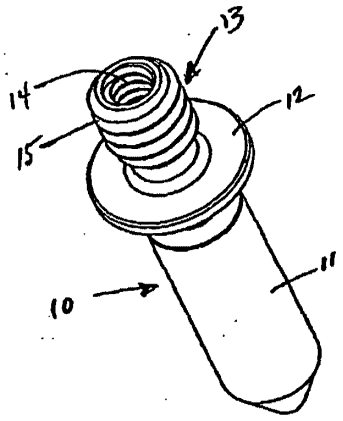


FIG. 4

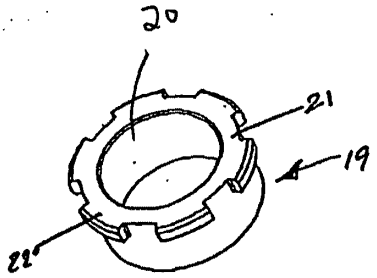
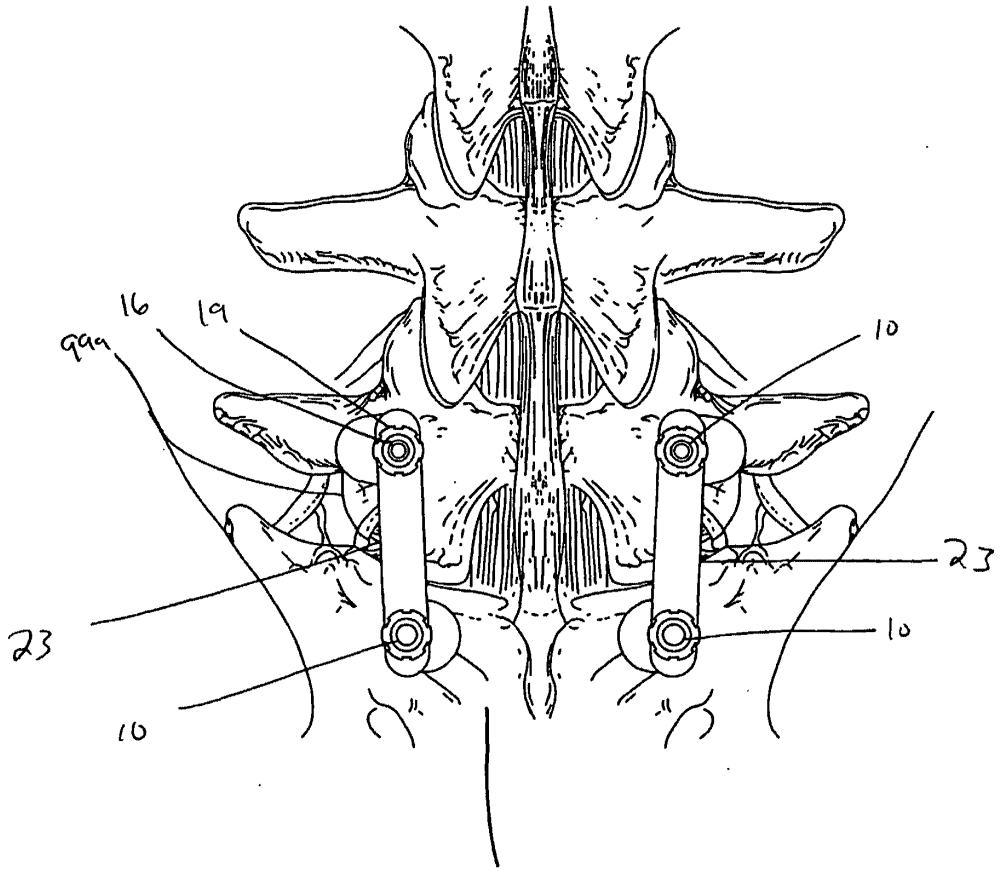


FIG. 6

FIG. 8



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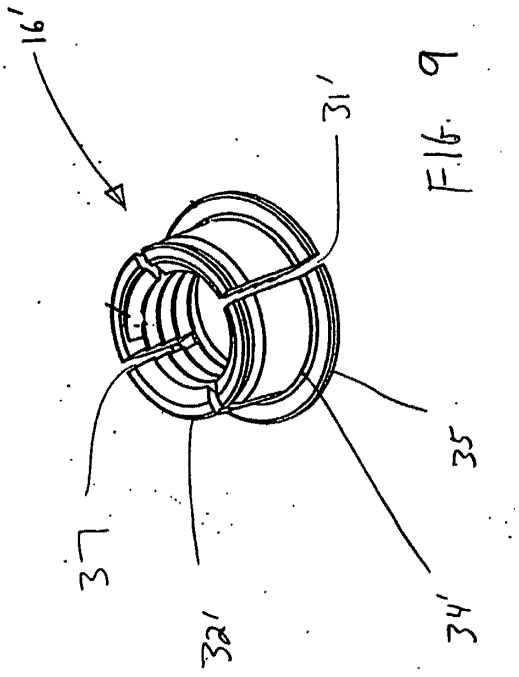


FIG. 9

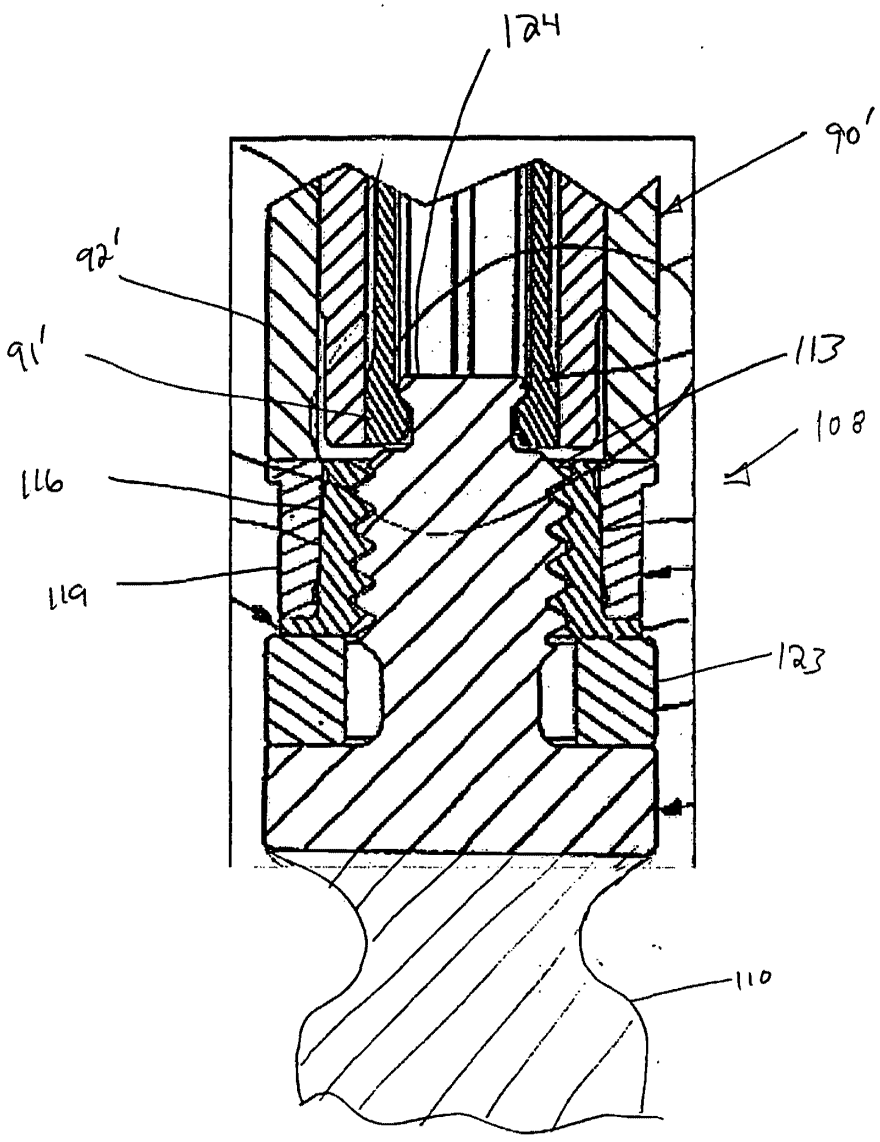


FIG. 10

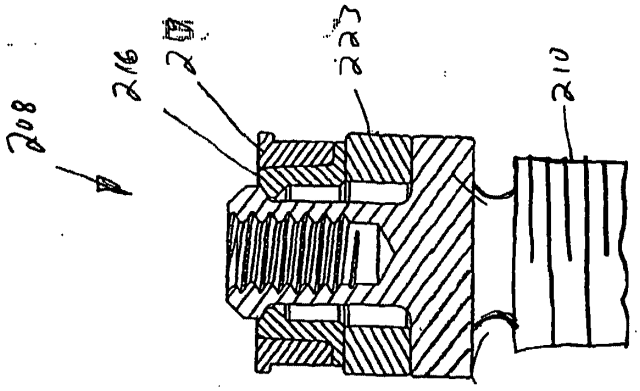


FIG. 13

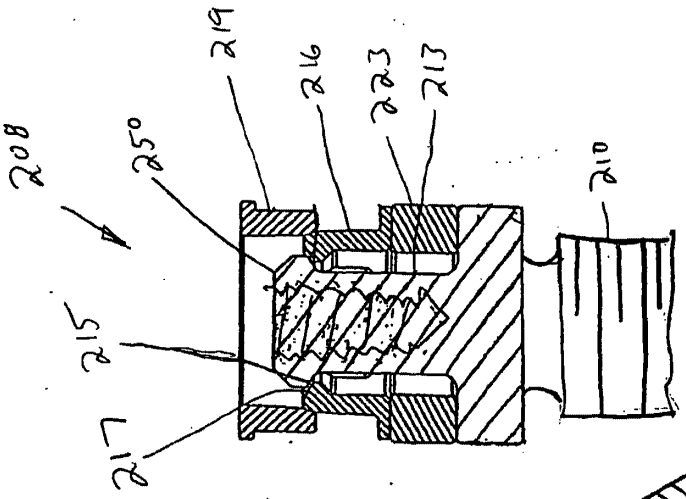


FIG. 12

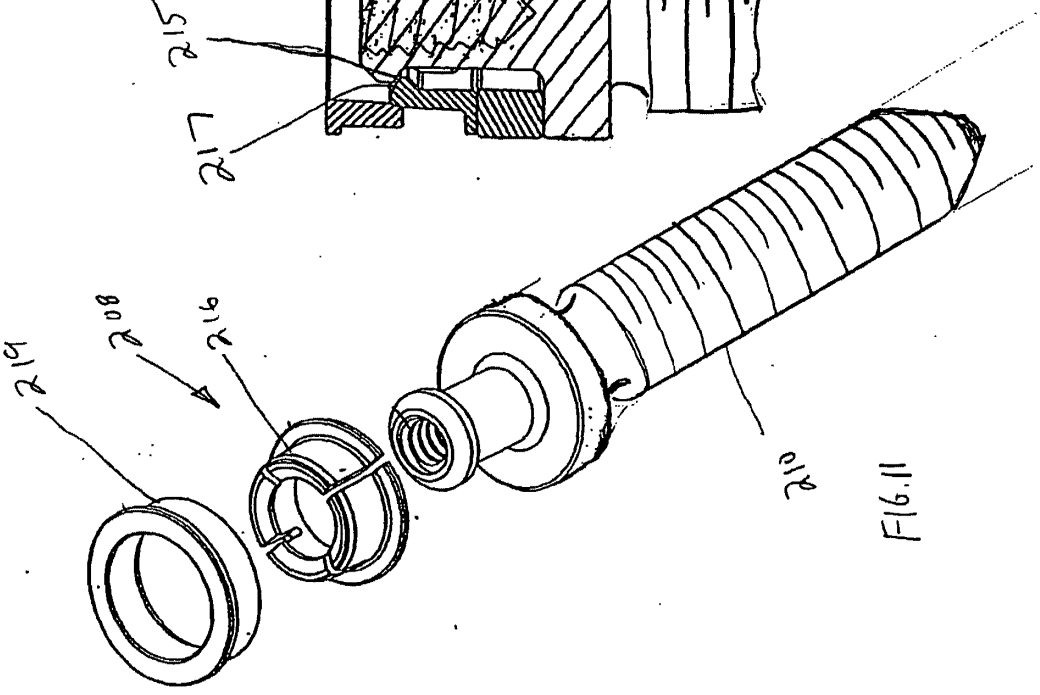


FIG. 11

FIG. 14

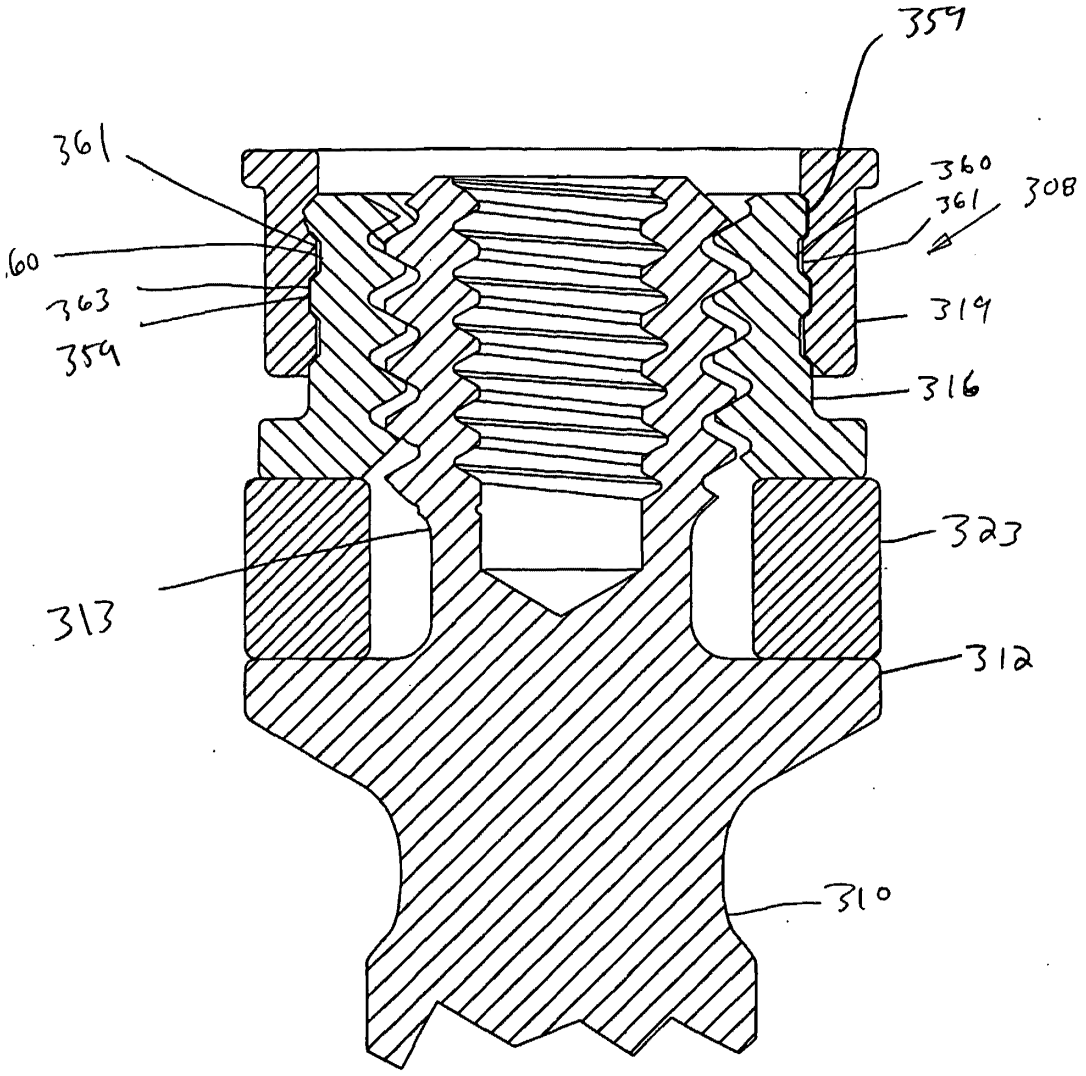
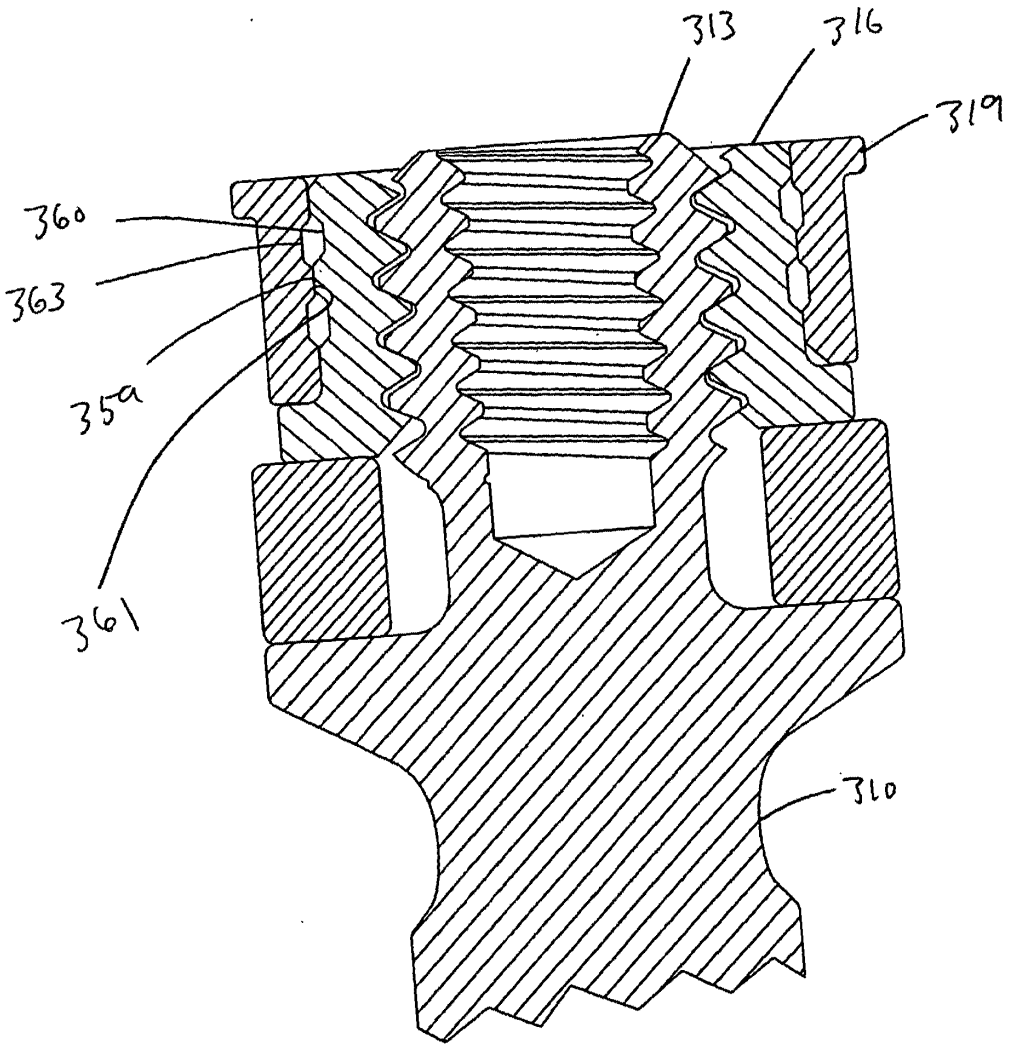


FIG. 15



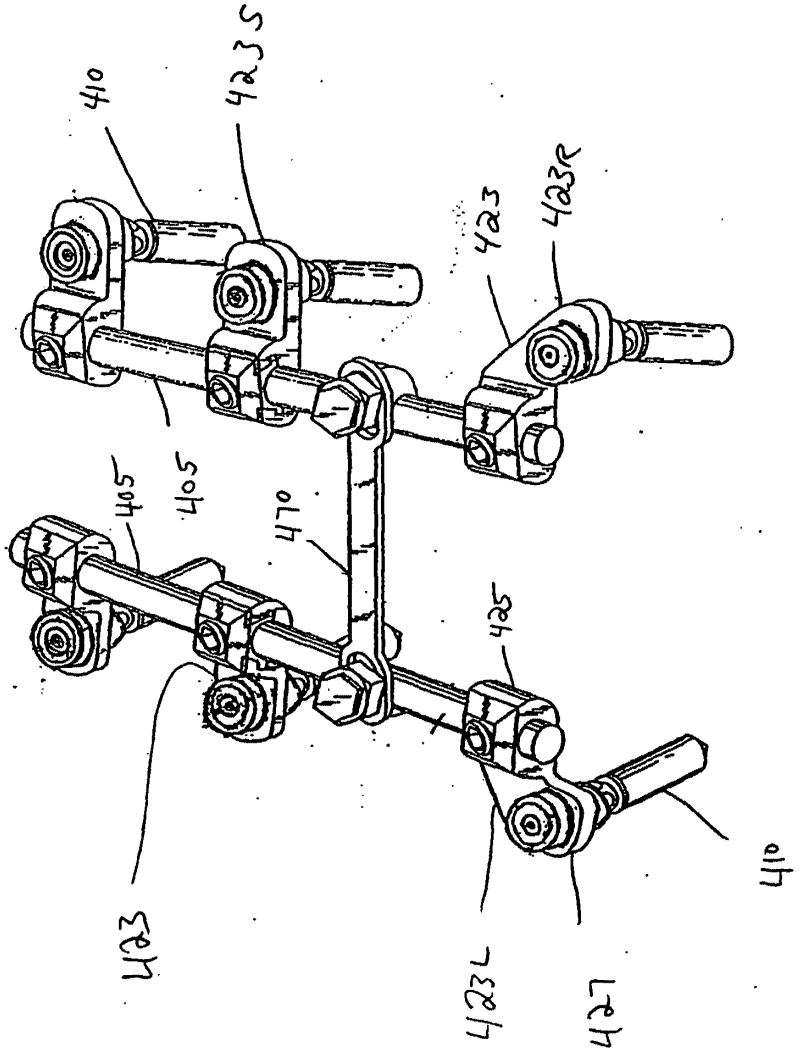


FIG. 16

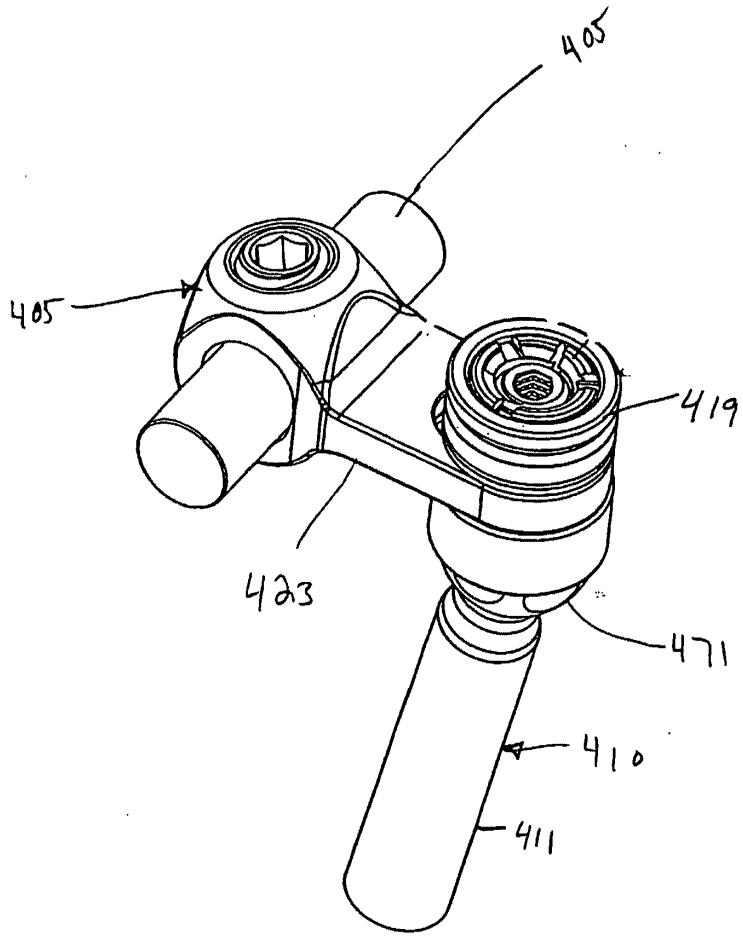


FIG. 17

FIG. 18

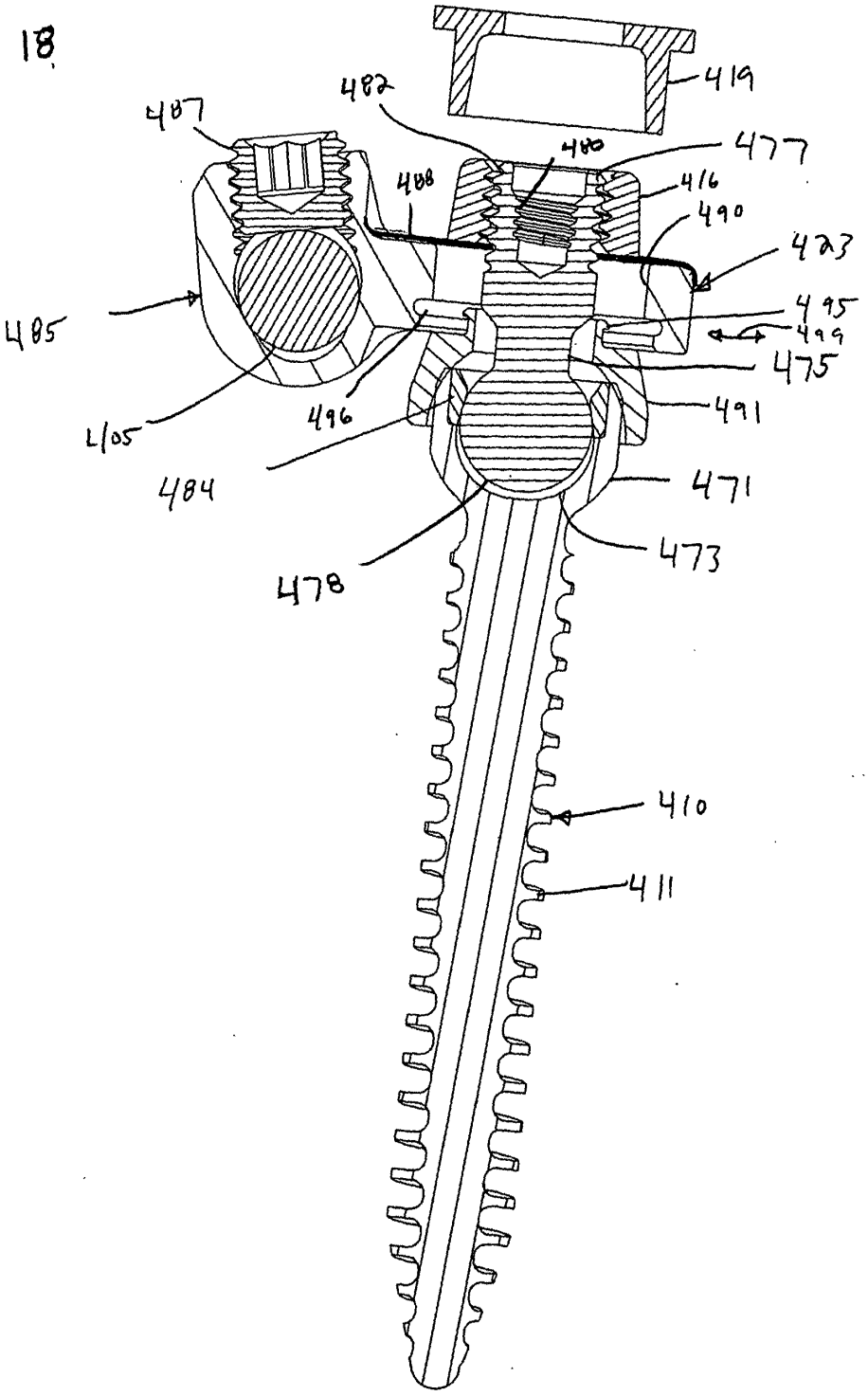
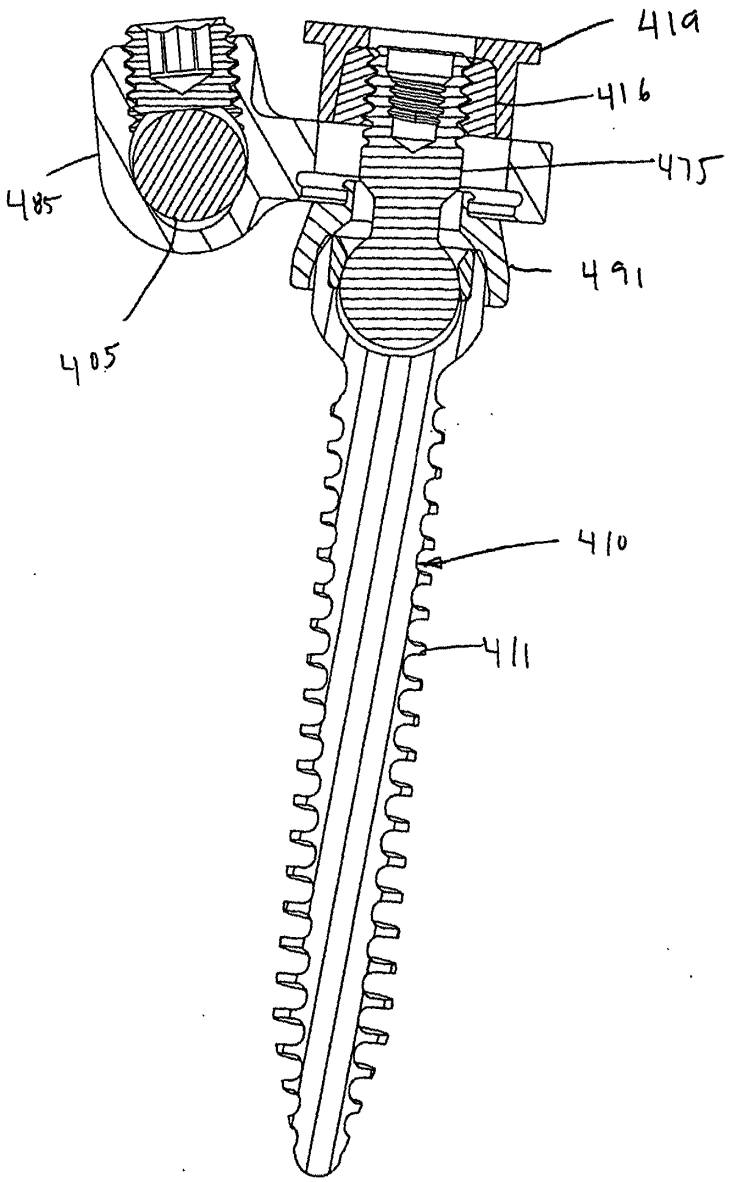

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FIG. 19



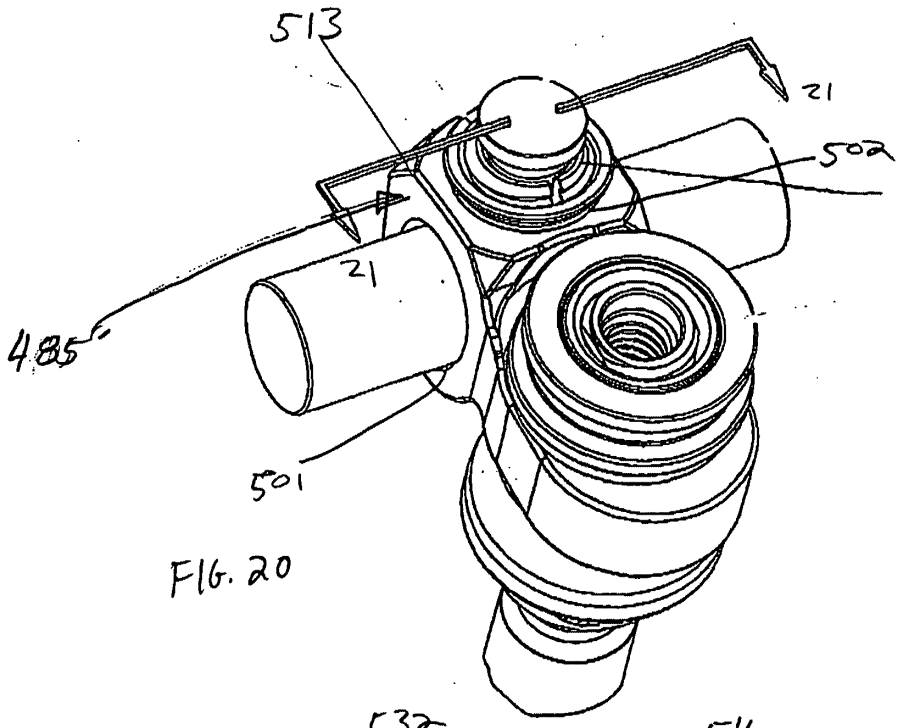


FIG. 20

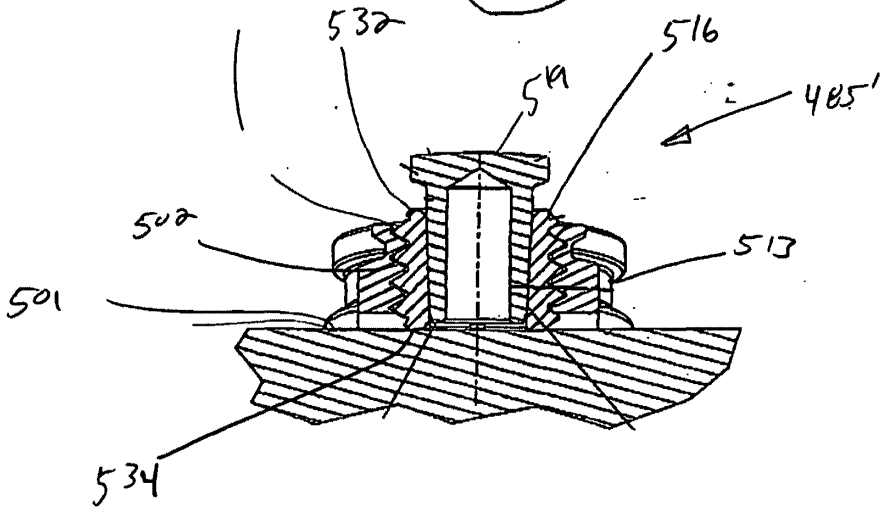
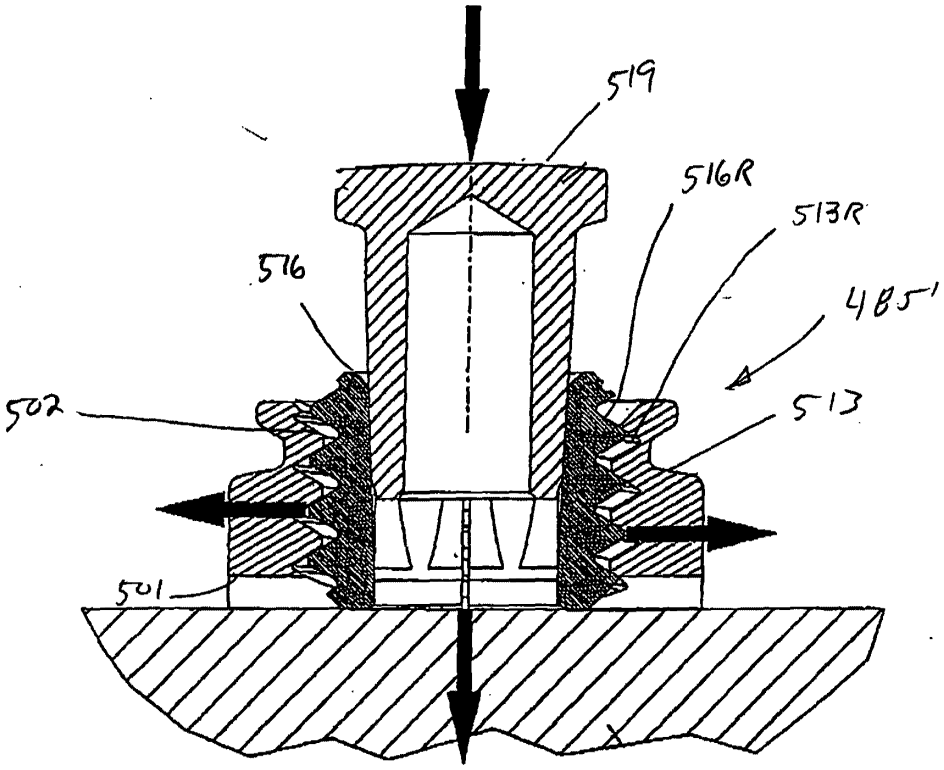
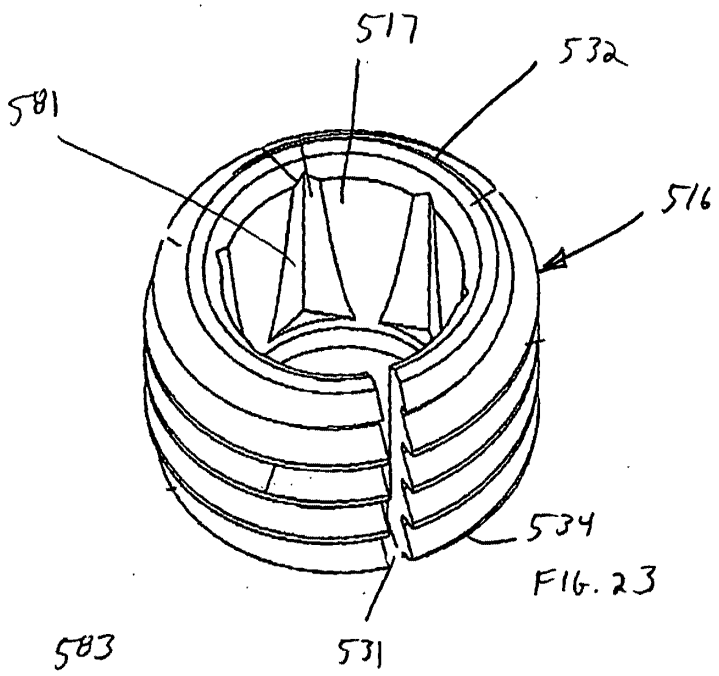


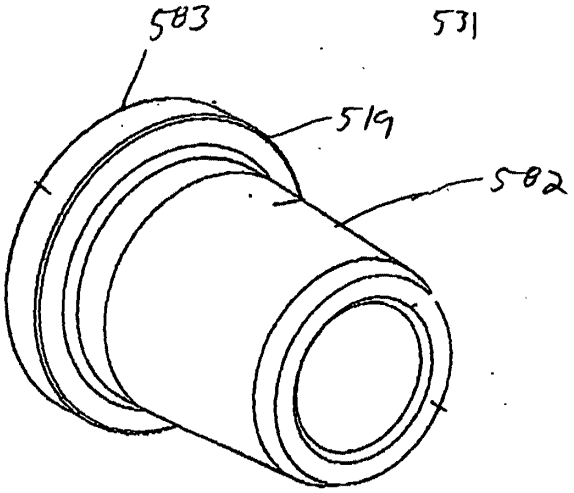
FIG. 21



F16.22



F16.23



F16.24

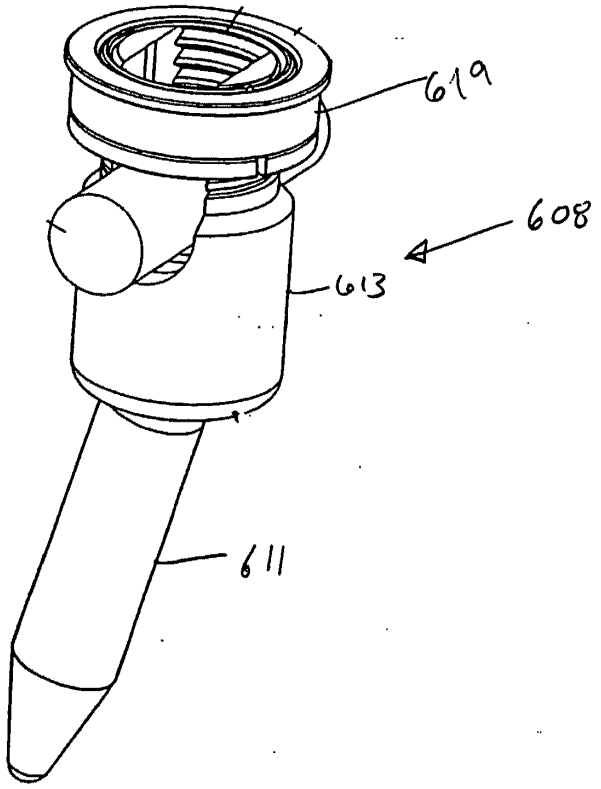


FIG. 25

FIG. 26

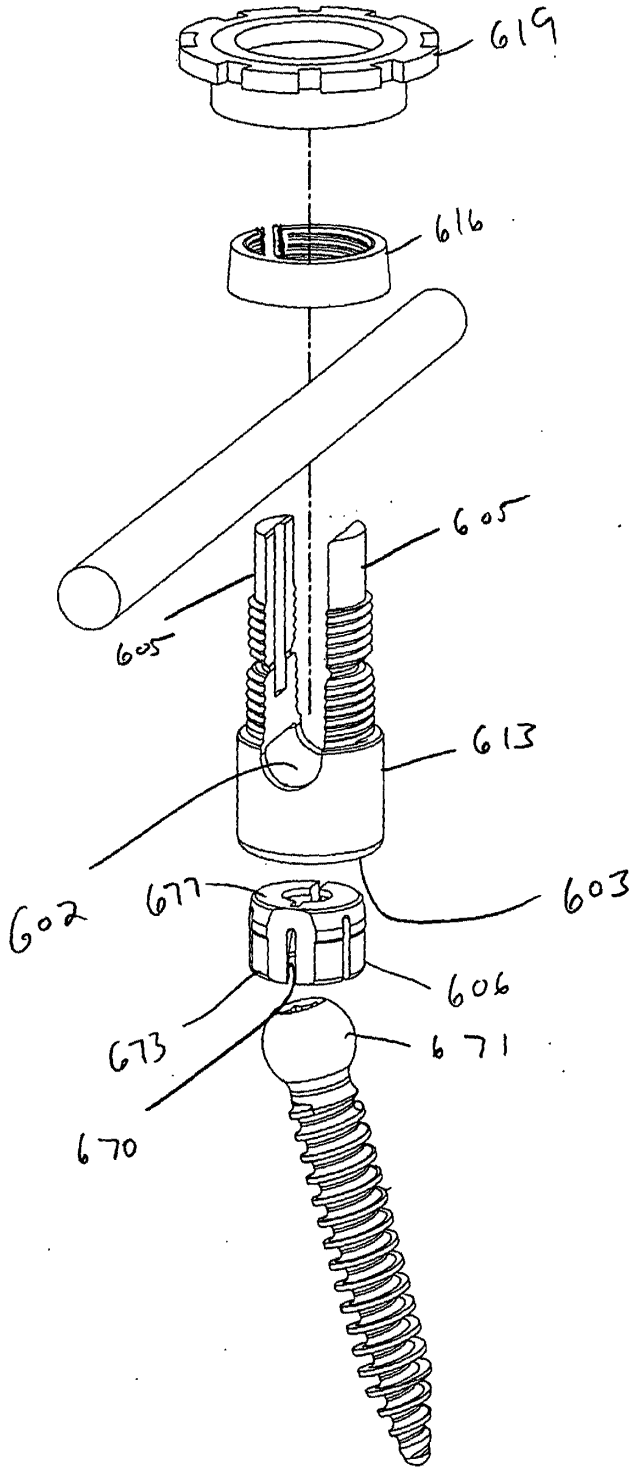
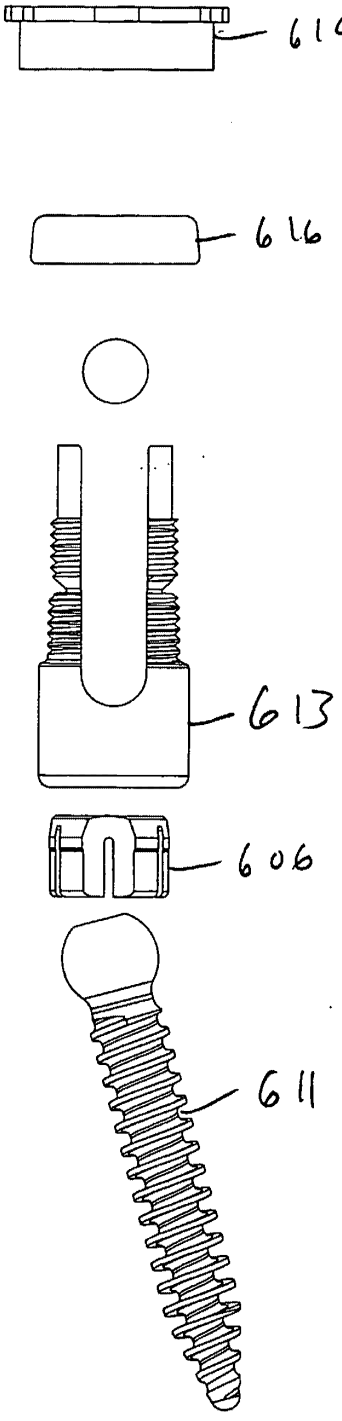
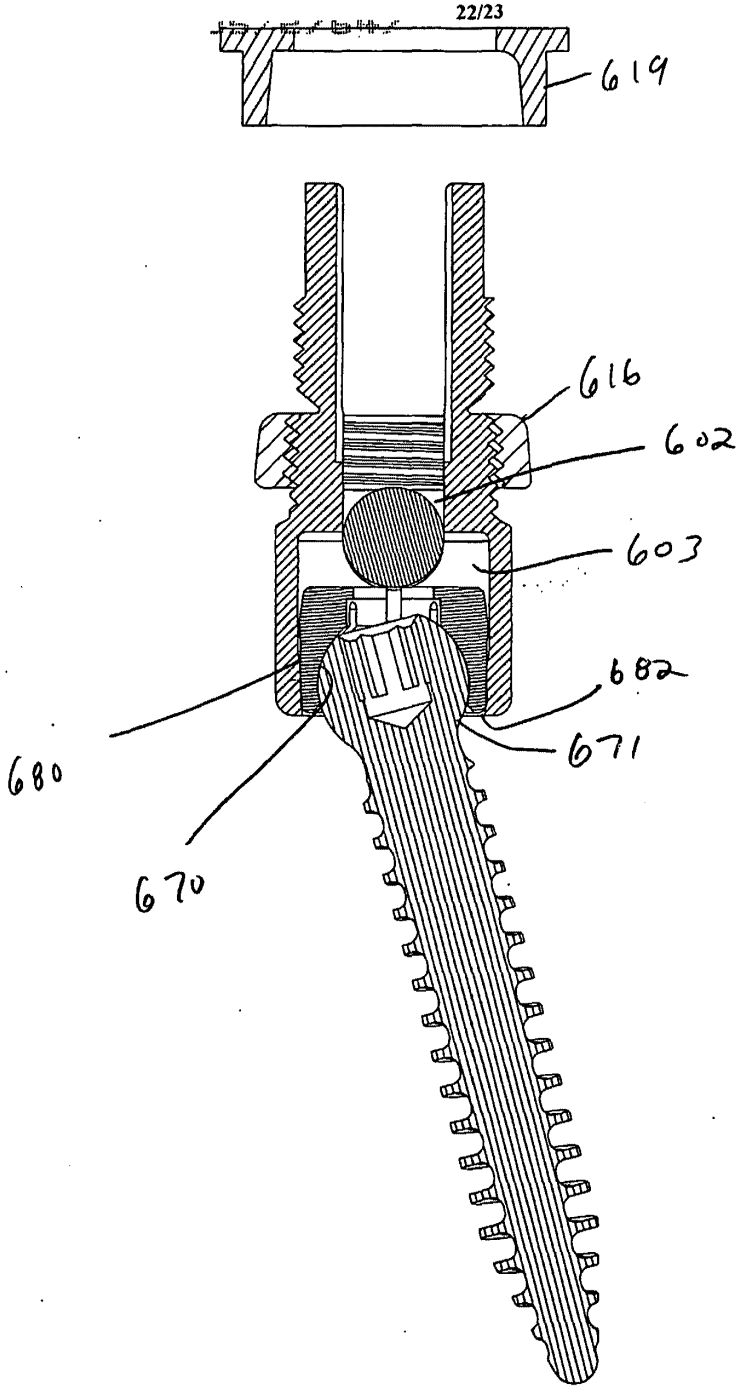
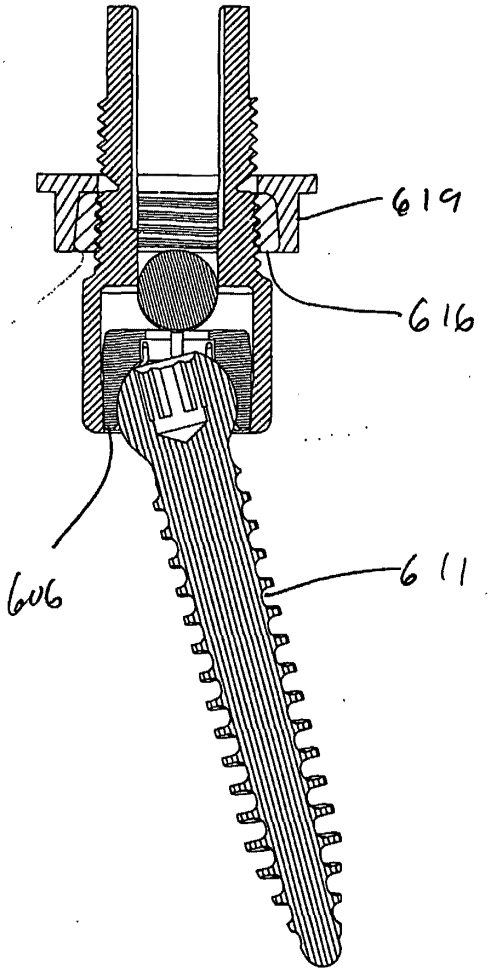


FIG. 27




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INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2005/027647

A. CLASSIFICATION OF SUBJECT MATTER
A61B17/70 A61B17/88

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

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

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2003/073996 A1 (DOUBLER ROBERT L ET AL) 17 April 2003 (2003-04-17) paragraph '0033! - paragraph '0044! paragraph '0056! - paragraph '0067! figures	24-27
Y	US 2003/149487 A1 (DOUBLER ROBERT L ET AL) 7 August 2003 (2003-08-07) the whole document	24-27
A	US 2004/006342 A1 (ALTARAC MOTI ET AL) 8 January 2004 (2004-01-08) paragraph '0023! - paragraph '0028!; figures 1-4	24

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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"A" document defining the general state of the art which is not considered to be of particular relevance

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
14 November 2005	22/11/2005

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax (+31-70) 340-3016	Nistor, L

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Zimvie_Zimmer Biomet v. Jackson
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Page 1605 of 2152

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2005/027647

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 00/15125 A (SYNTHES AG CHUR; SYNTHES ; BRACE, MICHAEL; LANGE, ERIC) 23 March 2000 (2000-03-23) page 4, line 18 - page 7, line 34 figures	24
A	DE 197 20 782 A1 (SYNTHES AG CHUR, CHUR, GRAUBUENDEN, CH; SYNTHES AG CHUR, CHUR) 19 November 1998 (1998-11-19) column 3, line 7 - line 52 figure 1	24
A	US 5 613 968 A (LIN ET AL) 25 March 1997 (1997-03-25) column 4, line 12 - column 5, line 24; figures	24

1

Form PCT/ISA/210 (continuation of second sheet) (January 2004)

Zimvie_Zimmer Biomet v. Jackson
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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2005/027647

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 1-23
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

Zimvie_Zimmer Biomet v. Jackson
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Page 1607 of 2152

INTERNATIONAL SEARCH REPORT

ıation on patent family members

International Application No
PCT/US2005/027647

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2003073996 A1	17-04-2003	US 2003073997 A1	17-04-2003
US 2003149487 A1	07-08-2003	NONE	
US 2004006342 A1	08-01-2004	NONE	
WO 0015125 A	23-03-2000	AU 751174 B2	08-08-2002
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		AU 723894 B2	07-09-2000
		AU 3022397 A	11-12-1998
		CA 2289629 A1	26-11-1998
		WO 9852482 A1	26-11-1998
		CN 1254266 A	24-05-2000
		DK 984730 T3	10-11-2003
		EP 0984730 A1	15-03-2000
		ES 2203807 T3	16-04-2004
		HK 1023710 A1	31-10-2003
		JP 2001525707 T	11-12-2001
		PT 984730 T	31-12-2003
		TW 409048 B	21-10-2000
		ZA 9804064 A	24-11-1998
US 5613968 A	25-03-1997	NONE	

Form PCT/ISA/210 (patent family annex) (January 2004)

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
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(43) International Publication Date
2 February 2006 (02.02.2006)

PCT

(10) International Publication Number
WO 2006/012088 A1

(51) International Patent Classification[7]: A61B 17/70

(21) International Application Number:
PCT/US2005/021767

(22) International Filing Date: 21 June 2005 (21.06.2005)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/582,893 25 June 2004 (25.06.2004) US
11/156,435 20 June 2005 (20.06.2005) US

(63) Related by continuation (CON) or continuation-in-part (CIP) to earlier application:
US 10/669,927 (CIP)
Filed on 24 September 2003 (24.09.2003)

(71) Applicant and
(72) Inventor: **CHIN, Kingsley, Richard** [US/US]; 2020 Walnut Street, Suite 17H, Philadelphia, PA 19103 (US).

(74) Agent: **COLLINS, Aliki, K.**; AKC Patents, 215 Grove Street, Newton, MA 02466 (US).

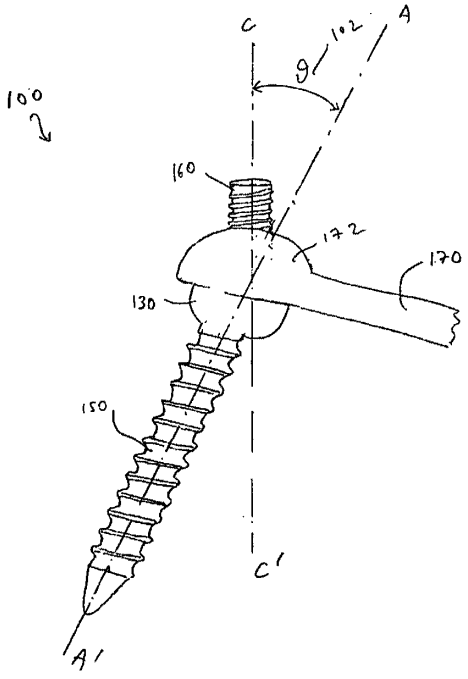
(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US (patent), UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*

[Continued on next page]

(54) Title: MULTI-AXIAL SCREW WITH A SPHERICAL LANDING



(57) Abstract: A multi-axial screw assembly with a spherical landing surface is disclosed. The multi-axial screw assembly (100) includes a bone anchor (150), a head (130) with a spherical outer surface and an extension member (160) extending from the top of the head (130). The multi-axial screw is designed to attach a planar or semispherical end member of a plate to a vertebra. The plate is part of a spine fixation or stabilization assembly. The multi-axial screw provides multi-axial pivoting of the screw relative to the plate.

WO 2006/012088 A1

Zimvie_Zimmer Biomet v. Jackson
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Page 1609 of 2152

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

MULTI-AXIAL SCREW WITH A SPHERICAL LANDING

Cross Reference to related Co-Pending Applications

This application claims the benefit of U.S. provisional application Serial No. 60/582,893 filed on June 25, 2004 and entitled MULTI-AXIAL SCREW WITH A SPHERICAL LANDING which is commonly assigned and the contents of which are expressly incorporated herein by reference.

This application is also a continuation in part of U.S. application Serial No. 10/669,927 filed on September 24th, 2003 and entitled APPARATUS AND METHOD FOR CONNECTING SPINAL VERTEBRAE the contents of which are expressly incorporated herein by reference.

Field of the Invention

The present invention relates to a multi-axial screw, and more particularly to a multi-axial screw with a spherical landing surface for receiving a plate stabilization element.

Background of the Invention

Patents US 6626909 and US 6669729, the entire contents of which are expressly incorporated herein by reference describe spine fixation assemblies that utilize plates as connecting and stabilization elements. Plates are secured to vertebral bones via screws. The screws presented in these two patents are capable of pivoting around a fixed axis of the stabilization plates to achieve variable angular positions relative to the plates. This limited range of relative angular positioning is acceptable for many spinal pathologies. However, in some cases it is preferred to have screws that provide multi-axial pivoting relative to the stabilization plates.

Summary of the Invention

In general, in one aspect, the invention features a bone anchor assembly for engaging an elongated plate element including a bone engaging anchor, a spherical member, a head, and a locking member. The bone engaging anchor has a body portion configured to engage a bone, a spherical top end and a sharp bottom end. The spherical member is configured to grip and lock the spherical top of the bone engaging anchor. The head has a spherical outer surface for receiving a semispherical

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end member of the elongated plate element and is configured to sit upon the spherical member. The locking member is used for securing the semispherical end member to the head and the head to the spherical member.

Implementations of this aspect of the invention may include one or more of the following features. The spherical top of the bone engaging anchor comprises a rough outer surface and a bore designed to receive a tool for screwing the bone engaging anchor into a bone. The rough outer surface of the spherical top comprises elements including serrations, knurling or horizontal elevations. The spherical member comprises a circular cross-section or a c-shaped cross-section. The spherical member comprises a smooth outer surface, an opening configured to receive the tool, and a rough inner surface configured to grip and lock with the rough outer surface of the spherical top of the bone engaging anchor. The rough inner surface of the spherical member comprises elements including serrations, knurling or horizontal elevations and these elements are configured to cooperate with the corresponding elements of the outer surface of the spherical top. The head comprises an opening configured to receive the locking member, and a spherical inner surface configured to be interference fitted with the spherical outer surface of the spherical member. The head opening comprises inner threads configured to cooperate and engage with outer threads of the locking member thereby securing the head to the spherical member. The bone anchor assembly may further include a removable extension member configured to connect to the locking member. The locking member comprises a cylindrical body having threads on its outer surface and a bore on its top end for receiving an appendage of the removal extension member. The semispherical end member of the elongated plate element comprises an opening for receiving the locking member. The opening of the elongated plate element comprises inner threads adapted to cooperate with the threads of the locking member. The bone anchor assembly may further include a retention nut adapted to be threaded around outer threads of the removable extension member or the threads of the locking member. The extension member is an integral part of the locking member and is designed to be broken off or otherwise manually removed.

In general, in another aspect, the invention features a bone anchor assembly for engaging an elongated plate element including a bone engaging anchor, a spherical

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member, a crown, and a locking member. The bone engaging anchor has a body portion configured to engage a bone, a sharp bottom end and a top member. The top member comprises an upper opening portion extending into the center of the top member and a spherical head extending from the bottom of the upper opening portion. The top member further comprises a spherical outer surface for receiving a semispherical end member of the elongated plate member. The spherical member is configured to grip and lock the spherical head of the bone engaging anchor. The crown has a spherical inner surface and a cylindrical top and is configured to sit upon the spherical member. The locking member is used for securing the crown to the spherical member.

Implementations of this aspect of the invention may include one or more of the following features. The spherical head of the bone engaging anchor comprises a rough outer surface and a bore designed to receive a tool for screwing the bone engaging anchor into a bone. The rough outer surface of the spherical head comprises elements including serrations, knurling or horizontal elevations. The spherical member comprises a circular cross-section or a c-shaped cross-section. The spherical member comprises a smooth outer surface, an opening configured to receive the tool, and a rough inner surface configured to grip and lock with the rough outer surface of the spherical head of the bone engaging anchor. The rough inner surface of the spherical member comprises elements including serrations, knurling or horizontal elevations and these elements are configured to cooperate with the corresponding elements of the outer surface of the spherical head. The crown comprises an opening configured to receive the locking member, and a spherical inner surface configured to be interference fitted with the spherical outer surface of the spherical member. The crown opening comprises inner threads configured to cooperate and engage with outer threads of the locking member thereby securing the crown to the spherical member. The semispherical end member of the elongated plate element comprises an opening for receiving the locking member. The opening of the elongated plate element comprises inner threads adapted to cooperate with outer threads of the crown.

Brief Description of the Drawings

Referring to the figures, wherein like numerals represent like parts throughout the several views:

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FIG. 1 is a side elevational view of a multi-axial screw assembly with a spherical landing surface;

FIG. 2A is an exploded view of the multi-axial screw embodiment of FIG. 1;

FIG. 2B is an exploded cross-sectional view of the multi-axial screw embodiment of FIG.1;

FIG. 2C is cross-sectional view of one embodiment of the spherical member 120;

FIG. 2D is a cross-sectional view of another embodiment of the spherical member 120;

FIG. 3 is a cross-sectional view of the multi-axial screw assembly of FIG. 1 with an attached elongated plate;

FIG. 4 is an exploded cross-sectional side view of another embodiment of a multi-axial screw with a spherical landing surface;

FIG. 5 is a cross-sectional view of the multi-axial screw assembly of FIG. 4 with an attached elongated plate; and

FIG. 6 is a cross-sectional view of another embodiment of the multi-axial screw assembly of FIG. 4 with an attached elongated plate.

Detailed Description of the Invention

The invention provides a multi-axial screw with a spherical landing surface for receiving a plate stabilization element.

Referring to FIG. 1, a multi-axial screw 100 assembly includes a bone anchor 150, a head 130 with a spherical outer surface and an extension member 160. The multi-axial screw 100 is designed to attach an elongated plate 170 with a semispherical end member 172 to a vertebral bone or any other bone. Referring to FIG. 2A and FIG.

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2B, the bone anchor 150 includes a body 155 with outer threads 154 and terminates in a spherical top end 110 and a sharp bottom end 152. The spherical top end 110 has a rough outer surface 112 and a bore 114 designed to receive a tool (not shown) for screwing the bone anchor 150 into the bone. In other embodiments the outer surface of the spherical top end 110 includes serrations, knurling or horizontal elevations. The rough outer surface 112, the serrations, knurling or horizontal elevations provide a good gripping surface. On top of the spherical top end 110 sits a hollow spherical member 120. Spherical member 120 has a circular cross-section along the BB' axis, shown in FIG. 2C. In other embodiments spherical member 120 has a c-shaped cross-section along the BB' axis, shown in FIG. 2D. Spherical member 120 has an opening 122 and a spherical inner surface 126 that is configured to accommodate and grip the rough outer surface 112 of the spherical top end 110. Inner surface 126 can be rough or have serrations, horizontal elevations or knurling that can cooperate with the roughness, serrations, horizontal elevations or knurling of the outer surface 112 of the spherical top end 110. Opening 122 is provided so that a tool can be inserted through the opening 122 to reach the bore 114 of the spherical top end 110 for screwing the bone anchor 150 into the bone. The radius of the spherical member 120 is slightly larger that the radius of the spherical top end 110 and slightly smaller than the radius of the head 130 so that it can be interference fitted between them. Head 130 has a spherical outer surface 135 configured to provide a spherical landing surface for the end member 172 of the elongated plate 170, shown in FIG. 3 and FIG. 1. Head 130 has an opening 132 that allows the above mentioned tool to reach the bore 114 of the spherical top end 110 for screwing the bone anchor 150 into the bone. Head 130 sits on top of the spherical member 120 and the inner surface 136 of the head 130 is interference fitted with the outer surface 128 of the spherical member 120. The top portion of opening 132 has inner threads 138 for receiving a locking member 140. Locking member 140 has a cylindrical shape and outer threads 142 that cooperate with the inner threads 138 of the head 130 thereby tightening head 130 to spherical member 120 and to spherical top end 110. Locking member 140 has a bore 144 on its top end for receiving a cylindrical appendage 162 of the removable extension member 160. This configuration allows the extension member 160 to be positioned so that it always points in the vertical direction CC' while the screw axis AA' is oriented at an angle 102 away from the vertical CC' axis, shown in FIG. 1. Referring to FIG. 3, semispherical end member 172 of the elongate plate 170 has a through opening 174

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that allows it to be placed over the locking member 140. The bottom surface176 of the semispherical end member 172 sits on top of the spherical outer surface 135 of head 130. End member 172 can be rotated around axis AA' while the extension member 160 always points in the vertical CC' axis. Opening 174 may also have inner threads that cooperate with the outer threads 142 of the locking member 140. A retention nut 180 is threaded around outer threads 164 of the extension member 160 and the outer threads 142 of the locking member 140 in order to tighten the end member 172 to the spherical outer surface 135 of the head 130. In one example, the length 156 of the threaded body 155 is in the range of 14 mm to 30 mm for screws used in cervical vertebrae and 35 mm to 50 mm for screws used in lumbar vertebrae. In other examples, length 156 is in the range of 10 mm to 60 mm. In one example, multi-axial screw assembly 100 is made of titanium metal. In this configuration the head 130 may be rotated at any angle 102 relative to the screw axis AA' and tighten down to the top end 110 via the locking member 140. Preferably, head 130 is rotated so that the extension member 160 points in the vertical direction CC' while the bone anchor 150 is placed at any other angle 102 relative to the vertical axis CC'. In this example, bone anchor 150 is a screw. In other embodiments bone anchor 150 may be a hook. Furthermore, in other embodiments extension member 160 is an integral member of the locking member 140 and it can be broken off after the multi-axial screw assembly 100 is properly oriented and secured to the bone.

Referring to FIG. 4 and FIG. 5, in another embodiment of a multi-axial screw assembly with a spherical landing surface, assembly 200 includes a bone anchor 250 having a spherical head 205. Spherical head 205 has a cylindrical bore opening 206 extending from the top surface 201 of spherical head 205 halfway into the center 202 of the spherical head 205. From the bottom 203 of the bore opening 206 extends a spherical top end 210. Spherical top end 210 has a rough outer surface 212 and a top bore opening 214 for receiving a tool (not shown) for screwing the bone anchor 250 into a bone. In other embodiments the outer surface 212 of the spherical top end 210 includes serrations, knurling or horizontal elevations. The rough outer surface 212, the serrations, knurling or horizontal elevations provide a good gripping surface. On top of the spherical top end 210 sits a spherical member 220. Spherical member 220 has a circular cross-section along the BB' axis, as shown in FIG. 2C. In other embodiments spherical member 220 has a c-shaped cross-section along the BB' axis,

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as shown in FIG. 2D. Spherical member 220 has an opening 222 and a spherical inner surface 226 that is configured to accommodate and grip the rough outer surface 212 of the spherical top end 210. Inner surface 226 can be rough or have serrations, horizontal elevations or knurling that can cooperate with the roughness, serrations, horizontal elevations or knurling of the outer surface 212 of the spherical top end 210. Opening 222 is provided so that a tool can be inserted through the opening 222 to reach the bore 214 of the spherical top end 210 for screwing the bone anchor 250 into the bone. The radius of the spherical member 220 is slightly larger that the radius of the spherical top end 210 and slightly smaller than the radius of crown 230 that sits on top of it so that it can be interference fitted between them. Crown 230 has a spherical outer surface 235 and a cylindrical extension 236. Crown 230 has an opening 232 that allows the above mentioned tool to reach the bore 214 of the spherical top end 210 for screwing the bone anchor 250 into the bone. Crown 230 sits on top of the spherical member 220 and the inner surface 238 of the crown 230 is interference fitted with the outer surface 228 of the spherical member 220. The top portion of opening 232 has inner threads 237 for receiving a locking member 240. Locking member 240 has a cylindrical shape and outer threads 242 that cooperate with the inner threads 237 of the crown 230 thereby tightening crown 230 to spherical member 220 and to spherical top end 210. Locking member 240 has a bore 244 on its top end for receiving a cylindrical appendage 262 of the removable extension member 260. This configuration allows the extension member 260 to always point in the vertical direction CC' while the screw axis AA' is oriented at an angle 102 away from the vertical CC' axis, as shown in FIG. 1.

Referring to FIG. 5, planar end member 272 of the elongate plate 270 has a through opening 274 that allows it to be placed over the cylindrical extension 236 of the crown 230. The bottom surface276 of the semispherical end member 272 sits on top of the spherical outer surface 201 of spherical head 205. End member 272 can be rotated around axis AA' while the extension member 260 always points in the vertical CC' axis. Opening 274 may also have inner threads that cooperate with outer threads 239 of the cylindrical extension 236. A retention nut 280 is threaded around outer threads 239 of the cylindrical extension 236 in order to tighten the end member 272 to the spherical outer surface 201 of the spherical head 205. In this configuration crown 230 may be rotated at any angle 102 relative to the screw axis AA' and tighten down

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to the top end 210 via the locking member 240. Preferably, crown 230 is rotated so that the extension member 260 points in the vertical direction CC' while the bone anchor 250 is placed at any other angle 102 relative to the vertical axis CC'.

In the embodiment of FIG. 6, the retention nut 280 is threaded around the locking member 240 and the inner threads 282 of nut 280 engage the outer threads 242 of the locking member 240. In another embodiment, nut 280 counter sinks with a crater-type groove in the elongated plate 270.

Several embodiments of the present invention have been described. Nevertheless, it will be understood that various modifications may be made without departing from the spirit and scope of the invention. Accordingly, other embodiments are within the scope of the following claims.

What is claimed is:

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1. A bone anchor assembly for engaging an elongated plate element comprising:

a bone engaging anchor having a body portion configured to engage a bone, a spherical top end and a sharp bottom end;

a spherical member configured to grip and lock said spherical top of said bone engaging anchor;

a head with a spherical outer surface for receiving a semispherical end member of said elongated plate element and configured to sit upon said spherical member; and

a locking member for securing said semispherical end member to said head and said head to said spherical member.

2. The bone anchor assembly of claim 1 wherein said spherical top of said bone engaging anchor comprises a rough outer surface and a bore designed to receive a tool for screwing said bone engaging anchor into a bone.

3. The bone anchor assembly of claim 2 wherein said rough outer surface of said spherical top comprises elements selected from a group consisting of serrations, knurling and horizontal elevations.

4. The bone anchor assembly of claim 1 wherein said spherical member comprises a circular cross-section.

5. The bone anchor assembly of claim 1 wherein said spherical member comprises a c-shaped cross-section.

6. The bone anchor assembly of claim 3 wherein said spherical member comprises a smooth outer surface, an opening configured to receive said tool, and a rough inner surface configured to grip and lock with said rough outer surface of said spherical top of said bone engaging anchor.

7. The bone anchor assembly of claim 6 wherein said rough inner surface of said spherical member comprises elements selected from a group consisting of serrations, knurling and horizontal elevations and wherein said elements are configured to cooperate with the corresponding elements of said outer surface of said spherical top.

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8. The bone anchor assembly of claim 1 wherein said head comprises an opening configured to receive said locking member, and a spherical inner surface configured to be interference fitted with the spherical outer surface of said spherical member.

9. The bone anchor assembly of claim 8 wherein said head opening comprises inner threads configured to cooperate and engage with outer threads of said locking member thereby securing said head to said spherical member.

10. The bone anchor assembly of claim 1 further comprising a removable extension member configured to connect to said locking member.

11. The bone anchor assembly of claim 10 wherein said locking member comprises a cylindrical body having threads on its outer surface and a bore on its top end for receiving an appendage of said removal extension member.

12. The bone anchor assembly of claim 11 wherein said semispherical end member of said elongated plate element comprises an opening for receiving said locking member.

13. The bone anchor assembly of claim 12 wherein said opening of said elongated plate element comprises inner threads adapted to cooperate with said threads of said locking member.

14. The bone anchor assembly of claim 13 further comprising a retention nut adapted to be threaded around outer threads of said removable extension member or said threads of said locking member.

15. The bone anchor assembly of claim 10 wherein said extension member is an integral part of said locking member and is designed to be broken off.

16. A bone anchor assembly for engaging an elongated plate element comprising:

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a bone engaging anchor having a body portion configured to engage a bone, a sharp bottom end and a top member, wherein said top member comprises an upper opening portion extending into the center of said top member and a spherical head extending from the bottom of said upper opening portion and wherein said top member comprises a spherical outer surface for receiving a semispherical end member of said elongated plate member;

a spherical member configured to grip and lock said spherical head of said bone engaging anchor;

a crown with a spherical inner surface and a cylindrical top and configured to sit upon said spherical member; and

a locking member for securing said crown to said spherical member.

17. The bone anchor assembly of claim 16 wherein said spherical head of said bone engaging anchor comprises a rough outer surface and a bore designed to receive a tool for screwing said bone engaging anchor into a bone.

18. The bone anchor assembly of claim 17 wherein said rough outer surface of said spherical head comprises elements selected from a group consisting of serrations, knurling and horizontal elevations.

19. The bone anchor assembly of claim 16 wherein said spherical member comprises a circular cross-section.

20. The bone anchor assembly of claim 16 wherein said spherical member comprises a c-shaped cross-section.

21. The bone anchor assembly of claim 18 wherein said spherical member comprises a smooth outer surface, an opening configured to receive said tool, and a rough inner surface configured to grip and lock with said rough outer surface of said spherical head of said bone engaging anchor.

22. The bone anchor assembly of claim 21 wherein said rough inner surface of said spherical member comprises elements selected from a group consisting of serrations, knurling and horizontal elevations and wherein said elements are

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configured to cooperate with the corresponding elements of said outer surface of said spherical head.

23. The bone anchor assembly of claim 16 wherein said crown comprises an opening configured to receive said locking member, and a spherical inner surface configured to be interference fitted with the spherical outer surface of said spherical member.

24. The bone anchor assembly of claim 23 wherein said crown opening comprises inner threads configured to cooperate and engage with outer threads of said locking member thereby securing said crown to said spherical member.

25. The bone anchor assembly of claim 16 wherein said semispherical end member of said elongated plate element comprises an opening for receiving said locking member.

26. The bone anchor assembly of claim 25 wherein said opening of said elongated plate element comprises inner threads adapted to cooperate with outer threads of said crown.

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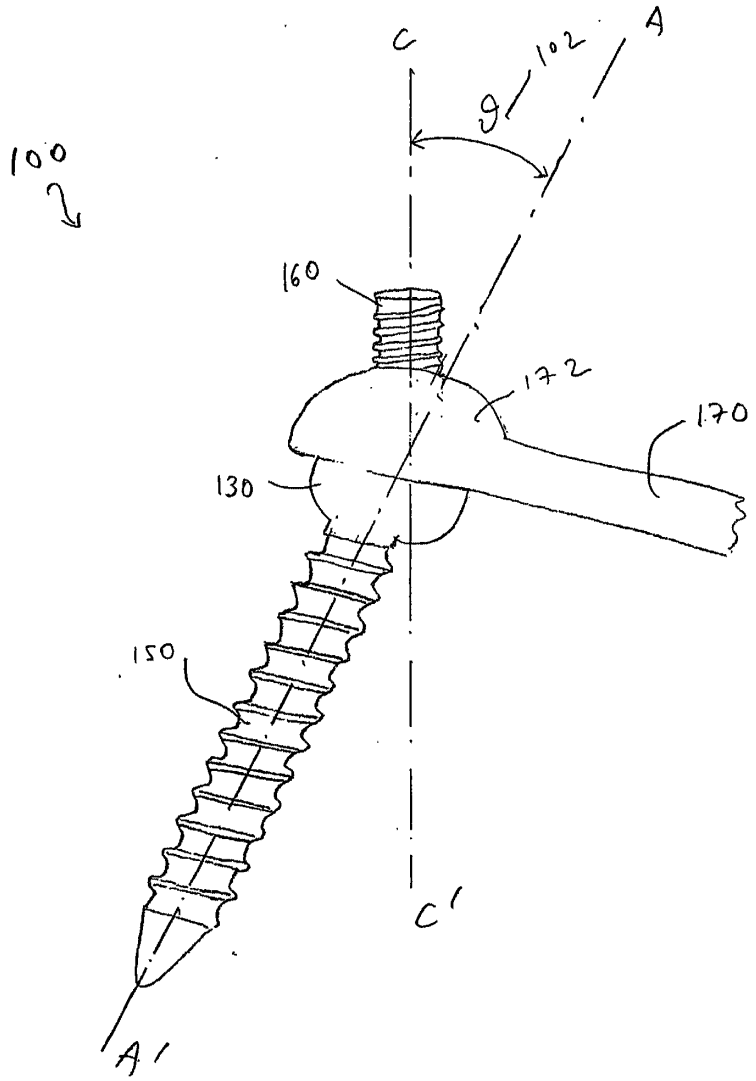
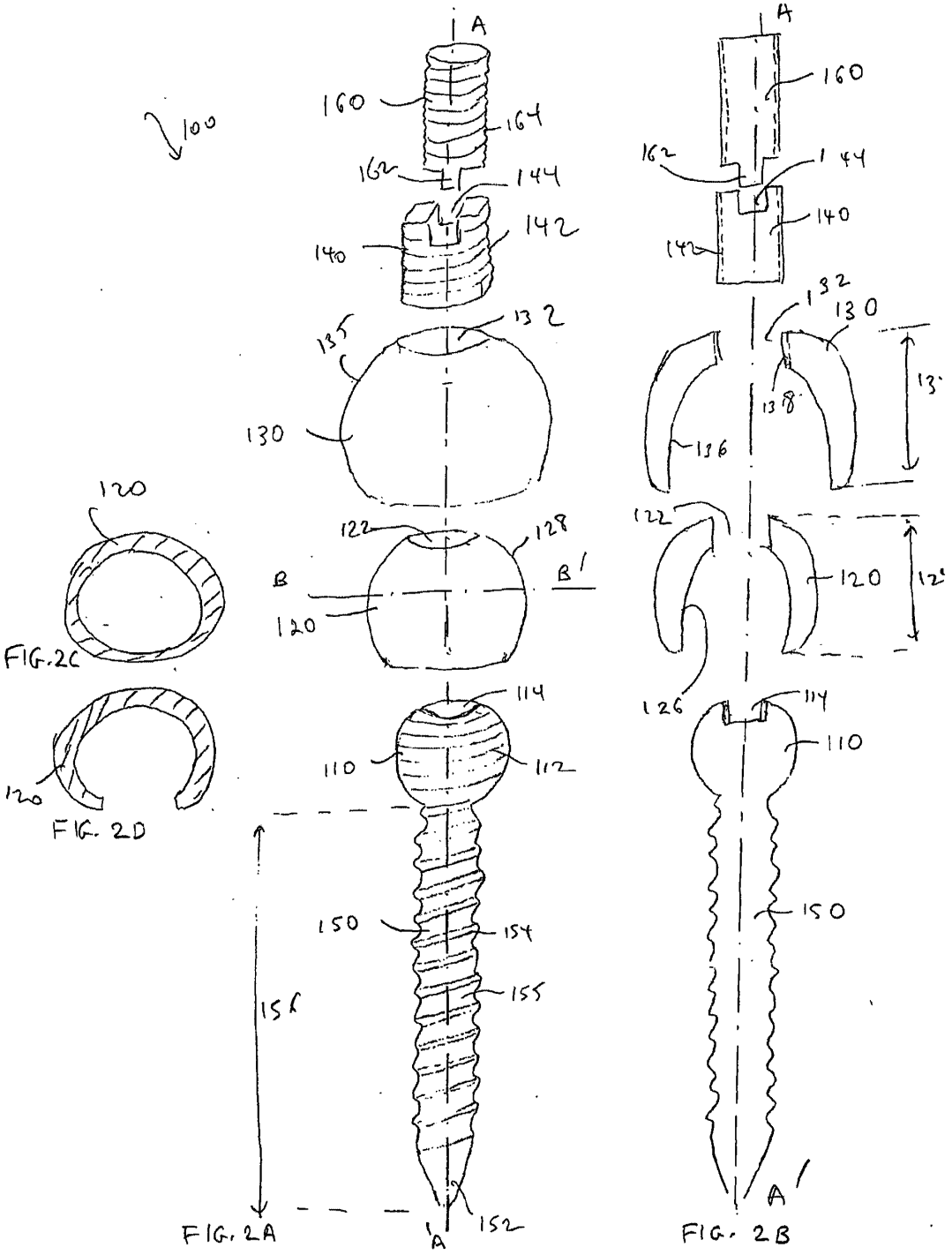


FIG. 1


100
A
160
164
162
144
142
140
132
135
130
122
128
B
B'
120
114
110
112
150
154
155
151
152
A'
FIG. 2A
120
FIG. 2C
120
FIG. 2D
A
160
162
144
140
142
132
130
138
136
122
120
126
114
110
150
A'
FIG. 2B

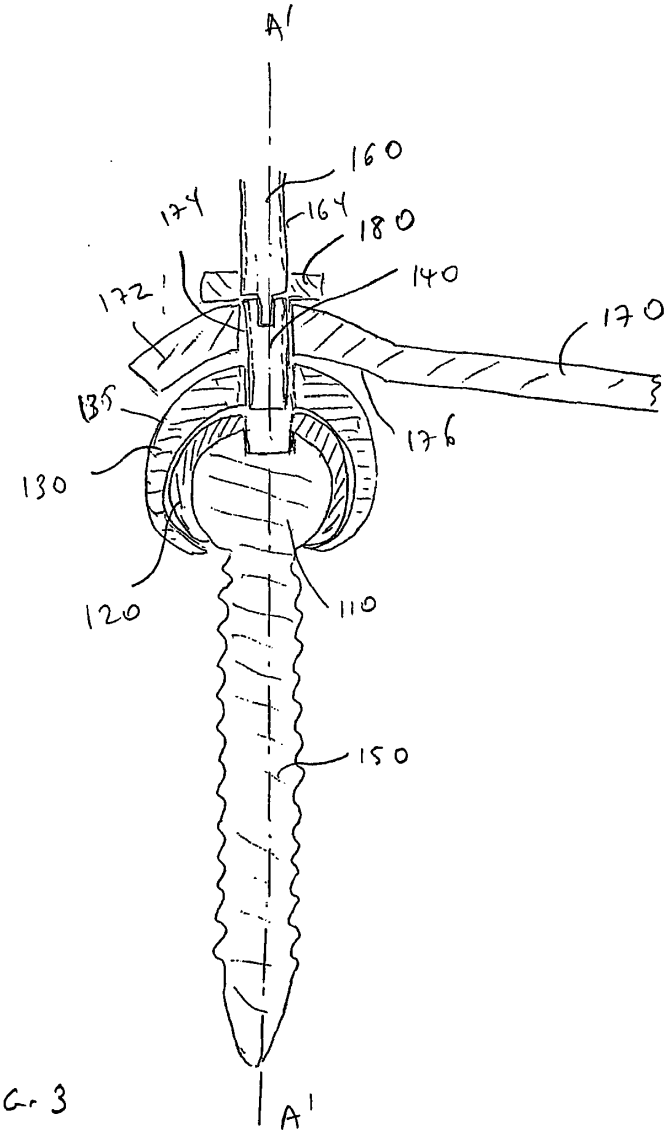


FIG. 3

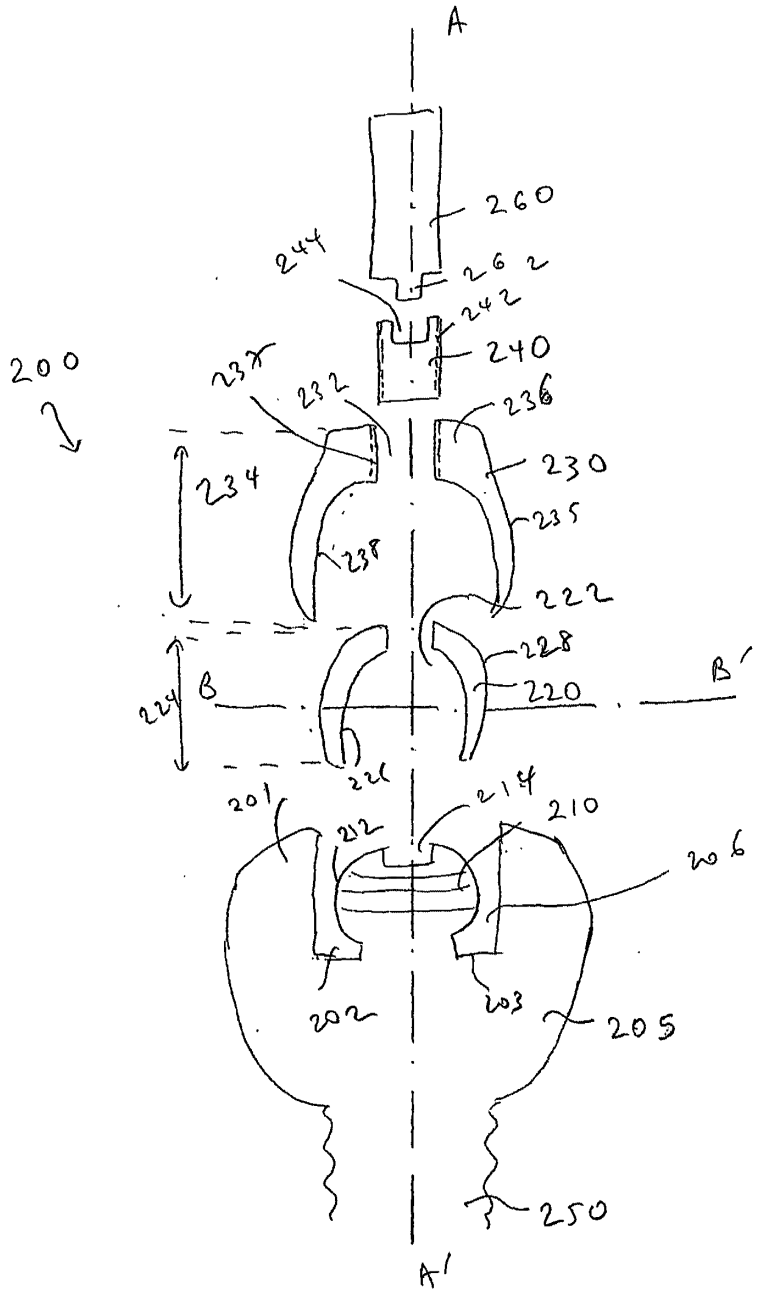

A
260
244
262
242
240
200
237
232
236
234
230
235
238
222
228
224
B
220
B'
226
201
214
210
212
206
202
203
205
250
A'

FIG. 4

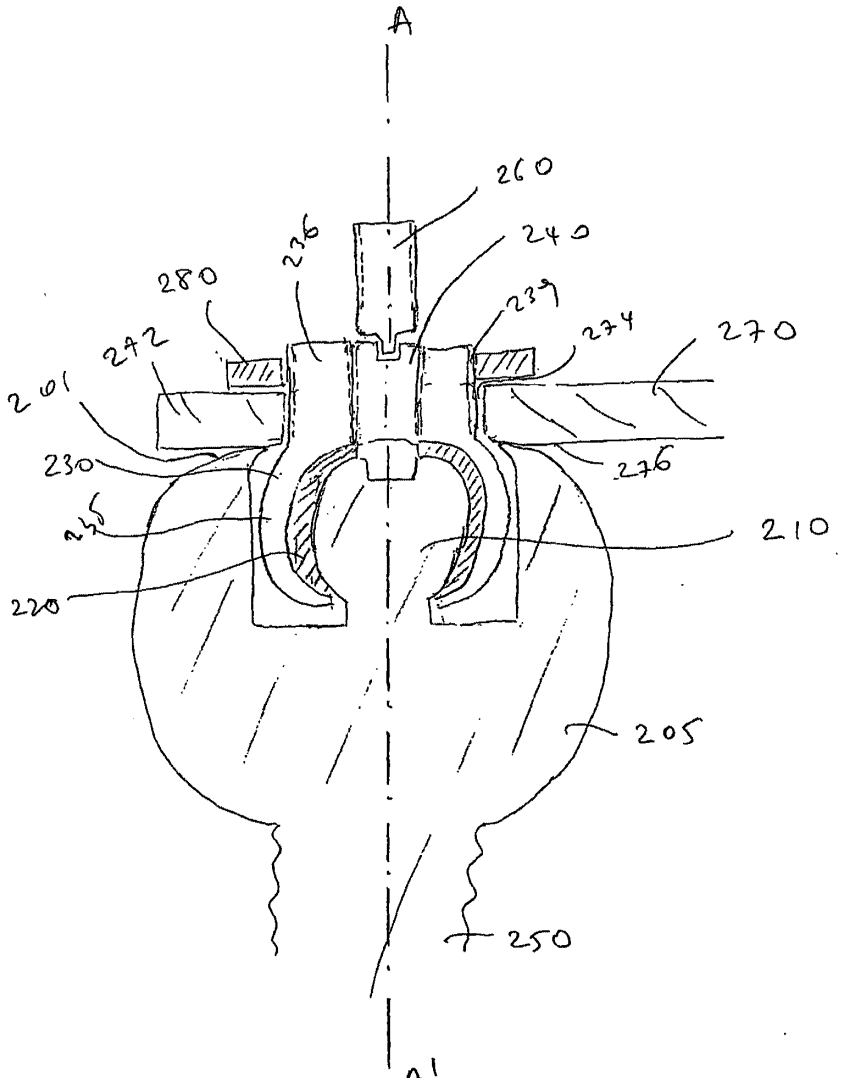


FIG. 5

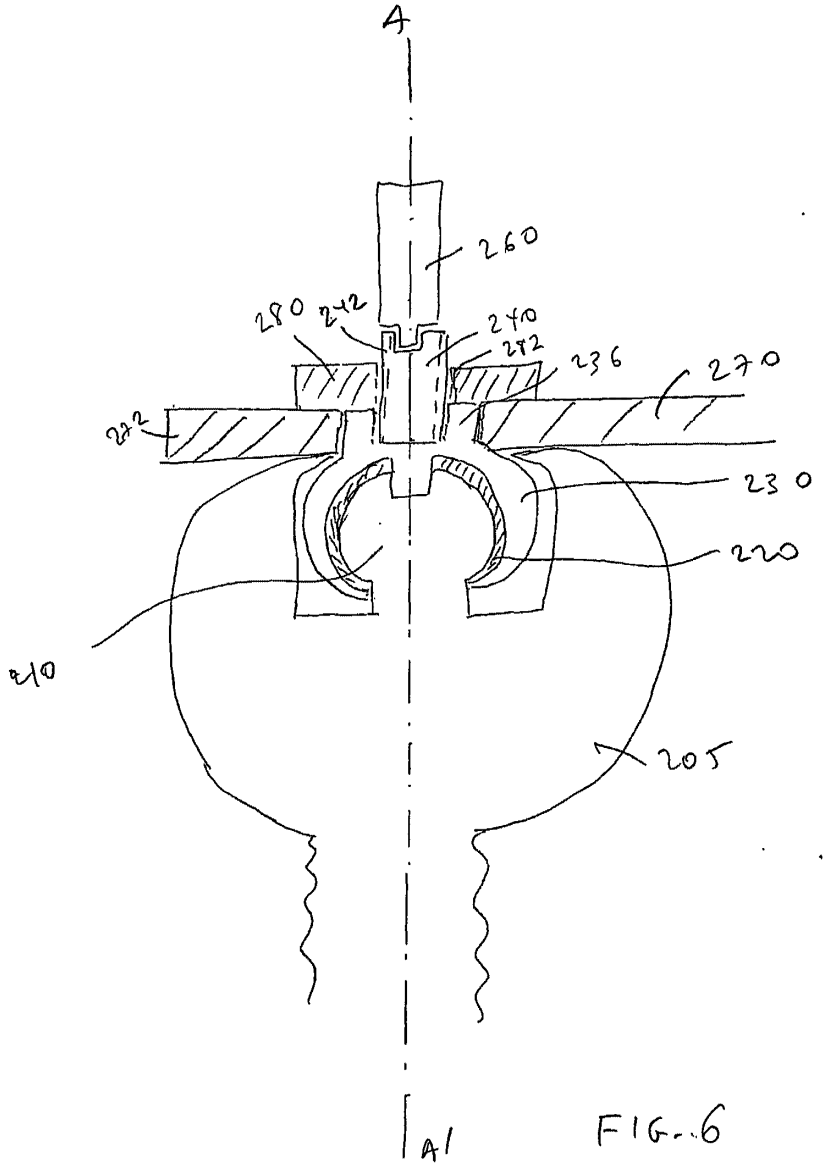


FIG. 6

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US05/21767

A. CLASSIFICATION OF SUBJECT MATTER
IPC(7) : A61B 17/70
US CL : 606/61
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 606/61, 60,72,73,69

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 6,660,004 B2 (Barker et al.) 09 December 2003 (09.12.2003) see entire document	1-26
A	US 5,879,350 A (Sherman et al) 09 March 1999 (09.03.1999) see entire document	1-26
A	US 5,885,286 A (Sherman et al) 23 March 1999 (23.03.1999) see entire document	1-26

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

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"O" document referring to an oral disclosure, use, exhibition or other means

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"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

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(75) Inventors/Applicants *(for US only)*: **IOTT, Andrew** [US/US]; 921 Trellis Lane, West Chester, PA 19380 (US). **LEE, Andrew** [US/US]; 2004 Lantern Lane, Oreland, PA 19075 (US).

(74) Agent: **MALM, Brian**; Castellano Malm Ferrario & Buck PLLC, 2121 K Street N.W., Suite 800, Washington, District of Columbia 20037 (US).

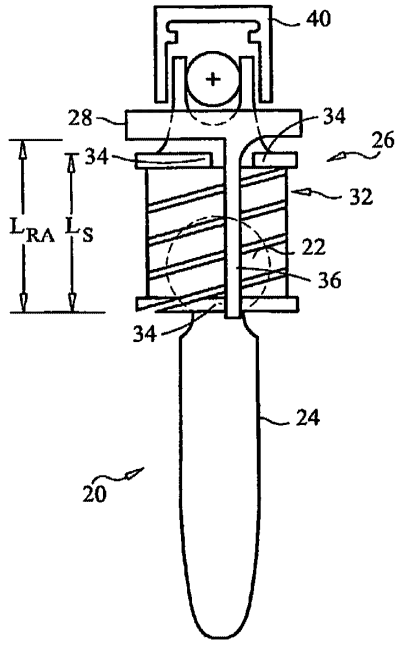
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[Continued on next page]

(54) Title: POLYAXIAL SCREW

(57) Abstract: The present invention generally is directed toward a spinal fixation system whereby a coupling element allows the physician to selectively lock or unlock either the connection between the coupling element and a fastener, such as to allow for repositioning of the coupling element, or the connection between the coupling element and an elongate rod. The locking or unlocking of these connections may be made independently and as desired by the physician.



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GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *without international search report and to be republished upon receipt of that report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

POLYAXIAL SCREW

FIELD OF THE INVENTION

The present invention relates to orthopedic fixation devices comprising a rod and a bone screw having a variable angle head. The variable angle head of the bone screw has a coupling element that can independently lock the angulation of the head relative to the screw axis and securely prevent movement of the rod within the variable angle head.

BACKGROUND OF THE INVENTION

Many types of spinal irregularities can cause pain, limit range of motion, or injure the nervous system within the spinal column. These irregularities can result from, without limitation, trauma, tumor, disc degeneration, and disease. Often, these irregularities are treated by immobilizing a portion of the spine. This treatment typically involves affixing a plurality of screws and/or hooks to one or more vertebrae and connecting the screws or hooks to an elongate rod that generally extends in the direction of the axis of the spine.

Treatment for these spinal irregularities often involves using a system of pedicle screws and rods to attain stability between spinal segments. Instability in the spine can create stress and strain on neurological elements, such as the spinal cord and nerve roots. In order to correct this, implants of certain stiffness can be implanted to restore the correct alignment and portion of the vertebral bodies. In many cases, an anchoring member such as a pedicle screw along with a vertical solid member can help restore spinal elements to a pain free situation, or at least may help reduce pain or prevent further injury to the spine.

Some systems are directed toward immobilization of the vertebral bodies by implantation of bone screws, couplings, and elongate rods. Examples of such systems include U.S. Patent Nos. 5,690,630, 5,669,911, and 5,672,176. It is well known that difficulties can arise during a surgical procedure when attempting to connect a vertical solid member, such as a rod, to a bone screw. As a result, it may be desirable to use a variable angled coupling element to connect a rod to a bone screw. This lessens the need to modify the system , such as by bending the rod, by repositioning the screw, or the like. The coupling element acts as an elbow which can "reach out" to the rod and allow for easier adjustment and installation of the rod in the patient.

Typically, a conventional polyaxial screw described by the prior art often has a cap of some kind is used to compress the rod onto the coupling element. This compression of the rod enables the locking mechanism within the coupling element to fix the angle between the

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bone screw and said element. Therefore, the vertical compression of the rod is paramount in the design of the bone screw system.

Conventional polyaxial screws also typically require that compression of the coupling element and the bone screw be achieved through the clamping of some form of taper within the coupling element. This is achieved usually by means of slits which are placed within the members of the coupling element. When these elements are placed in compression the tines created by the slits contract on the head of the screw by means of a cylindrical taper. In addition to the references mentioned above, additional examples of such systems requiring pressure from the rod to lock the position of the polyaxial screw head also can be found in U.S. Patent Nos. Re 37,665, 5,733,286, and 5,476,464. Some systems, such as described in U.S. Patent No. 6,248,105, describe the possibility of separately fastening the connecting body to the spherical head and elongated rod.

While these designs may provide an advantage of reducing assembly time over earlier screw designs by requiring clamping of only one fastener to hold the rod and coupling element by applying pressure against the head of the bone screw, such systems lack the ability to separately unlock or release one element, such as the rod or the coupling element.

SUMMARY OF THE INVENTION

The present invention is generally directed towards an improved anchoring system using a polyaxial screw that is capable of independently affixing a coupling member to the screw head while also permitting an elongate rod to be held securely in a desired position. In general, the present invention may be used in a variety of spine stabilization systems. For instance, one embodiment has an elongate rod, a bone fastener having a rounded or seim-spherical head, a coupling element, and a skirt having an interior space for receiving the fastener head and coupling element. The coupling element may be formed of one piece or may comprise a plurality of connectors. A plurality of stops may be disposed on the coupling element or on the plurality of connectors, which may be configured and adapted to slidingly communicate with a coupling ring having one or more arms extending toward the fastener. The arms of the coupling ring may be selectively engaged with the stops to lock the position of the skirt with respect to the position of the fastener. Some embodiments of the present invention further comprise a cap capable of engaging with a first end of the skirt and capturing the elongate rod within a recess, channel, or opening in the skirt when the cap is rotated to a first position relative to the skirt.

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In one embodiment, the cap is capable of rotating to first and second positions relative to the skirt. Rotation of the cap relative to the skirt may cause the cap to press the elongate rod toward the coupling ring so that the coupling ring arms apply pressure against the plurality of stops and lock the skirt in position relative to the bone fastener.

In another embodiment, the cap comprises a locking element capable of securely holding the elongated rod in a fixed position relative to the skirt. The cap also may have a threaded opening and the locking element may be a threaded set screw disposed within the threaded opening. Preferably, the set screw is capable of applying downward pressure on the elongate rod to lock the elongate rod in position relative to the skirt.

In still yet another embodiment of the invention, the cap and skirt may have at least one detent or protrusion and corresponding recess or depression that contact each other when the cap is in its second position to resist inadvertent loosening of the cap from the skirt. This feature may be particularly beneficial if a set screw or other locking element is used in the cap to selectively lock or unlock the elongate rod. Depending upon its configuration, rotation of the cap toward to the first or second position may cause the detent and corresponding recess to provide a tactile or audible signal to the physician. In some embodiments, a plurality of detents and recesses may be provided for each predetermined position of the cap relative to the skirt. Thus, in one embodiment, rotation of the cap to a first position relative to the skirt causes the cap and skirt to provide a tactile or audible signal, such as a click, to the physician. Moreover, in some embodiments rotation of the cap to a second position relative to the skirt results in a tactile or audible signal to the physician.

In some embodiments, the cap comprises a sidewall having a first and second channel formed therein. The first and second channels may be wider than the diameter of the elongate rod so as to allow some rotation of the cap without obstruction by the elongated rod. In one embodiment, the first and second channels are configured to permit the cap to rotate from 5° to 90° when in communication with the skirt without being impeded by the elongate rod. In yet another embodiment, unimpeded rotation of the cap is from about 20° to about 40° when in communication with the skirt and with the elongate rod.

The cap may be capable of rotating up to about 30° before reaching the first position. Moreover, the cap may be configured to provide a tactile or audible click when rotated to the first position. In addition, at least one channel in the cap sidewall may comprise a cammed upper edge that is capable of urging the elongate rod toward the coupling ring as the cap is rotated. Moreover, in one embodiment the skirt may have a plurality of threads capable of engaging with the cap and drawing the cap toward the elongate rod as the cap is rotated.

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Additionally, bone fastener head may be textured with helical grooves or have some other textured surface. In one embodiment, a first connector has a first textured surface, a second connector has a second textured surface, and the first and second textured surfaces contact the rounded head when the coupling element is locked to the rounded head.

In still other embodiments of the invention, the spine stabilization system has an elongate rod, a bone fastener having a securing element and a rounded head, and a coupling element. The coupling element may have a lower clamp element disposed on a first end of said head proximal to said securing element, said lower clamp comprising a seating surface corresponding approximately to receive a portion of the rounded surface of said head. One embodiment further includes an upper clamp element disposed on a second end of said head distal to said securing element. In some cases, the lower clamp and upper clamp may have a projection and a notch that can interconnect to restrict rotation of one clamp with respect to the other. Moreover, the system may also have a locking element disposed substantially around said first and second clamp elements. The locking element also may further have an interior surface that is at least partially threaded. In some embodiments, the threaded portion of said locking element may be selectively engaged with said threaded portion of said lower clamp. These embodiments may also have a rod locking element in communication with the upper clamp and locking element. Preferably, the rod locking element comprises a seating surface for receiving said elongate rod. As discussed above, a locking cap may be selectively engaged with said rod locking element to secure said elongate rod to said coupling element.

In still yet another embodiment of the present invention, the system may have a bone fastener having a rounded head and a coupling element. In this embodiment, the first end of the coupling element may have a skirt disposed over said rounded head, wherein said skirt comprises a slit extending from a portion of the skirt proximal to the bone fastener toward a distal end of said skirt, and wherein each of said distal and proximal ends of said skirt has one or more stops. The coupling ring may be disposed over said distal end of said skirt, wherein said coupling ring comprises one or more arms extending from said coupling ring to the proximal end of said skirt, and wherein said arms may be selectively engaged with said stops to lock said coupling element to said head. Once again, a locking cap may be selectively engaged with said coupling element to lock said elongate rod to said coupling element.

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BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 illustrates one embodiment of the invention having an elongated rod and a variable angle fastener with a wedge ring, a slotted body disposed around the head of a screw, and a locking cap;

FIG. 2 shows an isometric view of one embodiment of a wedge ring of the embodiment of FIG. 1;

FIG. 3 illustrates one embodiment of a variable angle fastener having a 2-piece body, a wedge ring, and a locking cap;

FIG. 4 shows a top view of the variable angle fastener of FIG. 3;

FIG. 5 illustrates a variation of the embodiment of FIG. 3 using a 1-piece body;

FIG. 6 is a partial, exploded of the wedge ring of FIGS. 3 and 4 in communication with the body;

FIG. 7 is an isometric view of the 1-piece body of the embodiment of FIG. 5;

FIG. 8 is a top view of the 1-piece body of the embodiment of FIG. 5;

FIG. 9 is a partial cross-sectional view of another embodiment of a variable angle fastener;

FIGS. 10-12 are additional illustrations of the variable angle fastener of FIG. 9;

FIG. 13 illustrates another embodiment of the invention having a screw, a body, a locking ring slidably engaged with the body, and an optional cap;

FIG. 14 illustrates an isometric view of the embodiment of FIG. 13;

FIG. 15 illustrates another embodiment of the invention having a fastener with a flexible head configured to receive an elongated rod;

FIG. 16 illustrates a variation of the embodiment of FIG. 15;

FIG. 17 illustrates an isometric view of another embodiment of the present invention prior to assembly;

FIG. 18 illustrates an isometric view of the embodiment of FIG. 17 when assembled;

FIG. 19 illustrates an isometric view of a cap of the embodiment of FIG. 17;

FIG. 20 is an exploded side view of one embodiment of the present invention;

FIG. 21 is an exploded isometric view of the embodiment of the present invention of FIG. 20;

FIG. 22 is a closer exploded isometric view of a portion of the invention of FIG. 17;

FIG. 23 is a closer exploded side view of a portion of the invention of FIG. 17;

FIG. 24 is an assembled view of a portion of the invention of FIG. 17; and

FIG. 25 is an isometric view of a skirt of the present invention of FIG. 17.

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DETAILED DESCRIPTION OF THE INVENTION

The present invention generally is directed toward a spinal fixation system whereby the locking of an elongate rod plays may not be necessary in order to lock the angle between a fastener, such as a screw, and a coupling element. Instead of requiring full application of locking pressure on an elongated rod in order to lock the coupling element securely in place with respect to the screw head, some embodiments of the present invention utilize a coupling locking device that is capable of securing the coupling element to the screw independent of the rod or with forces imparted by the rod that are less than the forces used to lock the rod in place. Likewise, some embodiments of the present invention also may utilize a rod locking device that is capable of securing the rod to the coupling element in a manner that is independent of the coupling locking device. In addition, some embodiments of the present invention permit a coupling element to lock in place relative to the fastener head by downward movement of the elongated rod. Once the coupling element is locked, the rod may be moved upward or repositioned without causing the coupling element to unlock or come loose. Thus, unlike prior spine stabilization systems, many embodiments of the present invention permit separately locking or unlocking of either the rod and coupling element or the coupling element and screw.

As explained by the examples and illustrations below, the coupling locking device and the rod locking device can be configured and adapted in several different ways while still allowing independent operation or independent locking. Through the means of cams, wedges, or threads, this invention can place a compression on the head of the screw without use of the elongated rod. The invention further seeks to reduce the number of steps in the procedure, reduce the size of the coupling element, and reduce the number of separate pieces associated with the implant. This will reduce intra operative time, create less complicated procedures, and work well in a wider variety of patient anatomy.

While many features of the invention will be described more fully below with reference to the accompanying drawings illustrating several embodiments of the invention, it is to be understood at the outset that skilled artisans having the benefit of this disclosure may recognize further variations or modifications of the invention that may also achieve the functions and results of this invention. Accordingly, the descriptions which follow are to be understood as illustrative and exemplary of specific structures, aspects, and features within the broad scope of the invention and not as limiting of such broad scope.

Each of the embodiments described below and in the associated figures describes a polyaxial fastener having a screw and coupling element assembly for use with an orthopedic

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rod implantation apparatus. While the embodiments are described and illustrated as having a screw that has a head and a shaft that extends from the head, it should be understood that other fasteners or securing elements may also be used such as, for example, lamina hooks and sacral blocks. Thus, the present invention may be used with a wide variety of fasteners or securing elements in addition to a bone screw as described herein.

Accordingly, FIG. 1 illustrates a side view of a screw 20 suitable for use in the invention. The screw 20 includes a head 22 and a shaft 24 that extends from the head 22. The shaft 24 is shown as having a tapered shape, which may be configured with a high pitch thread, although once again, skilled artisans would recognize that other shaft designs also would be compatible with the invention. Thus, the physician is free to select from a variety of shaft features, such as thread pitch, shaft diameter to thread diameter ratio, overall shaft shape, and the like according to the conditions of the individual patient's bone.

While the head 22 may have any shape, it is preferred that the head has a tapered neck with a rounded head to provide increased adjustability. Thus, at least a portion of the head may be shaped to form a portion of a ball or at least a portion of a sphere above the neck in order to allow for rotational or angular adjustment of the coupling element 26 with respect to the fastener 20. This preferred configuration also allows the coupling element 26 to more securely grip the head 22. In other words, at least a portion of the head 22 has a curved surface from which the shaft extends. The curved portion of the head can be a semi-spherical in shape, exhibiting an external contour that is equidistant from a center point of the head. In addition, the head may have an engagement surface that can be engaged by a screwdriving tool or other device, it is preferable that the engagement surface does not disrupt the functionality of the curved surface.

The diameter of the head 22 may be approximately the same as the largest diameter of the shaft 24. The neck may be tapered to provide greater curvature of the head 22 in order to provide a greater variety of angles and positions in which the coupling body and screw or fastener may be arranged. It should be noted that in other embodiments, the diameter of the shaft 24 can be less than or greater than the diameter of the head 22, and the neck may be un-tapered or differently tapered.

The head 22 also may have an engagement surface that permits the physician to apply torsional or axial forces to the screw with a wrench or screwdriving tool to drive the screw into the bone. For instance, the engagement surface of the head 22 may be a polygonal recess as shown in FIG. 10 in which the head of a tool can engage. For example, the head 22 may have a hexagonal recess that receives a hexagonal tool such as an allen wrench. The

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engagement surface also may be configured with a protruding engagement surface that likewise may engage with a tool or device having a corresponding recess, although preferably the protruding engagement surface would not significantly interfere with the capability to vary the angle of the coupling element with respect to the screw 20. The engagement surface may have other shapes as well, such as a slot or a cross found typically used with other types of screwdrivers.

Prior to being locked into place, a coupling element 26 associated with the head 26 can be moved and rotated into a plurality of positions. The coupling element is configured and adapted with a seat or interior surface that receives the head 22 on a first end and an elongated rod on the opposing end. At least a portion of the head may have a roughened or textured surface that improvise engagement between it and other component of the polyaxial screw when in a locked or tightened position. With respect to the embodiment shown in FIG. 1, the coupling element comprises a coupling ring 28 and a coupling body 30. The coupling body has a skirt 32 that defines the seat or interior surface that receives the head 22. Preferably, the skirt may be selectively locked or unlocked against the head by providing one or more slits or openings that allow the seat or interior surface of the coupling element to constrict and securely engage with the head 22 in a locked position or be expanded or unlocked as desired. In one embodiment, shown in FIG. 1, the coupling body has one or more generally helical slits. More preferably, the slits or openings extend from a free end of the skirt proximate to the screw or fastener 20 to a location above the head 22.

The coupling body 30 has a plurality of stops 34, preferably disposed near the upper and lower ends of the coupling body skirt 32. The stops 34 may be configured with flanges with openings or slots through which the coupling ring may be placed so that the skirt 32 approximates the shape of a spool. The stops 34 are positioned so that as the coupling ring 28 is connected to the coupling body 30 torsional forces are applied to the skirt 32 causing it to twist and constrict against the head 22.

As shown in FIG. 1, the coupling ring 28 is configured to have one, two, or more arms 36 that extend from the ring 28 and engage with the stops 34. As the coupling ring 28 is placed onto the coupling body 30, the arms 36 slidably engage with the stops with minimal torsional forces imparted to the skirt until a wedge near the base of the arms proximal to the ring contacts one of the stops. After the wedge has engaged with one of the stops, further insertion of the ring over the coupling body will cause it to turn about the longitudinal axis of the skirt. As the ring is turned, the distal end of the arms will engage with stops 34 and apply torsional forces to the skirt. In one embodiment, the locking ring rotates from about 2° to

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about 15° from its initial, unlocked position until reaching a locked position where the coupling element is immovably secured to the screw. In another embodiment, the locking ring rotates from about 5° to about 10° from an unlocked to a locked position.

Preferably, the distal end of the ring arms 36 are configured to radially engage with a lip on the skirt once the skirt has been sufficiently turned to lock against the screw head 22. As shown in FIG. 2, for example, the distal end of the ring arm may have protrusions 38 that extend radially inward. The protrusions 38 can slide over the lip of the skirt and snap into place once the skirt is in its locked position. Initially, when the skirt is not in a locked position, the length of the ring arms L_{ra} from the proximal end to the protrusion may be less than the length of the skirt L_s. As the skirt is twisted, however, its overall length may gradually decrease, and the ring arms will splay outward as the protrusions are forced over the lip. Once the length of the skirt L_s becomes approximately the same length or shorter than the length of the ring arms L_{ra}, the protrusions will be released over the lip and hold the skirt in its locked position. In this embodiment, unlocking the coupling body skirt 32 from the screw head 22 can be accomplished by applying a radially outward force to the ring arms until the protrusions no longer engage with the lip. Once the protrusions are clear of the lip, the coupling ring may be rotated to unlock the coupling element. In this manner, the coupling element may be selectively locked or unlocked to the screw or fastener 20 without requiring the elongated rod to be locked in position. Thus, no forces need be imparted by the elongated rod to lock the coupling element to the screw or fastener.

Returning to FIG. 1, the coupling body also is configured and adapted to receive an elongated rod on an upper end opposite the end of the coupling body 30 configured with the coupling body skirt 32. Preferably, this portion of the coupling body is configured with a U-shaped or wedge shaped seat against which the elongate rod will be locked. Substantially rigid tines or wedges extend upward from the seat for the rod, which are configured with slots or detents that receive a cap 40. The cap, such as illustrated in FIG. 3 and 17, may have corresponding protrusions or slots that permit the cap to engage with and rotate with respect to the coupling body 30. In one embodiment, rotation of the cap causes it to move downward and toward the screw, thereby applying a downward force against the elongate rod to hold it securely in place.

In another embodiment, the cap applies a downward pressure on the elongate rod that, in turn, causes the coupling element to be locked in position relative to the fastener while not completely locking the elongate rod in position. A set screw disposed in the cap may then apply additional downward pressure on the elongate rod to hold it firmly in position. Thus, in

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some embodiments the downward pressure of the cap on the rod may be sufficient to lock one component of the system while still allowing adjustability of the other component.

In an another alternative embodiment, the tines or wedges of the coupling body that extend upward from the seat for the rod may be flexible so that they bend or flex around the rod as the cap is turned toward a locking position. For instance, either the cap, the tines or wedges, or both may be configured to have a tapered or ramped surface that causes gradually increasing radial interference with the cap and coupling element as the cap is rotated. As the radial forces resulting from this interference increases, the tines or wedges may bend or flex radially inward and press against the elongate rod. One or more detents and depressions may be placed on either the cap or the coupling body to hold the cap in a locked position by engaging with each other at a desired cap position. Rotation of the cap in the opposite direction likewise causes the elongated rod to become unlocked.

Thus, in several embodiments of the invention the elongate rod may be selectively locked or unlocked in place without requiring the coupling body to be unlocked from its position with respect to the screw.

FIGS. 3-8 illustrate several features and variations of yet another embodiment of the invention. Several features of this embodiment are similar to those described above. For example, the screw or fastener 20 may be configured or varied according to the physician's preference. It has a head 22 on which a coupling element 26 communicates. As mentioned above, the head 22 may be generally spherical in shape. The coupling element 26 may be positioned and rotated in several directions, and may be selectively locked or unlocked in position. The coupling element likewise has a coupling body 30 and coupling ring 28 with ring arms 36 that is capable of locking the coupling element 26 to the screw or fastener 20.

Rather than using a skirt that twists or rotates to lock the coupling element to the screw or fastener, however, the coupling body of this embodiment may be formed of one, two, or more coupling body components 42 that are configured with at least two stops that slidably engage with at least one ring arm 36. As shown in FIG. 5, the coupling body has at least one slit or opening extending substantially along the length of the coupling body component. More preferably, at least one slit or opening extends entirely along the length of the coupling body component, as shown for example in FIGS. 5 and 7. In one embodiment, the number of slits or opening configured in this manner increases as the number of coupling body components 42 increases. Thus, a coupling body 30 comprising at least two coupling body components 42 also will have at least two slits or openings extending generally along the axial length of the coupling body components.

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The slit or opening is thus defined by corresponding terminating edges of material formed on or more coupling body components 42. As shown in FIGS. 5 and 7, the shape of the slit or opening may be configured such that a portion of a first terminating edge may protrude into a recessed area of a corresponding portion of a second terminating edge. As mentioned previously, at least two stops 34 are configured to slidably engage with at least one ring arm 36. These stops are positioned so that as the tapered portions of the ring arms contact one or more of the stops the terminating edges defining the slit or opening are forced toward each other so that the coupling element can be locked to the head of the screw or fastener. This is accomplished by placing at least one stop on each side of the terminating edges defining the slit or opening. Thus, each ring arm may communicate with two or more stops. More preferably, at least three stops are configured to contact at least one ring arm in order to close the coupling body onto the head 22. Thus, one edge of the slit or opening may have two or more stops, while the other may have one or more stops. Even more preferably, each ring arm is configured to communicate with at least three stops arranged in this manner.

As shown in FIGS. 3, 5, and 6A, the terminating edges or the coupling body components 42 may be configured in a tongue and groove fashion so that the tapered surface of the ring arm contacts the stops on the trailing edge of the stop rather than at the leading edge. It is not necessary, however, that the terminating edges have this configuration. FIGS. 6B-D, for instance, illustrate some variations of this embodiment that do not utilize a tongue and groove configuration. More particularly, FIG. 6B illustrates that multiple wedges may be provided on the ring arms 36. This allows stops to be placed in different locations along the axial length of the coupling body, such as to allow the application of different amounts of gripping force on different portions of head 22.

FIG. 6C shows that the stops may be angled in a manner that helps encourage the terminating edges closer together as the ring arms 36 are moved toward a locking position. For instance, the angle of the stops may be from about 3° to about 15° off from the longitudinal axis of the coupling element 26, and more preferably the stops may be angled from about 5° to about 10°.

The embodiment of FIG. 6D uses a plurality of slits or openings that generally are perpendicular to the longitudinal axis of the coupling element 26. These slits or openings create an appearance of generally horizontal bands. Stops disposed near free ends of one or more horizontal bands may slidingly engage with the ring arms as they are moved toward a locking position, thereby causing the terminating surfaces of the horizontal bands to move toward each other to grip the head 22.

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Locking mechanisms may be used in any of the embodiments described herein to hold the ring arms onto the coupling body in a locked position. As mentioned above, many different types of forces, such as torsional loading around or axial loading along the longitudinal axis of the coupling element 26, may be applied to the coupling ring 28 and ring arms 36 in order to lock the coupling element in position. The embodiments shown in FIGS. 6A-D, for example, have locking mechanisms disposed on the free ends of one or more ring arms.

The coupling element 26 may have a seat for receiving an elongated rod, and further may have tines that engage with a cap to independently lock the coupling element to an elongated rod. In some embodiments, the coupling element may be securely positioned with respect to the fastener head with little or no additional pressure applied to the head 22. For example, the cap may provide pressure to the sides of the tines on the coupling element, which in turn flex or bend to securely grip the elongated rod.

FIGS. 9-12 illustrate an embodiment of the invention that does not utilize a coupling ring with ring arms applying forces to stops in order to cause the coupling element to flex or bend around the head 22. Instead, this embodiment uses a multiple piece threaded lock to clamp the coupling element to the fastener 20. For example, FIG. 9 illustrates a coupling element formed from a lower clamp element 44, an upper clamp element 46, a threaded locking nut 48, and an elongated rod locking nut 50.

FIG. 11 illustrates the assembly of the polyaxial screw of this embodiment of the invention. During assembly, the upper clamp element 46, elongated rod locking nut 50, and threaded locking nut 48 are positioned over the head 22 of the fastener 20 that is distal to the screw shaft 24. The lower clamp element 44 then is placed onto the head 22 by passing the screw head through its open center. The lower clamp element 44 preferably has threads that engage with the threads of the threaded locking nut 48. As these threads are increasingly engaged, the upper and lower clamp elements 44 and 46 gradually clamp onto the head 22 until the coupling element is securely in place.

FIG. 9 shows that the interface between the upper and lower clamp elements may be engaged in a manner that prevents rotation of the clamp elements as the threaded locking nut is turned. In one embodiment, the upper and lower clamp elements utilize corresponding square tooth patterns on the clamping elements. Other patterns also may be used for the interconnecting surfaces, such as a sawtooth, a ratchet, or the like. The edges also may have roughened surfaces, such as a star grind, to help prevent rotation of the clamp elements,

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although it is more preferred that the interlocking surfaces of larger dimensions be used in order to ensure that the surfaces interconnect and resist rotation.

The elongated rod may be locked in place by turning the elongated rod locking washer or nut so that the tines of the coupling element flex or bend to grip the rod. As shown in FIG. 9, the tines may be formed on the upper clamp. In this embodiment a cap as previously described for locking the elongated rod in place may or may not be present. For example, the elongated rod locking washer may have one or more cams on its internal surface that urges the tines to bend or flex tightly around the elongated rod when the washer is turned or rotated. Preferably, turning the washer from about 5° to about 25° causes the elongated rod to be either locked or unlocked. More preferably, the washer can be turned from about 10° to about 25°. If desired, a cap may be provided to further ensure that the rod is securely held in place. A set screw may also be provided in the cap to apply additional locking forces to the elongated rod.

FIGS. 13 and 14 illustrate another embodiment of the invention that once again uses a coupling body skirt with slots or openings formed therein. In this embodiment, the coupling body skirt may be angled by from about 5° to about 30°, and more preferably is from about 7° to about 15°. While the figures illustrate that the taper of the coupling element gradually expands the diameter of the tapered portion of the coupling body skirt 32 from the end proximate the screw shaft 24 to the upper end near the elongated rod, skilled artisans would appreciate that the taper could be inverted.

A locking ring 52 disposed around the coupling body skirt is capable of causing the coupling element to clamp securely to the fastener 20 simply by moving it in an axial direction along a tapered surface of the coupling body skirt 32. One advantage of this embodiment over the embodiments of FIGS. 9-11 is that there is no need to apply a wrench to a threaded locking nut. Additionally, in this embodiment the coupling body may be formed from only two elements instead of four. Thus, this embodiment may be advantageous over other embodiments at least for it simplicity of operation and design.

In operation, once the coupling element is in a desired position, the locking ring 52 may be moved vertically along the axis of the coupling body skirt. As the ring is moved, it engages with and compresses the tapered region of the skirt, which in turn causes the skirt to flex and bend toward the head 22. Although not shown, a second ring may be provided on the skirt to help independently lock the elongated rod to the coupling body. This can be accomplished, for instance, by providing tines that reach above the elongated rod after the rod has been positioned within a seat of the coupling element.

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In much the same manner as described above for locking the coupling element 26 to the fastener 20, the second locking ring can be moved along the axis of a second tapered coupling body skirt that is configured and adapted for locking the elongated rod. It may be advantageous to configure the first and second tapered skirts and locking rings so that the direction of movement for moving one locking ring into a locked position would cause the second locking ring to move into an unlocked position if moved in the same direction. In other words, for this embodiment it may be advantageous to configure the coupling element so that locking of all components of the polyaxial screw is effected by either moving the locking rings far apart or by moving them toward each other.

Another alternative for locking the elongated rod is to use a cap 40. Any cap design for locking an elongated rod, including those already described herein, may be used to securely connect the elongated rod with the coupling element.

In general, the embodiments described above may be used to establish a substantially rigid, immobilization of at least a portion of the spine. In some cases, however, it may be advantageous to use a system that allows for some flexible support for at least a portion of the spine. The embodiment illustrated in FIGS. 15 an 16 describe one aspect of the invention where the fastener 20 is capable of flexing or bending even after the components have been secured together. Although not required in order to practice the invention, in a preferred embodiment, the fastener and coupling element may be integrally formed.

The coupling element may have one or more slits or openings that provide limited range of flexibility. For instance, the coupling elements may be configured to permit from about 2° to about 7° of flex. To provide this flexibility, the coupling element may be formed from one or more slits or openings formed in its surface. In one embodiment, the slits or openings in the coupling element are generally helical in shape. Other flexible constructions also may be used. For instance, U.S. Patent Application No. 10\443,755, filed May 23, 2003, and which is incorporated herein in its entirety, provides several methods and constructions for a flexible coupling element that may be used in the present invention. In addition, U.S. Patent Application No. 10/762,533, filed January 23, 2004 and which is also incorporated by reference in its entirety, provides additional methods and constructions that may be used with the present invention.

A seat for receiving the elongated rod may also be integrally formed into the fastener, although once again such a construction is not required in order to practice the invention. The seat may be formed from a plurality of tines in the manner previously described, or alternatively may have a threaded surface in which a locking cap 54 is placed over the rod.

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As the locking cap is turned, its lower surface presses against the upper surface of the elongated rod until the rod is securely held in place.

FIGS. 17-19 illustrate another embodiment of the invention using a multiple piece threaded locking nut to clamp the coupling element 26 to the fastener 20. As shown in FIG. 17, the coupling element 26 comprises a lower clamp element 44, an upper clamp element 46, a threaded locking nut 48. The upper and lower clamp elements 44 and 46 have interconnecting edges that, when joined, help prevent rotation of one clamp element with respect to the other. As shown in FIG. 17, for example, the interconnected edges of the upper and lower clamp elements 44 and 46 may have an interconnecting pattern of teeth. Skilled artisans would recognize that other interconnecting edge patterns also may be used to help prevent rotation of the clamp elements with respect to each other.

A portion of the lower clamp element 44 is threaded on its outer surface in order to receive corresponding threads on the inner surface of the threaded locking nut 48. Tightening of the threaded locking nut 48 causes the upper and lower clamp elements 44 and 46 to move towards each other in order to lock the coupling body 30 onto the head 22.

The upper and lower clamp elements 44 and 46 have seating surfaces that conform to a portion of the curved surface of the fastener head 22. Preferably, the radius of curvature of the rounded or semi-spherical portion of the head 22 is the substantially the same as the radius of curvature for the seating surfaces of the upper and lower clamp elements. Once the clamp elements have fully contacted the head 22, however, a gap or opening may remain between the upper most or lower most regions of the interconnecting edges. For instance, the space between the uppermost edge of an upwardly extending square tongue of the lower clamping element 44 and the uppermost edge of a corresponding square groove of the upper clamping element 46 may be from about .1 mm to about 5 mm in height.

While the upper clamp element 46 has a lower edge that interconnects with the edge of the lower clamp, it also has an upper edge on the distal end from the interconnecting edge that engages with other elements of the coupling body to form a seat that receives the elongated rod. In particular, the distal end of the upper clamp element 46 extends above the threaded locking nut 48 and through an aperture formed in a rod seating and locking element 58 disposed above the threaded locking nut 48. The rod seating and locking element 58 has a curved seating surface that receives the elongated rod, but also is configured with a recess 60 to receive the distal end of the upper clamp element 46.

In particular, the distal end of the upper clamp 46 has two or more wings 56 that extend radially outward from the distal end of the clamp. As shown in FIG. 17, the threaded

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locking nut 48 and rod seating and locking element 58 are notched to permit the wings 56 to pass through them when the wings are aligned with the notches. Once the wings are disposed above the seating surface of the rod seating and locking element 58, either the upper clamp 46 or the locking element 58 may be rotated until the recess 60 is aligned with the wings 56. The wings 56 are then placed within the recess 60 to form the seating surface on which the elongated rod will be placed.

Once the elongated rod is positioned over the seating surface of the locking element 58 and the wings 56 of the upper clamping element 46, a locking cap 62 may be joined with the locking element 58 to securely connect the coupling element 26 to the rod. The manner in which the cap 62 and locking element 58 apply a locking force on the elongated rod may vary. In one embodiment, the locking cap is configured to apply a downward force on the elongated rod as it is joined with the locking element 58. As shown in FIG. 17, the locking element 58 may have one or more tabs that engage with the cap 62 to move the cap downward upon the rod.

Referring to FIG. 19, the cap may have a curved ridge or tooth 66 extending along a portion of the circumference of the cap on its interior surface. The length of the curved ridge 66 may be determined in part upon the amount or rotation the cap will undergo when moving from an unlocked position to a locked position over the elongated rod. For instance, one or more curved ridges may extend from about 3° to about 30° of the cap, and more preferably extends from about 10° to about 20°. The curved ridge 66 engages with the underside of the tab 64.

Either the curved ridge 66, the tab 64, or both may be configured to create a cammed surface that forces the cap downward as it is rotated toward a locked position. The tab and ridge also may be configured with one or more detents and recesses that are capable of providing a tactile or audible signal to the physician, such as click that may be felt or heard, of when the cap has reached its locked position. The detents and recesses also may assist in maintaining the cap in its locked position.

Referring to FIG. 17, in a preferred embodiment the locking element 58 has an outer surface 68 below the tabs 64 that is generally cylindrical in shape. The cap 62 likewise has a corresponding generally cylindrical surface 70 of similar diameter. When the cap is placed over the locking element, these two surfaces may help maintain radial positioning of the cap 62 relative to the locking element 58 as the cap is turned toward a locking position.

In one alternative embodiment, the locking element 58 and cap 62 may be configured compress a portion of the seating surface around the rod to lock it in place in a manner

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similar to FIGS. 9 and 14. Thus, this alternative embodiment may involve modifying the generally cylindrical surfaces 68 and 70 to create a cammed surface that applied radially inward forces upon a portion of the locking element. As the cap 62 is rotated toward a locking position, the radial forces increase and cause a portion of the locking element 58 to flex, bend, and compress the elongate rod.

As shown in FIGS. 17-19, the cap of this embodiment may have a sidewall 72 that extends from the top of the cap 62 toward the screw shaft 24. Preferably the cap sidewall 72 terminates near a lip or base of the locking element 58, and both elements are configured to have approximately the same outer diameter. In order to place the cap over the elongated rod the sidewalls 72 may have cutouts or notches 74 that permit the rod to extend through the sidewall 72 when the cap is placed over the locking element 58 in either a locked or unlocked position. Thus, the length of the cutouts or notches generally correspond to the amount of rotation needed to move the cap into or out of a locked position. The cutouts 74 also may be slightly larger than needed to rotate the cap 62 in order to allow for possible tolerances in the design of the cap 62, the locking element 58, and the rod. For instance, the cutouts 74 may permit from about 1° to about 5° of additional rotation than needed to lock or unlock the cap 62.

Several of the features or elements of the various embodiments described herein may be modified and/or used with other embodiments without departing from the spirit and scope of the invention. FIGS. 20-25 illustrate yet another embodiment of the invention that uses several features or elements described above. FIGS. 20-24 show how the components of this embodiment may be configured, arranged, and assembled. As shown in FIG. 21, for instance, the coupling element 26 may be formed of a coupling body and coupling ring. The coupling body may have one, two, or more coupling body components with at lest one, preferably two, slits or openings extending substantially, if not completely, along the axial length of the coupling body. The slits or openings need not be straight, but rather may be defined by the terminating edges of material on the coupling body components 42. FIGS. 20, 23 and 24 illustrate that the terminating edges of the coupling body components may be configured with a tongue and groove configuration. Likewise, a single coupling body component such as shown in FIGS. 7 and 8 may be used in place of a plurality of coupling body components.

Likewise, one terminating edge may define a first substantially horizontal protrusion disposed above a second substantially horizontal protrusion defined by the opposing terminating edge so that the first and second protrusions are substantially layered or

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sandwiched together. Stops may be disposed on the coupling body components near each slit. At least one stop may be provided on opposite sides of the slit or opening. Thus, where the illustrated example uses two coupling body components, there are at least two stops on both components. The coupling body components may be disposed around the rounded fastener head. Subsequently, a ring may be pressed or lowered downward over the coupling body components. As the ring is lowered, one or more arms slidingly engage with the stops. Further downward movement of the ring and arms may then cause the coupling body components to securely grip the fastener head. FIG. 24 illustrates that the arm may define a wedge shape that pushes the stops on the coupling body components further apart from each other, which in turn causes the components to apply greater gripping force upon the fastener head.

Skilled artisans would appreciate, however, that other configurations of stops may also be used to securely grip the fastener head, including any of the other configurations previously described above. For instance, the configurations illustrated in FIGS. 1 and 6B-E may also be utilized to push the stops closer together in order to increase the gripping forces applied to the fastener head.

Turning to FIG. 24, the coupling body components may be configured to join together to grip the screw head. In this embodiment, a first coupling body component may have two prongs or arms on each side that extend outward to define a recess therebetween. The second coupling body component may then be configured with one arm on each side that corresponds generally to the recesses formed in the first component.

The interior surfaces of the coupling body components may be roughened or textured to more securely grip the screw head. As shown, the interior surfaces may be textured with a plurality of grooves or circular cuts. The interior surfaces of both components may have similar textured formed thereon, or alternatively may have different textures or texture orientations. For instance, the grooves or circular cuts on one interior surface may be oriented in one direction, such as being directed generally horizontally, while grooves or cuts on a second interior surface may be oriented in a different direction, such as vertically, so that the angle formed between the direction of the grooves or cuts of the first surface and the direction of the grooves or cuts of the second surface is from about 60° to about 90°. In one embodiment, the gripping pressure applied to the fastener head causes the raised portions of the surfaces having grooves to deform or cut into an opposing grooved surface, thereby further resisting unintended movement or repositioning of the components. Additionally,

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helical grooves may be provided on either a portion of the fastener head, on a gripping surface of one or more coupling elements, or both.

Once the coupling body component are place around the screw head, ring arm 36 may be place over the coupling element so that downward extending arms of the ring arm begin to engage with the stops to hold the coupling body components onto the screw head. In addition, the coupling body components and screw head may be lowered into the skirt. Turning to FIG. 25, the lower portion of the skirt may have a lip or retaining ring that is capable of supporting the fastener and assembled components disposed around its head. The lip may be a unitary surface extending inward around the entirety of the perimeter of the lower portion of the skirt, or alternatively may be formed of a plurality of tabs or protrusions that cooperate to prevent the assembled components from passing through the lower end of the skirt. The portion of the fastener head and assembly that rests against the lip may be shaped or configured to distribute the axial loading placed on the lip in substantially equal portions. In one embodiment, the surface of the lip that contacts the assembly is substantially flat and resides in a plane that is perpendicular to the longitudinal axis of the skirt. The shape of the contacting surface of the lip may have other shapes as well, such as a frustoconical shape, a partially spherical shape, a sawtooth or ridged shape such as illustrated in FIG. 9, or the like.

Above the lip, the skirt has a recess formed therein where the assembly may be placed. The ring arm may then be disposed over the assembly in the manner described above. The ring arm is configured with a curved seating surface on its upper side that is shaped to receive an elongate rod. The skirt also has two openings or slots on its upper side for receiving the elongate rod.

As the rod is fitted through the opening or slots on the skirt and pressed on the ring arm seating surface, the ring arm may be urged further down, thereby causing the coupling element to close further upon the screw head. The forces applied on the screw head, however, may not yet fully prevent the skirt and assembly from being rotated, moved, or adjusted. A cap may then be lowered onto the skirt over the rod. As shown in FIG. 25, the cap may have two enlarged openings or slots that are wider than the opening of the skirt and wider than the diameter of an elongated rod that may be placed in the skirt. This embodiment permits the cap to be turned or rotated without the sidewalls of the openings or slots from being obstructed by the rod. Preferably, the openings or slots are configured to permit from about 5° to about 90° of rotation of the cap, or alternatively permit from about 15° to about 60° of rotation of the cap. In yet another embodiment, the openings or slots in the cap are

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configured to permit from about 20° to about 40° of rotation of the cap without being obstructed by the rod.

When the cap is turned to a first position, it engages with the skirt to prevent its inadvertent removal. In this position, the rod may remain free to be moved or slide through the openings of the skirt and cap, and the skirt may still be adjusted or moved relative to the screw or fastener. As the cap is turned further to a second position, however, a cam or inclined surface on the upper portion of the enlarged openings or slots may urge the rod further downward onto the ring arm, thereby causing the ring arm and coupling body components to securely grip the fastener head so that the skirt can no longer move relative to the screw or fastener. As mentioned above, the locking of the coupling body components in this manner may not also cause the cap to fully lock the elongated rod to the skirt. In fact, once the coupling body is locked onto the fastener head, the cap may be loosened and the elongated rod repositioned without inadvertently causing the coupling body to become unlocked from the fastener head.

Alternatively, the cap may be urged further down into the skirt as it is turned toward the second, locking position. As the cap is lowered, the upper portion of the enlarged opening or slot, which may or may not have a cam or incline, will press the rod against the seat of the ring arm. For instance, the cap and skirt may be configured with threads that draw the cap into the skirt when it is turned in one direction and releases the cap from the skirt when turned in the opposite direction.

Preferably, the skirt and/or cap are configured to provide a tactile feel or audible click when the cap reaches either the first or second position, or both positions. One advantage of this is that the physician will receive confirmation that the assembly is in a desired position. In addition, the cap and skirt may be configured with one or more detents or similar mechanisms to help prevent the cap from inadvertently backing out of either the first or second positions.

While the skirt and fastener may be fixed in position relative to each other once the cap is in the second position, the rod may still be capable of sliding through the openings of the skirt and cap. The cap may be configured with an aperture disposed on its upper surface where a set screw may be utilized to securely hold the rod in place once it is in its desired position.

As illustrated by the many embodiments described above, the present invention is capable of providing greater flexibility for the physician for installing and adjusting a spinal fixation system. In practice, the physician installs a plurality of fasteners to the treated area

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of the spine. The fasteners 20 are configured with coupling elements 26 that can be moved and rotated into several positions. The physician may lock in a desired position for the coupling element 26 without requiring the elongated rod to also be locked in position. Likewise, the physician may unlock coupling element 26 from the fastener 20 even after the rod has been locked to the coupling element. Thus, the physician is free to readjust the rotation and angle of the coupling element 26 with respect to the fastener 20 at any time.

In sum, the embodiments described above show that the present invention provides several advantages not previously achieved by the prior art. For instance, one advantage realized by allowing independent locking and unlocking of the rod locking device and the coupling locking device is that the polyaxial screw permits significantly greater adjustability than could be accomplished in the past. Adjustment of the connection between the rod and the coupling device need not risk losing a desired positioning of the coupling element with respect to the screw. Thus, the present invention allows for fine tuning whereas prior systems required were designed to loosen all of the components in order to reposition any component.

In addition to providing greater adjustability, the present invention also reduces the complexity and number of the surgical steps involved for installing a spine stabilization system. The present invention also provides for a more compact design than could be achieved in the past, and reduces the number of separate pieces associated with the implant. Altogether, these advantages will help reduce intra operative time, simplify the surgical procedure, and work well in a wider variety of patient anatomy.

While it is apparent that the invention disclosed herein is well calculated to fulfill the objects stated above, it will be appreciated that numerous modifications and embodiments may be devised by those skilled in the art. Therefore, it is intended that the appended claims cover all such modifications and embodiments that fall within the true spirit and scope of the present invention.

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THE CLAIMS

1. A spine stabilization system comprising:

an elongate rod;

a bone fastener having a rounded head;

a coupling element comprising a first connector, a second connector, and a coupling ring;

wherein the first and second connector may be joined and disposed over the rounded head of the fastener, and wherein said first and second connectors have a plurality of stops formed thereon that are configured and adapted to slidingly communicate with the coupling ring;

wherein the coupling ring is configured with a seating surface for receiving the elongate rod, and wherein the coupling ring comprises one or more arms extending from the coupling ring toward the fastener so that the arms may be selectively engaged with the stops;

a skirt having a sidewall defining a recess that is capable of receiving the fastener and the coupling element;

a cap capable of engaging with a first end of the skirt and capturing the elongate rod within the recess of the skirt when the cap is rotated to a first position relative to the skirt.

2. The spine stabilization system of claim 1, wherein the cap is capable of further rotating to a second position relative to the skirt to press the elongate rod toward the coupling ring so that the coupling ring arms apply pressure against the plurality of stops and lock the skirt in position relative to the bone fastener.

3. The spine stabilization system of claim 1, wherein the cap comprises a locking element capable of securely holding the elongated rod in a fixed position relative to the skirt.

4. The spine stabilization system of claim 3, wherein the cap comprises a threaded opening and the locking element comprises a threaded set screw disposed within the threaded opening, wherein the set screw is capable of applying downward pressure on the elongate rod.

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5. The spine stabilization system of claim 2, wherein the cap and skirt are configured with at least one detent and corresponding recess that contact each other when the cap is in its second position to resist inadvertent loosening of the cap from the skirt.

6. The spine stabilization system of claim 5, wherein rotation of the cap toward to the second position causes the detent and corresponding recess to provide a tactile or audible signal to the physician.

7. The spine stabilization system of claim 1, wherein said skirt further comprises a first and second opening in said sidewall that are configured to receive the elongate rod.

8. The spine stabilization system of claim 1, wherein the cap comprises a sidewall having a first and second channel formed therein, wherein the first and second channels are wider than the diameter of the elongate rod.

9. The spine stabilization system of claim 8, wherein the first and second channels are configured to permit the cap to rotate from 5° to 90° when in communication with the skirt without being impeded by the elongate rod.

10. The spine stabilization system of claim 9, wherein the first and second channels are configured to permit the cap to rotate from 20° to 40° when in communication with the skirt without being impeded by the elongate rod.

11. The spine stabilization system of claim 1, wherein the cap is capable of rotating up to about 30° before reaching the first position.

12. The spine stabilization system of claim 2, wherein the cap is configured to provide a tactile or audible click when rotated to the first position.

13. The spine stabilization system of claim 8, wherein at least one channel in the cap sidewall comprises a cammed upper edge that is capable of urging the elongate rod toward the coupling ring as the cap is rotated.

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14. The spine stabilization system of claim 13, wherein the skirt has a plurality of threads capable of engaging with the cap and drawing the cap toward the elongate rod as the cap is rotated.

15. The spine stabilization system of claim 1, wherein the rounded head is textured with helical grooves.

16. The spine stabilization system of claim 15, wherein the first connector has a first textured surface and the second connectors has a second textured surface, and wherein the first and second textured surfaces contact the rounded head when the coupling element is locked to the rounded head.

17. A spine stabilization system comprising:

an elongate rod;

a bone fastener having a rounded head;

a coupling element and coupling ring assembly;

wherein the coupling element may be disposed over the rounded head of the fastener, and wherein the coupling element has an opening or slit extending along its axial length and a plurality of stops formed on its outer surface that are configured and adapted to slidingly communicate with the coupling ring;

wherein the coupling ring is configured with a seating surface for receiving the elongate rod, and wherein the coupling ring comprises one or more arms extending from the coupling ring toward the fastener so that the arms may be selectively engaged with the coupling element stops;

a skirt having a sidewall defining a recess that is capable of receiving the fastener and the coupling element;

a cap capable of engaging with a first end of the skirt and capturing the elongate rod within the recess of the skirt when the cap is rotated to a first position relative to the skirt.

18. The spine stabilization system of claim 17, wherein the cap is capable of further rotating to a second position relative to the skirt to press the elongate rod toward the coupling ring so that the coupling ring arms apply pressure against the plurality of stops and lock the skirt in position relative to the bone fastener.

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19. The spine stabilization system of claim 17, wherein the cap comprises a locking element capable of securely holding the elongated rod in a fixed position relative to the skirt.

20. The spine stabilization system of claim 19, wherein the cap comprises a threaded opening and the locking element comprises a threaded set screw disposed within the threaded opening, wherein the set screw is capable of applying downward pressure on the elongate rod.

21. The spine stabilization system of claim 18, wherein the cap and skirt are configured with at least one detent and corresponding recess that contact each other when the cap is in its second position to resist inadvertent loosening of the cap from the skirt.

22. The spine stabilization system of claim 21, wherein rotation of the cap toward to the second position causes the detent and corresponding recess to provide a tactile or audible signal to the physician.

23. The spine stabilization system of claim 17, wherein said skirt further comprises a first and second opening in said sidewall that are configured to receive the elongate rod.

24. The spine stabilization system of claim 17, wherein the cap comprises a sidewall having a first and second channel formed therein, wherein the first and second channels are wider than the diameter of the elongate rod.

25. The spine stabilization system of claim 24, wherein the first and second channels are configured to permit the cap to rotate from 5° to 90° when in communication with the skirt without being impeded by the elongate rod.

26. The spine stabilization system of claim 25, wherein the first and second channels are configured to permit the cap to rotate from 20° to 40° when in communication with the skirt without being impeded by the elongate rod.

27. The spine stabilization system of claim 17, wherein the cap is capable of rotating up to about 30° before reaching the first position.

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28. The spine stabilization system of claim 18, wherein the cap is configured to provide a tactile or audible click when rotated to the first position.

29. The spine stabilization system of claim 24, wherein at least one channel in the cap sidewall comprises a cammed upper edge that is capable of urging the elongate rod toward the coupling ring as the cap is rotated.

30. The spine stabilization system of claim 29, wherein the skirt has a plurality of threads capable of engaging with the cap and drawing the cap toward the elongate rod as the cap is rotated.

31. The spine stabilization system of claim 17, wherein the rounded head is textured with helical grooves.

32. The spine stabilization system of claim 31, wherein the first connector has a first textured surface and the second connectors has a second textured surface, and wherein the first and second textured surfaces contact the rounded head when the coupling element is locked to the rounded head.

33. A spine stabilization system comprising:

an elongate rod;

a bone fastener having a securing element and a rounded head;

a coupling element comprising:

a lower clamp element disposed on a first end of said head proximal to said securing element, said lower clamp comprising a seating surface corresponding approximately to receive a portion of the rounded surface of said head, and an exterior surface, wherein at least a portion of said exterior surface is threaded;

an upper clamp element disposed on a second end of said head distal to said securing element, wherein said lower clamp and upper clamp have a projection and a notch that can interconnect to restrict rotation of one clamp with respect to the other;

a locking element disposed substantially around said first and second clamp elements, said locking element further comprising an interior surface that is at least partially threaded, and wherein said threaded portion of said locking element may be selectively engaged with said threaded portion of said lower clamp; and

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a rod locking element in communication with said upper clamp and said locking element, wherein said rod locking element comprises a seating surface for receiving said elongate rod; and

a locking cap that may be selectively engaged with said rod locking element to secure said elongate rod to said coupling element.

34. A spine stabilization system comprising:

a bone fastener having a rounded head;

a coupling element, wherein a first end of said coupling element comprises:

a skirt disposed over said rounded head, wherein said skirt comprises a slit extending from a portion of the skirt proximal to the bone fastener toward a distal end of said skirt, and wherein each of said distal and proximal ends of said skirt has one or more stops;

a coupling ring disposed over said distal end of said skirt, wherein said coupling ring comprises one or more arms extending from said coupling ring to the proximal end of said skirt, wherein said arms may be selectively engaged with said stops to lock said coupling element to said head;

an elongate rod disposed in a rod seating surface on a second end of said coupling element; and

a locking cap that may be selectively engaged with said coupling element to lock said elongate rod to said coupling element.

35. The spine stabilization system of claim 34, wherein said slit has a generally helical pattern.

36. The spine stabilization system of claim 35, wherein the stops lock said coupling element to said head by rotating said coupling ring.

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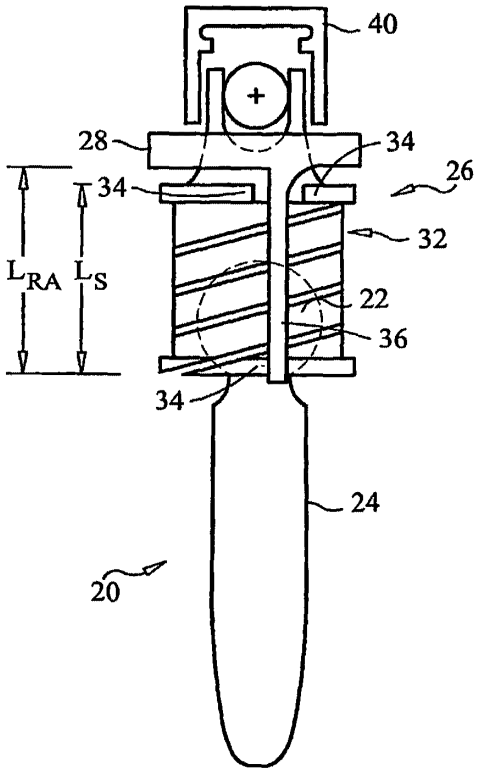


FIG. 1

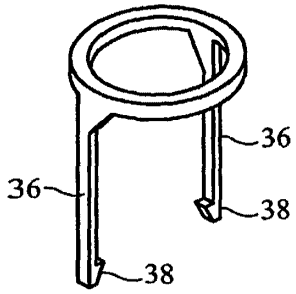


FIG. 2

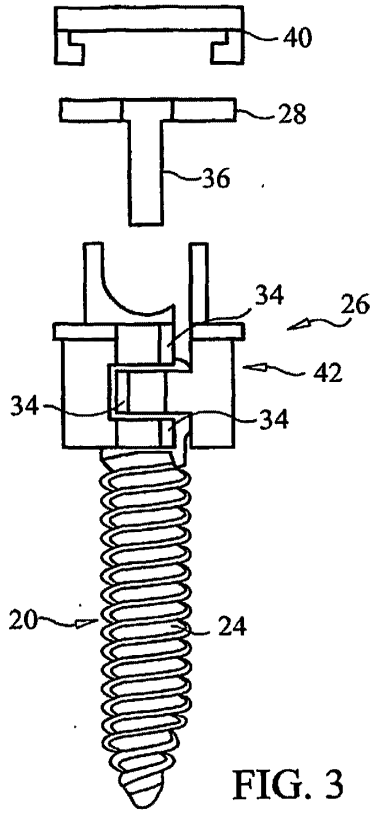


FIG. 3

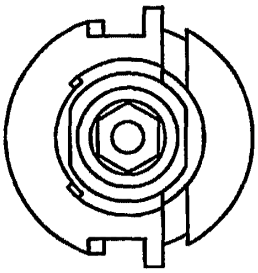


FIG. 4

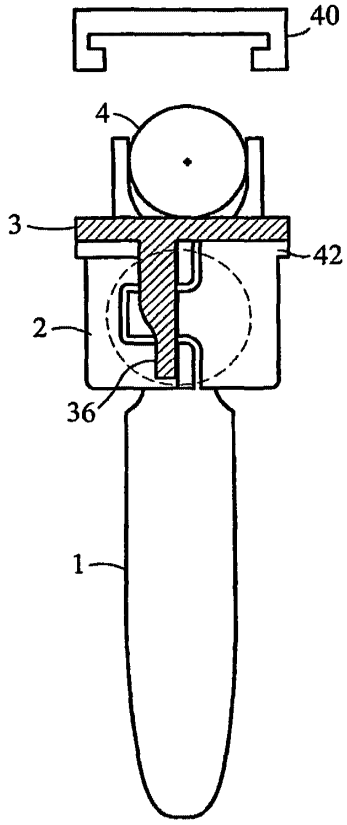


FIG. 5

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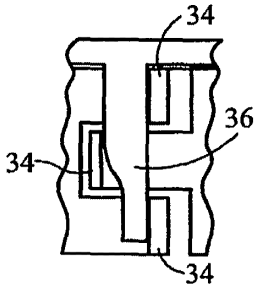


FIG. 6A

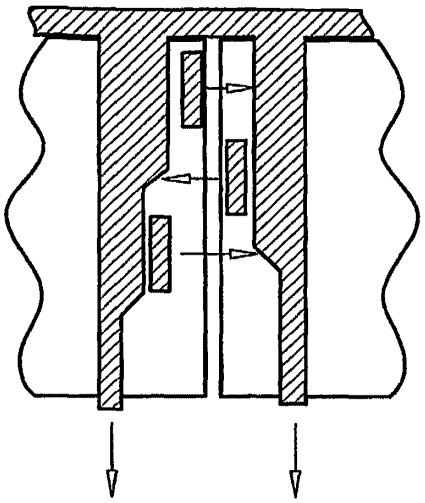


FIG. 6B

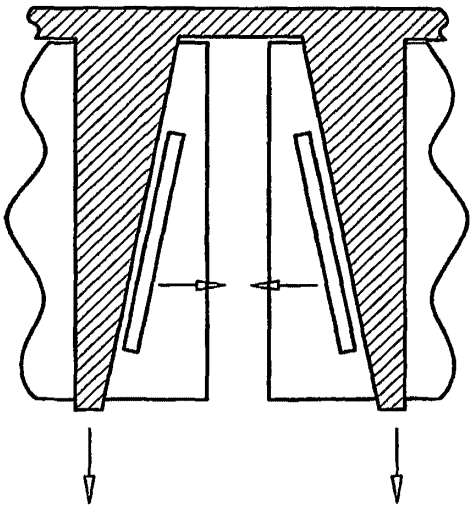


FIG. 6C

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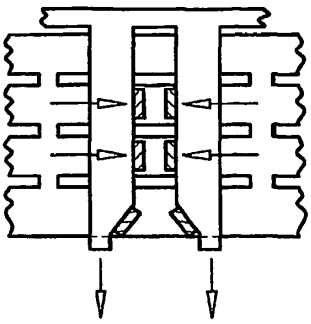


FIG. 6D

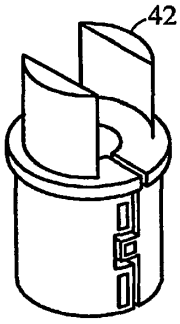


FIG. 7

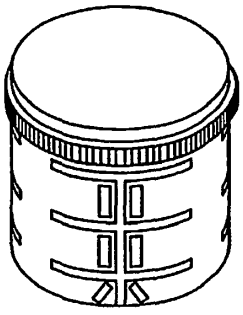


FIG. 6E

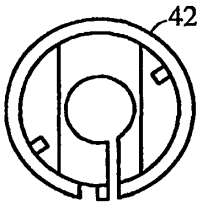


FIG. 8

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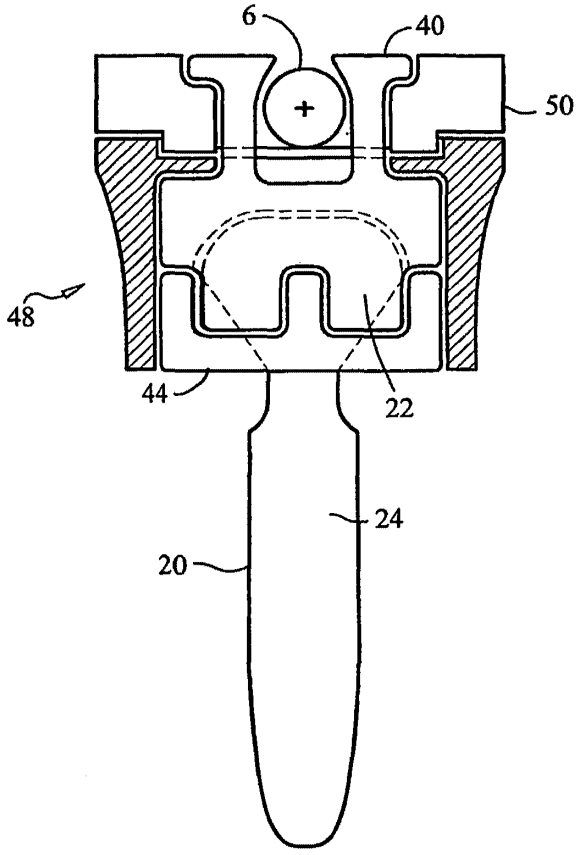


FIG. 9

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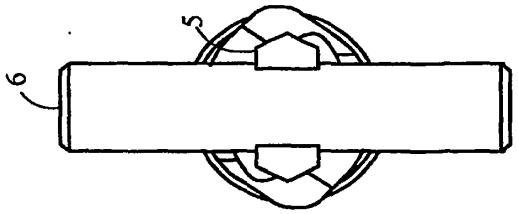


FIG. 12

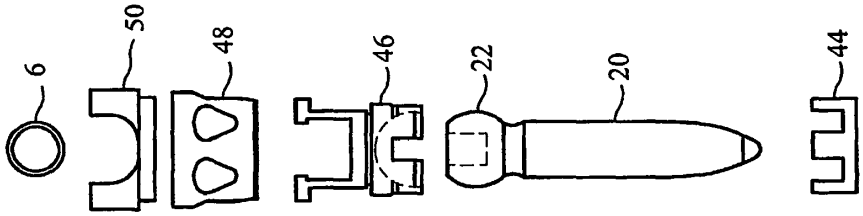


FIG. 11

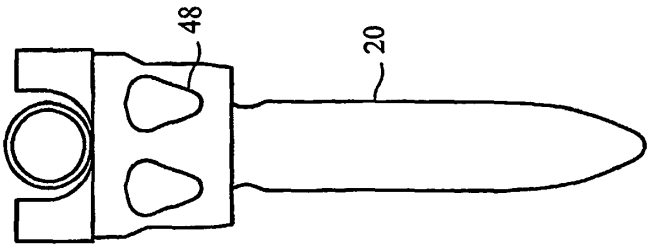


FIG. 10

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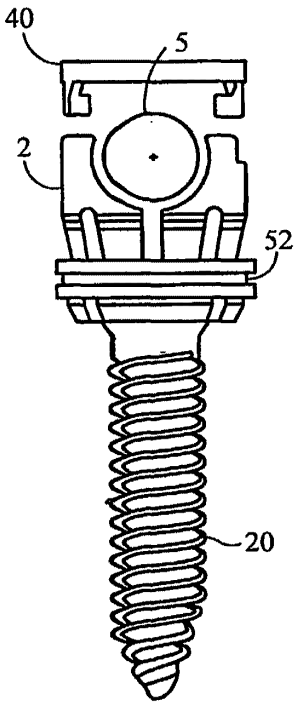


FIG. 13

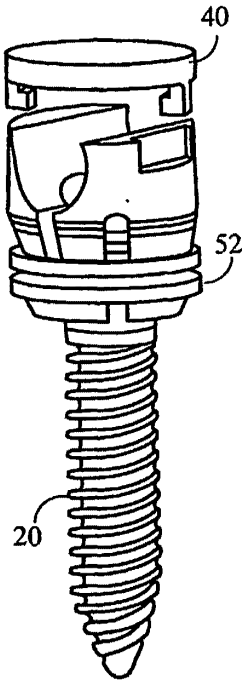


FIG. 14

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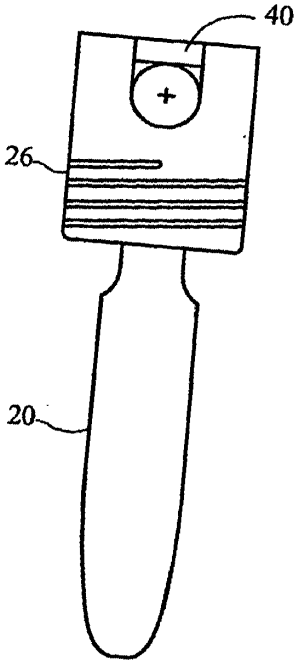


FIG. 15

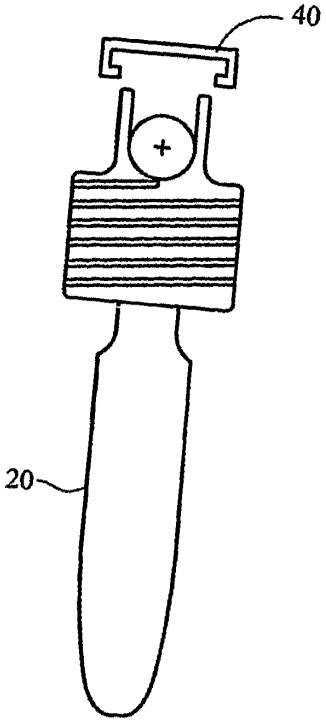


FIG. 16

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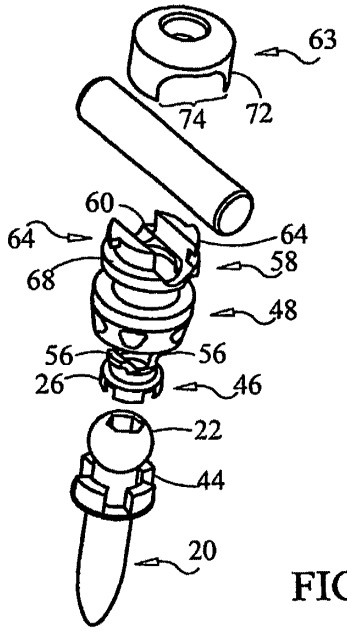


FIG. 17

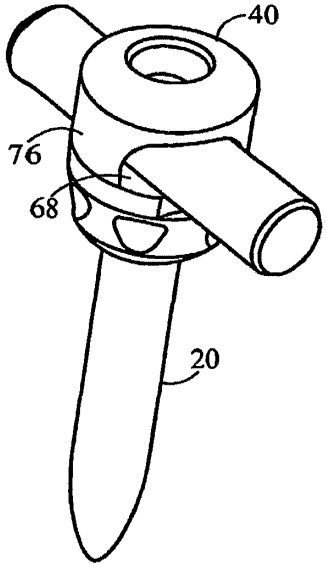


FIG. 18

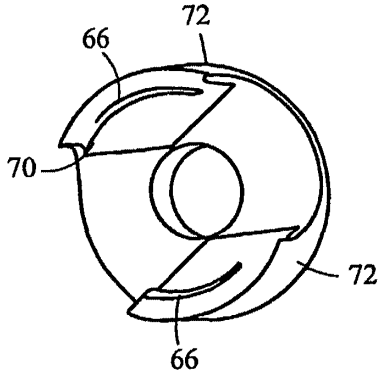


FIG. 19

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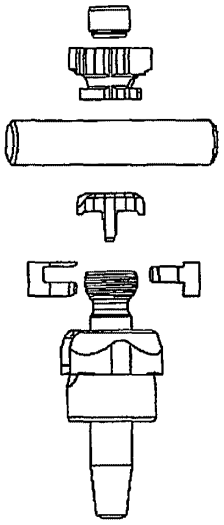


FIG. 20

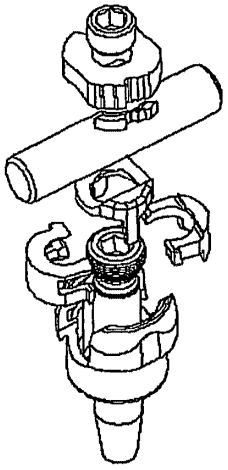


FIG. 21

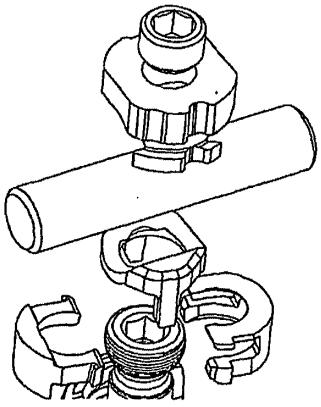


FIG. 22

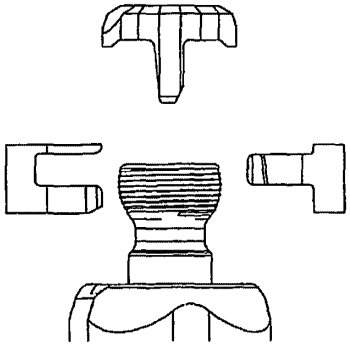


FIG. 23

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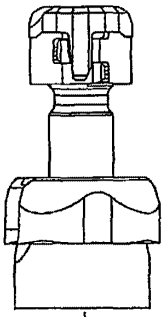


FIG. 24

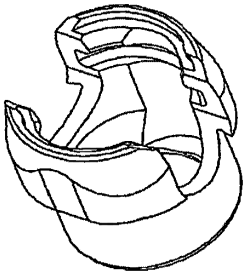


FIG. 25

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(54) Fixierelement für Halteelemente von Wirbelsäulenimplantaten

DE 299 03 342 U 1

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BUNDESDRUCKEREI 05.99 902 228/190/30A 3

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Fixierelement für ein Halteelement eines Wirbelsäulenimplantats

Die Erfindung bezieht sich auf ein Fixierelement für ein Halteelement eines Wirbelsäulenimplantats nach dem Oberbegriff des Anspruchs 1.

Bei Wirbelsäulenimplantaten besteht häufig die Aufgabe, bestimmte Wirbel der Wirbelsäule zu Fixieren, einen Zug oder Druck zwischen den Wirbeln aufzubauen oder, um eine relative Lage beizubehalten oder zu verändern. Dazu werden geeignete Mittel im Wirbel eingebracht, z.B. Pedikelschrauben, oder mit den Wirbeln Verbunden, die nachfolgend als Halteelemente bezeichnet werden und durch Verbindungsmittel miteinander verbunden sein können. Der Kopf der Pedikelschraube ist entweder ringförmig oder gabelförmig. Bei gabelförmigen Köpfen sind entweder im inneren oder Äußerem oder beiderseits Gewindeabschnitte vorgesehen in die dann mittels einer Ring oder Stiftschraube eine zuvor eingelegter Stab oder Gewindestange oder dergleichen festgelegt werden können.

Ein ähnliches Fixierelement für einen Distraktionsstab oder dergleichen ist auch bei hakenförmigen Halteelementen bekannt, beispielsweise bei sog. Lamina- oder Pedikelhaken, die in die entsprechenden Wirbelpartien eingehakt werden.

Bei gabelförmigen Fixierelementen besteht die Gefahr, daß bei der Ausübung einer entsprechenden Preßkraft auf den Distraktionsstab oder dergleichen die Schenkel des gabelförmigen Teils auseinander gebogen und oder Torquiert werden, wodurch die Fixierung beeinträchtigt oder sogar aufgehoben werden kann.

Es ist bekannt dem z.B. entgegenzuwirken, einen Ring um den Gabelförmigen Kopf zu legen oder eine Ringschraube außen um das Fixierelement am offenen Ende übergreift. Der Erfindung liegt die Aufgabe zugrunde, ein Fixierelement für ein Halteelement eines Wirbelsäulenimplants zu schaffen, bei dem das Halteelement sicher festgelegt werden kann, ohne daß der gabelförmige Abschnitt verformt wird.

Diese Aufgabe wird durch die Merkmale des Anspruchs 1 gelöst.

Bei dem erfindungsgemäßen Fixierelement, das z.B. der geschlitzte Kopf einer Pedikelschraube sein kann oder ein Abschnitt eines Lamina- oder Pedikelhakens, sind Innengewindeabschnitte derart ausgestaltet, daß die tragende Flanke der Gewindeabschnitte einen negativen Flankenwinkel besitzen, im folgenden als Kompressionsgewinde bezeichnet, da bei der Ausübung einer entsprechenden Presskraft auf den Distraktionsstab oder dergleichen die Schenkel des gabelförmigen Teiles zusammengezogen werden. Entsprechend ist das Außengewinde der Schraube komplementär mit einem Kompressionsgewinde versehen. Die tragende Flanke des Kompressionsggewindes des Fixierelementes ist der Öffnung des gabelförmigen Abschnittes zugewandt. Eine derartige Ausbildung des Gewindes verursacht nicht nur eine wesentliche Zugkraft an den Schenkelabschnitten des gabelförmigen Abschnittes, wenn die Schraube gegen das festzulegende Halteelement angepreßt wird, sondern verursacht gleichzeitig eine deutliche Kompressionskraft, die die Zinken oder Schenkel des gabelförmigen Teils gegen die Innenschraube ziehen und somit ein Spreizen und vor allem ein Torquieren derselben verhindert wird.

Ein Vorteil des erfindungsgemäßen Fixierelementes besteht auch darin, daß es geringer dimensioniert werden kann, da Spreizkräfte aufgrund der Ausbildung als Kompressionsgewinde des Fixierelementes nicht vorhanden sind.

Wie schon erwähnt, kann die Erfindung überall dort eingesetzt werden, wo in einem gabelförmigen Abschnitt Halteelemente von Wirbelsäulenimplanten festgelegt werden müssen. Das Halteelement kann nach einer Ausgestaltung der Erfindung ein stabförmiges Element sein, vorzugsweise ein Distraktionsstab. Das Halteelement kann jedoch auch vom Schaft einer Pedikelschraube gebildet sein, dessen kopfnahes Ende in einem gabelförmigen Abschnitt aufgenommen ist.

Eine andere Ausgestaltung der Erfindung sieht vor, daß das Kompressionsgewinde (Fig. 4) mit zwei negativen Flankenwinkeln (8) in die gabelförmigen Ausbildungen des Fixierelementes eingearbeitet werden (Fig. 7).

Die Erfindung kann überall dort eingesetzt werden wo in einem gabelförmigen Abschnitt Halteelemente von Wirbelsäulenimplantaten festgeklemmt werden müssen. Das Halteelement kann ein stabförmiges Element oder ein Gewindestab sein.

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Die Erfindung wird nachfolgend anhand von Zeichnungen näher erläutert.

Fig. 1 zeigt ein Fixierelement nach der Erfindung im Schnitt.

Fig. 2 zeigt ein Fixierelements nach Fig. 1 zur Aufnahme von Polyaxialschrauben o.ä.

Fig. 3 zeigt eine Pedikelschraube deren geschlitzter Kopf (Fig. 1) das Fixierelement nach Anspruch 1 kennzeichnet.

Fig. 4 zeigt einen Pedikelhaken mit einem Fixierelement nach der Erfindung.

Fig. 5 zeigt den Halbschnitt eines Fixierelementes mit der speziellen Ausbildung des Kompressionsgewindes mit dem negativen Tragflankenwinkel 9 und der Tragflanke 5.

Fig. 6 zeigt ein Fixierelement nach der Erfindung mit Schraube 3 und Halteelement 6 mit Manipulationsaussparungen 7 und den Innengewindeabschnitten 4.

Fig. 7 zeigt eine Abwandlung des Kompressionsgewindes bei dem beide Flanken mit einem negativen Flankenwinkel versehen wurden wodurch es zur Ausbildung eines schwalbenschwanzförmigen Gewindes kommt.

Fig. 8 zeigt die präzise Ausbildung des Gewindes mit der detaillierten Darstellung des negativen Flankenwinkels 9, der Tragflanke 5 und zum Vergleich dargestellt ein positiver Flankenwinkel 10.

Fig. 9 zeigt ein Fixierelement zusammen mit einer Polyaxialschraube.

Ansprüche

1. Fixierelement für ein Halteelement eines Wirbelsäulenimplantates, mit einem gabelförmigen Abschnitt für die Aufnahme des Halteelementes, wobei in der Innenwandung des gabelförmigen Abschnittes Innengewindeabschnitte geformt sind, in die eine Schraube einschraubbar ist, die über ein Druckelement oder unmittelbar auf das Halteelement im gabelförmigen Abschnitt wirkt. Dies wird dadurch gekennzeichnet, daß die Innengewinde (4) des gabelförmigen Abschnittes (1) und das Außengewinde (2) der Schraube (3) ein Kompressionsgewinde aufweisen dergestalt, daß die tragenden Flanken (5) der Innengewindeabschnitte (4) auf die Öffnung des gabelförmigen Abschnittes (1) hinweisen.

2. Fixierelement nach Anspruch 1, dadurch gekennzeichnet, daß der gabelförmige Abschnitt, der geschlitzte Kopf (Fig. 1) einer Pedikelschraube (Fig. 3) ist.

3. Fixierelement nach Anspruch 1, dadurch gekennzeichnet, daß der gabelförmige Abschnitt vom Schaft eines Hakens (Fig. 4) gebildet wird.

4. Fixierelement nach einem der Ansprüche 1 bis 3, dadurch gekennzeichnet, daß das Halteelement ein stabförmiges Element, oder ein Gewindestab ist.

5. Fixierelement nach Anspruch 1, dadurch gekennzeichnet, daß der gabelförmige Abschnitt der geschlitzte Kopf einer beweglichen , sog. Polyaxialschraube ist.

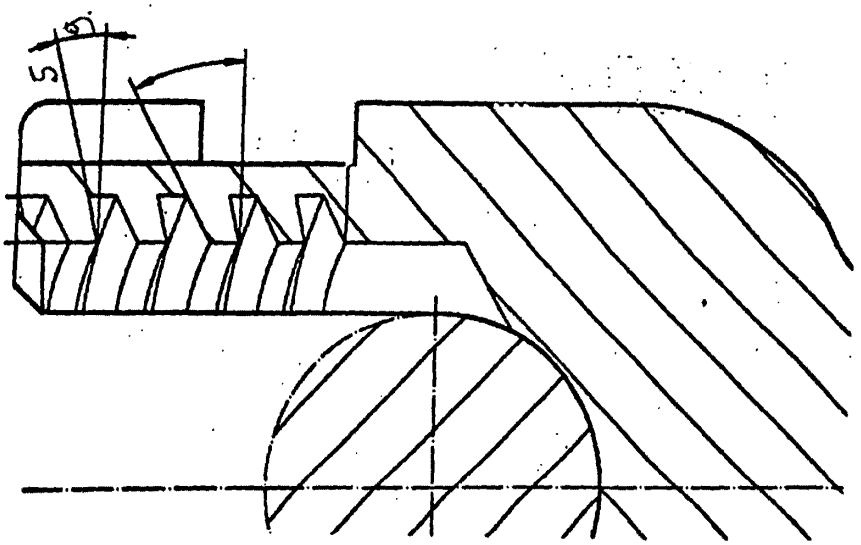


Fig. 5

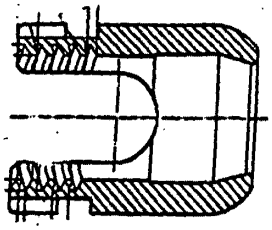


Fig. 2

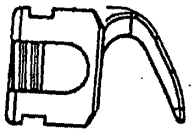


Fig. 4

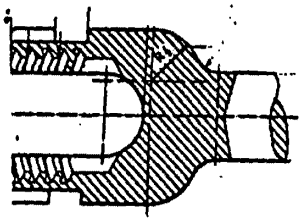


Fig. 1

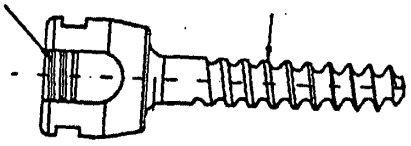


Fig. 3

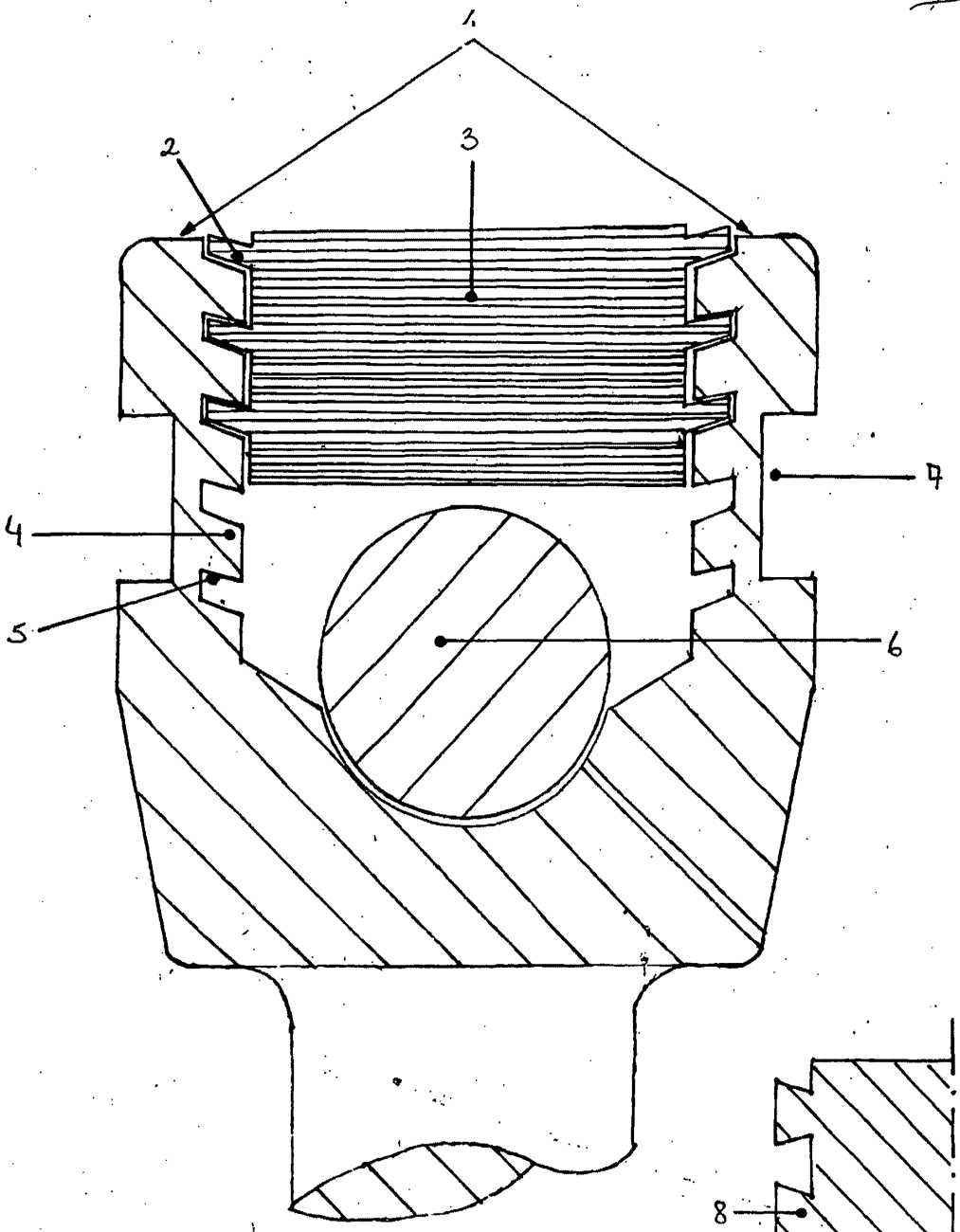


Fig. 6

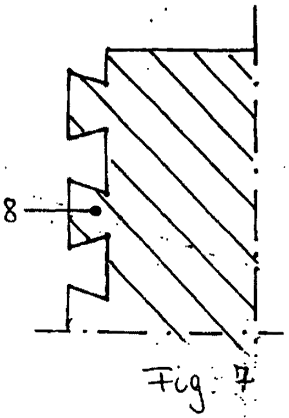


Fig. 7

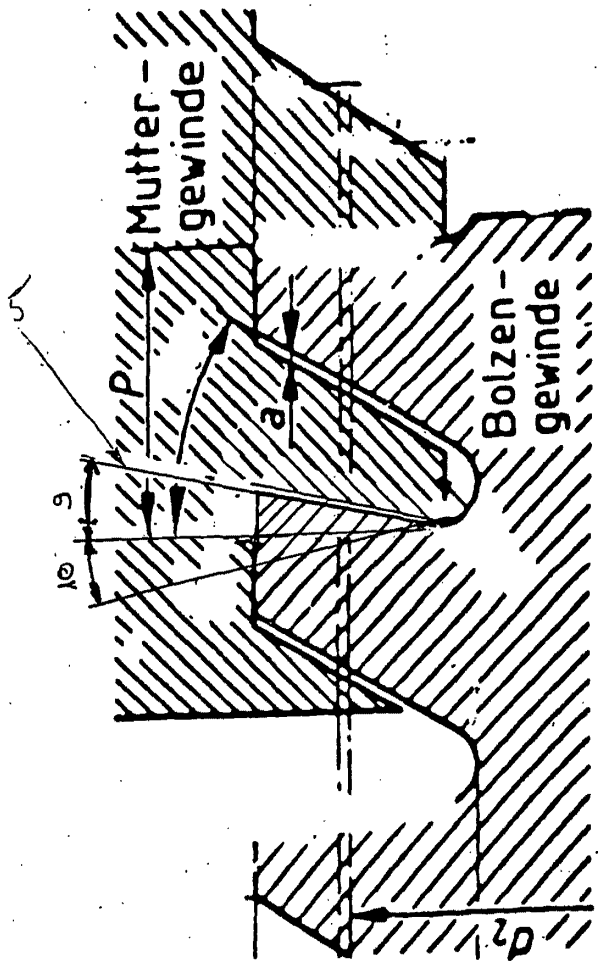


Fig. 8

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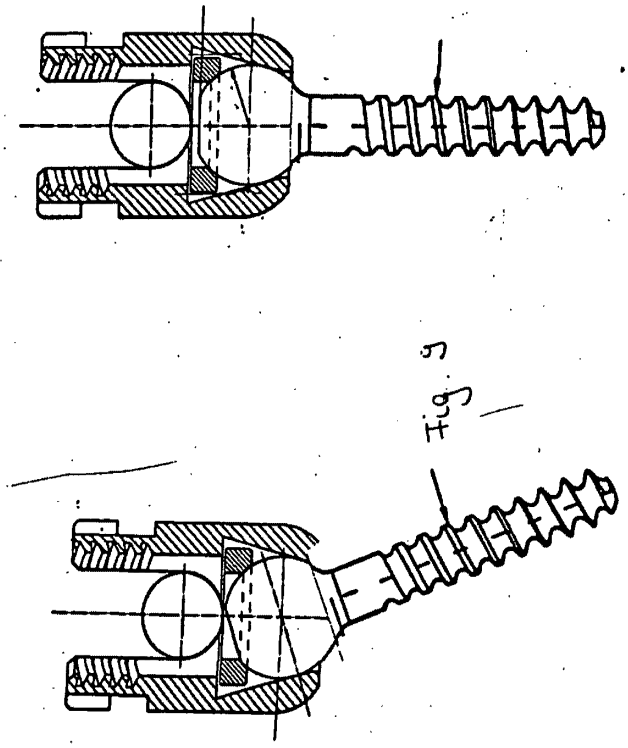


Fig. 5

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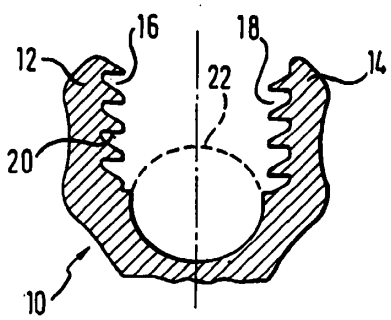
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(54) A receiving part for a retaining component of a vertebral column implant

(57) A receiving part for a retaining component of a vertebral column implant, having a fork-shaped section for receiving the retaining component, with the inner wall of the fork-shaped section including inner threaded portions into which there may be screwed a screw which via a pressing element or directly, acts on the retaining component in the fork-shaped section. The inner threaded portions and the outer thread of the screw comprises a saw tooth thread of a shape that the steep flank of the inner threaded portions face away from the opening of the fork-shaped section.

Fig. 1



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Description

The invention relates to a receiving part for a retaining component of a vertebral column implant according to the preamble of claim 1.

With vertebral column implants there exists often the object of supporting certain vertebra of the vertebral column, of creating a tension between the vertebra or a compression in order to retain or change a relative position. For this purpose suitable means are connected to the vertebrae which are subsequently described as retaining components and may be connected to one another by connecting means. As retaining components there may serve e.g. so-called pedicle screws which are screwed into the pedicle of the vertebrae. The head of the pedicle screw is either annular or fork-shaped. With annular pedicle screw heads e.g. a distraction rod is guided through and is fixed on both sides of the head with the help of a nut. With fork-shaped heads it is known in the inside to provide threaded sections for a gudgeon with which a previously inserted distraction rod or likewise may be fastened.

A similar receiving part for a distraction rod or likewise is also known for hook-like retaining components, for example with so-called lamina hooks or pedicle hooks which are hooked into the corresponding vertebra parts.

With fork-shaped receiving parts there is the danger that on exerting a suitable pressing force on the distraction rod or likewise the arms of the fork-shaped part are bent apart by which means the fixation is compromised or even eliminated. It is known for example to counteract this in that a lifting eye bolt is screwed on the outside around the receiving part in order to prevent the arms from bending apart. A so-called cap bolt has a similar effect, this overlapping the receiving part at the open end and comprising centrally a peg-like section projecting into the recess of the fork-like part for fixation e.g. of a distraction rod.

From EP 0 242 708 it is also known the equip the end, on the head side, of a shank of a pedicle screw with a spherical bearing surface which is fastened in a corresponding bearing section of the head. By way of this the shank of the pedicle screw may assume any angle with respect to the screw head. It has however been shown that it causes problems to securely fix the relative position of the pedicle screw on the one hand and the receiving part or the head on the other hand.

It is the object of the invention to provide a receiving part for a retaining component of a vertebral column implant with which the retaining component may be securely fixed without the fork-shaped section being deformed.

This object is achieved by the features of claim 1.

With the receiving part according to the invention which may e.g. be the slotted head of a pedicle screw or a section of a lamina or pedicle hook, inner threaded sections are formed as a saw tooth thread. The steep flank of the saw tooth thread of the receiving part is distant to the opening of the fork-shaped section. It is to be understood that the thread of the screw is complementary, i.e. the steep flank is aligned oppositely. Such a design of the thread causes essentially only a tension force on the arm sections of the fork-shaped section when the screw is pressed against the retaining component to be fastened. A bending apart of the tongs or arms does not occur.

The thread within the receiving part may be provided at a distance to the free end. In this way it is achieved that the screw cannot be screwed skewly. Also the screw at one end may have a smooth section in order to simplify the introduction of the screw particularly into the smooth initial section in the receiving part.

An advantage of the receiving part according to the invention also lies in the fact that it may be dimensioned smaller, since the bending forces on account of the fastening of the component with the help of a screw largely do not occur.

As has been previously mentioned the invention may be applied everywhere where, in a fork-shaped section, retaining components of vertebral column implants are to be fastened. The retaining component may according to one formation of the invention be a rod-like element, preferably a distraction rod. The retaining component may however also be formed by the shank, whose end near to the head is accommodated in a fork-shaped section. So that such a pedicle screw permits an angular position between the screw shank and the head, one formation of the invention provides that the end of the shank near to the head, which is broadened in diameter, comprises a spherical bearing surface which cooperates with a spherical bearing surface in the fork-shaped head. The end surface of the shank is convex, and between the screw and the inner surface there is arranged a disk which on the side facing the end surface may be plane or concave. Preferably the curvatures of the end surface of the screw shank and of the facing side of the disk are formed with an approximately equal radius. On the opposite side the disk according to a further formation of the invention may be plane. A screw which cooperates with the fork-shaped head via a saw tooth thread then presses onto the disk which for its part fastens the shank of the pedicle screw at any angular position. It has been shown that such a design in the head region of the pedicle screw has the result of higher retaining forces so that the once assumed relative position of the shank to the head remains kept even with larger forces. It is to be understood that between the screw and the disk a distraction rod or likewise may be applied via which then the pressing force is transmitted to the disk, wherein the shank for its part is fastened in the head of the pedicle screw.

The disk may comprise an outer thread and be screwed into the head of the pedicle screw, wherein of course the inner sides of the recess must be provided

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with a threaded section. Below this threaded section there may be present a free rotation which reaches the disk when it is completely screwed in, bearing on the crowned surface of the end of the screw shank on the head side.

The disk may be provided on the periphery with radial slots so that a better bearing on the spherical end of the pedicle screw is made possible. The disk may further be provided centrally with an opening. Via the opening a tool may engage with the facing end of the shank of the pedicle screw and turn the shank. Moreover the opening may be so dimensioned together with the concave surface of the disk, that a rod accommodated by the receiving part bears against the end, near to the head, of the pedicle screw shank when it is pressed with the screw in the receiving part.

With conventionally parted pedicle screws it is necessary that the head is pushed over the shank before the shank is rotated in. The handling of such a unit is however complicated. For this reason one formation of the invention provides for the fork-shaped head to laterally comprise a slot which is dimensioned such that the broadened end can be laterally introduced into the receiving space of the head. In this manner the shank alone may be screwed into a vertebra. The head may subsequently laterally be put onto the end of the shank, which is near the head. Although the slot weakens the corresponding arm region of the head but since the saw tooth thread, as has been cited several times, prevents a bending apart of the head section, the weaking is tolerable.

Another formation of the invention provides that on the outer side of the arms of the fork-shaped head diametrical recess are formed. The recesses serve for accommodating a fork-shaped section which is part of a rotating or tensioning tool. With the help of the tool which can be applied in the recesses, the pedicle screw may be rotated. The tool may also laterally grasp the head so that a simultaneous access from above is still possible. It is to be understood that the recesses may be advantageous also with pedicle screws with a one-piece formed-on head.

In order to securely fix a pedicle screw relative to the receiving part at any angle one formation of the invention provides that the receiving part accommodates an annular cage. The cage comprises several slots which are formed by the lower side parallel to the axis. Furthermore on the inside the cage has a spherical concave bearing surface which cooperates with a convex end of the shank of the pedicle screw. On the outer side the cage has a conical surface which cooperates with a complementary conical surface in the receiving part. If a force is exerted on the cage in the direction of the pedicle screw the cage is pressed radially together and by way of this exerts a pressing force onto the spherical surface of the screw shank. This pressure is sufficient in order to obtain a secure fastening of the screw shank relative to the receiving part.

The invention is described in more detail by way of the drawings.

Fig. 1 shows a receiving part according to the invention, in section.

Fig. 2 shows a part of the receiving part according to Fig. 1 together with a screw.

Fig. 3 perspectively shows a pedicle hook with a receiving part according to the invention.

Fig. 4 shows perspectively a lamina hook with a receiving part according to the invention.

Fig. 5 shows the arrangement of two hooks for forming a bridge with a receiving part according to the invention.

Fig. 6 shows a two-part pedicle screw with a receiving part according to the invention, in section.

Fig. 7 shows a receiving part similar to that according to claim 6, but with additional features.

Fig. 8 schematically shows a possible modification of the receiving part according to Fig. 6.

Fig. 9 shows schematically a disk modified with respect to Fig. 6.

Fig. 10 shows a pedicle screw with a modified receiving part.

Fig. 11 shows a section through the representation according to Fig. 10 taken along the line 11-11.

Fig. 12 shows in a larger scale the receiving part of the embodiment form according to Figs. 10 and 11.

Fig. 13 shows perspectively the cage of the embodiment form according to Figs. 10 and 11.

Fig. 14 shows a section through the cage according to Fig. 13.

In Fig. 1 there is represented a receiving part 10 with is fork-shaped with arm sections 12, 14. The receiving part 10 may be the head of a pedicle screw or a section of a hook for an vertebral column implant. As can be recognized on the inner side of the arm sections 12, 14 there are formed threaded sections 16, 18 with a saw tooth shape. It is essential that the steep flank 20 of the saw tooth thread is distant to the open side of the

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receiving part 10. From the open side in the corresponding recess of the receiving part 10 a distraction rod may be placed in as is shown dashed at 22.

In Fig. 2 only the arm section 12 of the receiving part 10 is to be recognized. Further a gudgeon 24 is to be seen which for its part comprises a saw tooth thread 26 which cooperates with the threaded sections 16, 18. The distraction rod 22 may be fixed in the receiving part 10 with the help of the gudgeon 24. Due to the shape of the thread on the arm sections 12, 14 with an axial force on the gudgeon 24 essentially a tensional loading is exerted so that by way of this it is prevented that the arm sections 12, 14 are bent apart.

Fig. 3 shows a pedicle hook 28 with a fork-shaped receiving part 10a which comprises threaded sections 16a, 18a in the shape of a saw tooth thread. A gudgeon 24a with a hexagon socket 30 comprises a corresponding saw tooth thread 26a.

A lamina hook 32 comprises a receiving part 10b with inner threaded sections 16b, 18b for receiving a gudgeon 24b with a saw tooth thread 26b. In both cases in the receiving parts of the hooks 28 or 32 e.g. a distraction rod may be fixed.

In Fig. 5 there are shown two hooks 34, 36 which receive rod-like elements 38, 40. In the receiving parts of the hooks 34, 36 there is accommodated a distraction rod 42 which is channeled or provided with a thread and which bears against the rods 38, 40. With the help of gudgeons 44 or 46 the device shown, which forms a type of bridge, may be fixed. The gudgeons 44, 46 or the receiving parts of the hooks 34, 36 are in turn provided with a saw tooth thread of the above mentioned type and manner.

In Fig. 6 there is represented a pedicle screw 50 with a shank 52 and a head 54. The head 52 comprises a normal thread 54. The shank 52 is at the end near to the head formed with a broadened section 56 which on the lower side comprises an annular spherical bearing surface 58. Furthermore the end surface of the broadened section is shaped spherically convex, as is shown at 60. The broadening has a hexagon socket 62 for receiving a corresponding rotational tool.

The head 54 is fork-shaped similar to the receiving part 10 and at the end facing the shank 52 is provided with an opening 64 through which the shank 52 extends. A part of the walling of the opening 64 comprises an annular spherical bearing surface 66 which cooperates with the spherical bearing surface 58. The shank 52 may therefore assume in a limited spacial angle, any angular position to the head 54.

In the receiving space of the head 54 there is arranged a disk 68 which on the upper side is plane but on the lower side comprises a concavely curved surface with a curvature which corresponds to the end surface 60 of the shank 52. The disk 68 is inserted approximately fittingly into the inner space of the end 54 so that it is radially secured. The disk 68 may be provided with an outer thread, and the inner thread of the head 54 may extend until shortly above the opening 64, 66. In this way the disk 68 may be screwed in until it reaches free rotation and here by way of a corresponding contact pressure can be pressed into engagement with the crowned end of the shank 52. The outer thread of the disk 68 and the inner threaded sections in the inside of the head 54 are not provided with reference numerals.

A screw 72 is threaded into inner threaded sections of the head 54, wherein the threaded sections again comprise a saw tooth thread, which however here is not shown in detail. A shank 74 of the screw 72 cooperates with the plane surface of the disk 68 and presses this against the end surface 60 of the shank 52. In this manner the angular position between the head 54 and the shank 52 can be effectively fixed.

At 76 there is shown dashed a distraction rod via which a pressure may be exerted onto the disk 68, wherein the rod for its part may be fixed in its position. It is to be understood that the shank 74 of the screw 72 must be designed correspondingly shorter. It is still to be mentioned that the shank 74 at the lower end is convexly rounded.

In Fig. 7 the head of a pedicle screw similar to that according to Fig. 6 is shown, it however has some modifications. Thus the head is indicated at 54a. One recognizes that the head 54a laterally in the region near the shank comprises a slot 78, via which the end, near the head, of the shank 52 may be inserted. Thus the shank 52 firstly can be screwed into a pedicle of a vertebra after which subsequently the head 54a is placed on.

On the outer side of the arm sections of the head 54a there are formed slots 80, 82 for receiving the prongs of a hook-like tool section which laterally grasps the head on the outside in order to exert a tension effect or to rotate the head. It is to be understood that the slots 80, 82 may also be mounted on a head formed as one piece with the shank.

The embodiment form according to Fig. 8 differs from the receiving part or the head 54 according to Fig. 6 or 7 in that in the inside near to the free end there is provided a thread-free section 86 to which connects a threaded section 84. The screw 72b comprises at one end likewise a thread-free section 88. The outer diameter of the thread-free section 88 corresponds approximately to the inner diameter of the thread-free section 86. In this way the screw 72b may be inserted straight into the head 54b and subsequently screwed.

The screw 68b according to Fig. 9 differs from the disk 68 according to Fig. 6 in that proceeding from the periphery a row of radial slots 90 is formed which are distanced in the circumferential direction. The slots permit an effective bearing of the disk 68b on the spherical convex surface 60 of the screw shank 52 according to Fig. 6. Moreover the disk 68b comprises a passage opening 92. This permits the guiding through of a tool for engagement into the recess 62 of the screw shank 52 according to Fig. 6.

In the Figs. 10 to 14 there is shown a further

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embodiment form of the invention. The pedicle screw represented in Figs. 10 and 11 comprises a screw shank 100 which is formed roughly as the screw shank 52 according to Fig. 6. At the upper end the shank 100 comprises a spherical section 102 which from the free end is provided with a recess 104 for a rotational tool. As can be recognized in Fig. 11 the section 102 is accommodated by a cage 106 which can be more clearly recognized in Figs. 13 and 14. The cage is seated in a receiving part 108 which in the upper region comprises oppositely lying recesses and is thus fork-shaped, as can be recognized in Fig. 10.

The receiving part 108 which forms the head for the pedicle screw is provided with diametrically opposite threaded sections 110 which are formed corresponding to the threaded sections 16 according to the Figs. 1 and 2. In the part lying thereunder the receiving part 108 is formed in the manner of an annular housing 112 which on the inner side comprises a conical annular surface 114 which converges downwards. Via a lower opening 116, the cage 106 which is represented in the Figs. 13 and 14, may be introduced.

Diametrically opposite on the outer side of the head 108 recesses 118 are formed for receiving a tool, not shown, for screwing in the pedicle screw.

The annular cage 106 comprises on the outer side a conical annular surface 120 which cooperates with the conical surface 114 of the receiving part 108 as can be recognized in Fig. 11. The cage 106 is furthermore provided with three slots 122 parallel to the axis, wherein one of the slots is continuous so that the annular cage 106 is parted in the circumferential direction. On the inner side the cage 106 comprises a spherical bearing surface 124 which accommodates the spherical section 102 of the shank 100, as is shown in Fig. 11.

Into the threaded sections 110 there is screwed a screw 126 (Fig. 11) which centrally comprises a continuous hole 128 for leading through a tool with which the shank 100 can be rotated. With the help of the screw 126 there is fastened a distraction rod which is not shown and which is accommodated by the fork-shaped section of the head 108. The rod is pressed against the cage 106. By way of this the cage 106 is moved downwards in the direction of the screw shank 100 and is radially pressed together. In this manner the spherical section 102 in clamped in the cage 106 and the angular position between the shank 100 and the head or the receiving part may be fixed.

Claims

1. A receiving part for a retaining component of a vertebral column implant, including a fork-shaped section for receiving the retaining component, the inner wall of the fork-shaped section is formed with inner threaded portions into which a screw may be threaded to act on the retaining component in the fork-shaped section via a pressing element or directly, characterized in that the inner threaded portions (16, 18) and the outer thread (26) of the screw (24) comprise a saw tooth thread of a shape that the steep flanks (20) of the inner threaded sections (16, 18) face away from the opening of the fork-shaped section (10).

2. The receiving part according to claim 1, characterized in that the fork-shaped section is the slotted head (54, 54a) of a pedicle screw (50).

3. The receiving part according to claim 1, characterised in that the fork-shaped section is formed by the shank of a hook (28, 32, 34, 36).

4. The receiving part according to claim 1,characterized in that the retaining component is a rod-like element (22, 42, 76), preferably a distraction rod.

5. The receiving part according to claim 1, characterized in that the retaining component is the shank (52) of a pedicle screw (50) whose end near to the head is accommodated in the fork-shaped section (54).

6. The receiving part according to claim 5, characterized in that the end (56) of the shank (52), which is broadened in diameter, comprises a spherical bearing surface (58) which cooperates with a spherical counter bearing surface (66) in the fork-shaped head (54), the end surface (60) of the shank is convex and a disk (68) is located between the screw (72) and the end surface (60) there.

7. The receiving part according to claim 6, characterized in that the disk is approximately fittingly accommodated by the fork-shaped head (54).

8. The receiving part according to claim 6, characterized in that the side of the disk facing the screw (72) is formed plane.

9. The receiving part according to claim 6, characterized in that the end surface of the side of the disk facing the screw is concave.

10. The receiving part according to claim 6, characterized in that the disk (68b) comprises several radial slots (90) distanced in the circumferential direction which are formed in from the periphery.

11. The receiving part according to claim 6, characterized in that the disk (68b) comprises a central opening (92).

12. The receiving part according to claim 11, characterized in that the concave surface of the disk and the opening (92) are dimensioned such that a rod

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accommodated by the receiving part (54b) bears against the spherical surface of the end, of the pedicle screw, which is near the head.

13. The receiving part according to claim 6, characterized in that the disk (68) comprises an outer thread and the head (54) comprises inner threaded portions with which the outer thread of the disk (68) engages, wherein the thread near to head-side end of the shank allows a free rotation in which the disk (68) can be loosely accommodated.

14. The receiving part according to claim 6, characterized in that the fork-shaped head (54a) laterally comprises a slot (78) which is dimensioned such that the broadened end (56) of the shank may be laterally introduced into the receiving space of the head (54).

15. The receiving part according to claim 2, characterized in that on the outer side of the arms of the fork-shaped head (54a) diametrical recesses (80, 82) are formed for receiving a fork-shaped tool.

16. The receiving part according to claim 2, characterized in that the shank (100) of the pedicle screw at the upper end comprises a spherical section (102), an annular cage (106) is provided which comprises several slots (122) parallel to its axis which are distanced in the circumferential direction and which are formed proceeding from the lower end, and which on the inside comprises a spherical bearing surface (124) and the cage (106) on the outer side comprises a conical surface (120) which cooperates with a conical inner surface (114) of the receiving part (108) in a manner such that on pressing the cage (106) into the receiving part in the direction of the shank (100) the cage is compressed radially.

17. The receiving part according to claim 16, characterized in that the cage (106) is parted by a radial continuous slot (122).

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Fig. 1

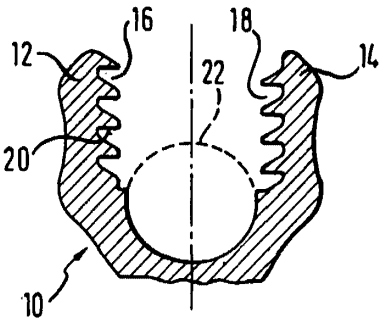


Fig. 2

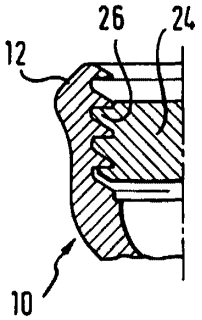


Fig. 3

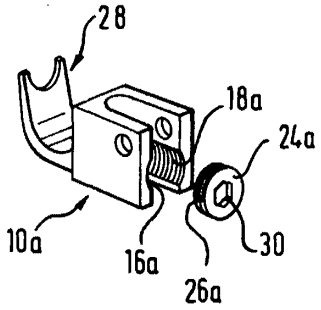


Fig. 4

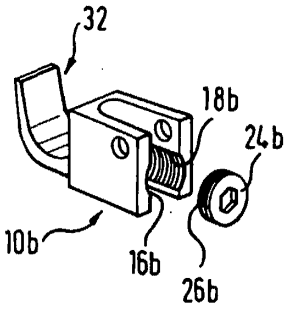
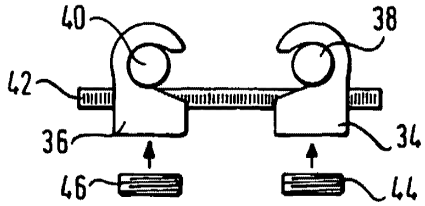


Fig. 5



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Fig. 6

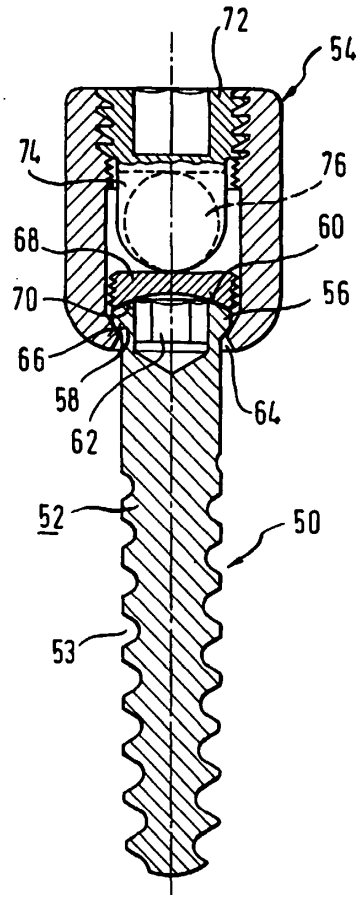


Fig. 7

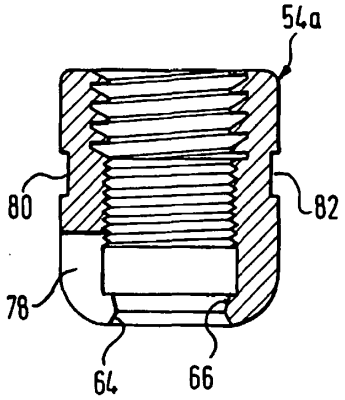


Fig. 8

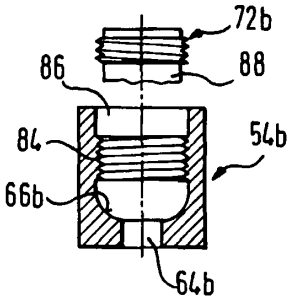
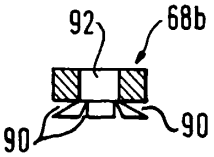


Fig. 9



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Fig. 10

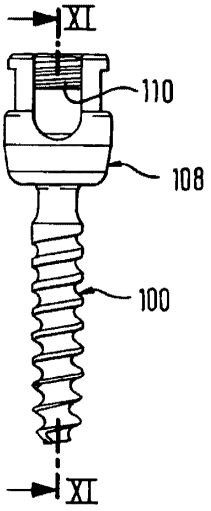


Fig. 11

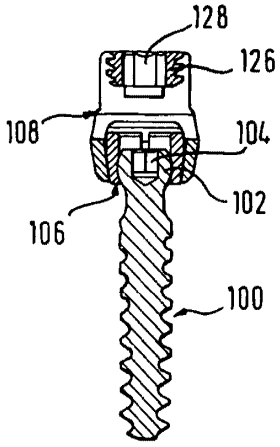


Fig. 12

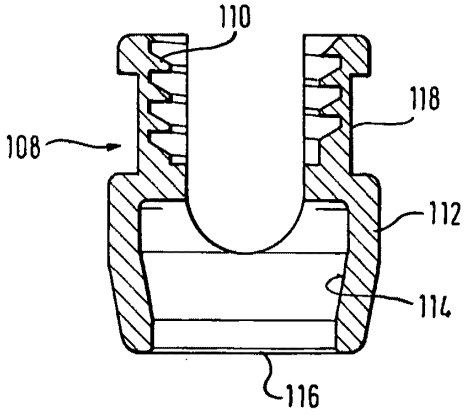


Fig. 13

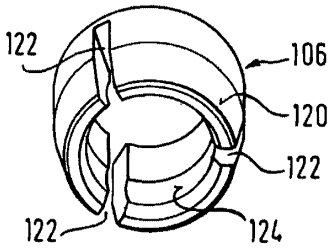
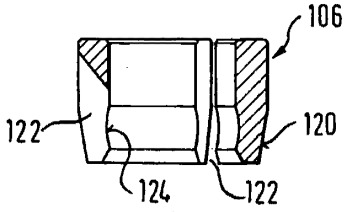


Fig. 14



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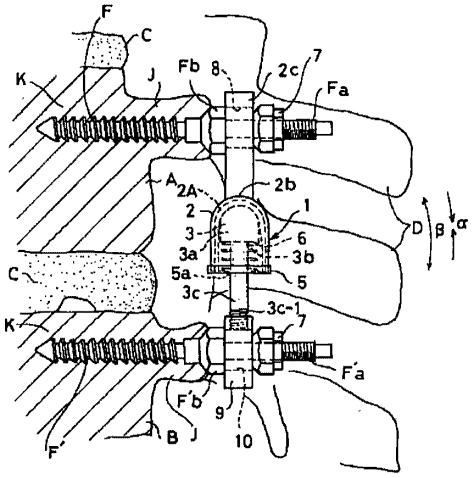
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(54)【発明の名称】　人工椎間関節

(57)【要約】
【課題】　脊椎を無理なストレスを掛けずに動かし、しかも無理に身体を屈伸したり、曲げたり、捻ろうとすると、その動きを制動して、椎間関節や椎間板を傷つけないようにして脊椎関節の機能を再建する人工椎間関節を提供する。
【解決手段】　本発明の人工椎間関節は、シリンダー状部２とこれに移動自在に嵌合するピストン状部３からなる。ピストン状部３は、前記シリンダー状部２内の移動方向に直交する方向にも、健常者の脊椎の回旋する角度と同等の角度まで回旋できるようにシリンダー状部２内に嵌合されている。障害椎間板Ｃを挟んで上下に隣接する二つの脊椎Ａ、ＢのそれぞれにスウリューＦ、Ｆ′を設置し、前記脊椎Ａ、Ｂの間に人工椎間関節１を取り付ける。



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【特許請求の範囲】
【請求項１】　シリンダー状部とこれに移動自在に嵌合するピストン状部からなり、該ピストン状部は、シリンダー状部内の移動方向に直交する方向にも、健常者の脊椎の回旋する角度と同等又はそれ以下の角度に回旋できるように嵌合させると共に、シリンダー状部とピストン状部のそれぞれの端部に、損傷した椎間板を挟んで隣接する脊椎間に取り付けるための取付部を設けたことを特徴とする人工椎間関節。
【請求項２】　請求項１の人工椎間関節において、シリンダー状部内でのピストン状部の回旋を許容するためにシリンダー状部の内面を弾性物質でライニングし、更に、前記ピストン状部の底部と蓋体の間にばねを設けたことを特徴とする人工椎間関節。
【請求項３】　請求項１又は２の人工椎間関節において、シリンダー状部とピストン状部の双方の横断面を長円にして、ピストン状部をシリンダー状部に対して健常者の脊椎の回旋する角度と同等又はそれ以下の角度で回旋させることを特徴とする人工椎間関節。
【請求項４】　請求項１又は２の人工椎間関節において、シリンダー状部とピストン状部の双方の横断面が楕円であることを特徴とする人工椎間関節。
【請求項５】　請求項２、３又は４の人工椎間関節において、弾性物質がポリウレタンであることを特徴とする人工椎間関節。
【請求項６】　請求項１、２、３、４又は５に記載の人工椎間関節において、ピストン状部がポリオレフィン製であることを特徴とする人工椎間関節。
【発明の詳細な説明】
【０００１】
【発明の属する技術分野】　椎間板ヘルニアなどの疾病のためや、加齢性変化や、長年の習慣に起因する脊柱の変形や、椎間板や椎間関節に障害などがあるときに、手術によって患部を処置した後に、脊椎と脊椎の間に取り付けられる人工椎間関節に関する。
【０００２】
【従来の技術】　従来、椎間板や椎間関節の障害が、疾病や加齢性変化や長年の習慣により、高度になってしまった場合には、手術によって、障害椎間板を取り除いたり、障害椎間関節や変形脊椎の一部を削除し、更に、脊髄や神経根などの神経に対して靭帯や骨による圧迫がある場合には、これらの圧迫を完全に切除し、その後に腸骨や人工骨（アパタイトなどの無機材料）を埋設するなどの処置した後に、図６に示すように、障害椎間板Ｃを挟んで上下に隣接する二つの脊椎Ａ、Ｂの夫々にその棘突起Ｄの左右両側の椎弓根Ｊから椎体Ｋに金属製スクリューＦをねじ込み、上下に対応する２本のスクリューＦ、Ｆの先端に一枚の金属板Ｇを取り付け、前記上下に隣接する脊椎ＡとＢを完全に固定して、疼痛や脊椎の不安定性に対処していた。
【０００３】しかしながら、このような脊椎Ａ、Ｂは本来可動であるにもかかわらず、それらを金属板で完全に固定して動かないようにしてしまうため、固定脊椎に大きなストレスがかかってしまい、更には、無理に身体を屈伸したり、曲げたり、捻ろうとすると、前記固定された脊椎の上と下に隣接する脊椎にも過度の負荷がかかり、前記固定された脊椎の直上と直下の椎間板を傷つけ新たな障害を引き起こすことも少なくなかった。
【０００４】
【発明が解決しようとする課題】　本発明は、脊椎に無理なストレスを掛けずに動かし、しかも無理に身体を屈伸したり、曲げたり、捻ろうとすると、その動きを制動して、椎間関節や椎間板を傷つけないようにして脊椎の機能を再建する人工椎間関節を提供することを課題とする。
【０００５】
【課題を解決するための手段】　本発明は、上記の課題を解決するものであって、その手段は、請求項１に記載のとおり、シリンダー状部とこれに移動自在に嵌合するピストン状部からなり、該ピストン状部は、シリンダー状部内の移動方向に直交する方向にも、健常者の脊椎の回旋する角度と同等又はそれ以下の角度に回旋できるように嵌合させると共に、シリンダー状部とピストン状部のそれぞれの端部に、損傷した椎間板を挟んで隣接する脊椎間に取り付けるための取付部を設けたことを特徴とする人工椎間関節である。
【０００６】損傷した椎間板の上下に隣接する二つの脊椎に、シリンダー状部の端部の取付部とピストン状部の端部の取付部をそれぞれ取り付けて、前記上下に隣接する二つの脊椎の間に人工椎間関節を取り付ける。
【０００７】ピストン状部がシリンダー状部内に移動自在に嵌合されており、しかもピストン状部は、シリンダー状部内の移動方向に直交する方向にも、健常者の脊椎の回旋する角度と同等又はそれ以下の角度に回旋できるので、身体を前後に屈伸したり、左右に曲げたり、捻ったりする場合にもシリンダー状部内でピストン状部が動き、前記上下に隣接する二つの脊椎は固定されずに動くことができる。それによって、脊椎には無理なストレスがかからない。
【０００８】また、別の手段は、請求項２に記載のとおり、請求項１の人工椎間関節において、シリンダー状部内でのピストン状部の回旋を許容するためにシリンダー状部の内面を弾性物質でライニングし、更に、前記ピストン状部の底部と蓋体の間にばねを設けたことを特徴とする人工椎間関節である。
【０００９】ピストン状部が回旋するときに、シリンダー状部の内面にライニングされた弾性物質が撓む範囲内で、シリンダー状部内でのピストン状部の回旋が許容される。ピストン状部が移動するときに、ピストン状部の底部と蓋体の間に設けたばねが圧縮されて、シリンダー

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状部内でのピストン状部の移動を許容する。

【００１０】他の手段は、請求項３又は４に記載のとおり、請求項１又は２の人工椎間関節において、シリンダー状部とピストン状部の双方の横断面を長円とし、又は楕円として、ピストン状部をシリンダー状部に対して健常者の脊椎の回旋する角度と同等又はそれ以下の角度で回旋させることを特徴とする人工椎間関節である。

【００１１】身体を捻ろうとすると、シリンダー状部とピストン状部のそれぞれの横断面が長円であるので、ピストン状部をシリンダー状部に対して健常者の脊椎の回旋する角度と同等又はそれ以下の角度にしか回旋せず、それ以上動かない。

【００１２】更に、他の手段は、請求項５に記載のとおり、請求項２、３又は４の人工椎間関節において、弾性物質がポリウレタンであることを特徴とする人工椎間関である。

【００１３】ポリウレタンは大きな弾性を有するので、シリンダー状部内でのピストン状部の回旋を大きく許容する。

【００１４】また、請求項６に記載のとおり、請求項１、２、３、４又は５に記載の人工椎間関節において、ピストン状部がポリオレフィン製であることを特徴とする人工椎間関節である。

【００１５】ポリオレフィンは自己潤滑性や耐摩耗性を有しているので、シリンダー状部内でのピストン状部の潤滑な動きを確保し、長期間の使用によっても摩耗が少ない。

【００１６】

【発明の実施の形態】　図１において、１は、本発明の人工椎間関節であるが、該人工椎間関節１は、シリンダー状部２とこれに移動自在に嵌合するピストン状部３からなる。

【００１７】シリンダー状部２には、障害椎間板Ｃに隣接する脊椎Ａに取り付けるための取付部２ｃがその閉塞端２ｂに固設されている。

【００１８】また、ピストン状部３は、図１及び図４に示すように、ピストン部３ａとその底部３ｂに取り付けられた棒状体３ｃからなる。ピストン状部３は、前記シリンダー状部２内の移動方向に直交する方向にも、健常者の脊椎の回旋する角度（最大で左右に１５度程度）と同等の又はそれ以下の角度、例えば、約１０度回旋できるようにシリンダー状部２内に嵌合されている。

【００１９】ピストン部３ａは、図４に示すように、シリンダー状部２内でピストン状部３が傾動できるように上半部を略円形とした。

【００２０】前記棒状体３ｃの先端部３ｃ－１は、図１に示すように、取付部９に螺着され、該取付部９は、障害椎間板Ｃに隣接する前記とは別の脊椎Ｂに取り付けられる。

【００２１】シリンダー状部２の内面を、例えば、ポリウレタンである弾性物質２Ａでライニングするが、これによって、シリンダー状部２内でピストン状部３を回旋させるとき、弾性物質２Ａが撓むことで、その回旋を一定範囲だけ許容する。また、シリンダー状部２内でピストン状部３を円滑に傾動できるように、図４に示すように、弾性物質２Ａの下半部にテーパー面２Ｂを形成した。

【００２２】また、図４に示すように、前記シリンダー状部２の開放端２ａには、中央に前記棒状体３ｃを通す穴５ａを有する蓋体５を取り付け、前記ピストン部３ａの底部３ｂと蓋体５の間に、例えば、コイルバネであるばね６を設けて、該ばね６に抗してピストン状部３はシリンダー状部２内で移動できるようにする。

【００２３】前記穴５ａに棒状体３ｃを通すので、前記穴５ａの直径は、棒状体３ｃの直径よりも大きい。しかし、蓋体５はばね６を支持するので、前記穴５ａの直径は、ばね６の直径よりも小さい。

【００２４】シリンダー状部２は、チタン製としたが、ステンレス製やコバルト・クロム合金製のものであってもよい。

【００２５】シリンダー状部２は、横断面が長円形、又は、図３において示すような横断面が楕円とする。

【００２６】シリンダー状部２の取付部２ｃは、中央部の長手方向に、図１に示すように、スクリューＦの先端部Ｆａを挿入する長溝８を有する。

【００２７】シリンダー状部２の内面にライニングされた弾性物質２Ａとしては、前記のように、ポリウレタンを用いるが、デルリン（登録商標）などのポリアセタールやポリメタクリル酸メチル（ＰＭＭＡ）なども用いられる。

【００２８】ピストン状部３は、横断面が長円形、又は、図３において示すような横断面が楕円とし、該ピストン状部３を、高密度ポリエチレン（ＨＤＰ）やポリプロピレン（ＰＰ）などのポリオレフィン製としたが、セラミックス製やチタン製やステンレス製やコバルト・クロム合金製のものであってもよい。

【００２９】棒状体３ｃは、チタンやステンレスなどの金属製である。

【００３０】また、前記取付部９は、幅狭の直方体であり、図１に示すように、中央部の長手方向に、スクリューＦ′の先端部Ｆ′ａの直径よりも若干大きな幅を有する長溝１０を有する。

【００３１】図４に示すように、内面に弾性物質２Ａをライニングしたシリンダー状部２内にピストン状部３を挿入し、棒状体３ｃを囲繞するように、例えば、コイルバネであるばね６を前記取付部９を通過させてシリンダー状部２内に挿入する。更に、蓋体５を前記シリンダー状部２の開放端２ａに取り付け、その中央部に設けた穴５ａから前記棒状体３ｃを外に延在させ、ねじ５ｂにより蓋体５をシリンダー状部２に結着する。そして、前記

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のように、棒状体３ｃの先端部３ｃ－１に前記取付部９を螺着する。

【００３２】図１及び図２（Ａ）（Ｂ）に示したように、障害椎間板Ｃを挟んで上下に隣接する脊椎Ａ、Ｂの椎弓根Ｊ、Ｊから椎体Ｋ、Ｋに、スクリューホールを明け、該各ホールにスクリューＦ、Ｆ′、Ｆ－１、Ｆ－１′をねじ込む。該スクリューのうち、上下に対応する２本のスクリューＦ、Ｆ′とＦ－１、Ｆ－１′の先端に、二つの人工椎間関節１Ａ、１Ｂを取り付ける。

【００３３】スクリューＦ、Ｆ′、Ｆ－１、Ｆ－１′は、チタン製であるが、ステンレス製にしてもよい。また、骨への接着をよくするために、スクリューＦ、Ｆ′、Ｆ－１、Ｆ－１′にハイドロキシアパタイトをコーティングしてもよい。

【００３４】この人工椎間関節１のスクリューＦとＦ′への取り付けを以下に詳述するが、他のスクリューＦ－１とＦ－１′への取り付け方法も同様である。

【００３５】障害椎間板Ｃの上に位置する脊椎Ａにねじ込まれたスクリューＦにシリンダー状部２の取付部２ｃを装着して、該取付部２ｃをスクリューＦの着座部Ｆｂ上に置くが、このときスクリューＦの先端部Ｆａは前記長溝８を挿通する。この状態で、前記取付部２ｃを移動して、スクリューＦに対するシリンダー状部２の取り付け位置を調節してから、取付部２ｃをナット７で締着する。

【００３６】更に、障害椎間板Ｃの下に位置する脊椎Ｂにねじ込まれたスクリューＦ′に取付部９を装着して、該取付部９をスクリューＦ′の着座部Ｆ′ｂ上に置くが、このときスクリューＦ′の先端部Ｆ′ａは前記長溝１０を挿通する。この状態で、前記取付部９を移動し、スクリューＦ′に対するピストン状部３の取り付け位置を調節してから、取付部９をナット７で締着する。

【００３７】図２（Ａ）に示すように、前記脊椎Ａ、Ｂの棘突起Ｄ、Ｄの左右両側に２個の本発明の人工椎間関節１Ａ、１Ｂを取り付けた場合に、身体を反らすと、前記脊椎Ａ、Ｂは、図１の矢示αのように動くが、このとき、前記ピストン状部３の頭部３ｄが前記シリンダー状部２の内面の頂部２ｄにライニングされた弾性物質２Ａに当たるまで、ピストン状部３がシリンダー状部２の頂部２ｄに向かって移動するので、脊椎Ａ、Ｂは固定されずに動き、身体を背後に反らすことができる。

【００３８】しかも、一定範囲を越えて、無理に身体を反らそうとすると、シリンダー状部２の頂部２ｄにおいてライニングされた弾性物質２Ａにピストン状部３が当たり、ピストン状部３はシリンダー状部２内で動きを規制され、それ以上身体が反ることを制動する。

【００３９】また、身体を屈める場合、前記上下に隣接する脊椎Ａと脊椎Ｂは、図１の矢示βのように動くが、このとき前記ピストン状部３はばね６に抗してその軸方向に移動するので、脊椎Ａ、Ｂは固定されずに動き、身体を屈めることができる。

【００４０】しかし、無理に身体を前方に屈めようとすると、ピストン状部３は動きを規動されるので、それ以上に身体が前方に屈むことが制動される。

【００４１】更に、身体を左右に曲げる場合、前記上下に隣接する脊椎Ａと脊椎Ｂは図２（Ｂ）の矢示γのように動くが、このとき、脊椎と脊椎の間が縮んだ側においては、ピストン状部３の頭部３ｄが弾性物質２Ａに当たるまでシリンダー状部２の頂部２ｄに向かって移動するので、人工椎間関節１Ｂは縮むが、一方、脊椎と脊椎の間が拡がった側においては、前記ピストン状部３がばね６を圧縮するようにシリンダー状部２内で動くので、人工椎間関節１Ａは伸びる。そのために、脊椎Ａ、Ｂは固定されずに動き、身体は左右に曲がる。

【００４２】しかし、無理に身体を左右に曲げようとする場合には、縮んだ側の人工椎間関節１Ｂにおいては、シリンダー状部２の頂部２ｄにライニングされた弾性物質２Ａにピストン状部３が当たり、ピストン状部３はシリンダー状部２内で動きが規制される。また、拡がった側の人工椎間関節１Ａにおいては、前記ばね６がそれ以上圧縮しなくなり、ピストン状部３のシリンダー状部２内での動きが規制される。そのために、それ以上に身体が曲がることが制動される。

【００４３】次いで、身体を捻る場合、人工椎間関節１Ａ、１Ｂにおいては、長円形、又は、図３に示すような楕円形の横断面を有するピストン状部３が、シリンダー状部２の内面にライニングされた弾性物質２Ａを撓ませて、長円形、又は、楕円形の横断面を有するシリンダー状部２に対して健常者の脊椎の回旋する角度と同等又はそれ以下の角度に回旋すると共に、前記ピストン状部３はばね６も圧縮するので、人工椎間関節１Ａ、１Ｂは、共に伸びる。それによって、脊椎Ａ、Ｂは固定されずに動き、身体を捻ることができる。

【００４４】上記の発明の実施の形態とは別に図５に示すような実施の形態があるが、この実施の態様は二つの人工椎間関節１Ｃ、１Ｃを棘突起Ｄ、Ｄを挟んでその両側に取り付けたものである。

【００４５】この人工椎間関節１Ｃ、１Ｃは、前記のスクリューＦの代わりに、取り付け部材１１Ａ、１１Ｂ、１１′Ａ、１１′Ｂとボルト１３とナット１４を用いて、脊椎Ａの棘突起Ｄと脊椎Ｂの棘突起Ｄの間に取り付けられるものである。また、この人工椎間関節１Ｃは、シリンダー状部２の取付部２ｃに、長溝８に代えて、取り付け孔８′を設けたことと、棒状体３ｃの取付部９に、長溝１０に代えて、取り付け孔１０′を設けたことを除いて、前記の実施の態様の人工椎間関節１Ａ、１Ｂとは異ならない。

【００４６】取り付け部材１１Ａ、１１′Ａ、１１Ｂ、１１′Ｂは、図５（Ｂ）に示すように、中央部の長手方向に長溝１１ａを有し、一方の面にネジ部１２を設け、

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図５（Ｃ）に示すように、棘突起Ｄに装着された時に固定を確実にするために、挟持面１１ｂをラック状に構成したものである。

【００４７】前記ネジ部１２に、図５（Ａ）に示すように、シリンダー状部２の取付部２ｃを装着し、該ネジ部１２の先端部を前記取り付け孔８′に挿通し、取付部２ｃをナット７で締着して、取付部２ｃを取り付け部材１１Ａに予め取り付けておく。

【００４８】また、別の取り付け部材１１′Ａのネジ部１２にピストン状部３の取付部９を装着し、該ネジ部１２の先端部を前記取り付け孔１０′に挿通し、該取付部９をナット７で締着して、取付部９を取り付け部材１１′Ａに予め取り付けておく。

【００４９】同様に、取付部材１１Ｂについてもネジ部１２にシリンダー状部２の取付部２ｃを装着し、該ネジ部１２の先端部を前記取り付け孔８′に挿通し、取付部２ｃをナット７で締着して、取付部２ｃを取り付け部材１１Ｂに予め取り付けておく。

【００５０】更に、他の取り付け部材１１′Ｂのネジ部１２にピストン状部３の取付部９を装着し、該ネジ部１２の先端部を前記取り付け孔１０′に挿通し、該取付部９をナット７で締着して、取付部９を取り付け部材１１′Ｂに予め取り付けておく。

【００５１】障害椎間板Ｃの上に位置する脊椎Ａの棘突起Ｄに穴を明け、図５（Ａ）に示すように、前記取り付け部１１Ａ、１１Ｂを前記棘突起Ｄを挟んでその両側に取り付け、前記棘突起Ｄの穴と取り付け部材１１Ａ、１１Ｂの長溝１１ａ、１１ａにボルト１３を挿通し、ナット１４により仮締めして、取り付け部材１１Ａ、１１Ｂを移動して該取り付け部材１１Ａ、１１Ｂとシリンダー状部２、２の取り付け位置を調節してから本締する。

【００５２】同様に、障害椎間板Ｃの下に位置する脊椎Ｂの棘突起Ｄにも穴を明け、図５（Ａ）に示すように、前記取り付け部材１１′Ａ、１１′Ｂを前記棘突起Ｄを挟んで取り付け、前記棘突起Ｄの穴と取り付け部材１１′Ａ、１１′Ｂの長溝１１ａ、１１ａにボルト１３を挿通し、ナット１４により仮締めし、取り付け部材１１′Ａ、１１′Ｂを移動して、該取り付け部材１１′Ａ、１１′Ｂとピストン状部３の取り付け位置を調節してから本締する。

【００５３】この実施の形態の人工椎間関節１Ｃ、１Ｃは、身体を背後に反らすと、前記ピストン状部３の頭部３ｄが前記シリンダー状部２の内面の頂部にライニングされた弾性物質２Ａに当たるまで移動するので、脊椎Ａ、Ｂは拘束されずに動き、身体を反らすことができる。

【００５４】しかし、無理に身体を背後に反らすと、シリンダー状部２の頂部にライニングされた弾性物質２Ａにピストン状部３が当たり、ピストン状部３はシリンダー状部２内での動きを規制されるので、それ以上に身体が反ることが制動される。

【００５５】また、前方に身体を屈める場合には、前記ピストン状部３はばね６に抗してその軸方向に移動するので、脊椎Ａ、Ｂは固定されずに動き、身体を前方に屈めることができる。

【００５６】しかし、無理に身体を前方に屈めようとすると、前記ばね６がそれ以上圧縮しなくなり、ピストン状部３がシリンダー状部２内での動きを規動され、それ以上身体は前方に屈めなくなる。

【００５７】更に、身体を左右に曲げる場合には、脊椎Ａと脊椎Ｂの間が縮んだ側においては、ピストン状部３の頭部３ｄが弾性物質２Ａに当たるまでシリンダー状部２の頂部に向かって移動するので、人工椎間関節１Ｃは縮むが、一方、脊椎Ａと脊椎Ｂの間が拡がった側においては、前記ピストン状部３がばね６を圧縮するようにシリンダー状部２内で動くので、該人工椎間関節１Ｃは伸びる。そのために、脊椎Ａ、Ｂは固定されずに動き、身体は左右に曲がる。

【００５８】しかし、無理に身体を左右に曲げようと、縮んだ側の人工椎間関節１Ｃにおいては、シリンダー状部２の頂部にライニングされた弾性物質２Ａにピストン状部３が当たり、ピストン状部３はシリンダー状部２内で動きが規制され、拡がった側の人工椎間関節１Ｃにおいては、前記ばね６がそれ以上圧縮しなくなり、ピストン状部３がシリンダー状部２内で動きを規制される。そのために、それ以上に身体が曲がることが制動される。

【００５９】次いで、身体を捻る場合には、この人工椎間関節１Ｃ、１Ｃにおいて、長円形若しくは楕円形の横断面を有するピストン状部３が、シリンダー状部２の内面にライニングされた弾性物質２Ａを撓ませて、長円形若しくは楕円形の横断面を有するシリンダー状部２に対して健常者の脊椎の回旋する角度と同等又はそれ以下の角度に回旋すると共に、前記ピストン状部３がばね６を圧縮するので、脊椎Ａ、Ｂは固定されずに動き、身体を捻ることができる。

【００６０】しかし、弾性物質２Ａの撓み量を越えて身体を捻ろうとすると、ピストン状部３のシリンダー状部２内での回旋は規制されるので、それ以上身体は捻れなくなる。

【００６１】

【発明の効果】　本発明の請求項１に記載の人工椎間関節においては、ピストン状部がシリンダー状部内に移動自在に嵌合されており、しかもピストン状部は、シリンダー状部内の移動方向に直交する方向にも、健常者の脊椎の回旋する角度と同等の角度又はそれ以下の角度だけ回旋できるので、身体を前後に屈伸したり、左右に曲げたり、捻ったりする場合に、人工椎間関節で規制される範囲内で、前記上下に隣接する二つの脊椎を動かすことができて、障害椎間板の上下の脊椎に無理なストレスがかからない効果を有する。

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【００６２】本発明の請求項２に記載の人工椎間関節は、身体を左右に捻るとき、シリンダー状部の内面にライニングされた弾性物質が撓んでシリンダー状部内でのピストン状部の回旋を許容し、更に、ピストン状部の底部と蓋体の間に設けたばねも圧縮して、シリンダー状部内でのピストン状部の移動を許容するので、取り付けられた脊椎を人工椎間関節で規制される範囲内で動かすことができ、脊椎に無理なストレスがかからない効果を有する。

【００６３】本発明の請求項３又は４に記載の人工椎間関節は、シリンダー状部とピストン状部のそれぞれの横断面が長円若しくは楕円であるので、身体を捻ったときに、ピストン状部がシリンダー状部に対して若干の角度しか回旋しないので、無理に身体を捻ろうとしても、シリンダー状部内でのピストン状部の動きがすぐに規制され、脊椎に過度の負荷がかからず、しかも椎間板を傷つけないで脊椎関節の機能を再建できる効果を有する。

【００６４】本発明の請求項５に記載の人工椎間関節は、弾性物資をポリウレタンにしたことで、その大きな弾性により撓んでシリンダー状部内でのピストン状部の回旋を許容するので、脊椎に無理なストレスがかからない効果を有する。

【００６５】本発明の請求項６に記載の人工椎間関節は、ピストン状部をポリオレフィン製にしたことで、ポリオレフィンの自己潤滑性や耐摩耗性により、シリンダー状部内でのピストン状部の潤滑な動きが確保でき、長期間の使用によっても摩耗が少ない効果を有する。

【図面の簡単な説明】

【図１】　脊椎に取り付けた本発明の人工椎間関節を示す略図。

【図２】　（Ａ）は、二つの本発明の人工椎間関節を脊椎に取り付けたときの状態を示す略図。（Ｂ）は、二つの本発明の人工椎間関節を脊椎に取り付けて、身体を左右に捻った場合の人工椎間関節の状態を示す略図。

【図３】　本発明の人工椎間関節の横断面図。

【図４】　本発明の人工椎間関節の縦断面図。

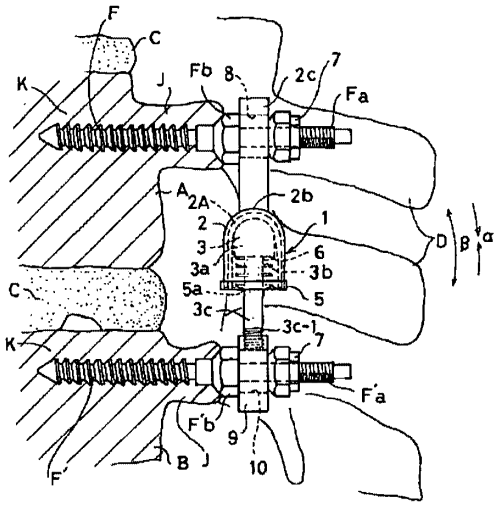
【図５】　（Ａ）は、本発明の別の実施の態様の人工椎間関節を脊椎の棘突起を挟んで両側に取り付けたときの状態を示す略図。（Ｂ）は、取り付け部材の平面図。（Ｃ）は、取り付け部材の底面図。

【図６】　従来の脊椎内固定器具を示す略図。

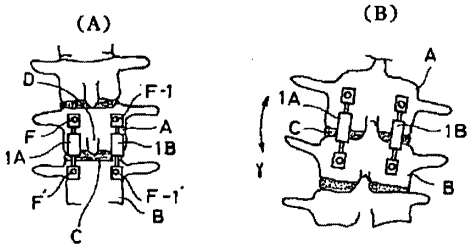
【符号の説明】

１　人工椎間関節　　２　シリンダー状部　　２Ａ　弾性物質　　２ａ　開放端　　２ｂ　閉塞端　　２ｃ　取付部　　３　ピストン状部６　ばね　　９　別の取付部

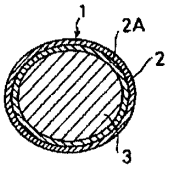
【図１】



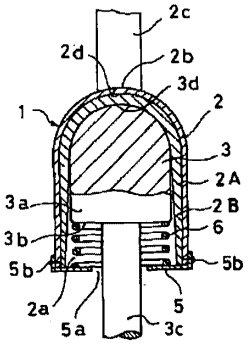
【図２】



【図３】

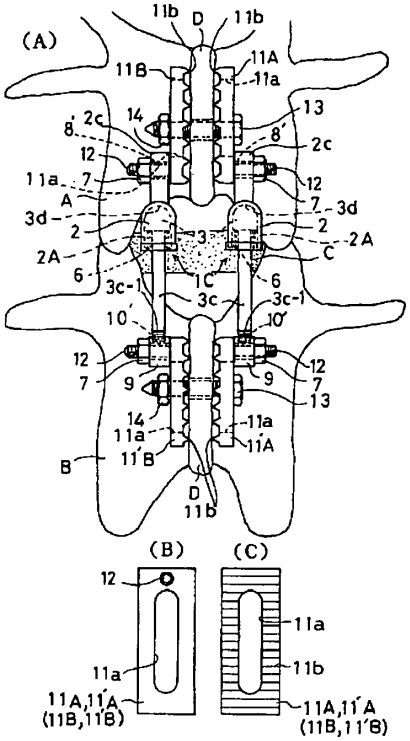


【図４】

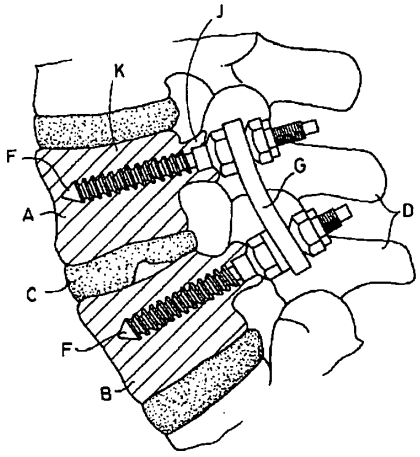


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【図５】



【図６】



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(54) Pedikelschraube und Montagehilfe dafür

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ZUSTELLUNGSANSCHRIFT/ PLEASE REPLY TO:

HAMBURG, 8. April 1998

Pedikelschraube und Montagehilfe dafür

Die Erfindung bezieht sich auf eine Pedikelschraube und eine Montagehilfe dafür nach dem Oberbegriff des Anspruchs 1.

Zur Reponierung von Wirbeln der menschlichen Wirbelsäule, zur Distraktion der Wirbelsäule, zur Stabilisierung von Wirbeln und dergleichen ist bekannt, sogenannte Pedikelschrauben zu verwenden. Sie werden in die Pedikel der Wirbel eingeschraubt und weisen einen Kopf auf, der mit geeigneten Vorkehrungen verbunden wird, beispielsweise einem Stabilisierungssystem, mit Distraktionsstäben und dergleichen. Es ist bekannt, Pedikelschrauben mit einem ringartigen Kopf zu versehen, der an den Stirnseiten eine Zahnung aufweist. Es ist jedoch auch bekannt, den Schraubenkopf gabelartig zu gestalten, damit er einen Distraktionsstab, einen Verbindungsstab oder

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dergleichen aufzunehmen in der Lage ist. Zur Festlegung des Stabes im gabelartigen Kopf kann ein geeignetes Schraubelement mit dem Kopf in Eingriff gebracht werden. Das Schraubelement kann hutartig sein und auf Außengewindeabschnitte des Kopfes aufgeschraubt werden. Es ist jedoch auch bekannt, den Kopfabschnitten ein Innengewinde zuzuordnen zur Aufnahme einer Madenschraube oder dergleichen, mit welche der eingelegte Stab im Kopf festgelegt wird.

Es ist ferner bekannt, zur einfacheren Handhabung der Pedikelschraube diese mit einem Kopf zu versehen, der relativ zum Schaft beweglich ist, vorzugsweise in allen Richtungen schwenkbar. Zu diesem Zweck kann das Kopfende des Schaftes kugelig ausgeführt werden, wobei die Kugelfläche mit einer sphärischen Lagerfläche im Kopf zusammenwirkt. In diesem Fall ist erforderlich, nach erfolgter Einstellung von Schaft und Kopf zueinander diese Winkelstellung beizubehalten. Dies kann beispielsweise dadurch geschehen, daß der vom Kopf aufgenommene Stab gegen den kugeligen Kopf des Schaftes gepreßt wird, wodurch die Teile in ihrer Lage zueinander festgelegt sind.

Bei der Versorgung werden im allgemeinen zuerst die Pedikelschrauben eingedreht. Anschließend erfolgt das Einlegen des Stabes. Hierbei müssen jedoch unter Umständen erhebliche Kräfte aufgewendet werden, um den Stab in den gabelartigen Kopf hineinzubewegen. Die Einführkraft muß so lange aufrechterhalten werden, bis mit Hilfe des Schraubelements ein Herausgleiten aus der Aufnahme im Kopf nicht mehr

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möglich ist. Hierzu bedarf es erheblicher Geschicklichkeit und auch eines erheblichen Kraftaufwandes seitens des Chirurgen.

Der Erfindung liegt daher die Aufgabe zugrunde, die Pedikelschraube so auszubilden und eine Montagehilfe derart auszuführen, daß das Einlegen und Festlegen von Stäben in den Pedikelschraubenköpfen erleichtert ist.

Diese Aufgabe wird durch die Merkmale des Anspruchs 1 gelöst.

Ein wesentliches Merkmal der Erfindung besteht darin, daß die Kopfabschnitte auf der Außenseite eine Ausnehmung aufweisen. Die Ausnehmung dient zur Aufnahme von Greifabschnitten, die am Ende von Armen ausgebildet sind, die ihrerseits mit einem Schaft verbunden sind. Der Schaft ist gleitend, jedoch drehfest in einer Hülse geführt, und zwischen Hülse und Schaft wirkt ein Verstellmechanismus, der bei Betätigung den Schaft relativ zur Hülse verschiebt.

Die Greifabschnitte erfassen von der Außenseite den Pedikelschraubenkopf, so daß der Kopf mit Hilfe des beschriebenen Verstellmechanismus in Richtung Hülse bewegt werden kann. Der Stab ist zuvor zwischen die Arme eingeführt worden, bevor der Pedikelschraubenkopf erfaßt wurde. Wird nunmehr der Schraubenkopf in Richtung Hülse bewegt, drückt die Hülse den Stab automatisch zwischen die Kopfabschnitte in die Ausnehmung hinein.

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