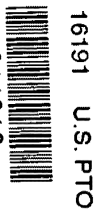
Express Mail EM626520557US

PATENT



Case Docket No.: 11,433

U.S. PTO
13/694849
01/10/2013

COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, VA 22313-1450

Date: January 10, 2013

Sir:

Transmitted herewith for filing is the patent application of:

Inventor: Roger P. Jackson

For: MULTI-START CLOSURES FOR OPEN IMPLANTS

Enclosed are:

X	Abstract of the Disclosure (1 page) and
34	Pages of Specification and Claims
7	Sheets of drawings
X	Information Disclosure Statement and Form 1449
X	Declaration
X	Power of Attorney and Transmit Sheet
X	Application Data Sheet
X	Fee Transmittal Sheet
X	Applicant is a small entity for purposes of filing patent applications
X	The filing fee has been calculated as shown on the attached fee transmittal sheet:

X The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment, to Account No. 50-1253. A duplicate copy of this sheet is attached.

X Our check No. 8096 is also enclosed to cover, among other items, the above filing fee.

Respectfully submitted,

John C. McMahon

JCM:lm
PO Box 860305
Shawnee, Kansas 66286
Telephone: (913) 422-5222

Reg. No. 29,415

PTO/SB/17 (10-12)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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FEE TRANSMITTAL

Complete if known	
Application Number	
Filing Date	
First Named Inventor	Roger P. Jackson
Examiner Name	
Art Unit	
Practitioner Docket No.	11,433

■ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) 1017.00

METHOD OF PAYMENT (check all that apply)

■ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): _____

■ Deposit Account Deposit Account Number: 50-1253 Deposit Account Name: _____

For the above-identified deposit account, the Director is hereby authorized to (check all that apply):

☐ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, **except for the filing fee**

■ Charge any additional fee(s) or underpayment of fee(s) under 37 CFR 1.16 and 1.17 ☐ Credit any overpayment of fee(s)

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FEE CALCULATION

1. BASIC FILING, SEARCH, AND EXAMINATION FEES

	FILING FEES		SEARCH FEES		EXAMINATION FEES		
Application Type	**Fee ($)**	**Small Entity Fee ($)**	**Fee ($)**	**Small Entity Fee ($)**	**Fee ($)**	**Small Entity Fee ($)**	**Fees Paid ($)**
Utility	390	195	620	310	250	125	630
Design	250	125	120	60	160	80	
Plant	250	125	380	190	200	100	
Reissue	390	195	620	310	760	380	
Provisional	250	125	0	0	0	0	

2. EXCESS CLAIM FEES

Fee Description	**Fee ($)**	**Small Entity Fee ($)**
Each claim over 20 (including Reissues)	62	31
Each independent claim over 3 (including Reissues)	250	125
Multiple dependent claims	460	230

Total Claims		**Extra Claims**	**Fee ($)**		**Fee Paid ($)**
22	-20 or HP =	2 x	31	=	62

HP = highest number of total claims paid for, if greater than 20.

Indep. Claims		**Extra Claims**	**Fee ($)**		**Fee Paid ($)**
4	-3 or HP =	1 x	125	=	125

HP = highest number of independent claims paid for, if greater than 3.

Multiple Dependent Claims	
Fee ($)	**Fee Paid ($)**
0	0

3. APPLICATION SIZE FEE

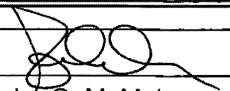
If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is $320 ($160 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets		**Extra Sheets**		**Number of each additional 50 or fraction thereof**	**Fee ($)**		**Fee Paid ($)**
41	- 100 =	0	/ 50 =	0 (round **up** to a whole number)	0	x =	0

4. OTHER FEE(S)

	Fees Paid ($)
Non-English specification, $130 fee (no small entity discount)	0
Non-electronic filing fee under 37 CFR 1.16(t) for a utility application, $400 fee ($200 small entity)	200
Other (e.g., late filing surcharge): _____	0

SUBMITTED BY

Signature		Registration No. (Attorney/Agent) 29,415	Telephone 913-422-5222
Name (Print/Type)	John C. McMahon		Date 2013-01-10

This collection of information is required by 37 CFR 1.136. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Express Mail EM626520557US PATENT

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34	Pages of Specification and Claims
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FEE TRANSMITTAL

Complete if known	
Application Number	
Filing Date	
First Named Inventor	Roger P. Jackson
Examiner Name	
Art Unit	
Practitioner Docket No.	11483

☒ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) 1017.00

COPY

METHOD OF PAYMENT (check all that apply)

☒ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): _____

☒ Deposit Account Deposit Account Number: 50-1253 Deposit Account Name: _____

For the above-identified deposit account, the Director is hereby authorized to (check all that apply):

☐ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, **except for the filing fee**

☒ Charge any additional fee(s) or underpayment of fee(s) under 37 CFR 1.16 and 1.17 ☐ Credit any overpayment of fee(s)

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1. BASIC FILING, SEARCH, AND EXAMINATION FEES

	FILING FEES		SEARCH FEES		EXAMINATION FEES		
Application Type	**Fee ($)**	**Small Entity Fee ($)**	**Fee ($)**	**Small Entity Fee ($)**	**Fee ($)**	**Small Entity Fee ($)**	**Fees Paid ($)**
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HP = highest number of total claims paid for, if greater than 20.

Indep. Claims		**Extra Claims**		**Fee ($)**		**Fee Paid ($)**
4	-3 or HP =	1	x	125	=	125

HP = highest number of independent claims paid for, if greater than 3.

Multiple Dependent Claims	
Fee ($)	**Fee Paid ($)**
0	0

3. APPLICATION SIZE FEE

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Total Sheets		**Extra Sheets**		**Number of each additional 50 or fraction thereof**		**Fee ($)**		**Fee Paid ($)**
41	- 100 =	0	/ 50 =	0 (round **up** to a whole number)	x	0	=	0

4. OTHER FEE(S)

	Fees Paid ($)
Non-English specification, $130 fee (no small entity discount)	0
Non-electronic filing fee under 37 CFR 1.16(t) for a utility application, $400 fee ($200 small entity)	200
Other (e.g., late filing surcharge): _____	0

SUBMITTED BY

Signature		Registration No. (Attorney/Agent) 29,415	Telephone 913-422-5222
Name (Print/Type)	John C. McMahon		Date 2013-01-10

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	11,433
	Application Number	
Title of Invention	MULTI-START CLOSURES FOR OPEN IMPLANTS	

The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.
This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.

Secrecy Order 37 CFR 5.2

☐ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

Inventor Information:

Inventor 1 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Roger	P.	Jackson	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Prairie Village	State/Province	KS	Country of Residence	US

Mailing Address of Inventor:

Address 1	4706 W. 86th Street		
Address 2			
City	Prairie Village	State/Province	KS
Postal Code	66207	Country	US

Inventor 2 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	James	L.	Surber	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Kansas City	State/Province	KS	Country of Residence	US

Mailing Address of Inventor:

Address 1	1434 W. 88th Street		
Address 2			
City	Kansas City	State/Province	KS
Postal Code	66111	Country	US

All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the **Add** button. Add

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below.
For further information see 37 CFR 1.33(a).

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	11,433
	Application Number	
Title of Invention	MULTI-START CLOSURES FOR OPEN IMPLANTS	

☐ An Address is being provided for the correspondence Information of this application.			
Customer Number	27456		
Email Address	john@mcmahonpatentlaw.com	Add Email	Remove Email

Application Information:

Title of the Invention	MULTI-START CLOSURES FOR OPEN IMPLANTS		
Attorney Docket Number	11,433	**Small Entity Status Claimed**	☒
Application Type	Nonprovisional		
Subject Matter	Utility		
Suggested Class (if any)		**Sub Class (if any)**	
Suggested Technology Center (if any)			
Total Number of Drawing Sheets (if any)		**Suggested Figure for Publication (if any)**	

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)
☐ **Request Not to Publish.** I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32).
Either enter Customer Number or complete the Representative Name section below. If both sections are completed the customer Number will be used for the Representative Information during processing.

Please Select One:	◉ Customer Number	○ US Patent Practitioner	○ Limited Recognition (37 CFR 11.9)
Customer Number	27456		

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, or 365(c) or indicate National Stage entry from a PCT application. Providing this information in the application data sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.

Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
	non provisional of	61631746	2012-01-10

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	11,433
	Application Number	
Title of Invention	MULTI-START CLOSURES FOR OPEN IMPLANTS	

Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
	non provisional of	61634361	2012-02-28

Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the **Add** button.

Foreign Priority Information:

This section allows for the applicant to claim benefit of foreign priority and to identify any prior foreign application for which priority is not claimed. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55(a).

Remove

Application Number	Country[1]	Filing Date (YYYY-MM-DD)	Priority Claimed
			◉ Yes ○ No

Additional Foreign Priority Data may be generated within this form by selecting the **Add** button.

Authorization to Permit Access:

☒ Authorization to Permit Access to the Instant Application by the Participating Offices

If checked, the undersigned hereby grants the USPTO authority to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the World Intellectual Property Office (WIPO), and any other intellectual property offices in which a foreign application claiming priority to the instant patent application is filed access to the instant patent application. See 37 CFR 1.14(c) and (h). This box should not be checked if the applicant does not wish the EPO, JPO, KIPO, WIPO, or other intellectual property office in which a foreign application claiming priority to the instant patent application is filed to have access to the instant patent application.

In accordance with 37 CFR 1.14(h)(3), access will be provided to a copy of the instant patent application with respect to: 1) the instant patent application-as-filed; 2) any foreign application to which the instant patent application claims priority under 35 U.S.C. 119(a)-(d) if a copy of the foreign application that satisfies the certified copy requirement of 37 CFR 1.55 has been filed in the instant patent application; and 3) any U.S. application-as-filed from which benefit is sought in the instant patent application.

In accordance with 37 CFR 1.14(c), access may be provided to information concerning the date of filing this Authorization.

Applicant Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	11,433
	Application Number	
Title of Invention	MULTI-START CLOSURES FOR OPEN IMPLANTS	

Applicant 1

If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.

Clear

○ Assignee	○ Legal Representative under 35 U.S.C. 117	○ Joint Inventor
○ Person to whom the inventor is obligated to assign.	○ Person who shows sufficient proprietary interest	

If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:

Name of the Deceased or Legally Incapacitated Inventor :

If the Applicant is an Organization check here. ☐

Prefix	**Given Name**	Middle Name	**Family Name**	Suffix

Mailing Address Information:

Address 1			
Address 2			
City		**State/Province**	
Country		Postal Code	
Phone Number		Fax Number	
Email Address			

Additional Applicant Data may be generated within this form by selecting the Add button.

Non-Applicant Assignee Information:

Providing assignment information in this section does not subsitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Assignee 1

Complete this section only if non-applicant assignee information is desired to be included on the patent application publication in accordance with 37 CFR 1.215(b). Do not include in this section an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest), as the patent application publication will include the name of the applicant(s).

Best Available Copy

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	11,433
	Application Number	
Title of Invention	MULTI-START CLOSURES FOR OPEN IMPLANTS	

If the Assignee is an Organization check here. ☐

Prefix	Given Name	Middle Name	Family Name	Suffix

Mailing Address Information:

Address 1			
Address 2			
City		**State/Province**	
Country i		Postal Code	
Phone Number		Fax Number	
Email Address			

Additional Assignee Data may be generated within this form by selecting the Add button.

Signature:

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications

Signature				Date (YYYY-MM-DD)	
First Name	John	Last Name	McMahon	Registration Number	29415

Additional Signature may be generated within this form by selecting the Add button.

This collection of information is required by 37 CFR 1.76. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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MULTI-START CLOSURES FOR OPEN IMPLANTS

Cross-Reference to Related Applications

[0001] This application claims the benefit of U.S. Provisional Patent Application Serial No. 61/631,746 filed January 10, 2012, that is incorporated by reference herein. This application also claims the benefit of U.S. Provisional Patent Application Serial No. 61/634,361 filed February 28, 2012, that is incorporated by reference herein.

Background of the Invention

[0002] The present invention is directed to structure for joining together parts of a medical implant, in particular to closure mechanisms for use with open bone anchors in spinal surgery, and in some embodiments thereof, for use with spinal bone anchors such as polyaxial screws.

[0003] Bone anchors, such as bone screws and hooks are utilized in many types of spinal surgery in order to secure various implants to vertebrae along the spinal column for the purpose of stabilizing and/or adjusting spinal alignment. For example, the most common mechanism for providing vertebral support is to implant bone screws into certain bones which then in turn support a rod or are supported by the rod. Although both closed-ended and open-ended bone anchors are known, open-ended anchors are particularly well suited for connections to longitudinal

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IPR2023-01430; Petitioners' EX1002
Page 10 of 2152

connecting members such as hard, soft or deformable rods, dynamic or elastic connectors and connector arms, because such rods or other connector members do not need to be passed through a closed bore, but rather can be laid or urged into an open channel within a receiver or head of such a bone anchor. Generally, the anchors must be inserted into the bone as an integral unit or a preassembled unit, in the form of a shank or hook and connected pivotal receiver. In some instances, a portion of such a preassembled unit, such as a shank of a polyaxial bone screw assembly, may be independently implanted into bone, followed by push- or pop-on assembly of a receiver portion of the unit.

[0004] Typical open-ended bone screws include a threaded shank with a head or receiver having a pair of parallel projecting branches or arms which form a yoke with a U-shaped slot or channel to receive a rod or other longitudinal connecting member. Hooks and other types of connectors, as are used in spinal fixation techniques, may also include similar open ends for receiving rods or portions of other fixation and stabilization structure. The open-ended head or rod receiver portion of such implants typically includes a pair of spaced arms forming a channel closed by a closure member after the rod or other longitudinal connecting member is placed in the channel. Known closures include slide-on types, twist-on varieties that are rotated ninety degrees to a locked in position, and

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 11 of 2152

a variety of single start helically wound guide and advancement structures including, for example, thread forms having v-thread, reverse-angle buttress or square thread forms, to name a few, as well as other non-threadlike helically wound forms. Sometimes threaded plugs are utilized with outer threaded nuts to prevent splaying of the receiver arms.

[0005] As indicated above, the force required to press a closure structure down onto a rod or other connector located between arms of an open implant is considerable. Even though a head or receiver portion of an open polyaxial bone anchor may be pivoted in a direction to make it easier for the arms of the open implant to receive a rod or other connector, spinal misalignments, irregularities and the placement of other surgical tools make it difficult to place the rod or other connector between the arms of the implant while a closure structure is mated with the open implant as well as used to push the rod or other connector downwardly into the implant. For example, when the closure is a cylindrical plug having a single start helically wound guide and advancement structure, such structure must be aligned with mating structure on one of the implant arms and then rotated until a portion of the structure is captured by mating guide and advancement structure on both arms of the implant, all the while the closure is being pressed down on the rod while other forces are pushing and pulling the rod

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back out of the implant. Integral or mono-axial open implants that cannot be pivoted to receive the rod are even more difficult to manipulate during the initial placement of the rod and initial mating rotation of a closure plug between the spaced, open arms of the implant. Therefore, extraordinary forces are placed on the implant and closure plug while the surgeon either pushes down on the rod or pulls up on the bone to get the rod in position between the implant arms and to initially push down upon the rod with the closure plug.

Summary of the Invention

[0006] A closure structure, top or plug of the invention for insertion between spaced arms of an open medical implant includes one or more helically wound guide and advancement features, each feature having a start surface or structure located at or near a bottom surface of the closure plug, each start structure simultaneously engaging and being captured by each of the spaced arms of the open implant upon initial rotation of the closure structure with respect to the open implant arms. According to an aspect of the invention, a double-start closure is disclosed having two helically wound forms thereon, each form having a start structure for simultaneously engaging a mating helical form on a respective open implant arm. Each time the illustrated duel- or double- start closure plug is rotated one turn

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(three hundred sixty degrees) between the implant arms, the closure plug advances axially into the implant and toward the rod by a width of two helical forms. The helically wound forms of the multi-start closure spiral around a cylindrical plug body thereof to an extent that the closure rotates over ninety degrees to fully or substantially receive the entire closure plug between the arms of the open implant. The illustrated closure is sized for at least one complete rotation (three hundred sixty degrees) of the plug with respect to the open implant to substantially receive the plug between the implant arms. Multi-start closures of the invention may have two or more coarse or fine helical forms, resulting in fewer or greater forms per axial distance spiraling about the closure plug body and thus resulting in plugs that rotate less (when more coarse) or more (when thin or fine) than one complete rotation to be fully received between the implant arms, typically, at least a ninety-one degree rotation is preferred.

[0007] An illustrated multi-start closure and mating open implant is in the form of non-threaded, interlocking flange forms. Also disclosed are multi-start closure structures provided with helically wound forms of other geometry, including, but not limited to helically wound threads such as reverse angle, buttress, square and v-threads. The multi-start closure may be cannulated for minimally invasive surgical applications.

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[0008] Another illustrated multi-start closure embodiment of the invention is shown with a bone screw assembly having an open receiver with a pair of opposed arms, each arm having guide and advancement structure for simultaneous mating engagement with a start of the helically wound multi-start closure. A further embodiment according to the invention includes an open bone anchor receiver having integral upwardly extending break-off tabs that also have the guide and advancement structure for mating with the multi-start closure. A further embodiment includes an attachable/detachable guide tool cooperating with such a multi-start open receiver, the tool having inner guide and advancement structures located near a bottom thereof for rotatably and matingly receiving the multi-start closure and being synchronized with the receiver guide and advancement structure for rotating and driving the multi-start closure downward from the guide tool to the receiver.

[0009] Objects of the invention further include providing apparatus and methods that are easy to use and especially adapted for the intended use thereof and wherein the tools are comparatively inexpensive to produce. Other objects and advantages of this invention will become apparent from the following description taken in conjunction with the accompanying drawings wherein are set forth, by way of illustration and example, certain embodiments of this invention.

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[0010] The drawings constitute a part of this specification and include exemplary embodiments of the present invention and illustrate various objects and features thereof.

Brief Description of the Drawings

[0011] Fig. 1 is a perspective view of an embodiment of a multi-start closure according to the invention.

[0012] Fig. 2 is another perspective view of the multi-start closure of Fig. 1.

[0013] Fig. 3 is a front elevational view of the closure of Fig. 1 shown with a portion of a receiver of a polyaxial bone screw according to Fig. 8, the receiver shown in partial front elevation with portions broken away to show the detail thereof, and further showing a rod being pressed upon by the closure, the rod also in partial front elevation with portions broken away to show the detail thereof.

[0014] Fig. 4 is a reduced top plan view of the closure of Fig. 1.

[0015] Fig. 5 is a reduced bottom plan view of the closure of Fig. 1.

[0016] Fig. 6 is an enlarged front elevational view of the closure of Fig. 1 with portions broken away to show the detail thereof.

[0017] Fig. 7 is a reduced cross-sectional view taken along the line 7-7 of Fig. 6.

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[0018] Fig. 8 a partial front elevational view of an open bone screw assembly, with portions broken away to show the detail thereof, including a receiver, a shank, a compression insert and also shown in engagement with the closure top of Fig. 1 (in reduced view) and a longitudinal connecting member in the form of a hard rod.

[0019] Fig. 9 is a front elevational view of an alternative closure of an embodiment of the invention, similar to the closure of Fig. 1, but including a break-off head, the alternative closure shown with a portion of a receiver of the polyaxial bone screw of Fig. 8 shown in enlarged and partial front elevation with portions broken away to show the detail thereof, and further showing a rod being pressed upon by the alternative closure, the rod also in partial front elevation with portions broken away to show the detail thereof.

[0020] Fig. 10 is another front elevational view of the closure of Fig. 9 with portions broken away to show the detail thereof.

[0021] Fig. 11 is a front elevational view of an alternative square-thread closure of an embodiment of the invention with portions broken away to show the detail thereof, the closure shown with a portion of a receiver of the polyaxial bone screw of Fig. 8 shown in enlarged and partial front elevation with portions broken away to show the detail thereof, and further showing a rod being pressed

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upon by the alternative closure, the rod also in partial front elevation with portions broken away to show the detail thereof.

[0022] Fig. 12 is a front elevational view of an alternative reverse angle closure of an embodiment of the invention with portions broken away to show the detail thereof, the closure shown with a portion of a receiver of the polyaxial bone screw of Fig. 8 shown in enlarged and partial front elevation with portions broken away to show the detail thereof, and further showing a rod being pressed upon by the alternative closure, the rod also in partial front elevation with portions broken away to show the detail thereof.

[0023] Fig. 13 is a front elevational view of an alternative v-thread closure embodiment of the invention with portions broken away to show the detail thereof, the closure shown with a portion of a receiver of the polyaxial bone screw of Fig. 8 shown in enlarged and partial front elevation with portions broken away to show the detail thereof, and further showing a rod being pressed upon by the alternative closure, the rod also in partial front elevation with portions broken away to show the detail thereof.

[0024] Fig. 14 is a front elevational view of an alternative buttress-thread closure embodiment of the invention with portions broken away to show the detail thereof, the closure shown with a portion of a receiver of

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the polyaxial bone screw of Fig. 8 shown in enlarged and partial front elevation with portions broken away to show the detail thereof, and further showing a rod being pressed upon by the alternative closure, the rod also in partial front elevation with portions broken away to show the detail thereof.

[0025] Fig. 15 is a partial front elevational view of an embodiment of a multi-start open bone anchor receiver of an embodiment of the invention with portions broken away to show the detail thereof, the receiver including break-off tabs.

[0026] Fig. 16 is an enlarged and partial front elevational view of the receiver of Fig. 15 with portions broken away to show the detail thereof.

[0027] Fig. 17 is a partial front elevational view of an embodiment of a bone anchor receiver having a guide and advancement structure that matingly cooperates with the multi-start closure of Fig. 1, also shown in front elevation, the receiver having portions broken away to show the detail thereof, and further shown with a guide tool, shown in phantom, the guide tool having a multi-start guide and advancement structure receiving inner surface synchronized with the bone anchor receiver guide and advancement structure.

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Detailed Description of the Invention

[0028] As required, detailed embodiments of the present invention are disclosed herein; however, it is to be understood that the disclosed embodiments are merely exemplary of the invention, which may be embodied in various forms. Therefore, specific structural and functional details disclosed herein are not to be interpreted as limiting, but merely as a basis for the claims and as a representative basis for teaching one skilled in the art to variously employ the present invention in virtually any appropriately detailed structure. It is also noted that any reference to the words top, bottom, up and down, and the like, in this application refers to the alignment shown in the various drawings, as well as the normal connotations applied to such devices, and is not intended to restrict positioning of the bone attachment structures in actual use.

[0029] Furthermore, the terms lead, pitch and start, as such terms are used to describe helically wound guide and advancement structures, are to be understood as follows: Lead is a distance along the axis of a closure plug that is covered by one complete rotation (360 degrees)of the closure plug with respect to a mating open implant. Pitch is the distance from a crest (or outer point or location) of one guide and advancement structure form to the next. For example in a single-start thread-form, such as a single start, helically wound v-thread closure plug, lead and pitch

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are the same. Single start means that there is only one ridge or helically wound form wrapped around a cylindrical core, or in the case of the present invention, wrapped around a cylindrical closure plug body and thus there is only one start structure or surface at a base or forward end of the closure body that initially engages a mating structure on the open implant. Each time a single start closure rotates one turn (360 degrees), the closure has advanced axially by a width of one ridge or one helical form. Double-start means that there are two ridges or forms wrapped around a core body and thus there are two starting surfaces or structures on the closure plug. Therefore, each time a double-start body rotates one turn (360 degrees), such a body has advanced axially by a width of two ridges or forms. Multi-start means that there are at least two and may be up to three or more of such ridges or forms wrapped around a core body.

[0030] With reference to Figs. 1-8, and in particular to Fig. 8, the reference number 1 generally represents an open implant in the form of a polyaxial bone screw apparatus or assembly that cooperates with an illustrated closure structure 18 embodiment of the invention. The bone screw assembly 1 is described in detail in U.S. Provisional Patent Application No. 61/631,746 filed January 10, 2012 and incorporated by reference herein (hereafter the '746 application) and therefore will not be described in great

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detail herein. The description set forth in the '746 application includes a more detailed explanation of all the components referenced in Fig. 8. It is noted that multi-start closure embodiments of the invention, such as the closure 18 may be used with a variety of open implants including, but not limited to a wide variety of polyaxial screws, mono-axial or fixed screws, hooks and other types of open implants requiring a plug or closure mechanism to fix a rod or other implant member to a vertebra or other bone. Thus, the assembly 1 is only one example of how multi-start closures of the invention may be used.

[0031] Briefly, the illustrated assembly 1 includes a shank 4 with an upwardly extending upper portion or capture structure 8; an open receiver 10; a retaining structure or retainer (not shown) that pivots with the shank 4, a compression or pressure insert 14 and the multi-start closure structure or plug 18 in the form of a cylindrical plug having a double-start helically wound flange-form. The closure structure 18 presses against and captures a longitudinal connecting member, for example, a rod 21 which in turn engages the compression insert 14 that presses against the shank upper portion 8 that is attached to the retaining structure that in turn presses against an inner surface of the receiver 10, so as to capture and fix the longitudinal connecting member 21 within the receiver 10 and thus fix the member 21 relative to a vertebra (not shown).

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The illustrated receiver 10 and the shank 4 cooperate in such a manner that the receiver 10 and the shank 4 can be secured at any of a plurality of angles, articulations or rotational alignments relative to one another and within a selected range of angles both from side to side and from front to rear, to enable flexible or articulated engagement of the receiver 10 with the shank 4 until both are locked or fixed relative to each other near the end of an implantation procedure.

[0032] The illustrated rod 21 is hard, stiff, non-elastic and cylindrical, having an outer cylindrical surface 22. However, in other embodiments, the rod 21 may be elastic, deformable and/or of a different cross-sectional geometry. The rod 21 may be made from a variety of metals, metal alloys and deformable and less compressible plastics, including, but not limited to rods made of elastomeric, polyetheretherketone (PEEK) and other types of materials, such as polycarbonate urethanes (PCU) and polyethylenes. Furthermore, in lieu of a rod, longitudinal connecting members for use with the assembly 1 may take a variety of shapes, and/or may include a tensioned cord as described in greater detail in the '746 application that is incorporated by reference herein.

[0033] It is noted that the receiver 10 includes guide and advancement structures 168 that are shown as interlocking flange forms described in greater detail in

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applicant's U.S. Patent No. 6,726,689, also incorporated by reference herein. Alternately, when the closure structure includes a different helical form, the receiver cooperating structures (e.g., 168) must also be of a cooperating, mating geometry, such as a square-shaped thread receiving form, a buttress thread receiving form, a reverse angle thread receiving form or other thread-like or non-thread-like helically wound discontinuous advancement structure receiving forms for operably guiding under rotation and advancing a multi-start closure structure downward between the receiver arms 160, as well as eventual torquing when the closure structure abuts against the rod 21 or other connecting member.

[0034] With particular reference to Figs. 1-7, the illustrated multi-start closure structure 18 is a double start closure having a substantially cylindrical plug body 40 having an axis of rotation that is the same as that of the receiver 10 and including a helically wound guide and advancement structure in the form of a pair of helically wound forms 42 and 43, each illustrated as an interlocking flange form that operably joins with mating flange form guide and advancement structures 168 disposed on the arms of the receiver 10. The form 42 includes a start surface or structure 46 and the form 43 includes a start surface or structure 47. Each helically wound form 42 and 43 may take a variety of forms and geometries, including those described

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in Applicant's U.S. Patent No. 6,726,689, which is incorporated by reference herein. It is noted (and also described in greater detail subsequently herein) that each of the closure structure guide and advancement structures or forms 42 and 43 could alternatively be in the form of a buttress thread, a square thread, a reverse angle thread, a v-thread or other thread like or non-thread like helically wound advancement structures, for operably guiding under rotation and advancing the closure structure downward between the arms of the receive 10 and preferably having such a nature as to resist splaying of the receiver arms when the closure structure 18 is advanced into the receiver channel. The specific flange forms 42 and 43 illustrated in Figures 1-7, as well as acceptable alternative locking forms, are described in detail in Applicant's U.S. Patent No. 6,726,689, incorporated by reference herein, and thus shall not be discussed further herein. Such interlocking flange forms are preferred as the added strength provided thereby beneficially cooperate with and counter any reduction in strength caused by the any reduced profile of the receiver 10 that may more advantageously engage longitudinal connecting member components.

[0035] The illustrated closure structure 18 also includes a top surface 54 with an internal drive 56 in the form of an aperture that is illustrated as a star-shaped internal drive such as that sold under the trademark TORX, or may be, for

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example, a hex drive, or other internal drives such as slotted, tri-wing, spanner, two or more apertures of various shapes, and the like. A driving tool (not shown) sized and shaped for engagement with the internal drive 56 is used for both rotatable engagement and, if needed, disengagement of the closure 18 from the receiver 10 at arms 160. A base or bottom surface 58 of the closure is planar and further includes a rim 60 for engagement and penetration into the surface 22 of the rod 21 in certain embodiments of the invention. The closure top 18 further includes a cannulation through bore 62 extending along a central axis thereof and through a drive base surface 63 and the bottom surface 58 thereof. Such a through bore provides a passage through the closure 18 interior for a length of wire (not shown) inserted therein to provide a guide for insertion of the closure top into the receiver arms 160.

[0036] The closure structure 18 helically wound flange form start structures 46 and 47 of the respective forms 42 and 43 are located on opposite sides of the closure plug body 40 and are both located adjacent the bottom surface 58. As illustrated in Fig. 3, for example, when the closure structure 18 is rotated into the receiver 10 between receiver arms 160, each having a guide and advancement structure 168, the start 46 engages mating guide and advancement structure 168 on one arm 160 and the start 47 simultaneously engages guide and advancement structure 168

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on the opposing arm 160, both forms 42 and 43 being simultaneously captured by the mating forms 168 on the opposed arms 160. As the structure 18 is rotated, the structure advances axially downwardly between the arms 160 and presses evenly down upon the captured rod 21. Each time the illustrated duel- or double- start closure plug 18 is rotated one complete turn or pass (three hundred sixty degrees) between the implant arms, the closure plug 18 advances axially into the implant and toward the rod by a width of two helical flange forms. The illustrated closure 18 is sized for at least one complete rotation (three hundred sixty degree) of the plug 18 with respect to the receiver 10 open arms 160 to substantially receive the plug between the implant arms. Multi-start closures of the invention may have two or more coarse or fine helical forms, resulting in fewer or greater forms per axial distance spiraling about the closure plug body and thus resulting in plugs that rotate less or more than one complete rotation to be fully received between the implant arms. Preferably, helically wound forms of the multi-start closure of the invention are sized so as to spiral around a cylindrical plug body thereof to an extent that the closure rotates at least ninety-one degrees to fully or substantially receive the closure plug between the arms of the bone screw receiver or other open implant. Particularly preferred guide and advancement structures are sized for at least one complete

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turn or pass (three-hundred sixty degree) of the closure between the receiver 10 arms and as many as two to three rotations to be fully received between implant arms.

[0037] In use, the receiver 10, the retainer 12 and the compression insert 14 are assembled with the shank 4 either before or after the shank is implanted into a vertebra, and the resulting assembly 1 is ultimately attached to the rod 21 or other longitudinal connecting member as described in the '746 application incorporated by reference herein. It is noted that the shank 4 and other bone screw assembly parts, the rod 21 (also having a central lumen in some embodiments) and the closure top 18 having the central bore 62 can be inserted in a percutaneous or minimally invasive surgical manner, utilizing guide wires. After the rod 21 or other longitudinal connecting member is positioned in an open or percutaneous manner in cooperation with the at least two bone screw assemblies 1 (or other open implants), the closure structure 18 is then inserted into and advanced between the arms 160 of each of the receiver 10. The closure structure 18 is rotated, using a tool engaged with the inner drive 56 until a selected pressure is reached at which point the rod 21 engages a U-shaped seating surface of the compression insert 14, further pressing the insert against the shank upper portion 8 and attached retainer into locked frictional engagement with the receiver 10. Prior to locking the insert 14 against the shank head 8, the shank 4

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may be pivoted to a plurality of potentially desirable positions with respect to the receiver 10, followed by locking of the polyaxial mechanism by fully mating the multi-start closure top 18 with the receiver 10. Different angular or articulated positions of the shank 4 with respect to the receiver 10 are shown in the '746 application incorporated by reference herein.

[0038] With specific reference to Figs. 3 and 8, as the multi-start closure structure 18 rotates and moves downwardly into the respective receiver 10, the rim 60 engages and penetrates the rod surface 22, the closure structure 18 pressing downwardly against and biasing the rod 21 into compressive engagement with the insert 14 that urges the shank upper portion 8 and attached retainer into locking engagement with the receiver, the retainer outer surface frictionally abutting an inner spherical seating surface of the receiver 10. For example, about 80 to about 120 inch pounds of torque on the closure top may be applied for fixing the bone screw shank 6 with respect to the receiver 10. Also, for example, when the shank 4 is disposed at an angle with respect to the receiver 10, a part of the shank upper portion 8 may also be in frictional engagement with a portion of the receiver spherical seating surface.

[0039] If removal of the rod 21 from any of the bone screw assemblies 1 is necessary, or if it is desired to release the rod 21 at a particular location, disassembly is

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accomplished by using the driving tool (not shown) that mates with the internal drive 56 on the closure structure 18 to rotate and remove such closure structure from the cooperating receiver 10. Disassembly is then accomplished in reverse order to the procedure described previously herein for assembly.

[0040] With reference to Figs. 9 and 10, an alternative closure top 18' is shown that is almost identical to the closure top 18. However, the top 18' differs from the top 18 in that the top 18' includes a break-off head 70' that further includes a top surface 72' having tooling notches 73', an outer faceted driving surface 74', illustrated as having a hex-shaped profile, and an inner bore 76'. Otherwise, the closure top 18' includes a body 40', a first helical form 42', a second helical form 43', a body top surface 54', a body internal drive 56', a base 58', a rim 60', a cannulation bore 62' and a drive base surface 63' that is the same or substantially similar to the respective body 40, first helical form 42, second helical form 43, body top surface 54, internal drive 56, base 58, rim 60, cannulation bore 62 and drive base surface 63 previously described herein with respect to the closure top 18. The break-off head 70' is integral with the body 40' at the body top surface 54'. The inner bore 76' communicates with the inner drive 56' and the cannulation bore 62'. The break-off head 70' is designed to allow such head 70' to break from

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the body 40' at or near the top surface 54' at a preselected torque, for example, 70 to 140 inch pounds, when a hex-shaped tool (not shown) engages the outer surfaces 74' and drives the closure structure 18' into the receiver 10 as shown in Fig. 9. The inner drive 56' is used for disassembly or loosening of the closure 18' from the receiver 10, and re-tightening, if needed.

[0041] With reference to Fig. 11, another alternative multi-start closure top 318 is shown that is almost identical to the closure top 18 with the exception that the two flange forms 42 and 43 with respective starts 46 and 47 have been replaced with square threads 342 and 343 with respective starts 346 (not shown) and 347. Otherwise, the dual or double start closure top 318 includes a body 340, a body top surface 354, a body internal drive 356, a base 358, a rim 360', a cannulation bore 362 and a drive base surface 363 that is the same or substantially similar to the respective body 40, body top surface 54, internal drive 56, base 58, rim 60, cannulation bore 62 and drive base surface 63 previously described herein with respect to the closure top 18. In Fig. 11, the closure top 318 is shown partially wound into a polyaxial bone screw receiver 310 having opposed arms 360 with inner surfaces equipped with guide and advancement structures 368 that are sized and shaped to simultaneously closely receive and mate with the square threads 342 and 343 of the double closure structure 318.

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Otherwise, the receiver 310 is identical or substantially similar to the receiver 10 described in detail in the '746 application incorporated by reference herein.

[0042] With reference to Fig. 12, an alternative multi-start closure top 418 is shown that is almost identical to the closure top 18 with the exception that the two flange forms 42 and 43 with respective starts 46 and 47 have been replaced with reverse angle threads 442 and 443 with respective starts 446 (not shown) and 447. Otherwise, the dual or double start closure top 418 includes a body 440, a body top surface 454, a body internal drive 456, a base 458, a rim 460', a cannulation bore 462 and a drive base surface 463 that is the same or substantially similar to the respective body 40, body top surface 54, internal drive 56, base 58, rim 60, cannulation bore 62 and drive base surface 63 previously described herein with respect to the closure top 18. The closure top 418 is shown partially wound into a polyaxial bone screw receiver 410 having opposed arms 460 with inner surfaces equipped with guide and advancement structures 468 that are sized and shaped to simultaneously closely receive and mate with the reverse angle threads 442 and 443 of the double start closure structure 418. Otherwise, the receiver 410 is identical or substantially similar to the receiver 10 described in detail in the '746 application incorporated by reference herein.

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[0043] With reference to Fig. 13, another alternative multi-start closure top 518 is shown that is almost identical to the closure top 18 with the exception that the two flange forms 42 and 43 with respective starts 46 and 47 have been replaced with v-threads 542 and 543 with respective starts 546 (not shown) and 547. Otherwise, the dual or double start closure top 518 includes a body 540, a body top surface 554, a body internal drive 556, a base 558, a rim 560', a cannulation bore 562 and a drive base surface 563 that is the same or substantially similar to the respective body 40, body top surface 54, internal drive 56, base 58, rim 60, cannulation bore 62 and drive base surface 63 previously described herein with respect to the closure top 18. The closure top 518 is shown partially wound into a polyaxial bone screw receiver 510 having opposed arms 560 with inner surfaces equipped with guide and advancement structures 568 that are sized and shaped to simultaneously closely receive and mate with the threads 542 and 543 of the double start closure structure 518. Otherwise, the receiver 510 is identical or substantially similar to the receiver 10 described in detail in the '746 application incorporated by reference herein.

[0044] With reference to Fig. 14, another alternative multi-start closure top 618 is shown that is almost identical to the closure top 18 with the exception that the two flange forms 42 and 43 with respective starts 46 and 47

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have been replaced with buttress threads 642 and 643 with respective starts 446 and 447 (not shown). Otherwise, the dual or double start closure top 618 includes a body 640, a body top surface 654, a body internal drive 656, a base 658, a rim 660', a cannulation bore 662 and a drive base surface 663 that is the same or substantially similar to the respective body 40, body top surface 54, internal drive 56, base 58, rim 60, cannulation bore 62 and drive base surface 63 previously described herein with respect to the closure top 18. The closure top 618 is shown partially wound into a polyaxial bone screw receiver 610 having opposed arms 660 with inner surfaces equipped with guide and advancement structures 668 that are sized and shaped to simultaneously closely receive and mate with the buttress threads 642 and 643 of the double start closure structure 618. Otherwise, the receiver 610 is identical or substantially similar to the receiver 10 described in detail in the '746 application incorporated by reference herein.

[0045] With reference to Figs. 15 and 16, an open receiver 710 is illustrated that is substantially similar to the receiver 10 previously described herein with the exception that the receiver 710 includes opposed arms 760, each having an integral upstanding break-off extension 761. Each receiver arm 760 and integral extension 761 has an inner helically wound guide and advancement structure 768 that is sized and shaped to mate with the flange forms 42

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and 43 of the dual start closure 18 previously described herein. The break-off extensions 761 are initially integral with the respective arms 760 and are then broken off by a user after the closure 18 has been rotatingly advanced along the arm extensions 761 and into the channel located between the receiver arms 760. In the illustrated embodiment, in addition to an outer groove or notch 770 located at or near a top surface 769 of each of the arms 760 where the extensions 761 break off from the receiver arms, illustrated inner arm surfaces include a recess or cut 771, best shown in Fig. 16, that runs substantially horizontally. Each recess 771 is curved and elongate and disposed somewhat cross-wise or transverse to the respective flange form 768. For example, with reference to the arm 760 shown in Fig. 16, the recess 771 cuts into a weakened region, generally 780, where the arm 760 joins with the respective attached adjacent extension 761, the curved and elongate recess 771 beginning at a lower portion or location 781 of the flange form recess or segment and terminating at an opposed upper end location of the flange form segment, while otherwise leaving the flange form 768 intact. Stated in another way, the substantially horizontally extending recess 771 cuts into both a lead portion and a trailing portion of each of the flange form segments located near and directly above the opposed arms 760 and substantially opposite the notch 770, thus further weakening the region where the extension and

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the arm attach, without destroying the flange form path, so that the closure 18 is not derailed by the recess 771 or otherwise prohibited from moving downwardly into the receiver channel formed between the receiver arms 760.

[0046] With reference to Fig. 17, the multi-start closure 18 is shown cooperating with a spinal implant receiver, such as a bone screw receiver 10' and a discrete, detachable guide tool 801. The elongate guide tool 801, only partially shown in Fig. 17, is typically sized for extending from the bone screw receiver 10' upwardly to a location outside of a patient, the tool providing a guide channel for operably guiding the rod 21 or other longitudinal connecting member from a position exterior of the bone screw receiver 10' toward and into the bone screw receiver 10'. The illustrated guide tool has opposed arms 805, each arm having a helical guide and advancement structure 810 thereon that is illustrated as a square thread form, but may be of other geometry, including a flange form the same or similar to the flange forms 168' of the receiver 10' that mates with the flange forms 42 and 43 of the closure structure 18. Thus, the illustrated structures 810 are sized and shaped for receiving and rotating engagement with a dual start closure. The closure 18 is shown partially wound into the receiver 10' that is identical or substantially similar to the receiver 10 with the exception of certain outer arm surface features (not shown). Thus, the receiver 10' includes

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opposed arms 160' with inner surfaces having guide and advancement structures 168' that are sized and shaped to simultaneously closely receive and mate with the flange forms 42 and 43 of the dual start closure structure 18. The guide tool 801 includes attachment structure for detachable attachment to the receiver 10'(not shown), that may take a variety of forms and methods, including, but not limited to a slide-on, slide-off attachment, a snap-on, rotate off attachment, a rotate-on and rotate-off attachment, to name a few. For example, cooperating attachment structure for both the tool and the receiver may be used that is disclosed in U.S. Patent 7,470,279 and incorporated by reference herein. Returning to the inner helically wound guide and advancement structure 810 formed on each arm 804 of the guide tool 801, the structure 810 is sized and shaped for being aligned with the receiver arms 160' during removable attachment of the tool 801 with the respective bone screw receiver 10' so as to continue the helical pathway for the closure 18, the structures 810 being synchronized with the flange forms 168' to allow for the rotation and driving transfer of the closure 18 from the tool 801 into the receiver 10'.

[0047] It is to be understood that while certain forms of the present invention have been illustrated and described herein, it is not to be limited to the specific forms or arrangement of parts described and shown.

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C L A I M S

What is claimed and desired to be secured by Letters Patent is as follows:

1. In a medical implant having a substantially cylindrical closure member and a receiver member having first and second spaced arms forming an open channel, the closure member having an axis of rotation for closing the open channel, the improvement comprising:

a) first and second helically wound forms located on the closure member, the first form having a first start and the second form having a second start; and

b) a first discontinuous helically wound structure on the receiver first arm and a second discontinuous helically wound structure on the receiver second arm and wherein simultaneous mating of the first start with the arm first helically wound structure and the second start with the arm second helically wound structure occurs when the closure member is rotated between the first and second arms of the receiver member.

2. The improvement of claim 1 wherein the first and second helically wound forms are each a flange form that interlocks with the respective helically wound structures on the receiver.

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3. The improvement of claim 1 wherein the first and second helically wound forms are v-threads.

4. The improvement of claim 1 wherein the first and second helically wound forms are square threads.

5. The improvement of claim 1 wherein the first and second helically wound forms are reverse angle threads.

6. The improvement of claim 1 wherein the first and second helically wound forms are buttress threads.

7. The improvement of claim 1 wherein the closure member has a break-off head.

8. The improvement of claim 1 wherein the receiver has break-off extensions.

9. The improvement of claim 1 further comprising a guide tool having third and fourth arms detachably attached to the receiver, the guide tool having a third discontinuous helically wound structure on the guide tool third arm and a fourth discontinuous helically wound structure on the guide tool fourth arm and wherein simultaneous mating of the first start with the third helically wound structure and the second start with the fourth helically wound structure

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occurs when the closure member is rotated between the third and fourth arms of the guide tool, the guide tool third and fourth helically wound structures sized and shaped to provide transfer of the closure member between the guide tool and the bone screw upon rotation of the closure.

10. A medical implant comprising:

a) a receiver having a body and a pair of upstanding spaced arms forming a channel for receiving a longitudinal connecting member, each arm having an inwardly facing surface with a first discontinuous helically wound guide and advancement structure located thereon; and

b) a closure structure having a cylindrical body and a second helically wound guide and advancement structure having at least two starts.

11. The implant of claim 10 wherein the first and second helically wound guide and advancement structures are interlocking flange forms.

12. The improvement of claim 10 wherein the second helically wound guide and advancement structure includes at least two v-threads.

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13. The improvement of claim 10 wherein the second helically wound guide and advancement structure includes at least two square threads.

14. The improvement of claim 10 wherein the second helically wound guide and advancement structure includes at least two reverse angle threads.

15. The improvement of claim 10 wherein the second helically wound guide and advancement structure includes at least two buttress threads.

16. The improvement of claim 10 wherein the closure structure has a break-off head.

17. The improvement of claim 19 wherein the receiver has break-off extensions.

18. In a medical implant, the improvement comprising:

a) an open receiver member with spaced arms having inwardly facing surfaces, each with a helically wound guide and advancement form located thereon; and

b) a helically wound multi-start closure member having an axis of rotation, the closure member rotatably mounted on the receiver member at the spaced arm inwardly facing surfaces.

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19. The improvement of claim 18 wherein the multi-start closure is a double-start closure.

20. The improvement of claim 18 wherein the multi-start closure includes at least two helically wound forms, each form being one of a flange form, a v-thread, a square thread, a reverse angle thread and a buttress thread, the form mating with the first helically wound guide and advancement form.

21. In a polyaxial bone anchor having a shank and a receiver, the shank being pivotable with respect to the receiver prior to locking of a position of the shank with respect to the receiver, the improvement wherein:

the receiver has spaced arms having inwardly facing surfaces, each surface having a helically wound guide and advancement form located thereon, each guide and advancement form being sized and shaped to mate with a helically wound multi-start closure member having at least two starts.

22. The improvement of claim 21 further comprising an attachable and detachable guide tool cooperating with the receiver, the guide tool having at least two arms, each arm having helically wound guide and advancement structure thereon in synchronized relationship with the receiver helically wound guide and advancement forms to provide

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transfer of the multi-start closure member between the guide tool and the bone anchor upon rotation of the closure.

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Abstract of the Disclosure

An open implant closure structure includes a helically wound guide and advancement structure having at least two helically wound forms thereon providing a multi-start closing mechanism for use between spaced arms of a cooperating open medical implant having mating helically wound structure thereon. Illustrated structures include interlocking flange forms, v-threads, square threads, reverse angle threads and buttress threads and receivers with break-off extensions and cooperating tooling.

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Fig. 1.

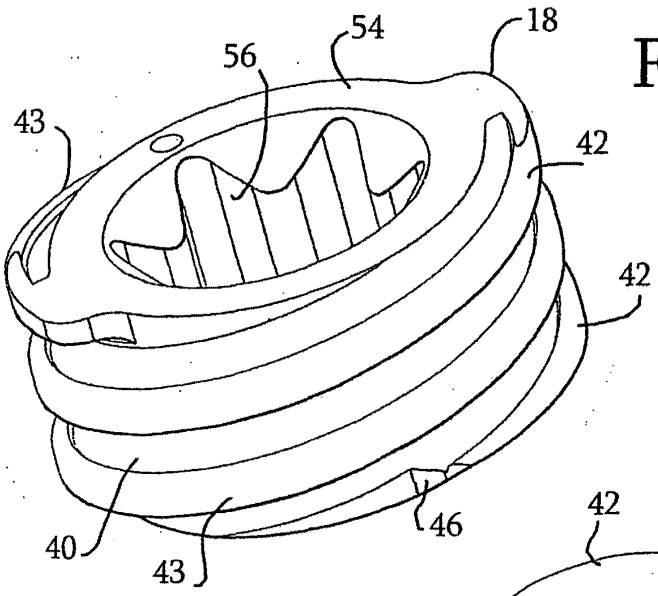


Fig. 2.

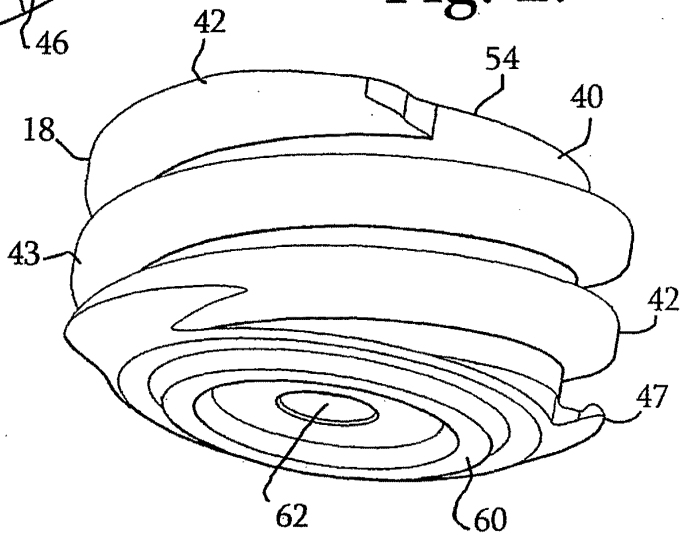
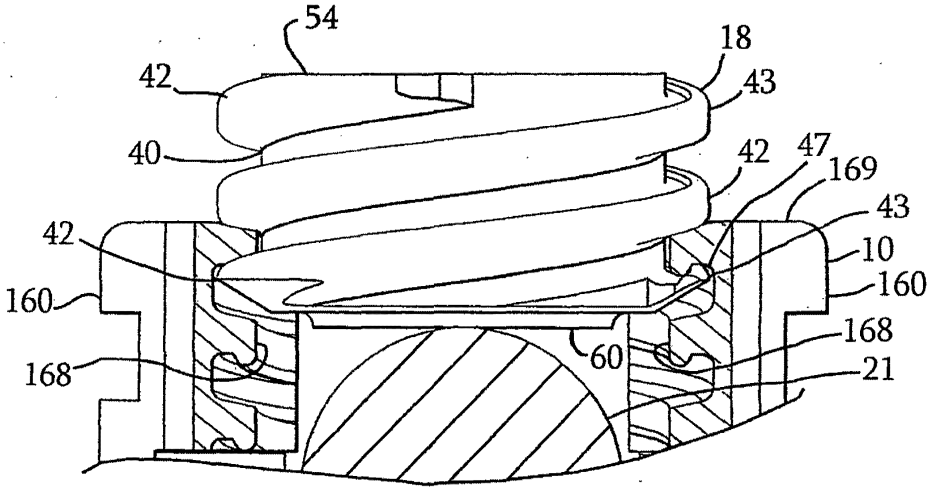


Fig. 3.



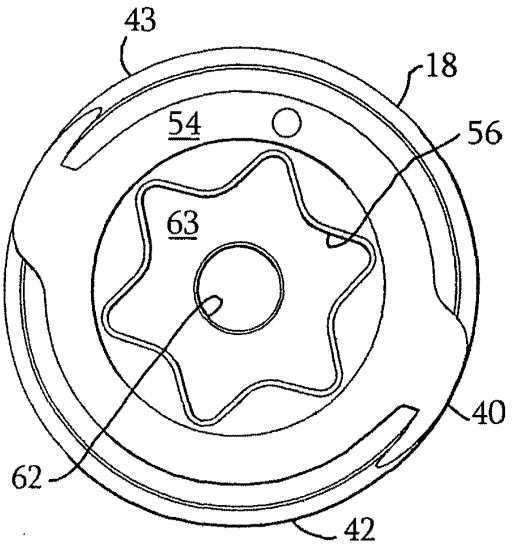


Fig. 4.

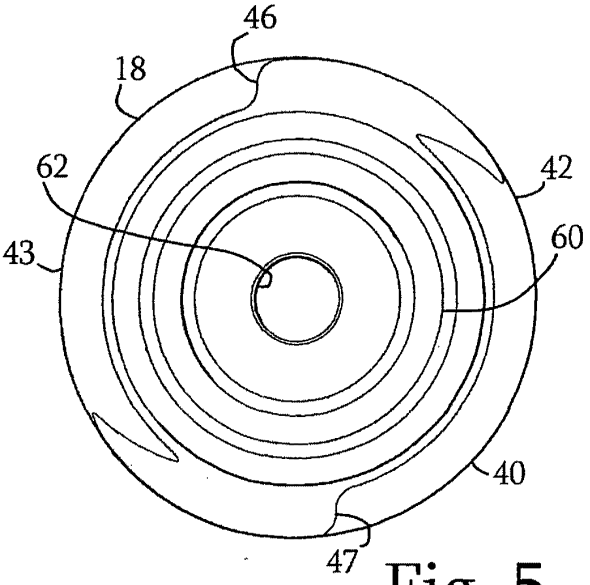


Fig. 5.

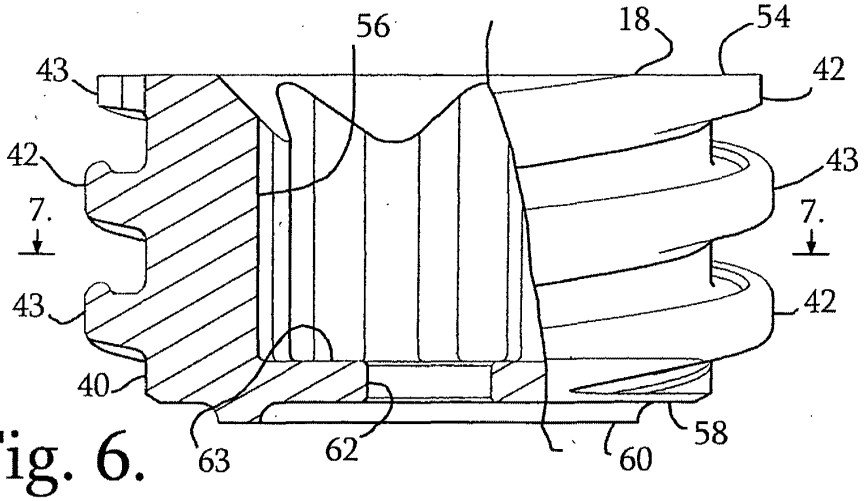


Fig. 6.

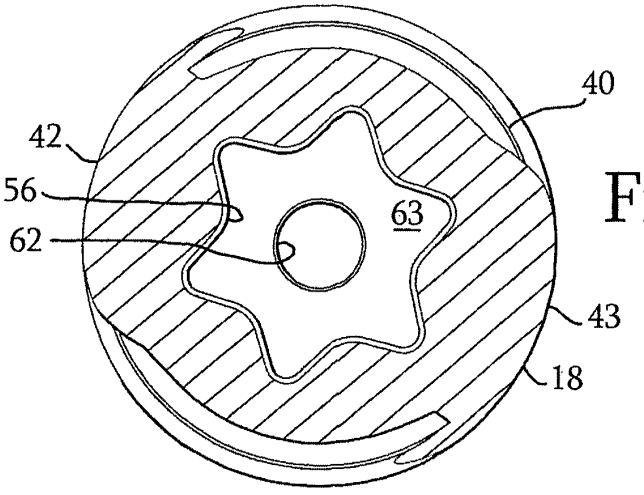


Fig. 7.

Fig. 8.

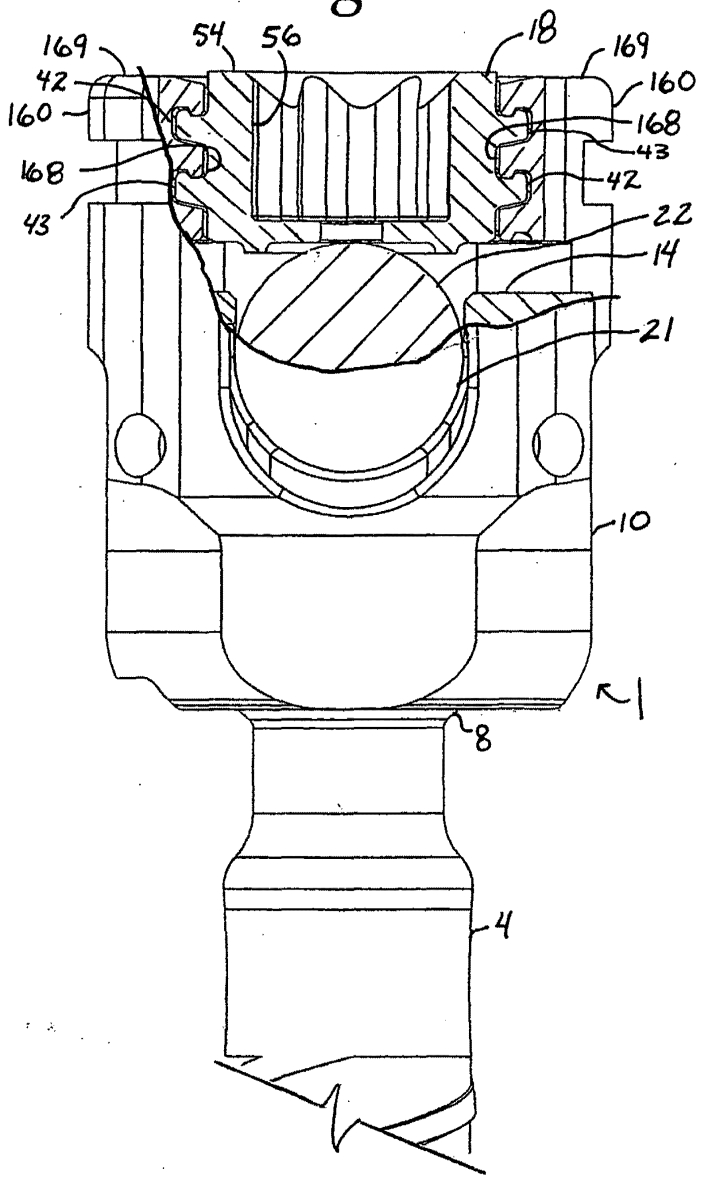


Fig. 9.

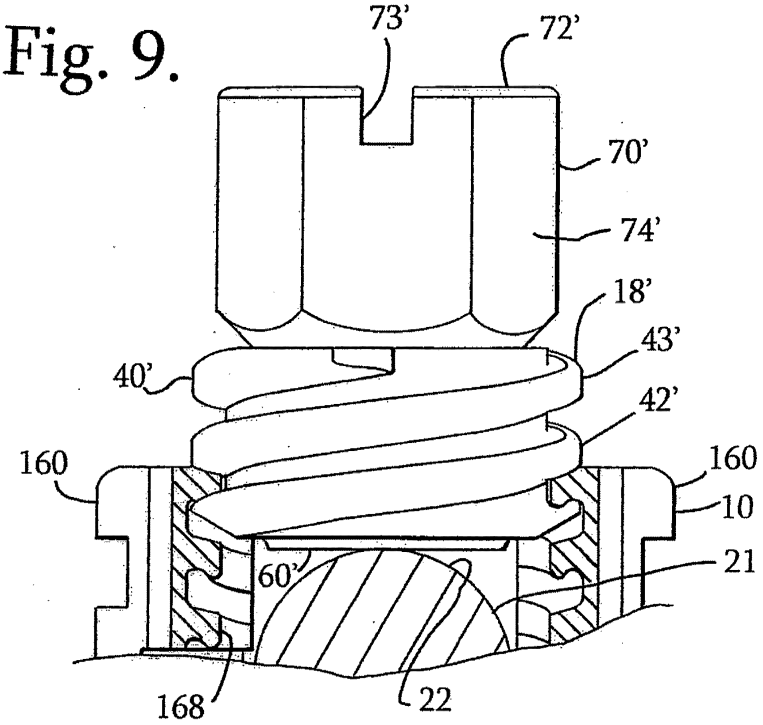

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Fig. 10.

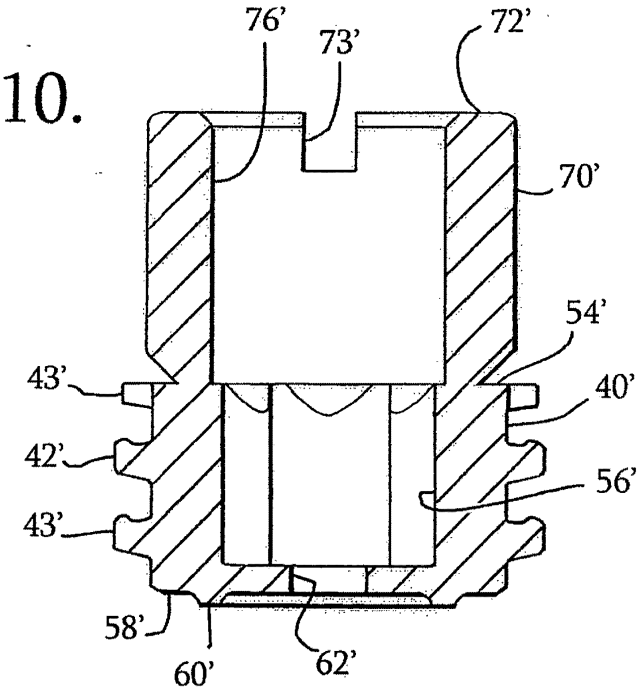

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Fig. 11.

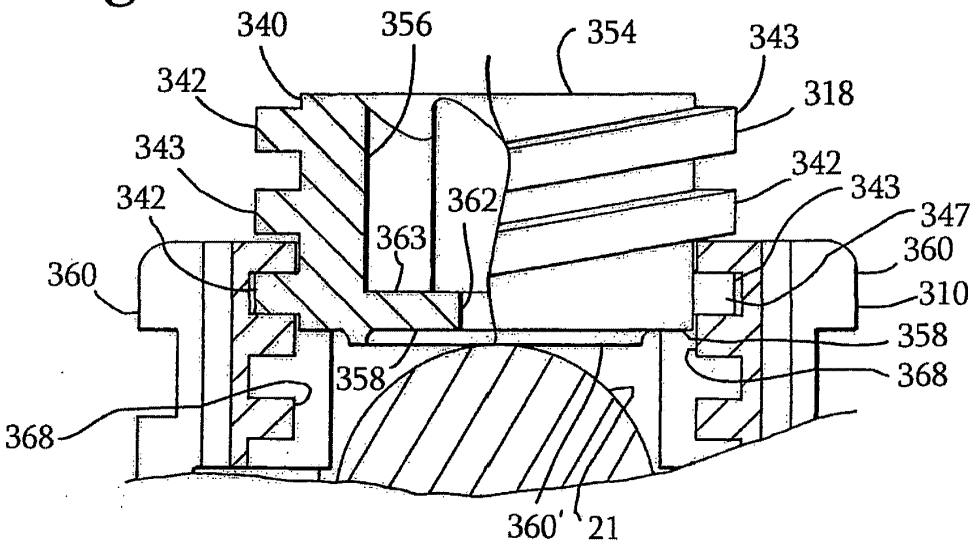
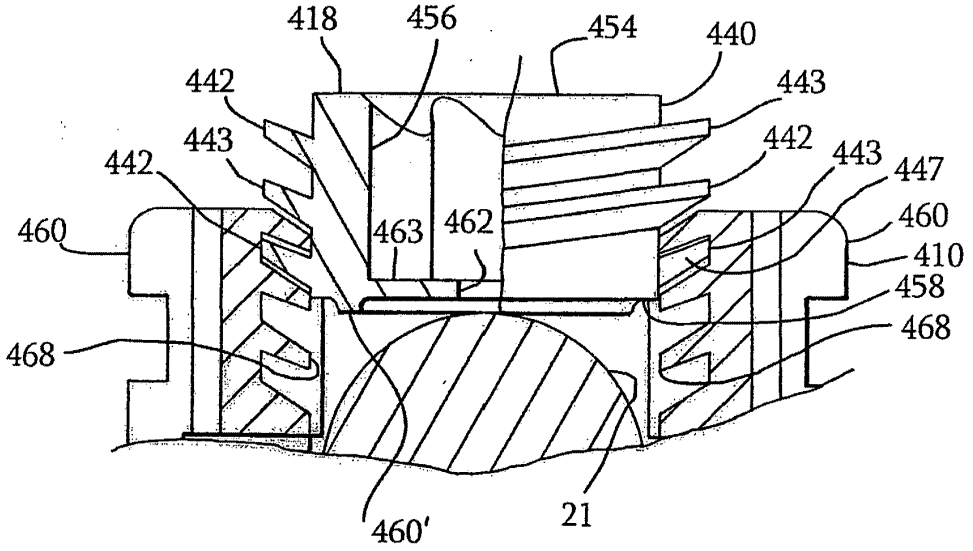

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Fig. 12.


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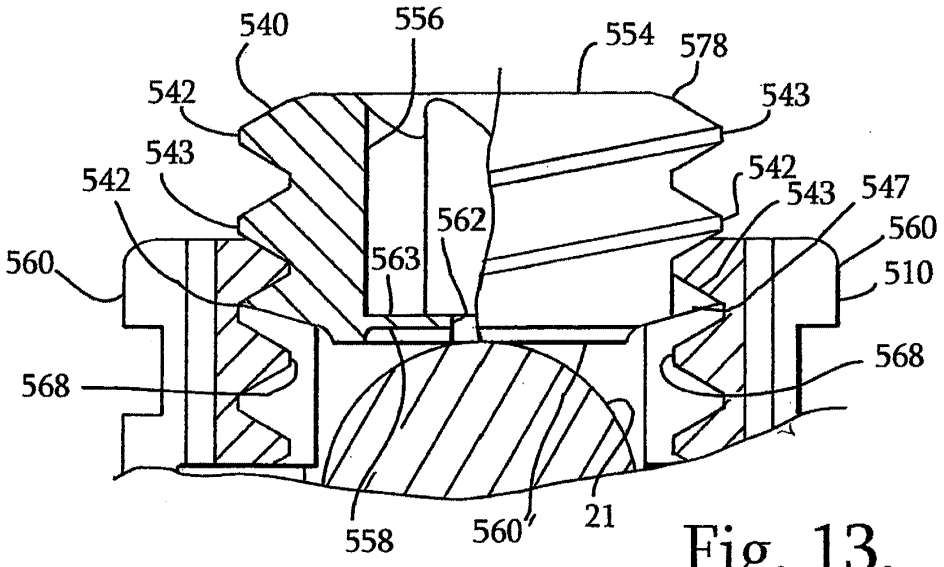

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Fig. 13.

Fig. 14.

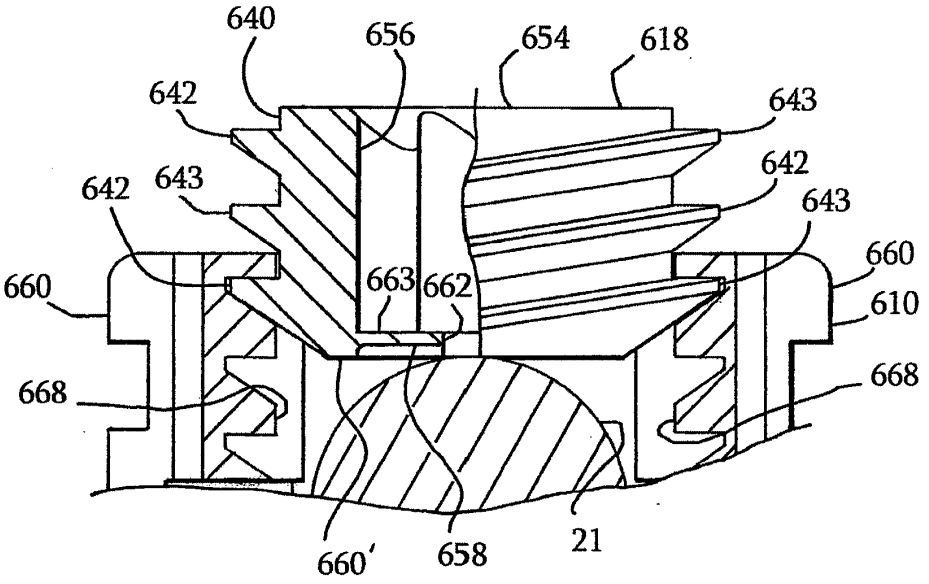
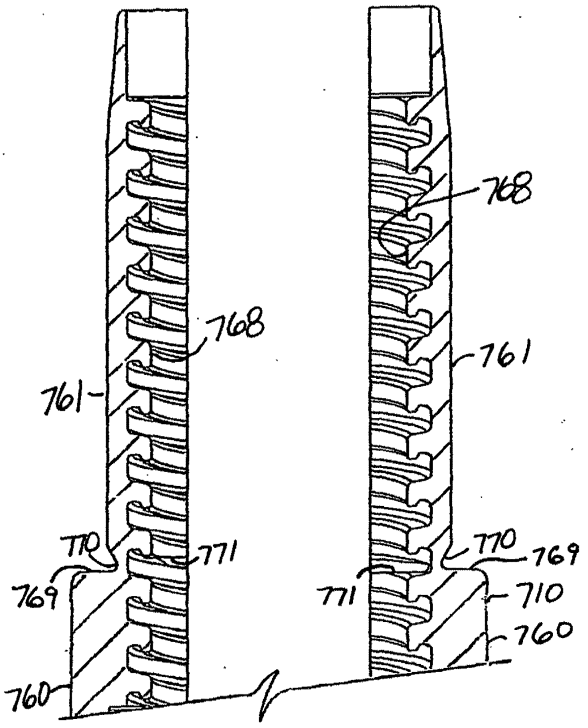

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Fig. 15.



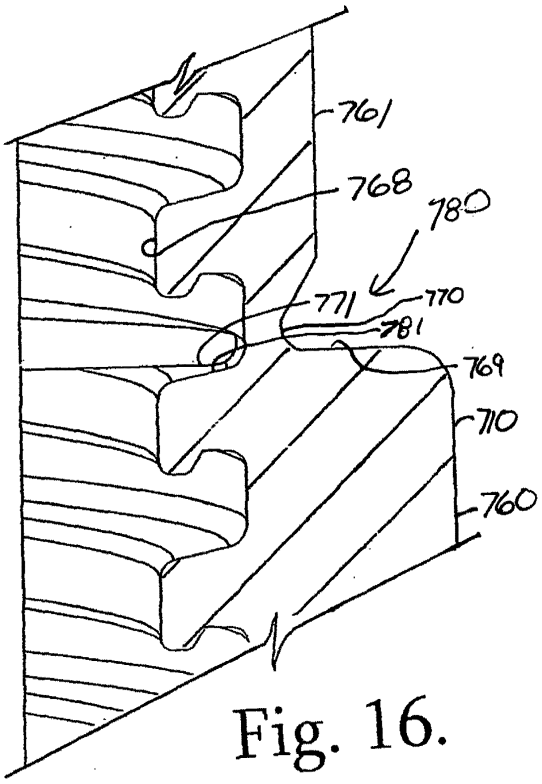
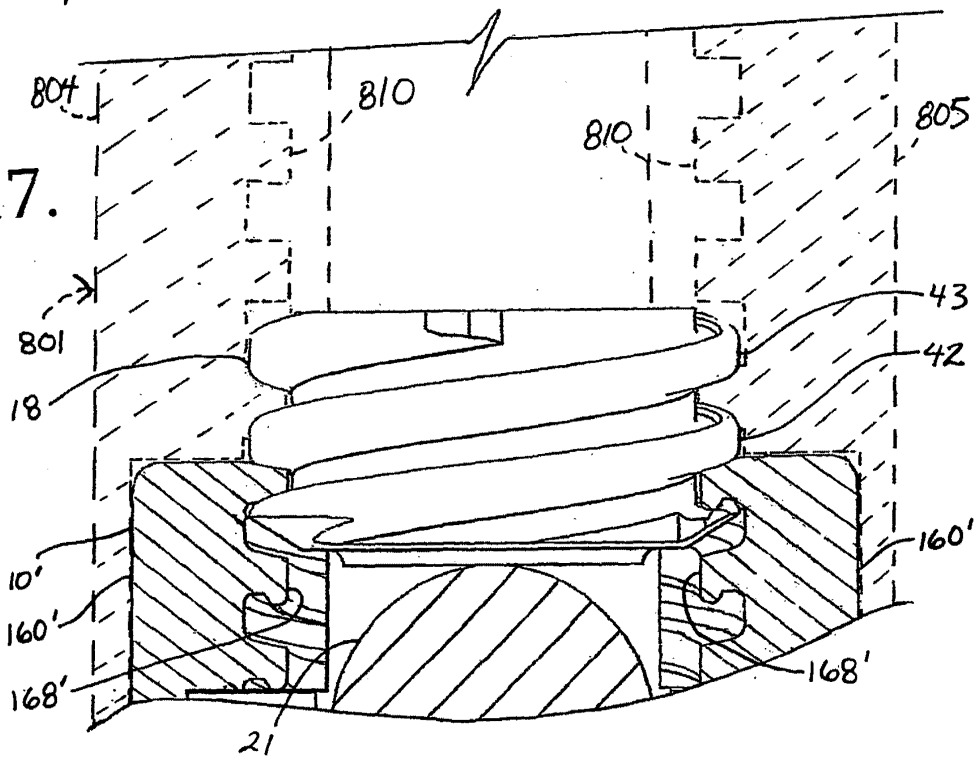


Fig. 16.

Fig. 17.



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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

INFORMATION DISCLOSURE STATEMENT

Applicant: Roger P. Jackson, et al.

Date: 1-10-13

For: MULTI-START CLOSURES FOR OPEN IMPLANTS

Docket No.: 11,433

* *

Shawnee, Kansas

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

Applicant is aware of the following references listed on the attached PTO-1449, copies of which are enclosed:

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The above-listed references are, in the belief and opinion of the undersigned, the closest art of which the applicant is aware as of the date of execution of the Declaration in the above-captioned application.

Respectfully submitted,

1-8-13
Date

Roger P. Jackson, Inventor

Respectfully submitted,

1-9-2013
Date

James L. Surber, Inventor

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Sheet 1 of 50

Complete if Known	
Application Number	
Filing Date	
First Named Inventor	Roger P. Jackson
Art Unit	
Examiner Name	
Attorney Docket Number	11,433

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Examiner Initials*	Cite No.[1]	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 Signature		Date Considered	

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				Art Unit	
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		WO2005/000136	01/06/05	Clement, et al.		

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		WO2005/000137	01/06/05	Clement, et al.		
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		WO2004/089245	10/21/04	Mueller		
		FR 2865378	10/22/04	Sournac, et al.		
		WO2004/041100	05/21/04	Landry, et al.		
		FR 2857850	04/01/04	Clement, et al.		

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		FR2865377	01/27/04	Clement, et al.		
		FR2865375	01/27/04	Sournac, et al.		
		FR2865373	01/27/04	Sournac, et al.		
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		WO02/054966	07/18/02	Glascott		

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				Examiner Name	
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		US-6,663,635	12/16/03	Frigg, et al.	
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		EP1190678	03/27/02	Bono, et al.		
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				Examiner Name	
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		US-5,728,098	03/17/98	Sherman, et al.	
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				Examiner Name	
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				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
		US-7,081,116	07/25/06	Carly	
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		US-2007/0270830	11/22/2007	Morrison	
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		US-2008/0021454	01/24/2008	Chao, 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
				Art Unit	
				Examiner Name	
Sheet	41	of	50	Attorney Docket Number	11,433

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	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-2008/0249570	10/09/2008	Carson, et al.	
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				Examiner Name	
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		US-2009/0076552	03/19/2009	Tornier	
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				Art Unit	
				Examiner Name	
Sheet	44	of	50	Attorney Docket Number	11,433

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		US-7,819,902	10/26/10	Abdelgany, et al.	
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		US-2010/0262196	10/14/10	Barrus, et al.	
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		US-7,972,364	07/05/11	Biedermann, et al.	
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		US-2011/0178558	07/21/11	Barry	
		US-2011/0184471	07/28/11	Foley, et al.	
		US-2011/0190822	08/04/11	Spitler, et al.	
		US-2011/0190823	08/04/11	Bergeron, et al.	
		US-2011/0190826	08/04/11	Ogilvie, et al.	
		US-2011/0196427	08/11/11	Trautwein, et al.	
		US-2011/0202095	08/18/11	Semler, et al.	
		US-2011/0208251	08/25/11	Hammill, Sr., et al.	
		US-2011/0230917	09/22/11	Carson, et al.	
		US-2011/0251644	10/13/11	Hestad, et al.	
		US-2011/0257687	10/20/11	Trieu, et al.	
		US-2011/0257689	10/20/11	Fiechter, et al.	
		US-2011/0257690	10/20/11	Rezach	

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.[1]	Foreign Patent Document Country Code [3] Number[4] Kind Code[5] (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	T[6]

Examiner Signature		Date Considered	

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[1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.
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Substitute for form 1449/PTO				*Complete if Known*	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	
				Filing Date	
(Use as many sheets as necessary)				First Named Inventor	Roger P. Jackson
				Art Unit	
				Examiner Name	
Sheet	48	of	50	Attorney Docket Number	11,433

U. S. PATENT DOCUMENTS

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-8,048,124	11/01/2011	Chin, et al.	
		US-8,048,126	11/01/2011	A Harac, et al.	
		US-8,052,720	11/08/2011	Kuester, et al.	
		US-8,057,519	11/15/2011	Justis, et al.	
		US-8,062,339	11/22/2011	Hammer, et al.	
		US-8,066,744	11/29/2011	Justis, et al.	
		US-8,075,599	12/13/2011	Johnson, et al.	
		US-8,075,603	12/13/2011	Hammill, Sr., et al.	
		US-8,083,776	12/27/2011	Alvarez	
		US-8,100,946	01/24/2012	Strausbaugh, et al.	
		US-8,100,947	01/24/2012	Ensign, et al.	
		US-8,100,948	01/24/2012	Ensign, et al.	
		US-8,137,387	03/20/2012	Garamszegi	
		US-8,162,990	04/24/2012	Potash, et al.	
		US-8,162,991	04/24/2012	Strauss, et al.	
		US-8,167,913	05/01/2012	Albert, et al.	
		US-8,167,914	05/01/2012	Hunt, et al.	
		US-8,197,517	06/12/2012	Lab, et al.	
		US-8,197,518	06/12/12	Hammill, Sr., et al.	
		US-8,221,471	07/17/2012	Kovach, et al.	

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(Use as many sheets as necessary)				First Named Inventor	Roger P. Jackson
				Art Unit	
				Examiner Name	
Sheet	49	of	50	Attorney Docket Number	11,433

U. S. PATENT DOCUMENTS

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-8,221,472	07/17/2012	Peterson, et al.	
		US-8,236,032	08/07/2012	Ramsay, eta l.	
		US-8,236,035	08/07/2012	Bedor	
		US-7,878,351	02/01/2011	Falzoni, et al.	
		US-4,771,905	09/20/1988	Perne, et al.	
		US-6,968,966	11/29/2005	Gregory	
		US-6,726,689	04/27/2004	Jackson	
		US-7,008,228	03/07/2006	Bjorn, et al.	
		US-7,582,107	09/01/2009	Trail, et al.	
		US-US-			
		US-			
		US-			

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				Filing Date	
				First Named Inventor	Roger P. Jackson
				Art Unit	
				Examiner Name	
Sheet	50	of	50	Attorney Docket Number	11,433

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue numbers(s), publisher, city and/or country where published.	T[2]
		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	
		Xia Spinal System Brochure, Stryker Howmedica Osteonics, no publish date	
		The Rod Plate System Brochure, Stryker Howmedica Osteonics, pub. Oct., 1999	
		Silhouette Spinal Fixation System Brochure, Sulzer Medica Spine-Tech, no publish date	
		SDRS Surgical Dynamics Rod System Brochure, Surgical Dynamics, pub. 1998-99	
		Versalok Low Back Fixation System Brochure, Wright Medical Technology, Inc., pub. 1997	
		The Strength of Innovation Advertisement, Blackstone Medical Inc., no publish date	
		The Moss Miami 6.0mm System Advertisement, author unknown, no publish date	

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DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	MULTI-START CLOSURES FOR OPEN IMPLANTS

As the below named inventor, I hereby declare that:

This declaration is directed to:

- [■] The attached application, or
- [ ] United States application or PCT international application number _____

filed on _____.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

LEGAL NAME OF INVENTOR

Inventor: Roger P. Jackson Date (Optional): 1-8-13

Signature: Roger P. Jackson

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 1 minute to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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LEGAL NAME OF INVENTOR

Inventor: James L. Surber Date (Optional): 1-9-2013

Signature: _____

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

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Application Number	
Filing Date	
First Named Inventor	Roger P. Jackson
Title	MULTI-START CLOSURES FOR OPEN IMPLANTS
Art Unit	
Examiner Name	Unassigned
Attorney Docket Number	11,433

SIGNATURE of Applicant or Patent Practitioner

Signature		Date	
Name	John C. McMahon	Telephone	(913) 422-5222
Registration Number	29,415		

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications.

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I hereby revoke all previous powers of attorney given in the application identified in the attached transmittal letter.

☒ I hereby appoint Practitioner(s) associated with the following Customer Number as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the application referenced in the attached transmittal letter (form PTO/AIA/82A or equivalent):

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OR

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☐ Firm or Individual Name					
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City		State		Zip	
Country					
Telephone		Email			

I am the Applicant:

☒ Inventor or Joint Inventor

☐ Legal Representative of a Deceased or Legally Incapacitated Inventor

☐ Assignee or Person to Whom the Inventor is Under an Obligation to Assign

☐ Person Who Otherwise Shows Sufficient Proprietary Interest (*e.g.*, a petition under 37 CFR 1.46(b)(2) was granted in the application or is concurrently being filed with this document)

SIGNATURE of Applicant for Patent

Signature		Date	1-9-2013
Name	James L. Surber	Telephone	
Title and Company			

NOTE: Signature - This form must be signed by the applicant in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. Submit multiple forms for more than one signature, see below *.

☐ *Total of 3 forms are submitted.

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Doc Code: PA..

Document Description: Power of Attorney

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☐ The address associated with Customer Number:

OR

☐ Firm or Individual Name					
Address					
City		State		Zip	
Country					
Telephone		Email			

I am the Applicant:

☒ Inventor or Joint Inventor

☐ Legal Representative of a Deceased or Legally Incapacitated Inventor

☐ Assignee or Person to Whom the Inventor is Under an Obligation to Assign

☐ Person Who Otherwise Shows Sufficient Proprietary Interest (*e.g.*, a petition under 37 CFR 1.46(b)(2) was granted in the application or is concurrently being filed with this document)

SIGNATURE of Applicant for Patent

Signature	Roger P. Jackson	Date	1-8-13
Name	Roger P. Jackson	Telephone	
Title and Company			

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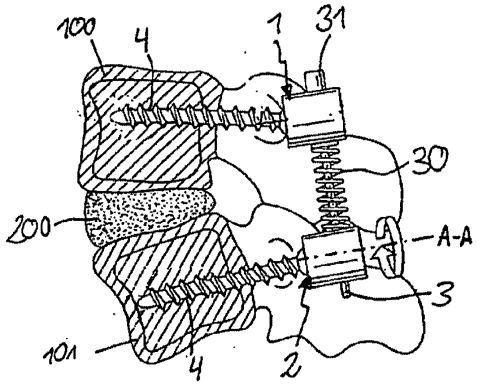
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Die folgenden Angaben sind den vom Anmelder eingereichten Unterlagen entnommen

(54) Bezeichnung: **Dynamische Stabilisierungseinrichtung für Knochen, insbesondere für Wirbel**

(57) Zusammenfassung: Es wird eine dynamische Stabilisierungseinrichtung für Knochen, insbesondere für Wirbel, bereitgestellt mit wenigstens einem ersten (1) und einem zweiten (2) Knochenverankerungselement, mit jeweils einem ersten, in einem Knochen zu verankernden Abschnitt (4) und einem zweiten, mit einem Stab (3) zu verbindenden Abschnitt (6), einem die Knochenverankerungselemente (1, 2) verbindenden Stab (3), wobei die Knochenverankerungselemente mit dem Stab wahlweise fest oder in Richtung der Stabachse verschiebbar verbindbar sind, wobei ein zwischen den Knochenverankerungselementen (1, 2) angeordnetes, in Richtung der Stabachse elastisch vorspannbares Element (30) vorgesehen ist. Ein Knochenverankerungselement ist fest und eines verschiebbar mit dem Stab verbunden. Der Stab weist ferner einen Anschlag zur Begrenzung der Bewegung des verschiebbaren Verankerungselements auf.



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Beschreibung

[0001] Die Erfindung betrifft eine dynamische Stabilisierungseinrichtung für Knochen, insbesondere für Wirbel nach dem Oberbegriff des Patentanspruches 1.

Stand der Technik

[0002] Eine bekannte Methode der Behandlung von Bandscheibendefekten ist die operative Entnahme der defekten Bandscheibe und die Versteifung des Bandscheibenzwischenraums mit den beiden Wirbelkörpern oder nach Entnahme der defekten Bandscheibe der anschließende Einsatz einer künstlichen Bandscheibe. Im ersten Fall werden die an den versteiften Abschnitt angrenzenden Abschnitte der Wirbelsäule unnatürlich belastet und im zweiten Fall ist eine Simulierung der Eigenschaften einer natürlichen Bandscheibe noch unbefriedigend.

[0003] Aus der EP 0 669 109 B1 ist eine Vorrichtung zum Stabilisieren von benachbarten Rückenwirbeln bekannt, mit der eine geschädigte Bandscheibe und die Zwischenwirbelgelenke posterior teilentlastet werden können. Die Vorrichtung weist zwei Pedikelschrauben auf, die mit einem aus einem elastischen Kunststoff bestehenden Band jeweils fest verbunden sind und über das vorgespannte Band miteinander verbunden. Zur Übertragung von Druckkräften ist ferner ein auf das elastische Band aufgeschobener druckfester Körper zwischen den, zwei Schraubenköpfen vorgesehen. Die Verwendung eines solchen Bandes ergibt jedoch keine Führungsstabilität des Bewegungssegmentes einer Wirbelsäule. Ferner ist eine Justierung der benachbarten Wirbel in ihrer Positionierung relativ zueinander nicht möglich, da das Kraftübertragungsverhalten des Bandes und des Druckelementes über die Knochenschrauben unspezifisch ist.

[0004] Aus der EP 0 518 567 B1 ist eine Vorrichtung zur Stabilisierung benachbarter Wirbel bekannt, welche ein aus einem Elastomer bestehendes Dämpfungselement aufweist, das zwischen zwei in die Wirbel eingeschraubte Monoaxialschrauben vorgesehen ist. Das Dämpfungselement weist an seinen mit den Schrauben zu verbindenden Enden jeweils einen Kugelkopf auf, welcher in jeweils ein Aufnahmeteil der Knochenschrauben einsetzbar und darin fixierbar ist. Somit ist eine geringfügige Justierung des Winkels der Knochenschraube relativ zu der Längsachse des Dämpfungselementes möglich. Es muß jedoch für jedes miteinander zu verbindende Wirbelpaar ein individuell passendes Dämpfungselement mit exakter Länge und exaktem Querschnitt gefertigt sein. Ferner ist das Kraftübertragungsverhalten des Dämpfungselements undefiniert, da es nicht nur axialen sondern auch Biege- und Torsionskräften nachgibt.

[0005] Es ist ferner bekannt, zur Fixierung der Wirbelsäule bzw. von Abschnitten der Wirbelsäule ein Implantatsystem bestehend aus einem Stab und wenigstens zwei mit dem Stab fest verbundenen Pedikelschrauben, die in entsprechende Wirbel eingeschraubt sind, vorzusehen. Damit ist jedoch keine dynamische Bewegungskontrolle der Bandscheibe oder eine dynamische Lastübernahme zum Entlasten einer Bandscheibe möglich.

Aufgabenstellung

[0006] Es ist Aufgabe der Erfindung eine dynamisch wirkende Stabilisierungseinrichtung für Knochen, insbesondere für benachbarte Wirbel bereitzustellen, mit der es sowohl möglich ist, die Knochen bzw. Wirbel und Zwischenwirbelgelenke zueinander zu positionieren und gleichzeitig die dazwischen angebundene Bandscheibe und Zwischenwirbelgelenke hinsichtlich der zu übertragenden Kräfte in definierter Weise zu unterstützen und teilzuentlasten.

[0007] Die Aufgabe wird gelöst durch eine Stabilisierungseinrichtung gemäß Patentanspruch 1. Weiterbildungen der Erfindung sind in den Unteransprüchen angegeben.

Ausführungsbeispiel

[0008] Weitere Merkmale und Zweckmäßigkeiten ergeben sich aus der Beschreibung von Ausführungsbeispielen anhand der Figuren. Von den Figuren zeigen:

[0009] **Fig.** 1 eine schematische Seitenansicht der erfindungsgemäßen Vorrichtung in montiertem Zustand,

[0010] **Fig.** 2 eine Draufsicht auf die erfindungsgemäße Vorrichtung gemäß **Fig.** 1;

[0011] **Fig.** 3 eine Schnittdarstellung einer in der Vorrichtung verwendeten Polyaxialschraube gemäß der Linie VII in **Fig.** 1;

[0012] **Fig.** 4 eine teilgeschnittene Darstellung durch die in der Vorrichtung verwendete Polyaxialschraube gemäß **Fig.** 1 entlang der Linie in **Fig.** 2;

[0013] **Fig.** 5 bis **Fig.** 8 eine Darstellung einer Abfolge von Schritten, die die Montage der Stabilisierungseinrichtung zeigt.

[0014] Wie insbesondere aus den **Fig.** 1 bis 4 ersichtlich ist, weist die Stabilisierungseinrichtung zum Stabilisieren zweier benachbarter Wirbel **100**, **101** zwei polyaxiale Pedikelschrauben **1**, **2** und einen diese verbindenden Stab **3** auf. Die Pedikelschrauben **1**, **2** sind bevorzugt wie in **Fig.** 3 und 4 dargestellt ist, -ausgebildet. Eine Pedikelschraube **1**, **2** weist ein Schraubenelement mit einem Gewindeschaft **4** mit einem Knochengewinde und einem kugelsegmentförmigen Kopf **5** auf, der mit einem Aufnahmeteil **6** verbunden ist. Das Aufnahmeteil **6** hat an seinem einen Ende eine axialsymmetrisch ausgerichtete erste Bohrung **7**, deren Durchmesser größer ist, als der des Gewindeabschnitts des Schafts **4** und kleiner als der des Kopfes **5** ist. Ferner weist es eine koaxiale zweite Bohrung **8** auf, die an dem der ersten Bohrung **7** gegenüberliegendem Ende offen ist und deren

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Durchmesser so groß ist, daß das Schraubenelement durch das offene Ende mit seinem Gewindeabschnitt durch die erste Bohrung **7** hindurch und mit dem Kopf **5** bis zum Grund der zweiten Bohrung führbar ist. Der Grund des Aufnahmeteils ist derart ausgebildet, daß das Schraubenelement im eingeführten und unbelasteten Zustand in dem Aufnahmeteil **6** schwenkbar ist. Das Aufnahmeteil weist ferner eine zur Mitte hin symmetrisch angeordnete U-förmige Ausnehmung auf, deren Grund zur ersten Bohrung **7** hin gerichtet ist und durch die zwei freie Schenkel **10**, **11** gebildet sind. In einem Bereich angrenzend an das freie Ende weisen die Schenkel **10**, **11** ein Innengewinde **12** auf.

[0015] Die Pedikelschraube beinhaltet außerdem ein Druckelement **13**, welches mit einem geeigneten Außendurchmesser so ausgebildet ist, daß es in das Aufnahmeteil **6** eingeschoben werden kann. An seinem einen Ende ist eine sich zu der ersten Bohrung **7** des Aufnahmeteils **6** hin erweiternde kugelsegmentförmige Ausnehmung **14** vorgesehen, deren Kugelradius so gewählt, daß er in einem in das Aufnahmeteil eingesetzten Zustand den Kopf **5** des Schraubenelements teilweise umfaßt. In Richtung des freien Endes der Schenkel **10**, **11** weist das Druckelement **13** eine U-förmige Ausnehmung **15** auf, deren Abmessungen so bemessen sind, daß in den dadurch gebildeten Kanal der Stab **3** eingelegt werden kann. Die in Richtung der Zylinderachse des Aufnahmeteils **6** gesehene Tiefe der U-förmigen Ausnehmung **15** ist größer als der Durchmesser des aufzunehmenden Stabs **3**, so daß das Druckelement **13** mit seitlichen Schenkeln **16** über den eingelegten Stab **3** nach oben hervorsteht. Das Druckelement **13** weist ferner eine zentrale Bohrung **17** auf, die sich durch dieses hindurch erstreckt zum Ineingriffbringen eines Schraubwerkzeuges mit einer entsprechenden in dem Kopf **5** vorgesehenen Ausnehmung **18**.

[0016] Zum Fixieren des Schraubenelements in dem Aufnahmeteil ist ein zwischen die Schenkel **10**, **11** einschraubbares muffen- bzw. mutterartiges Verschlußelement **20** vorgesehen, welches ein Außengewinde **21** aufweist, das mit dem Innengewinde **12** der Schenkel zusammenwirkt und welches ferner ein Innengewinde **22** aufweist. Zum Einschrauben weist das Verschlußelement **20** ferner an seinem einen Ende radial verlaufende Einschnitte **23** auf. Die Abmessungen des Verschlußelements **20** in axialer Richtung des Aufnahmeteils, sowie die Abmessungen der freien Schenkel **10**, **11** des Aufnahmeteils und die Abmessungen der zusammenwirkenden Gewinde bzw. die Höhe der freien Schenkel **16** des Druckelements sind derart bemessen, daß das Verschlußelement **20** in eingeschraubtem Zustand auf die Schenkel **16** des Druckelements eine Kraft ausübt, so daß dieses den Kopf **5** in dem Aufnahmeteil **6** blockiert.

[0017] Ferner ist eine in das Verschlußelement **20** einschraubbare Innenschraube bzw. Klemm- oder Setzschraube **25** vorgesehen, deren Außengewinde **26** mit dem Innengewinde **22** des Verschlußelements **20** zusammenwirkt. Die Abmessungen der Innenschraube **25**, des Verschlußelements **20** und des Druckelements **13** sind so gewählt, daß die Innenschraube **25** in eingeschraubtem Zustand auf den eingelegten Stab **3** drückt.

[0018] **Fig.** 4 zeigt einen Schnitt durch die Pedikelschraube **1** gemäß den **Fig.** 1 und 2. Die Pedikelschraube **1** unterscheidet sich von der Pedikelschraube **2** durch die Ausbildung der Innenschraube. Wie aus **Fig.** 4 ersichtlich ist, weist die Innenschraube **25'** der Pedikelschraube **1** an ihrer dem Stab zugewandten Seite einen Gleitboden **26** aus einem Gleitmaterial auf, um im Betrieb ein reibungsarmes Gleiten des Stabes zu ermöglichen. Als Gleitmaterial wird beispielsweise ein hochmolekulares Polyethylen eingesetzt.

[0019] Wie aus den **Fig.** 1 und 2 ersichtlich ist, beinhaltet die Stabilisierungseinrichtung ferner ein Federelement **30**, welches zwischen den zwei über den Stab miteinander verbundenen Pedikelschrauben **1**, **2** vorgesehen ist. Das Federelement **30** ist als eine Schraubenfeder mit einem Durchmesser, der etwas größer ist, als der Durchmesser des Stabes **3**, ausgebildet, so daß die Schraubenfeder auf den Stab **3** aufschiebbar ist. Die Länge der Schraubenfeder in axialer Richtung ist angepaßt an die Größenordnung des mit dem Stab zwischen den zwei Pedikelschrauben zu überbrückenden Abstandes der benachbarten Wirbel. Ferner ist die Länge der Schraubenfeder und die Federkraft so bemessen, daß eine für ein vorliegendes Funktionsdefizit der Bandscheibe gewünschte Extensions- bzw. Kompressionswirkung mit der Feder erzielbar ist. Die Feder ist bevorzugt mit einem abriebfesten Material z.B. mit einem abriebfesten Kunststoff beschichtet.

[0020] Der Stab **3** weist an seinem einen Ende einen Anschlag **31**, z.B. in Form einer ringförmigen Schulter auf, die einen Durchmesser hat, der größer ist, als der Durchmesser der U-förmigen Ausnehmung des Aufnahmeteils **6** und des Druckelements **13**, so daß in montiertem Zustand die dem Anschlag **31** benachbarte Pedikelschraube **1** nur bis zu diesem verschiebbar ist. Bevorzugt ist der Stab mit einem Material, insbesondere mit einem geeigneten Kunststoff, beschichtet, das ein Gleiten des Stabes in dem Aufnahmeteil **6** bzw. in dem darin vorgesehenen Druckelement **13** erleichtert. Bevorzugt ist ferner auch das Druckelement **15** wenigstens einer der Pedikelschrauben mit einem die Gleitfähigkeit erhöhenden Material, z.B. einem Kunststoff beschichtet.

[0021] Im Betrieb werden, wie in **Fig.** 5 ersichtlich ist, zuerst die in die Aufnahmeteile **6** eingesetzten Schraubenelemente der Pedikelschrauben **1**, **2** durch den Chirurgen in die einer defekten Bandscheibe **200** benachbarten Wirbel eines Patienten im entlasteten Zustand eingeschraubt und die Aufnahmeteile **6** so ausgerichtet, daß der Stab **3** einsetzbar ist. Die Druckelemente **13** sind bereits in die Aufnahmeteile eingeführt. Als nächstes wird, wie in **Fig.** 6 ge-

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zeigt ist, der Stab **3** mit der auf diesen aufgeschobenen Feder **30** in die Aufnahmeteile **6** eingesetzt. Der Stab **3** wird dabei so orientiert, daß der Anschlag **31** in Richtung des Kopfes des Patienten zeigt. Ferner wird die Feder **30** mittels eines Werkzeuges vorkomprimiert, um sie unter einer Vorspannung zwischen die beiden Aufnahmeteile **6** einzubringen. Im nächsten Schritt, der in **Fig. 7** dargestellt ist, stellt der Chirurg die optimale Winkelstellung von Schraubenelement zu Aufnahmeteil bzw. Stab für jede der Pedikelschrauben **1**, **2** ein. Diese Winkelstellung wird anschließend durch Einschrauben der Verschlußelemente **20** in die Aufnahmeteile fixiert. Wie aus **Fig. 3** und 4 ersichtlich ist, erfolgt die Blockierung der Winkelstellung dadurch, daß das Verschlußelement **20** eine Kraft so auf das Druckelement **13** ausübt, daß dieses den Kopf **5** in dem Aufnahmeteil in seiner Stellung fixiert. Da die Schenkel **16** des Druckelements über den eingelegten Stab **3** hinaus hervorstehen, wird durch das Einschrauben des Verschlußelementes **20** der Stab **3** nicht berührt und ist in dem Aufnahmeteil **6** jeweils noch frei verschiebbar.

[0022] Durch die Winkeleinstellung von Schraubenelement und Aufnahmeteil zueinander läßt sich ein gewünschter Keilwinkel zwischen den einander gegenüberliegenden Oberflächen der benachbarten Wirbel einstellen, um es der dazwischen befindlichen Bandscheibe zu ermöglichen, ihre natürliche Form wieder anzunehmen. Durch Verwendung von je zwei Stabilisierungseinrichtungen wie in **Fig.** 2 gezeigt ist, ist dabei die Einstellung des Winkels in seitlicher und frontaler Sicht unabhängig voneinander möglich. Damit kann auch die Position der Zwischenwirbelgelenke zueinander bestimmt werden.

[0023] Wie ferner aus **Fig.** 7 ersichtlich ist, expandiert die unter Vorspannung eingesetzte Feder **30** nach dem Einsetzen und drückt somit die Aufnahmeteile **6** auseinander. Auf einer Seite wird die Expansion durch den Anschlag **31** begrenzt. Durch die Expansion erfolgt eine Aufweitung des Zwischenwirbelraumes und der Zwischenwirbelgelenke, wodurch die Bandscheibe **200** durch Aufnahme von Flüssigkeit aus dem Zwischenwirbelraum sich ausdehnen kann und die Zwischenwirbelgelenke entlastet werden, was durch die Pfeile in **Fig.** 7 veranschaulicht ist. Somit kann eine beschädigte Bandscheibe ihre natürliche Form teilweise wieder annehmen.

[0024] Wie in **Fig.** 8 gezeigt ist, wird anschließend die Feder durch Aufeinanderzubewegen der Aufnahmeteile **6** etwas komprimiert um sie wieder unter Vorspannung zu bringen. Dadurch verkleinert sich auch der Zwischenwirbelraum und die Bandscheibe wird wieder etwas zusammengedrückt bzw. verkürzt und die Zwischenwirbelgelenke werden belastet, was durch die Pfeile in **Fig.** 8 dargestellt ist. In der gewünschten Endstellung wird schließlich der Stab **3** mit dem Aufnahmeteil **6** derjenigen Pedikelschraube fest verbunden, die an dem dem Anschlag gegenüberliegenden Ende des Stabes **3** positioniert ist. Die Stabfixierung erfolgt durch Einschrauben der Innenschraube **25**. Bei der angrenzend an den Anschlag **31** des Stabes vorgesehenen Pedikelschraube **1** bleiben das Aufnahmeteil **6** und der Stab **3** zueinander beweglich. Die Innenschraube **25'** mit dem Gleitboden **26'** ermöglicht ein reibungsarmes Gleiten des Stabes.

[0025] In der in den **Fig.** 1 und 2 gezeigten Endstellung wirkt das System als Kraftübertragungs- und Dämpfungssystem. Die bei aufrechter Haltung des Patienten auf die Wirbelsäule einwirkenden Kräfte werden zum Teil über das System aus Pedikelschrauben, Feder und Stab übertragen, so daß die Bandscheibe entlastet wird. Ferner wirkt die Feder sowohl als Extensionselement zum Aufweiten des Zwischenwirbelraums im Ruhe- bzw. entlasteten Zustand, z.B. beim Liegen, als auch als Dämpfer zum Dämpfen von Stößen bei Belastungen, wie z.B. beim Gehen.

[0026] Das System weist den Vorteil auf, daß bei der Montage eine optimale Justierung der Knochenschrauben und des Stabes möglich ist. Durch die steife Verbindung über den Stab ist es möglich, axiale Kräfte zu übertragen und somit die Bandscheibe zu entlasten. Das System ist jedoch biege- und torsionssteif, was einen weiteren Vorteil im Hinblick auf eine präzise Kraftübertragung auf die Bandscheibe beinhaltet.

[0027] Die Erfindung ist nicht auf die Verbindung von nur zwei polyaxialen Pedikelschrauben durch einen Stab beschränkt. Wenn es erforderlich ist, können auch mehrere Wirbel miteinander verbunden sein, wobei dann eine entsprechende Anzahl von Polyaxial-Knochenschrauben vorhanden ist. Je nach gewünschter Beweglichkeit ist an geeigneter Stelle ein Anschlag auf dem Stab vorgesehen und die entsprechende angrenzende Knochenschraube relativ zum Stab verschiebbar gehalten.

[0028] Obwohl in dem beschriebenen Ausführungsbeispiel Polyaxial-Knochenschrauben verwendet werden, ist die Erfindung nicht darauf beschränkt. Wenn es die Anatomie des entsprechenden Abschnittes auf der Wirbelsäule zuläßt, daß Monoaxial-Knochenschrauben verwendet werden können, ist es auch möglich, gemäß der Erfindung eine fest mit dem Stab verbundene Monoaxial-Knochenschraube und eine mit dem Stab beweglich verbundene Monoaxial-Knochenschraube zu verwenden. Auch Kombinationen aus Monoaxial-Knochenschrauben und Polyaxial-Knochenschrauben können verwendet werden.

[0029] Das Federelement **30** kann auch anders ausgebildet sein. Beispielsweise kann das Federelement **30** als eine Schraubenfeder ausgebildet sein, die im Inneren des Stabes vorgesehen ist. Hierzu ist der Stab zweiteilig aus zwei ineinandergesteckten Hülsen gebildet, die jeweils einen Hülsenboden aufweisen, an dem die Enden der Schraubenfeder anliegen. Das Federelement kann ferner auch als ein elastisches Rohr aus einem Polymer ausgebildet sein.

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Patentansprüche

1. Dynamische Stabilisierungseinrichtung für Knochen, insbesondere für Wirbel,
mit wenigstens einem ersten (**1**) und einem zweiten (**2**) Knochenverankerungselement, mit jeweils einem ersten, in einem Knochen zu verankernden Abschnitt (**4**) und einem zweiten, mit einem Stab (**3**) zu verbindenden Abschnitt (**6**), und
einem die Knochenverankerungselemente (**1**, **2**) verbindenden Stab (**3**),
wobei die Knochenverankerungselemente mit dem Stab wahlweise fest oder in Richtung der Stabachse verschiebbar verbindbar sind,
gekennzeichnet durch
ein zwischen den Knochenverankerungselementen (**1**, **2**) angeordnetes, in Richtung der Stabachse elastisch vorspannbares Element (**30**).

2. Dynamische Stabilisierungseinrichtung nach Anspruch 1, dadurch gekennzeichnet, daß eines der Knochenverankerungselemente (**1**) mit dem Stab verschiebbar verbunden ist und daß ein Anschlag (**31**) zur Begrenzung der Bewegung des verschiebbaren Knochenverankerungselementes vorgesehen ist.

3. Dynamische Stabilisierungseinrichtung nach Anspruch 1 oder 2, dadurch gekennzeichnet, daß wenigstens ein Knochenverankerungselement (**1**, **2**) mit dem Stab (**3**) polyaxial verbindbar ist.

4. Dynamische Stabilisierungseinrichtung nach Anspruch 3, dadurch gekennzeichnet, daß das Knochenverankerungselement einen Schaft (**4**) zum Verankern im Knochen und ein mit dem Schaft gelenkig verbundenes Aufnahmeteil (**6**) zur Aufnahme des Stabes aufweist, und daß der Schaft (**4**) und das Aufnahmeteil (**6**) relativ zueinander in ihrer Winkelstellung unabhängig von einer Fixierung des Stabes fixierbar sind.

5. Dynamische Stabilisierungseinrichtung nach Anspruch 4, dadurch gekennzeichnet, daß das polyaxiale Knochenverankerungselement (**1**) mit dem Stab verschiebbar verbunden und dem Anschlag benachbart angeordnet ist.

6. Dynamische Stabilisierungseinrichtung nach einem der Ansprüche **1** bis **5**, dadurch gekennzeichnet, daß eines der Knochenverankerungselemente (**2**) fest mit dem Stab (**3**) verbunden ist.

7. Dynamische Stabilisierungseinrichtung nach einem der Ansprüche 1 bis 6, dadurch gekennzeichnet, daß der Stab (**3**) und/oder Teile eines der Knochenverankerungselemente (**1**, **2**) mit einem Gleitmaterial beschichtet ist.

8. Dynamische Stabilisierungseinrichtung nach einem der Ansprüche 1 bis 7, dadurch gekennzeichnet, daß das elastische Element (**30**) als Feder ausgebildet ist.

9. Dynamische Stabilisierungseinrichtung nach Anspruch 8, dadurch gekennzeichnet, daß die Feder (**30**) als eine den Stab umschließende Schraubenfeder ausgebildet ist.

10. Dynamische Stabilisierungseinrichtung nach Anspruch 8, dadurch gekennzeichnet, daß der Stab (**3**) zweiteilig und hülsenförmig ausgebildet ist, und daß die Feder im Stabinneren vorgesehen ist.

11. Dynamische Stabilisierungseinrichtung nach einem der Ansprüche 1 bis 10, dadurch gekennzeichnet, daß die Knochenverankerungselemente als Knochenschrauben oder Knochenhaken ausgebildet sind.

Es folgen 2 Blatt Zeichnungen

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Anhängende Zeichnungen

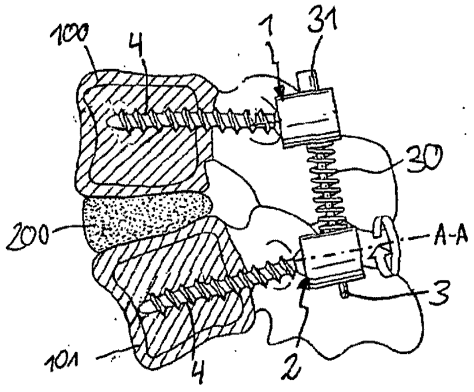


Fig.1

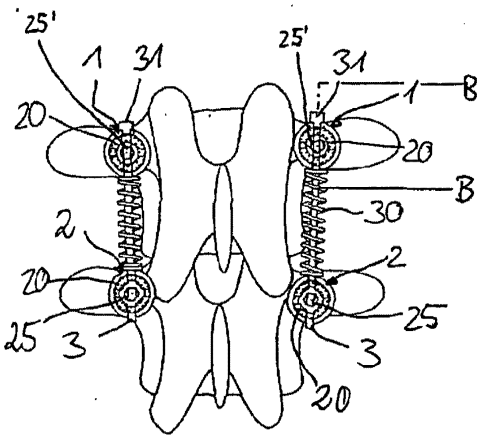


Fig.2

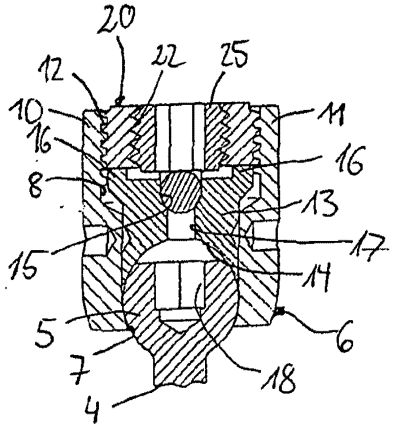


Fig.3

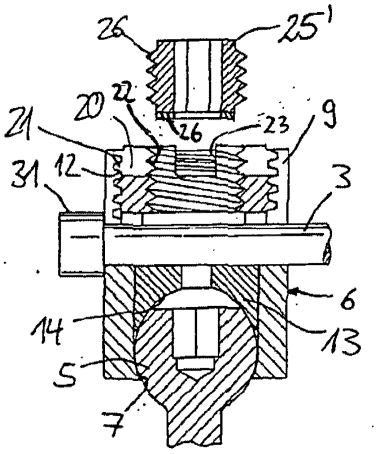


Fig.4

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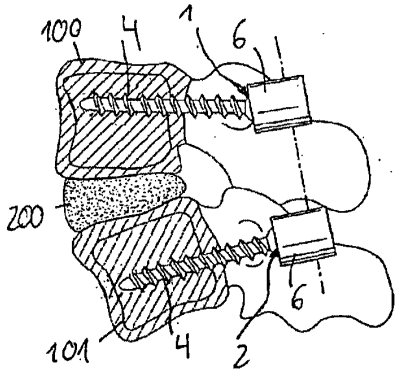


Fig.5

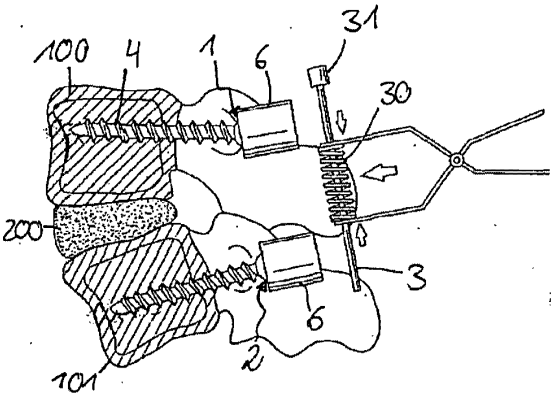


Fig.6

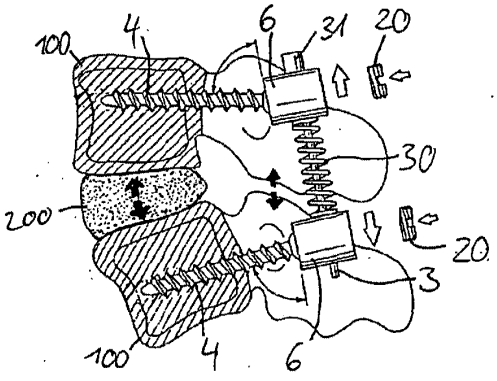


Fig.7

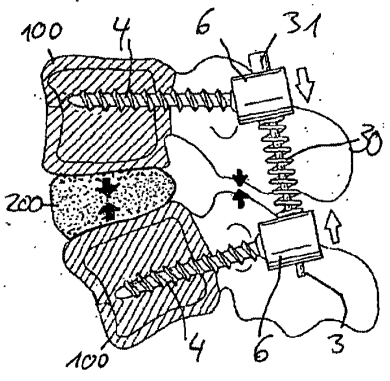


Fig.8

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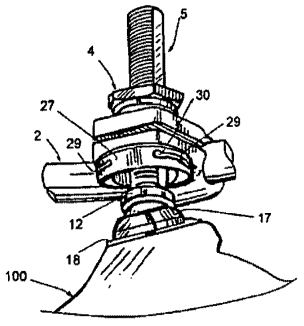
(73) **Titulaire(s) :**

(74) **Mandataire(s) :**

(54) MATERIEL D'OSTEOSYNTHESE VERTEBRALE.

(57) Ce matériel comprend des organes d'ancrage osseux, une ou deux tiges de liaison (2), et des pièces de connexion (3) de cette ou ces tiges (2) à ces organes d'ancrage, au moins un de ces organes d'ancrage et de ces pièces de connexion (3) étant du type "polyaxial".

Selon l'invention, au moins un parmi ledit organe d'ancrage (1) et ladite pièce de connexion (3) de type "polyaxial" comprend au moins une pièce ou une partie de pièce (27, 31) à structure élastiquement déformable, interposée, après montage, entre ladite pièce de connexion (3) et ledit organe d'ancrage (1), cette pièce ou une partie de pièce (27, 31) à structure élastiquement déformable permettant une mobilité de la pièce de connexion (3), et donc de la tige de liaison (2), par rapport à l'organe d'ancrage (1), avec amortissement.



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La présente invention concerne un matériel d'ostéosynthèse vertébrale.

Un matériel d'ostéosynthèse vertébrale comprend généralement des organes d'ancrage osseux, tels que des vis pédiculaires ou des crochets lamaires, une ou deux tiges de liaison, destinées à être reliées à ces organes d'ancrage, et des pièces de connexion de cette ou ces tiges de liaison à ces organes d'ancrage. Le matériel peut également comprendre des traverses réglables en longueur, qui relient transversalement deux tiges de liaison parallèles pour maintenir ces tiges l'une par rapport à l'autre.

Dans un type de matériel existant, chaque organe d'ancrage comprend un pion proximal fileté sur lequel peut être vissé un écrou, et chaque pièce de connexion peut être sous forme d'un étrier comprenant une partie arrondie destinée à entourer une tige de liaison et deux ailes parallèles percées de trous. Ces ailes sont destinées à être engagées sur ledit pion proximal fileté et à être serrées, au moyen de cet écrou, contre une surface d'appui aménagée sur l'organe d'ancrage, ce serrage provoquant le serrage de ladite partie arrondie autour de la tige de liaison et assurant ainsi l'immobilisation longitudinale de cette tige par rapport à l'organe d'ancrage. Les organes d'ancrage et pièces de connexion peuvent être de type "monoaxial", c'est-à-dire ne permettant pas, avant serrage, une articulation de la pièce de connexion par rapport à la partie destinée à être insérée dans l'os, ou peuvent être de type "polyaxial", c'est-à-dire permettant une telle articulation avant serrage.

Les matériels d'ostéosynthèse vertébrale existants sont destinés à immobiliser deux vertèbres l'une par rapport à l'autre, pour éliminer tout mouvement relatif de ces vertèbres, susceptible d'être douloureux, ou pour rétablir la position adéquate d'une vertèbre par rapport à l'autre. Pour l'obtention de cette immobilisation, ces matériels sont conçus pour assurer un assemblage parfaitement rigide des tiges de liaison avec les organes d'ancrage.

Cet assemblage rigide peut cependant ne pas être souhaitable dans tous les cas. Il conduit en particulier à l'exercice de sollicitations importantes au niveau des zones osseuses d'ancrage desdits organes d'ancrage, ainsi qu'à des sollicitations augmentées au niveau des articulations vertébrales situées

de part et d'autre du segment vertébral traité, qui peuvent conduire à des dégénérescences de ces articulations. En outre, il n'est pas adapté à des traitements d'affections non dégénératives, notamment au traitement de scolioses chez des patients jeunes.

La présente invention vise à remédier à ces inconvénients essentiels.

Le matériel concerné comprend, de manière connue en soi, des organes d'ancrage osseux, tels que des vis pédiculaires ou des crochets lamaires, une ou deux tiges de liaison, destinées à être reliées à ces organes d'ancrage, et des pièces de connexion de cette ou ces tiges à ces organes d'ancrage, au moins un de ces organes d'ancrage et de ces pièces de connexion étant du type "polyaxial", c'est-à-dire permettant une articulation de la pièce de connexion par rapport à l'organe d'ancrage, des moyens de serrage étant prévus pour immobiliser une tige de liaison dans la pièce de connexion que reçoit cet organe d'ancrage.

Selon l'invention, au moins un parmi ledit organe d'ancrage et ladite pièce de connexion de type "polyaxial" comprend au moins une pièce ou une partie de pièce à structure élastiquement déformable, interposée, après montage, entre ladite pièce de connexion et ledit organe d'ancrage, cette pièce ou une partie de pièce à structure élastiquement déformable permettant une mobilité de la pièce de connexion, et donc de la tige de liaison, par rapport à l'organe d'ancrage, avec amortissement.

Ainsi, dans le matériel selon l'invention, ladite pièce de connexion n'est pas immobilisée par rapport à l'organe d'ancrage mais peut jouer vis-à-vis de celui-ci, afin d'autoriser des mouvements limités des vertèbres. Les sollicitations exercées sur les zones osseuses d'ancrage de l'organe d'ancrage sont ainsi notablement réduites, de même que les risques de sur-sollicitations au niveau des articulations vertébrales situées de part et d'autre du segment vertébral traité.

Lesdits moyens de serrage peuvent être conçus pour serrer la pièce de connexion contre ladite pièce ou une partie de pièce à structure élastiquement déformable et pour serrer cette pièce ou une partie de pièce contre l'organe d'ancrage.

Le jeu de la pièce de connexion est alors rendu possible uniquement par la déformation de ladite pièce ou partie de pièce à structure élastiquement déformable.

L'organe d'ancrage peut comprendre sinon une surface formant une butée axiale, contre laquelle vient reposer la pièce de connexion, lesdits moyens de serrage serrant cette pièce de connexion contre cette surface.

L'immobilisation de la tige de liaison par rapport à la pièce de connexion est ainsi réalisée indépendamment de tout serrage de ladite pièce ou partie de pièce élastiquement déformable.

Ladite pièce ou partie de pièce à structure élastiquement déformable peut être conformée de manière à réaliser un amortissement du mouvement de la pièce de connexion sur l'ensemble du débattement de cette pièce de connexion, notamment en étant en un matériau compressible. Cette pièce ou partie de pièce peut également être conformée pour réaliser cet amortissement seulement dans les positions extrêmes de ce débattement. Selon une forme de réalisation possible de l'invention dans ce deuxième cas, ladite pièce ou partie de pièce à structure élastiquement déformable est formée par une paroi circulaire raccordée à la pièce de connexion, cette paroi comprenant au moins une fente transversale qui la traverse, aménagée sur un côté de cette paroi selon une direction sensiblement perpendiculaire à celle qu'occupe une tige de liaison quand cette tige est engagée dans la pièce de connexion, cette fente permettant une réduction de l'épaisseur de cette paroi circulaire lorsqu'une contrainte est exercée sur cette paroi dans le sens axial, du côté où se trouve la fente.

Avantageusement, ladite paroi circulaire comprend deux fentes aménagées sur deux de ses côtés opposés, permettant un amortissement sur ces deux côtés.

L'organe d'ancrage peut comporter un pion proximal articulé ; les parois du pion proximal et de l'organe d'ancrage qui glissent l'une contre l'autre lors du débattement de ce pion peuvent alors comporter un revêtement lisse et résistant, propre à résister à de très nombreux mouvements de glissement de ces parois l'une contre l'autre, tel qu'un revêtement en céramique ou en nitrure de titane.

Lorsque l'articulation de ce pion proximal est réalisée par glissement de faces en forme de sphère ou de portions de sphère l'une contre l'autre, avantageusement, ces faces présentent un diamètre nettement supérieur à celui du pion proximal, notamment au moins du double du diamètre de ce pion, afin d'augmenter la surface de contact de ses faces l'une avec l'autre.

Les frottements s'exercent ainsi sur des surfaces augmentées, réduisant le risque d'usure desdites faces.

Selon une autre forme de réalisation possible de l'invention, le matériel comprend, outre les moyens de serrage prévus pour immobiliser une tige de liaison dans la pièce de connexion que reçoit l'organe d'ancrage, des deuxièmes moyens de serrage permettant de serrer, indépendamment du serrage réalisé par lesdits moyens de serrage, ladite pièce ou partie de pièce à structure élastiquement déformable entre la pièce de connexion et l'organe d'ancrage.

Lesdits deuxièmes moyens de serrage peuvent ainsi être serrés de manière contrôlée, par exemple au moyen d'un tournevis dynamométrique, selon le degré d'amortissement recherché en fonction des caractéristiques du patient (état des disques intervertébraux, degré d'instabilité vertébrale, poids), puis lesdits moyens de serrage sont serrés pour immobiliser la tige dans la pièce de connexion.

Le matériel peut comporter des moyens formant repère permettant de repérer différents degrés de serrage de ladite pièce ou partie de pièce à structure élastiquement déformable entre la pièce de connexion et l'organe d'ancrage, et permettre ainsi le serrage contrôlé précité.

L'organe d'ancrage peut comprendre une pièce à structure élastiquement déformable et la pièce de connexion peut comporter une autre pièce à structure élastiquement déformable, ces deux pièces venant porter l'une contre l'autre au cours du serrage.

Par ailleurs, au moins une tige de liaison du matériel peut comprendre :

- une partie de tige comportant une pièce à structure élastiquement déformable et un pion articulé,
- une autre partie de tige comprenant une zone d'appui contre cette pièce à structure élastiquement déformable, et

- des moyens de serrage pour serrer cette zone d'appui contre cette pièce à structure élastiquement déformable.

La tige de liaison peut ainsi également présenter un degré de souplesse élastique.

Ladite zone d'appui peut comporter également une pièce à structure élastiquement déformable.

L'invention sera bien comprise, et d'autres caractéristiques et avantages de celle-ci apparaîtront, en référence au dessin schématique annexé, représentant, à titre d'exemples non limitatifs, plusieurs formes de réalisation de pièces que comprend le matériel qu'elle concerne.

La figure 1 est une vue partielle d'une vis pédiculaire polyaxiale et d'une tige de liaison que comprend ce matériel, et, en coupe transversale, d'une pièce de connexion et d'un écrou permettant d'assembler une tige de liaison à cette vis, avant montage ;

la figure 2 est une vue de ces pièces similaire à la figure 1, après montage ;

la figure 3 est une vue de ces pièces similaire à la figure 2, selon une direction perpendiculaire à celle selon cette figure 2, dans une position ;

la figure 4 est une vue de ces pièces similaire à la figure 3, dans une deuxième position ;

la figure 5 est une vue de ces pièces similaire à la figure 3, dans une troisième position ;

la figure 6 est une vue des mêmes pièces en perspective, après mise en place de la vis dans une vertèbre et avant serrage définitif ;

la figure 7 est une vue de ces pièces similaires à la figure 6, après serrage définitif ;

la figure 8 est une vue similaire à la figure 1 des mêmes pièces du matériel, selon une deuxième forme de réalisation, avant montage ;

la figure 9 est une vue similaire à la figure 2 de ces pièces, après montage ;

la figure 10 est une vue en coupe partielle d'une tige de liaison, avant assemblage ;

la figure 11 est une vue similaire à la figure 10, après assemblage ;

la figure 12 est une vue partielle, en coupe, d'une troisième forme de réalisation de l'invention, incluant une vis pédiculaire, une tige de liaison, une pièce de connexion en forme de "tulipe" et un écrou permettant d'assembler la tige de liaison à cette pièce de connexion, et

la figure 13 est une vue partielle, en coupe, d'une quatrième forme de réalisation de l'invention, incluant une vis pédiculaire polyaxiale, une tige de liaison, une pièce de connexion et un écrou permettant d'assembler la tige de liaison à cette vis.

La figure 1 représente une vis pédiculaire polyaxiale 1, une tige 2 de liaison de plusieurs de ces vis 1, une pièce 3 de connexion de cette tige 2 à une de ces vis 1 et un écrou 4 permettant d'assembler la tige de liaison 2 à cette vis 1.

La vis 1 comprend un pion proximal fileté 5 et un corps de vis distal fileté 6. Le pion 5 est destiné à recevoir la pièce 3 engagée sur lui et l'écrou 4 vissé sur lui tandis que le corps 6 est destiné à être inséré dans le pédicule 100 d'une vertèbre, comme le montrent les figures 6 et 7.

Le pion 5 présente une partie cylindrique filetée 10, une tête distale élargie 11 et une collerette 12 formant une surface de butée.

La partie 10 présente une zone 15 de diamètre réduit, permettant de casser sa portion proximale après mise en place et serrage de l'écrou 4, comme cela apparaît par comparaison des figures 2 et 3.

La tête 11 présente un diamètre double du diamètre de la partie 10 et a une forme de calotte sphérique. Cette tête 11 est destinée à être engagée dans une cavité proximale 16 que délimite la zone proximale du corps 6 et à être retenue dans cette cavité 16 par sertissage d'une paroi proximale 17 que présente ce corps 6. Après sertissage, la paroi 17 est façonnée de manière à présenter une forme proximale hémisphérique. Comme cela apparaît sur la figure 1, les dimensions de la cavité 16 et de l'ouverture délimitée par la paroi 17 après sertissage pour le passage du pion 5 sont telles qu'un débattement multidirectionnel de ce pion 5 par rapport au corps 6 est possible.

Le corps 6 comprend également une collerette proximale 18, destinée à venir en butée contre le pédicule 100. Cette collerette 18 présente plusieurs

encoches radiales 19, notamment quatre encoches à 90° les unes des autres, permettant le maintien du corps 6 en rotation pendant le serrage de l'écrou 4.

La tige de liaison 2 est cylindrique et présente une rigidité telle qu'elle permet le maintien de plusieurs vertèbres les unes par rapport aux autres. Cette tige 2 est toutefois déformable de manière à pouvoir être conformée en fonction de la correction du rachis à réaliser.

La pièce de connexion 3 comprend une partie arrondie 20 destinée à entourer la tige de liaison 2 et deux ailes latérales parallèles 21 percées de trous pour l'engagement de la pièce 3 sur le pion 5. Ces ailes 21 sont mutuellement distantes de telle sorte que, dans une position d'écartement, la tige 2 puisse être insérée et puisse coulisser dans la partie 20, et que, dans une position de rapprochement que leur confère le serrage de l'écrou 4, elles serrent la partie 20 autour de la tige 2, immobilisant cette dernière par rapport à la pièce 3.

Comme le montrent les figures 1 et 2, l'aile 21 proximale présente une cuvette proximale 25 de forme adaptée à la prise d'appui de l'écrou 4, tandis que l'aile 21 distale comprend une cavité circulaire 26 permettant l'engagement de cette aile sur la collerette 12.

Cette aile 21 distale comprend en outre une paroi circulaire 27 solidaire d'elle. Cette paroi 27 a une hauteur inférieure à celle de la paroi 17, et délimite une face sphérique concave interne 28 de diamètre supérieur au diamètre de cette paroi 17.

En outre, deux fentes transversales 29 sont aménagées dans cette paroi 27, sur deux côtés opposés de la paroi 27, et selon une direction sensiblement perpendiculaire à celle qu'occupe la tige de liaison 2 quand cette tige est engagée dans la partie arrondie 20. Chaque fente 29 s'étend angulairement sur environ 120° de la paroi 27 et se termine par une zone élargie 30 en forme de cercle.

Comme cela se comprend en référence à la figure 5, les portions distales de la paroi 27 délimitées par les fentes 29 ont, au niveau de ces zones arrondies 30, une hauteur réduite, telle que ces portions peuvent fléchir au niveau de ces zones 30, permettant ainsi une réduction de la hauteur de la paroi 27.

En pratique, le nombre de vis 1 nécessaire au traitement à réaliser est mis en place dans les pédicules 100 des vertèbres concernées, puis les pièces de connexion 3, avec la tige 2 engagée dans les parties 20, sont placées sur les pions 5, jusqu'à engagement des collerettes 12 dans les cavités 26. Les écrous 4 sont ensuite serrés pour réaliser l'immobilisation de la tige 2 par rapport aux pièces 3 et les portions proximales des pions 5 sont sectionnées.

La venue en butée de chaque pièce 3 contre la collerette 12 correspondante permet de réaliser un serrage de la tige 2 dans cette pièce 3 indépendamment de tout serrage de la pièce 3 contre la paroi 17.

Une fois le serrage de l'écrou 4 réalisé, le pion 5 reste ainsi mobile par rapport au corps 6, cette mobilité étant libre tant que la paroi 27 n'est pas venue en butée contre le corps 6 (cf. figure 4) puis étant possible avec déformation de la paroi 27 au-delà, réalisant un amortissement du mouvement du pion 5 dans les angles maximaux de débattement de ce pion. La limite du débattement possible de ce dernier correspond à la venue en contact des bords de la paroi 27 délimitant les fentes 29.

Grâce au diamètre de sa face 28, supérieur au diamètre de la paroi 17, la paroi 27 ne fait pas obstacle au débattement du pion 5.

Cette face 28 peut cependant, comme le montre la figure 2, être conformée de manière à venir en appui contre la zone sensiblement hémisphérique de la paroi 17. Les frottements résultant de cet appui réalisent un freinage du mouvement du pion 5, si nécessaire.

Les zones de glissement de la tête 11 contre la paroi 17 et de la face 28 contre la paroi 17 peuvent comporter un revêtement lisse et résistant, propre à résister à de très nombreux mouvements de glissement de ces parois l'une contre l'autre, tel qu'un revêtement en céramique ou en nitrure de titane.

Les figures 8 et 9 représentent des pièces 2 à 5 similaires à celles décrites en référence aux figures 1 et 2, les pièces se retrouvant de manière identique ou similaire étant désignées par les mêmes références numériques.

Dans ce cas, la collerette 18 présente un rebord périphérique 30 et contient une pièce 31 sous forme d'une rondelle en matériau à structure élastiquement déformable, notamment en silicone ou en PMMA. Dans

l'exemple représenté, la pièce 3 comporte une pièce 31 similaire, ces deux pièces 31 venant en appui l'une contre l'autre lors du montage.

La pièce 3 peut dans ce cas recevoir complètement un écrou 40 dans la cavité 25 de sa branche proximale 21, cette cavité 25 étant telle que cet écrou 40 peut venir en appui contre la branche 21 distale de la pièce 3 sans appuyer contre la branche 21 proximale.

L'écrou 40 comporte des encoches périphériques 32 pour sa manœuvre en rotation.

Le matériel comprend en outre l'écrou 4, pouvant être vissé sur le pion proximal 5.

En pratique, l'écrou 40 peut être serré de manière contrôlée, par exemple au moyen d'un tournevis dynamométrique, pour serrer les pièces 31 selon le degré d'amortissement recherché en fonction des caractéristiques du patient (état des disques intervertébraux, degré d'instabilité vertébrale, poids). L'écrou 4 est ensuite serré pour immobiliser la tige 2 dans la pièce de connexion 3.

Les figures 10 et 11 montrent une tige de liaison 2 du matériel qui comprend :

- une partie de tige 2a comportant une pièce 41 à structure élastiquement déformable et un pion fileté articulé 5, cette articulation étant réalisée de manière identique à celle décrite précédemment,
- une autre partie de tige 2b, comprenant une zone 42 d'appui contre cette pièce 41 et un alésage taraudé 43 permettant le vissage de cette partie 2b sur le pion 5 pour serrer la zone d'appui 42 contre la pièce 41.

La tige de liaison 2 peut ainsi également présenter un degré de souplesse élastique.

La figure 12 montre une vis pédiculaire 1 comprenant une tête hémisphérique 45 qui peut être engagée dans la pièce de connexion 3, laquelle présente la forme d'une "tulipe".

La pièce 3 comprend une cavité inférieure hémisphérique de réception de la tête 45, cette cavité permettant l'articulation de la pièce 3 par rapport à la vis 1.

La pièce 3 comprend en outre des encoches pour la réception de la tige 2 et forme des surfaces d'appui pour celle-ci, et un filet supérieur permettant le vissage d'un bouchon fileté 46 d'immobilisation de la tige 2 en elle.

Sous la tête 45, la vis 1 comprend un filet sur lequel peut être vissée une collerette 18 de support d'une pièce 31, cette pièce 31 étant comprimée par la pièce de connexion 3 lorsque cette pièce 3 est inclinée par rapport à la vis 1 et permettant ainsi l'amortissement du mouvement de cette pièce 3.

La figure 13 montre quant à elle une vis 1 telle que décrite en référence à la figure 1, une pièce 3 similaire à celle décrite en référence à cette figure 1 mais dépourvue de la paroi 27, une pièce 31 sous forme d'une rondelle en matériau à structure élastiquement déformable, notamment en silicone ou en PMMA, une rondelle rigide 50, notamment métallique, présentant un alésage taraudé permettant son vissage sur le pion 5 jusqu'à serrer la pièce 31 entre elle et la partie 6 de la vis, et un écrou 4 tel que décrit en référence à la figure 1.

La rondelle 50 peut être vissée sur le pion 5 jusqu'à réaliser un serrage de la pièce 31 en fonction de l'amortissement recherché. Une fois ce serrage obtenu, la pièce 3, avec la tige 2 engagée en elle, est mise en place sur le pion 5 puis l'écrou 4 est serré de manière à immobiliser la tige par rapport à la pièce 3.

Comme cela apparaît de ce qui précède, l'invention fournit un matériel d'ostéosynthèse vertébrale permettant un jeu limité de la pièce de connexion 3, et donc de la tige de liaison 2, par rapport à l'organe 1 d'ancrage à la vertèbre, afin d'autoriser des mouvements limités des vertèbres traitées. Les sollicitations exercées sur les zones osseuses d'ancrage de l'organe d'ancrage sont ainsi notablement réduites, de même que les risques de sur-sollicitations au niveau des articulations vertébrales situées de part et d'autre du segment vertébral traité.

Il va de soi que l'invention n'est pas limitée à la forme de réalisation décrite ci-dessus à titre d'exemple mais qu'elle s'étend à toutes les formes de réalisations couvertes par les revendications ci-annexées. Ainsi, l'on ne sortirait pas du cadre de l'invention en remplaçant la paroi 27 par une rondelle

en matériau élastique ou à structure élastique, par exemple sous forme de ressort.

REVENDICATIONS

1 – Matériel d'ostéosynthèse vertébrale, comprenant des organes d'ancrage osseux, tels que des vis pédiculaires (1) ou des crochets lamaires, une ou deux tiges de liaison (2), destinées à être reliées à ces organes d'ancrage et à être fixées aux vertèbres au moyen de ceux-ci, et des pièces de connexion (3) de cette ou ces tiges (2) à ces organes d'ancrage, au moins un de ces organes d'ancrage et de ces pièces de connexion (3) étant du type "polyaxial", c'est-à-dire permettant une articulation de la pièce de connexion (3) par rapport à l'organe d'ancrage, des moyens de serrage (4) étant prévus pour immobiliser une tige de liaison (2) dans la pièce de connexion (3) que reçoit cet organe d'ancrage ;

matériel caractérisé en ce qu'au moins un parmi ledit organe d'ancrage (1) et ladite pièce de connexion (3) de type "polyaxial" comprend au moins une pièce ou une partie de pièce (27) à structure élastiquement déformable, interposée, après montage, entre ladite pièce de connexion (3) et ledit organe d'ancrage (1), cette pièce ou une partie de pièce (27, 31) à structure élastiquement déformable permettant une mobilité de la pièce de connexion (3), et donc de la tige de liaison (2), par rapport à l'organe d'ancrage (1), avec amortissement.

2 – Matériel selon la revendication 1, caractérisé en ce que l'organe d'ancrage (1) comprend une surface (12, 50) formant une butée axiale, contre laquelle vient reposer la pièce de connexion (3), lesdits moyens de serrage (4) serrant cette pièce de connexion (3) contre cette surface (12).

3 – Matériel selon la revendication 1 ou la revendication 2, caractérisé en ce que ladite pièce (31) ou partie de pièce à structure élastiquement déformable est conformée de manière à réaliser un amortissement du mouvement du pion proximal sur l'ensemble du débattement de ce pion.

4 – Matériel selon la revendication 1 ou la revendication 2, caractérisé en ce que ladite pièce ou partie de pièce (27, 31) à structure élastiquement déformable est conformée de manière à réaliser un amortissement du mouvement de la pièce de connexion (3) seulement dans les positions extrêmes du débattement de cette pièce de connexion.

5 – Matériel selon la revendication 4, caractérisé en ce que ladite pièce ou partie de pièce à structure élastiquement déformable est formée par une paroi circulaire (27) raccordée à la pièce de connexion (3), cette paroi (27) comprenant au moins une fente transversale (29) qui la traverse, aménagée sur un côté de cette paroi (27) selon une direction sensiblement perpendiculaire à celle qu'occupe une tige de liaison (2) quand cette tige est engagée dans la pièce de connexion (3), cette fente (29) permettant une réduction de l'épaisseur de cette paroi circulaire (27) lorsqu'une contrainte est exercée sur cette paroi dans le sens axial, du côté où se trouve la fente (29).

6 – Matériel selon la revendication 5, caractérisé en ce que ladite paroi circulaire (27) comprend deux fentes (29) aménagées sur deux de ses côtés opposés, permettant un amortissement sur ces deux côtés.

7 – Matériel selon l'une des revendications 1 à 6, caractérisé en ce que l'organe d'ancrage (1) comporte un pion proximal articulé (5), et en ce que les parois (11, 17) de ce pion proximal (5) et de l'organe d'ancrage (1) qui glissent l'une contre l'autre lors du débattement de ce pion (5) comportent un revêtement lisse et résistant, propre à résister à de très nombreux mouvements de glissement de ces parois l'une contre l'autre, tel qu'un revêtement en céramique ou en nitrure de titane.

8 – Matériel selon la revendication 7, caractérisé en ce que l'articulation dudit pion proximal (5) est réalisée par glissement de faces (11, 17) en forme de sphère ou de portions de sphère l'une contre l'autre, et en ce que ces faces (11, 17) présentent un diamètre nettement supérieur à celui du pion proximal, notamment au moins du double du diamètre de ce pion.

9 – Matériel selon l'une des revendications 1 à 8, caractérisé en ce qu'il comprend, outre les moyens de serrage (4) prévus pour immobiliser une tige de liaison (2) dans la pièce de connexion (3) que reçoit l'organe d'ancrage (1), des deuxièmes moyens de serrage (40, 50) permettant de serrer, indépendamment du serrage réalisé par lesdits moyens de serrage (4), ladite pièce ou partie de pièce à structure élastiquement déformable (31) entre la pièce de connexion (3) et l'organe d'ancrage (1).

10 – Matériel selon l'une des revendications 1 à 9, caractérisé en ce qu'il comprend des moyens formant repère permettant de repérer différents degrés

de serrage de ladite pièce ou partie de pièce à structure élastiquement déformable entre la pièce de connexion et l'organe d'ancrage.

11 – Matériel selon l'une des revendications 1 à 10, caractérisé en ce qu'au moins une tige de liaison comprend :

- une partie de tige comportant une pièce à structure élastiquement déformable et un pion articulé,

- une autre partie de tige comprenant une zone d'appui contre cette pièce à structure élastiquement déformable, et

- des moyens de serrage pour serrer cette surface d'appui contre cette pièce à structure élastiquement déformable.

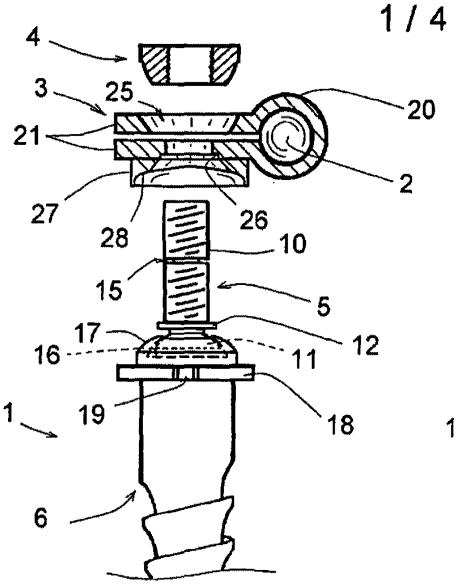


FIG. 1

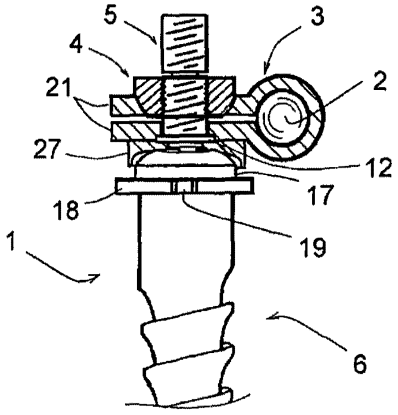


FIG. 2

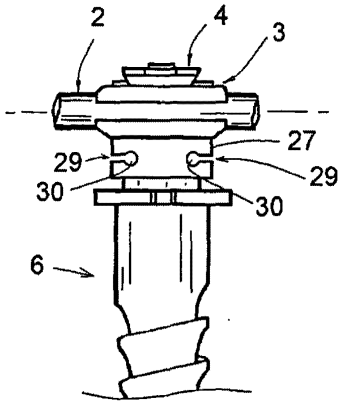


FIG. 3

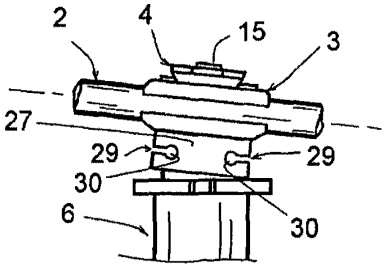


FIG. 4

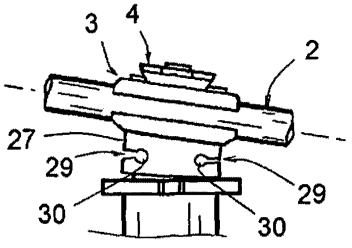


FIG. 5

FIG. 6

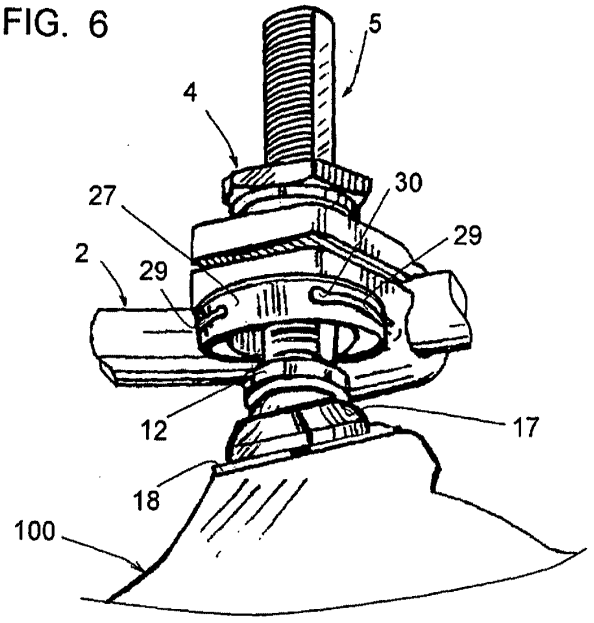
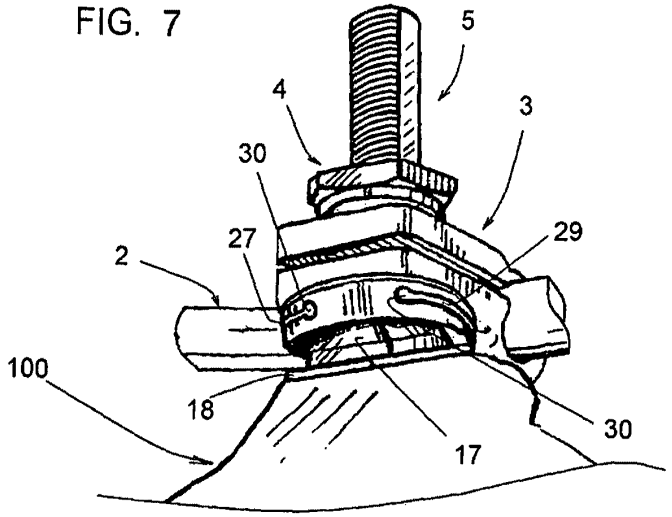


FIG. 7



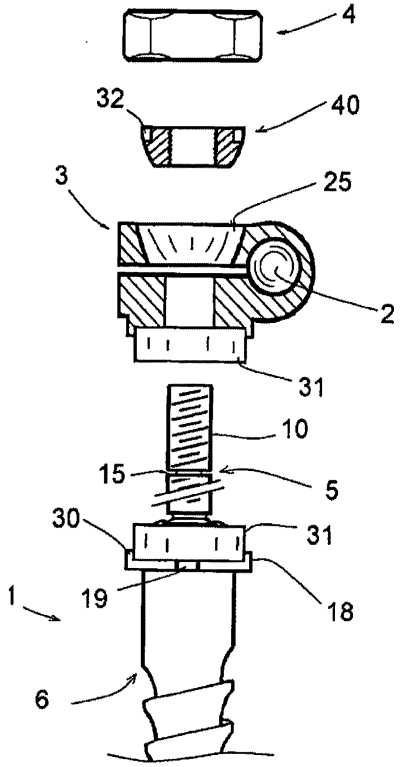


FIG. 8

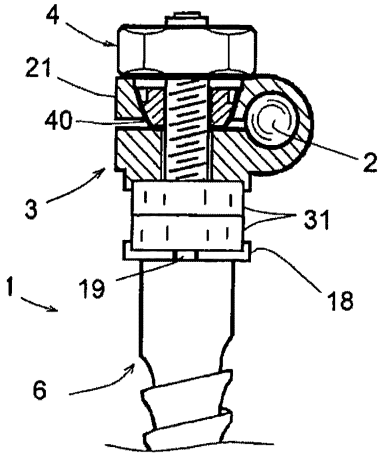


FIG. 9

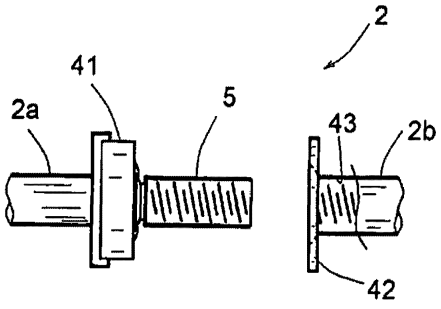


FIG. 10

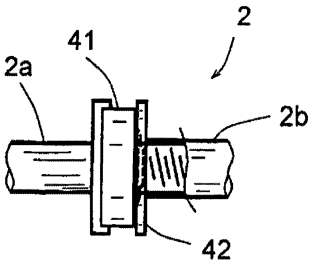


FIG. 11

FIG. 12

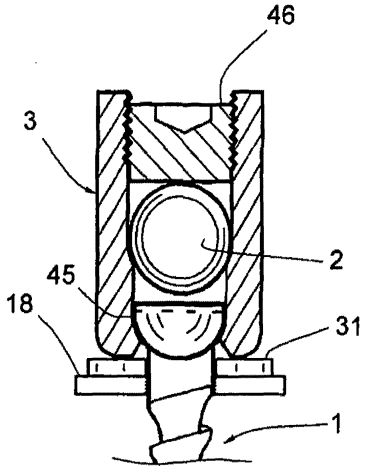
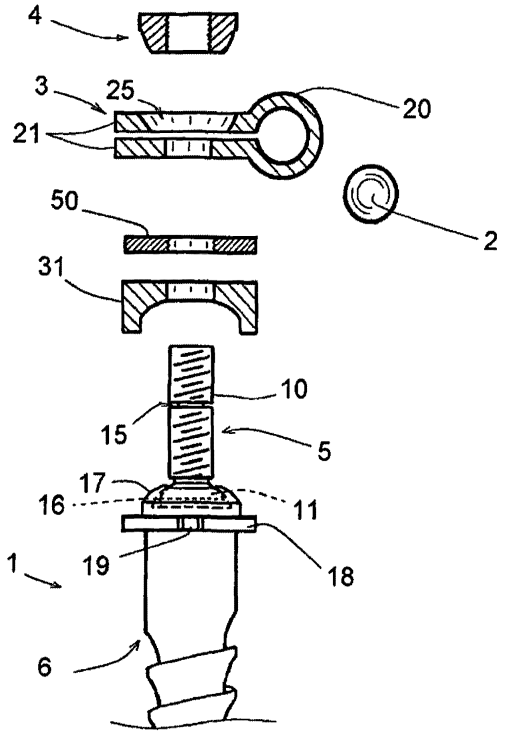


FIG. 13



RÉPUBLIQUE FRANÇAISE

2865377

INPI
INSTITUT NATIONAL DE LA PROPRIETE INDUSTRIELLE

RAPPORT DE RECHERCHE PRÉLIMINAIRE

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

N° d'enregistrement national

FA 644378
FR 0400747

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		
X	EP 0 242 708 A (HARMS J. & BIEDERMANN L.) 28 octobre 1987 (1987-10-28) * colonne 3, ligne 6 - ligne 10; figures 1-3 * * colonne 3, ligne 55 - colonne 44, ligne 15 *	1,3,4,7, 8	A61B17/70
Y	US 5 735 851 A (ERRICO J.P. ET AL) 7 avril 1998 (1998-04-07) * figure 10a *	1,3,4,9	
Y	FR 2 697 742 A (BIOMAT) 13 mai 1994 (1994-05-13) * page 11, ligne 14 - page 12, ligne 9; figure 1 * * page 8, ligne 22 - page 9, ligne 7 *	1,3,4,9	
			DOMAINES TECHNIQUES RECHERCHÉS (Int.CL.7)
			A61B

4

Date d'achèvement de la recherche	Examinateur
7 septembre 2004	Nice, P

CATÉGORIE DES DOCUMENTS CITÉS

X : particulièrement pertinent à lui seul
Y : particulièrement pertinent en combinaison avec un autre document de la même catégorie
A : arrière-plan technologique
O : divulgation non-écrite
P : document intercalaire

T : théorie ou principe à la base de l'invention
E : document de brevet bénéficiant d'une date antérieure à la date de dépôt et qui n'a été publié qu'à cette date de dépôt ou qu'à une date postérieure.
D : cité dans la demande
L : cité pour d'autres raisons

& : membre de la même famille, document correspondant

EPO FORM 1503 12.99 (P04C14)

ANNEXE AU RAPPORT DE RECHERCHE PRÉLIMINAIRE
RELATIF A LA DEMANDE DE BREVET FRANÇAIS NO. FR 0400747 FA 644378

La présente annexe indique les membres de la famille de brevets relatifs aux documents brevets cités dans le rapport de recherche préliminaire visé ci-dessus.
Les dits membres sont contenus au fichier informatique de l'Office européen des brevets à la date du 07-09-2004
Les renseignements fournis sont donnés à titre indicatif et n'engagent pas la responsabilité de l'Office européen des brevets, ni de l'Administration française

Document brevet cité au rapport de recherche		Date de publication	Membre(s) de la famille de brevet(s)		Date de publication
EP 0242708	A	28-10-1987	DE	3614101 C1	22-10-1987
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			CA	1328591 C	19-04-1994
			DE	3782678 D1	24-12-1992
			EP	0242708 A2	28-10-1987
			ES	2035826 T3	01-05-1993
			JP	1802142 C	26-11-1993
			JP	5008011 B	01-02-1993
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			US	5380325 A	10-01-1995

EPO FORM P0465

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

(19) RÉPUBLIQUE FRANÇAISE

INSTITUT NATIONAL
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PARIS

(11) N° de publication : **2 865 375**
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(12) DEMANDE DE BREVET D'INVENTION A1

(22) **Date de dépôt :** 27.01.04.

(30) **Priorité :**

(43) **Date de mise à la disposition du public de la demande :** 29.07.05 Bulletin 05/30.

(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) :** *MEDICREA INTERNATIONAL Société anonyme* — FR.

(72) **Inventeur(s) :** SOURNAC DENYS, CAFFIERO JEAN PHILIPPE et CARLIER FRANCOIS.

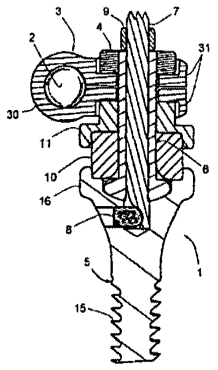
(73) **Titulaire(s) :**

(74) **Mandataire(s) :**

(54) MATERIEL D'OSTEOSYNTHESE VERTEBRALE.

(57) Ce matériel d'ostéosynthèse vertébrale comprend des organes d'ancrage osseux, tels que des vis pédiculaires (1), une ou deux tiges de liaison (2) destinées à être reliées à ces organes d'ancrage, et des ensembles de connexion (6, 3) de cette ou ces tiges (2) à ces organes d'ancrage, au moins un de ces organes d'ancrage (1) étant du type "polyaxial", c'est-à-dire comprenant une pièce de connexion (6) articulée par rapport à la partie de base (5) de l'organe d'ancrage (1) destinée à être fixée à la vertèbre.

Selon l'invention, ledit organe d'ancrage "polyaxial" (1) comprend un élément flexible (7) de jonction reliant ladite pièce de connexion (6) et ladite partie de base (5), cet élément flexible de jonction (7) permettant l'articulation recherchée de la pièce de connexion (6) par rapport à la partie de base (5).



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La présente invention concerne un matériel d'ostéosynthèse vertébrale.

Un matériel d'ostéosynthèse vertébrale comprend généralement des organes d'ancrage osseux, tels que des vis pédiculaires, des pinces ou des crochets, une ou deux tiges de liaison, destinées à être reliées à ces organes d'ancrage, et des pièces de connexion de cette ou ces tiges de liaison à ces organes d'ancrage. Le matériel peut également comprendre des traverses réglables en longueur, qui relient transversalement deux tiges de liaison parallèles pour maintenir ces tiges l'une par rapport à l'autre.

Dans un type de matériel existant, chaque organe d'ancrage peut comporter un pion proximal fileté sur lequel peut être vissé un écrou et chaque pièce de connexion peut comprendre une partie arrondie destinée à entourer une tige de liaison et deux ailes parallèles percées de trous. Ces ailes sont destinées à être engagées sur ledit pion proximal fileté et à être serrées, au moyen de cet écrou, contre une surface d'appui aménagée sur l'organe d'ancrage, ce serrage provoquant le serrage de ladite partie arrondie autour de la tige de liaison et assurant ainsi l'immobilisation longitudinale de cette tige par rapport à l'organe d'ancrage.

Les organes d'ancrage peuvent être de type "polyaxial", c'est-à-dire permettant, avant serrage, une articulation du pion proximal fileté par rapport à la partie de base de l'organe d'ancrage, destinée à être insérée dans l'os. Cette articulation facilite l'assemblage des tiges de liaison aux organes d'ancrage.

Dans un organe d'ancrage "polyaxial" existant à pion proximal fileté, l'articulation est réalisée en aménageant une sphère à l'extrémité distale du pion proximal fileté et une cavité dans ladite partie de base, cette cavité recevant la sphère du pion et étant refermée en partie proximale pour retenir cette sphère.

Ce type d'articulation a pour inconvénient de ne permettre qu'un débattement limité du pion proximal fileté, compte tenu de la venue en butée du pion contre le bord de la partie de base qui referme la cavité recevant la sphère. Ce débattement limité peut rendre difficile dans certains cas la mise en place d'une tige sur des organes d'ancrage. De plus, la surface de contact de la sphère avec ledit bord est restreinte et le serrage de la tige dans la pièce

de connexion génère une tension axiale relativement importante sur ce bord, ce qui n'est pas optimal d'un point de vue mécanique. En outre, les sollicitations répétées que subit le matériel une fois implanté, résultant des mouvements du patient, génèrent des frottements répétés de la sphère contre la partie de base, ce qui conduit à un risque de diffusion non souhaitable de particules de métal dans l'organisme.

Par ailleurs, les matériels d'ostéosynthèse vertébrale existants sont destinés à immobiliser deux vertèbres l'une par rapport à l'autre, pour éliminer tout mouvement relatif de ces vertèbres, ou pour rétablir la position adéquate d'une vertèbre par rapport à l'autre. Pour l'obtention de cette immobilisation, ces matériels sont conçus de façon à assurer un assemblage parfaitement rigide des tiges de liaison avec les organes d'ancrage.

Cet assemblage rigide peut cependant ne pas être souhaitable dans tous les cas. Il conduit en particulier à l'exercice de sollicitations importantes au niveau des zones osseuses d'ancrage desdits organes d'ancrage, ainsi qu'à des sollicitations augmentées au niveau des articulations vertébrales situées de part et d'autre du segment vertébral traité, qui peuvent conduire à des dégénérescences de ces articulations. En outre, cet assemblage rigide n'est pas adapté à des traitements d'affections non dégénératives, notamment au traitement de scolioses chez des patients jeunes.

La présente invention vise à remédier à l'ensemble de ces inconvénients.

Son objectif principal est donc de fournir un matériel d'ostéosynthèse vertébrale comprenant au moins un organe d'ancrage polyaxial, dans lequel la pièce de connexion a un débattement important par rapport à la partie de base de l'organe d'ancrage destinée à être fixée à l'os, et dans lequel le risque de diffusion de particules de métal dans l'organisme est nettement réduit par rapport à un matériel existant.

Un autre objectif de l'invention est de fournir un matériel d'ostéosynthèse vertébrale permettant un assemblage non rigide, voire souple, des tiges de liaison avec les organes d'ancrage, avec un éventuel amortissement du mouvement des pièces mobiles.

Le matériel concerné comprend, de manière connue en soi, des organes d'ancrage osseux, tels que des vis pédiculaires, des pinces ou des crochets,

une ou deux tiges de liaison, destinées à être reliées à ces organes d'ancrage, et des ensembles de connexion de cette ou ces tiges à ces organes d'ancrage, au moins un de ces organes d'ancrage étant du type "polyaxial", c'est-à-dire comprenant une pièce de connexion articulée par rapport à une partie de base destinée à être fixée à l'os.

Selon l'invention, ledit organe d'ancrage "polyaxial" comprend un élément flexible de jonction reliant ladite pièce de connexion et ladite partie de base, cet élément flexible de jonction permettant l'articulation recherchée de la pièce de connexion par rapport à la partie de base.

L'articulation de cette pièce de connexion est ainsi réalisée par la seule flexion dudit élément flexible de jonction. Le débattement de la pièce de connexion n'est, dès lors, pas limité par la structure de l'articulation comme cela est le cas de l'articulation selon la technique antérieure. Ce débattement peut être très nettement supérieur à celui de la pièce de connexion d'un organe d'ancrage existant.

De plus, la tension axiale exercée entre la pièce de connexion et la partie de base une fois le montage réalisé s'applique sur l'ensemble de l'élément flexible de jonction et non sur une surface restreinte comme selon la technique antérieure.

L'organe d'ancrage selon l'invention peut être conçu de telle sorte que la pièce de connexion et la partie de base ne soient jamais en contact l'une de l'autre, tant avant serrage d'une tige de liaison dans la pièce de connexion qu'après ce serrage.

Cette absence de contact élimine le risque de diffusion de particules de métal dans l'organisme.

Alternativement, et de préférence, l'élément flexible de jonction est légèrement étirable longitudinalement, et des moyens sont prévus pour réaliser un léger étirement longitudinal de cet élément flexible de jonction, permettant un écartement des surfaces par lesquelles la pièce de connexion et la partie de base viennent en contact l'une de l'autre.

Ces surfaces de la pièce de connexion et de la partie de base peuvent être conformées pour réaliser un guidage du mouvement d'articulation de la pièce de connexion par rapport à la partie de base. Il peut notamment s'agir

de surfaces en portion de sphère, respectivement concave et convexe, et aménagées coaxialement audit élément flexible de jonction.

Ces surfaces permettent ainsi, au moment de la réduction des vertèbres en vue de l'ostéosynthèse, de guider le mouvement de la pièce de connexion par rapport à la partie de base afin d'éviter de soumettre l'élément flexible de jonction à des contraintes transversales trop importantes.

Dans le même but, ces mêmes surfaces de la pièce de connexion et de la partie de base peuvent être bordées par des surfaces latérales d'appui, permettant un calage latéral de la pièce de connexion par rapport à la partie de base.

De préférence, ledit organe d'ancrage de type "polyaxial" comprend au moins une pièce ou une partie de pièce à structure élastiquement déformable, placée, après montage, entre ladite pièce de connexion et ladite partie de base, cette pièce ou partie de pièce à structure élastiquement déformable permettant une mobilité de la pièce de connexion, et donc de la tige de liaison, par rapport à la partie de base, avec amortissement.

Ainsi, dans le matériel selon l'invention, ladite pièce de connexion n'est pas immobilisée par rapport à la partie de base après montage mais peut, en fonction de la déformabilité élastique de ladite pièce ou partie de pièce, jouer vis-à-vis de la partie de base afin d'autoriser des mouvements limités des vertèbres. Les sollicitations exercées par l'organe d'ancrage sur les zones osseuses d'ancrage sont ainsi notablement réduites, de même que les risques de sur-sollicitations au niveau des articulations vertébrales situées de part et d'autre du segment vertébral traité.

La partie de base peut comprendre une pièce à structure élastiquement déformable et la pièce de connexion peut comporter une autre pièce à structure élastiquement déformable, ces deux pièces venant porter l'une contre l'autre en position de montage.

Le matériel peut comprendre, outre les moyens de serrage prévus pour immobiliser une tige de liaison dans la pièce de connexion destinée à recevoir cette tige de liaison, des deuxièmes moyens de serrage permettant de serrer, indépendamment du serrage réalisé par lesdits moyens de serrage, ladite

pièce ou partie de pièce à structure élastiquement déformable entre la pièce de connexion et l'organe d'ancrage.

Lesdits deuxièmes moyens de serrage peuvent ainsi être serrés de manière contrôlée, par exemple au moyen d'un tournevis dynamométrique, selon le degré d'amortissement recherché en fonction des caractéristiques du patient (état des disques intervertébraux, degré d'instabilité vertébrale, poids), puis lesdits moyens de serrage sont serrés pour immobiliser la tige dans la pièce de connexion.

L'invention sera bien comprise, et d'autres caractéristiques et avantages de celle-ci apparaîtront, en référence au dessin schématique annexé, représentant, à titre d'exemple non limitatif, une forme de réalisation possible de pièces que comprend le matériel qu'elle concerne.

La figure 1 est une vue en coupe axiale des différents éléments constituant un organe d'ancrage et un ensemble de connexion que comprend ce matériel ;

la figure 2 est une vue latérale de cet organe d'ancrage, de cet ensemble de connexion et d'une tige de liaison, après montage ;

la figure 3 est une vue de ces organe d'ancrage, ensemble de connexion et tige de liaison en coupe selon la ligne III-III de la figure 2, et

la figure 4 est une vue de ces organe d'ancrage, ensemble de connexion et tige de liaison, de dessus.

Les figures 2 à 4 représentent une vis pédiculaire polyaxiale 1, une tige 2 de liaison de plusieurs de ces vis 1, un étrier 3 de connexion de cette tige 2 à une de ces vis 1 et un écrou 4 permettant d'assembler la tige de liaison 2 à cette vis 1.

Comme le montre plus particulièrement la figure 1, la vis 1 comprend une pièce de base 5 sous forme de vis, un pion proximal fileté 6, un élément allongé 7, de jonction de la pièce de base 5 et du pion 6, un bouchon vissable 8 d'assemblage de l'élément 7 à la pièce de base 5 et une bague sertissable 9 d'assemblage de l'élément 7 au pion 6. La vis 1 comprend également une pièce 10 à structure élastiquement déformable et une bague 11 d'appui contre cette pièce 10.

La pièce de base 5 est métallique, notamment en titane, de même que le pion 6, la tige 2, l'étrier 3, l'écrou 4, le bouchon 8, la bague sertissable 9 et la bague d'appui 11. Elle comprend une partie cylindrique filetée 15 permettant son insertion dans le pédicule d'une vertèbre, et une tête élargie 16 destinée à venir en appui contre ce pédicule.

Cette tête 16 comprend une cavité supérieure cylindrique 17, propre à recevoir la pièce 10 de manière ajustée, une cavité intermédiaire cylindrique 18 à fond sphérique concave, propre à recevoir la base du pion 6, et un alésage inférieur 19, propre à recevoir une extrémité de l'élément 7, ces cavités 17, 18 et alésage 19 étant coaxiaux à l'axe de la partie de base 5.

La tête 16 comprend également un perçage transversal taraudé 20, débouchant dans l'alésage 19. Comme cela apparaît sur la figure 3, le bouchon 8 est destiné à être vissé dans le perçage 20 de manière à venir serrer l'élément 7 dans l'alésage 19 et assurer ainsi l'assemblage de cet élément 7 avec la partie de base 5.

Le pion 6 comprend un alésage axial 22 pouvant être traversé par l'élément 7, un filetage proximal 23 et une base élargie 24 à face distale sphérique convexe, cette base 24 étant propre à être reçue de manière ajustée , mais avec possibilité de mouvement, dans la cavité 18.

L'élément 7 peut notamment être constitué par une tresse de fils de polyester. Après son engagement au travers de l'alésage 22, cet élément 7 reçoit la bague 9, qui est sertie sur lui de manière à maintenir la base 24 dans la cavité 18. La partie de l'élément 7 en excès est ensuite sectionnée au-delà de la bague 9.

La pièce 10 peut notamment être en silicone ou en PMMA. Elle comprend un perçage axial 25 permettant son engagement sur le pion 6, cet alésage 25 étant évasé en partie inférieure pour favoriser le débattement du pion 6 par rapport à la partie de base 5.

La pièce d'appui 11 comprend une partie supérieure 26 percée d'un alésage taraudé 27 permettant son vissage sur le pion 6 et une partie inférieure élargie 28, délimitant une cavité cylindrique inférieure 29 propre à recevoir de manière ajustée la pièce 10.

La pièce 10 est ainsi destinée à être engagée sur le pion 6 jusqu'à prendre appui contre le fond de la cavité 17 et la pièce 11 est destinée à être vissée sur le pion 6 de manière à exercer un serrage de la pièce 10 entre elle et la partie de base 5, indépendamment du serrage réalisé par l'écrou 4. La pièce 11 peut être serrée de manière contrôlée, par exemple au moyen d'un tournevis dynamométrique, selon le degré d'amortissement recherché du mouvement du pion 5, en fonction des caractéristiques du patient (état des disques intervertébraux, degré d'instabilité vertébrale, poids). Ce serrage a également pour effet d'opérer un léger étirement de l'élément 7, qui permet d'écarter mutuellement la face convexe de la base 24 et le fond convexe de la cavité 18.

Il en résulte que le mouvement multidirectionnel du pion 6 par rapport à la partie de base 5 est possible grâce à la seule flexibilité de l'élément 7, selon un débattement important, sans zone d'appui restreinte du pion 6 contre un bord de la partie de base 5, et sans frottement substantiel des surfaces adjacentes du pion 6 et de la partie de base 5.

La tige de liaison 2 est cylindrique et présente une rigidité telle qu'elle permet le maintien de plusieurs vertèbres les unes par rapport aux autres. Cette tige 2 est toutefois déformable de manière à pouvoir être conformée en fonction de la correction vertébrale à réaliser.

L'étrier 3 comprend une partie arrondie 30 destinée à entourer la tige de liaison 2 et deux ailes latérales parallèles 31 percées de trous 32 pour l'engagement de l'étrier 3 sur le pion 6. Ces ailes 31 sont mutuellement distantes de telle sorte que, dans une position d'écartement, la tige 2 puisse être insérée et puisse coulisser dans la partie 30, et que, dans une position de rapprochement que leur confère le serrage de l'écrou 4, elles serrent la partie 30 autour de la tige 2, immobilisant cette dernière par rapport à l'étrier 3.

Comme le montre la figure 1, chaque aile 31 présente une cavité 33, 34 sur sa face extérieure, destinées à recevoir respectivement l'écrou 4 et la bague d'appui 11.

En pratique, le nombre de vis 1 nécessaire au traitement à réaliser est mis en place dans les pédicules des vertèbres concernées, puis les étriers 3, avec la tige 2 engagée dans les parties 30, sont placés sur les pions 6.

Le débattement important des pions 6 permet de faciliter très notablement cette mise en place des étriers 3 sur ses pions 6. Durant cette opération, au cours de laquelle est réalisé la réduction des vertèbres vers leur position d'ostéosynthèse, les têtes 16 des parties de base 15 maintiennent transversalement les bases 24 des pions 6 et éliminent ainsi tout risque d'exercice sur les éléments 7 de sollicitations transversales trop importantes.

Les écrous 4 sont ensuite serrés pour rapprocher les branches 31 et serrer ainsi les tiges 2 dans les parties 30 des étriers 3.

Comme cela apparaît de ce qui précède, l'invention fournit un matériel d'ostéosynthèse vertébrale dans lequel la pièce de connexion a un débattement important par rapport à la partie de base de l'organe d'ancrage destinée à être fixée à l'os et dans lequel le risque de diffusion de particules de métal dans l'organisme est nettement réduit par rapport à un matériel existant.

Ce matériel d'ostéosynthèse vertébrale permet en outre un assemblage non rigide, voire souple, des tiges de liaison avec les organes d'ancrage, avec un éventuel amortissement du mouvement des pièces mobiles.

Il va de soi que l'invention n'est pas limitée à la forme de réalisation décrite ci-dessus à titre d'exemple mais qu'elle s'étend à toutes les formes de réalisations couvertes par les revendications ci-annexées.

En particulier, le terme "pièce de connexion" doit être compris dans une acception large : il peut s'agir d'un pion proximal fileté 6 ou d'une pièce de connexion en forme de "tulipe", c'est-à-dire comprenant un logement de réception d'une tige de liaison.

De même, le terme "partie de base" 5 doit être compris comme toute structure permettant la fixation de l'organe d'ancrage 1 à une vertèbre, notamment sous forme de vis pédiculaire, de pince ou de crochet.

REVENDICATIONS

1 – Matériel d'ostéosynthèse vertébrale, comprenant des organes d'ancrage osseux, tels que des vis pédiculaires (1), des pinces ou des crochets, une ou deux tiges de liaison (2) destinées à être reliées à ces organes d'ancrage, et des ensembles de connexion (6, 3) de cette ou ces tiges (2) à ces organes d'ancrage, au moins un de ces organes d'ancrage (1) étant du type "polyaxial", c'est-à-dire comprenant une pièce de connexion (6) articulée par rapport à la partie de base (5) de l'organe d'ancrage (1) destinée à être fixée à la vertèbre ;

matériel caractérisé en ce que ledit organe d'ancrage "polyaxial" (1) comprend un élément flexible (7) de jonction reliant ladite pièce de connexion (6) et ladite partie de base (5), cet élément flexible de jonction (7) permettant l'articulation recherchée de la pièce de connexion (6) par rapport à la partie de base (5).

2 – Matériel selon la revendication 1, caractérisé en ce que l'élément flexible de jonction (7) est légèrement étirable longitudinalement, et en ce que des moyens sont prévus pour réaliser un léger étirement longitudinal de cet élément flexible de jonction (7), cet étirement permettant un écartement des surfaces par lesquelles la pièce de connexion (6) et la partie de base (5) viennent en contact l'une de l'autre.

3 – Matériel selon la revendication 1 ou la revendication 2, caractérisé en ce que les surfaces par lesquelles la pièce de connexion (6) et la partie de base (5) viennent en contact l'une de l'autre sont conformées pour réaliser un guidage du mouvement d'articulation de la pièce de connexion (6) par rapport à la partie de base (5).

4 – Matériel selon la revendication 3, caractérisé en ce que lesdites surfaces sont en portion de sphère, respectivement concave et convexe, et aménagées coaxialement audit élément flexible de jonction (7).

5 – Matériel selon la revendication 3 ou la revendication 4, caractérisé en ce que lesdites surfaces sont bordées par des surfaces latérales d'appui, permettant un calage latéral de la pièce de connexion (6) par rapport à la partie de base (5).

6 – Matériel selon l'une des revendications 1 à 5, caractérisé en ce que ledit organe d'ancrage (1) de type "polyaxial" comprend au moins une pièce ou une partie de pièce (10) à structure élastiquement déformable, placée, après montage, entre ladite pièce de connexion (6) et ladite partie de base (5), cette pièce ou partie de pièce (10) à structure élastiquement déformable permettant une mobilité de la pièce de connexion (6), et donc de la tige de liaison (2), par rapport à la partie de base (5), avec amortissement.

7 – Matériel selon la revendication 6, caractérisé en ce que la partie de base comprend une pièce à structure élastiquement déformable et la pièce de connexion comporte une autre pièce à structure élastiquement déformable, ces deux pièces venant porter l'une contre l'autre en position de montage.

8 – Matériel selon la revendication 6 ou la revendication 7, caractérisé en ce qu'il comprend, outre les moyens de serrage (4) prévus pour immobiliser une tige de liaison (2) dans la pièce de connexion (3) destinée à recevoir cette tige de liaison (2), des deuxièmes moyens de serrage (11) permettant de serrer, indépendamment du serrage réalisé par lesdits moyens de serrage (4), ladite pièce ou partie de pièce (10) à structure élastiquement déformable entre la pièce de connexion (6) et l'organe d'ancrage (1).

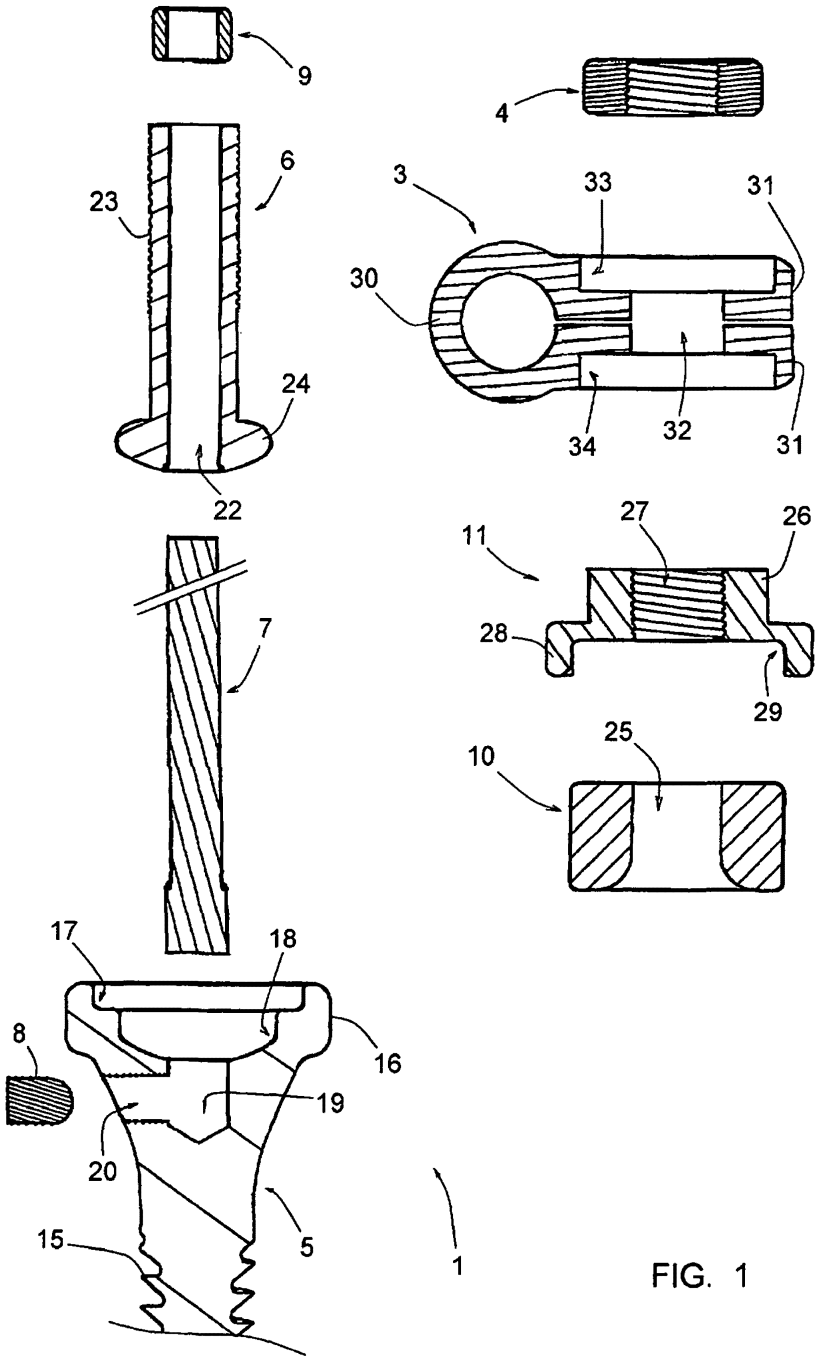
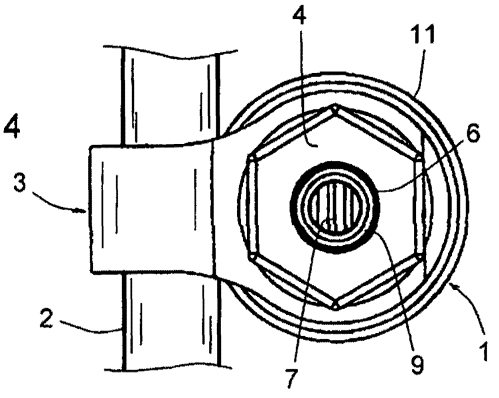

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FIG. 1

FIG. 4



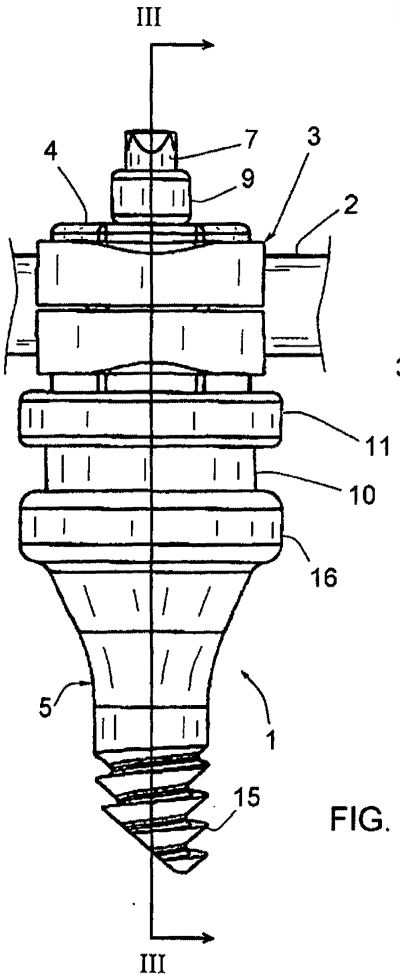


FIG. 2

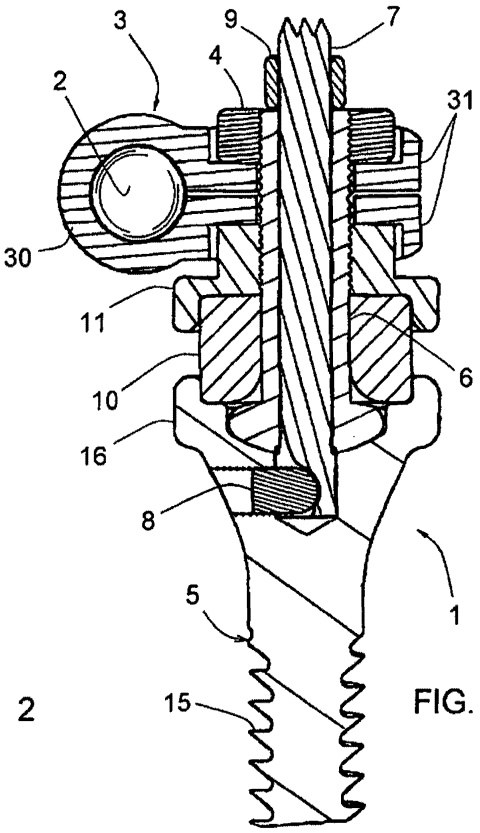


FIG. 3

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RAPPORT DE RECHERCHE PRÉLIMINAIRE

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

N° d'enregistrement national

FA 644376
FR 0400745

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		
X	US 5 882 350 A (RALPH JAMES D ET AL) 16 mars 1999 (1999-03-16) * colonne 6, ligne 32 - ligne 39; figure 5 * * colonne 7, ligne 4 - ligne 13; figure 7 * * colonne 8, ligne 7 - ligne 45; figures 9,10 *	1	A61B17/70
X	WO 00/15125 A (SYNTHES AG ; BRACE MICHAEL (US); SYNTHES USA (US); LANGE ERIC (US)) 23 mars 2000 (2000-03-23) * page 4, alinéa 8 - page 5, alinéa 3; figures 1,2 *	1	
A	WO 03/068088 A (CROSS MED PROD INC) 21 août 2003 (2003-08-21) * page 5, ligne 3 - page 6, ligne 9; figures 1,2 *	1,3-5	
A	FR 2 735 011 A (MECANURGIE SA SOC) 13 décembre 1996 (1996-12-13) * abrégé; figure 1 *	6	DOMAINES TECHNIQUES RECHERCHÉS (Int.CL.7) A61B

1

Date d'achèvement de la recherche	Examinateur
6 septembre 2004	Ducreau, F

CATÉGORIE DES DOCUMENTS CITÉS

X : particulièrement pertinent à lui seul
Y : particulièrement pertinent en combinaison avec un autre document de la même catégorie
A : arrière-plan technologique
O : divulgation non-écrite
P : document intercalaire

T : théorie ou principe à la base de l'invention
E : document de brevet bénéficiant d'une date antérieure à la date de dépôt et qui n'a été publié qu'à cette date de dépôt ou qu'à une date postérieure.
D : cité dans la demande
L : cité pour d'autres raisons

& : membre de la même famille, document correspondant

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ANNEXE AU RAPPORT DE RECHERCHE PRÉLIMINAIRE
RELATIF A LA DEMANDE DE BREVET FRANÇAIS NO. FR 0400745 FA 644376

La présente annexe indique les membres de la famille de brevets relatifs aux documents brevets cités dans le rapport de recherche préliminaire visé ci-dessus.
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Les renseignements fournis sont donnés à titre indicatif et n'engagent pas la responsabilité de l'Office européen des brevets, ni de l'Administration française

Document brevet cité au rapport de recherche		Date de publication	Membre(s) de la famille de brevet(s)		Date de publication
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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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(12) DEMANDE DE BREVET D'INVENTION A1

(22) **Date de dépôt :** 27.01.04.

(30) **Priorité :**

(43) **Date de mise à la disposition du public de la demande :** 29.07.05 Bulletin 05/30.

(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) :** *MEDICREA INTERNATIONAL Société anonyme* — FR.

(72) **Inventeur(s) :** SOURNAC DENYS, CAFFIERO JEAN PHILIPPE et CARLIER FRANCOIS.

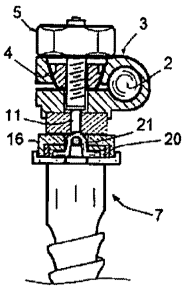
(73) **Titulaire(s) :**

(74) **Mandataire(s) :**

(54) MATERIEL D'OSTEOSYNTHESE VERTEBRALE.

(57) Ce matériel d'ostéosynthèse vertébrale comprend des organes d'ancrage osseux, tels que des vis pédiculaires (1), des pinces ou des crochets, une ou deux tiges de liaison (2) destinées à être reliées à ces organes d'ancrage et à être fixées aux vertèbres au moyen de ceux-ci, et des ensembles de connexion (6, 3) de cette ou ces tiges (2) à ces organes d'ancrage, au moins un de ces organes d'ancrage (1) étant du type "polyaxial", c'est-à-dire comprenant une pièce de connexion (6) articulée par rapport à la pièce de base (7) de l'organe d'ancrage (1) destinée à être fixée à la vertèbre;

Selon l'invention, ladite pièce de connexion (6) et ladite pièce de base (7) comprennent chacune un passage transversal et une partie transversale rigide (11, 24) de direction sensiblement perpendiculaire à la direction dudit passage, ladite partie transversale rigide (11, 24) de l'une de ces pièces (6, 7) étant engagée dans le passage transversal de l'autre pièce (7, 6), et réciproquement, avec possibilité de pivotement de ces parties transversales rigides (11, 24) dans ces passages.



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La présente invention concerne un matériel d'ostéosynthèse vertébrale.

Un matériel d'ostéosynthèse vertébrale comprend généralement des organes d'ancrage osseux, tels que des vis pédiculaires, des pinces ou des crochets, une ou deux tiges de liaison, destinées à être reliées à ces organes d'ancrage et à être fixées aux vertèbres au moyen de ceux-ci, et des pièces de connexion de cette ou ces tiges de liaison à ces organes d'ancrage. Le matériel peut également comprendre des traverses réglables en longueur, qui relient transversalement deux tiges de liaison parallèles pour maintenir ces tiges l'une par rapport à l'autre.

Dans un type de matériel existant, chaque organe d'ancrage comporte un pion proximal fileté sur lequel peut être vissé un écrou, et chaque pièce de connexion comprend une partie arrondie destinée à entourer une tige de liaison et deux ailes parallèles percées de trous. Ces ailes sont destinées à être engagées sur ledit pion proximal fileté et à être serrées, au moyen de cet écrou, contre une surface d'appui aménagée sur l'organe d'ancrage, ce serrage provoquant le serrage de ladite partie arrondie autour de la tige de liaison et assurant ainsi l'immobilisation longitudinale de cette tige par rapport à l'organe d'ancrage.

Dans un autre type de matériel existant, chaque organe d'ancrage comporte une pièce de connexion en forme de "tulipe", présentant un logement dans lequel une tige de liaison peut être engagée.

Les organes d'ancrage peuvent être de type "polyaxial", c'est-à-dire permettant, avant serrage, une articulation du pion proximal fileté ou de la "tulipe" par rapport à la pièce de base de l'organe d'ancrage destinée à venir en prise avec l'os. Cette articulation facilite grandement l'assemblage des tiges de liaison aux organes d'ancrage.

Dans un organe d'ancrage "polyaxial" existant à pion proximal fileté, l'articulation est réalisée en aménageant une sphère à l'extrémité du pion proximal fileté et une cavité dans ladite pièce de base, cette cavité recevant la sphère et étant refermée en partie proximale pour retenir cette sphère.

Dans un organe d'ancrage "polyaxial" existant à "tulipe", ladite pièce de base comprend une sphère autour de laquelle vient s'articuler la pièce de connexion en forme de "tulipe".

Ces types d'articulation ont pour inconvénient de ne permettre qu'un débattement limité du pion proximal fileté ou de la "tulipe", ce qui peut rendre difficile dans certains cas la mise en place d'une tige sur des organes d'ancrage. De plus et surtout, les mouvements du patient conduisent à des mouvements du pion proximal fileté ou de la "tulipe" par rapport à la pièce de base, qui génèrent des frottements répétés de la sphère contre la paroi venant en appui contre cette sphère. Il en résulte un risque de diffusion non souhaitable de particules de métal dans l'organisme, et ce d'autant plus que les surfaces qui frottent les unes contre les autres sont relativement importantes.

Par ailleurs, les matériels d'ostéosynthèse vertébrale existants sont destinés à immobiliser deux vertèbres l'une par rapport à l'autre, pour éliminer tout mouvement relatif de ces vertèbres, ou pour rétablir la position adéquate d'une vertèbre par rapport à l'autre. Pour l'obtention de cette immobilisation, ces matériels sont conçus de façon à assurer un assemblage parfaitement rigide des tiges de liaison avec les organes d'ancrage.

Cet assemblage rigide peut cependant ne pas être souhaitable dans tous les cas. Il conduit en particulier à l'exercice de sollicitations importantes au niveau des zones osseuses d'ancrage desdits organes d'ancrage, ainsi qu'à des sollicitations augmentées au niveau des articulations vertébrales situées de part et d'autre du segment vertébral traité, qui peuvent conduire à des dégénérescences de ces articulations. En outre, il n'est pas adapté à des traitements d'affections non dégénératives, notamment au traitement de scolioses chez des patients jeunes.

La présente invention vise à remédier à l'ensemble de ces inconvénients.

Son objectif principal est donc de fournir un matériel d'ostéosynthèse vertébrale comprenant au moins un organe d'ancrage polyaxial, dans lequel le pion proximal fileté ou la "tulipe" de cet organe d'ancrage a un débattement important par rapport à la pièce de base de l'organe d'ancrage destinée à être fixée à l'os, et dans lequel le risque de diffusion de métal dans l'organisme est nettement réduit par rapport à un matériel existant.

Un autre objectif de l'invention est de fournir un matériel d'ostéosynthèse vertébrale permettant un assemblage non rigide, voire souple, des tiges de

liaison avec les organes d'ancrage, avec un éventuel amortissement du mouvement des pièces mobiles.

Le matériel concerné comprend, de manière connue en soi, des organes d'ancrage osseux, tels que des vis pédiculaires, des pinces ou des crochets, une ou deux tiges de liaison, destinées à être reliées à ces organes d'ancrage et à être fixées aux vertèbres au moyen de ceux-ci, et des ensembles de connexion de cette ou ces tiges à ces organes d'ancrage, au moins un de ces organes d'ancrage étant du type "polyaxial", c'est-à-dire comprenant une pièce de connexion articulée par rapport à la pièce de base de l'organe d'ancrage destinée à être fixée à la vertèbre.

Selon l'invention, ladite pièce de connexion et ladite pièce de base comprennent chacune un passage transversal et une partie transversale rigide de direction sensiblement perpendiculaire à la direction dudit passage, ladite partie transversale rigide de l'une de ces pièces étant engagée dans le passage transversal de l'autre pièce, et réciproquement, avec possibilité de pivotement de ces parties transversales rigides dans ces passages.

La pièce de connexion articulée peut ainsi avoir un débattement très important, jusqu'à 180 degrés, alors que ce débattement n'excède pas 30 degrés dans un matériel existant. De plus et surtout, les deux parties transversales rigides ont des surfaces de contact mutuel réduites, limitant grandement les frottements au niveau de l'articulation. Cette limitation des frottements limite par conséquent dans une même mesure le risque de diffusion de particules métalliques dans l'organisme du patient.

Le terme "pièce de connexion" doit être compris dans une acception large : il peut en particulier s'agir d'un pion proximal fileté ou d'une pièce de connexion en forme de "tulipe" tels que décrit plus haut.

Ledit passage transversal et ladite partie transversale rigide d'une pièce peuvent notamment être réalisés en aménageant un anneau sur cette pièce, les deux anneaux des deux pièces étant engagés l'un dans l'autre à la manière de maillons d'une chaîne.

Ces passage transversal et partie transversale rigide peuvent également être aménagés sous forme de deux pattes latérales recevant un axe à travers

elles, ces pattes et axe délimitant ledit passage et ledit axe formant ladite partie transversale rigide.

Lesdits passages transversaux et parties transversales rigides peuvent être ajustés l'un à l'autre de la même façon que des maillons de chaîne ; de préférence toutefois, chaque partie transversale rigide présente une surface de contact arrondie avec l'autre partie transversale rigide, le rayon de courbure de cette surface de contact étant supérieur au rayon de la section de l'autre partie transversale rigide.

Cette surface de contact arrondie rend ainsi possible un mouvement de roulement d'une partie transversale rigide par rapport à ladite surface de contact de l'autre partie transversale rigide, limitant encore les frottements d'une partie transversale rigide sur l'autre.

Les parties transversales rigides peuvent venir directement au contact l'une de l'autre, ou l'organe d'ancrage peut comporter une pièce intermédiaire, interposée entre ces parties transversales rigides. Dans le premier cas, les parties transversales rigides peuvent être en un matériau dur à faible coefficient de friction, ou peuvent comporter un revêtement, ou avoir subi un traitement, leur permettant d'avoir une dureté élevée et un faible coefficient de friction au niveau de leurs zones de contact réciproques. Dans le deuxième cas, ladite pièce intermédiaire peut être elle-même en un matériau à dureté élevée et à faible coefficient de friction.

Cette pièce intermédiaire peut notamment être conformée de manière à être retenue entre les deux parties transversales rigides grâce à la forme que présentent ces parties transversales rigides.

Selon un autre aspect de l'invention, ledit organe d'ancrage de type "polyaxial" comprend au moins une pièce ou une partie de pièce à structure élastiquement déformable, placée, après montage, entre ladite pièce de connexion et ladite pièce de base, cette pièce ou partie de pièce à structure élastiquement déformable permettant une mobilité de la pièce de connexion, et donc de la tige de liaison, par rapport à la pièce de base, avec amortissement.

Ainsi, dans le matériel selon l'invention, ladite pièce de connexion n'est pas immobilisée par rapport à la pièce de base mais peut jouer vis-à-vis de

celle-ci, afin d'autoriser des mouvements limités des vertèbres. Les sollicitations exercées par l'organe d'ancrage sur les zones osseuses d'ancrage sont ainsi notablement réduites, de même que les risques de sur-sollicitations au niveau des articulations vertébrales situées de part et d'autre du segment vertébral traité.

La pièce de base peut comprendre une pièce à structure élastiquement déformable et la pièce de connexion peut comporter une autre pièce à structure élastiquement déformable, ces deux pièces venant porter l'une contre l'autre en position de montage.

Ladite pièce de connexion peut comporter une surface courbe d'appui, propre à venir en appui contre une surface courbe d'appui correspondante de ladite pièce de base et à glisser contre cette surface lors des mouvements de ladite pièce de connexion par rapport à ladite pièce de base. Notamment, ladite pièce de connexion peut comporter une surface périphérique convexe, en forme de calotte sphérique, et ladite pièce de base peut comporter une surface périphérique concave correspondante.

L'invention sera bien comprise, et d'autres caractéristiques et avantages de celle-ci apparaîtront, en référence au dessin schématique annexé, représentant, à titre d'exemples non limitatifs, deux formes de réalisation possibles de pièces que comprend le matériel qu'elle concerne.

La figure 1 est une vue de côté, avant montage, de pièces formant une vis pédiculaire polyaxiale conforme à l'invention, selon une première forme de réalisation ; cette figure montre également une tige de liaison, un étrier de connexion en coupe transversale, et deux écrous permettant d'assembler une tige de liaison à cette vis ;

la figure 2 est une vue desdites pièces similaire à la figure 1 mais selon une direction perpendiculaire à la vue selon la figure 1 ;

la figure 3 est une vue des pièces montrées par la figure 1, après montage ;

la figure 4 est une vue de côté, avant montage, de deux pièces permettant de former une vis pédiculaire polyaxiale conforme à l'invention, selon la deuxième forme de réalisation ;

la figure 5 est une vue de côté de deux pièces permettant de former la vis pédiculaire polyaxiale, en cours de montage, et

la figure 6 est une vue de côté de trois pièces permettant de former la vis pédiculaire polyaxiale, après montage.

Les figures 1 et 2 représentent une vis pédiculaire polyaxiale 1, une tige 2 de liaison de plusieurs de ces vis 1, un étrier 3 de connexion de cette tige 2 à une de ces vis 1 et deux écrous 4, 5 permettant d'assembler la tige de liaison 2 à cette vis 1.

La vis 1 comprend un pion proximal fileté 6 et un corps de vis distal fileté 7. Le pion 6 est destiné à recevoir l'étrier 3 engagé sur lui et les écrous 4, 5 vissés sur lui tandis que le corps 7 est destiné à être inséré dans le pédicule d'une vertèbre.

Le pion 6 présente une partie cylindrique filetée 10, un anneau distal 11 et une zone 12 de diamètre réduit, permettant de casser sa portion proximale après mise en place et serrage de l'écrou 5, comme cela apparaît par comparaison des figures 1 et 3.

Le corps 7 comprend une collerette proximale 15, pourvue d'un rebord périphérique 15a, cette collerette 15 délimitant ainsi un logement de réception d'une rondelle 16 en matériau à structure élastiquement déformable, notamment en silicone ou en PMMA. Cette rondelle 16 permet, après montage, un amortissement du mouvement du pion 6 par rapport au corps 7, comme cela sera décrit plus loin.

La collerette 15 présente également plusieurs encoches radiales 17, notamment quatre encoches à 90° les unes des autres, permettant le maintien du corps 7 en rotation pendant le serrage des écrous 4 et 5.

Le corps 7 comprend en outre une paroi cylindrique proximale 18, délimitant un alésage taraudé 19.

La vis 1 comprend également une rondelle filetée 20 et une pièce en forme d'oméga 21.

La rondelle filetée 20 comprend un trou central 22 permettant le passage du pion 6 et de l'anneau 11, et une rainure diamétrale inférieure 23.

La pièce en forme d'oméga 21 comprend une partie centrale 24 pouvant être engagée dans l'anneau 11 et pouvant être engagée dans le trou 22 de la

rondelle 20, et deux branches latérales 25 pouvant être reçues dans la rainure 23.

Comme cela se comprend, l'assemblage du pion 6 au corps 7 est réalisé en engageant la partie centrale 24 de la pièce 21 dans l'anneau 11, puis en engageant la rondelle 20 sur le pion 6 et l'anneau 11 jusqu'à introduction de ladite partie centrale 24 dans le trou 22 et desdites branches 25 dans la rainure 23, puis en vissant à bloc la rondelle 20 dans l'alésage taraudé 19. Pour son vissage, cette rondelle 20 comprend des cavités (non représentées) débouchant dans sa face proximale.

La rondelle 16 est ensuite mise en place sur la collerette 15, cette rondelle comprenant un trou central 26 permettant son engagement sur le pion 6 et l'anneau 11 et un embrèvement 27 recevant la paroi 18.

S'agissant des autres pièces montrées sur la figure 1, la tige de liaison 2 est cylindrique et présente une rigidité telle qu'elle permet le maintien de plusieurs vertèbres les unes par rapport aux autres. Cette tige 2 est toutefois déformable de manière à pouvoir être conformée en fonction de la correction du rachis à réaliser.

L'étrier 3 comprend une partie arrondie 30 destinée à entourer la tige de liaison 2 et deux ailes latérales parallèles 31 percées de trous pour l'engagement de l'étrier 3 sur le pion 6. Ces ailes 31 sont mutuellement distantes de telle sorte que, dans une position d'écartement, la tige 2 puisse être insérée et puisse coulisser dans la partie 30, et que, dans une position de rapprochement que leur confère le serrage de l'écrou 5, elles serrent la partie 30 autour de la tige 2, immobilisant cette dernière par rapport à l'étrier 3.

Comme le montre la figure 1, l'aile 31 proximale présente une cuvette proximale 35 de forme adaptée à la réception de l'écrou 4 sans appui axial, tandis que l'aile 31 distale comprend une paroi circulaire 36 formant un logement de réception d'une rondelle 37 à structure élastiquement déformable, notamment en silicone ou en PMMA, propre à coopérer avec la rondelle 16 pour amortir le mouvement du pion 6 par rapport au corps de vis 7.

L'écrou 4 comporte des encoches périphériques 38 pour sa manœuvre en rotation. Il est dimensionné pour prendre appui uniquement contre la branche 31 distale de l'étrier 3 lorsqu'il est serré.

L'écrou 5 est dimensionné pour prendre appui contre la branche 31 proximale de l'étrier 3 lorsqu'il est serré.

En pratique, le nombre de vis 1 nécessaire au traitement à réaliser est mis en place dans les pédicules des vertèbres concernées, puis les étriers 3, avec la tige 2 engagée dans les parties 30, sont placés sur les pions 6.

L'écrou 4 est ensuite serré de manière contrôlée, par exemple au moyen d'un tournevis dynamométrique, pour réaliser un plus ou moins fort serrage des rondelles 16 et 37, selon le degré de l'amortissement recherché en fonction des caractéristiques du patient (état des disques intervertébraux, degré d'instabilité vertébrale, poids), puis l'écrou 5 est serré pour rapprocher les branches 31 et serrer ainsi la tige 2 dans la partie 30 de l'étrier 3.

Chaque étrier 3 peut comprendre une graduation gravée sur lui aux abords de la cavité 35 et l'écrou 4 peut comprendre un repère gravé sur lui, ce repère coopérant avec cette graduation pour permettre le serrage contrôlé de l'écrou 4.

Les portions proximales des pions 6 sont ensuite sectionnées.

Les figures 4 à 6 représentent une deuxième forme de réalisation de l'invention. Les pièces ou parties se retrouvant de manière identique ou similaire sont désignées par les mêmes références numériques.

Dans cette deuxième forme de réalisation, le corps de vis 7 comprend un anneau fixe 24, et l'anneau 11 se termine, du côté proximal, par deux branches 11a venant au contact l'une de l'autre. Les portions d'extrémité de ces branches 11a ont une forme hémi-cylindrique et sont filetées de manière à former, dans cette position de contact, un filet continu.

Le pion 6 comprend, quant à lui, un alésage taraudé 40 débouchant dans sa face distale.

Ainsi que le montre la figure 5, les deux branches 11a peuvent être écartées par déformation élastique de l'anneau 11 pour permettre l'engagement de l'anneau 24 à l'intérieur de l'anneau 11. Une fois cet

engagement réalisé, les deux branches 11a viennent à nouveau en contact et l'anneau 11 peut être vissé et bloqué dans l'alésage 40.

Comme cela apparaît de ce qui précède, l'invention fournit un matériel d'ostéosynthèse vertébrale dans lequel le pion 6 a un débattement important par rapport au corps 7, et dans lequel le risque de diffusion de métal dans l'organisme est nettement réduit par rapport à un matériel existant, compte tenu des surfaces de contact réduites qu'ont les anneaux 11 et 24.

L'invention fournit également un matériel d'ostéosynthèse vertébrale permettant un assemblage non rigide des tiges de liaison 2 avec les organes d'ancrage 1.

Il va de soi que l'invention n'est pas limitée à la forme de réalisation décrite ci-dessus à titre d'exemple mais qu'elle s'étend à toutes les formes de réalisations couvertes par les revendications ci-annexées.

En particulier, le terme "anneau" doit être compris dans une acception la plus large, comme étant une partie d'assemblage définissant une ouverture et une zone de jonction, la zone de jonction d'un anneau pouvant être engagée dans l'ouverture de l'autre anneau et réciproquement, de telle sorte que les zones de jonction des deux anneaux puissent prendre appui l'une contre l'autre et assembler ladite pièce de base à ladite pièce de connexion (pion proximal fileté ou "tulipe").

Ainsi, l'on ne sortirait pas du cadre de l'invention :

- en réalisant l'un des deux anneaux ouverts, pour permettre l'interpénétration des deux anneaux, puis en refermant l'anneau ouvert, notamment en réalisant un soudage de cet anneau à la pièce qui le comporte ;
- en réalisant l'un des deux anneaux ouverts, ou les deux anneaux ouverts ;
- en réalisant l'un des deux anneaux sous forme d'une chape recevant une goupille.

Le terme "pièce de connexion articulée" doit également être compris dans une acception large : il peut s'agir d'un pion proximal fileté 6 tel que décrit plus haut ou d'une pièce de connexion en forme de "tulipe", présentant un logement dans lequel une tige de liaison 2 peut être engagée.

REVENDICATIONS

1 – Matériel d'ostéosynthèse vertébrale, comprenant des organes d'ancrage osseux, tels que des vis pédiculaires (1), des pinces ou des crochets, une ou deux tiges de liaison (2) destinées à être reliées à ces organes d'ancrage et à être fixées aux vertèbres au moyen de ceux-ci, et des ensembles de connexion (6, 3) de cette ou ces tiges (2) à ces organes d'ancrage, au moins un de ces organes d'ancrage (1) étant du type "polyaxial", c'est-à-dire comprenant une pièce de connexion (6) articulée par rapport à la pièce de base (7) de l'organe d'ancrage (1) destinée à être fixée à la vertèbre ;

matériel caractérisé en ce que ladite pièce de connexion (6) et ladite pièce de base (7) comprennent chacune un passage transversal et une partie transversale rigide (11, 24) de direction sensiblement perpendiculaire à la direction dudit passage, ladite partie transversale rigide (11, 24) de l'une de ces pièces (6, 7) étant engagée dans le passage transversal de l'autre pièce (7, 6), et réciproquement, avec possibilité de pivotement de ces parties transversales rigides (11, 24) dans ces passages.

2 – Matériel selon la revendication 1, caractérisé en ce que ledit passage transversal et ladite partie transversale rigide (11, 24) d'une pièce (6, 7) sont réalisés en aménageant un anneau (11, 24) sur cette pièce (6, 7), les deux anneaux (11, 24) des deux pièces (6, 7) étant engagés l'un dans l'autre à la manière de maillons d'une chaîne.

3 – Matériel selon la revendication 1 ou la revendication 2, caractérisé en ce que chaque partie transversale rigide (11, 24) présente une surface de contact arrondie avec l'autre partie transversale rigide (24, 11), le rayon de courbure de cette surface de contact étant supérieur au rayon de la section de l'autre partie transversale rigide (24, 11).

4 – Matériel selon la revendication 1 ou la revendication 2, caractérisé en ce que l'organe d'ancrage comporte une pièce intermédiaire, interposée entre lesdites parties transversales rigides (11, 24).

5 – Matériel selon la revendication 3 ou la revendication 4, caractérisé en ce que les parties transversales rigides sont en un matériau dur à faible coefficient de friction, ou comportent un revêtement, ou ont subi un traitement, leur permettant d'avoir une dureté élevée et un faible coefficient de friction au

niveau de leurs zones de contact réciproques, ou en ce que ladite pièce intermédiaire est elle-même en un matériau à dureté élevée et à faible coefficient de friction.

6 – Matériel selon la revendication 4 ou la revendication 5, caractérisé en ce que ladite pièce intermédiaire est conformée de manière à être retenue entre les deux parties transversales rigides grâce à la forme que présentent ces parties transversales rigides.

7 – Matériel selon l'une des revendications 1 à 6, caractérisé en ce que ledit organe d'ancrage (1) de type "polyaxial" comprend au moins une pièce (16, 37) ou une partie de pièce à structure élastiquement déformable, placée, après montage, entre ladite pièce de connexion (6, 3) et ladite pièce de base (7), cette pièce (16, 37) ou partie de pièce à structure élastiquement déformable permettant une mobilité de la pièce de connexion (6, 3), et donc de la tige de liaison (2), par rapport à la pièce de base (7), avec amortissement.

8 – Matériel selon la revendication 7, caractérisé en ce que ladite pièce de base (7) comprend une pièce (16) à structure élastiquement déformable et ladite pièce de connexion (3) comporte une autre pièce (37) à structure élastiquement déformable, ces deux pièces (16, 37) venant porter l'une contre l'autre en position de montage.

9 – Matériel selon l'une des revendications 1 à 6, caractérisé en ce que ladite pièce de connexion comporte une surface courbe d'appui, propre à venir en appui contre une surface courbe d'appui correspondante de ladite pièce de base et à glisser contre cette surface lors des mouvements de ladite pièce de connexion par rapport à ladite pièce de base.

10 – Matériel selon la revendication 9, caractérisé en ce que ladite pièce de connexion comporte une surface périphérique convexe, en forme de calotte sphérique et ladite pièce de base comporte une surface périphérique concave correspondante.

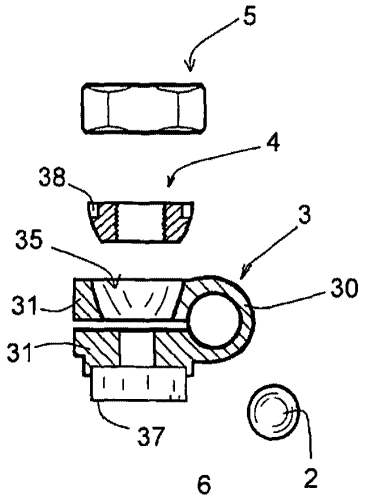


FIG. 4

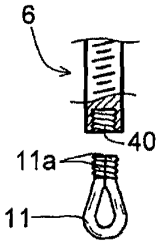


FIG. 5

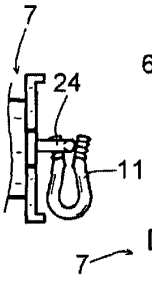
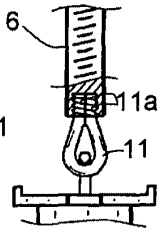
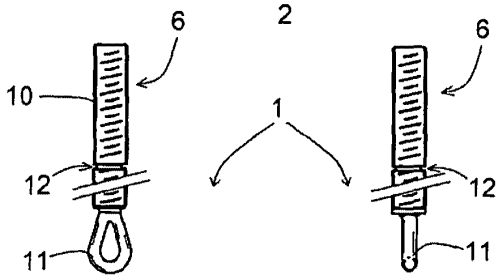


FIG. 6





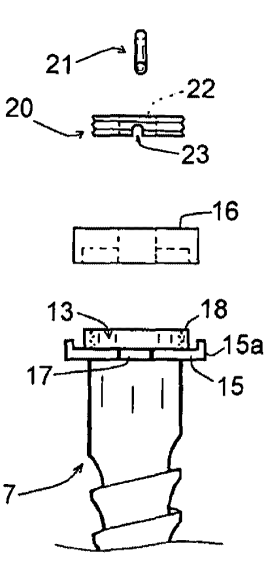


FIG. 1

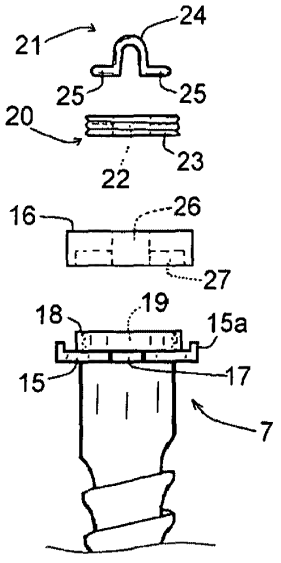


FIG. 2

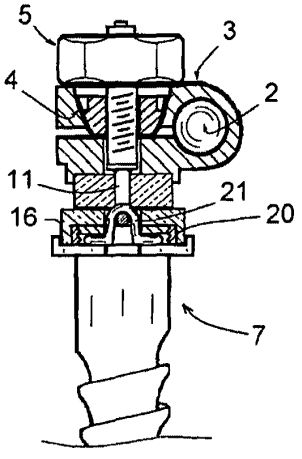


FIG. 3

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INSTITUT NATIONAL DE LA PROPRIETE INDUSTRIELLE

RAPPORT DE RECHERCHE PRÉLIMINAIRE

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

N° d'enregistrement national

FA 644060
FR 0400743

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		
A	US 5 242 446 A (JANSON FRANK S ET AL) 7 septembre 1993 (1993-09-07) * colonne 2, ligne 16 - ligne 21 * * colonne 3, ligne 13 - ligne 23; figure 5 *	1-3	A61B17/70
A	WO 01/60271 A (DICKERSON RICHARD P ; ELECTRO BIOLOGY INC (US); SHAH GRETCHEN DOUGHERT) 23 août 2001 (2001-08-23) * figures 6,7a *	1	
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A	EP 0 582 857 A (SYNTHES AG) 16 février 1994 (1994-02-16) * abrégé; figure 1 *	1	
			DOMAINES TECHNIQUES RECHERCHÉS (Int.CL.7)
			A61B

Date d'achèvement de la recherche	Examinateur
7 septembre 2004	Ducreau, F

CATÉGORIE DES DOCUMENTS CITÉS

X : particulièrement pertinent à lui seul
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A : arrière-plan technologique
O : divulgation non-écrite
P : document intercalaire

T : théorie ou principe à la base de l'invention
E : document de brevet bénéficiant d'une date antérieure à la date de dépôt et qui n'a été publié qu'à cette date de dépôt ou qu'à une date postérieure.
D : cité dans la demande
L : cité pour d'autres raisons

& : membre de la même famille, document correspondant

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EPO FORM 1503 12.99 (P04C14)

ANNEXE AU RAPPORT DE RECHERCHE PRÉLIMINAIRE
RELATIF A LA DEMANDE DE BREVET FRANÇAIS NO. FR 0400743 FA 644060

La présente annexe indique les membres de la famille de brevets relatifs aux documents brevets cités dans le rapport de recherche préliminaire visé ci-dessus.
Les dits membres sont contenus au fichier informatique de l'Office européen des brevets à la date du 07-09-2004
Les renseignements fournis sont donnés à titre indicatif et n'engagent pas la responsabilité de l'Office européen des brevets, ni de l'Administration française

Document brevet cité au rapport de recherche		Date de publication	Membre(s) de la famille de brevet(s)		Date de publication
US 5242446	A	07-09-1993	AUCUN		
WO 0160271	A	23-08-2001	AU	7207101 A	27-08-2001
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Pour tout renseignement concernant cette annexe : voir Journal Officiel de l'Office européen des brevets, No.12/82

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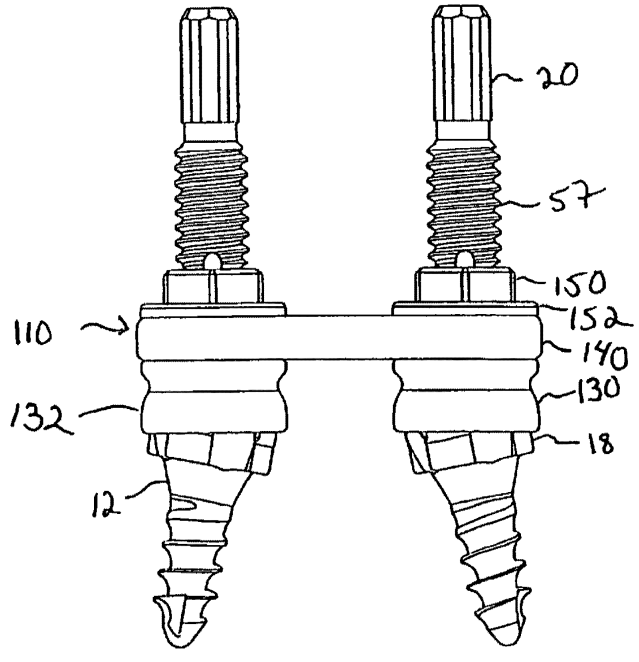
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[Continued on next page]

(54) Title: POSTERIOR POLYAXIAL SYSTEM FOR THE SPINE



(57) Abstract: The invention provides a rod assembly for implantation into the spine which includes a bone anchor assembly providing two points of angulation for the connection between the point of fixation and the rod. Further, the distance of offset between the point of fixation and the rod can be varied. The invention uses a bone screw having a pronged cage with a recess that accommodates the head of a post member. The cage can be tightened around the head by the camming surfaces of a locking cap that is drawn down around the compressible cage as the head is screwed upward in the recess by the engagement of the threads of the post by a locking nut. Further, the locking cap has a slotted bushing that is positionable in the elongated slot of a rod connector member. The locking nut includes an external taper that expands the bushing outward to lock it into position in the slot. In a further embodiment, the head has an internal hollow that receives a spindle journaled in a cavity in the recess to limit the amount of play in the assembly prior to tightening. In a further embodiment, the connection between bone anchors is provided by a plate that has locking caps pre-assembled into the plate.

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POSTERIOR POLYAXIAL SYSTEM FOR THE SPINE

THIS PATENT APPLICATION IS A CONTINUATION-IN PART APPLICATION BASED UPON A U.S. APPLICATION FILED FEBRUARY 7, 2003 AND CLAIMING PRIORITY TO PROVISIONAL APPLICATION SERIAL NO. 60/356,996, FILED 02/13/02

The invention relates to an implant for the spine. In particular, the invention relates to a construct based on a rod which is held in a posterior relation to the spine using a multi-component bone anchor that includes multiple joints in order to achieve multiple degrees of freedom that can when desired be locked in a particular axial alignment. In a further embodiment, the invention relates to a plate and locking cap assembly that is provided in a pre-assembled state to span several vertebrae.

BACKGROUND OF THE INVENTION

Constructs have been designed for some time for implantation in the spine which generally include a series of bone fasteners, such as hooks or screws, that are secured to the vertebrae, and which are used to hold stabilizer means such as a rod or plate that spans several vertebrae for stabilization, fixation, and/or for alignment of the vertebrae.

Typically, a spinal rod assembly includes two sets of rods that are fixed to adjacent vertebrae on either side of the spinous process to span a section of spine. The bone anchors may include a number of fixation means, such as screws or hooks, which are used for fixation to the spine, and anchor means, such as rod anchors that includes means to secure the rod to the fixation means. In some systems these component parts are a single integral unit, while other systems utilize a number of assembled components such as for the anchor portion of the assembly.

There are a number of considerations which go into the design of the assembly. The constructs need to be relatively easy to assemble, to be safe for the area of implantation, to provide for flexibility of use to accommodate a number of different indications for implantation and for variations in individuals who require their use, to be strong, yet minimally invasive and low profile, to be useful for manipulation, as well as for the maintenance of the desired alignment of the spine.

SUMMARY OF THE INVENTION

The present invention provides a multi-component bone anchor for use primarily with a rod in any area of the spine. The anchor includes multiple joints in order to provide many degrees of freedom by providing two selectively variable axes of alignment for the fixation assembly which

can however, be easily locked to form a solid (i.e. fixed) point of fixation in the bone.

The invention has a bone screw with a concavely rounded interior surface formed within a cage (i.e. a compressible open recess having a series of resilient prongs) that receives the convexly rounded exterior surface of a post member, preferably to form a ball and socket, or more preferably a partial ball and socket type cooperation to define the first variable axis of rotation. A locking cap cooperates with a screw rod connector to form the second point of rotation for the second axis. The inwardly curving inner surface of the locking cap is preferably slightly smaller (i.e. relative to normal tolerances) than the corresponding top tapering surface of the cage so that it may act as a camming surface against the outwardly tapering camming surface defined by the pronged portion of the cage. A locking nut is screwed onto the post to cause locking of both the locking cap in the screw rod connector and of the cage in the locking cap as the post is drawn upward. Thus, a single locking step causes both axes of rotation to become fixed to make the construct more rigid in the bone.

More specifically, the system includes a bone screw having a pronged cage that retains the rounded and preferably hemi-spherical head of a post member. The bottom of the post head has a concave recess or dimple that engages a resilient spindle member captured in a recess at the bottom of the cage. The spindle member biases the post member upward against the inside of the restraining prongs of the cage. The post head has an upper rounded camming surface that urges the prongs outward to allow the post to be snap fit into place in the cage for assembly and also as a locking mechanism. The interior surface of the cage is slightly smaller than the outer diameter of the post head to ensure a fit which can be locked in place by compression by the downward action of the locking cap. Also the outer surface of the cage prongs collectively taper outwardly along the vertical axis of the screw to form a camming surface with the tapered (i.e. conical or curved) interior recess of the locking cap. Again, the locking cap interior surface has a slight corresponding taper to cause the cage to be biased inward and downward against the top surface of the post head engagement member as the post is screwed upward in relation to the locking cap. The locking cap has a slotted bushing that engages an elongated slot in a screw rod connector, which may also have an interior curve which mates with an exterior curve of the bushing to allow movement transverse to the rod axis as well as optionally at a variable angle. The screw rod connector includes a channel or recess for the rod which allows it to be offset from the point of fixation. The amount of offset is determined by the position of the

locking cap in the rod connector slot. A locking nut has a bottom portion along a through bore with interior threads and a tapered exterior surface which increases in diameter towards the top. The top portion is a slightly larger head which includes an exterior hex driving surface, such as a hexagon shape. The interior threads of the hex headed locking nut engage the exterior threads on the post head, upward of the post engagement member. As the locking nut is screwed downward on the post, the taper biases the slotted bushing of the locking cap outward to lock it into place within the rod-connector slot. The post engagement member is drawn upward and locked into position against the prongs of the screw cage, which are in turn captured between the engagement member and the interior recess of the locking cap. The top portion of the post also has an external hex in order to allow the system to be tightened by turning the nut relative to the post while the post is held in a fixed position. In some cases, the surgeon may even decide to refrain from tightly locking the nut against the post member in order to retain some of the play of the fixation assembly which still acts as a tether and to accept some of the loading of the rod.

The proposed product is unique in allowing multiple degrees of freedom prior to tightening. The angle of the post can be varied about a first center of rotation with respect to the screw. The angle of the screw can be varied about a second center of rotation with respect to the locking cap which is secured in the slot in the screw-rod connector. The location of the locking cap in the slot of the screw-rod connector can also be varied.

In a further embodiment, a plate is used in place of the rod as the longitudinal stabilizer. The plate includes slotted apertures that each includes a locking cap which fits down over the post and onto the exterior surface of the screw. The caps are press fit from the bottom into the plate. In this instance, the locking nut includes a flanged area, or a washer that fits over the top of the locking cap and abuts the top surface of the plate in the vicinity of the flange.

OBJECTS OF THE INVENTION

It is an object of the invention to provide a bone anchor assembly that allows multiple degrees of freedom within defined parameters during surgical implantation and assembly and subsequent locking with an easy mechanism. These degrees of freedom include one or more of a variable angle for the bone screw relative to the rod axis, a variable angle for the bone screw connector relative to the rod axis, a variable amount of offset relative to the rod axis, and a variable height of the screw rod connector

through the amount of tightening. Moreover, the construct allows for multiple ranges of movement after assembly, but prior to tightening, where all of theses can be locked by a single locking or tightening mechanism. It is an additional object to provide an additional method of stabilizing the vertebrae in a manner that permits ease of assembly.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is end view of the rod anchor assembly in accordance with the present invention;

Figure 2 is an exploded assembly view taken 90 degrees from Figure 1;

Figure 3 is a top view of the assembly of Figure 1;

Figure 4 is a cross-section of the assembly taken along line 4-4 of Figure 1;

Figure 5 is a cross-section showing an alternative embodiment of the invention;

Figure 6 is a oblique perspective of an alternative embodiment of the screw using a stabilizer plate having preassembled locking caps in the plate;

Figure 7 is a side view of the embodiment of Figure 6;

Figure 8 is a top view of the embodiment of Figure 7;

Figure 9 is a cross-sectional view of the view of Figure 7;

Figure 10 is a top view of the plate and cap assembly shown in Figure 6; and

Figure 11 is a side perspective view of the plate and cap assembly shown in Figure 10.

Detailed Description of the Invention

The present invention provides a spinal implant assembly including a rod which is preferably not a threaded rod, and which is not shown, but which is held in position relative to the spine by a series of bone anchor assemblies as shown generally at 10 in Figure 1. Specifically, the bone anchor assembly 10 includes a fixation member which comprises a bone screw 12 having a threaded lower portion which has a fluted area 14 and a suitable thread, such as a cancellous thread 16. The top of the bone screw 12 includes a receptacle such as a cage 18 for a post member 20. The cage comprises a plurality of resilient prongs 21 that are constructed by forming slots 22 in the top of the cage. At the top the prongs terminate to form a circular opening with a small bevel 25 to the top which is slightly smaller in diameter than the diameter of the engagement head 23. These prongs 21can be deformed outward for the insertion of the engagement head of the screw, or inwardly for a compressive locking of the engagement head in a recess 24 which is shown as a spherical recess that receives the outwardly rounded engagement head 23 of the post member 20. Again the engagement head is shown as a sphere or in a second embodiment as a modified sphere. However, the top portion of the sphere of the engagement head 23 may preferably be slightly larger than the inner recess or cavity 24 of the cage.

The prongs also collectively have an outer surface 26 that tapers inward toward the central longitudinal axis of the screw and anchor assembly so that the bone screw has a pear type shape. A locking cap 30 has a through bore so that it can be fitted over the post member 20. The lower portion of the locking cap 30 forms a skirt 32 that has an upwardly tapered surface 34 on the inside. This can be a curving surface or a conical surface, but in any case, it is slightly smaller than the outer surface 26 of the prongs so as to enable a compressive contraction of the prongs 21 inward about the head of the engagement member 23. At the top, the locking cap includes a bushing 36 that may include a rounded surface 38 which mates with the elongated slot 42 in a flanged area of a screw rod connector 40. The slot may also include a corresponding inner rounded contour to allow the bone anchor assembly to be positioned at a variable angle, as well as at a variable distance of offset from the longitudinal axis of the stabilization rod. The rod is received in a channel 39 and secured in position by means such as a set screw which is received in the threaded recess 44 of the screw rod connector. The bushing 36 of the locking cap also includes a plurality of slots 37 that allow the bushing to be expanded outwardly against the sides of the slots 42 of the screw rod connector so that it may be locked in position.

The bone anchor assembly further includes a locking nut 50 having a tapered lower portion 52 and a torque receiving head 54 and an internal threaded throughbore. The lower portion 52 has a terminal bevel 56 that can be received in the terminal beveled opening 58 at the top of the bushing 36. The lower portion also includes a tapered portion 52 having an outer diameter which is slightly larger than the inner diameter of the bore on the inside of the bushing.

The post member includes a threaded portion 57 that mates with the internal threads on the locking nut 50. Specifically, before the assembly is locked, there are two points of axial angulation: A, which corresponds to the angulation of the post engagement head in the cage of the bone screw, and B, which corresponds to the angulation of the locking cap in the slot. However, both of these angles can be locked by the same locking mechanism. When the locking nut is tightened on the post member, the post member is drawn up against the inner recess of the cage which is drawn up in a tight contact with the locking cap. At the same time, the locking nut is drawn down into the bushing of the locking cap which expands to lock the cap in the slot of the screw rod connector.

The top of the post has a hexagon shape to allow it to be held during tightening. However, this top can subsequently be sheared off.

The embodiment shown in Figure 5 is a preferred modification wherein the bottom portion of the engagement head 23 is contoured, to form a hollow recess 70 that is pressed upward by a resilient spindle member 72 which is captured in a cavity 74 in the cage. In this embodiment, the post member retains its ability to be variably angled in the cage, but it is biased outward against the cavity of the cage so that it is more apt to stay in a position in the cage before it is tightened (i.e. it is less apt to flop.)

A construct generally includes two rods on either side of the spinous process, and a series of bone anchor assemblies implanted in adjacent vertebrae. The assembly may also include other components, such as for example, plates, transverse connectors, cables, and hooks. The implants may be made of suitable implantable biocompatible materials, such as stainless steel and titanium, as well as ceramics, and composite materials.

The embodiment shown in Figures 6-11 includes many components parts that are substantially similar, if not identical, to those shown in the

first five Figures. In particular, the assembly 110 includes at least two, and even three, or more bone screws 12 which each have the cage 18 that acts as a receptacle for the post member 20. The post includes the ball which is received in the cage, and the post further includes a threaded portion 57 that mates with a hexagonal locking nut 150. The locking nut has a flanged area 152 which tightens down onto the plate, or alternatively, a separate washer can be provided. The screws are connected by means of a screw connector 140 which forms part of the plate assembly 120. The plate assembly includes the screw connector, which is a plate having several apertures 142 that are longer in length along the longitudinal axis of the plate than the diameter of the bushing 136 of the locking cap 130. This allows some play in the placement of the cap with respect to the plate. This in turn facilitates assembly onto the posts of the screw assembly. The locking cap includes a skirt 132 which functions as previously described. The caps 130 are press fit into the slots 142 prior to the assembly with the screw, and preferably prior to surgery.

While in accordance with the patent statutes the best mode and preferred embodiment have been set forth, the scope of the invention is not limited thereto, but rather by the scope of the attached claims.

WHAT IS CLAIMED IS:

1. A spinal implant comprising a rigid elongated stabilizer, and a plurality of bone anchor assemblies, said bone anchor assemblies comprising at least one assembly having a fixation means defining an axis and having a recess about this axis, said recess receiving the head of a post member and having a mating interface so that the head is variably positionable within the recess, the recess being compressible about the head to lock it into position, and the post member being connected to the elongated stabilizer.

2. A spinal implant as set forth in claim 1 wherein the bone anchor assembly further includes a locking cap having an internal camming surface and said fixation member having an external surface which cooperates with the camming surface to cause locking of the post member relative to the fixation member.

3. A spinal implant as set forth in claim 2 wherein the connection between the stabilizer and the post includes a slot and the locking cap includes a bushing and the bushing is received in the slot of the connector.

4. A spinal implant as set forth in claim 3 wherein the bushing includes means to lock the position of the bushing in the slot.

5. A spinal implant as set forth in claim 4 wherein the bushing includes a bore defining an internal surface and the bushing has one or more slots and the means to lock the position of the bushing in the slot is a locking nut having an external taper which cooperates with the internal surface of the bore to expand the bushing.

6. A spinal implant as set forth in claim 5 wherein the post member has external threads which receive the locking nut.

7. A spinal implant as set forth in claim 1 wherein the head is locked into position by drawing the head of the post member into the recess to cause a compression fit.

8. A spinal implant as set forth in claim 7 wherein the anchor includes a locking cap having an internal recess that receives the external portion of the fixation means defining the surface and which causes the head to be locked in position in the recess.

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9. A spinal implant as set forth in claim 8 wherein the recess is formed as a cage having a plurality of resilient prongs.

10. A spinal implant as set forth in claim 1 wherein the recess and head form a ball and socket joint.

11. A spinal implant as set forth in claim 10 wherein the head includes a hollow that mates with a spindle in the recess to allow limited variable positioning of the head in the recess.

12. A spinal implant as set forth in claim 2 wherein the internal camming surface is concave.

13. A spinal implant as set forth in claim 2 wherein the external surface of the fixation member is convex.

14. A spinal implant as set forth in claim 1 wherein the stabilizer is a plate.

15. A spinal implant as set forth in claim 1 wherein the stabilizer is a rod and the connection between the rod and the plate includes a connector.

16. A spinal rod assembly as set forth in claim 15 wherein the rod has a longitudinal axis and the anchor defines a longitudinal axis and there is an offset between the longitudinal axis of the rod and the longitudinal axis of the anchor and further wherein the distance of offset between the point of fixation and the rod can be varied.

17. A spinal rod assembly as set forth in claim 16 wherein the angle between the axis of the anchor and the axis of the rod, and also the distance of the offset can be selectively locked by a single mechanism.

18. A spinal rod assembly as set forth in claim 17 wherein the single mechanism comprises the engagement of one set of threads by a mating set of threads.

19. A spinal rod assembly as set forth in claim 18 wherein one set of threads is included on a cap member which is screwed downward toward the point of fixation.

20. A spinal implant as set forth in claim 10 wherein the socket of the ball and socket joint further includes a top portion which is compressible about the ball of the ball and socket joint to lock it into position.

21. A spinal rod implant as set forth in claim 20 wherein the ball and socket joint includes a cap which compresses the top portion of the socket to lock it into position.

22. A spinal rod implant as set forth in claim 21 wherein the joint includes a post which terminates in the ball of the ball and socket joint, and the post has a portion which includes threads and further wherein the cap has threads which mates with the threads of the post to lock the cap.

23. A spinal rod implant as set forth in claim 22 wherein the cap includes a bushing and the joint includes a connector that has a slot that engages the bushing.

24. A spinal rod implant as set forth in claim 23 wherein the bushing is locked in the slot by tightening the cap on the threads of the post.

25. A spinal rod implant as set forth in claim 10 wherein the ball portion of the ball and socket joint is mounted on a spindle in the socket portion of the ball and socket joint.

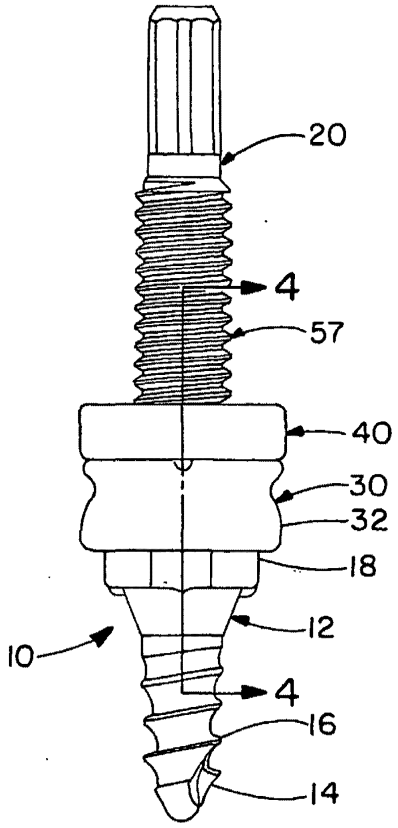

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FIG.-1

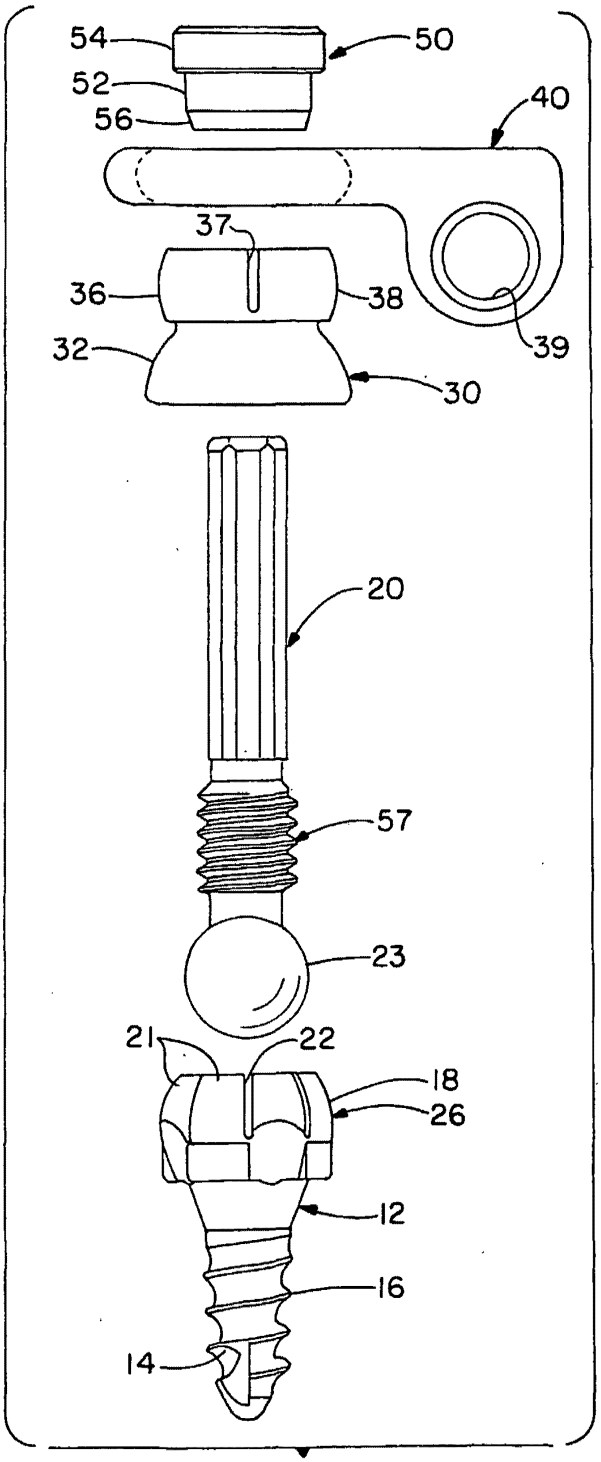
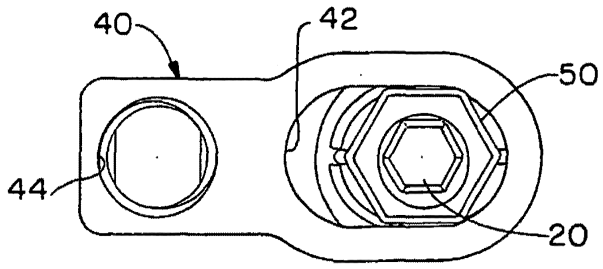

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FIG.-2

FIG.-3



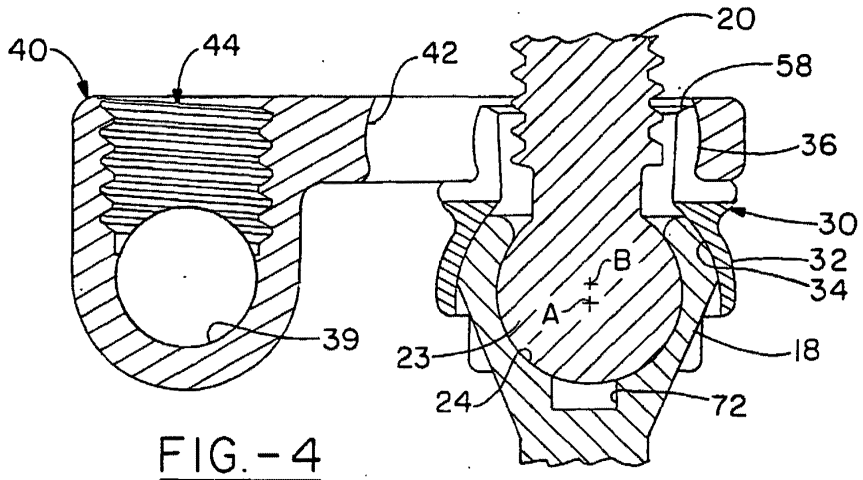


FIG.-4

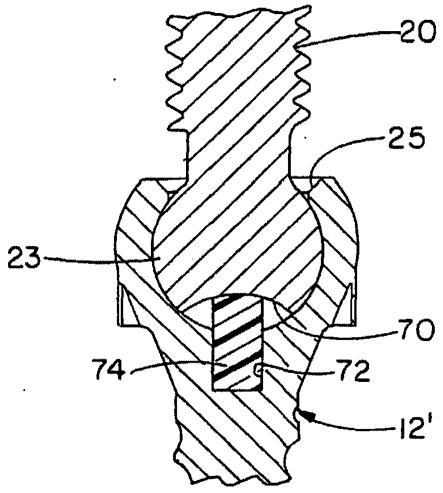


FIG.-5

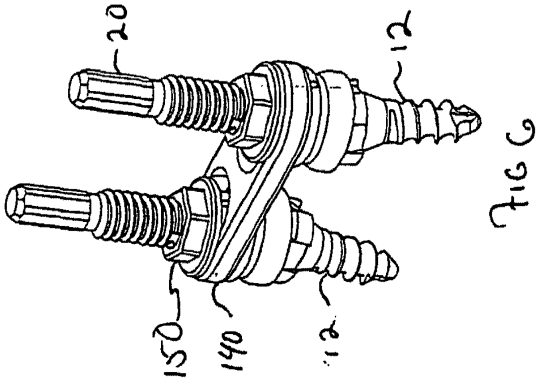


FIG 6

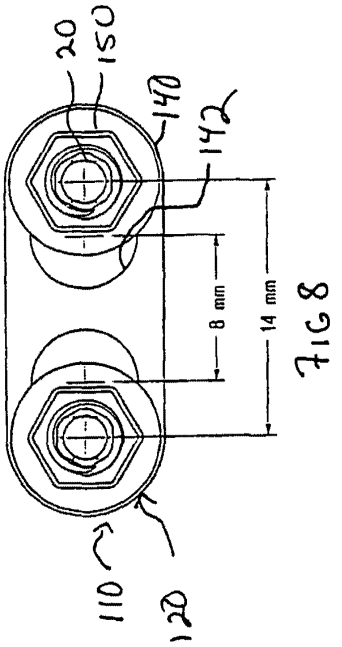


FIG 8

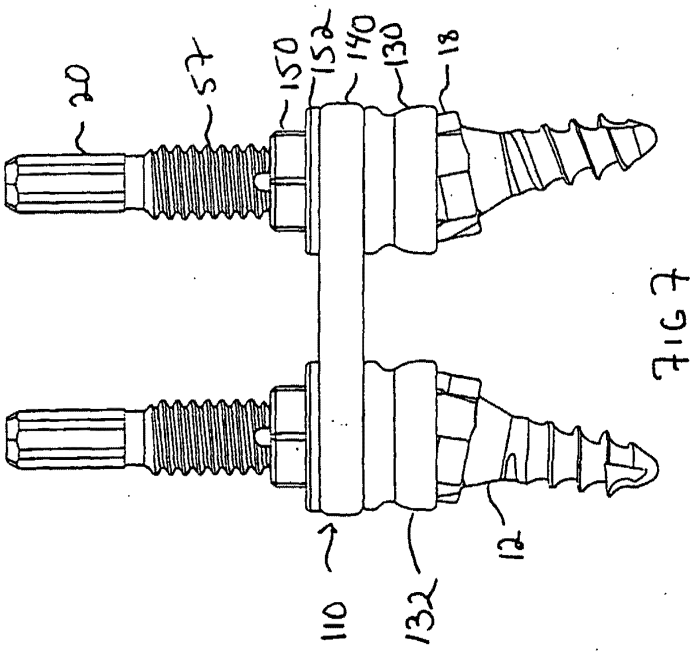


FIG 7

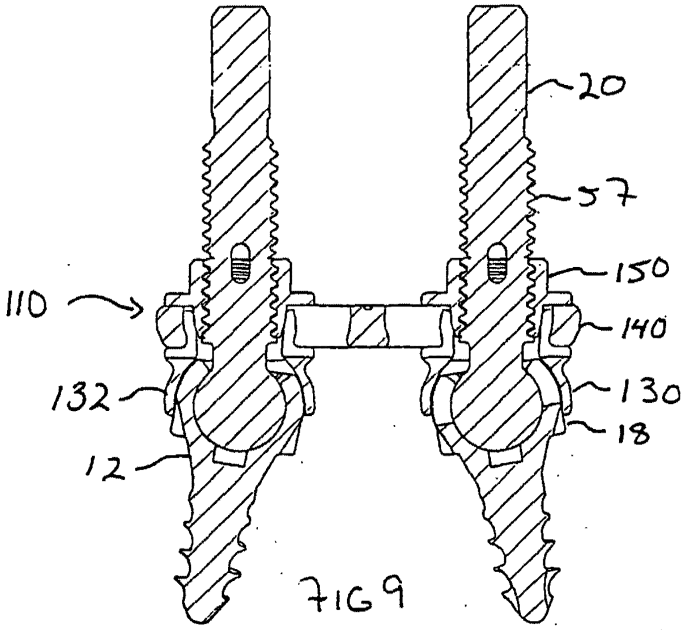


FIG 9

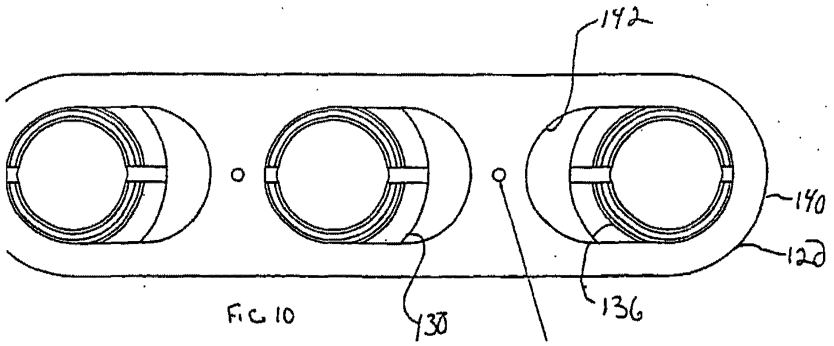


FIG 10

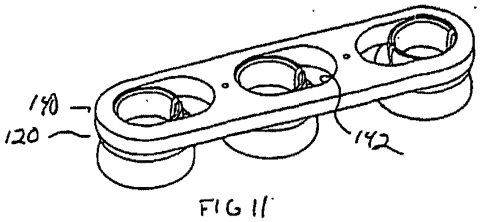


FIG 11

INTERNATIONAL SEARCH REPORT

Int onal Application No
PCT/US 03/04040

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/70

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 7 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 6 050 997 A (MULLANE THOMAS S) 18 April 2000 (2000-04-18) abstract; claim 1; figure 1.3.14 ---	1-4,6-8, 10,12, 13,15-20
A	EP 1 090 595 A (STRYKER SPINE SA) 11 April 2001 (2001-04-11) abstract; claims 2-6; figures 1,12,22 ---	1,7-9,15
A	DE 198 07 827 A (DEUTSCH ZENTR LUFT & RAUMFAHRT) 26 November 1998 (1998-11-26) abstract; figures 1A-1C column 2, line 65 -column 3, line 13 column 5, line 3-12,42-56 --- -/--	1,6,7, 10,12-14

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

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'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)

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Date of the actual completion of the international search	Date of mailing of the international search report
21 May 2003	03/06/2003

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	Macaire, S

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INTERNATIONAL SEARCH REPORT

Int. ional Application No
PCT/US 03/04040

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 ;BRACE MICHAEL (US); SYNTHES USA (US); LANGE ERIC (US)) 23 March 2000 (2000-03-23) abstract; claims 11-13; figures 2,11,15	1,2,9, 10,15
A	WO 01 22893 A (BLACKSTONE MEDICAL INC) 5 April 2001 (2001-04-05) abstract; claim 1; figure 1 page 10, line 2-18	1,15

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Int ional Application No
PCT/US 03/04040

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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INSTITUT NATIONAL
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PARIS

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(12) DEMANDE DE BREVET D'INVENTION A1

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(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) :** *MEDICREA Société anonyme* — FR.

(72) **Inventeur(s) :** CLEMENT JEAN LUC, FIERE VINCENT, TAYLOR JEAN, ADAM YVES et VILLARET BERNARD.

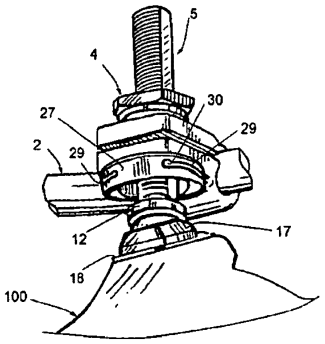
(73) **Titulaire(s) :**

(74) **Mandataire(s) :**

(54) MATERIEL D'OSTEOSYNTHESE VERTEBRALE.

(57) Ce matériel comprend des organes d'ancrage osseux, une ou deux tiges de liaison (2), et des pièces de connexion (3) de cette ou ces tiges (2) à ces organes d'ancrage, au moins un de ces organes d'ancrage étant du type "polyaxial".

Selon l'invention, ledit organe d'ancrage polyaxial (1) comprend au moins une pièce ou une partie de pièce (27) à structure élastiquement déformable, interposée, après montage, entre ladite pièce de connexion (3) et la partie (6) de l'organe d'ancrage destinée à venir en prise avec une vertèbre, cette pièce ou une partie de pièce (27) à structure élastiquement déformable permettant une mobilité de la pièce de connexion (3), et donc de la tige de liaison (2), par rapport à la partie (6) de l'organe d'ancrage destinée à venir en prise avec une vertèbre, avec amortissement.



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La présente invention concerne un matériel d'ostéosynthèse vertébrale.

Un matériel d'ostéosynthèse vertébrale comprend généralement des organes d'ancrage osseux, tels que des vis pédiculaires ou des crochets lamaires, une ou deux tiges de liaison, destinées à être reliées à ces organes d'ancrage et à être fixées aux vertèbres au moyen de ceux-ci, et des pièces de connexion de cette ou ces tiges de liaison à ces organes d'ancrage. Le matériel peut également comprendre des traverses réglables en longueur, qui relient transversalement deux tiges de liaison parallèles pour maintenir ces tiges l'une par rapport à l'autre.

Dans un type de matériel existant, chaque organe d'ancrage comprend un pion proximal fileté sur lequel peut être vissé un écrou, et chaque pièce de connexion comprend une partie arrondie destinée à entourer une tige de liaison et deux ailes parallèles percées de trous. Ces ailes sont destinées à être engagées sur ledit pion proximal fileté et à être serrées, au moyen de cet écrou, contre une surface d'appui aménagée sur l'organe d'ancrage, ce serrage provoquant le serrage de ladite partie arrondie autour de la tige de liaison et assurant ainsi l'immobilisation longitudinale de cette tige par rapport à l'organe d'ancrage. Les organes d'ancrage peuvent être de type "monoaxial", c'est-à-dire comprendre un pion proximal fileté solidaire de la partie de l'organe d'ancrage destinée à venir en prise avec l'os, ou peuvent être de type "polyaxial", c'est-à-dire comprendre un pion proximal fileté articulé par rapport à cette partie destinée à venir en prise avec l'os.

Les matériels d'ostéosynthèse vertébrale existants sont destinés à immobiliser deux vertèbres l'une par rapport à l'autre, pour éliminer tout mouvement relatif de ces vertèbres, susceptible d'être douloureux, ou pour rétablir la position adéquate d'une vertèbre par rapport à l'autre. Pour l'obtention de cette immobilisation, ces matériels sont conçus pour assurer un assemblage parfaitement rigide des tiges de liaison avec les organes d'ancrage.

Cet assemblage rigide peut cependant ne pas être souhaitable dans tous les cas. Il conduit en particulier à l'exercice de sollicitations importantes au niveau des zones osseuses d'ancrage desdits organes d'ancrage, ainsi qu'à des sollicitations augmentées au niveau des articulations vertébrales situées

de part et d'autre du segment vertébral traité, qui peuvent conduire à des dégénérescences de ces articulations.

La présente invention vise à remédier à ces inconvénients essentiels.

Le matériel concerné comprend, de manière connue en soi, des organes d'ancrage osseux, tels que des vis pédiculaires ou des crochets lamaires, une ou deux tiges de liaison, destinées à être reliées à ces organes d'ancrage et à être fixées aux vertèbres au moyen de ceux-ci, et des pièces de connexion de cette ou ces tiges à ces organes d'ancrage, au moins un de ces organes d'ancrage étant du type "polyaxial", c'est-à-dire comprenant un pion proximal articulé par rapport à la partie de l'organe d'ancrage destinée à venir en prise avec une vertèbre, des moyens de serrage étant prévus pour immobiliser une tige de liaison dans la pièce de connexion que reçoit cet organe d'ancrage.

Selon l'invention, ledit organe d'ancrage polyaxial comprend au moins une pièce ou une partie de pièce à structure élastiquement déformable, interposée, après montage, entre ladite pièce de connexion et ladite partie de l'organe d'ancrage destinée à venir en prise avec une vertèbre, cette pièce ou une partie de pièce à structure élastiquement déformable permettant une mobilité de la pièce de connexion, et donc de la tige de liaison, par rapport à la partie de l'organe d'ancrage destinée à venir en prise avec une vertèbre, avec amortissement.

Ainsi, dans le matériel selon l'invention, ladite pièce de connexion n'est pas immobilisée par rapport à l'organe d'ancrage mais peut jouer vis-à-vis de celui-ci, afin d'autoriser des mouvements limités des vertèbres. Les sollicitations exercées sur les zones osseuses d'ancrage de l'organe d'ancrage sont ainsi notablement réduites, de même que les risques de sur-sollicitations au niveau des articulations vertébrales situées de part et d'autre du segment vertébral traité.

Lesdits moyens de serrage peuvent être conçus pour serrer la pièce de connexion contre ladite pièce ou une partie de pièce à structure élastiquement déformable et pour serrer cette pièce ou une partie de pièce contre ladite partie de l'organe d'ancrage destinée à venir en prise avec une vertèbre, jusqu'à immobiliser le pion proximal par rapport à la partie de l'organe d'ancrage destinée à venir en prise avec une vertèbre.

Le jeu de la pièce de connexion est alors rendu possible uniquement par la déformation de ladite pièce ou partie de pièce à structure élastiquement déformable.

De préférence, toutefois, le pion proximal comprend une surface formant une butée axiale, contre laquelle vient reposer la pièce de connexion, lesdits moyens de serrage serrant cette pièce de connexion contre cette surface.

L'immobilisation de la tige de liaison par rapport à la pièce de connexion est ainsi réalisée indépendamment de tout serrage de ladite pièce ou partie de pièce élastiquement déformable.

Avantageusement dans ce cas, cette surface formant butée axiale est disposée sur le pion proximal de telle sorte que l'immobilisation de la tige de liaison dans la pièce de connexion ne conduit pas à exercer sur ladite pièce ou partie de pièce à structure élastiquement déformable un serrage de nature à bloquer le mouvement du pion proximal.

Ce dernier reste par conséquent mobile par rapport à la partie de l'organe d'ancrage destinée à venir en prise avec une vertèbre, permettant de cette manière la mobilité de la pièce de connexion, et donc de la tige de liaison, par rapport à cette partie de l'organe d'ancrage.

Ladite pièce ou partie de pièce à structure élastiquement déformable peut être conformée de manière à réaliser un amortissement du mouvement du pion proximal sur l'ensemble du débattement de ce pion, ou peut être conformée pour réaliser cet amortissement seulement dans les positions extrêmes de ce débattement.

Selon une forme préférée de réalisation de l'invention dans ce deuxième cas, ladite pièce ou partie de pièce à structure élastiquement déformable est formée par une paroi circulaire raccordée à la pièce de connexion, cette paroi comprenant au moins une fente transversale qui la traverse, aménagée sur un côté de cette paroi selon une direction sensiblement perpendiculaire à celle qu'occupe une tige de liaison quand cette tige est engagée dans la pièce de connexion, cette fente permettant une réduction de l'épaisseur de cette paroi circulaire lorsqu'une contrainte est exercée sur cette paroi dans le sens axial, du côté où se trouve la fente.

Avantageusement, ladite paroi circulaire comprend deux fentes aménagées sur deux de ses côtés opposés, permettant un amortissement sur ces deux côtés.

Avantageusement, les parois du pion proximal et de ladite partie destinée à venir en prise avec une vertèbre qui glissent l'une contre l'autre lors du débattement de ce pion comportent un revêtement lisse et résistant, propre à résister à de très nombreux mouvements de glissement de ces parois l'une contre l'autre, tel qu'un revêtement en céramique ou en nitrure de titane.

Lorsque l'articulation de ce pion proximal est réalisée par glissement de faces en forme de sphère ou de portions de sphère l'une contre l'autre, avantageusement, ces faces présentent un diamètre nettement supérieur à celui du pion proximal, notamment au moins du double du diamètre de ce pion, afin d'augmenter la surface de contact de ses faces l'une avec l'autre.

Les frottements s'exercent ainsi sur des surfaces augmentées, réduisant le risque d'usure desdites faces.

Selon une autre forme de réalisation de l'invention, le matériel comprend, outre les moyens de serrage prévus pour immobiliser une tige de liaison dans la pièce de connexion que reçoit l'organe d'ancrage, des deuxièmes moyens de serrage permettant de serrer, indépendamment du serrage réalisé par lesdits moyens de serrage, la pièce de connexion contre ladite partie de l'organe d'ancrage destinée à venir en prise avec une vertèbre.

Lesdits deuxièmes moyens de serrage peuvent ainsi être serrés de manière contrôlée, par exemple au moyen d'un tournevis dynamométrique, selon le degré de souplesse recherchée en fonction des caractéristiques du patient (état des disques intervertébraux, degré d'instabilité vertébrale, poids), puis lesdits moyens de serrage sont serrés pour immobiliser la tige dans la pièce de connexion.

La pièce de connexion peut comporter une graduation et ces deuxièmes moyens de serrage peuvent comporter un repère venant en regard de cette graduation pour permettre le serrage contrôlé précité.

Ladite partie de l'organe d'ancrage destinée à venir en prise avec une vertèbre peut notamment comprendre une pièce à structure élastiquement déformable et la pièce de connexion peut comporter une autre pièce à

structure élastiquement déformable, ces deux pièces venant porter l'une contre l'autre au cours du serrage.

Par ailleurs, au moins une tige de liaison du matériel peut comprendre :

- une partie de tige comportant une pièce à structure élastiquement déformable et un pion articulé,

- une autre partie de tige comprenant une zone d'appui contre cette pièce à structure élastiquement déformable, et

- des moyens de serrage pour serrer cette zone d'appui contre cette pièce à structure élastiquement déformable.

La tige de liaison peut ainsi également présenter un degré de souplesse élastique.

Ladite zone d'appui peut comporter également une pièce à structure élastiquement déformable.

L'invention sera bien comprise, et d'autres caractéristiques et avantages de celle-ci apparaîtront, en référence au dessin schématique annexé, représentant, à titre d'exemples non limitatifs, plusieurs formes de réalisation de pièces que comprend le matériel qu'elle concerne.

La figure 1 est une vue partielle d'une vis pédiculaire polyaxiale et d'une tige de liaison que comprend ce matériel, et, en coupe transversale, d'une pièce de connexion et d'un écrou permettant d'assembler une tige de liaison à cette vis, avant montage ;

la figure 2 est une vue de ces pièces similaire à la figure 1, après montage ;

la figure 3 est une vue de ces pièces similaire à la figure 2, selon une direction perpendiculaire à celle selon cette figure 2, dans une position ;

la figure 4 est une vue de ces pièces similaire à la figure 3, dans une deuxième position ;

la figure 5 est une vue de ces pièces similaire à la figure 3, dans une troisième position ;

la figure 6 est une vue des mêmes pièces en perspective, après mise en place de la vis dans une vertèbre et avant serrage définitif ;

la figure 7 est une vue de ces pièces similaires à la figure 6, après serrage définitif ;

la figure 8 est une vue similaire à la figure 1 des mêmes pièces du matériel, selon une deuxième forme de réalisation, avant montage ;

la figure 9 est une vue similaire à la figure 2 de ces pièces, après montage ;

la figure 10 est une vue en coupe partielle d'une tige de liaison, avant assemblage, et

la figure 11 est une vue similaire à la figure 10, après assemblage.

La figure 1 représente une vis pédiculaire polyaxiale 1, une tige 2 de liaison de plusieurs de ces vis 1, une pièce 3 de connexion de cette tige 2 à une de ces vis 1 et un écrou 4 permettant d'assembler la tige de liaison 2 à cette vis 1.

La vis 1 comprend un pion proximal fileté 5 et un corps de vis distal fileté 6. Le pion 5 est destiné à recevoir la pièce 3 engagée sur lui et l'écrou 4 vissé sur lui tandis que le corps 6 est destiné à être inséré dans le pédicule 100 d'une vertèbre, comme le montrent les figures 6 et 7.

Le pion 5 présente une partie cylindrique filetée 10, une tête distale élargie 11 et une collerette 12 formant une surface de butée.

La partie 10 présente une zone 15 de diamètre réduit, permettant de casser sa portion proximale après mise en place et serrage de l'écrou 4, comme cela apparaît par comparaison des figures 2 et 3.

La tête 11 présente un diamètre double du diamètre de la partie 10 et a une forme de calotte sphérique. Cette tête 11 est destinée à être engagée dans une cavité proximale 16 que délimite la zone proximale du corps 6 et à être retenue dans cette cavité 16 par sertissage d'une paroi proximale 17 que présente ce corps 6. Après sertissage, la paroi 17 est façonnée de manière à présenter une forme proximale hémisphérique. Comme cela apparaît sur la figure 1, les dimensions de la cavité 16 et de l'ouverture délimitée par la paroi 17 après sertissage pour le passage du pion 5 sont telles qu'un débattement multidirectionnel de ce pion 5 par rapport au corps 6 est possible.

Le corps 6 comprend également une collerette proximale 18, destinée à venir en butée contre le pédicule 100. Cette collerette 18 présente plusieurs encoches radiales 19, notamment quatre encoches à 90° les unes des autres, permettant le maintien du corps 6 en rotation pendant le serrage de l'écrou 4.

La tige de liaison 2 est cylindrique et présente une rigidité telle qu'elle permet le maintien de plusieurs vertèbres les unes par rapport aux autres. Cette tige 2 est toutefois déformable de manière à pouvoir être conformée en fonction de la correction du rachis à réaliser.

La pièce de connexion 3 comprend une partie arrondie 20 destinée à entourer la tige de liaison 2 et deux ailes latérales parallèles 21 percées de trous pour l'engagement de la pièce 3 sur le pion 5. Ces ailes 21 sont mutuellement distantes de telle sorte que, dans une position d'écartement, la tige 2 puisse être insérée et puisse coulisser dans la partie 20, et que, dans une position de rapprochement que leur confère le serrage de l'écrou 4, elles serrent la partie 20 autour de la tige 2, immobilisant cette dernière par rapport à la pièce 3.

Comme le montrent les figures 1 et 2, l'aile 21 proximale présente une cuvette proximale 25 de forme adaptée à la prise d'appui de l'écrou 4, tandis que l'aile 21 distale comprend une cavité circulaire 26 permettant l'engagement de cette aile sur la collerette 12.

Cette aile 21 distale comprend en outre une paroi circulaire 27 solidaire d'elle. Cette paroi 27 a une hauteur inférieure à celle de la paroi 17, et délimite une face sphérique concave interne 28 de diamètre supérieur au diamètre de cette paroi 17.

En outre, deux fentes transversales 29 sont aménagées dans cette paroi 27, sur deux côtés opposés de la paroi 27, et selon une direction sensiblement perpendiculaire à celle qu'occupe la tige de liaison 2 quand cette tige est engagée dans la partie arrondie 20. Chaque fente 29 s'étend angulairement sur environ 120° de la paroi 27 et se termine par une zone élargie 30 en forme de cercle.

Comme cela se comprend en référence à la figure 5, les portions distales de la paroi 27 délimitées par les fentes 29 ont, au niveau de ces zones arrondies 30, une hauteur réduite, telle que ces portions peuvent fléchir au niveau de ces zones 30, permettant ainsi une réduction de la hauteur de la paroi 27.

En pratique, le nombre de vis 1 nécessaire au traitement à réaliser est mis en place dans les pédicules 100 des vertèbres concernées, puis les

pièces de connexion 3, avec la tige 2 engagée dans les parties 20, sont placées sur les pions 5, jusqu'à engagement des collerettes 12 dans les cavités 26. Les écrous 4 sont ensuite serrés pour réaliser l'immobilisation de la tige 2 par rapport aux pièces 3 et les portions proximales des pions 5 sont sectionnées.

La venue en butée de chaque pièce 3 contre la collerette 12 correspondante permet de réaliser un serrage de la tige 2 dans cette pièce 3 indépendamment de tout serrage de la pièce 3 contre la paroi 17.

Une fois le serrage de l'écrou 4 réalisé, le pion 5 reste ainsi mobile par rapport au corps 6, cette mobilité étant libre tant que la paroi 27 n'est pas venue en butée contre le corps 6 (cf. figure 4) puis étant possible avec déformation de la paroi 27 au-delà, réalisant un amortissement du mouvement du pion 5 dans les angles maximaux de débattement de ce pion. La limite du débattement possible de ce dernier correspond à la venue en contact des bords de la paroi 27 délimitant les fentes 29.

Grâce au diamètre de sa face 28, supérieur au diamètre de la paroi 17, la paroi 27 ne fait pas obstacle au débattement du pion 5.

Cette face 28 peut cependant, comme le montre la figure 2, être conformée de manière à venir en appui contre la zone sensiblement hémisphérique de la paroi 17. Les frottements résultant de cet appui réalisent un freinage du mouvement du pion 5, si nécessaire.

Les zones de glissement de la tête 11 contre la paroi 17 et de la face 28 contre la paroi 17 peuvent comporter un revêtement lisse et résistant, propre à résister à de très nombreux mouvements de glissement de ces parois l'une contre l'autre, tel qu'un revêtement en céramique ou en nitrure de titane.

Les figures 8 et 9 représentent des pièces 2 à 5 similaires à celles décrites en référence aux figures 1 et 2, les pièces se retrouvant de manière identique ou similaire étant désignées par les mêmes références numériques.

Dans ce cas, la collerette 18 présente un rebord périphérique 30 et contient une pièce 31 en matériau à structure élastiquement déformable, notamment en silicone ou en PMMA, et la pièce 3 comporte une pièce 31 similaire, ces deux pièces 31 venant en appui l'une contre l'autre lors du montage.

La pièce 3 présente une épaisseur supérieure à celle représentée sur les figures 1 et 2 et peut recevoir complètement l'écrou 4 dans la cavité 25 de sa branche proximale 21, cet écrou 4 comportant des encoches périphériques 32 pour sa manœuvre en rotation.

Le matériel comprend en outre un deuxième écrou 40, pouvant également être vissé sur le pion proximal 5.

En pratique, l'écrou 4 peut être serré de manière contrôlée, par exemple au moyen d'un tournevis dynamométrique, selon le degré de souplesse recherchée en fonction des caractéristiques du patient (état des disques intervertébraux, degré d'instabilité vertébrale, poids), ce degré de souplesse étant obtenu par serrage plus ou moins important des pièces 31. L'écrou 40 est ensuite serré pour immobiliser la tige 2 dans la pièce de connexion 3.

Les figures 10 et 11 montrent une tige de liaison 2 du matériel qui comprend :

- une partie de tige 2a comportant une pièce 41 à structure élastiquement déformable et un pion fileté articulé 5, cette articulation étant réalisée de manière identique à celle décrite précédemment,

- une autre partie de tige 2b, comprenant une zone 42 d'appui contre cette pièce 41 et un alésage taraudé 43 permettant le vissage de cette partie 2b sur le pion 5 pour serrer la zone d'appui 42 contre la pièce 41.

La tige de liaison 2 peut ainsi également présenter un degré de souplesse élastique.

Comme cela apparaît de ce qui précède, l'invention fournit un matériel d'ostéosynthèse vertébrale permettant un jeu limité de la pièce de connexion 3, et donc de la tige de liaison 2, par rapport au corps 6 d'ancrage à la vertèbre, afin d'autoriser des mouvements limités des vertèbres traitées. Les sollicitations exercées sur les zones osseuses d'ancrage de l'organe d'ancrage sont ainsi notablement réduites, de même que les risques de sur-sollicitations au niveau des articulations vertébrales situées de part et d'autre du segment vertébral traité.

Il va de soi que l'invention n'est pas limitée à la forme de réalisation décrite ci-dessus à titre d'exemple mais qu'elle s'étend à toutes les formes de réalisations couvertes par les revendications ci-annexées. Ainsi, l'on ne

sortirait pas du cadre de l'invention en remplaçant la paroi 27 par une rondelle en matériau élastique ou à structure élastique, par exemple sous forme de ressort.

REVENDICATIONS

1 – Matériel d'ostéosynthèse vertébrale, comprenant des organes d'ancrage osseux, tels que des vis pédiculaires (1) ou des crochets lamaires, une ou deux tiges de liaison (2), destinées à être reliées à ces organes d'ancrage et à être fixées aux vertèbres au moyen de ceux-ci, et des pièces de connexion (3) de cette ou ces tiges (2) à ces organes d'ancrage, au moins un de ces organes d'ancrage étant du type "polyaxial", c'est-à-dire comprenant un pion proximal (5) articulé par rapport à la partie (6) de l'organe d'ancrage destinée à venir en prise avec une vertèbre, des moyens de serrage (4) étant prévus pour immobiliser une tige de liaison (2) dans la pièce de connexion (3) que reçoit cet organe d'ancrage ;

matériel caractérisé en ce que ledit organe d'ancrage polyaxial (1) comprend au moins une pièce ou une partie de pièce (27) à structure élastiquement déformable, interposée, après montage, entre ladite pièce de connexion (3) et ladite partie (6) de l'organe d'ancrage destinée à venir en prise avec une vertèbre, cette pièce ou une partie de pièce (27) à structure élastiquement déformable permettant une mobilité de la pièce de connexion (3), et donc de la tige de liaison (2), par rapport à la partie (6) de l'organe d'ancrage destinée à venir en prise avec une vertèbre, avec amortissement.

2 – Matériel selon la revendication 1, caractérisé en ce que le pion proximal (5) comprend une surface (12) formant une butée axiale, contre laquelle vient reposer la pièce de connexion (3), lesdits moyens de serrage (4) serrant cette pièce de connexion (3) contre cette surface (12).

3 – Matériel selon la revendication 2, caractérisé en ce que ladite surface (12) formant butée axiale est disposée sur le pion proximal (5) de telle sorte que l'immobilisation de la tige de liaison (2) dans la pièce de connexion (3) ne conduit pas à exercer sur ladite pièce ou partie de pièce (27) à structure élastiquement déformable un serrage de nature à bloquer le mouvement du pion proximal (5).

4 – Matériel selon la revendication 3, caractérisé en ce que ladite pièce ou partie de pièce à structure élastiquement déformable est conformée de

manière à réaliser un amortissement du mouvement du pion proximal sur l'ensemble du débattement de ce pion.

5 – Matériel selon la revendication 3, caractérisé en ce que ladite pièce ou partie de pièce (27) à structure élastiquement déformable est conformée de manière à réaliser un amortissement du mouvement du pion proximal (5) seulement dans les positions extrêmes du débattement de ce pion.

6 – Matériel selon la revendication 5, caractérisé en ce que ladite pièce ou partie de pièce à structure élastiquement déformable est formée par une paroi circulaire (27) raccordée à la pièce de connexion (3), cette paroi (27) comprenant au moins une fente transversale (29) qui la traverse, aménagée sur un côté de cette paroi (27) selon une direction sensiblement perpendiculaire à celle qu'occupe une tige de liaison (2) quand cette tige est engagée dans la pièce de connexion (3), cette fente (29) permettant une réduction de l'épaisseur de cette paroi circulaire (27) lorsqu'une contrainte est exercée sur cette paroi dans le sens axial, du côté où se trouve la fente (29).

7 – Matériel selon la revendication 6, caractérisé en ce que ladite paroi circulaire (27) comprend deux fentes (29) aménagées sur deux de ses côtés opposés, permettant un amortissement sur ces deux côtés.

8 – Matériel selon l'une des revendications 3 à 7, caractérisé en ce que les parois (11, 17) du pion proximal (5) et de ladite partie (6) destinée à venir en prise avec une vertèbre qui glissent l'une contre l'autre lors du débattement de ce pion (5) comportent un revêtement lisse et résistant, propre à résister à de très nombreux mouvements de glissement de ces parois l'une contre l'autre, tel qu'un revêtement en céramique ou en nitrure de titane.

9 – Matériel selon l'une des revendications 3 à 8, caractérisé en ce que l'articulation dudit pion proximal (5) est réalisée par glissement de faces (11, 17) en forme de sphère ou de portions de sphère l'une contre l'autre, et en ce que ces faces (11, 17) présentent un diamètre nettement supérieur à celui du pion proximal, notamment au moins du double du diamètre de ce pion.

10 – Matériel selon l'une des revendications 1 à 9, caractérisé en ce qu'il comprend, outre les moyens de serrage (4) prévus pour immobiliser une tige de liaison (2) dans la pièce de connexion (3) que reçoit l'organe d'ancrage (1), des deuxièmes moyens de serrage (40) permettant de serrer,

indépendamment du serrage réalisé par lesdits moyens de serrage (4), la pièce de connexion (3) contre ladite partie (6) de l'organe d'ancrage destinée à venir en prise avec une vertèbre.

11 – Matériel selon la revendication 10, caractérisé en ce que la pièce de connexion comporte une graduation et en ce que ces deuxièmes moyens de serrage comportent un repère venant en regard de cette graduation.

12 – Matériel selon l'une des revendications 3 à 8, caractérisé en ce qu'au moins une tige de liaison comprend :

- une partie de tige comportant une pièce à structure élastiquement déformable et un pion articulé,
- une autre partie de tige comprenant une zone d'appui contre cette pièce à structure élastiquement déformable, et
- des moyens de serrage pour serrer cette surface d'appui contre cette pièce à structure élastiquement déformable.

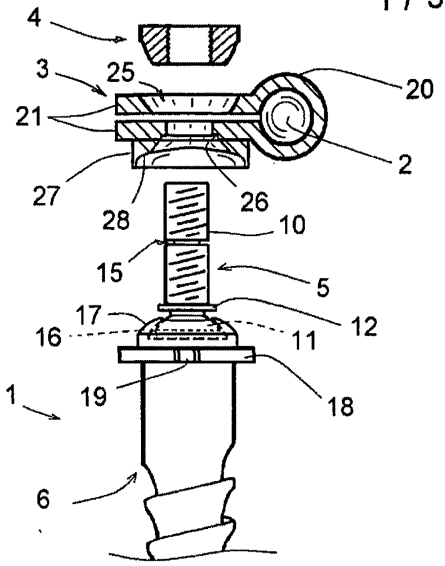


FIG. 1

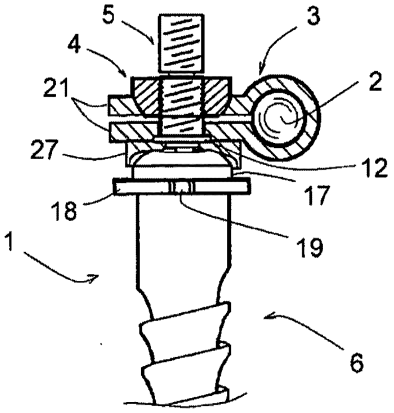


FIG. 2

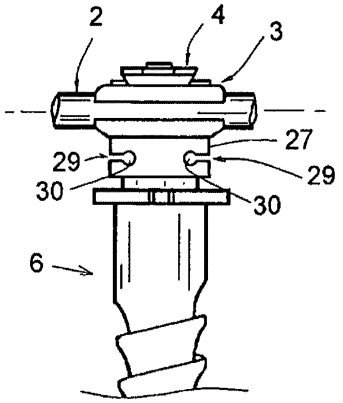


FIG. 3

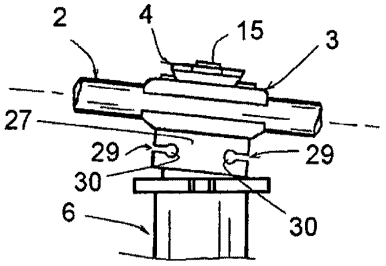


FIG. 4

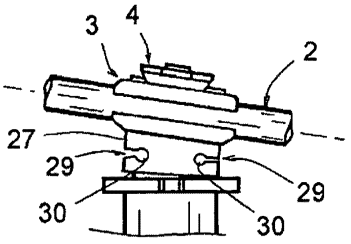


FIG. 5

FIG. 6

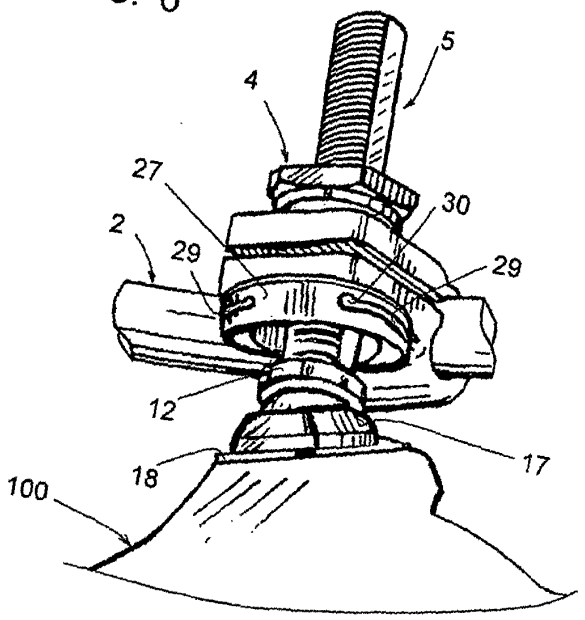
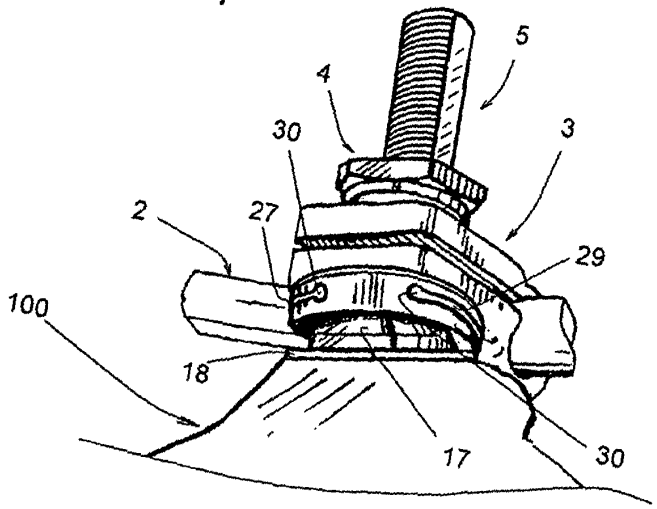


FIG. 7



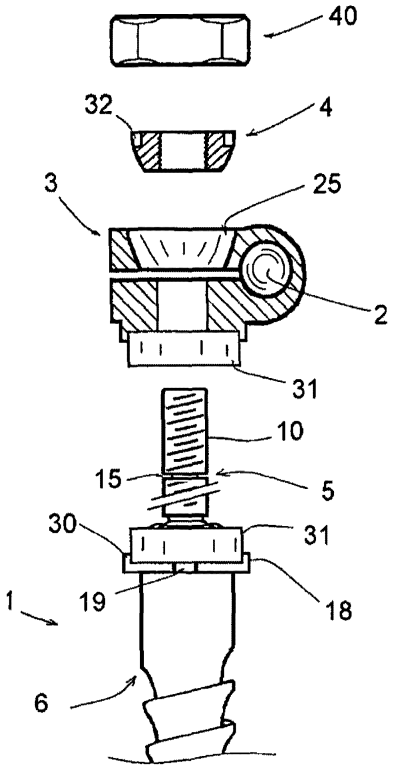


FIG. 8

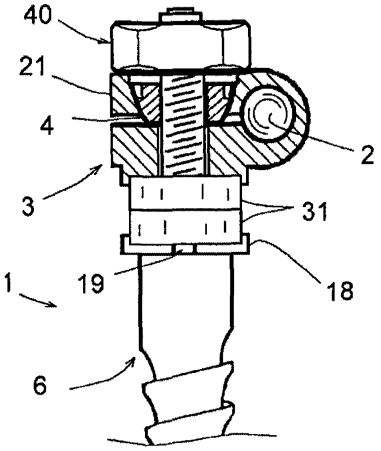


FIG. 9

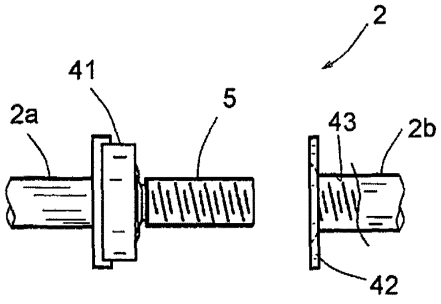


FIG. 10

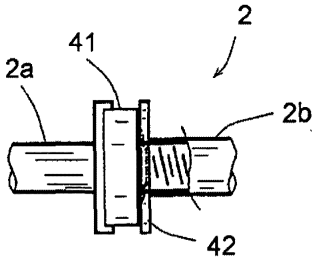


FIG. 11

RÉPUBLIQUE FRANÇAISE

INPI
INSTITUT NATIONAL DE LA PROPRIETE INDUSTRIELLE

RAPPORT DE RECHERCHE PRÉLIMINAIRE

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

N° d'enregistrement national

FA 637258
FR 0307776

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		
X	EP 0 242 708 A (HARMS J. & BIEDERMANN L.) 28 octobre 1987 (1987-10-28) * colonne 3, ligne 6 - ligne 10 * * colonne 3, ligne 55 - colonne 4, ligne 15 * * colonne 4, ligne 28 - ligne 30 * * figures 1,3 *	1,10	A61B17/70
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Y	FR 2 697 742 A (BIOMAT) 13 mai 1994 (1994-05-13) * page 11, ligne 14 - page 12, ligne 9; figure 1 *	1,2,10	
			DOMAINES TECHNIQUES RECHERCHÉS (Int.CL.7)
			A61B

Date d'achèvement de la recherche	Examinateur
8 septembre 2004	Nice, P

CATÉGORIE DES DOCUMENTS CITÉS

X : particulièrement pertinent à lui seul
Y : particulièrement pertinent en combinaison avec un autre document de la même catégorie
A : arrière-plan technologique
O : divulgation non-écrite
P : document intercalaire

T : théorie ou principe à la base de l'invention
E : document de brevet bénéficiant d'une date antérieure à la date de dépôt et qui n'a été publié qu'à cette date de dépôt ou qu'à une date postérieure.
D : cité dans la demande
L : cité pour d'autres raisons

& : membre de la même famille, document correspondant

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EPO FORM 1503 12.99 (P04C14)

ANNEXE AU RAPPORT DE RECHERCHE PRÉLIMINAIRE RELATIF A LA DEMANDE DE BREVET FRANÇAIS NO. FR 0307776 FA 637258

La présente annexe indique les membres de la famille de brevets relatifs aux documents brevets cités dans le rapport de recherche préliminaire visé ci-dessus.
Les dits membres sont contenus au fichier informatique de l'Office européen des brevets à la date du 08-09-2004
Les renseignements fournis sont donnés à titre indicatif et n'engagent pas la responsabilité de l'Office européen des brevets, ni de l'Administration française

Document brevet cité au rapport de recherche		Date de publication	Membre(s) de la famille de brevet(s)		Date de publication
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Pour tout renseignement concernant cette annexe : voir Journal Officiel de l'Office européen des brevets, No.12/82

(12) UK Patent Application (19) GB (11) 2 382 304 (13) A

(43) Date of A Publication 28.05.2003

(21) Application No 0124291.6

(22) Date of Filing 10.10.2001

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BIRMINGHAM, B3 3HP, United Kingdom

(51) INT CL[7]
A61B 17/70

(52) UK CL (Edition V)
A5R RX7

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(58) Field of Search
UK CL (Edition V) A5R
INT CL[7] A61B
Other: ONLINE: WPI, EPODOC, PAJ

(54) Abstract Title

An assembly for soft stabilisation of vertebral bodies of the spine

(57) An assembly for soft stabilisation of vertebral bodies 12, 14 of the spine comprises a pair of pedicle screws 20 each having a threaded shaft 20a with a tapering first end 20b and a head portion 20c with a second end 20d; a helical spring member 18 having first and second ends; and a pair of fixation mechanisms (26, fig 3a) for securing the first and second ends of the helical spring member to the pair of pedicle screws. The helical screw member may be made from titanium or stainless steel wire and may further include a plastic sleeve (18c, fig 2a) covering the spring member. The assembly may further comprise an elastic member (60, fig 9) securable to the head ends of a pair of pedicle screws. Another embodiment also shows an assembly where the elastic member has been substituted for the helical spring member.

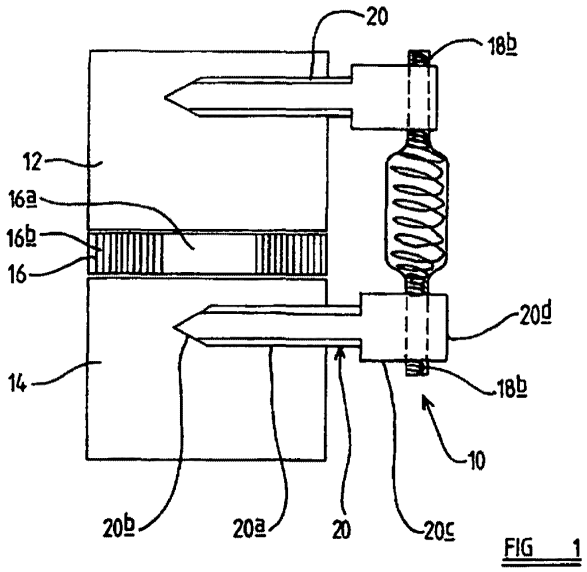


FIG 1

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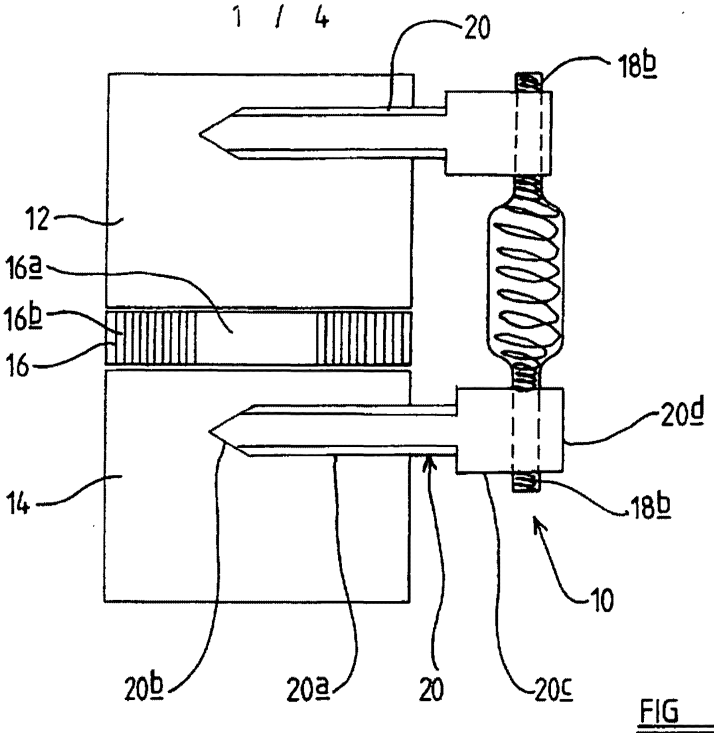


FIG 1

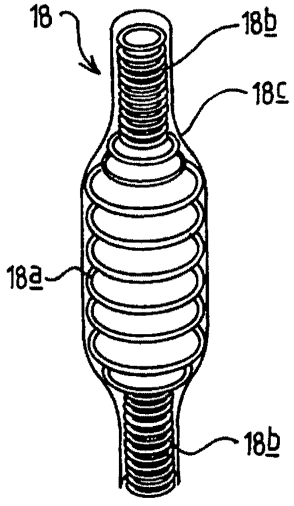


FIG 2a

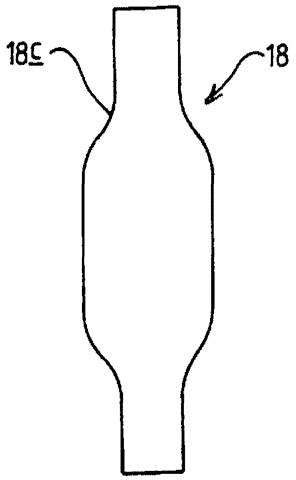


FIG 2b

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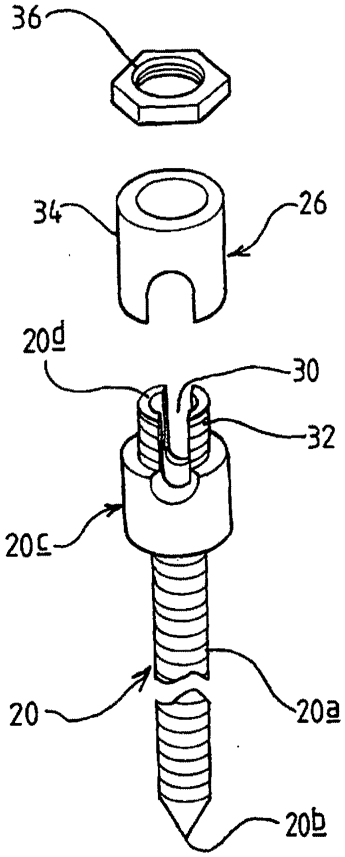


FIG 3a

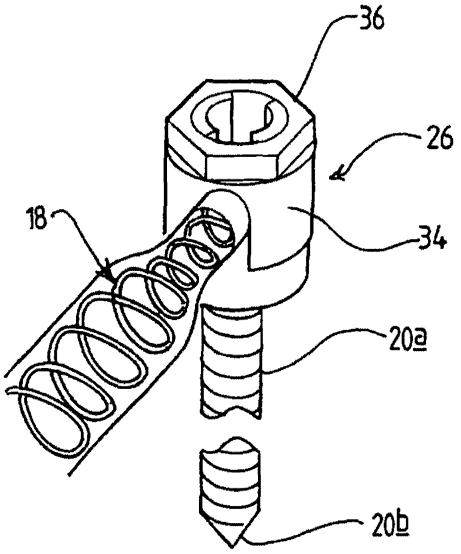


FIG 3b

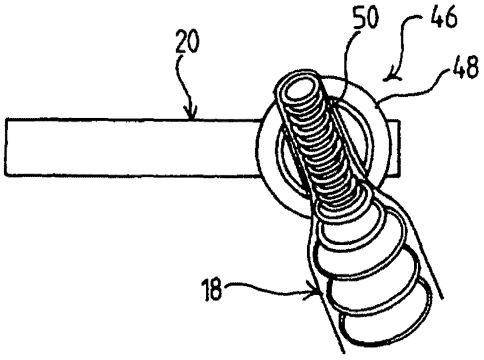


FIG 4a

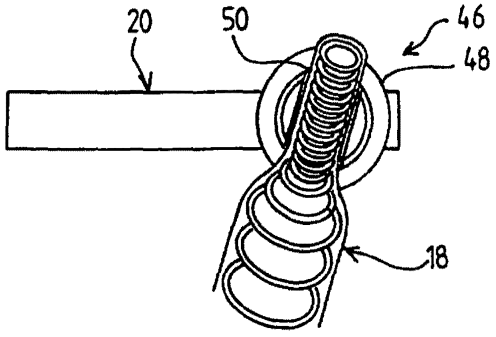


FIG 4b

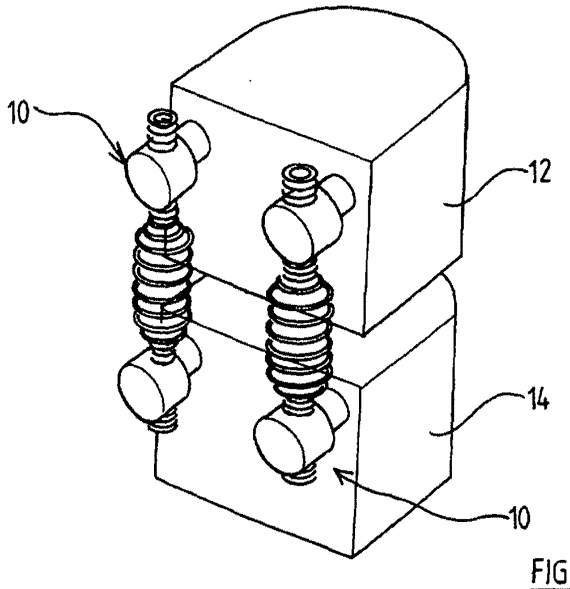


FIG 5

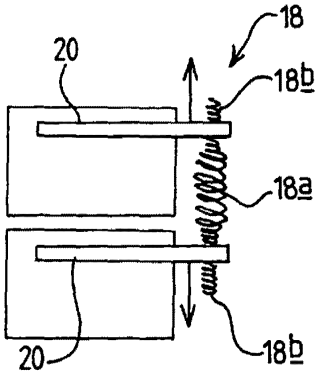


FIG 6a

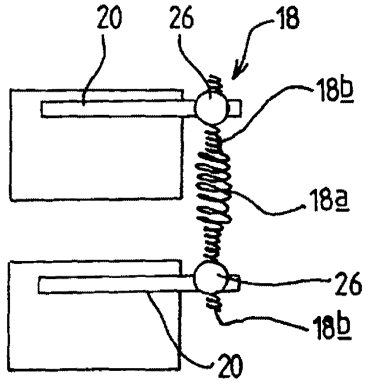


FIG 6b

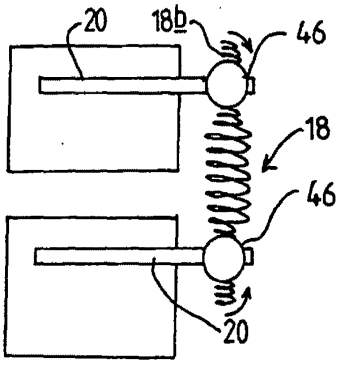


FIG 7a

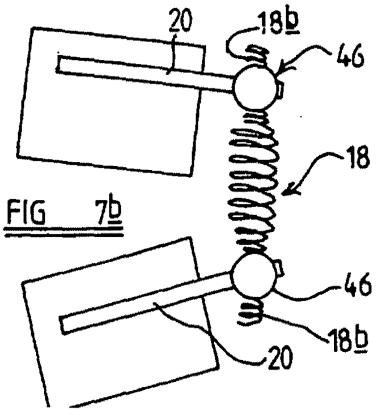


FIG 7b

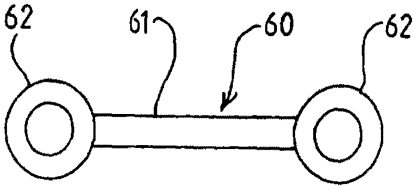


FIG 8a

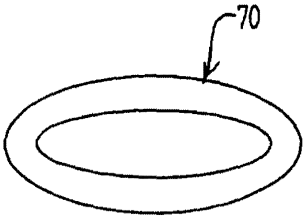


FIG 8b

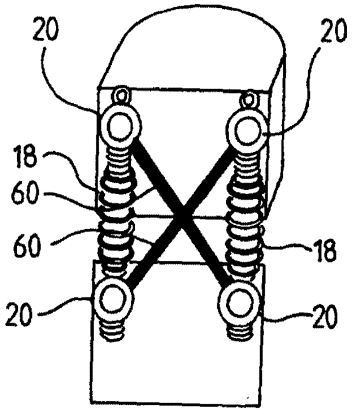


FIG 9

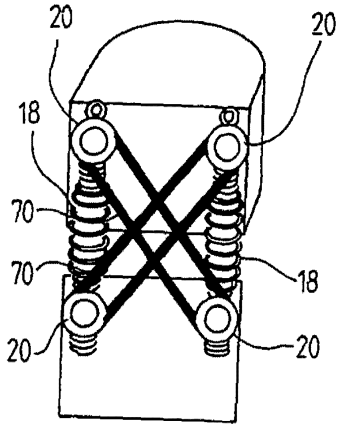


FIG 10

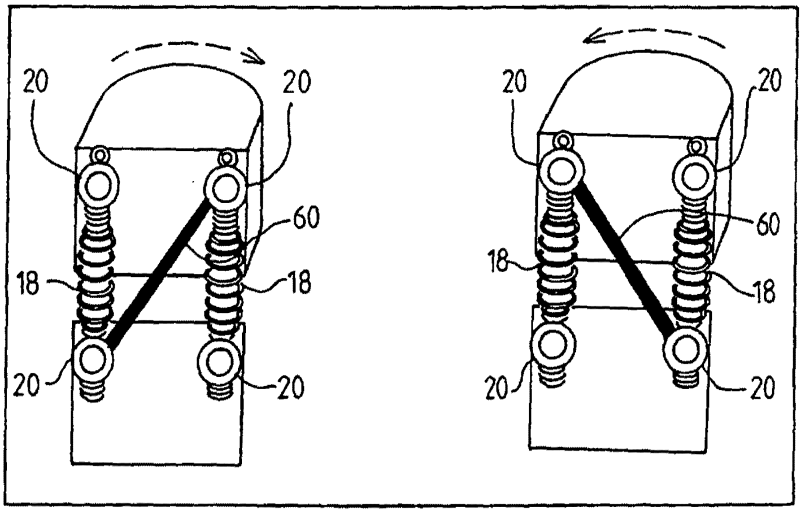


FIG 11

PATENTS ACT 1977

A10418GB-DMW

Title: An assembly for soft stabilisation of vertebral bodies of the spine

Description of Invention

The invention relates to an assembly for soft stabilisation of vertebral bodies of the spine of the kind which is secured to the adjacent vertebral bodies by pedicle screws, and in particular although not exclusively to such an assembly for stabilisation of two adjacent vertebral bodies.

The present invention is applicable for the treatment of a range of spinal pathologies including low back pain and deformity.

A number of stabilisation techniques have previously been described for the treatment of low back pain. The lower, or lumbo-sacral region of the human spine consists of five lumbar vertebrae located above the large triangular bone called the sacrum. Between adjacent lumbar vertebrae are inter-vertebral discs (IVD) which have a complex structure, with a central jelly like nucleus pulposus and a peripheral rim of tough fibrous layers, the annulus fibrosus. Each lumbar vertebra is made up of a vertebral body, with upper and lower end plates, which contact the IVD's, and facet joints located posteriorlly. Movement in the lumbo-sacral spine occurs in the IVD's at the front and at the facet joints at the rear. Thus, the IVD's and the facet joints provide stability of the motion segment between adjacent vertebra. However, they also transfer load from one vertebra to the next, and it is estimated that the IVD bears approximately 80% of the load and the pair of facet joints at the rear bear approximately 20% of the load. A normal IVD can distribute the load uniformly across the surface of the end plate of the vertebral body. However, when the IVD and/or the facet joints are damaged or degenerate this can lead to

instability of the motion segment between adjacent vertebra and commonly to low back pain. It is considered that the pain can be caused by abnormal movement, and/or by abnormal distribution of load across the end plates of the vertebrae.

Conventional treatment of low back pain is to limit movement between adjacent vertebrae, typically by fusing the adjacent vertebrae together. However, fusion has a high failure rate for pain relief.

More recently treatment with prosthetic IVD's has been tried in an attempt to preserve the normal movement and normal load bearing of the inter-vertebral joints. However, thus far the results are no better than in fusion of adjacent vertebrae.

An alternative approach is that of "soft stabilisation" which aims to prevent abnormal motion in painful motion segments of the lumbo-sacral spine, but to save as much as possible of the normal motion. Several methods of soft stabilisation have been described in the literature, but only two are currently in use.

The Graf ligament system consists of a fabric ligament secured across pedicle screws located in the adjacent vertebrae. Typically two such ligaments are located across each motion segment, one to each side of the spinous processes on the rear of the spine. This system creates lordosis (curvature of the spine, convex forwards) and restricts the movement of the motion segment between the vertebrae concerned, but it also increases the load at the posterior part of the IVD. In one such system (Dynesys-Sulzer, as described in European patent application published under No. EP 0 669 109) excessive lordosis is prevented by a cylinder embracing the ligament between the pedicle screws. However, actual distraction of the disc space can only be achieved by producing flexion of the motion segment. This results in a kyphotic (convex backwards) segment, and kyphotic segments in the lumbo-sacral spine can

produce back pain. Hence, there are significant problems with the use of such a system.

Another soft stabilisation system which is in the process of development is a fulcrum assisted soft stabilisation system (FASS) which is described in International patent application No. PCT/CH99/00612. In this system the compressing effect of the ligament found in the Graf ligament system is converted into a distraction effect by the use of a fulcrum bridging between the pedicle screws, and located between the ligament and the spine. This system can unload the IVD in forward flexion but not in extension. However, it is known from the literature that the IVD is loaded both in flexion and extension and the facet joints are specifically loaded in extension. Hence, this system also is expected to suffer from disadvantages.

None of the soft stabilisation systems described above therefore addresses the important aim of addressing uniform IVD distraction to create a normal loading pattern across the end plates of the vertebrae, both in flexion and extension. An Alternative soft stabilisation system which addresses that aim, and mitigates the problems described above is described in the applicant's copending UK patent application No. 0114783.4.

The soft stabilisation systems described above serve the basic requirements of unloading the disc and creating or maintaining lordosis as appropriate. However, all such systems restrict motion of the spinal segment, and in general the greater the unloading of the disc the greater the degree of stiffness imparted to the spinal segment. However, whilst the stiffness reduces the flexibility of the segment in flexion/extension and in lateral bending, it has least effect against rotation.

It is an aim of the present invention to provide a further alternative soft stabilisation system which, whilst unloading the disc and maintaining lordosis, has minimal effect in restriction of flexion/extension and lateral bending and

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greater effect in restriction of rotation of the spinal segment, and/or to correct spinal deformity.

According to a first aspect of the present invention there is provided an assembly for soft stabilisation of vertebral bodies of the spine comprising a pair of pedicle screws each having a threaded shaft with a tapering first end for introduction into a vertebral body and a head portion with a second end, characterised in that it further comprises a helical spring member having first and second ends and a pair of fixation mechanisms for securing the first and second ends of the helical spring member to the pair of pedicle screws.

Preferably the helical spring member comprises an active central portion between first and second passive end portions.

Conveniently the active central portion of the helical spring member comprises spaced apart coils of a first diameter, and the passive end portions of the helical spring member comprise closely adjacent coils of a second diameter, the second diameter being smaller then the first diameter.

The second diameter may be between two thirds and one third of the first diameter.

The second diameter may be substantially half the first diameter.

Preferably the spring member is formed from wire. The wire may have a diameter in the range 1 to 6 mm, or in the range 2 to 5 mm. The wire may be round in cross section, or alternatively may be square or rectangular in cross section. The wire is preferably titanium or stainless steel.

The assembly may further include a sleeve covering the helical spring member.

Typically the sleeve is made of plastics material.

The assembly may further comprise an elastic member securable to the heads of a pair of pedicle screws.

According to a second aspect of the invention there is provided an assembly for soft stabilisation of vertebral bodies of the spine may further

comprise a pair of pedicle screws each having a threaded shaft with a tapering first end for introduction into a vertebral body and a head portion with a second end, characterised in that it further comprises an elastic member having first and second ends; and a pair of fixation mechanisms for securing the first and second ends of the elastic member to the pair of pedicle screws.

The elastic member may comprise an active central portion and loops at each end for securing to the pedicle screws. Alternatively the elastic member may comprise a continuous band.

The assembly may be for stabilisation of two adjacent vertebral bodies of the spine.

An embodiment of the invention will now be described, by way of example only, with reference to the accompanying drawings in which:

Figure 1 is a schematic illustration of an assembly according to the invention in use;

Figure 2 illustrates a helical spring member for incorporation in the assembly of Figure 1;

Figure 3 illustrates a fixation mechanism suitable for use in the assembly of Figure 1;

Figure 4 illustrates an alternative fixation mechanism;

Figure 5 illustrates schematically a pair of assemblies according to the invention in use, from perspective angle;

Figure 6 illustrates schematically how the assembly of Figure 1 can be used for distraction of the motion segment;

Figure 7 illustrates schematically how the assembly of Figure 1 can be used to create lordosis;

Figure 8 illustrates two forms of elastic member for inclusion in assemblies according to the invention;

Figure 9 illustrates the elastic member of Figure 8a in use;

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Figure 10 illustrates the elastic member of Figure 8b in use; and

Figure 11 illustrates the use of assemblies according to the invention for correction of the spinal deformity.

Referring first to Figure 1, an assembly 10 for the stabilisation of two adjacent vertebral bodies 12, 14 of the spine is illustrated schematically. The vertebral bodies 12, 14 are separated by an inter-vertebral disc 16 which has a nucleus pulposus 16a and a fibrous outer-annulus, called the annulus fibrosus, 16b. For simplicity the facets joints have been omitted from the posterior of the vertebral bodies 12, 14.

The assembly 10 comprises a helical spring member 18, illustrated in Figure 2, which has a central active portion 18a and first and second passive end portions 18b extending outward therefrom. The active portion 18a of the helical spring member 18 comprises spaced apart coils whilst the first and second passive end portions 18b comprise tighter closely adjacent coils. The coils of the active portion 18a are of a first diameter, and the coils of the first and second end portions 18b are a second diameter, the first diameter being substantially greater than the second diameter. Typically, the second diameter will be in the region of $^1/_3$ to $^2/_3$ of the first diameter, although it may be substantially ½ the first diameter. The helical spring member 18 is covered by a sleeve 18c made of plastics material or some other inert material which is acceptable for implantation into the body. This will prevent tissue being trapped between the coils, or indeed growing inbetween the coils of the helical spring member 18.

The assembly 10 further comprises a pair of pedicle screws 20 each of which comprises a threaded shaft portion 20a with a tapering first end 20b and a head portion 20c with a second end 20d.

The assembly 10 is illustrated in Figure 1 in position secured to a pair of adjacent vertebral bodies 12, 14 with the threaded shaft portions 20a of the pedicle screws 20 inserted into the vertebral bodies 12, 14 to the same side of

the spine. The helical spring member 18 is secured to the heads 20c of each of the pedicle screws 20 by a fixation mechanism as appropriate. An example of a fixation mechanism will now be described.

Referring now to Figure 3 an example of a fixation mechanism 26 is illustrated, the mechanism being known in the prior art. The head 20c of the pedicle screw 20 is shown with a particular form. It comprises a slot 30 which provides the dual purpose of accepting the blade of a screw driver for insertion of the pedicle screw 20 into a vertebral body, and for receipt of the inactive portions 18b of the spring member 18. The head 20c further comprises adjacent its second end 20d, and around the upper part of the slot 30, a threaded portion 32. The fixation mechanism 26 further comprises a sleeve member 34 and threaded nut 36.

The fixation mechanism 26 is shown assembled in Figure 3b. Once the screw 20 has been inserted into the vertebral body one inactive portion 18b of the spring member 18, is located in the slot 30. The sleeve member 34 is then placed over the head 20c of the pedicle screw 20, and the nut 36 screwed down onto the threaded portion 32 to retain the spring member 18 in place. The fixation mechanism 26 may further include a check nut (not shown), as is known in the prior art, to further secure the mechanism together and to reduce the possibility of it loosening over time.

It should be appreciated that the fixation mechanism 26 is one example of many options which would be available, and any appropriate fixation mechanism may be used. A modified form of fixation mechanism is illustrated simplistically in Figure 4. In this fixation mechanism 46 a head portion 48 may be rotated relative to the pedicle screw 20 and fixed such that slot 50 is provided at a desired angle to the pedicle screw 20. Use of the fixation mechanism 46 provides the ability to secure the helical spring member 18 to adjacent vertebra in such a manner as to exert forces on the motion segment to create lordosis or kyphosis.

Referring now in particular to Figure 2, a helical spring member 18 for incorporation into the assembly 10 is illustrated more clearly. Figure 2a shows the helical spring member 18 from Figure 1, with the sleeve 18c partially cut away to show the helical spring member 18 more clearly. In Figure 2b the sleeve 18c completely covers the helical spring member 18.

The helical spring member 18 is made from titanium or stainless steel wire, each spring member being formed from a single piece. The wire will typically have a diameter in the range 1 to 6mm, but preferably in a range of 2 to 5mm. The wire may be round in cross-section or may be of other forms e.g. square, rectangular, or oval in cross section.

Helical spring member 18 designed to be used between adjacent vertebral bodies, have an overall length in the range 20mm to 65mm, but preferably in the range 25mm to 60mm.

Referring now in particular to Figure 5, a pair of assemblies 10 according to this invention are shown secured to a pair of adjacent vertebral bodies 12, 14. This is the manner in which the assembly 10 will generally be used, with one assembly 10 applied to either side of the vertebral bodies on the posterior aspect of the spine.

Referring now to Figure 6 one effect of use of the assemblies 10 is illustrated. In Figure 6, it can be seen that unloading of the inter-vertebral disc can be achieved by separation of the pedicle screws 20, or distraction of them, along the passive end portions 18b of the helical spring member 18 before securing the helical spring member 18 to the pedicle screws 20 using the fixation mechanisms 26. Thus the assembly 10 will hold the vertebral bodies 12, 14 further apart, unloading the disc, yet still permit some movement which is relatively normal.

Referring now to Figure 7, another effect of the use of the assemblies 10 is illustrated. In particular, it can be seen that lordosis of the motion segment can be achieved by controlling the angle of fixation of the inactive portions 18b

of the helical spring member 18 with respect to the pedicle screws 20 using the fixation mechanisms 46.

The assembly 10 may also comprise elastic members 60 as illustrated in Figure 8a, or elastic members 70 as illustrated in Figure 8b. Elastic member 60 comprises an active central portion 61 and loops 62 at each end for connection to the head ends of the pedicle screws 20 in the manner shown in Figure 9. Elastic member 70, being a continuous loop of material can simply be secured around the head ends of the pedicle screws 20 as shown in Figure 10. In such assemblies 10 the pedicle screws may appropriately have specific provision (not shown) for receipt of the elastic members. Where two elastic members are used crossed across the motion segment, in combination with two assemblies as previously described, as in Figures 9 and 10, it will control the rotation of the vertebral bodies in relation to each other in either direction. Such an arrangement is for the treatment of low back pain.

For the treatment of deformity, the elastic members 60, 70 are used to resist rotation of the motion segments in either clockwise or anticlockwise directions as required, and as illustrated in Figure 11. Thus for the treatment of deformity a single elastic member will generally be used in each motion segment being treated, connecting a pedicle screw inserted on one side of the upper vertebra and a pedicle screw inserted on the opposite side of the lower vertebra. The elastic member may be used on its own or in combination with a helical spring member.

It is anticipated that a combination of helical spring members 18 and/or elastic members 60, 70 may be used to correct a range of deformities. For example, use of one helical spring member on one side of a motion segment will try to bend the spine laterally, whilst a single elastic member crossing across the motion segment will tend to rotate the spine in one direction. Hence, a combination of helical spring members 18 and/or elastic members 60, 70 may be used in several motion segments to correct scoliosis of the spine.

It is anticipated that the assemblies according to the invention will normally be implanted incorporating both helical springs and elastic members. However, the exact form of assembly used for any particular patient will be selected by the surgeon performing the operation to provide the appropriate treatment for the condition being treated. In some cases this will mean implantation of the assembly incorporating just one or more helical springs, and no use of elastic members, or just one or more elastic members and no use of helical spring member.

The exact design of helical spring members for use in a particular case will depend on a large number of factors. These will include the sizes of the vertebral bodies, the number of motion segments requiring stabilisation, and the particular condition being treated. Similar considerations apply to the form of elastic members 60, 70 which will be chosen to provide the required forces.

In the present specification "comprises" means "includes or consists of" and "comprising" means "including or consisting of".

The features disclosed in the foregoing description, or the following claims, or the accompanying drawings, expressed in their specific forms or in terms of a means for performing the disclosed function, or a method or process for attaining the disclosed result, as appropriate, may, separately, or in any combination of such features, be utilised for realising the invention in diverse forms thereof.

Claims

1. An assembly for soft stabilisation of vertebral bodies of the spine comprising a pair of pedicle screws each having a threaded shaft with a tapering first end for introduction into a vertebral body and a head portion with a second end, characterised in that it further comprises:

a helical spring member having first and second ends; and

a pair of fixation mechanisms for securing the first and second ends of the helical spring member to the pair of pedicle screws.

2. An assembly according to claim 1 characterised in that the helical spring member comprises an active central portion between first and second passive end portions.

3. An assembly according to claim 2 characterised in that the active central portion of the helical spring member comprises spaced apart coils of a first diameter.

4. An assembly according to claim 3 characterised in that the passive end portions of the helical spring member comprise closely adjacent coils of a second diameter, the second diameter being smaller then the first diameter.

5. An assembly according to claim 4 characterised in that the second diameter is between two thirds and one third of the first diameter.

6. An assembly according to claim 5 characterised in that the second diameter is substantially half the first diameter.

7. An assembly according to any one of the preceding claims characterised in that the helical spring member is formed from wire.

8. An assembly according to claim 7 characterised in that the wire has a diameter in the range 1 to 6 mm.

9. An assembly according to claim 8 characterised in that the wire has a diameter in the range 2 to 5 mm.

10. An assembly according to any one of claims 7 to 9 characterised in that the wire is round in cross section.

11. An assembly according to any one of claims 7 to 10 characterised in that the wire is titanium or stainless steel.

12. An assembly according to any one of the preceding claims characterised in that it further includes a sleeve covering the helical spring member.

13. An assembly according to Claim 12 characterised in that the sleeve is made of plastics material.

14. An assembly according to any one of the preceding claims characterised in that it further comprises an elastic member securable to the head ends of a pair of pedicle screws.

15. An assembly for soft stabilisation of vertebral bodies of the spine comprising a pair of pedicle screws each having a threaded shaft with a

tapering first end for introduction into a vertebral body and a head portion with a second end, characterised in that it further comprises:

an elastic member having first and second ends; and

a pair of fixation mechanisms for securing the first and second ends of the elastic member to the pair of pedicle screws.

16. An assembly according to Claim 14 or 15 characterised in that the elastic member comprises an active central portion and loops at each end for securing to the pedicle screws.

17. An assembly according to Claim 14 or 15 characterised in that the elastic member comprises a continuous band.

18. An assembly according to any one of the preceding claims characterised in that it is for stabilisation of two adjacent vertebral bodies of the spine.

19. An assembly for the stabilisation of two adjacent vertebral bodies of the spine substantially as hereinbefore described with reference to the accompanying drawings.

20. Any novel feature or novel combination of features described herein and/or in the accompanying drawings.

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Application No: GB 0124291.6 **Examiner:** Dr Jonathan Corden
Claims searched: 1-14 **Date of search:** 27 March 2003

Patents Act 1977 : Search Report under Section 17

Documents considered to be relevant:

Category	Relevant to claims	Identity of document and passage or figure of particular relevance	
X	1, 7, 11	US 5733284 A	(MARTIN) see figs, column 2 lines 12-29, column 3 line 50 - column 5 line 14 and column 6 lines 1-24
X	1, 7, 11	US 5423816 A	(LIN) see figs, column 2 line 28 - column 3 line 16
X	1	US 5180393 A	(COMMARMOND) see figs, column 1 lines 1-3 and 18-35, column 2 lines 6-18, column 3 lines15-16
A, E	1, 2, 7-11	WO 02/102259 A2	(SENGUPTA et al) see figs, abstract, page 3 line 9 - page 4 line 24 and claims especially
A	-	WO 01/45576 A1	(SYNTHES)
A	-	GB 2269753 A	(SURGICRAFT)
A	-	EP 0669109 A	(PROTEK) and also WPI Abstract Acc. No. 1995-294163

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X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
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Field of Search:

Search of GB, EP, WO & US patent documents classified in the following areas of the UKC[V]:

A5R

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A61B

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EPODOC, WPI, PAJ

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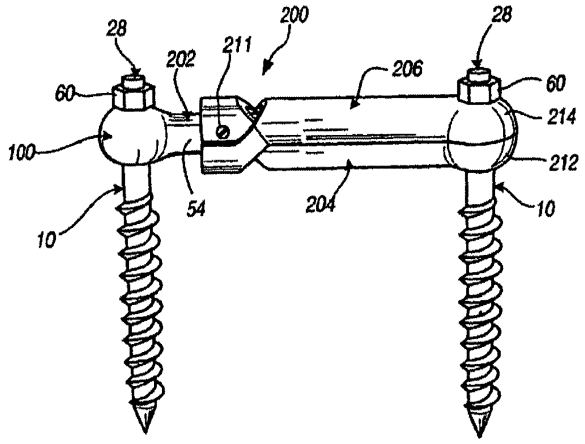
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(54) Title: CONNECTION ROD FOR SCREW OR HOOK POLYAXIAL SYSTEM AND METHOD OF USE



(57) Abstract: A low-profile surgical implant assembly is provided that includes a connector device (28) that is an integral part of a rod, the connector device allowing the rod to be attached directly to a bone screw, such as a pedicle screw (10). Another aspect of the invention is a clamp device (200) that allows the length of a rod spanning to attachment devices to be adjusted at the time of implantation, and further allows the clamp device to be secured by tightening a securing end of the clamp at the attachment device. The assemblies are useful for insertion into bone and connecting a foreign object to bone via a polyaxial coupling mechanism. A method for implanting the assembly is also provided.

WO 03/026523 A1

CONNECTION ROD FOR SCREW OR HOOK POLYAXIAL SYSTEM AND METHOD OF USE

FIELD OF THE INVENTION

This invention relates generally to an adjustable rod for stabilizing a portion of the spine, or two or more bone segments and a method of using the same. More specifically, the device and method include a series of components that provide a low-profile configuration when assembled, thereby minimizing tissue displacement and interference with nearby joint articulation.

BACKGROUND OF THE INVENTION

The use of fixation devices for the treatment of vertebrae deformities and injuries is well known in the art. Various fixation devices are used in medical treatment to correct curvatures and deformities, treat trauma and remedy various abnormal spinal conditions. Treatment of these conditions generally requires the implantation of various component pieces such as support rods, crosslinks, caudal facing hooks, cranial facing hooks and like components, which form a spinal implant system.

It is necessary in spinal implant systems to properly anchor the system to bone to provide necessary support of the implant. Bone screws are commonly used for anchoring spinal implant systems. However, there are several problems with the use of fixed screws for anchoring spinal implants. The exact final position of a bone screw is difficult, if not impossible, to predict prior to the exposure of the patient's bone. This unpredictability results from the uncertainty of exact bone formation and shape within an individual patient. Additionally, it can be difficult to predetermine the structure of the bone, i.e. whether the bone is soft or even osteoporotic. Even if the final position of the screw can be predetermined, the necessary shape and position of a spinal rod implant may create unwanted stress upon the bone screw or the bone itself. This is especially true where a plurality of screws is required along the spinal column for securement of an implant. The alignment of the rod with several screws along the vertebrae compounds this problem and makes undesired stress much more probable. Moreover, this misalignment may influence the extent and speed of correction of the spinal defect.

It is thus desirable to have a polyaxial securement method. There exists a number of patents drawn to polyaxial bone screws. Unfortunately, the advantage of many of these

designs comes at the expense of bulk in the connection means or complexity of implantation. Such devices included complicated retention collets or securing systems that eliminate the device from functioning as a polyaxial system. In addition, as the size of a bone screw increases, so too does the displacement of normal bodily formations, such as muscular tissue or bone. It is common in the insertion of spinal implants to necessarily remove portions of vertebral bone to allow proper insertion of a bone screw. Moreover, this bulk may result in long-term muscular displacement that may lead to a patient's pain or discomfort.

Increased complexity of the installation procedure is undesirable because it increases a patient's time in surgery. Increased operating time is known to increase the risk of many complications associated with surgery. The additional time necessary to remove, or even temporarily dislocate, bone or muscular tissue also increases operating time, and thus the risk of complications.

In addition, the prior art fails to provide a low-profile multi-piece connector that includes poly-axial adjustability and that can be used to accommodate a variety of geometry requirements that may arise for certain patients. Therefore, a need exists to provide a low-profile multi-piece connector that can be adapted to a variety of geometry requirements.

The prior art also fails to provide a tool for implantation of an attachment device that has an entry channel for a tension link, or that otherwise has an expansion slot. Thus, a need exists for a tool that fittingly accepts the head of a attachment device that has a hollow core with either an entry channel and/or at least one expansion slot, and that can be used to accept and drive into bone the attachment device.

In addition to the above noted shortcomings of the prior art, the prior art also fails to provide a low-profile device that includes a connector that can be positioned at the very end of a stabilizing rod, thereby providing a device that does not disturb the adjacent vertebra. More specifically, the connectors of the prior art require attachment to the rod with a section of rod extending beyond the connector itself. Accordingly, a need exists to reduce or otherwise minimize the length of rod run-out beyond the end connector to prevent interference with the articulation of the neighboring vertebrae.

The prior art also fails to provide a low-profile device that allows the rod length to be easily adjusted during implantation with a minimal amount of effort by the installing surgeon. More particularly, where two bone segments, such as a first vertebra and a second

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vertebra, are being bridged by existing devices, the rod typically extends beyond the connector, and needs to be specifically chosen or otherwise cut to accommodate the dimensions of the subject patient. Therefore, a need exists to provide an adjustable length rod implantation assembly that can be installed relatively easily by a surgeon, and that further has an ability to be adjusted at the moment of implantation to thereby accommodate the geometry requirements of the patient. In addition, a need exists for an extended shaft to a tension link that can thereby act as a guide or leader for installation of a number of the assembly components. Such a device can serve to simply the installation process and minimize the size of the incision necessary to access the patient's interior surgical site.

The prior art also fails to provide a rod implant that can be telescopically adjusted at the time of implantation. Such a device is needed to further accommodate the individual patient's requirements that exist and that are encountered upon performing and incision and encountering *in situ* conditions.

It is also desirable with some patients to have a spinal implant system that allows the vertebral column to settle naturally under the weight of the human body. Human bone heals more readily under some pressure. In a rigid spinal implant system, the patient's spinal column may be unnaturally held apart by the structure of the implant. It is possible that this stretching of the vertebrae, in relation to one another, results in delayed or incomplete healing of the bone.

In view of the above, there is a long felt but unsolved need for a method and system that avoids the above-mentioned deficiencies of the prior art and that provides an effective system that is relatively simple to employ and requires minimal displacement or removal of bodily tissue.

SUMMARY OF THE INVENTION

In accordance with the present invention, a polyaxial attachment device is provided with a socket for receiving a headed connecting link. A surgical implant assembly employing the polyaxial attachment device is also disclosed. The surgical implant assembly of the present invention includes an attachment device, a headed anchor shaft (or tension link), a connector formed as an integral part of a first stabilizing rod, and a clamp device that grasps

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the first stabilizing rod while also attaching to a second attachment device using a second interconnecting mechanism, such as a tension link.

The attachment device of the present invention has a shank with a securement mechanism on one end and an enlarged area on the other end. The securement mechanism may be selected from any known method of securing one article to another, for example, a hook, a plate, a flanged device, or an adhesive, however, it is anticipated that the most common securement mechanism used will be screw threads. The enlarged area includes a hollow core, i.e., a socket, and a central aperture providing access to the hollow core. The enlarged area need only be large enough to envelop the head of the tension link and provide a wall thickness necessary for strength considerations.

The attachment device may include additional features to enable the insertion of the head end of the tension link into the hollow core. The enlarged area of the attachment device may include an entry channel leading to the hollow core that accommodates the tension link head end so that the tension link may be advanced, shaft end first, until the head of the tension link is positioned within the hollow core. Additionally, the entry channel and the central aperture may be connected by a slot through the wall of the enlarged area. In this way, the tension link head end may be positioned within the hollow core without extending the entire length of the tension link beyond the enlarged area of the attachment device opposite the central aperture. The surgeon may place only the head end of the tension link at the entry channel, slide the tension link shaft through the tension link slot, and draw the head end into the hollow core. Alternatively, in lieu of an entry channel or tension link slot, the enlarged area may include one or more expansion slots. In this embodiment, the head of the tension link may be inserted into the hollow core through the central aperture by the application of enough force to expand the central aperture. Once the head of the tension link is properly received into the hollow core, the enlarged area returns to its original size and shape. Unwanted expansion of the enlarged area is prevented by the connector once the enlarged area is properly seated into a head receptacle on the connector during implantation. This maintains the head of the tension link within the hollow core.

The external surface of the enlarged area of the attachment device may be formed into one of limitless geometries. For example, the external surface may be spherical, or at least semi-spherical. The external surface may be at least slightly aspheric. By controlling the

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degree of asphericity, the contact surface between the attachment device and the connector can thereby control the degree of freedom of the connector relative to the attachment device. Alternatively, the external surface may be conical, or a truncated cone shape, to allow rotational freedom while maintaining a coaxial relationship between the attachment device and the connector. Also, the external surface may be polyhedral or provided with facets to allow angular displacement in only finite steps or prevented altogether. In embodiments including conical, truncated cone shape, polyhedral or faceted geometries of the external surface of the enlarged area, the mating head receptacle of the connector may have corresponding geometry.

The tension link secures and maintains the position of the connector relative to the attachment device. The tension link is a shaft with a head end and a thread end. The head end, as described above, is contained within the hollow core of the attachment device. The threaded end extends through the connector and is secured to the connector by a tension link nut (herein also referred to as a "link nut") threaded onto the thread end.

The tension link may be provided with a projection to prevent undesirable rotation of the link when tightening or loosening the link nut, yet still enable angular displacement necessary to provide a polyaxial connection. In one embodiment, a link retainer, or a projection, may be provided on the shaft of the tension link. In this embodiment, it is necessary to provide a link retainer recess within the tension link cavity of the connector. In an alternative embodiment, the link retainer, or projection, may be provided at the intersection of the tension link shaft and the head end, and extending over a portion of the surface of the head end. In this embodiment, used with the attachment device embodiment including a tension link slot, the rotation may be prevented by contacting the link retainer with one side of the tension link slot. In either of the two foregoing embodiments, it is desirable to undersize the link retainer, relative to the link retainer recess or the tension link slot, so that the polyaxial freedom of the tension link and attachment device combination is not unduly limited. In an alternative embodiment, a retaining process, or small projection, may be provided on the tension link head. The retaining process should be positioned such that the retaining process is within the entry channel. Undesired rotation may be prevented by contacting the small projection with the wall of the entry channel.

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The connector couples the attachment device to the implant component, such as a spinal rod implant. One type of connector described herein has a connecting end with a head receptacle, a rod end with a rod aperture, and a tension link cavity. The tension link, with its head positioned in the hollow core of the attachment device, is inserted through the tension link cavity so that an enlarged area of the attachment device nests in the head receptacle. The rod aperture secures the implant component in a desired position. The rod aperture may be secured by the tension link when the link nut is threaded and tightened on the link. In this embodiment, the rod end of the connector has a gap on one side of the rod aperture. The tension link cavity extends continuously through the tension link on both sides of the gap. The upper portion of the rod end forms a tab. As the tab is drawn toward the receiver end of the connector the gap narrows until the rod aperture firmly clamps the implant component or until the gap is drawn completely together.

In still other embodiments, it may also be desirable to provide a separate system for securing the connector to the attachment device and for securing the implant component to the connector. Therefore, in an alternative embodiment, the gap is connected to the rod aperture in a position that does not intersect the rod aperture. In this embodiment, a separate screw, or other connection device, is required to secure the implant component in the rod aperture. The tension link is then used to secure the connector to the attachment device.

In either of the two foregoing connector embodiments, it may be desirable to secure the rod within the rod aperture without clamping to the extent axial movement of the rod within the rod aperture is prevented. In this way, for example, the spine may settle under its own weight and provide a better healing environment for the bone. In conjunction with this embodiment, the implant component may be supplied with flanges, or other extensions to constrain axial movement of the implant component within a desired range.

To surgically implant a device of the present invention, the surgeon may attach an attachment device, selected from one of the embodiments of the present invention. After successful attachment, the surgeon may insert a tension link of the present invention by positioning the head end of the tension link within the hollow core of the attachment device. The surgeon may then place a connector, with a head receptacle designed for mating with the second end of the attachment device, upon the attachment device by inserting the tension link through the tension link cavity of the connector. At this point, the surgeon may select the

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desired angle of position of the connector for attaching a implant component. Once the connector is properly adjusted, the link nut may be secured to the tension link, thereby securing the elements together in the desired position. The link nut may be loosened, as necessary, to readjust the placement of the implant component. Alternatively, if a connector having a separate implant component securement device is used, the step of securing the link nut may be delayed until after the implant component is secured in the rod aperture and properly positioned.

Based on the foregoing summary, a number of worthwhile aspects of the present invention can be readily identified. An attachment device is provided with a small and simple polyaxial adjustment mechanism. The minimal size of the enlarged area of the attachment device allows attachment of the device to human bone without significant displacement of human tissue. Therefore, the complexity of surgery and the following pain and discomfort of the patient may be minimized. The polyaxial nature of the device, combined with the small size, may allow a surgeon to attach the securement device to a secure portion of the human body without the need to remove bony processes to accommodate a larger attachment device. Additionally, a simple surgical implant assembly, including the polyaxial attachment device, is provided. The simplicity of the elements, and the assembly process thereof, may reduce the patient's time in surgery, thus reducing the risk and probability of surgical complications. Finally, a number of embodiments of the present invention may be used in combination to allow the surgeon great latitude in selection of materials. The surgeon may select from different embodiments of the attachment device, the tension link, and the connector to best fit the surgical implant parameters. With these choices the surgeon may then best determine which embodiments of which elements to select to minimize removal or displacement of bodily tissue or bone, and thereby reduce both the patient's risk of surgical complications and post-surgical pain and discomfort.

A significant feature of the present invention is the ability to provide a construct used to stabilize the spine or a portion thereof. The construct utilizes a single tension link nut to tighten down the structure at each bone screw (also referred to herein as an attachment device) location. More particularly, the present invention utilizes a bone screw or attachment device that possesses threads at one end along a shaft and an enlarged head with a hollow core at the other end. The threads are used to secure the bone screw to bone. The enlarged

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head of the bone screw includes an entry channel, tension link slot, or both that allows the shaft of the tension link to be fed up through the entry channel or tension link slot. In addition, the hollow core is shaped to receive the head of a tension link. The enlarged area of the bone screw possesses an aperture that is sized to permit the shaft of the tension link to pass through it, while retaining the head of the tension link. The shaft of the tension link is then fed through a connector. The connector is a component that possesses a separate aperture to receive a stabilizing rod. A tension link nut is then secured to the end of the threaded tension link shaft, thereby securing the connector to the tension link and bone screw.

In a separate aspect of the invention, a tool is provided to insert the attachment device. The tool includes a head portion that cooperates with the structural features of the attachment device. More specifically, the head portion of the tool includes a projection to mate with the hollow core, and/or the expansion slot, and/or the entry channel of the attachment device. The tool is rotated to force the threads of the opposite end of the attachment device to advance into the target bone segment. After the attachment device is inserted, the tool is disengaged from the attachment device thereby leaving the attachment device installed.

In an another embodiment of the invention, a multi-piece connector is provided that allows additional adjustability of the connector device. The multi-piece connector includes use of the attachment device having a hollow core and a tension link that includes a head that is fitted into the hollow core. A first piece of the multi-piece connect is attached by feeding the shaft of the tension link through an opening in the first piece. The implant rod is then positioned proximate the first piece and adjacent a cam portion of the first piece. The second piece of the multi-piece connector is then positioned over the implant rod by again passing the shaft of the tension link through an opening in the second piece. Finally, after adjusting the desired angle of the multi-piece connector by rotating the tension link within the attachment device, a link nut is then applied to the threaded end of the shaft of the tension link thereby tightening the nut against the connector and the enlarged head of the attachment device.

In an alternate embodiment, a connector is formed in the implant rod itself. In this embodiment, the rod possesses a receptacle that is a socket, such that the ball of the enlarged area of the attachment device with the head of the tension link in place, fits into the socket

that is an integral part of the rod. Thus, a ball-and-socket arrangement is formed providing a polyaxial connector within the rod itself. A tension link nut is then secured to the end of the threaded shaft of the tension link, thereby securing the rod to the bone screw. When positioned at the end of a rod, this is a very low profile configuration that minimizes the length of the incision that is necessary to perform the surgery. Furthermore, a mechanical advantage is gained by the interaction of the components as previously described. Specifically, strength of the final connection is not simply attributable to the tightening of the tension link nut, but is also attributable, in part, to the placement of the head of the tension link within the hollow core of the bone screw, or attachment device. In so doing, the head of the tension link causes a slight expansion of the hollow core, much like how a wedge is used to secure an axe head at the top of an axe handle. The enlarged area of the screw is in turn partially encompassed by the receptacle socket of the rod itself.

In yet a separate aspect of the invention, a clamp device is furnished for providing an adjustable rod structure for implantation. In one embodiment of the clamp, the clamp includes a lower clamp portion and an upper clamp portion. The lower clamp portion has a clamp region that cooperates with a clamp region on the upper clamp portion. At a spaced distance from the clamp regions, the lower clamp portion has a securing end that cooperates with a securing end on the upper clamp portion. The lower and upper clamp portions are used in combination with an interior rod member that is grasped by the clamp regions of the lower and upper clamp portions when the securing ends of the lower and upper clamp portions are brought into a tight mating configuration. More specifically, the securing ends of the lower and upper clamp portions include receptacles that have sockets that mate with each other and that also mate with the enlarged area of an attachment device.

A method of use is also presented for the clamp device, wherein in a preferred embodiment the two attachment devices are installed by advancing an attachment device into each of two bone segments. The hollow core of each attachment device is then fitted with a the head of a tension link. Alternately, the tension link may be inserted into the hollow core of the tension link prior to insertion of the attachment devices into bone. After the attachment devices with their respective tension links are in place, one of the attachment devices is fitted with an interior rod member that includes a rod portion and an end connector in the form of a receptacle shaped like a socket. The socket includes a tension link cavity

such that the shaft of the tension link is passed through the tension link cavity as the socket is being placed over the enlarged area of the first attachment device. A clamp comprising a lower and upper clamp portion is then assembled to grasp the rod portion of the interior rod member as the upper and lower clamp are connected to the second attachment device by passing the shaft of the second tension link through tension link cavities in the securing ends of the lower and upper clamp portions. Link nuts are then threaded on to exposed ends of the tension link shafts and are tightened. The position of the interior rod member can be adjusted within the clamp as the link nuts are tightened, thereby allowing the surgeon to adjust the size of the assembly to accommodate the patient's needs for a customized fit. The assembly minimizes the need to create a large incision because implantation work can be substantially performed from a direction perpendicular to the bone segments. Furthermore, this low profile assembly is relatively simple to install, thereby reducing surgery time over existing stabilizing devices.

In a separate aspect of the invention, a telescoping rod is provided that allows adjustability of the rod. The telescoping rod includes an inner and an outer member that cooperate to allow the surgeon to adjust the length of the rod to span two attachment devices. A set screw may be used with this embodiment to interlock the inner and the outer rod members.

In yet a separate aspect of the invention, the tension links may include an extended shaft that serve as guides for lowering and/or installing implantation components over and onto the attachment devices. After acting as guides for the lowering of implantation components over the attachment devices, link nuts are guided to the thread portions of the tension links. The extended shafts are subsequently removed by a shearing tool, by breaking the extended shaft portion away from the tension link along a pre-existing score location, or by other appropriate means.

Additional advantages of the present invention will become readily apparent from the following discussion, particularly when taken together with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1a is a partial cross-sectional view of one embodiment of the attachment device of the present invention;

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Fig. 1b is an end perspective view of an alternative embodiment of the attachment device of the present invention;

Fig. 2 is an end perspective view of an alternative embodiment of the attachment device of the present invention;

Fig. 3 is a cross-sectional view of the attachment device shown if Fig. 2;

Fig. 4 is an end perspective view of another alternative embodiment of the attachment device of the present invention;

Fig. 5 is a top plan view of the attachment device shown in Fig. 4;

Fig. 6 is an end perspective view of yet another alternative embodiment of the attachment device of the present invention;

Fig. 7 is an end perspective view of still another alternative embodiment of the attachment device of the present invention;

Fig. 8 is an elevation view of the attachment device shown in Fig. 7;

Fig. 9a is an front elevation view of one embodiment of the tension link with a link retainer of the present invention;

Fig. 9b is a side elevation view of the tension link with link retainer shown in Fig. 7a;

Fig. 9c is an end view of the tension link with link retainer shown in Fig. 7a;

Fig. 10a is an front elevation view of an alternative embodiment of the tension link with a link retainer of the present invention;

Fig. 10b is a side elevation view of the tension link with link retainer shown in Fig. 8a;

Fig. 11 is a perspective view of the tension link with head end process of the present invention;

Fig. 12 is a side elevation view of one embodiment of the connector of the present invention;

Fig. 13 is a side perspective view of an alternative embodiment of the connector of the present invention;

Fig. 14 is an bottom perspective view of the connector shown in Fig. 11;

Fig. 15 is a side perspective view of another alternative embodiment of the connector of the present invention;

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Fig. 16 is a side elevation view of yet another alternative embodiment of the connector of the present invention;

Fig. 17 is a cross-sectional view of one embodiment of the surgical implant assembly of the present invention;

Fig. 18 is a perspective view of an alternative embodiment of the surgical implant assembly of the present invention;

Fig. 19a is a cross-sectional elevation view of another alternative embodiment of the surgical implant assembly of the present invention;

Fig. 19b is a plan view of the surgical implant assembly shown in Fig. 17a;

Fig. 20 is a top plan view of a separate embodiment of a connector;

Fig. 21 is a side cross-sectional view of the connector shown in Fig. 20;

Fig. 22 is a side cross-sectional view of a separate embodiment of an attachment device and tension link having truncated portions;

Fig. 23 is a perspective view separate embodiment comprising a tool to install the attachment device of the present invention;

Fig. 24 is a cross-sectional view the receptacle end of the tool shown in Fig. 23;

Fig. 25 is a side elevation view of a separate embodiment of an end connector;

Fig. 26 is a perspective view of the connector shown in Fig. 25;

Fig. 27 is a top elevation view of the connector shown in Fig. 25;

Fig. 28 is a bottom interior perspective view of the connector shown in Fig. 25;

Fig. 29 is a perspective view of the connector shown in Fig. 25 with the connector shown in combination with an attachment device and a tension link;

Fig. 30 is an end cross-sectional view of the combination of structures shown in Fig. 29;

Fig. 31 is a perspective view of a separate aspect of the invention comprising a clamp, wherein the clamp is depicted as a component of a stabilization assembly;

Fig. 32 is a perspective view of an upper clamp portion of the clamp;

Fig. 33 is a perspective view of a lower clamp portion of the clamp;

Fig. 34 is a perspective view of the lower and upper portions of the clamp in near interlocking proximity;

Fig. 35 is a cross-sectional view of a clamp having contact ridges;

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Fig. 36 is a plan view of a separate embodiment of the clamp, wherein the clamp is being retrofitted to an existing rod segment;

Fig. 37 is a plan view of yet a separate embodiment of the clamp, wherein the clamp is again being retrofitted to an existing rod segment;

Fig. 38 is a partially exploded perspective view of two stabilization assemblies including clamps, wherein the assemblies are aligned for implantation into two vertebra;

Fig. 39 is a side elevation view of one stabilization assembly including a clamp device after implantation into two vertebra;

Fig. 40a is a side cross-sectional view of one of the stabilization assemblies shown in Fig. 38;

Fig. 40b is a cross-sectional view taken along line 40b-40b shown in Fig. 40a;

Fig 41 is side cross-sectional view of stabilization assembly having a separate embodiment of a the clamp device;

Fig 42a is side cross-sectional view of a stabilization assembly having yet a separate embodiment of a the clamp device;

Fig. 42b is a cross-sectional view taken along line 42b-42b shown in Fig. 42a;

Fig. 42c is a cross-sectional view taken along line 42c-42c shown in Fig. 42a;

Fig. 43 is a plan view of a separate aspect of the invention;

Fig. 44a is a perspective view of an stabilization assembly having extended tension link shafts; and

Fig. 44b is an enlarged detail view of an aspect of an extended tension link shaft shown in Fig. 44a.

While the following disclosure describes the invention in connection with those embodiments presented, one should understand that the invention is not strictly limited to these embodiments. Furthermore, one should understand that the drawings are not necessarily to scale, and that in certain instances, the disclosure may not include details which are not necessary for an understanding of the present invention, such as conventional details of fabrication.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

With reference to Fig. 1, one embodiment of the attachment device (or connection device) of the present invention is shown in partial cross-section. The attachment device 10 includes a shank 12 having a first end 14 and a second end 16. The first end 14 of the shank 12 includes a securement mechanism 18. As shown in Fig. 1, the securement mechanism 18 may be screw threads. It is noted, however, that the securement mechanism 18 may include any known method of securing one item to another. For example, the securement mechanism 18 may be a hook, a plate, a flange, or adhesive. In the case of the securement mechanism 18 as a flange or plate, the securement mechanism 18 may require additional hardware such as screws, bolts, or adhesive to secure the plate or flange to the intended object. In the case of the securement mechanism 18 as an adhesive, or requiring the additional use of adhesive, the adhesive would necessarily be applied to the securement mechanism 18, not included within it. Additionally, adhesive could be used with the securement mechanism 18, e.g., applied to screw threads, for additional securement capacity.

The second end 16 of the shank 12 generally comprises an enlarged area 20 including a central core 22 and an aperture 24. The second end 16 of Fig. 1 is shown in cross-sectional view to more clearly show the central core 22 and the aperture 24.

With reference to Fig. 2, an embodiment of the second end 16 of the shank 12 is shown. In this embodiment, the enlarged area 20 includes a hollow core 22 and a central aperture 24. The enlarged area also includes an entry channel 26. The entry channel 26 is operatively connected with the hollow core 22 such that a tension link 28, having a shaft 30 with a threaded end 32 and a head end 34, may be inserted, threaded end 32 first, through the entry channel 26, the hollow core 22, and central aperture 24 until the head end 34 of the tension link 28 is retained within the hollow core 22 by the central aperture 24.

With reference to Fig. 3, the embodiment of the second end 16 of attachment device 10 is shown in cross-section. Fig. 3 clarifies the operational relationship between the entry channel 26, the hollow core 22 and the central aperture 24.

With reference to Fig. 4, an alternative embodiment of the attachment device 10 is shown. This embodiment is similar to the embodiment of Figs. 2 and 3, but with an additional element. In this embodiment, a tension link slot 36 is provided between the entry channel 26 and the central aperture 24. The tension link slot 36 allows the shaft 30 of the

tension link 28 to be inserted through the tension link slot 36. In this way, the tension link 28 may be inserted through the tension link slot 36 to pass through both central aperture 24 and the entry channel 26. The tension link 28 may then be drawn through the aperture 24 until the tension link head end 34 passes through the entry channel 26 and rests in the hollow core 22. This embodiment may allow the surgeon to insert a tension link 28 into an attachment device 10 secured to the human body in cases where the obstacles, including the human body itself, or parts thereof, prevent the length of the tension link 28 from extending completely beyond the entry channel 26 opposite the central aperture 24.

Fig. 5 shows an end view, from the second end 16, of the embodiment of the attachment device 10 from Fig. 4. Fig. 5 clarifies the relationship between the tension link slot 36 and the central aperture 24, the hollow core 22 and the entry channel 26. It should be noted that the central aperture 24 is shown in Fig. 5 as located at top, dead center of the enlarged portion 20 of the attachment device 10. However, the location of the central aperture 24 may be at any angular relationship to the shank 12. This location of the central aperture 24 applies to this, and every other, embodiment of the attachment device 10. The hollow core 22 should be sized to receive the head end 34 of the tension link 28, in this and other embodiments of the present invention. Similarly, the central aperture 24 should be sized to accommodate the tension link shaft 30, and with enough clearance to provide the desired angular displacement. For example, it may be desirable to provide from about 0 to 60 degrees of angular displacement of the tension link 28 from the longitudinal axis of the attachment device 10. In some instances, a smaller range may be advantageous.

With reference to Fig. 6, an additional alternative embodiment of the enlarged area 20 of the attachment device 10 is shown. In this embodiment, the enlarged area 20 includes a hollow core 22 and a central aperture 24, but does not include an entry channel 26. Instead, at least one expansion slot 38 extends from the central aperture 24 along the exterior surface of the enlarged area 20. The expansion slot 38 extends completely through the wall defined by the hollow core 22 and the exterior surface of the enlarged area 20. The embodiment of Fig. 6 includes two expansion slots 38 diametrically opposite from one another, however, the number of expansion slots 38 and their location in radial relation to the central aperture 24 may be selected in the design of the attachment device 10 according to, among other things, the application, or the size and material of construction of the attachment device 10. The

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expansion slot(s) 38 may allow insertion of the head end 34 of the tension link 28 into the hollow core 22 through the central aperture 24 by allowing deformation of the enlarged area 20. As explained in more detail below, the connector 40, more specifically, the head receptacle 42 of the connector 40, when properly installed over the enlarged area 20 prevents further deformation of the enlarged area 20, and thus the central aperture 24 retains the head 34 of the tension link 28 within the hollow core 22.

With reference to Fig. 7, yet another alternative embodiment of the enlarged area 20 of the attachment device 10 is shown. In this embodiment, at least a portion of the enlarged area 20 includes a substantially conical portion around the central aperture 24. The head receptacle 42 of the connector 40 has mating geometry to the enlarged area 20. Thus, the partially conical shape of the enlarged area 20 allows polyaxial positioning of the connector 40 while controlling movement in one degree of freedom. The connector 40 may rotate around the central axis of the conical section, however, the mating geometry of the head receptacle 42 prevents angular displacement relative to the central axis of the conical section. Obviously, the central aperture 24 may require that the shape of the enlarged area 20 not be truly conical. The central aperture 24 may necessitate the geometry of the enlarged area 20 to be more aptly described as a truncated cone shape.

Fig. 8 shows the embodiment of the attachment device 10 of Fig. 7 in an elevation view. While Fig. 8 shows the enlarged area 20 to include a hollow core 22, a central aperture 24, and an entry channel 26, it is noted that conical-shaped enlarged area 20 shown in Figs. 7 and 8 may be used with any alternative embodiments of the attachment device 10 related to the method of insertion of the tension link head 34 into the hollow core 22, including, for example, the expansion slot(s) 38, or the tension link slot 36.

In alternative embodiments not shown in the drawings, the exterior surface of the enlarged area 20 may include other configurations. For example, the exterior surface of the enlarged area 20 may be formed as a polyhedron, such as a dodecahedron, or be provided with facets. In this embodiment, the head receptacle 42 of the connector 40 will also have a corresponding geometry. In this way, a polyaxial relationship is provided between the attachment device 10 and the connector 40, yet limiting this polyaxial relationship to a finite number of angular displacement.

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The enlarged area 20 is shown in the drawings as at least approximately spheric. It is noted, however that the enlarged area 20 and/or the head receptacle 42 of the connector 40 may also be aspheric. The use of the aspheric construction of either the enlarged area 20 or the head receptacle 42, or both, may accommodate the elasticity and deformation of the material the structure. The amount of asphericity may be selected to control the area of surface contact between the enlarged area 20 and the head receptacle 42 of the connector 40. The amount of asphericity may also be selected to control or vary the degree of freedom required by the linkage.

Further, in any embodiment or configuration of the enlarged area 20, the external surface of the enlarged area 20 may be textured, i.e., provided with a specified surface roughness. The texture, or surface roughness, of the enlarged area 20 may be selected to properly control the friction between the enlarged area 20 and the head receptacle 42, and thus controlling, among other things, the tension force required to secure the devices together or degrees of freedom in their combination. It should be noted that the internal wall of the hollow core 22, the head end 34 of the tension link 28, and/or the head receptacle 42 of the connector 40 may also be provided with a texture, or surface roughness.

With reference to Figs. 9a, 9b, and 9c, a tension link 28 is shown. The tension link 28 is generally a shaft 30 with a head end 34 and a thread end 32. As shown in Figs. 9a, 9b, and 9c, one embodiment of the tension link 28 may include a link retainer 44. The link retainer 44, in this embodiment, comprises a projection on the shaft 30 of the tension link 28. The link retainer 44 may be used to prevent unwanted rotation, but not angular orientation, of the tension link 28 within the hollow core 22 of the attachment device 10. An extended tension link 28 is shown in Fig. 44, as will be discussed below.

Fig. 9a shows an embodiment of the tension link with a link retainer 44 in partial side elevation. Fig. 9b shows the same embodiment in front elevation. Fig. 9c shows this embodiment in plan view as seen from the thread end 32 of the tension link 28. The thread end 32 of the tension link 28 is not shown in Figs. 9a, 9b, and 9c.

With reference to Figs. 10a and 10b, an alternative embodiment of the link retainer 44 of the tension link 28 is shown. The tension link 28 is shown in partial side elevation and partial front elevation, in Fig. 10a and Fig. 10b, respectively. Again, this view is "partial" because the thread end 32 of the tension link 28 is omitted from the drawing. The link

retainer 44 in this embodiment is a projection that spans the intersection of the shaft 30 and the head end 34 of the tension link 28 and extends partially along the surface of the head end 34. This embodiment may be used in conjunction with the embodiment of the attachment device 10 including the tension link slot 36, as shown in Figs. 4 and 5 above. As in the previous embodiment, the tension link may be prevented from unwanted rotation of the tension link 28 within the hollow core 22. The link retainer 44 may be placed in contact with the wall of the tension link slot 36 to prevent such rotation.

With reference to Fig. 11, an alternative embodiment of the tension link 28 is shown. The tension link 28 again includes a shaft 30 with a head end 34 and a thread end 32, and, in this embodiment, a head end process 46. The head end process 46 is a projection on the head end 34 of the tension link 28. The head end process 46 may be used to prevent rotation of the tension link 28 within the hollow core 22 similar to the link retainer 44. However, this embodiment would most commonly be used with an attachment device 10 having a entry channel 26, and the head end process 46 could be placed in contact with a wall of the entry channel 26 to prevent the rotation.

With reference to Fig. 12, an embodiment of the connector 40 is shown. The connector has a receiving end 48 and a rod end 50. The receiving end 48 includes a head receptacle 42 for receiving the enlarged area 20 of the attachment device 10. The rod end 50 includes a rod aperture 52 for receiving a implant component 54, such as a spinal rod implant or other device. A tension link cavity 56 is provided from the head receptacle 42 to the rod end 50. The tension link cavity 56 is sized to allow the insertion of the thread end 32 of a tension link 28 through the connector 40. In the embodiment of the connector 40 shown in Fig. 12, a link nut recess 58 is provided at the rod end 50 adjacent to the tension link cavity 56 for seating a link nut 60 used to secure the connector 40 to the tension link 28. As shown in Fig. 12, the connector may include a gap 62 located medially between the receiving end 48 and the rod end 50, and in operative relationship with the rod aperture 52 such that when the gap 62 is closed, the rod aperture 52 may secure the implant component 54. In this embodiment, tightening of the link nut 60 on the tension link 28 closes the gap 62, and thus secures the implant component 54, concurrently with securing the connector 40 to the attachment device 10 in a desired position. The embodiment shown in Fig. 12 includes the alternative feature of a link retainer recess 64. The link retainer recess 64 is a void located

along the tension link cavity 56 and adjacent to the head receptacle 42. The link retainer recess 64 accommodates the link retainer 44 of the embodiment shown in Fig. 9a, 9b and 9c, such that the link retainer 44 may contact the wall of the link retainer recess 64 and prevent undesired rotation of the tension link 28. The link retainer recess 64 should be sized accordingly.

Referring now to Fig. 13, an alternative embodiment of the connector 40 of the present invention is shown. Like the embodiment of Fig. 13, the connector 40 of this embodiment has a receiving end 48 with a head receptacle 42, a rod end 50 with a rod aperture 52, and a tension link cavity 56. In this embodiment, however, the rod aperture 52 is offset from the body of the connector 40. The ability to offset the rod aperture 52 may provide greater latitude to the surgeon when attempting to avoid obstacles such as bones or other tissues.

Fig. 14 shows the embodiment of the connector 40 of Fig. 13 from the receiving end 48. The tension link cavity 56 in this embodiment does not include the alternative element of the link retainer recess 64.

With reference to Fig. 15, an alternative embodiment of the connector 40 is shown. In this embodiment, the implant component 54 is secured in the rod aperture 52 separately from securing the connector 40 to the attachment device 10 by the tension link 28. The tension link cavity 56 does not intersect the gap 62 in the wall of the rod aperture 52. Instead, a portion of the wall of the rod aperture forms a tab 66 with a implant securement hole 67. The tab 66 may be secured to the connector 40 by an implant securement screw 69 inserted through the implant securement hole 67 and into the connector 40. This configuration may provide further offset capacity for the connector from the attachment device 10.

Referring now to Fig. 16, a further embodiment of the connector 40 is provided wherein the implant component 54 is secured in the rod aperture 52 separately from securing the connector 40 to the attachment device 10. As in the embodiment of Fig. 15, a portion of the wall of the rod aperture forms a tab 66 with a implant securement hole 67. The tab 66 may be secured to the connector 40 by an implant securement screw 69 inserted through the implant securement hole 67 and into the connector 40. However, in this embodiment, the tab 66 is located toward the exterior of the connector 40.

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With reference to Fig. 17, a possible combination of the above described elements is provided to show a surgical implantation system. The surgical implant system 70 includes an attachment device 10, a tension link 28, a connector 40, and a link nut 60. The implant component 54 is omitted from this drawing. The tension link head end 34 is inserted into the hollow core 22 of the attachment device 10. The tension link 28 extends through the tension link cavity 56 of the connector 40 such that the enlarged area 20 of the attachment device 10 is received into the head receptacle 42 of the connector 40. The connector 40 may then be secured to the attachment device 10 in proper position by tightening the link nut 60 on the tension link 28. In this embodiment, tightening the link nut 60 will also close the rod aperture gap 62 and secure the implant component 54 within the rod aperture 52.

As an aside, the head receptacle wall 68 is shown extending to approximately the "equator" or diameter of the enlarged area 20 of the attachment device 10. It should be noted that the extent that the head receptacle wall 68 engages the enlarged area 20 may be varied. For instance, a smaller wall 68 engagement may be desirable to increase the polyaxial adjustment of the assembly. Alternatively, it may be desirable to provide greater wall 68 engagement with the enlarged area 20 to prevent unnecessary deformation of the enlarged area 20, for example when the enlarged area 20 is provided with an expansion slot 38 or a tension link slot 36. Further, if the head receptacle wall 68 is designed for engagement beyond the "equator" of the enlarged area, the head receptacle wall 68 may match the contour of the enlarged area 20. In other words, the size of the head receptacle 42, at the farthest point on the receiving end 48 of the connector 40, may be smaller than the maximum size of the enlarged area 20 at its "equator." This may provide an additional advantage to the surgeon. In this situation, a tactile or audible signal may be provided when the enlarged area 20 is properly received into the head receptacle 42.

With reference to Fig. 18, an alternative arrangement of the surgical implant system 70 is shown. In this embodiment, the connectors 40 secure a implant component 54, in this case a rod, to the attachment devices 10. The orientation of the attachment devices 10 illustrate the polyaxial nature of the system 70. The attachment devices may be secured to whatever structure is necessary at different angles and on different planes.

Referring now to Figs. 19a and 19b, an alternative embodiment of the surgical implantation system 70 is provided. In this embodiment, a dynamic system is created

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wherein the implant component 54 is allowed to move freely along its longitudinal axis within connector rod aperture 52. This is accomplished by manufacturing some clearance tolerance within the rod aperture 52 when the link nut 60 is completely tightened on tension link 28. Fig. 19a also shows an alternative embodiment of a retaining recess 72 adjacent to the connector rod aperture 52. The retaining recess 72 corresponds with a retaining process 74 on the implant component 54 to limit the extent of dynamic nature within the implant. The retaining recess 72 and the retaining process 74 are sized and work in relation to one another such that the longitudinal movement of the implant component 54 is arrested when the retaining process 74 nests in the retaining recess 72.

Although it is not shown in the drawings, it is also possible to use the retaining process 74 without the retaining recess 72. It this aspect, the longitudinal movement of the implant component 54 is arrested when the retaining process 74 contacts the exterior surface of the connector 40 at the rod aperture 52. It is also possible to use either of the two above embodiments on either side of the rod aperture 52, wherein the longitudinal movement of the implant component 54 can be constrained in one or both directions.

Additional embodiments of the present invention are not shown in the drawings. For example, it is expected that the attachment device 10 may be used in conjunction with a hook in place of the tension link 28. In this embodiment, the hook would have a ball end and a hook end. The ball end would be inserted into the central core 22 of the attachment device 10 and the hook end would be used to secure some bodily structure, such as a bone. The hook rod would be capable of polyaxial movement.

The present invention also relates to a method of using the embodiments as set forth above. In one embodiment, the method using a surgical implant system 70 would first require the selective insertion of the attachment device 10 into a human bone. The tension link head end 34 could then inserted into the hollow core 22 of the attachment device 10. The step of insertion of the head end 34 would depend upon the embodiment of the attachment device 10 selected. For example, if an attachment device 10 with an entry channel 26, but no tension link slot 36, is provided, the tension link 28 is positioned in the aperture 24 by way of the entry channel 26. The connector 40 is positioned on the tension link 28 by inserting the tension link 28 through the connector tension link cavity 56.

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At this point, the surgeon can position the connector 40 such that the implant component 54, when properly inserted in connector rod aperture 52, is held in the desired position along the spinal column. The surgeon can then secure the position of the implant component 54 and the connector 40 in relation to the attachment device 10 by tightening the link nut 60 on the tension link threaded end 32. This process is repeated, as necessary, along the spinal column at various points along the implant component 54. In this way, the surgeon has implemented the above described embodiments as a method for using the surgical implant system, for example, in repairing a degenerative spinal condition.

It is understood that the present invention has application outside the surgical implantation field. The polyaxial securing mechanism of the present invention is not limited to medical implants. The present invention, for example, could be used to secure guy wires or rods. In this application, the anchor screw could be inserted into the ground, e.g., set directly in to the soil, mounted in a concrete footing, or similar mounting. The guy wire or rod (i.e., the tension link) could then be inserted through the anchor screw and connected to the structure to be secured. The guy rod may include a turnbuckle. The turn buckle can then be adjusted to the desired tension in the guy rod. In this way, some room for error in the location of the anchor bolt is built into the installation process. The guy rod may be installed between the anchor screw and the structure without placing undue stress on the guy rod, or requiring unnecessary bending of the guy rod, due to misalignment between the connection point on the structure and the anchor bolt position. This is especially beneficial when a turnbuckle is implemented in the guy rod. The polyaxial nature of the anchor screw would allow the turnbuckle to be more easily adjusted since the stress within the guy rod is limited to the axial direction of the rod, i.e., no bending stress on the turnbuckle.

This is just one example of the possible applications of the present invention outside the field of medical implants. Other applications, by no means exhaustive, may include connecting legs of a tripod to a base and mounting track lighting fixtures.

Referring now to Figs. 20 and 21, a further aspect of the present invention is to provide a multi-piece connector 80. The advantage of a multi-piece connector 80 is its ability to offer different configurations for attachment of a rod 54 to bone screws or attachment devices 10 when geometry requirements of the implant area so dictate.

Fig. 20 is a top view of one possible configuration of an assembled multi-piece connector 80. Fig. 21 illustrates a side cross-sectional view of the same multi-piece connector 80. The multi-piece connector 80 includes a first anchor section 82 and a second hook section 84. The first anchor section 82 is positioned proximate the bone screw or attachment device 10. The second hook section 84 is positioned proximate the implant component or rod 54, such that it "hooks" around rod 54 and secures it against a cam 86 that is an integral part of first anchor section 82. After assembly of the multi-piece connector 80, a tension link 28 is used to secure the various components of the system together by tightening a tension link nut 60 at the distal end of the tension link 28. As may be appreciated, the aforementioned and described multi-piece connector 80 is illustrated as having two pieces, however, multi-piece connectors 80 with more than two pieces is possible and appropriate for a potential application or patient's needs.

Referring now to Fig. 22, in yet a further aspect of the invention, for attachment devices 10 having an entry channel 26 and an tension link slot 36, a truncated area 90 is incorporated into the entry channel 26 of the attachment device 10. In a corresponding manner, the head end 34 of tension link 28 possesses a corresponding flat or truncated area 92 that may be aligned with the truncated area 90. The attachment device 10 and tension link 28 are thereby mated for implanting such that they are configured in a manner that requires specific manipulation to enter and release the tension link 28 from the attachment device 10. These mating features allow the tension link 28 to be installed at the same time that the attachment device 10 is secured to the vertebra, with minimal chance that the tension link 28 will become uncoupled from the attachment device 10 prior to tightening using a tension nut because the tension link 28 has to be tipped to properly align the truncated areas 90 and 92 to release. However, this configuration allows the surgeon to remove the tension link 28 from the attachment device 10, if the surgeon so desires at some point during implantation. In this case, the surgeon would manipulate the tension link 28 to a proper angles such that it releases from the attachment device 10.

Referring now to Figs. 23 and 24, in a further embodiment of the invention, a tool 94 is provided to install the attachment device 10. The tool 94 possesses morphological or structural features that correspond to the shape of the attachment device 10 in such a way that the tool is used to provide both a downward force and a rotational force or torque to the

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attachment device 10, and thereby provide a means of implanting the attachment device 10 into the patient's bone. Therefore, the tool 94 possesses a tool receptacle end 95 that mates with the features of the enlarged area 20 of the attachment device 10. Specifically, the tool 94 preferably possesses a tool receptacle 96 that surrounds the outer and upper portion of enlarged area 20 of attachment device 10. More preferably, the tool 94 possesses a structure that mates with the hollow core 22 of the attachment device. More preferably yet, the tool 94 possesses a projection 97 that at least partially fits within the entry channel 26 of attachment device 10, and thereby allows the surgeon or installer to provide torque to the attachment device 10 by turning the tool, thereby providing force to screw the attachment device 10 into bone. Alternately, as shown in Fig. 24, the tool possesses a projection that at least partially fits into the tension link slot 36 of attachment device 10, and thereby allows the surgeon or installer to provide torque to the attachment device 10 to screw the attachment device 10 into bone. The tool 94 may also include a handle 99 or some other means that allows the tool 94 to be rotated by the surgeon. In summary, the tool 94 possesses a tool receptacle 96 that includes one or multiple projections 97 that at least partially fit into either the hollow core 22, the tension link slot 36, the entry channel 26, the expansion slot(s) 38, or any combination thereof, to allow the surgeon a means of providing torque to screw the attachment device 10 into bone.

Still referring to Fig. 24, in a different aspect of the tool embodiment, the tool 94 is used to install both the attachment device 10 and the tension link 28 at the same time. In use, the tension link 28 is fitted into the attachment device 10. Subsequently, the attachment device 10 and tension link 28 are simultaneously installed. Accordingly, the tool 94 preferably possesses a hollow interior shaft 98 that receivingly accepts the tension link shaft 30 of tension link 28. The tool receptacle 96 preferably fits over the upper and outer surface area of the enlarged area 20 of attachment device 10, with tension 28 in place. The receptacle 96 optionally includes a nylon, teflon or other type of insert to temporarily restrain the screw while the surgeon locates the location for insertion.

The tool 94 either possesses a projection 97 to at least partially fit into a structure of the attachment device 10, such as a tension link slot 36, or alternately, the tool 94 interacts with the enlarged area 20 of attachment device 10 utilizing a lathe-chuck-type of frictional fitting (not shown). The lathe-chuck-type of frictional fitting grasps the enlarged head area

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20 of attachment device 10 and allows the surgeon means to provide torque to the attachment device 10 to screw the attachment device 10 into bone. Alternately, the enlarged head area 20 of attachment device 10 possesses facets (not shown) that allow a mating tool receptacle 96 to be placed over or around the enlarged head area 20 to thereby permit torque to be applied to the attachment device 10. In yet an alternate embodiment, a nut-like multi-faceted structure (not shown) that is an integral part of attachment device 10, and existing preferably below the enlarged area 20 and preferably at the upper regions of shank 12 is used to provide a means of grasping attachment device 10 with a tool capable of providing a torque force to attachment device 10 to screw attachment device 10 into bone.

Referring now to Figs. 25-30, in a further embodiment of the present invention, an end connector 40' is incorporated directly into the rod 54 in the form of a receptacle 100. When placed at the end of a rod 54, the principal advantage of the end connector 40' feature is to shrink the profile of the attachment device 10, connector 40', and rod 54 configuration as a system, and thereby reduce the length of rod 54 that is longitudinally exposed beyond the attachment device 10 or screw location. In so doing, in spinal implant applications the next vertebra beyond the end of the rod is not exposed to potentially impacting the rod section that would have previously extended longitudinally beyond the connector location. This can reduce patient pain and increase patient mobility. A further advantage is that the smaller profile results in less tissue displacement in the vicinity of end connector 40'.

Still referring to Figs. 25-30, end connector 40' is shown located at the end of a rod 54; however, it is to be understood that the end connector 40' could be located within any portion of an implant. In a preferred embodiment, the end connector 40' includes a receptacle 100 that is in the form of a socket that preferably includes a socket exterior 102 and a socket interior 104. The socket interior 104 essentially acts as a low-profile connector. The socket interior 104 may be any shape that is configured to correspondingly accept an attachment device 10. Thus, the receptacle 100 is sized to fit over and receivingly accept the enlarged area 20 of the attachment device 10. Accordingly, socket interior 104 is preferably a recessed area at the end of a rod 54 that fits over the enlarged area 20 of the attachment device 10. As shown in Fig. 29, the socket interior 104 is preferably nearly semi-spherical, to match a spherical-type shape of enlarged area 20 of attachment device 10. However, socket interior 104 may be a vast variety of shapes that match the enlarged area 20 of the attachment device

10. Such shapes include rectangular cube, cubic, pyramid, ellipsoid, multi-faceted, conical, cylindrical, tetrahedral, elongated, combinations of these shapes, truncated portions of these shapes, or any other shape that may receivingly accept the enlarged area 20 of an attachment device 10. Within the center of the receptacle 100 is a tension link cavity 56 that is sized to accept the shaft 30 of the tension link 28. Referring to Figs. 26-28, tension link cavity 56 can be seen as an opening through the top of receptacle 100.

Figs. 29 and 30 show different views of attachment device 10, tension link 28, tension link nut 60, and receptacle 100. Installation of a rod 54 possessing the receptacle 100 would include installation of the attachment device 10, preferably by interconnecting the securement mechanism 18 of attachment device 10 to a target location on one of the patient's spinal vertebra or other bone segment. Subsequently, the tension link 28 is installed by feeding the shaft 30 of tension link 28 through the entry channel 26 of the attachment device 10, such that the shaft 30 of the tension link 28 is pulled through the central aperture 24 of the attachment device 10, thereby positioning the head end 34 of the tension link 28 within the hollow core 22 of the attachment device 10. Alternately, tension link 28 may be fitted into attachment device 10 prior to installation of the attachment device 10, or an attachment device having an expansion slot 38 may be used, whereby an entry channel 26 is not used to place the tension link head 34 into the hollow core 22 of the attachment device. In yet another alternative, the tension link 28 may be permanently mounted into attachment device 10 during manufacture, such that both the attachment device 10 and the tension link 28 form one piece of hardware, with the head end 34 of tension link 28 permanently mounted, but still rotatable, within the hollow core 22 of attachment device 10.

Following installation of the attachment device 10 with the tension link 28 in place, receptacle 100 of rod 54 is then placed over the attachment device 10 by feeding the tension link 28 through the tension link cavity 56 within the receptacle 100. The rod 54 is then secured to the attachment device 10 by advancing a tension link nut 60 on to the tension link 28.

The outside diameter of the receptacle 100 may vary depending upon the application; however, a diameter of about 10mm is typical for receptacles 100 used in spine related surgery. The receptacle wall 105, defined as the area between the socket exterior 102 and socket interior 104, will preferably have a thickness necessary to provide sufficient structural

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confinement of attachment device 10 after tension link 28 is installed and link nut 60 is tightened on to shaft 30 of tension link 28. The thickness of the receptacle wall 105 will, therefore, depend upon the types of material used to make the various components, such as the receptacle 100, attachment device 10 and tension link 28.

In a separate embodiment, a receptacle 100 is positioned at each end (not shown) of a rod 54. In this manner, the rod 54 is used to span the distance between at least two attachment devices 10. Therefore, a series of various lengths of rods may be produced that permit the surgeon or installer to choose the correct length for any given installation. Alternately, a custom made rod may be produced to match the needs of the given installation requirements. Preferably, a rod 54 that is used to span a single vertebral joint is between 10 to 60 mm in length. However, lengths are determined on a case-by-case basis depending upon the patient's needs or the alternate application. For example, should the invention described herein be used in veterinary medicine, obviously the dimensions of the components will vary depending upon the size and type of animal undergoing treatment.

In a separate embodiment of the invention, one or more receptacles are located within the interior length of a rod. When receptacles are used at an interior rod location (not shown), the advantage to the patient is less tissue displacement. Here, individual receptacle locations may be produced within a length of rod, thereby reducing the need for use of a separate connector at each location along the length of the rod.

In still a separate embodiment, a continuous channel socket (not shown) is produced along the length of the underside of a rod. In this embodiment, individual tension link cavities may be drilled at the desired location just prior to implanting the rod. Alternately, the rod of this embodiment may be manufactured with a continuous tension link cavity (not shown) that possesses means for maintaining the position of a tension link and thereby prevents movement of the tension link along the longitudinal length of the rod. These means preferably include a series of shapes that maintain the position of the shaft of the tension link after the shaft it is fed through an individual tension link cavity of the continuous tension link cavity. The exterior surface of the enlarged area of attachment device may include detents or depressions that receivingly accept spring loaded balls or surficial features such as ridge texturing that is interconnected to the underside of continuous channel socket. Alternately, the surface features are preferably located on the exterior surface of the enlarged area of the

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attachment device, thereby interlocking with indentations located on the underside of continuous channel socket. Surficial features may include texturing, ridges, bumps, projections, protrusions, indentations, adhesives, and coverings or coatings of alternate materials.

A further inventive aspect comprises a clamp device. Among its many potential uses, the clamp feature is used to attach a new section of rod to an existing section of rod, to extend a section of rod, to provide length adjustability to a rod, to provide a means of attaching a separate structure to the end of a new or existing rod, to provide a means of attaching a separate structure to the end of a new or existing rod while adjusting the length of the rod, or to reinforce an existing section of rod. In general, the purpose of clamp is to allow the length of the rod to be adjusted at the surgical site without having to cut the rod, or custom order a length of rod, or use a standardized rod length that may not fit the patient.

Referring now to Fig. 31, a perspective view of one embodiment of the stabilizing assembly of the present invention is shown. The assembly includes a section of rod, or rod member, that is grasped by adjustable clamp 200. The clamp 200 is preferably comprised of two pieces that work to clamp the rod member, thereby forming a rod assembly that may be adjusted at the surgical site to accommodate different length requirements.

Referring now to Figs. 31-34 the first piece in the assembly is the interior rod section or first rod member 202; the second piece is the lower clamp portion 204; and the third piece is the upper clamp portion 206. As shown in Fig. 33, lower clamp portion 204 includes a clamp region 208. Similarly, as shown in Fig. 32, upper clamp portion 206 includes a clamp region 210. The clamp regions 208 and 210 serve as an interlocking zone or compression zone. The lower clamp portion 204 and the upper clamp portion 206 interlock as shown in Fig. 34. During the interlocking of lower clamp portion 204 with upper clamp portion 206, the two pieces are brought together as shown in Fig. 34. The bringing together of the lower clamp portion 204 and the upper clamp portion 206 forces the two clamp regions 208 and 210 together. As shown in Fig. 31, upon complete assembly, such as after a surgical procedure, clamp regions 208 and 210 preferably substantially encircle or telescope around a portion of interior rod member 202. Accordingly, upon complete assembly, a portion of interior rod member 202 is preferably situated to the interior of lower clamp portion 204 and upper clamp portion 206 and is held in an interlocked configuration by the compressive

forces acting in the clamp regions 208 and 210 of the lower and upper clamp portions 204 and 206.

Interior rod member 202 and clamp regions 208 and 210 may possess surface features that interlock and aid in securing the interior rod member 202 to the clamp regions 208 and 210. For example, clamp regions 208 and 210 may include detents or depressions that receivingly accept spring loaded balls or surficial features such as ridge texturing that is interconnected to the exterior surface of interior rod member 202. Surficial features may include texturing, ridges, bumps, projections, protrusions, indentations, adhesives, and coverings or coatings of alternate materials. For example, Fig. 35 illustrates a series of four ridges 209 that are used to concentrate pressure from the lower clamp portion 204 and upper clamp portion 206 to the interior rod member 202. Furthermore, although not required, openings through the lower clamp portion 204 and the upper clamp portion 206 may be used to receive securing devices such as pins, screws, bolts, hooks or anchors that interconnect the interior rod member 202 with the lower clamp portion 204 and/or the upper clamp portion 206. For example, although not required, at least one set screw may be used to interlock the interior rod member to one of the lower or upper clamp portions 204, 206. Fig. 31 illustrates the use of an optional set screw 211 to further interlock the interior rod member 202 with the upper clamp portion 206. The screw(s) can be oriented in a variety of directions to achieve this goal. Metal or resilient bands (not shown) may also be used to wrap and secure the interior rod member 202 with the lower clamp portion 204 and/or the upper clamp portion 206.

As shown in Figs. 32-34, the lower clamp portion 204 includes a securing end 212, and upper clamp portion 206 includes a securing end 214. Securing ends 212 and 214 are used to secure the lower clamp portion 204 and the upper clamp portion 206 to the attachment device 10, such as by using a tension link 28. Accordingly, securing ends 212 and 214 are preferably sized to receive the enlarged area 20 of the attachment device 10. More particularly, the securing ends 212 and 214 preferably include receptacles 100 that receive the enlarged area 20 of the attachment devices 10. Preferably, the securing ends 212 and 214 include a socket-like shaped portion that fits over the enlarged area 20 of the attachment device 10. More preferably, securing end 212 fittingly cooperates with securing end 214. Although not required, securing end 212 and securing end 214, may also include

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surficial features (not shown) such as texturing, ridges, bumps, projections, protrusions, or indentations that cooperate with one another to prevent rotation or movement of the securing ends relative to one another once assembled.

Preferably, a tension link cavity 56 passes through securing ends 212 and 214, and provides for insertion of the shaft 30 portion of tension link 28 through securing ends 212 and 214. Link nut 60 may be used to secure the lower clamp portion 204 and the upper clamp portion 206 to the tension link 28, and therefore to the attachment device 10. Furthermore, by tightening the link nut 60 that is threaded onto the tension link 28, the lower clamp portion 204 and the upper clamp portion 206 are brought together in tight cooperation. This action tightens clamp region 208 and clamp region 210 around interior rod member 202, thereby securing interior rod member 202 from movement longitudinally relative to lower clamp portion 204 and upper clamp portion 206. Accordingly, clamp 200 shares similarities to a pliers-type tool by utilizing a compression force at the securing ends 212 and 214 of the lower clamp portion 204 and the upper clamp portion 206 to create a compression force around the interior rod member 202 at the clamp regions 208 and 210. The interlocking feature of the clamp 200 shares similarities to a pair of pliers because the compression force exerted at one end, the securing ends 212 and 214, is translated to compression forces at the interlocking zone, or compression zone, or clamp regions 208, 210. In addition, the installation of the clamp 200 shares similarities to forceps used in obstetrics during the delivery of a baby, whereby the device is assembled in pieces to provide a means of grasping the intended object. In the case of the present invention, however, means are employed to secure the grasping function or clamp regions 208 and 210 of the clamp 200 by tightening the securing ends 212 and 214 of the lower clamp portion 204 and upper clamp portion 206.

Lower clamp portion 204 and the upper clamp portion 206 are preferably of a shape that is approximately a half-cylinder. More preferably, as shown in Figs. 32-34, the half-cylinder shapes include bends in the clamp regions 208 and 210. In this aspect, the lower clamp portion 204 bends within clamp region 208 to encompass the upper region of interior rod member 202 after the assembly is complete. Similarly, the upper clamp portion 206 bends within clamp region 210 to encompass the lower region of interior rod member 202 after the assembly is complete. More specifically, in a preferred embodiment, the lower clamp portion 204 includes a first bend 218 at the lower side of interior rod member 202, and

a second bend 220 at the upper side of interior rod member 202. In a similar but mirrored fashion, upper clamp portion 206 includes a first bend 222 at the upper side of interior rod member 202, and a second bend 224 at the lower side of interior rod member 202.

Between the first bend 218 and the second bend 220 of the lower clamp portion 204, the lower clamp portion 204 includes an opening 219 wherein interior rod member 202 is slidably received when the interior rod member 202, lower clamp portion 204, and upper clamp portion 206 are assembled. Similarly, between the first bend 222 and the second bend 224 of the upper clamp portion 206, the upper clamp portion 206 includes an opening 223 wherein interior rod member 202 is slidably received when the interior rod member 202, lower clamp portion 204, and upper clamp portion 206 are assembled.

Among a number of favorable characteristics, the clamp 200 essentially allows the length of the structural member (typically a rod) spanning two bone screws or attachment devices 10 to be adjusted at the surgical site without having to cut the rod because the length of the rod is adjustable by moving the interior rod member 202 within the lower clamp portion 204 and the upper clamp portion 206 prior to fixing securing ends 212 and 214 by securing an interconnecting mechanism, such as by tightening a link nut 60. This eliminates the need for having to custom order a length of rod, or otherwise use a standardized rod length that may not fit the patient, and thereby cause decreased performance and potentially increased pain to the patient. Furthermore, utilizing the components of the present invention, the entire assembly can be tightened by securing a link nut 60 at each attachment device 10 after the interior rod member 202 is placed within the lower clamp portion 204 and the upper clamp portion 206. This greatly simplifies the surgeon's efforts and serves to reduce operation time and associated patient risk.

In addition to the above noted characteristics inherent to using a rod implant with the clamp 200 feature, the clamp 200 is also especially applicable to adding an additional length of rod 54, or providing length adjustability to a rod being implanted concurrently with the implantation of the clamp 200 device, or can be used to add additional length to an already existing portion of rod that had previously been implanted into the patient during a prior surgical procedure. A method for subsequently retro-fitting a portion of rod possessing the clamp 200 to an existing portion of rod is now presented.

Where an existing rod implant exists, the patient's surgical site would be partially exposed at the end of the existing rod requiring extension. If a sufficient length of rod or rod run-out length exists beyond an existing rod connector that attaches the existing rod to the bone, then the clamp 200 may be interconnected directly to the rod run-out length with additional length of new rod implanted as the patient's conditions may warrant. Alternately, if sufficient rod run-out length does not exist, as shown in Fig. 36, then the first existing connector can be removed, thereby exposing a sufficient length of rod for the clamp 200 to clamp the existing rod. More than one connector may have to be removed in certain cases.

A further option comprises clamping the clamp 200 over a sufficient length of rod that may be accessible between existing connectors. Here, the clamp 200 would preferably include at least one additional bend as shown in Fig. 37. Alternately, two additional bends may be used in order to align the clamp portions of the clamp 200 between the existing connectors. This option then eliminates the necessity for removing at least the first existing connector. The advantage of the above listed methods for attaching the clamp 200 invention to an existing rod is that the existing rod does not have to be completely exposed and removed, with a new longer rod implanted. Therefore, a smaller incision is necessary and consequently, multiple benefits are realized including decreased medical costs and less pain to the patient. Another advantage is that a second parallel rod does not need to be installed adjacent the first existing rod. Accordingly, structural support can be achieved in the form of an extension using clamp 200 and adapting the lower clamp portion 204 and the upper clamp portion 206 to accept the existing rod.

Referring now to Figs. 38-40a-b, in a separate embodiment, an assembly is provided that utilizes the various components listed above. Thus, one application of this embodiment then is the installation of two separate attachment devices 10 that are then fitted with the other devices. In use, attachment devices 10 are installed first. In one preferred method of use, the attachment devices 10 are pedicle screws that are installed into two vertebra, a first vertebra V_1 and a second vertebra V_2. More preferably, as shown in Fig. 38, right and left assemblies are installed on either side of the spinous process. Installation of the attachment devices 10 is followed by the installation of tension links 28 through or into the two attachment devices 10. Alternately, the tension links 28 may be placed into the attachment devices 10 prior to installing the attachment devices 10 into their intended positions. Subsequent to installing

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the attachment devices 10 with the tension links 28 in place, an interior rod member 202 having a receptacle 100 and a rod member 54 is implanted over one of the attachment devices 10 and secured with a first link nut 60. Installation of interior rod member 202 is preferably performed in conjunction with installing a lower clamp portion 204 and an upper clamp portion 206 over the remaining attachment device 10 while clamping the clamp regions 208 and 210 of the lower clamp portion 204 and an upper clamp portion 206, respectively, around the interior rod member 202. Subsequently, securing ends 212 and 214 are securedly attached to the second attachment device 10 by placing a second link nut 60 onto the exposed portion of the tension link 28 of the second attachment device 10. Of course, the clamp regions 208 and 210 may be adjusted during tightening securing ends 212 and 214 using second link nut 60 to ensure an appropriately configured arrangement of interior rod member 202, clamp 200, attachment devices 10, and tension links 28. The resulting assembly spans disk D. Accordingly, the interior rod member 202 serves as a first rod member, and the lower clamp portion 204 and an upper clamp portion 206 serve as a second rod member that combine to structurally bridge disk D when interconnected to attachment devices 10 by interconnecting mechanisms, such as tension links 28.

Referring now to Fig. 41, a separate embodiment of the clamp 200' is provided wherein the clamp 200' includes a lower clamp portion 204' and an upper clamp portion 206'. This embodiment provides a different configuration for the clamp. However, similar to the clamp 200 described above, the compressive forces are applied by the clamp regions 208' and 210' by tightening the securing ends 212' and 214' using an interconnection mechanism, which preferably is a link nut 60 applied to a tension link 28. As shown in Fig. 41, ridges 209 may be used within the interior of lower clamp portion 204' and an upper clamp portion 206'. As shown in Fig. 41, three ridges 209 are used, thereby wedging interior rod member 202 between the lower clamp portion 204' and an upper clamp portion 206' when link nut 60 is tightened. Thus, it is to be understood that the present invention encompasses various embodiments whereby an interlocking force can be applied to a clamp region of a structure that is at a spaced distance S away from the securing ends.

Referring now to Fig. 42a-c, a further illustrative example of an alternate embodiment of the clamp is shown. Clamp 200" includes a lower clamp portion 204" and an upper clamp portion 206". Lower clamp portion 204" includes a hollow interior 242 for receiving interior

rod member 202. The hollow interior 242 also includes an upper space 244 for receiving upper clamp portion 206". Upper clamp portion 206" is a member that includes a heal projection 246 and a toe projection 248. Upon tightening the securing end 214" of upper clamp portion 206", the heal projection 246 presses down on interior rod member 202 while the toe projection 248 presses up on an upper interior surface 250 of lower clamp portion 204". Upper clamp portion 206" may be biased to increase the forces applied to its heal projection 246 and toe projection 248 when it is tightened into place. The resulting forces compress and interlock the interior rod member 202 against the lower interior surface 252 of lower clamp portion 204", thereby securedly holding interior rod member 202 within the lower clamp portion 204" and upper clamp portion 206". As shown in Fig. 42a, two ridges 209 are preferably provided along the lower interior surface 252 of lower clamp member 204". The two ridges 209 are spaced apart such that heal projection 246 of upper clamp portion 204" is positioned intermediate the two ridges, thereby providing a triangulated force pattern on interior rod member 202.

Referring now to Fig. 43, a separate embodiment comprising a telescoping rod 230 is shown. The telescoping rod 230 preferably has a receptacle 100 placed at each end of the telescoping rod 230. An inner first rod portion 232 slidably receives a second outer rod portion 234, thereby allowing adjustment of the length of the rod prior to securing the receptacles over previously installed attachment devices 10 with corresponding tension links 28. The telescoping rod may be configured such that one portion fits within another portion, as shown, or one portion of the rod may be positioned above or below the other portion. The telescoping portions may interlock without the use of additional components by, for example: means of a friction fit between the telescoping portions; locking collars; pins; etc. One aspect of a preferred embodiment bares similarities to a Chinese finger trap toy, whereby movement is allowed in one direction, but resisted in the other direction. Alternately, the sections of the telescoping rod may thread into one another, thereby providing both a length adjustment feature and a locking feature. Alternately yet, the telescoping portion of the rod may optionally be secured using securing means such as a bolt, set screws 211 (as shown in Fig. 43), band, or other similar device, or multiple such devices. In yet another alternative, a shim of various possible shapes including tapered regions may be pushed into or otherwise placed along a portion of the length of the telescoping rod segments in order to lock the

segments together. In yet another alternative, the rod may be adjusted to its final intended length and secured using adhesives or an epoxy such as methyl metacrylate. The adhesives or epoxy may be applied to the surface of portions of the telescoping rod, or alternately, it may be injected in one or more injection ports. The telescoping rod may also feature a resilient member 236, such as a spring, within the rod to provide an expansive force between the two portions of rod.

Referring now to Fig. 44a, in a separate embodiment of the invention, the tension link 28 includes additional features that render it particularly suited to implanting during a surgical operation. It is known that a substantial number of implants involve the spanning or bridging of one vertebral disc. Therefore, one aspect of the present invention is to consecutively install the first and second attachment devices 10 with tension links 28 possessing extended shafts 30'. Specifically, the tension link 28 preferably is available in variable lengths. More preferably, the tension link 28 is long enough to provide easy manipulation while being implanted. More preferably yet, the tension link 28 has an extended shaft 30' that is substantially longer than is necessary, but is capable of being trimmed during the surgical implanting procedure. Here, the tension link 28 with an extended shaft 30' may preferably be 10 to 150 millimeters longer than necessary, and more preferably, 20 to 120 millimeters longer than necessary, and more preferably yet 40 to 80 millimeters longer than is necessary.

The extended shaft 30' is preferably used as a guide by the surgeon to provide a means of placing the interior rod member 202 having receptacle 100 and rod 54, clamp 200 including lower and upper clamp portions 204 and 206 having securing ends 212 and 214, and link nuts 60. Accordingly, each extended shaft serves to guide the stabilizing structures to be implanted. In use, the surgeon first installs the attachment device 10 either with or without the tension link 28 already in place. If the tension link 28 is not installed concurrently with the attachment device 10, the surgeon installs the tension link 28 after the attachment device 10 has been installed. After installation of the attachment device 10 and tension link 28, the extended shaft 30' is used to guide the interior rod member 202 possessing a receptacle 100 down to the enlarged area 20 of attachment device 10. As a further example, the other tension link 28 with an extended shaft 30' would serve to guide both clamp portions of clamp 200. That is, lower clamp portion 204 and upper clamp portion

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206 with securing ends 212 and 214 are guided down to and placed over the end of the second attachment device 10. Thus, these components may be slid down to the enlarged areas 20 of attachment devices 10 in one effort. Subsequently, tension link nuts 60 are slid down the extended shafts 30' of tension links 28, and may be fully or at least partially threaded onto the threaded portions of shaft 30 of the tension links 28. Subsequent to using the extended shaft 30' as a guide to the head of the attachment device 10, the extended shaft 30' is trimmed using a shearing tool familiar to those in the art, or the extended shaft 30' is broke along a pre-existing score 238, as shown in Fig. 44b. Thus, the extended shafts 30' of the tension links 28 are preferably trimmed by a surgical staff member, leaving a sufficient threaded portion in place to hold link nut 60. The extended shaft 30' is then discarded, leaving the trimmed tension link shaft 30 in place with the link nut 60 attached thereto. This embodiment offers the advantage being a minimally invasive surgical procedure by providing means of performing spinal stabilization surgery, by supplying surgical implant devices and methods that significantly limit the length of the surgical incision and the length of time necessary to perform the surgery. Thus, benefits are realized in the form of smaller incisions, less tissue displacement, less patient pain and recovery time, shorter surgical time, less cost, and less fatigue of surgical staff.

A further aspect of the above noted embodiment is the use of a flexible extension or leader (not shown) on to the end of the shaft 30 of tension link 28. In this aspect of the invention, the substantially rigid portion of shaft 30 of tension link 28 is fitted with a relatively flexible leader extending along the axis of the longitudinal axis of shaft 30 of tension link 28. The flexible leader is preferably attached to the tension link 28 sometime prior to surgery, and more preferably sometime during manufacture of the tension link 28. The flexible leader then serves to provide means of guiding any additional components down to the attachment device 10 as may be desired. The flexible leader is preferably made of a material capable of being manipulated without breaking during surgery. More preferably, the flexible leader is made of a metallic wire material or a plastic material. More preferably yet, the flexible leader is easily separated from the end of shaft 30 of tension link 28 after any desired stabilizing components are installed. Accordingly, an extended tension link 28 may take the form of simply an extended shaft 30', or it may take the form of a regular sized tension link 28 shaft 30 with a flexible leader attached thereto.

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Other than the flexible leaders discussed above, the interior rod member 202, lower clamp portion 204, upper clamp portion 206, rod 54, connectors 40, receptacles 100, attachment devices 10, tension links 28, and link nuts 60 and other structural features described herein are made from a material that possesses the appropriate strength characteristics necessary to withstand loading from the human body when used in medical applications. Tensile strength qualities of the materials used is a key consideration. Preferably, materials may include ceramics, plastics, metals, or carbon fiber composites. More preferably, the materials are made from titanium or stainless steel.

Devices disclosed herein can also be made of thermal memory materials or materials that possess different elastic properties at varying temperatures. In this aspect of the invention, the subject component(s) may be heated or cooled to a desired temperature, implanted, then subsequently allowed to cool or warm to the temperature of the ambient conditions that will exist during the usage period for the subject device, namely, normal body temperature.

The dimensions of the rod features may vary considerably depending upon the patient's needs. For example, a rod the entire length of the spine, such as 2 feet in length, may be used. Alternately, a rod only 10mm long may be all that is necessary to span and bridge the target segment of the spine. Therefore, the preferable length of rod is simply an adequate length to bridge the necessary vertebral disc or discs.

The curvature of the rod may also be variable depending upon the desired final curvature sought for the patient. The curvature may be established during manufacture of a given rod, and/or a given rod segment may have its curvature adjusted at the of time surgery prior to implantation.

While various embodiments of the present invention have been described in detail, it is apparent that modifications and adaptations of those embodiments will occur to those skilled in the art. However, it is to be expressly understood that such modifications and adaptations are within the spirit and scope of the present invention, as set forth in the following claims.

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What is claimed is:

1. A surgical implant assembly, comprising:

an attachment device having first and second ends, said second end having a hollow core bordered by curved walls;

a tension link having a proximal end and a distal end, said proximal end having a tension link head and said distal end being threaded, said tension link head rotatably mounted within said hollow core and maintained therein by contact with said curved walls; and

a rod having at least one preformed socket adapted for at least partially receiving said second end, said socket including at least one tension link cavity, wherein said rod is secured to said attachment device by a tension link nut that is threaded onto said distal end of said tension link.

2. The surgical implant assembly of claim 1, wherein said second end further comprises an entry channel adapted to allow said tension link head to be positioned within said hollow core.

3. The surgical implant assembly of claim 1, wherein said second end further comprises at least one expansion slot operatively associated with said hollow core.

4. The surgical implant assembly of claim 1, wherein said first end of said attachment device includes threads.

5. The surgical implant assembly of claim 1, wherein said socket is at least partially spherical in shape.

6. The surgical implant assembly of claim 1, wherein said socket is located at the end of said rod.

7. A method of installing a surgical implant assembly, comprising the steps of:

(a) securing an attachment device to human bone, the attachment device having a shank with first and second ends, the second end having a hollow core and a central aperture;

(b) inserting a tension link head of a tension link into the hollow core of the attachment device, the tension link having a tension link shaft that extends through the central aperture of the attachment device;

(c) seating a rod having a connecting receptacle onto the second end of the attachment device by passing the tension link shaft through a tension link cavity within the connecting receptacle; and

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(d) securing the rod to the attachment device by threading and tightening a tension link nut onto the tension link shaft.

8. The method of claim 7, further comprising the step of adjusting an angular relationship between the attachment device and the connecting receptacle.

9. The method of claim 8, wherein said adjusting step occurs between steps (c) and (d).

10. The method of claim 7, wherein the second end of the attachment device further comprises an entry channel operatively associated with the hollow core;

said inserting step further comprises inserting the tension link shaft through the entry channel and the hollow core, and pulling the tension link shaft through the central aperture until the tension link head is positioned in the hollow core.

11. The method of claim 7, wherein the second end of the attachment device further comprises an entry channel having an entrance operatively associated with the hollow core, and a tension link slot through the second end to the hollow core between the entry channel and the central aperture;

said inserting step comprising placing the tension link head at the entrance of the entry channel, inserting the tension link shaft into the tension link slot such that the tension link shaft is located within the central aperture, and pulling the tension link head into the hollow core.

12. In subcombination, a low-profile medical device connector used to connect a piece of hardware to organic tissue, the device used in combination with a tension link having a tension link head and a tension link shaft that threadably receives a tension link nut, and in combination with an attachment device having a hollow core for receiving the tension link head and a central aperture for passing the tension link shaft therethrough, said connector device comprising:

a rod portion having a receptacle, said receptacle including a socket adapted to receive the hollow core of the attachment device, said receptacle having a tension link cavity for passing the tension link shaft therethrough;

wherein said rod portion is secured to the attachment device by tightening the tension link nut on the tension link shaft after passing the tension link shaft through said tension link cavity upon placement of said receptacle over the attachment device.

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13. A tool for inserting a pedicle screw into a pedicle of a vertebra, the pedicle screw having a first end that is threaded and a second end that is an enlarged area having a hollow core, the hollow core including at least one of either an expansion slot, a tension link slot, or an entry channel, the tool comprising:

a receptacle adapted for mating with the enlarged area of the pedicle screw; and

a projection located within said receptacle, the projection adapted for mating with at least one of either the expansion slot, the tension link slot, or the entry channel of the pedicle screw;

wherein the tool is rotated to provide torque to the second end of the pedicle screw and drive the first end of the pedicle screw into the pedicle of the vertebra.

14. The tool as claimed in claim 13, further comprising a hollow shaft for receiving a tension link shaft of a tension link pre-positioned in the hollow core of the pedicle screw.

15. The tool as claimed in claim 13, further comprising an handle for grasping said tool.

16. The tool as claimed in claim 13, further comprising means for temporarily restraining the pedicle screw, said means located within said receptacle.

17. The tool as claimed in claim 16, wherein said means comprises a material selected from the group consisting of a nylon insert and a telflon insert.

18. The tool as claimed in claim 13, further comprising means for rotating said receptacle.

19. An attachment device adapted for use with a tension link, the tension link including a tension link head having a truncated area, the device comprising:

a shank having first and second ends,

said first end having a securing mechanism, and

said second end comprising a hollow core, an entry channel having a truncated surface, and a central aperture operatively associated with said hollow core and said entry channel, wherein said entry channel is sized for receiving the tension link, and said cental aperture is sized for retaining the anchoring shaft head within said hollow core, and wherein the truncated area of the tension link head must be substantially aligned with said truncated surface of said entry channel to insert or remove the tension link head from said hollow core.

20. A connector as in claim 19, wherein said second end further comprises at least one expansion slot operatively associated with said central aperture.

21. A connector device as in claim 19, wherein said securing mechanism is selected from the group consisting of screw threads, hooks, plates, and flanges.

22. A connector device as in claim 19, wherein said hollow core has an interior surface, said interior surface having a texture.

23. A connector device as in claim 19, wherein at least a portion of the second end of said connector device has a shape selected from the group consisting of: spherical, semi-spherical, aspherical, polyhedral, conical, and a truncated cone shape.

24. A surgical implant assembly attachable to an existing rod member, comprising:

an attachment device having first and second ends, said second end comprising a hollow core including a central aperture, and at least either one expansion slot or an entry channel;

a tension link having a proximal end and a distal end, said proximal end having a tension link head and said distal end being threaded, said tension link head insertable into said hollow core through said entry channel or through said central aperture by expanding said expansion slot, said tension link head retained within said central aperture;

a clamp connection attachably securable to the existing rod member, said clamp connection permitting adjustable positioning of a portion of the existing rod member within said clamp connection during implantation of said assembly, said clamp connection having at least one tension link cavity;

wherein a link nut is threaded onto said distal end of said tension link to secure said clamp connection to the existing rod member and said attachment device.

25. The surgical implant assembly of Claim 24, wherein said clamp connection comprises a lower clamp portion and an upper clamp portion.

26. The surgical implant assembly of Claim 25, wherein said lower clamp portion and said upper clamp portion each include a securing end.

27. The surgical implant assembly of Claim 26, wherein said securing end include a receptacle.

28. The surgical implant assembly of Claim 25, wherein said lower clamp portion and said upper clamp portion include a clamp region.

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29. The surgical implant assembly of Claim 28, wherein at least one said clamp region comprises at least one ridge.

30. A bone stabilization device for securing a first bone segment to a second bone, the first bone segment having been fitted with a first attachment device and the second bone segment having been fitted with a second attachment device, the stabilization device comprising:

a first rod member;

a first interconnection mechanism for attaching said first rod member to the first attachment device;

a second rod member including a compression zone that operatively engages at least a portion of said first rod member; and

a second interconnection mechanism for attaching said second rod member to the second attachment device;

wherein said compression zone of said second rod member is placed into compression against said at least a portion of said first rod member by tightening said second interconnection mechanism against said second rod member.

31. The stabilization device as claimed in claim 30, wherein the second rod member comprises at least two portions.

32. The stabilization device as claimed in claim 31, wherein said at least two portions include substantially half-cylinder sections.

33. The stabilization device as claimed in claim 32, wherein at least a portion of said half-cylinder sections at least partially surround a portion of said first rod member.

34. The stabilization device as claimed in claim 31, wherein said at least two portions each include an opening for receiving said first rod member.

35. The stabilization device as claimed in claim 30, wherein said first interconnection mechanism includes a tension link.

36. The stabilization device as claimed in claim 35, wherein said first interconnection mechanism includes a tension link nut.

37. The stabilization device as claimed in claim 30, wherein said second interconnection mechanism includes a tension link.

38. The stabilization device as claimed in claim 37, wherein said second interconnection mechanism includes a tension link nut.

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39. The stabilization device as claimed in claim 30, wherein said compression zone does not include a set screw.

40. The stabilization device as claimed in claim 30, wherein the first attachment device and the second attachment device are separated by a distance, said first rod member having a first length, said second rod member having a second length, and wherein said distance is greater than either of said first length or said second length.

41. The stabilization device as claimed in claim 30, wherein said first rod member includes an external surface having a surficial feature selected from the group consisting of: roughening, texturing, ridges, valleys, indentations, projections, coatings, and embossing.

42. The stabilization device as claimed in claim 30, wherein said first rod member is made of a material selected from the group consisting of stainless steel and titanium.

43. The stabilization device as claimed in claim 32, wherein said half-cylinder sections have an inner surface, said inner surface includes a surficial feature selected from the group consisting of: roughening, texturing, ridges, valleys, indentations, projections, coatings, and embossing.

44. The stabilization device as claimed in claim 31, wherein said at least two portions are made of a material selected from the group consisting of stainless steel and titanium.

45. A spinal stabilization device for securing at least two vertebra, the at least two vertebra including a first vertebra having been fitted with a first attachment device and a second vertebra having been fitted with a second attachment device, the stabilization device comprising:

a first rod member;

a first interconnection mechanism for attaching said first rod member to the first attachment device;

a clamp having a lower clamp portion and an upper clamp portion, said clamp portions including:

an interlocking zone that operatively engages at least a portion of said first rod member; and

a securing zone in spaced relation to said interlocking zone; and

a second interconnection mechanism for attaching said securing zone of said clamp to the second attachment device;

wherein said interlocking zone of said clamp is placed into compression against said at least a portion of said first rod member by tightening said securing zone of said clamp with said second interconnection mechanism.

46. The stabilization device as claimed in claim 45, wherein said lower clamp portion and said upper clamp portion are substantially half-cylinder sections.

47. The stabilization device as claimed in claim 45, wherein at least a portion of said lower clamp portion and said upper clamp portion at least partially surround a portion of said first rod member at said interlocking zone.

48. The stabilization device as claimed in claim 45, wherein said lower and upper clamp portions each include an opening for receiving said first rod member.

49. The stabilization device as claimed in claim 45, wherein said first interconnection mechanism includes a tension link.

50. The stabilization device as claimed in claim 49, wherein said first interconnection mechanism includes a tension link nut.

51. The stabilization device as claimed in claim 45, wherein said second interconnection mechanism includes a tension link.

52. The stabilization device as claimed in claim 51, wherein said second interconnection mechanism includes a tension link nut.

53. The stabilization device as claimed in claim 45, wherein said first interconnection mechanism includes an extended tension link shaft.

54. The stabilization device as claimed in claim 45, wherein said second interconnection mechanism includes an extended tension link shaft.

55. The stabilization device as claimed in claim 45, wherein said interlocking zone does not include a set screw.

56. The stabilization device as claimed in claim 45, wherein said interlocking zone includes a set screw.

57. The stabilization device as claimed in claim 45, wherein said securing zone includes at least one receptacle.

58. A bone stabilization assembly for securing a first bone segment to a second bone segment, comprising:

first and second attachment devices each including a first end and a second end, said first end having threads for inserting into the bone segments, said second end having an enlarged area having a hollow core bordered by curved walls and an aperture therethrough;

first and second tension links each including a proximal end and a distal end, said proximal end having a tension link head and said distal end having a threaded shaft, said tension link head rotatably mounted within said hollow core and maintained therein by contact with said curved walls, said threaded shaft extending through said aperture of said attachment devices;

a first rod member having a socket for accepting said enlarged area of said first attachment device and a tension link cavity for passing said shaft of said first tension link therethrough, said socket securable against said first attachment device by a link nut threaded over said shaft of said first tension link;

a clamp having a lower clamp portion and an upper clamp portion, each clamp portion including:

an interlocking zone that operatively engages at least a portion of said first rod member; and

a securing zone in spaced relation to said interlocking zone, each securing zone including a tension link cavity for passing said shaft of said second tension link therethrough,

wherein at least one said securing zone includes a receptacle adapted to accept said enlarged area of said second attachment device;

wherein said interlocking zones of said clamp are placed into compression against said at least a portion of said first rod member by tightening a tension link nut over said shaft of said second tension link.

59. The assembly as claimed in claim 58, wherein said attachment devices are pedicle screws.

60. The assembly as claimed in claim 58, wherein said shafts are extended.

61. A spinal stabilization device for securing at least two vertebra, the at least two vertebra including a first vertebra having been fitted with a first attachment device and a

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second vertebra having been fitted with a second attachment device, the stabilization device comprising:

an interior rod member having a socket including a cavity therethrough, and a rod portion;

a first connector for attaching said socket to the first attachment device;

a second rod member including:

a compression zone that operatively engages at least a portion of said rod portion; and

a securing zone in spaced relation to said compression zone; and

a second connector for attaching said securing zone of second rod member to the second attachment device;

wherein said compression zone of said second rod member is placed into compression against said at least a portion of said rod portion by tightening said securing zone of said second rod member with said second connector.

62. The device as claimed in claim 61, wherein said second rod member includes a lower clamp portion and an upper clamp portion.

63. The device as claimed in claim 61, wherein said first connector comprises a tension link and tension link nut.

64. The device as claimed in claim 63, wherein a portion of said tension link passes through said cavity.

65. The device as claimed in claim 63, further comprising an extended tension link shaft.

66. The device as claimed in claim 61, wherein said second connector comprises a tension link and tension link nut.

67. The device as claimed in claim 66, further comprising an extended tension link shaft.

68. In subcombination, a bone stabilization device for connecting a first area of bone to a second area of bone, the device used in combination with a first attachment device having a first interconnection mechanism, and a second attachment device having a second interconnection mechanism, said stabilization device comprising:

a first rod member;

a second rod member including:

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an interlocking zone that operatively engages at least a portion of said first rod member; and

a securing zone in spaced relation to said interlocking zone; and

wherein said interlocking zone of said second rod member is operatively interlocked with said at least a portion of said first rod member by tightening said securing zone of said second rod member with either of the first or second interconnection mechanisms.

69. The device as claimed in claim 68, wherein said second rod member includes a lower clamp portion and an upper clamp portion.

70. The device as claimed in claim 68, wherein said securing zone includes a receptacle.

71. The device as claimed in claim 68, wherein said second rod member includes ridges.

72. The device as claimed in claim 68, wherein said first rod member includes a socket adapted to receive the first attachment device.

73. A surgically implanted bone stabilization apparatus for securing a first bone segment to a second bone segment, the apparatus comprising:

a first attachment device attached to the first bone segment;

a second attachment device attached to the second bone segment;

a first rod member;

a first interconnection means for attaching said first rod member to said first attachment device;

a second rod member including an interlocking zone for operatively engaging at least a portion of said first rod member; and

a second interconnection means for attaching said second rod member to said second attachment device;

wherein said interlocking zone of said second rod member is interlocked with said at least a portion of said first rod member by tightening said second interconnection means.

74. The apparatus as claimed in claim 73, wherein said first interconnection means comprises a tension link and a tension link nut.

75. The apparatus as claimed in claim 73, wherein said second interconnection means comprises a tension link and a tension link nut.

76. The apparatus as claimed in claim 73, wherein said second rod member includes a lower clamp portion and an upper clamp portion.

77. The apparatus as claimed in claim 73, wherein said first attachment device is a pedicle screw.

78. The apparatus as claimed in claim 73, wherein said second attachment device is a pedicle screw.

79. A method of stabilizing a first vertebra to a second vertebra, the method comprising the steps of:

(a) attaching a first attachment device to the first vertebra and a second attachment device to the second vertebra, at least the second attachment device having a hollow core and a central aperture;

(b) connecting a first rod member to the first attachment device using a first interconnecting mechanism;

(c) inserting a tension link having a shaft and a tension link head into the hollow core of the second attachment device such that the shaft of the tension link extends through the central aperture of the second attachment device;

(d) installing a second rod member having:

an interlocking zone for clamping at least a portion of the first rod member; and

a securing zone in spaced relation to the interlocking zone,

said installing step further comprising passing the shaft of the tension link through a tension link cavity in the second rod member; and

(e) securing the second rod member to said second attachment device and the at least a portion of the first rod member by threading and tightening a tension link nut onto the shaft of the tension link.

80. The method as claimed in claim 79, wherein the first interconnecting mechanism comprises a tension link and link nut.

81. The method as claimed in claim 79, wherein the first interconnecting mechanism comprises receptacle formed in the end of the first rod member.

82. The method as claimed in claim 79, wherein the second rod member comprises a lower clamp portion and an upper clamp portion.

83. The method as claimed in claim 82, wherein the securing zone of the second rod member includes a receptacle at one end of the lower and upper clamp portions.

84. The method as claimed in claim 79, wherein the shaft of the tension link is an extended shaft.

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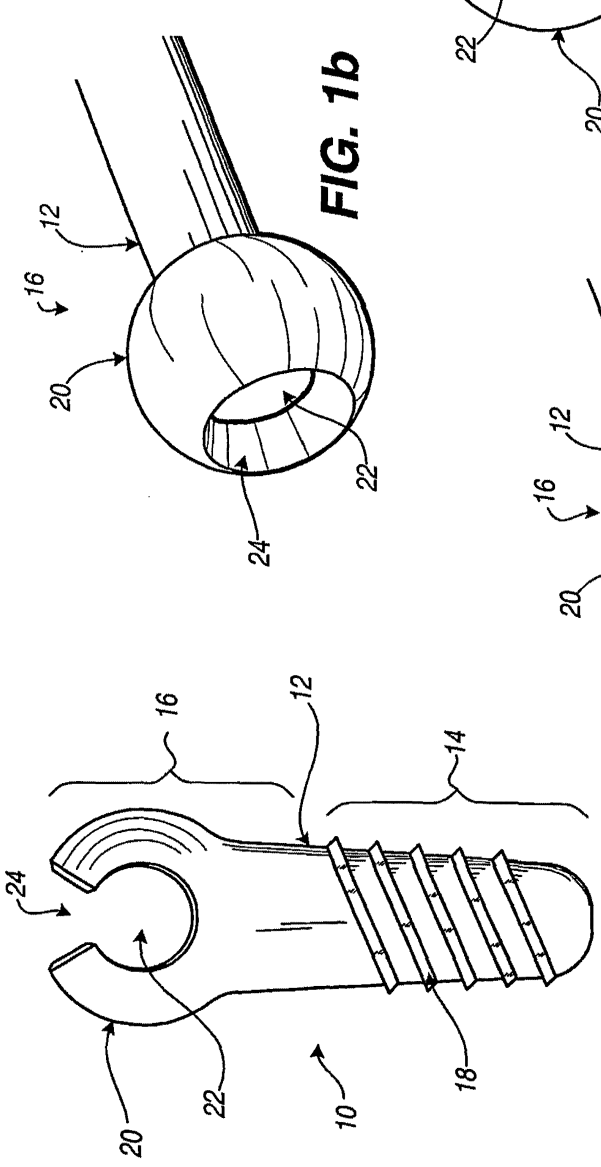


FIG. 1a

FIG. 1b

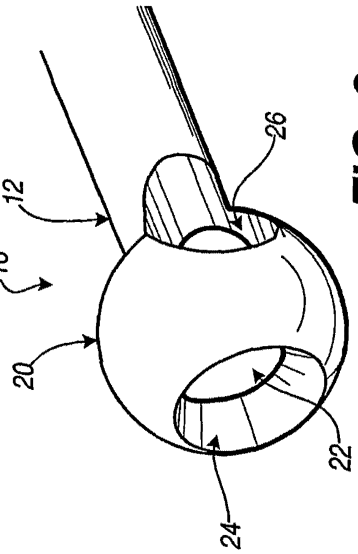


FIG. 2

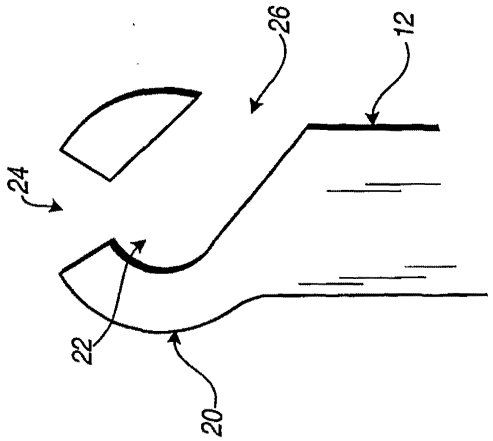


FIG. 3

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
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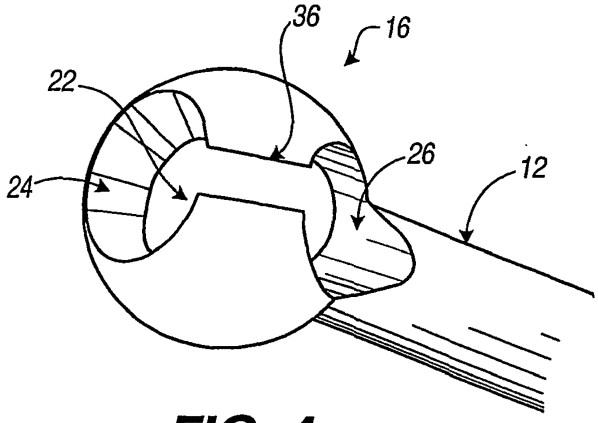


FIG. 4

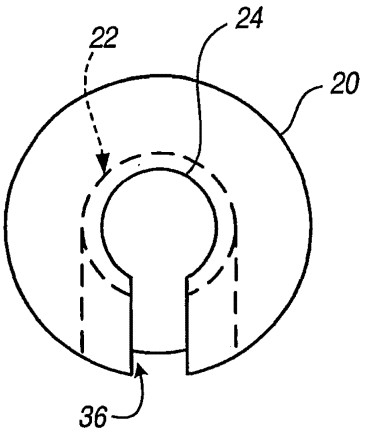


FIG. 5

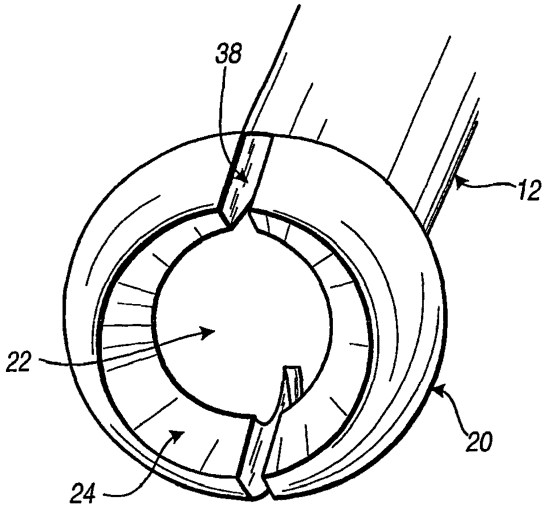


FIG. 6

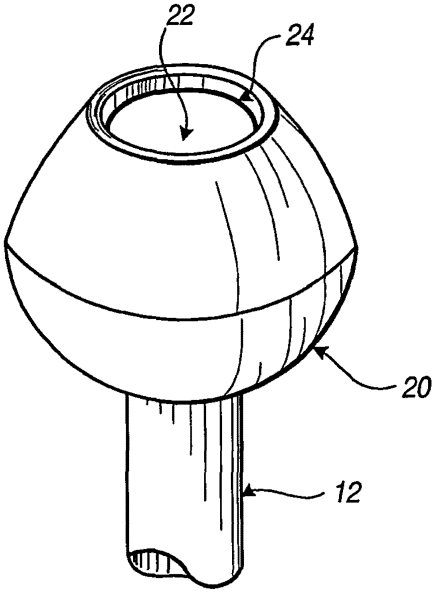


FIG. 7

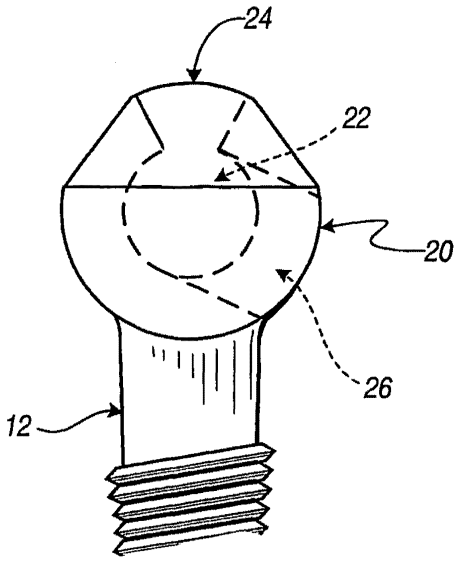


FIG. 8

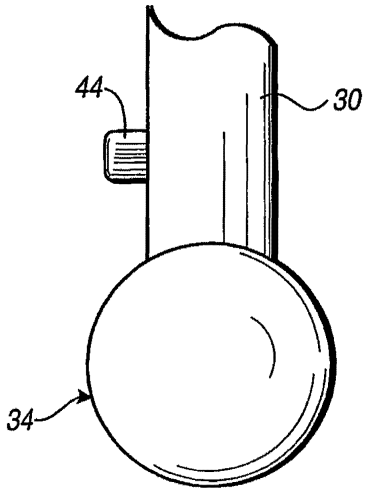


FIG. 9a

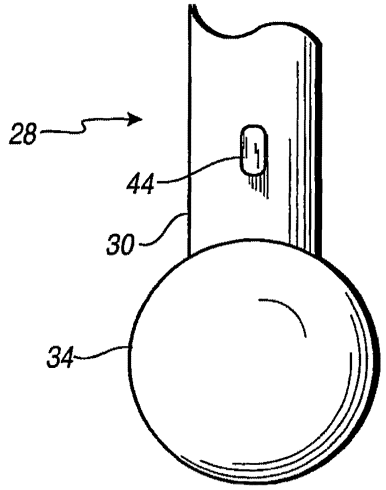


FIG. 9b

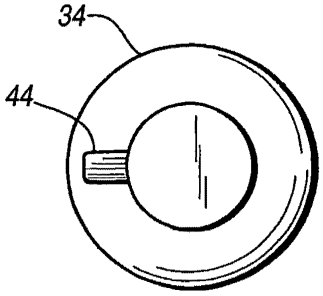


FIG. 9c

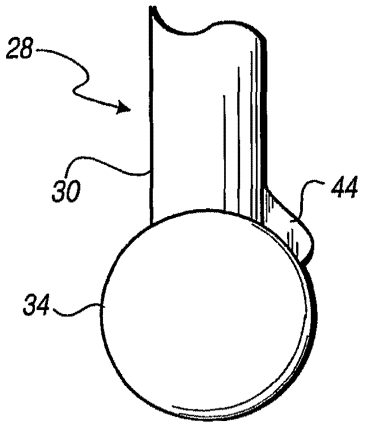


FIG. 10a

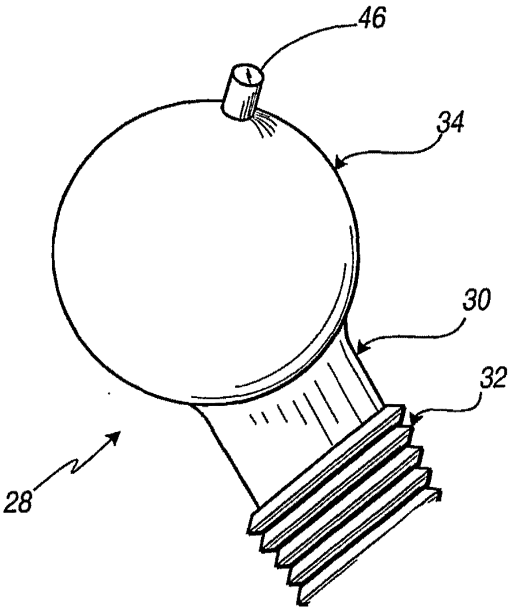


FIG. 11

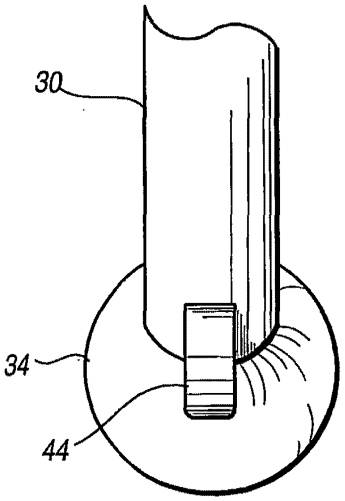


FIG. 10b

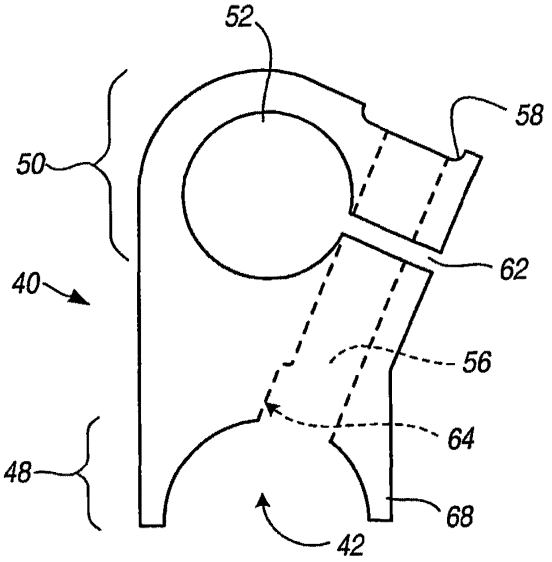


FIG. 12

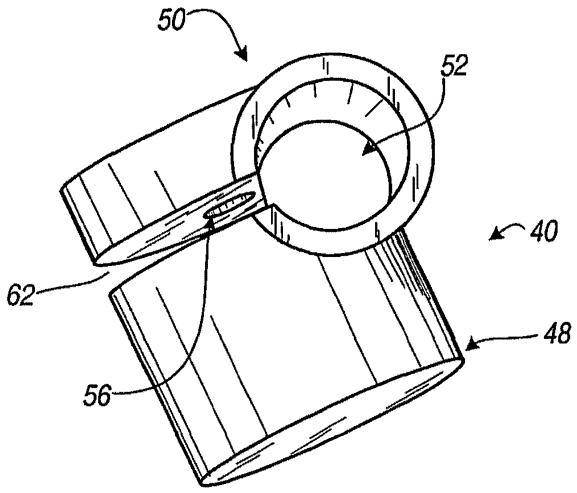


FIG. 13

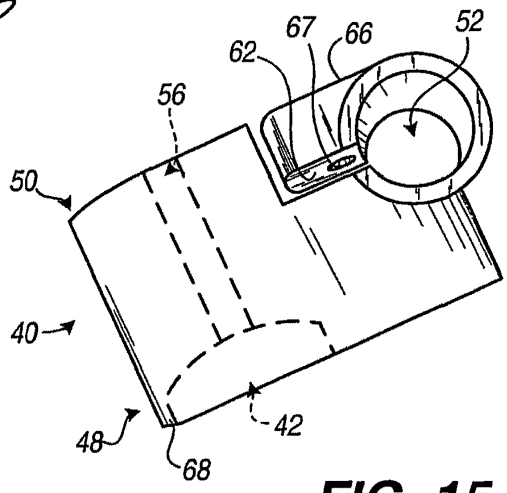


FIG. 15

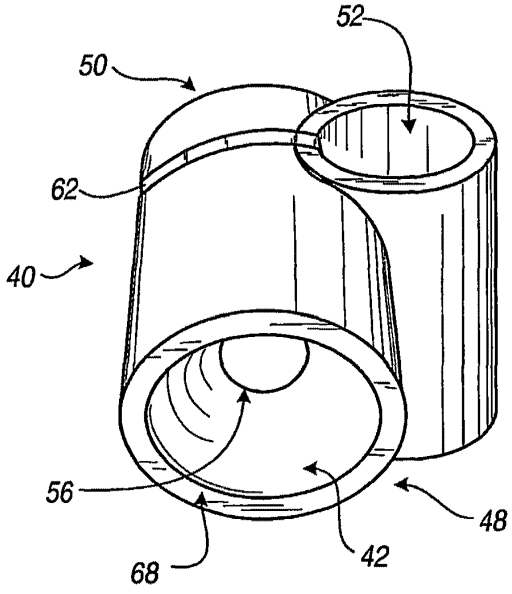


FIG. 14

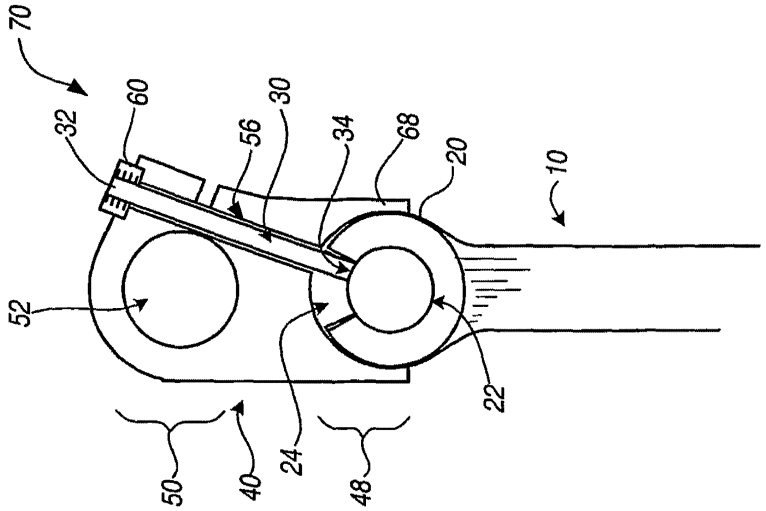


FIG. 17

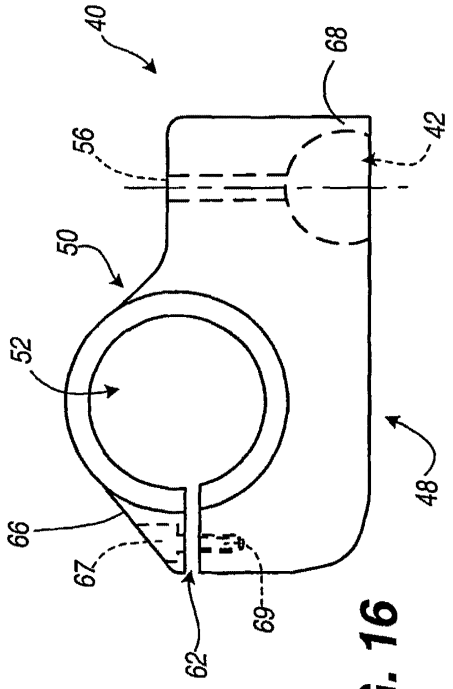


FIG. 16

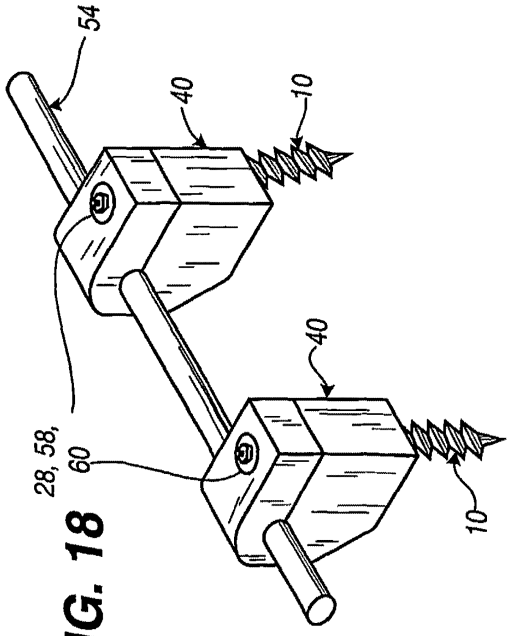


FIG. 18

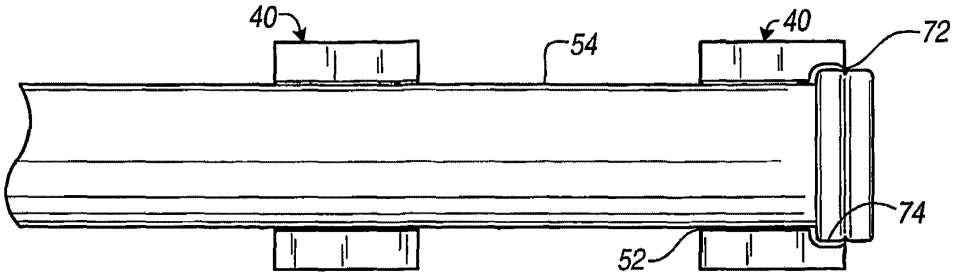


FIG. 19a

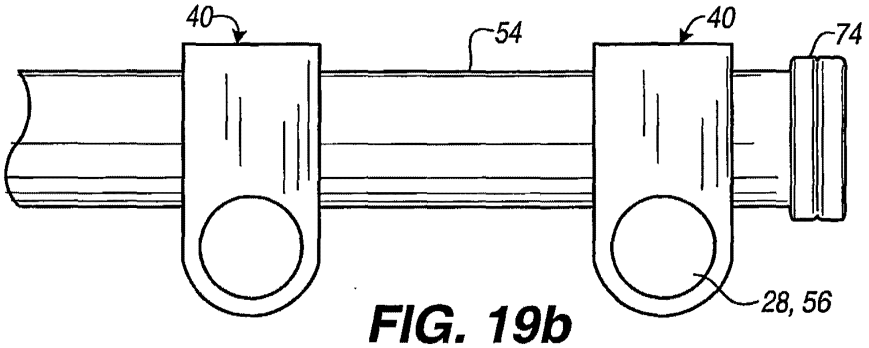
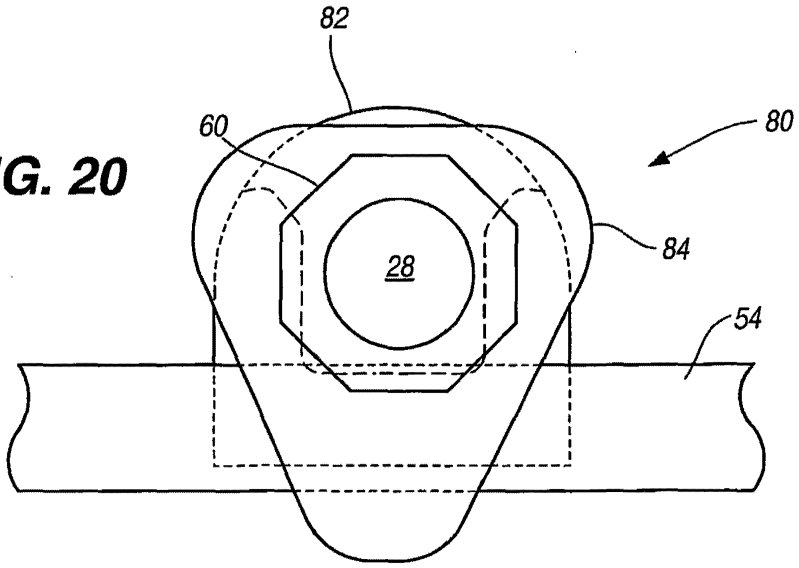


FIG. 19b

FIG. 20



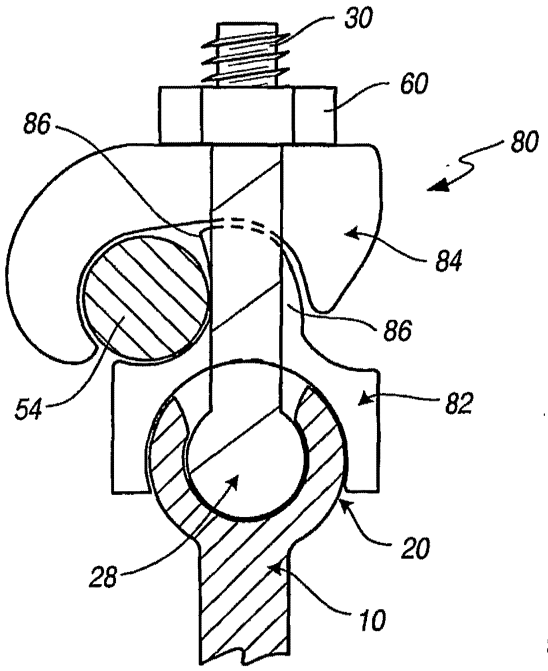


FIG. 21

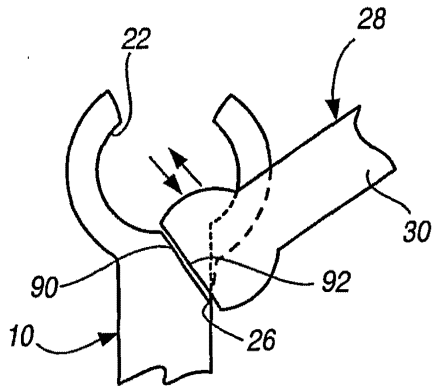


FIG. 22

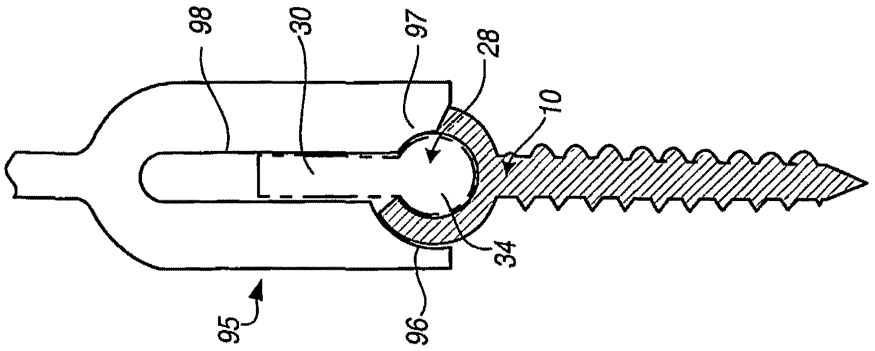


FIG. 24

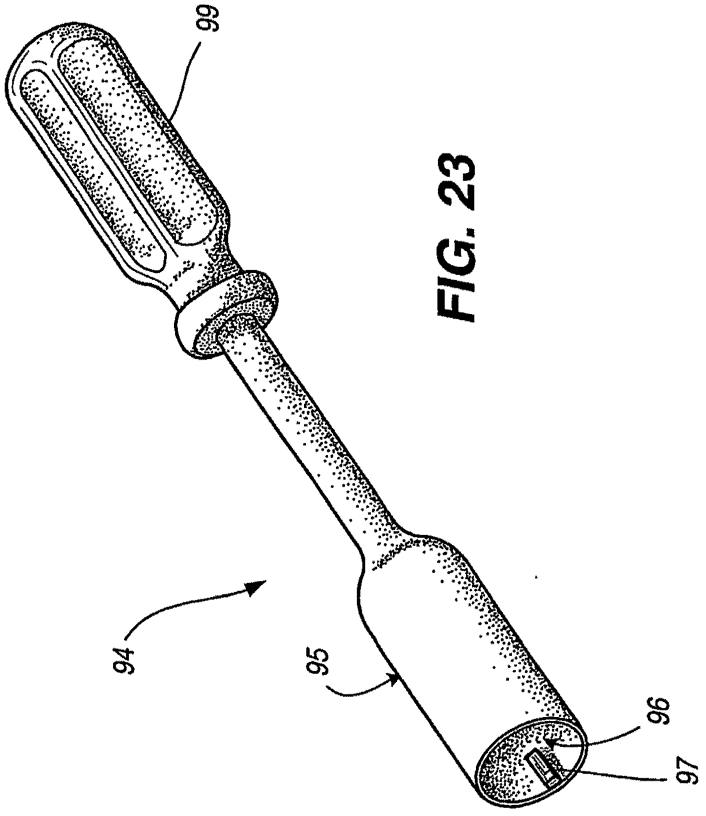


FIG. 23

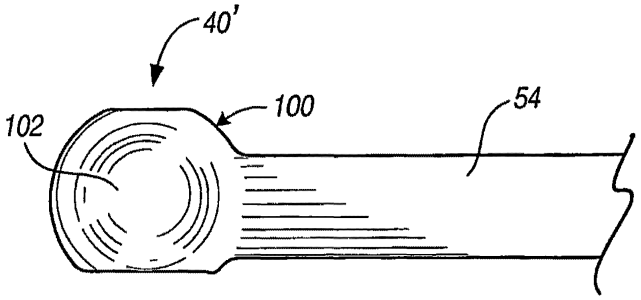


FIG. 25

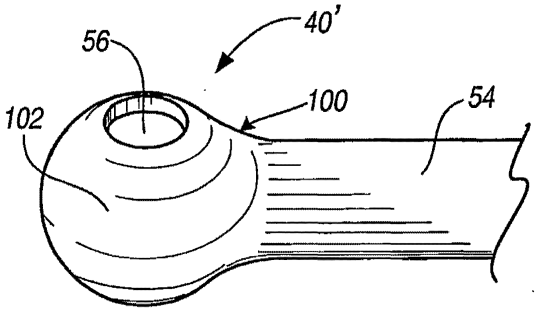


FIG. 26

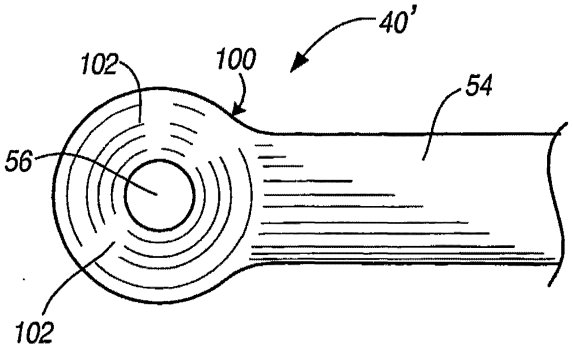


FIG. 27

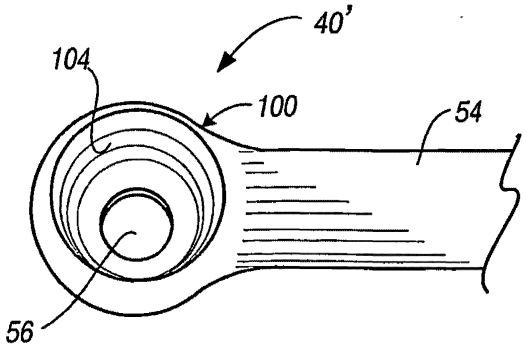


FIG. 28

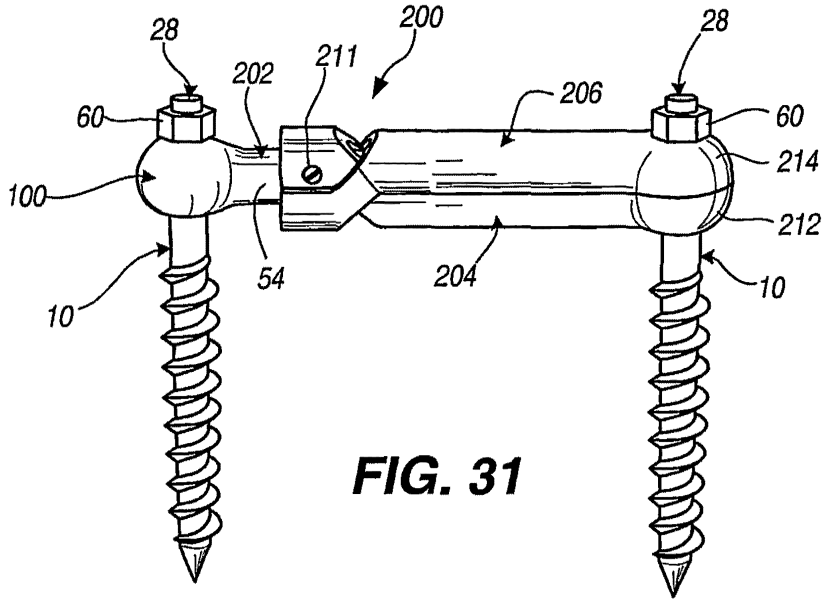


FIG. 31

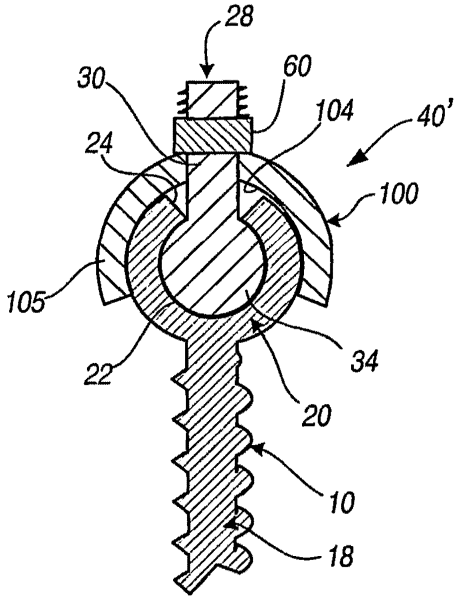


FIG. 30

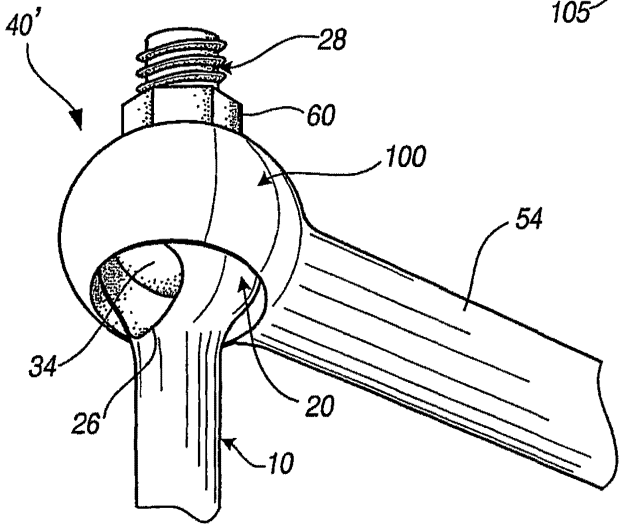


FIG. 29

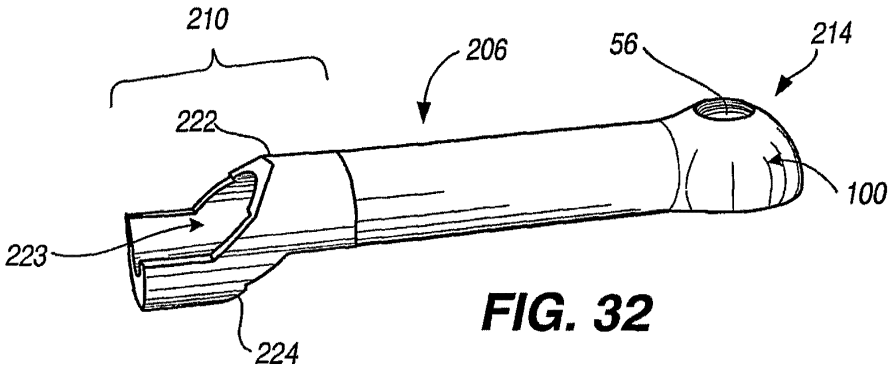


FIG. 32

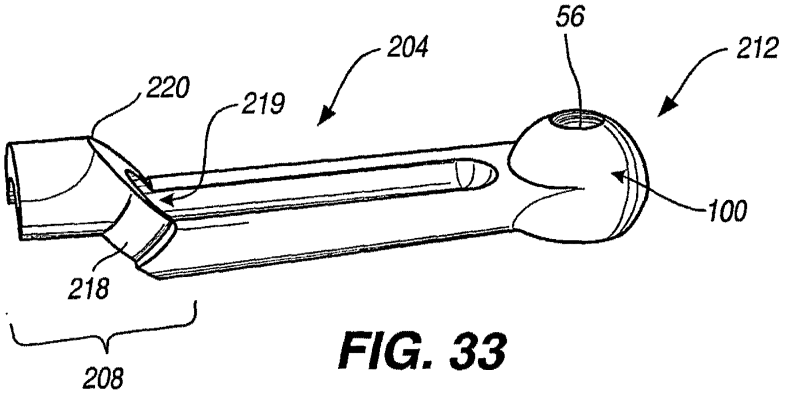


FIG. 33

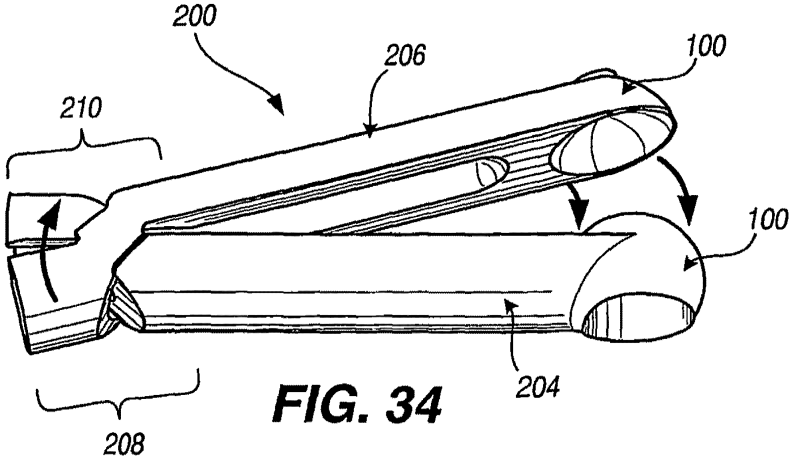


FIG. 34

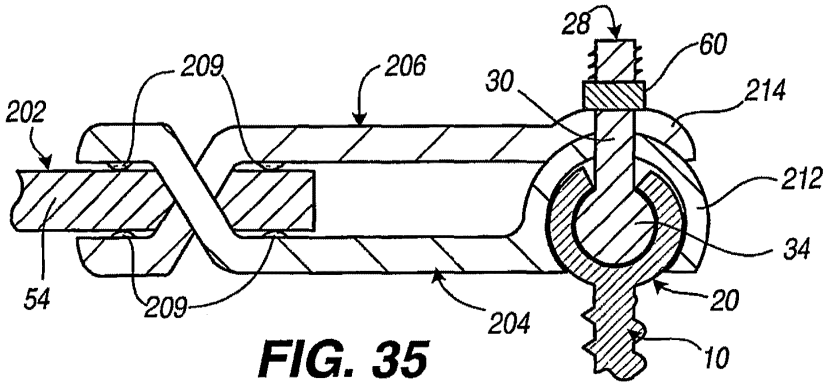


FIG. 35

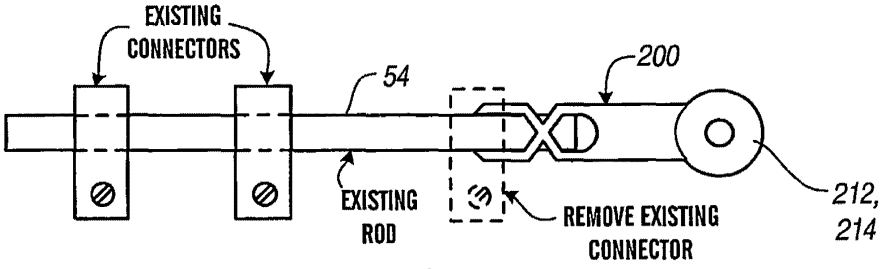


FIG. 36

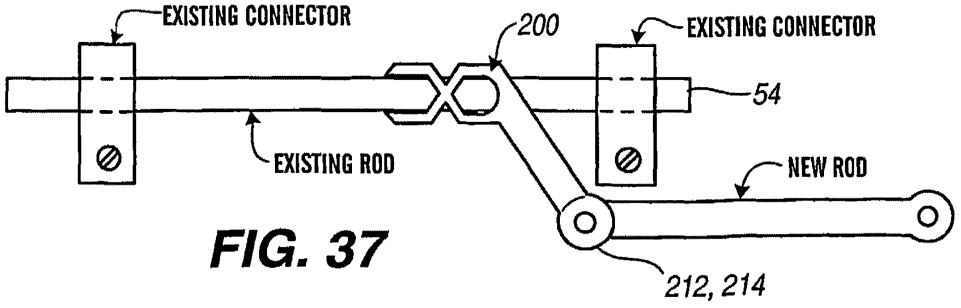
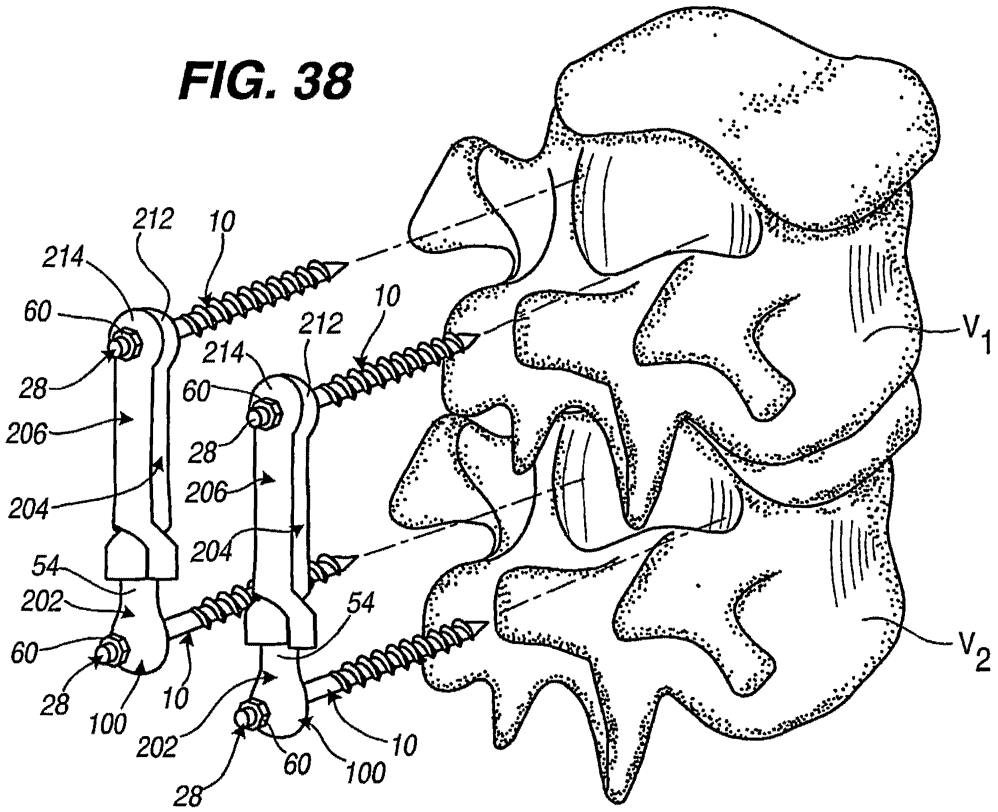


FIG. 37

FIG. 38


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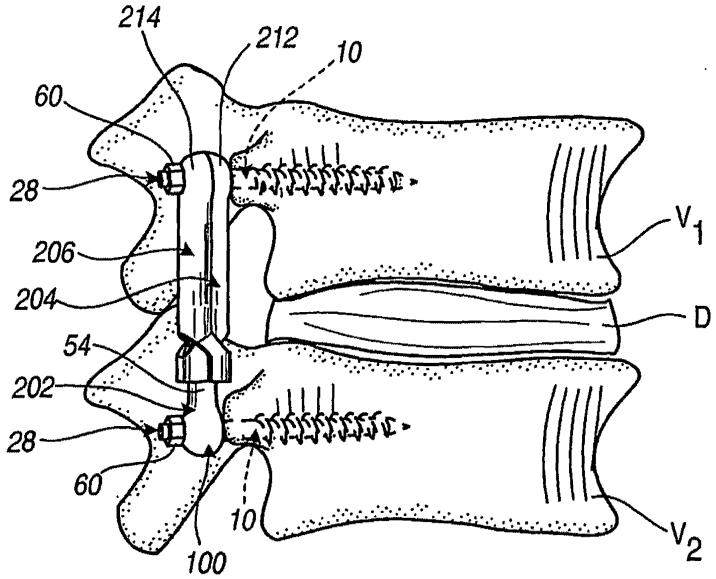
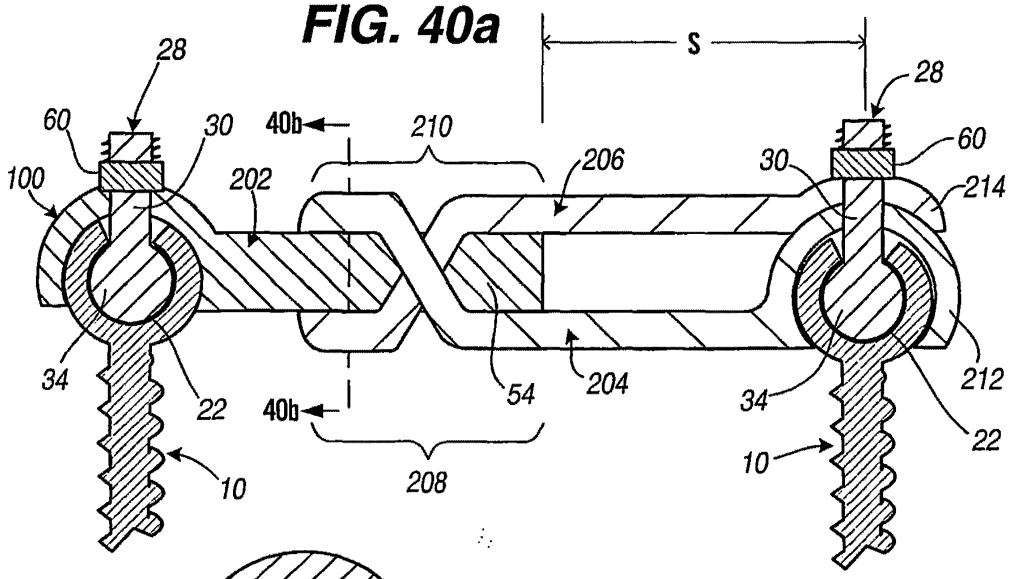

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FIG. 39

FIG. 40a



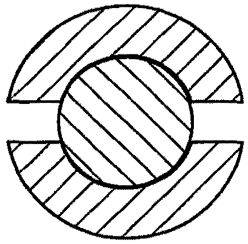


FIG. 40b

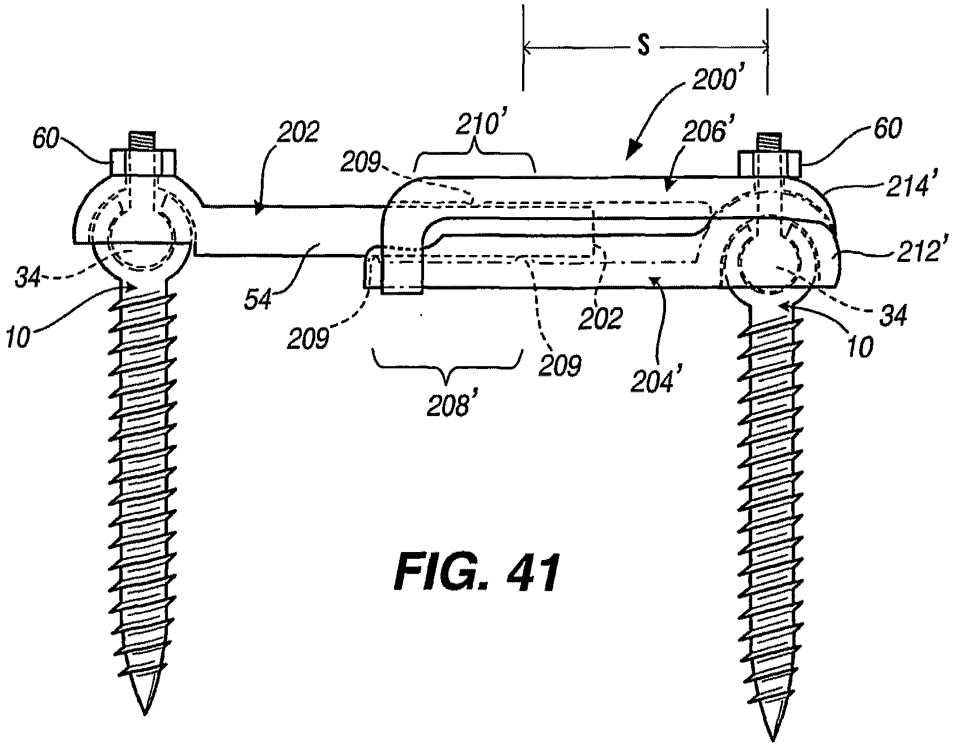


FIG. 41

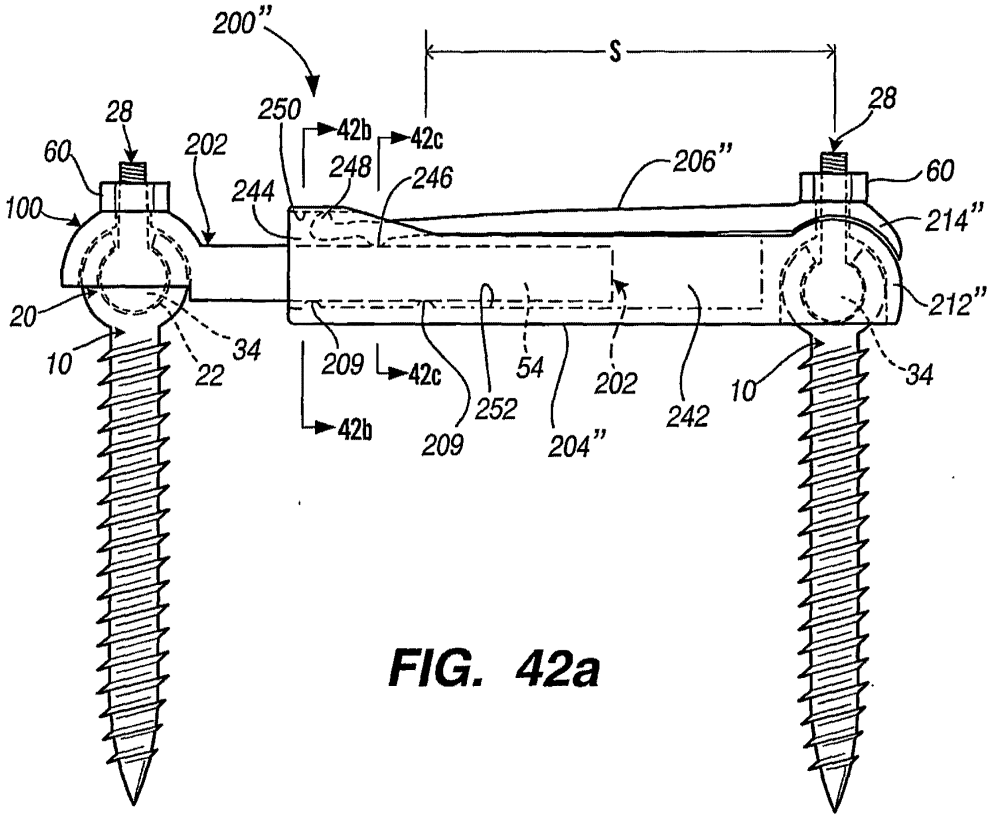


FIG. 42a

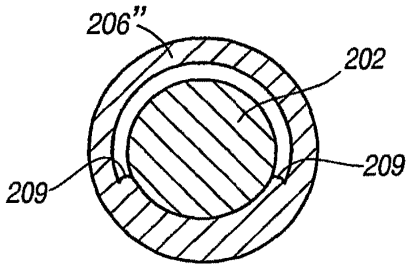


FIG. 42b

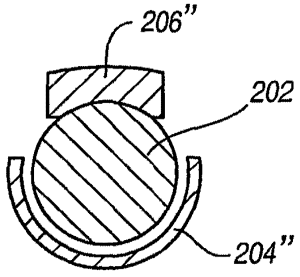


FIG. 42c

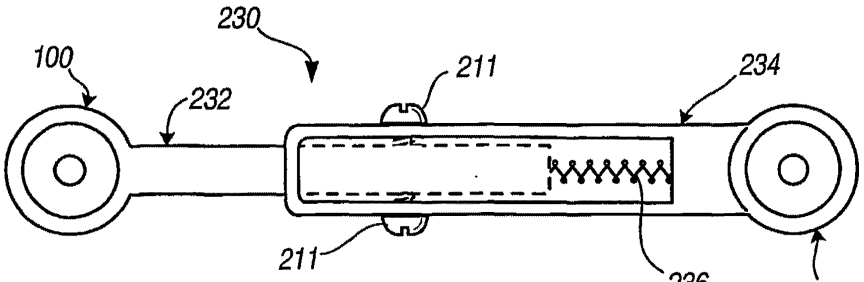


FIG. 43

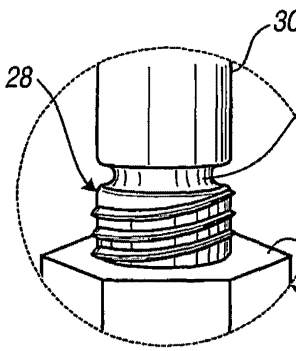


FIG. 44b

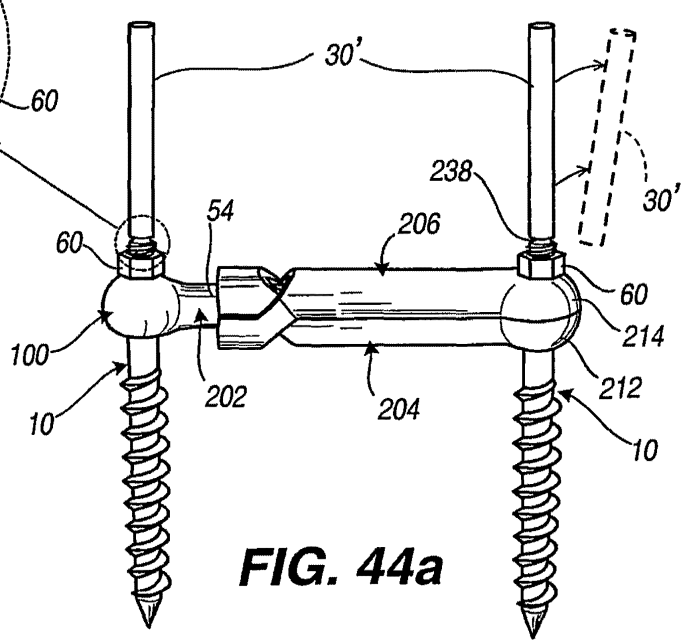


FIG. 44a

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US02/31201

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. : 606/54, 60, 61, 72, 73, 104

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
X	US 6,267,765 B1 (TAYLOR et al) 31 July 2001, Figs. 1-4 and 10-12.	1, 4-9, 12
A	US 5,800,435 A (ERRICO et al) 1 September 1998, Figs. 1-7.	
A	US 5,591,166 A (BERNHARDT et al) 7 January 1997, Figs. 2-5.	
X	US 5,312,405 A (KOROTKO et al) 17 May 1994, Figs. 1-2.	30, 31, 35, 37 40-42, 44
X	US 5,484,440 A (ALLARD) 16 January 1996, Figs. 3-9.	13, 15, 16, 18

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

*	Special categories of cited documents:	"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
"A"	document defining the general state of the art which is not considered to be of particular relevance	"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
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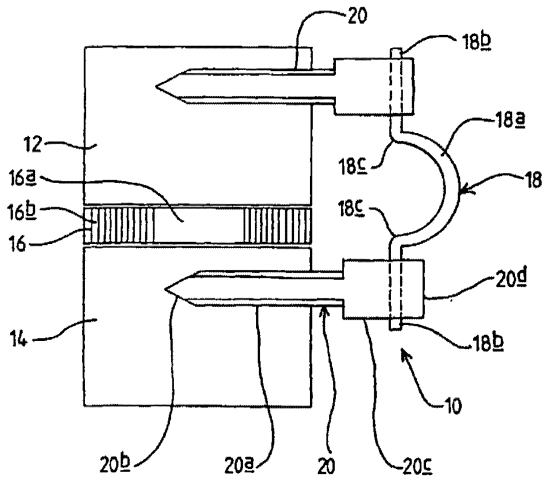
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(54) Title: AN ASSEMBLY FOR THE STABILISATION OF VERTEBRAL BODIES OF THE SPINE



(57) Abstract: An assembly for the stabilisation of vertebral bodies of the spine is described. It comprises a pair of pedicle screws each having a threaded shaft with a tapering first end for introduction into a vertebral body and a head portion with a second end, and is characterised in that it further comprises a spring member of the following form. The spring member has first and second ends, substantially straight portions adjacent each end and a substantially curvilinear central portion being substantially coplanar. The assembly also includes a pair of fixation mechanisms for securing the first and second ends of the spring member to the pair of pedicle screws. Typically the assembly will be for stabilisation of two adjacent vertebral bodies of the spine, that is one motion segment.

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Title: An assembly for the stabilisation of vertebral bodies of the spine

Description of Invention

The invention relates to an assembly for the stabilisation of vertebral bodies of the spine of the kind which is secured to the adjacent vertebral bodies by pedicle screws, and in particular although not exclusively to such an assembly for stabilisation of two adjacent vertebral bodies.

The lumbo-sacral region of the human spine consists of five lumbar vertebrae located above the large triangular bone called the sacrum. Between adjacent lumbar vertebrae are inter-vertebral discs (IVD) which have a complex structure, with a central jelly like nucleus pulposus and a peripheral rim of tough fibrous layers, the annulus fibrosus. Each lumbar vertebra is made up of a vertebral body, with upper and lower end plates, which contact the IVD's, and facet joints located posteriorlly. Movement in the lumbo-sacral spine occurs in the IVD's at the front and at the facet joints at the rear. Thus, the IVD's and the facet joints provide stability of the motion segment between adjacent vertebra. However, they also transfer load from one vertebra to the next, and it is estimated that the IVD bears approximately 80% of the load and the pair of facet joints at the rear bear approximately 20% of the load. A normal IVD can distribute the load uniformly across the surface of the end plate of the vertebral body. However, when the IVD and/or the facet joints are damaged or degenerate this can lead to instability of the motion segment between adjacent vertebra and commonly to low back pain. It is considered that the pain can be caused by abnormal movement, and/or by abnormal distribution of load across the end plates of the vertebrae.

Conventional treatment of low back pain is to limit movement between adjacent vertebrae, typically by fusing the adjacent vertebrae together. However, fusion has a high failure rate of pain relief.

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More recently treatment with prosthetic IVD's has been tried in an attempt to preserve the normal movement and normal load bearing of the inter-vertebral joints. However, thus far the results are no better than in fusion of adjacent vertebrae.

An alternative approach is that of "soft stabilisation" which aims to prevent abnormal motion in painful motion segments of the lumbo-sacral spine, but to save as much as possible of the normal motion. Several methods of soft stabilisation have been described in the literature, but only two are currently in use.

The Graf ligament system consists of a fabric ligament secured across pedicle screws located in the adjacent vertebrae. Typically two such ligaments are located across each motion segment, one to each side on the rear of the spine. This system creates lordosis (curvature of the spine, convex forwards) and restricts the movement of the motion segment between the vertebrae concerned, but it also increases the load at the posterior part of the IVD. In one such system (Dynesys-Sulzer, as described in European patent application published under No. EP 0 669 109) excessive lordosis is prevented by a cylinder embracing the ligament between the pedicle screws. However, actual distraction of the disc space can only be achieved by producing flexion of the motion segment. This results in a kyphotic (convex backwards) segment, and kyphotic segments in the lumbo-sacral spine can produce back pain. Hence, there are significant problems with the use of such a system.

The other soft stabilisation system which is in the process of development is a fulcrum assisted soft stabilisation system (FASS) which is described in International patent application No. PCT/CH99/00612. In this system the compressing effect of the ligament found in the Graf ligament system is converted into a distraction effect by the use of a fulcrum bridging between the pedicle screws, and located between the ligament and the spine. This system can unload the IVD in forward flexion but not in extension.

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However, it is known from the literature that the IVD is loaded both in flexion and extension and the facet joints are specifically loaded in extension. Hence, this system also is expected to suffer from disadvantages.

None of the available soft stabilisation systems therefore addresses the important aim of addressing uniform IVD distraction to create a normal loading pattern across the end plates of the vertebrae, both in flexion and extension.

It is an aim of the present invention to provide a new soft stabilisation system which addresses that aim, and mitigates the problems described above.

According to the present invention there is provided an assembly for the stabilisation of vertebral bodies of the spine comprising a pair of pedicle screws each having a threaded shaft with a tapering first end for introduction into a vertebral body and a head portion with a second end, characterised in that it further comprises:

a spring member having first and second ends, substantially straight portions adjacent each end and a substantially curvilinear central portion therebetween, the straight portions and the substantially curvilinear central portion being substantially coplanar; and

a pair of fixation mechanisms for securing the first and second ends of the spring member to the pair of pedicle screws.

The substantially curvilinear central portion of the spring member may be C-shaped or a coil.

The substantially curvilinear central portion of the spring member typically has a radius of curvature in the range 3 to 17 mm or in the range 5 to 15 mm.

The substantially straight portions of the spring member may be at an angle to each other in the range 0 to 180 degrees, or 90 to 180 degrees. When the straight portions are at 180 degrees they are substantially coaxial. When the substantially straight portions of the spring member are at 0 degrees they are parallel, and this is most likely when the central curvilinear portion is a coil.

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Preferably the spring member is formed from wire.

The spring member may have a diameter in the range 1 to 6 mm, or in the range 2 to 5 mm.

The spring member may have substantially straight portions of greater cross sectional area than that of the substantially curvilinear portion.

The assembly may have a pair of sleeves, one on each of the substantially straight portions, to effectively increase the external diameter of at least a part of each of the substantially straight portions.

Such sleeves may have external diameters in the range 5mm to 8mm.

The spring member may be round in cross section, or alternatively may be square or rectangular in cross section. The spring member is preferably formed from titanium or stainless steel.

The threaded shaft portions of the pedicle screws may have lengths in the range 30 to 60 mm, or in the range 35 to 55 mm. Preferably the pedicle screws are formed from titanium.

The assembly may be for stabilisation of two adjacent vertebral bodies of the spine, i.e. one motion segment. Typically for such embodiments the spring member has a length in the range 20 to 65 mm, but it may be in the range 25 to 60 mm.

The assembly may have a spring member which is specifically adapted for stabilisation of three vertebral bodies of the spine, that is two motion segments.

In such embodiments, the spring member typically has a length in the range 50-110mm, but it may be in the range 60-100mm.

Embodiments of the invention will now be described, by way of example only, with reference to the accompanying drawings in which:

Figure 1 is a schematic illustration of an assembly according to the invention in use;

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Figure 2 illustrates three alternative embodiments of a spring member for incorporation in the assembly of Figure 1;

Figure 3 schematically illustrates a pair of assemblies according to the invention in use, from perspective angle;

Figure 4 illustrates schematically how the assembly of Figure 1 can be used for distraction of the motion segment;

Figure 5 illustrates schematically how the assembly according to the invention can be used to cause backward angulation of the motion segment;

Figure 6 illustrates a fixation mechanism suitable for use in the assembly of Figure 1;

Figure 7 illustrates three further alternative spring members;

Figure 8 illustrates schematically two assemblies according to the invention used across adjacent motion segments, and

Figure 9 illustrates schematically an alternative embodiment of an assembly according to the invention for use across two motion segments.

Referring first to Figure 1, an assembly 10 for the stabilisation of two adjacent vertebral bodies 12, 14 of the spine is illustrated schematically. The vertebral bodies 12, 14 are separated by an inter-vertebral disc 16 which has a nucleus pulposus 16a and a fibrous outer-annulus, called the annulus fibrosus, 16b. For simplicity the facet joints have been omitted from the posterior of the vertebral bodies 12, 14. For clarity the assembly 10 is fixed to the posterior of the vertebral bodies 12, 14.

The assembly 10 comprises a spring member 18 which has a central substantially curvilinear portion 18a, which in this embodiment is C-shaped, and substantially straight portions 18b extending outward therefrom. The straight portions 18b and curvilinear portion 18a are joined by reverse curvature portions 18c.

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The assembly 10 further comprises a pair of pedicle screws 20 each of which comprises a threaded shaft portion 20a with a tapering first end 20b and a head portion 20c with a second end 20d.

The assembly 10 is illustrated in position secured to the posterior of a pair of adjacent vertebral bodies 12, 14 with the threaded shaft portions 20a of the pedicle screws 20 inserted into the vertebral bodes 12, 14. The spring member 18 is secured to the heads 20c of each of the pedical screws 20 by a fixation mechanism as appropriate. An example of a fixation mechanism will be described later, although any appropriate mechanism may be used.

Referring now in particular to Figure 2, three examples of spring members for incorporation into an assembly according to the invention are illustrated. Figure 2a shows the spring member 18 from Figure 1. In the spring member 18 the substantially straight portions 18b are coaxial, i.e. at an angle of 180° to each other, and the substantially curvilinear portion 18a is C-shaped and approximately a semi-circle. The reverse curvature portions 18c are of small radius and approximate to right angles.

In Figure 2b a first alternative spring member 22 is illustrated in which the substantially straight portions 22b are at an angle to each other of approximately 150°, and the substantially curvilinear portion 22a is again C-shaped and approximately a semi-circle. The substantially straight portions 22b and the substantially curvilinear portion 22a are joined by reverse curvature portions 22c which in this spring member 22 are of relatively small radius, but not as small as in the embodiment above.

In Figure 2c a third embodiment of a spring member 24 is illustrated. The spring member 24 again comprises two substantially straight portions 24b, with a substantially curvilinear portion 24a therebetween, these portions being joined by reverse curvature portions 24c which are of a larger radius of curvature than those 22c in the previous embodiment. The substantially

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straight portions 24b are again at an angle to each other, this time of approximately 140°.

The substantially curvilinear portions 18a, 22a, and 24a are all shown as being smooth curves approximating to a semi-circle. However, they could take other forms, such as for examples being smaller arcs of a circle, or indeed not being strictly curvilinear but comprising a plurality of short straight portions.

The substantially straight portions 18b, 22b and 24b, are all shown as being straight, but they could in alternative embodiments be very slightly curved. They will generally be at angles to each other in the range 90 to 180° for embodiments such as these with C-shaped curvilinear central portions 18a, 22a and 24a.

In each of the spring members 18, 22 and 24 the substantially straight portions and the substantially curvilinear portion are coplanar.

The spring members 18, 22 and 24 are made from titanium or stainless steel wire, each spring member being bent from a single piece. The wire will typically have a diameter in the range 1 to 6mm, but preferably in a range of 2 to 5mm. The wire may be round in cross-section or may be of other forms e.g. square, rectangular, or oval in cross section.

The spring members 18, 22 and 24, which are all designed to be used between adjacent vertebral bodies, have an overall length in the range 20mm to 65mm, but preferably in the range 25mm to 60mm.

Referring now in particular to Figure 3, a pair of assemblies 10 according to this invention are shown secured to a pair of adjacent vertebral bodies 12, 14. This is the manner in which the assembly 10 will generally be used, with one assembly 10 applied to either side of the vertebral bodies on the posterior aspect of the spine.

Referring now to Figures 4 and 5, two effects of use of the assemblies 10 are seen illustrated. In Figure 4, it can be seen that unloading of the inter-vertebral disc can be achieved by separation of the pedicle screws 20, or

distraction of them, along the substantially straight portions 18b of the spring member 18 before securing the spring member 18 to the pedicle screws 20 using the fixation mechanisms 26. Thus the assembly 10 will hold the vertebral bodies 12, 14 further apart, unloading the disc, yet still permit some movement which is relatively normal.

In Figure 5 the use of an alternative embodiment of spring member 24, in which the substantially straight portions 24b are at an angle to each other, can be seen providing backward angulation (lordosis) of the motion segment between the adjacent vertebral bodies which in some conditions will be desirable.

Referring now to Figure 6 an example of a fixation mechanism 26 is illustrated, the mechanism being known in the prior art. The head 20c of the pedicle screw 20 is shown with a particular form. It comprises a slot 30 which provides the dual purpose of accepting the blade of a screw driver for insertion of the pedicle screw 20 into a vertebral body, and for receipt of the substantially straight portions 24b of the spring member 24. The head 20c further comprises adjacent its second end 20d, and around the upper part of the slot 30, a threaded portion 32.

The fixation mechanism 26 further comprises a sleeve member 34 and threaded nut 36, also sleeves 38 which are located on the substantially straight portions 24b of the spring member 24 before the assembly 10 is put together as shown in Figure 6b. The sleeves 38 effectively increase the outer diameter of the spring member 24 as necessary for use in the fixation mechanism 26. For example, for a spring member 24 formed from wire with a diameter of 3mm or 4mm the sleeves 38 may typically increase the diameter to somewhere in the range 5mm to 8mm, as appropriate for the pedicle screw being used. As an alternative, the substantially straight portions 24b of the spring member 24 may be formed with a greater diameter than that of the substantially curvilinear

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portion 24a, and thus have a greater cross-sectional area than the substantially curvilinear portion 24a.

The fixation mechanism 26 is shown assembled in Figure 6c. Once the screw 20 has been inserted into the vertebral body one substantially straight portion 24b of the spring member 24, with sleeve 38 in place, is located in the slot 30. The sleeve member 34 is then placed over the head 20c of the pedicle screw 20, and the nut 36 screwed down onto the threaded portion 32 to retain the spring member 24 in place. The fixation mechanism 26 may further include a check nut (not shown), as is known in the prior art, to further secure the mechanism together and to reduce the possibility of it loosening over time.

It should be appreciated that the fixation mechanism 26 is one example of many options which would be available, and any appropriate fixation mechanism may be used.

Referring now to Figure 7 three further embodiments of spring members according to the invention are illustrated. In the first, as shown in Figure 7a, a spring member 40 comprises a substantially curvilinear central portion 40a in the form of a coil, and two substantially straight portions 40b extending therefrom at substantially 180° to each other. The second, shown in Figure 7b is a spring member 42 comprising a substantially curvilinear portion 42a, comprising a coil as for the previous embodiment, with two substantially straight portions 42b extending therefrom at an angle of approximately 120° to each other. The third embodiment, shown in Figure 7c, comprises a spring member 44 having a central substantially curvilinear portion 44a comprising a coil as previously, and two substantially straight portions 44b extending therefrom, but this time at approximately 0° to each other and substantially parallel. It will be appreciated that the spring members 40, 42 and 44 are shown unloaded, rather than as they would be after implantation with the patient in a normal rest position, by which time they would be loaded.

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In each of the embodiments of spring member 40, 42 and 44 the substantially straight portions 40b, 42b and 44b are substantially coplanar, in that they are as close to coplanar as can be achieved when the substantially curvilinear portions 40a, 42a and 44a comprise coils.

The embodiments of assemblies according to the invention described and discussed thus far are for use between two adjacent vertebral bodies. Such embodiments can be used across adjacent motion segments, as illustrated in Figure 8, if more than one motion segment requires stabilisation. In such cases the pedicle screw 20 located in the middle of the three vertebral bodies 14 has a modified fixation mechanism which can receive and secure the substantially straight portion of two spring members 18.

It is also possible for embodiments of assemblies according to the invention to be appropriate for use across more than a single motion segment. One such example, for use across two motion segments, is illustrated in Figure 9 in which three vertebral bodies are shown referenced 12, 14 and 14'. A pedicle screw 20 is inserted into the upper most vertebral body 12, and into the lower most vertebral body 14'. A spring member 46, substantially of the form of the spring member 18 but of larger dimension, is secured between the two pedicle screws 20. Spring member 18 will be longer than embodiments previously described, and may be as long as 110mm or 100mm.

The exact design of spring members for use in a particular case will depend on a large number of factors. These will include the sizes of the vertebral bodies, the number of motion segments requiring stabilisation, and the particular condition being treated.

In the present specification "comprises" means "includes or consists of" and "comprising" means "including or consisting of".

The features disclosed in the foregoing description, or the following claims, or the accompanying drawings, expressed in their specific forms or in terms of a means for performing the disclosed function, or a method or process

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for attaining the disclosed result, as appropriate, may, separately, or in any combination of such features, be utilised for realising the invention in diverse forms thereof.

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CLAIMS

1. An assembly for the stabilisation of vertebral bodies of the spine comprising a pair of pedicle screws each having a threaded shaft with a tapering first end for introduction into a vertebral body and a head portion with a second end, characterised in that it further comprises:

a spring member having first and second ends, substantially straight portions adjacent each end and a substantially curvilinear central portion therebetween, the straight portions and the substantially curvilinear central portion being substantially coplanar; and

a pair of fixation mechanisms for securing the first and second ends of the spring member to the pair of pedicle screws.

2. An assembly according to claim 1 wherein the substantially curvilinear central portion is C-shaped.

3. An assembly according to claim 1 wherein the substantially curvilinear central portion is a coil.

4. An assembly according to any one of the preceding claims characterised in that the substantially curvilinear central portion of the spring member has a radius of curvature in the range 3 to 17 mm.

5. An assembly according to claim 4 characterised in that the substantially curvilinear central portion of the spring member has a radius of curvature in the range 5 to 15 mm.

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6. An assembly according to any one of the preceding claims characterised in that the substantially straight portions of the spring member are at angle to each other in the range 0 to 180°.

7. An assembly according to claim 6 characterised in the substantially straight portions of the spring member are at an angle to each other in the range 90 to 180 degrees.

8. An assembly according to any one of claims 1 to 5 characterised in that the substantially straight portions of the spring member are coaxial with each other.

9. An assembly according to any one of claims 1 to 5 characterised in that the substantially straight portions of the spring member are parallel to each other.

10. An assembly according to any one of the preceding claims characterised in that the spring member is formed from wire.

11. An assembly according to any one of the preceding claims characterised in that the spring member has a diameter in the range 1 to 6 mm.

12. An assembly according to claim 11 characterised in that the spring member has a diameter in the range 2 to 5 mm.

13. An assembly according to any one of the preceding claims characterised in that at least the parts of the substantially straight portions adjacent the ends of the spring member are of a greater cross-sectional area than that of the substantially central curvilinear portion.

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14. An assembly according to any one of claims 1 to 12 characterised in that it further comprises a pair of sleeves, one on each of the substantially straight portions, to effectively increase the external diameter of at least a part of each of the substantially straight portions.

15. An assembly according to claim 14 characterised in that the sleeves have an external diameter in the range 5mm to 8mm.

16. An assembly according to any one of the preceding claims characterised in that the spring member is round in cross section.

17. An assembly according to any one of claims 1 to 15 characterised in that the spring member is square or rectangular in cross section.

18. An assembly according to any one of the preceding claims characterised in that the spring member is formed from titanium or stainless steel.

19. An assembly according to any one of the preceding claims characterised in that the threaded shaft portions of the pedicle screws have lengths in the range 30 to 60 mm.

20. An assembly according to claim 19 characterised in that the threaded shaft portions of the pedicle screws have lengths in the range 35 to 55 mm.

21. An assembly according to any one of the preceding claims characterised in that the pedicle screws are formed from titanium.

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22. An assembly according to any one of the preceding claims characterised in that the spring member is specifically adapted for stabilisation of two adjacent vertebral bodies of the spine, that is one motion segment.

23. An assembly according to claim 22 characterised in that the spring member has a length in the range 20 to 65 mm.

24. An assembly according to claim 23 characterised in that the spring member has a length in the range 25 to 60 mm.

25. An assembly according to any one of claims 1 to 21 characterised in that the spring member is specifically adapted for stabilisation of three vertebral bodies of the spine, that is two motion segments.

26. An assembly according to claim 25 characterised in that the spring member has a length in the range 50-110mm.

27. An assembly according to claim 26 characterised in that the spring member has a length in the range 60-100mm.

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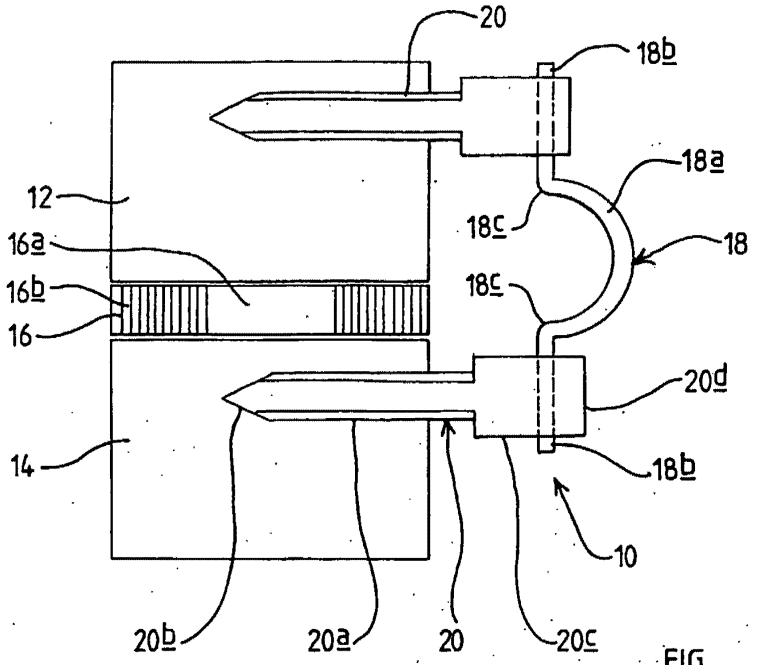


FIG 1

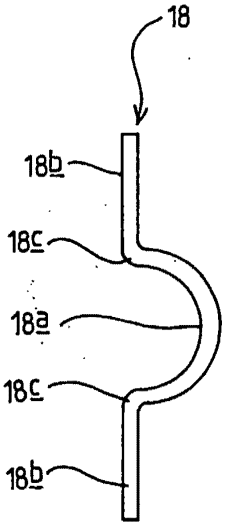


FIG 2a

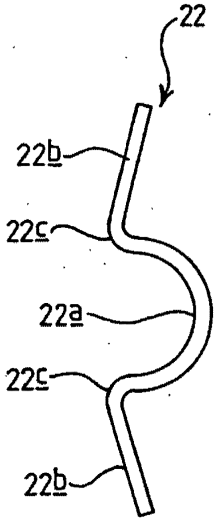


FIG 2b

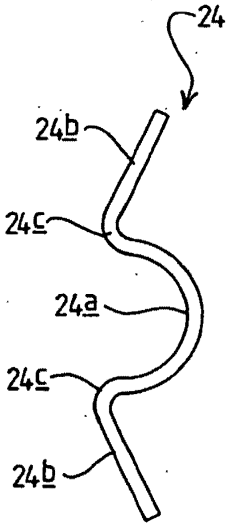


FIG 2c

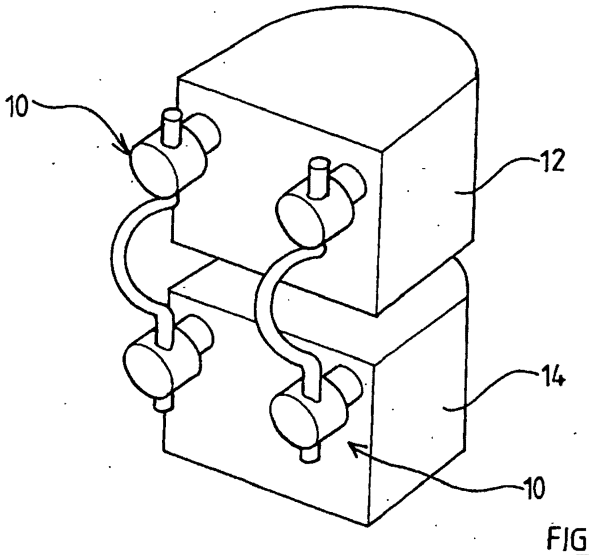


FIG 3

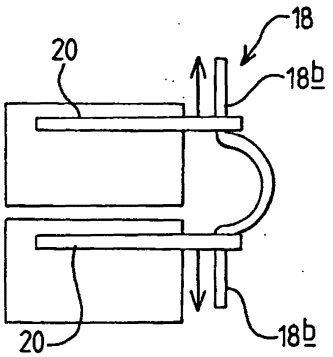


FIG 4a

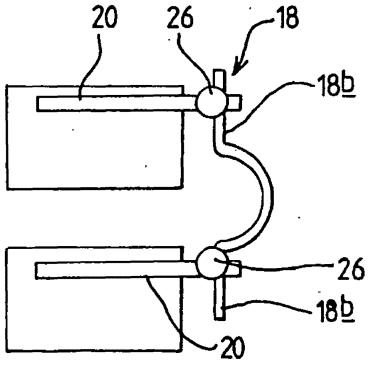


FIG 4b

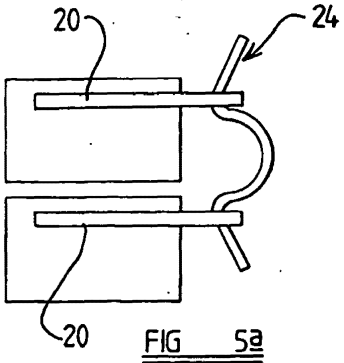


FIG 5a

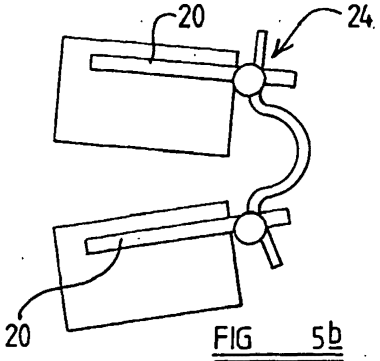


FIG 5b

FIG 6a

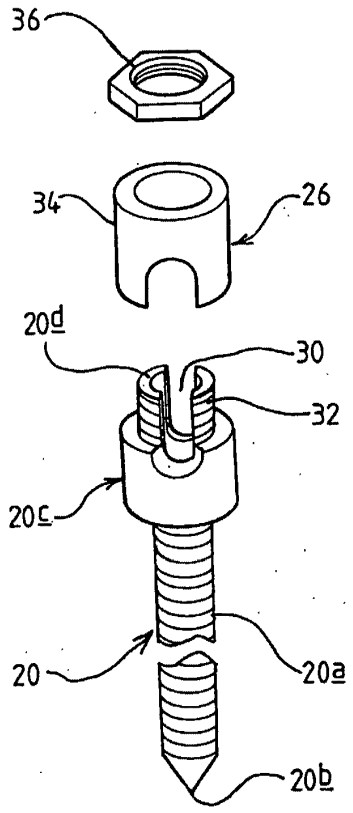
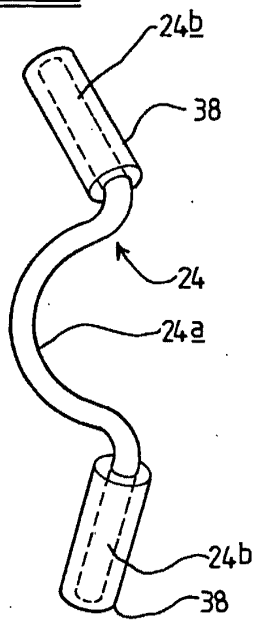


FIG 6b



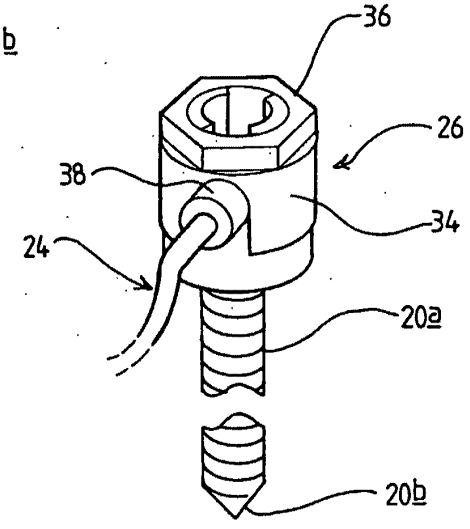


FIG 6c

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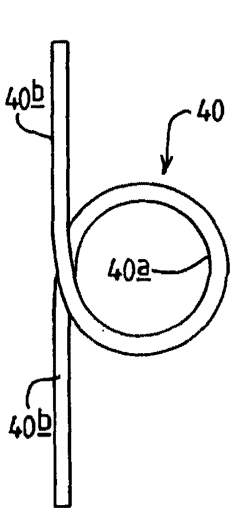


FIG 7a

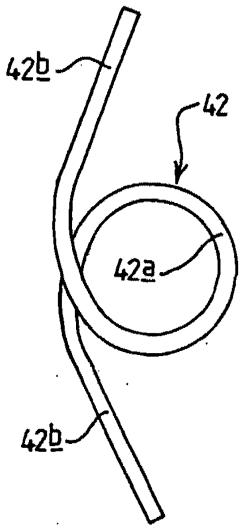


FIG 7b

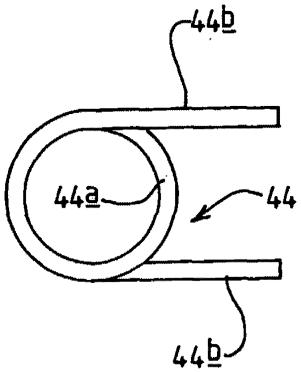


FIG 7c

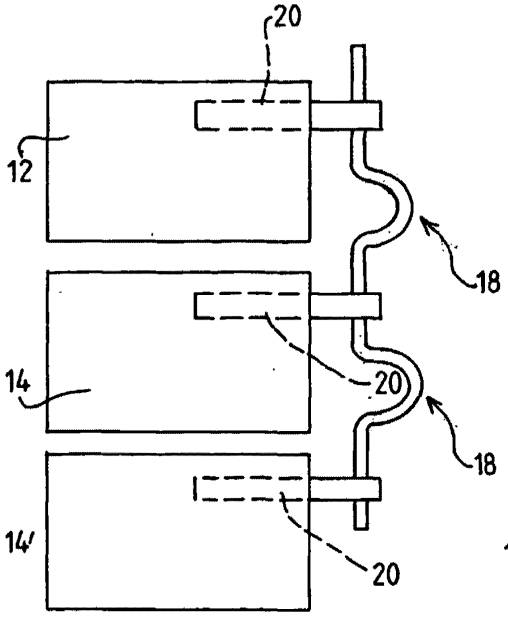


FIG 8

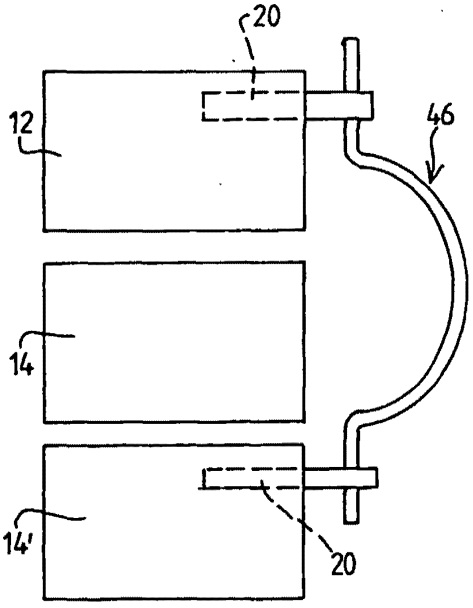


FIG 9

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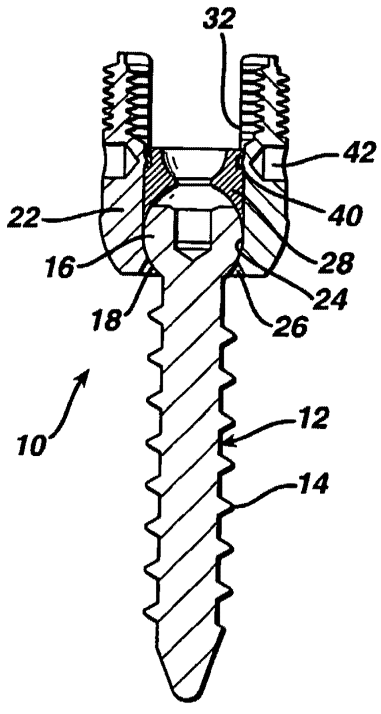
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[Continued on next page]

(54) Title: POLYAXIAL SCREW WITH IMPROVED LOCKING



(57) Abstract: A polyaxial pedicle screw assembly incorporates a concave portion on a receiver which mates with a convex surface on a head of the screw to form a ball joint. The radius of at least a portion of the concave surface is less than a radius of the mating convex portion whereby to create an interference fit.

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Polyaxial Screw with Improved Locking

Field of the Invention

The present invention relates to a polyaxial pedicle screw.

Background

Polyaxial pedicle screws such as disclosed in Biedermann et al.'s US Patent No. 5,443,467, incorporated herein by reference, are used for connecting vertebrae to rods in spinal surgery. They incorporate a ball joint at the connection to the rod to allow the surgeon some flexibility in placing the screws. Tightening a nut on the screw compresses the ball joint components to lock the angular position of the ball joint.

Summary of the Invention

The present invention, improves the locking force achieved when locking the ball joint.

A pedicle screw assembly according to the present invention comprises a screw having a head with a convex portion and a receiver receiving the head. The receiver also receives an elongate member, such as a spinal fixation rod. The receiver has a concave portion which has a radius of curvature which is less than a radius of curvature of the convex portion of the head whereby to create an interference fit between the convex portion of the head and the concave portion of the receiver.

Preferably, a nut on the receiver compresses the convex portion of the head into the concave portion of the receiver. In one convenient orientation, the receiver comprises a U-shaped portion for receiving the elongated member. Preferably, the concave portion of the receiver is formed of titanium. Although other shapes may be employed, in one preferred orientation each of the concave portion and convex portion have a spherical shape. Any shapes which allow rotational freedom of the head and receiver prior to engagement of the surfaces would suffice.

In one preferred embodiment the screw comprises an elongated shank having bone threads thereon and the head located at one end thereof and the receiver comprises a body having an aperture therethrough for receiving the shank and having the concave portion located at the aperture. The receiver further comprises a channel therethrough opposite the aperture, the channel receiving the elongate member.

The pedicle screw can further comprises a compression member between the elongate member and the head; the head having a second convex portion facing the compression member and the compression member having a second concave portion facing the head, the second concave portion having a radius of curvature less than a radius of curvature of the second convex portion whereby to create an interference fit between the head and the pressure member.

The difference in the radius of curvature between the convex and concave portions in one embodiment is about 0.05 mm.

Brief Description of the Drawings

FIG. 1 is a cutaway view of a pedicle screw according to the present invention;

FIG. 2 is an additional cutaway view of the screw of FIG. 1 with rod and locking nuts removed for clarity; and

FIG. 3 is a detailed cutaway view of a portion of the receiver of FIG. 1.

Detailed Description

FIGS. 1 and 2 illustrates a polyaxial screw assembly 10 according to the present invention. It comprises a screw 12 having cancellous threads 14 for insertion into the cancellous bone of a vertebra, especially through the pedicle. A spherically shaped head 16 has a convex surface 18 and a tool recess 20 for receiving a hex driver or other tool (not shown). The head 16 is received within a tubular receiver 22 having an internal concave surface 24 and an adjacent opening 26. The convex surface 18 of the head 16 mates with the concave surface 24. The opening 26 is smaller than the head 16 so that the screw 12 can project out of the opening 26 without falling out of the receiver 22.

A pressure disk 28 sits atop the head 26 and has a surface 30 of mating shape to that of the head 26. The receiver also has a U-shaped portion 32 which receives an elongated rod 34. The rod 34 is used to connect adjoining vertebrae as is known in the art. An internal nut 36 and external nut 38 compress the rod 34 against the pressure disk 28 which in turn compresses the head convex portion 18 into the receiver concave portion 24 and locks the angular position of the receiver 22 with respect to the screw 12.

The pressure disk 28 preferably has a lateral indentation 40 into which a material on the receiver 22 is swaged 42 to hold the pressure disk 28 within the receiver 22 but allow some movement therein.

FIG. 3 illustrates the feature which improves the locking of the receiver 22 with respect to the screw 12 over prior similar screw assemblies. The concave surface 26 has a slightly smaller radius of curvature than does the convex surface 18 so that when the two are compressed together, the material deforms somewhat to allow the surfaces to mate in an interference fit and thus enhances the grip between the surfaces.

Tests of the deflection of the screw 12 under a torque load versus a prior screw show a significant decrease in deflection versus the prior screw, thus less slippage and better locking. Tables 1 and show the results of tests of screws with and without the interference fit. The seven screws in Table 1 were formed of stainless steel and the seven screws in Table 2 of titanium. The screws labeled Magnum contain the interference fit and the others did not. The screws are of similar dimensions; the numbers listed after the screw refer to the rod size. The tests consist of locking the screws to a uniform torque and then applying a lateral force to the screw 12 to induce a torque at the head 16. The load at an offset of 0.5mm and the stiffness were assessed for each sample. The screws with the interference fit of the present invention exhibited gains in both parameters.

Table 1

Static Cantilever Beam Evaluation

Moss-Miami (no interference fit) vs.

Moss-Miami Magnum (interference fit)

Stainless Steel

Specimen	1	2	3	4	5	6	7	Avg	Std Dev
	Load at Offset 0.5mm (Kn)								
Moss-Miami 6.0	0.2107	0.2188	0.2121	0.2926	0.2483	0.2349	0.3571	0.25	0.05
Moss-Miami Magnum 6.34	0.2470	0.3101	0.3678	0.2752	0.2926	0.3074	0.2618	0.29	0.04
	Stiffness N/mm								
Moss-Miami 6.0	602.2	459.8	229.9	594.3	245.8	538.8	570.8	463.1	160.99
Moss-Miami Magnum 6.34	637.0	705.2	627.8	611.4	753.2	721.1	689.8	677.9	53.27

Table 2

Static Cantilever Beam Evaluation

Moss-Miami (no interference fit) vs.

Moss-Miami Magnum (interference fit)

Titanium

Specimen	1	2	3	4	5	6	7	Avg	Std Dev
	Load at Offset 0.5mm (Kn)								
Moss-Miami 6.0	0.2859	0.3047	0.2389	0.3074	0.2959	0.2403	0.3302	0.28	0.04
Moss-Miami Magnum 6.34	0.3730	0.4495	0.4502	0.4929	0.5348	0.5342	0.5114	0.48	0.06
	Stiffness N/mm								
Moss-Miami 6.0	451.9	404.9	293.3	467.7	404.1	316.9	396.4	390.7	64.58
Moss-Miami Magnum 6.34	707.4	572.1	573.9	526.6	580.0	578.7	517.1	584.5	58.38

In one preferred embodiment, the head convex surface 18 would have a diameter of 6.995 mm and the mating receiver

concave surface 24 would have a diameter of 6.88 mm. Similar interference dimensions could also be applied to the mating interface of the pressure disk surface 30 and the head 16.

While the invention has been described with regard to a particular embodiment thereof, those skilled in the art will understand, of course, that the invention is not limited thereto since modifications can be made by those skilled in the art, particularly in light of the foregoing teachings. Reasonable variation and modification are possible within the foregoing disclosure of the invention without the departing from the spirit of the invention.

IN THE CLAIMS

1. A pedicle screw assembly comprising:

a screw having a head with a convex portion;

a receiver receiving the head and an elongated member; and

the receiver having a concave portion, the concave portion having a radius of curvature which is less than a radius of curvature of the convex portion of the head whereby to create an interference fit between the convex portion of the head and the concave portion of the receiver.

2. A pedicle screw assembly according to claim 1 and further comprising a nut on the receiver which compresses the convex portion of the head into the concave portion of the receiver.

3. A pedicle screw assembly according to claim 2 wherein the receiver comprises a U-shaped portion for receiving the elongated member.

4. A pedicle screw assembly according to claim 2 wherein the concave portion of the receiver is formed of titanium.

5. A pedicle screw assembly according to claim 1 wherein each of the concave portion and convex portion have a spherical shape.

6. A pedicle screw assembly according to claim 1 wherein the screw comprises an elongated shank having bone threads thereon and the head located at one end thereof;

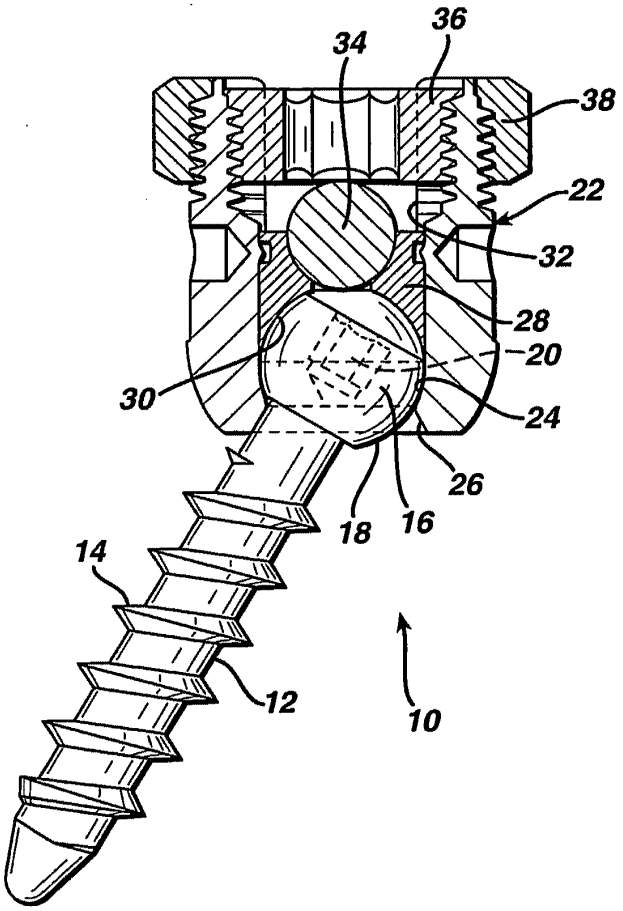
wherein the receiver comprises a body having an aperture therethrough for receiving the shank and having the concave portion located at the aperture;

wherein the receiver further comprises a channel therethrough opposite the aperture, the channel receiving the elongate member.

7. A pedicle screw according to claim 6 and further comprising a compression member between the elongate member and the head; the head having a second convex portion facing the compression member and the compression member having a second concave portion facing the head, the second concave portion having a radius of curvature less than a radius of curvature of the second convex portion whereby to create an interference fit between the head and the pressure member.

8. A pedicle screw according to claim 1 wherein the radius of curvature of the concave portion is about 0.05 mm smaller than the radius of curvature of the convex portion.

FIG. 1



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FIG. 2

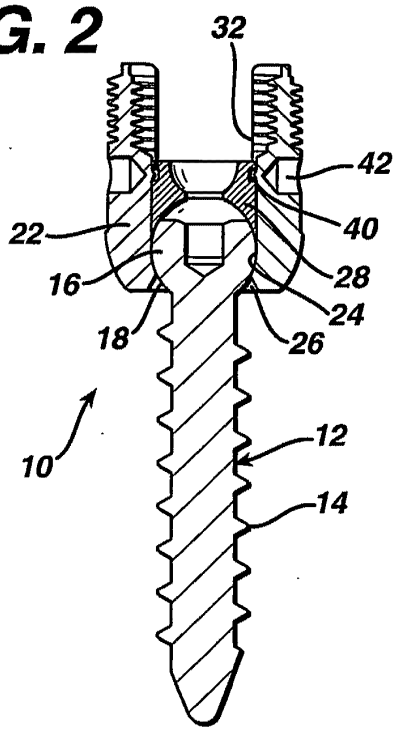
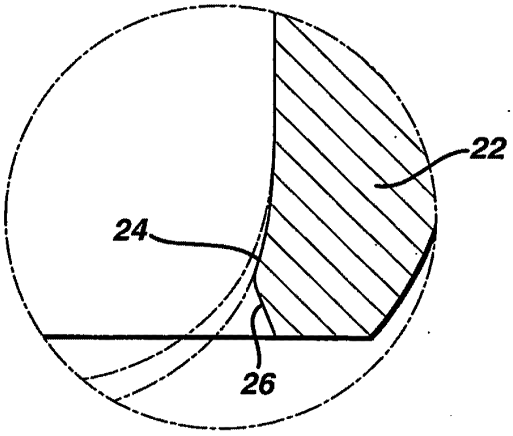


FIG. 3



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(54) **INTERVERTEBRAL FIXING SYSTEM USED IN TREATMENTS OF THE SPINAL COLUMN**

(57) Bone implantation screw (1) incorporates a considerably spherical head (2) provided with a blind axial orifice (3), which allows screwing onto the bone with an Allen type wrench, screw head (2) aided by an anchor plate (4) provided with an orifice (6) with a diameter greater than that of head (2), framed by a tronco-conical narrowing (5) on which rests an open washer (10) which, due to the axial pressure of an inner bushing (11) strangles the lower end of screw head (2), thereby locking it onto the anchor plate. Said anchor plate is provided with upper grooves (7) for implanting bar (8) which links the screws, which bar is permanently fixed by a second bushing (14) and a threaded plug (15) which is threaded on the inside (9) of anchor plate (4) and which generates the required axial pressure to strangle washer (10) and immobilise bar (8).

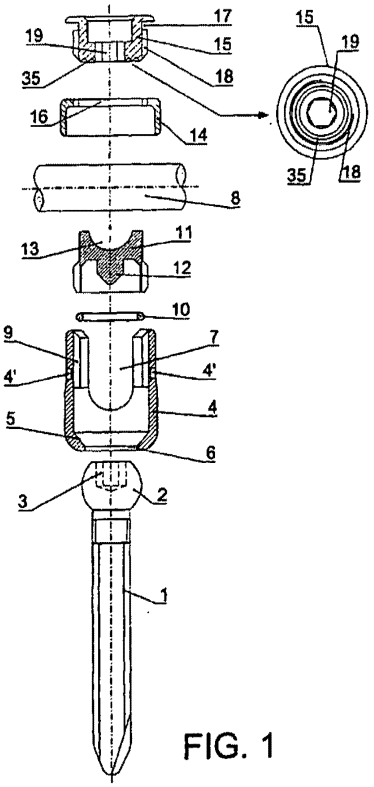


FIG. 1

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Description

OBJECT OF THE INVENTION

[0001] The present invention relates to an intervertebral fixation system particularly designed to immobilise two or more vertebrae by using bars which, suitably configured, are attached to the bone by pedicle nails.

[0002] The field of application of the invention is medicine, and particularly bone surgery, allowing to perform equally fixed, mobile fixations or linking plate fixations which laterally displace the area of fixation of the rod with respect to that of the screw.

[0003] A further object of the invention is to associate to said system means of fixation to the sacrum bone, in order to immobilise it with respect to the proximal area of the spinal column, that is, with respect to its lumbar area, in order to attain a tension-free fixation as the sacrum is of a spongier nature than the vertebrae and therefore less resistant.

BACKGROUND OF THE INVENTION

[0004] One of the systems employed to immobilise two or more bones consists of implanting in these corresponding pedicle screws, each with a head provided with means for attaching to it a bar, which acts as a linking bridge between the various screws, so that as each screw is rigidly connected to the common bar the corresponding bones are thereby immobilised.

[0005] Within this bone fixation system exist three types: fixed, mobile and with linking plate.

[0006] In the fixed system the bar is permanently attached perpendicular to the screw. In the second case between the bar and the screw is provided a knuckle joint which allows to vary the orientation of the bar with respect to the screw. In the third type the bar and screw are related by an intermediate plate which separates them laterally, providing a substantial separation between the aforementioned elements.

[0007] The problems presented by this type of fixation mainly stem from the fact that the means for attaching the bar to the screw are from the start already attached to the screw, hindering the implantation of the screw and impairing the view of the surgeon in establishing a proper insertion of the screw in the bone.

DESCRIPTION OF THE INVENTION

[0008] The intervertebral fixation system disclosed by the invention, which may be used with only slight modifications for both fixed and mobile fixations, as well as for systems requiring a link plate, solves the aforementioned problems in a fully satisfactory manner, allowing implantation of the screw to take place separately from the other parts which are involved with it, that is, in absence of the means of attaching the screw head nail to the screw connecting bar, so that it can be implanted in optimal conditions from the point of view of both handling and visibility.

[0009] For this purpose and more specifically, the screw involved in the system described in its fixed and mobile versions, consists of a functional combination of: a screw having a spherical head which is slightly cambered at its top, meant to be inserted in the bone; an anchor plate which can house the screw head, provided with large recesses for the bar to rest in, and a narrowing mouth having a tronco-conical shape which allows the screw head to pass and causes it to be retained with the aid of an open washer, which is narrowed as it is compressed axially onto the aforementioned tronco-conical mouth; a bushing which acts axially on said open washer and which is pressed in this sense by the bar itself, a second bushing for support and pressure on the opposite area o said bar, and finally a threaded plug which is coupled to the anchor plate mouth and through which is achieved the final fixation and tightening of the assembly. Said plug is provided on its lower part with a circular striation.

[0010] According to a further characteristic of the invention the head of the screw is provided with an axial orifice, blind and polygonal, which allows its implantation in the bone with the aid of an Allen wrench, prior to the implantation of the remaining screw mechanisms.

[0011] From this basic structure the bushing which acts on the open washer may incorporate at its end a polygonal prismatic shaped lug for coupling to the blind orifice of the head in a fixed system, or said bushing may have a hemispherical inner surface in order to establish a knuckle joint with the screw head.

[0012] If a linking plate system is used, said plate will include a housing similar to that of the anchor plate, but shorter and without recesses, receiving only the bushing which compresses the open washer, which will be threaded, while the bushing proper will be attached to the other end of the linking plate, and receives in it a pseudomorse cone which is used as a means for attaching to the link plate and as a seat for the bar, which will be finally fixed with the aid of a second bushing and a threaded plug as in the previous case.

[0013] Said pseudomorse cone extends as a short cylindrical threaded neck which is implanted in the linking plate, which after the implantation is attached by means of a pin and is integrally joined to the plate.

[0014] With the above described structure aids a device for transverse union of bars, which consists of a piece provided with a recess open on the sides, and suitable in shape and size for a implanting in it the bars to be joined, which recess is crosses by a transverse orifice of the piece itself, which is grooved and meant for implantation of the second bar, this piece further incorporating a threaded orifice which opens perpendicularly from the outside of the transverse orifice and which is meant to receive a tightening plug by which one bar is pressed against the other after their relative position is selected.

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[0015] In accordance with the described structure the implantation of the screw is made simple and convenient, with a perfect visibility for the surgeon of the work area, as well as ensuring an ideal structural rigidity for the assembly, that is, a perfect immobilisation of the rod with respect to the screw, without danger of unwanted motion of the cones to be joined, with a minimal effort required of the doctor as well as a minimal time of intervention, and the further possibility of conveniently stiffening with respect to each other of the bars which are part of the system after they are correctly positioned, all of this with the particular characteristic that the multiple parts which participate in the system to achieve fixation of the various elements are supplied to the doctor in a pre-assembled state, suitably connected to each other so that the doctor need only perform the tightening operations after each is correctly placed.

[0016] In an alternative embodiment, the open washer which is axially pressed against the truncated conical opening of the anchor plate is absent and the bushing which is axially acting on the washer has a tronco-conical lower area sectioned into segments which can deform upon tightening in order to allow a previous passage of the spherical screw head and to then clip onto said head, so that it remains attached to an joined to the system.

[0017] Additionally, a complementary element is provided which allows fixation of the corresponding bar relating the sacrum to the lumbar vertebra(e) without any tension whatsoever.

[0018] More specifically, fixation to the sacrum is based on the use of a template which after fixing the bar to the lumbar area of the spine allows to set the exact point at which the screw must be implanted, as well as its orientation, although the angle of the sacrum screws need not be precise since it must adapt to the screw head to form a knuckle. For this is used an angular linking plate, shaped so that it absorbs the angle formed by the spine where the sacrum meets the lumbar vertebrae, which linking plate is provided at one of its ends with a transverse orifice for coupling of the spinal fixation bar, an orifice which has a toothed inner face to improve grip on the bar, and which is crossed by a threaded orifice for implantation f a tightening screw, preferably with an Allen type head, while on the other end of the clinking plate are established the means of attachment to the screw head.

[0019] Such fixation means comprise a housing with a tronco-conical narrowing opening, through which may pass freely the screw head so that it can be implanted in the bone prior to coupling of the linking plate, establishing inside said housing with a threaded side wall an open washer whose diameter in a relaxed state is greater than both the diameter of the screw head and the diameter of the narrowed opening of the housing, also allowing passage through it of the screw head, this assembly complemented by an externally threaded bushing which is preferably provided with Allen operation means, and the tightening of which causes an axial displacement of the washer with its ensuing strangulation on the screw head and fixation of the latter, with the bushing having a hemispherical housing as a seat for the screw head which allows a knuckle joint movement of these elements prior to the final tightening of the assembly.

[0020] The particular configuration of the linking plate and the fixation means to both the screw head and the bar linking it to the rest of the spine make this fixation free of tensions which may damage the sacrum in the area of implantation of the screw.

DESCRIPTION OF THE DRAWINGS

[0021] The characteristics of the present invention will be better understood in view of the accompanying drawings made of a preferred embodiment of the invention, where for purposes of illustration only and as an integral part of the description the following is shown:

Figure 1.- Shows a perspective exploded view of an intervertebral fixation system for spinal treatments in accordance with the present invention, in which some of its elements are shown in a diametric cross section, according to a first embodiment where a fixed system is taught.

Figure 2.- Shows the same assembly of the previous figure duly assembled and in cross section.

Figures 3 and 4.- Show similar representations to figures 1 and 2 corresponding here to the mobile system embodiment.

Figures 5 and 6.- Shows representations also similar to those of figures 1 and 2 here corresponding to the system which uses a linking plate.

Figure 7.- Shows a side elevation view of the device meant for transverse union of bars which is also part of the system of the invention.

Figure 8.- Shows a detail of a transverse section of the device of the previous figure along the A-B line of said figure.

Figure 9.- Shows the transverse union device fully assembled together with the element which keeps all components united, which is shown in an independent perspective view.

Figure 10.- Shows a side elevation and sectional view of the linking plate which participates in the fixation system to the sacrum bone, on which are coupled the screw head and the bar which bypasses and stiffens the sacrum to other vertebra(e) of the spine.

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Figure 11.- Shows a plan view of said linking plate of the previous figure, here lacking the screw fixing it to the sacrum and the bar, as well as the latter's tightening screw.

Figure 12.- Shows a side elevation view of the bushing which presses and holds the screw head in an alternative embodiment for a mobile system.

Figure 13.- Shows a side elevation and sectional view of the bushing of the previous figure for a fixed system.

Figure 14.- Shows the assembly of the bushing of figure 12 onto the corresponding anchor plate which is part of the system object of the invention.

PREFERRED EMBODIMENT OF THE INVENTION

[0022] In view of these figures, and more specifically of figures 1 and 2, the intervertebral fixation system for spinal treatments disclosed by the invention comprises a screw (1), to be inserted in the bone, provided with a spherical head (2), provided with an axial blind orifice (3), with a polygonal section, to allow its implantation in the bone with the aid of an Allen wrench. Meant to be coupled to head (2) of screw (1) is an anchor plate (4) which is provided at its proximal end with respect to the screw with a tronco-conical narrowing (5), with this narrowing defining an orifice (6) which allows to pass screw head (2), and said anchor plate further incorporating large recesses (7), diametrically aligned, which allow implantation of bar (8), which is the actual piece which joins the vertebrae, as well as an inner threading (9) in the area which frames said recesses (7).

[0023] Anchor plate (4), is meant to receive within it an open washer (10) with a diameter in a relaxed state similar to the inner diameter of the lower sector of anchor plate (4), meant to narrow radially onto the lower area of screw head (2) by axial displacement of a bushing (11), which is basically cylindrical as anchor plate (4), and provided with a circular front for support on washer (10), provided with an axial lug (12), which emerges from its base and couples in blind orifice (3) of screw head (2), and through which these elements are immobilised, and further provided with an upper plate (13) where bar (8) rests.

[0024] Thus, plate (13) of bushing (11) is meant to support bar (8) and the axial pressure which is exerted through a second bushing (14) by a threaded plug (15) coupled to threaded opening (9) of the anchor plate (4), which bushing (14) is provided at its base with a threaded orifice (16) which allows it to remain attached to plug (15), which in turn for such purpose is provided with a smooth neck (17) set back with respect to its own threaded sector (18), where bushing (14) is inserted but free. Said plug (15) also incorporates an axial, polygonal orifice (19) which can be driven by means of an Allen wrench as that used to implant screw (1). Said part (15) is provided on its lower area with a circular striation meant to ensure its grip on bar (8), which is also striated.

[0025] Anchor plate (4) is provided with a pair of lateral recesses (4') which after insertion of part (11) are recut so that said bushing (11) cannot exit nor turn, remaining positioned so that it may properly receive bar (8).

[0026] The above described structure is essentially repeated for a mobile fixation system, except that here bushing (11'), equivalent to bushing (11) of the previous case, instead of incorporating the latter's axial lug (13) incorporates a hemispherical inner surface (20) with a curvature in accordance to that of screw head (2), thereby establishing a knuckle joint between the two which allows to change the fixed situation of the previous case with bar (8) perpendicular to screw (1), so that the bar may adopt the optimal inclination with respect to the direction of the screw.

[0027] In addition and as represented in figures 5 and 6, when the system incorporates a linking plate (21) this shall be provided with a housing (22) similar to the lower sector of anchor plate (4) of the previous cases, with the same narrowing tronco-conical opening (5) and equally provided with a threading (23) for coupling of a bushing (11"), also similar to bushing (11) of the fixed system with the same axial lug (12) but with an external thread for implantation in berth (22) of plate (21), and more specifically for axial pressure on open washer (10), causing it to strangle on head (2) of screw (1).

[0028] In a different sector of lining plate (21) is provided a threaded orifice (24) for attachment to the plate of anchor plate (4"), which here configures a lower housing (25) for a pseudomorse cone (26) with a tronco-conical sector (27) and a threaded neck (28), between which is defined a neck (29) meant to immobilise pseudomorse cone (26) in order to ensure that when it is pressed on by the bar it will form a single rigid body, which will be supplied to the doctor suitably coupled to anchor plate (4"), with the free end of neck (28) riveted to prevent its decoupling from said anchor plate, but allowing a certain mobility so that bar (8) may be suitably directed, with the doctor performing the final fixation with the aid of a set screw (62) which moves in a lateral orifice (61) of plate (21), open towards orifice (24), meant to act on said neck (29) and more specifically to permanently immobilise anchor plate (4") with respect to plate (21), said cone (26) determining the seat for bar (8) which is similarly attached with the aid of bushing (14) and threaded plug (15) in sector (8) of said anchor plate (4').

[0029] In addition to the described structure the system further includes a device for transverse union of the bars, represented in figures 7 and 8, which consists of a part (30) provided with a laterally open, concave, approximately C-shaped housing (31) for coupling and resting of one of bars (8) to be joined, which housing (31) is crossed by a transverse orifice (32), slit in the

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same sense as housing (31) and meant to receive the second bar (8'), with the final locking of the bars after their correct mutual positioning obtained with a threaded plug (33) which is coupled to an also threaded orifice (34) of part (30) which presses bar (8') against bar (8).

[0030] Figure 9 shows the transverse bar union device finally assembled, which comprises a cap (37) suited in shape and size to be coupled to the top of part (30) in order to prevent the latter from separating from bar (8') and retaining threaded plug (33), so that the transverse union device is mounted before or after its installation on bars (8), considerably simplifying its handling.

[0031] For this purpose cap (37) is provided on its top base with an orifice (38) through which can be accessed plug (33) so that it may be threaded, and is further provided with respective orifices (39) and (39') for passage of bar (8') through it and through transverse orifice (32). Cap (37) keeps together part (30), bar (8') and threaded plug (33), as bar (8') cannot move since it is inserted in said orifices, while cap (37) retains inside it threaded plug (33) but allows its axial displacement with respect to orifice (34) so that it may exert or release the pressure on bar (8).

[0032] To prevent part (30) and the elements joined to it from being removed through the ends of bar (8'), these ends are expanded or oversized, or any element which increases their diameter is added, characteristic which has not bee represented in the figures.

[0033] It only remains to point out that head (2) of screw (1) has striations to ensure stability of the assembly after it is tightened, and that bar (8) has a striated surface for the same purpose of providing a proper stability after it is fixed.

[0034] In addition to the described system, a method of attachment to the sacrum has been designed and shown in figures 10 and 11, which has as a basic element a linking plate (40) embodied as a part with two end sectors (43) and (44), the first provided with a housing (45) for head (46) of the sacrum implantation screw, and the second provided with an orifice (47) for implantation of the bar (48) meant to relate and attach the sacrum to one or more spinal vertebrae, with the particular characteristic, as seen in figure 9, that the two sectors (43) and (44) of said part form a suitable angle to compensate the angle between the sacrum and the rest of the spine.

[0035] Housing (45) for screw head (46), basically cylindrical, has a tronco-conical narrowing (49) at the end where it meets the sacrum, and a threaded sector (50) on the opposite end, with opening (51) defined by said tronco-conical narrowing (49) having a diameter greater than that of the spherical screw head (46) in order to allow the implantation of said screw in the sacrum prior to assembly on it of liking plate (40), with the truncated cone plane of narrowing (49) specifically meant to strangle an open washer (52) which rests on it, which when relaxed also has a diameter greater than that of the screw head (46) so that said head may pass through it, and which is axially displaced with the aid of a bushing (53), interiorly defining a cambered hemispherical housing (54) to allow a knuckle movement of head (46) of the screw, and which is provided with an external thread for attachment to threaded sector (50) of housing (45), and is further provided on its base with a polygonal orifice (55) for driving with an Allen wrench, all such that after screw head (46) is implanted in housing (45) and after the linking plate (40) is properly orientated with respect to axis (56) of said screw, the pressure applied by bushing (53) causes an axial displacement of washer (52) and its strangulation on the neck of the screw with the ensuing locking of the assembly, which locking is favoured by the presence of annular teeth (57) on screw head (46) which bite into the surface of housing (54) of bushing (53).

[0036] Furthermore, orifice (47) for implantation and fixation of bar (48) which links the linking plate attached to the sacrum to the adjacent area of the spine, has an inner surface provided with striations (58) meant to improve the grip on said bar, specifically when it is pressed in its housing by a screw (59) preferably with an Allen type head, which is threaded in an orifice (60) of sector (44) of linking plate (40), which opens perpendicularly towards orifice (47) for implantation of said bar.

[0037] Figures 12, 13 and 14 show an alternative embodiment for bushing (11) or (11'), when the system is not provided with open washer (10).

[0038] Specifically, in this case bushing (11a) is conical at its lower area and is divided into sectors (63) which allow deformation of the part when it is tightened and meets conical area (5) of anchor plate (4), which allows entry of spherical head (2) of screw (3), and clips when pressing said bushing (11^a) against anchor plate (4), making the conical areas clamp spherical head (2) of screw (3), so that the latter is fixed in place and attached to the system.

[0039] As described above bushing (11a) can be used for the fixed system, while bushing (11'a) can be used in the mobile system, in which case it is provided with a central and inner appendix (64), being in all other ways including its function identical to bushing (11a).

[0040] The assembly is delivered assembled, so that its disassembly requires special clamps, first loosening the system and then, through the groove of anchor plate (4) through which the bushing projects slightly, the special clamp is used on the threads, taking care not to move the bushing and lock it when pulling on the screw, thereby allowing exit of the screw.

Claims

1. Intervertebral fixation system for spinal treatments, which includes pedicle screws (1) having a spherical head (2) provided with a blind axial orifice (3) with a polygonal section, said screws (1) to be implanted in the bone, to which are attached bars act-

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ing as a linking means between the various screws for relative immobilisation of the corresponding bones, fixation system this which may be fixed or mobile, and including a complement for fixation of the sacrum, **characterised in that** the spherical head (2) of the screw (1) is aided by an anchor plate (4) which in its area proximal to screw (1) is provided with a tronco-conical narrowing opening (5) which defines an orifice (6) with a diameter greater than that of screw head (2), and with said anchor plate (4) designed to house within it a bushing (11) on which rests bar (8) to be fixed, , with an additional bushing (14) acting on the external area corresponding to bar (8), and axially pressed by a plug (15) which is threaded onto the also threaded opening (9) of anchor plate (4), which is provided with lateral recesses (4') to prevent separation or rotation of bushing (11) after it is inserted in anchor plate (4).

2. Intervertebral fixation system for spinal treatments, as claimed in claim 1, **characterised in that** for a fixed system bushing (11) includes an inner lug (12) emerging axially from its base, with a section having the same configuration as blind orifice (3) of screw head (2) for the relative immobilisation of these two elements.

3. Intervertebral fixation system for spinal treatments, as claimed in claim 1, **characterised in that** for a mobile fixation system bushing (11') has a concave inner surface (20) with a hemispherical shape, defining a knuckle type joint with head (2) of screw (1).

4. Intervertebral fixation system for spinal treatments, as claimed in previous claims, **characterised in that** the anchor plate (4) houses within it an open washer (10) so that the axial displacement of the bushing (11) causes a strangulation of the washer (10) on the lower area of screw head (2) and the ensuing locking of the latter onto the anchor plate (4).

5. Intervertebral fixation system for spinal treatments, which includes pedicle screws (1) having a spherical head (2) provided with a blind axial orifice (3) with a polygonal section, said screws (1) to be implanted in the bone, to which are attached bars acting as a linking means between the various screws for relative immobilisation of the corresponding bone, fixation system which is aided by a linking plate **characterised in that** the linking plate (21) includes on one of its ends a housing (22) which in is area proximal to screw (1) is provided with a tronco-conical narrowing opening (5), with an inner threading (23) for receiving bushing (11"), which is in turn provided with an external threading and which acts as a strangulation means of open washer (10) onto the screw head, while on the other end of the linking plate (21) is defined a threaded orifice (24) for fixation of an anchor plate (4"), here provided with a tronco-conical housing (25) for a pseudomorse cone (26), provided with a threaded neck (28) for fixation to orifice (24) and on which rests bar (8), which is also fixed with the aid of an upper bushing (14) and the complementary plug (15) for axial tightening.

6. Intervertebral fixation system for spinal treatments, as claimed in claim 5, **characterised in that** between tronco-conical sector (27) and cylindrical threaded sector (28) of pseudomorse cone (26) is provided a perimetral neck (29) which after assembly of said cone (26) on the threaded orifice (24) of linking plate (21) is facing an also threaded lateral orifice (61) of plate (21), in which lies a pin (62) which permanently immobilises cone (26) and anchor plate (4") with respect to base plate (21).

7. Intervertebral fixation system for spinal treatments, as claimed in previous claims, **characterised in that** the lower part of plug (15) is striated to improve the grip when it is tightened, while bar (8) which connects the screws is also striated for a similar purpose.

8. Intervertebral fixation system for spinal treatments, as claimed in previous claims, **characterised in that** in it also participates a transverse bar linking device, embodied as a part (30) provided with a lateral recess (31) with a concave shape, transversally elongated with respect to its opening and meant to house on of bars (8) to be linked, said recess (31) crossed by a transverse orifice (32) which is also grooved in the same direction, meant for implantation of the second bar (8') to be joined to the first, with part (30) including a threaded orifice (34) perpendicular to both recess (31) and orifice (32), and in which is placed a threaded plug (33) for tightening one bar (8') against the other bar (8) at the point where they cross, further aiding in this a cap (37) sized and shaped so that it couples to the top of part (30), to bar (8') and to threaded plug (33) during implantation or removal of the transverse linking device, but which allows the axial displacement of threaded plug (33), for which cap (37) is provided on its top base with an orifice (38) for access to threaded plug (33), and with orifices (39 - 39') for passage of bar (8').

9. Intervertebral fixation system for spinal treatments, as claimed in previous claims, **characterised in that** the component parts are pre-assembled prior to their final assembly.

10. Intervertebral fixation system for spinal treatments,

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as claimed in previous claims, **characterised in that** tightening plug (15) implies fixation of anchor plate (4) against screw (1) with the assembly forming a single piece.

11. Intervertebral fixation system for spinal treatments, as claimed in claim 1, **characterised in that** the initial fixation of screw (1) and anchor plate (4) is aided by an open washer (10) which is forced open to allow passage of the head of screw (1), and which closes firmly when said washer passes the largest diameter of the head of screw (1).

12. Intervertebral fixation system for spinal treatments, as claimed in claim 8, **characterised in that** the ends of bars (8') are widened or have attached elements which increase their diameter to prevent the their accidental exit from linking parts (30).

13. Intervertebral fixation system for spinal treatments, as claimed in claim 1, **characterised in that** the complement for fixation to the sacrum consists of a linking plate (40) meant to relate sacrum implantation screw (46) to the corresponding bar (48), adopting said linking plate an angular configuration so that between the area (43) of implantation of screw head (46) and area (44) of implantation of bar (48) is defined an angle which compensates the anatomical angle between the sacrum and the lumbar area of the spine, establishing at these ends (43) and (44) of linking plate (40) fixation means for head (46) of the screw and for bar (48).

14. Intervertebral fixation system for spinal treatments, as claimed in claim 13, **characterised in that** linking plate (40) incorporates as a means of fixation of screw head (43) a basically cylindrical housing (45) with a narrowed tronco-conical opening(49) at the height where it adapts to the sacrum, with a diameter greater than that of the screw spherical head (46), and on which tronco-conical surface (49) lies an open washer (52) which in its relaxed state has a greater diameter than the screw head to allow coupling of the linking plate to it after implanting said screw to the sacrum, and which strangles onto the neck of said screw head by action of a bushing (53) provided with a hemispherical housing (54), which defines a knuckle joint for the screw head, which bushing is threaded in the inner wall of housing (45) and is provided with an Allen type head (55) for its driving during the tightening operation.

15. Intervertebral fixation system for spinal treatments, as claimed in claims 13 and 14, **characterised in that** linking plate (40) has as fixation means to bar (48) a basically cylindrical orifice (47) through which opens radially a further orifice (60), this one threaded, in which is a screw (59), preferably Allen type, which presses bar (48) against the wall of orifice (47), which wall is provided with angular means (58) to improve grip on said bar (48).

16. Intervertebral fixation system for spinal treatments, as claimed in claims 1 to 3, **characterised in that** both bushing (11a) in the fixed system and bushing (11'a) in the mobile system are divided into sectors (63) which may deform to allow passage of head (2) of screw (1) and the later clipping of said head to hold the screw and attach it to the system.

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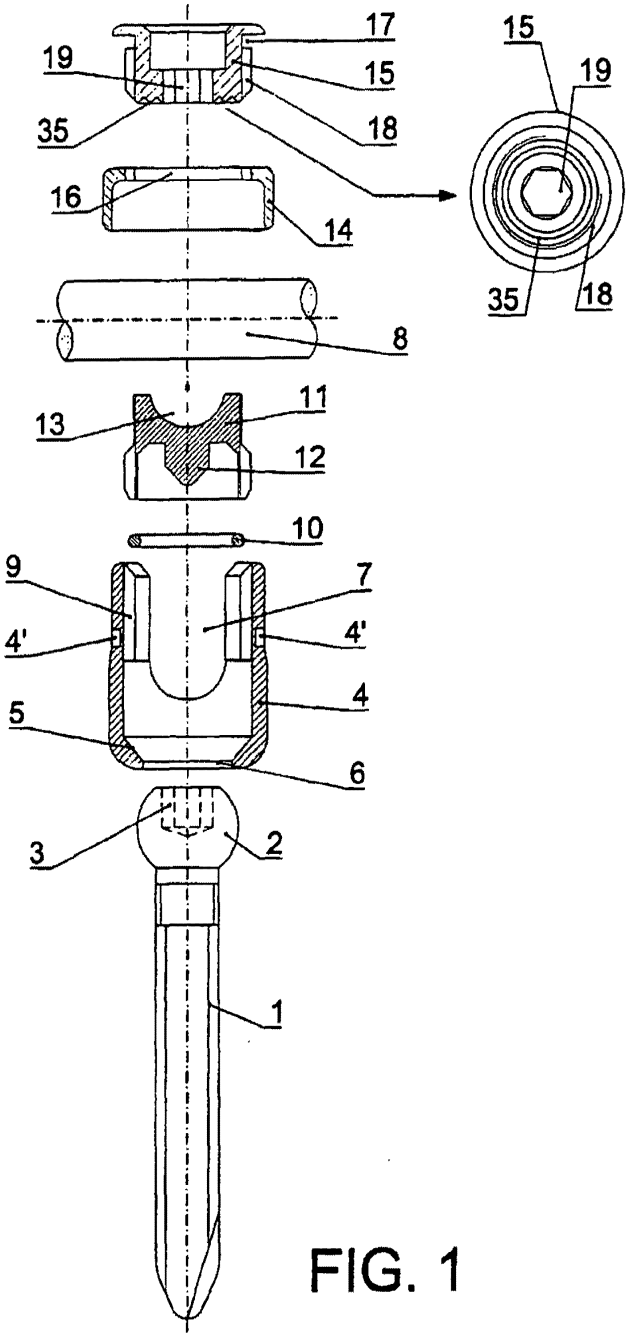


FIG. 1

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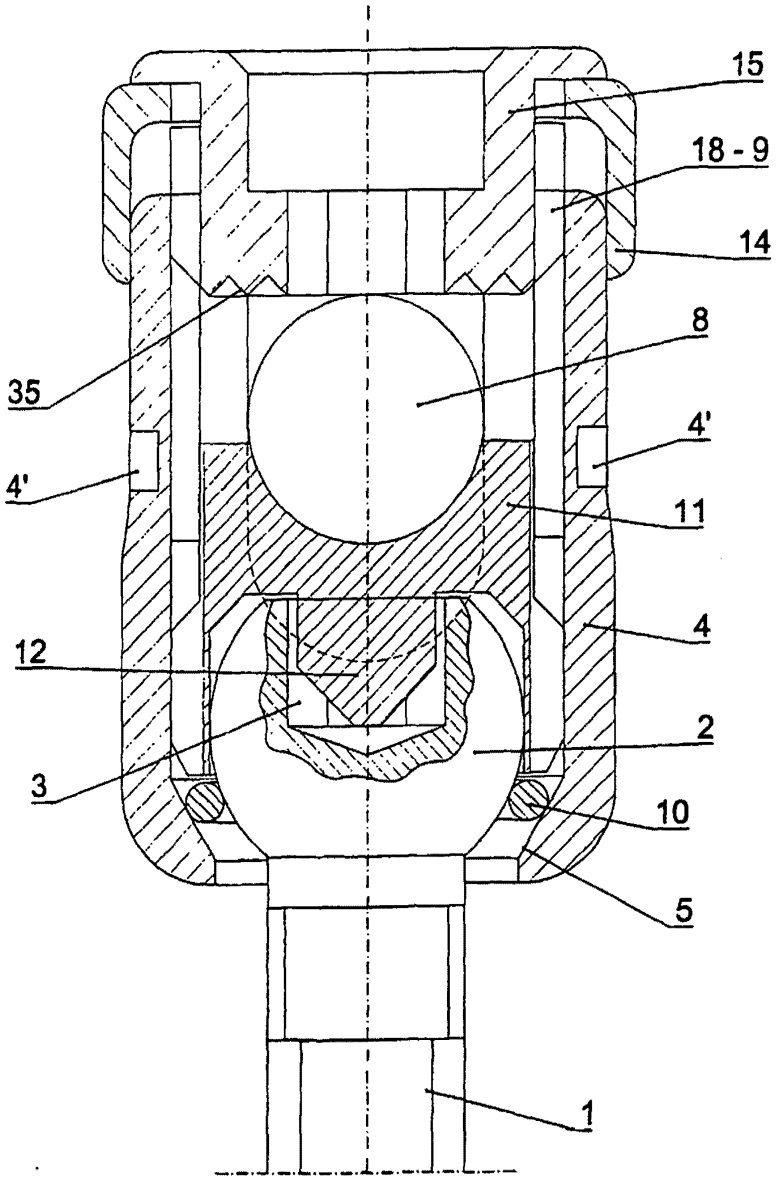


FIG. 2

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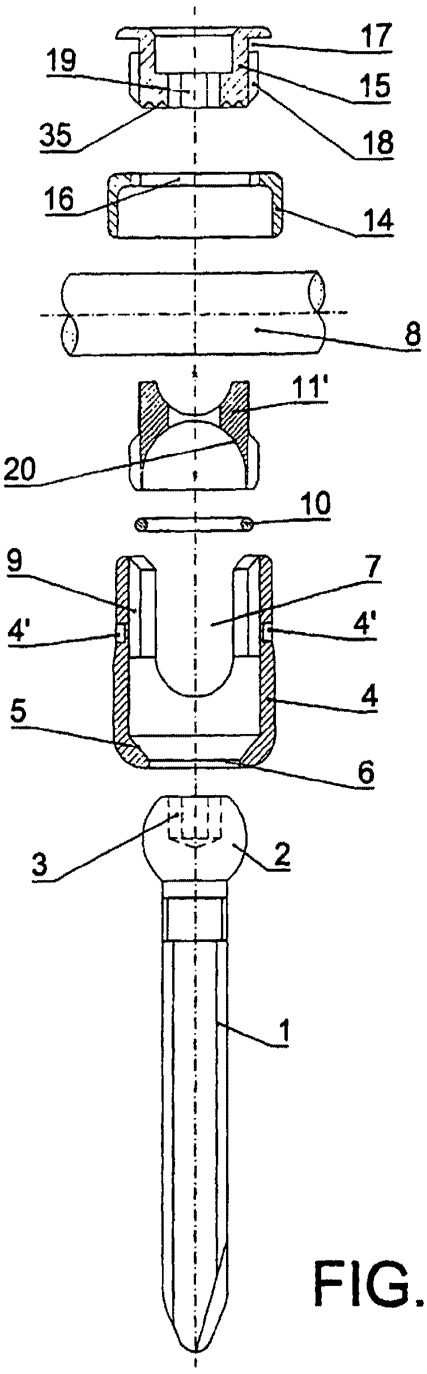


FIG. 3

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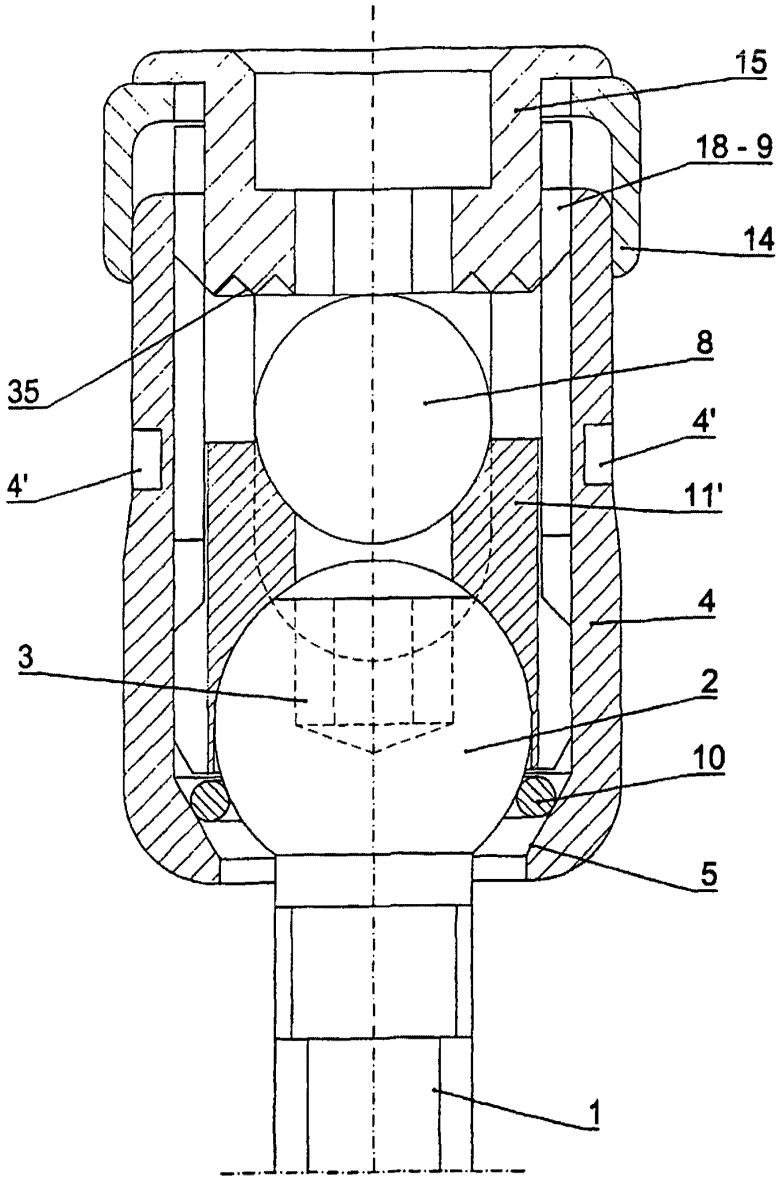


FIG. 4

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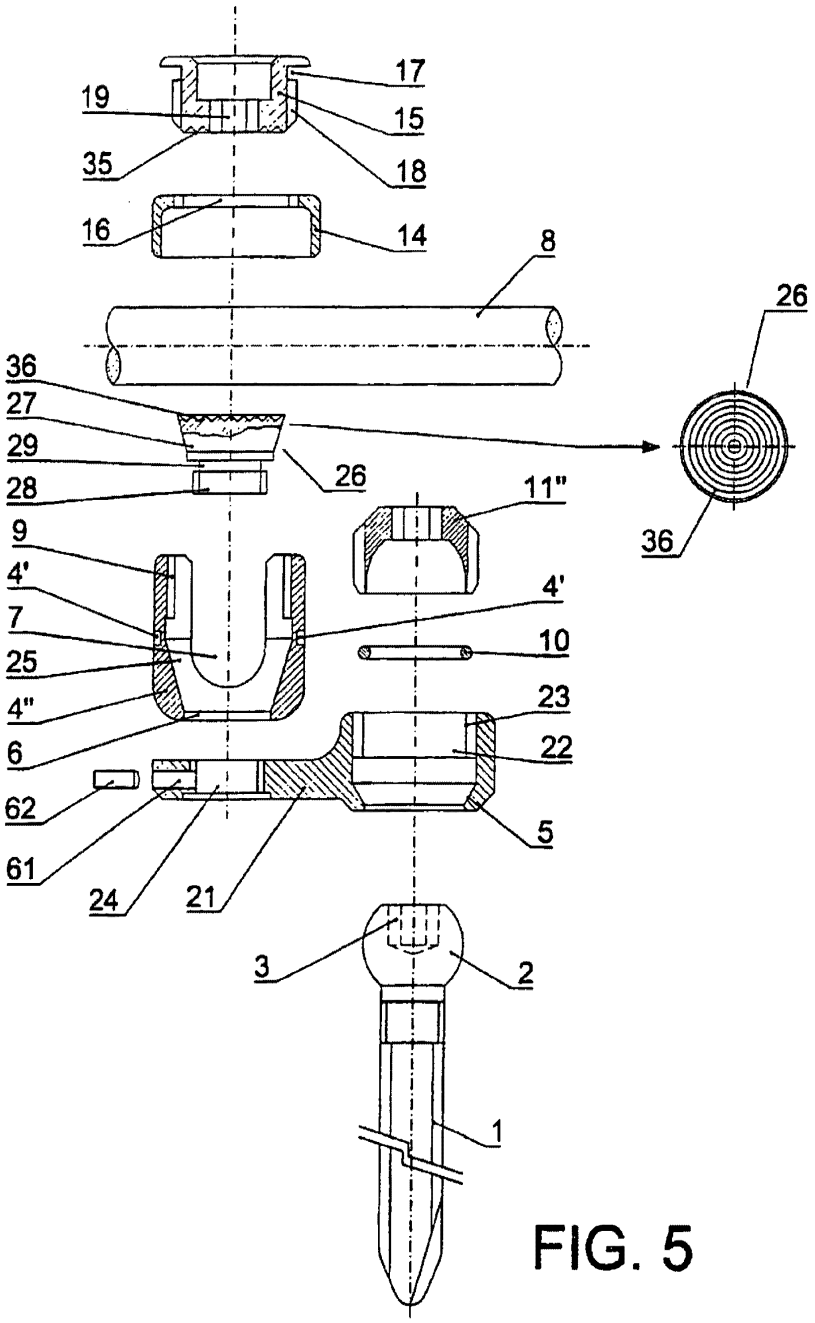


FIG. 5

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