Express Mail EM626520557US




PATENT

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

Case Docket No.: 11,433

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
Under the Paperwork Reduction Act of 1995 no persons are required to respond to a collection of information unless it displays a valid OMB control number

# 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)

**WARNING**: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

**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) 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 |

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

Case Docket No.: 11,433

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

COPY

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
Under the Paperwork Reduction Act of 1995 no persons are required to respond to a collection of information unless it displays a valid OMB control number

# 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)

**WARNING**: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

**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) | 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 |

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.*

COPY

PTO/AIA/14 (08-12)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

| 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 i | 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 i | 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).**

PTO/AIA/14 (08-12)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

| 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 |

PTO/AIA/14 (08-12)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

| 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[i] | 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.

PTO/AIA/14 (08-12)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

| 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

PTO/AIA/14 (08-12)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

| 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.**

EXPRESS MAIL EM 626520557 US




# 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



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



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 12 of 2152

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



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 13 of 2152

(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.



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 14 of 2152

[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.



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 15 of 2152

[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.



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 16 of 2152

[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



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 17 of 2152

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



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 18 of 2152

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.



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 19 of 2152

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



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 20 of 2152

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



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 21 of 2152

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).



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 22 of 2152

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



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 23 of 2152

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



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 24 of 2152

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



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 25 of 2152

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



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 26 of 2152

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



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 27 of 2152

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



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 28 of 2152

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



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 29 of 2152

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



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 30 of 2152

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.



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 31 of 2152

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.



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 32 of 2152

[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



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 33 of 2152

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



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 34 of 2152

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



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 35 of 2152

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



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 36 of 2152

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.



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 37 of 2152

## 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.



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 38 of 2152

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



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 39 of 2152

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.



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 40 of 2152

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.



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 41 of 2152

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



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 42 of 2152

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



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 43 of 2152

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.



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 44 of 2152

Fig. 1.

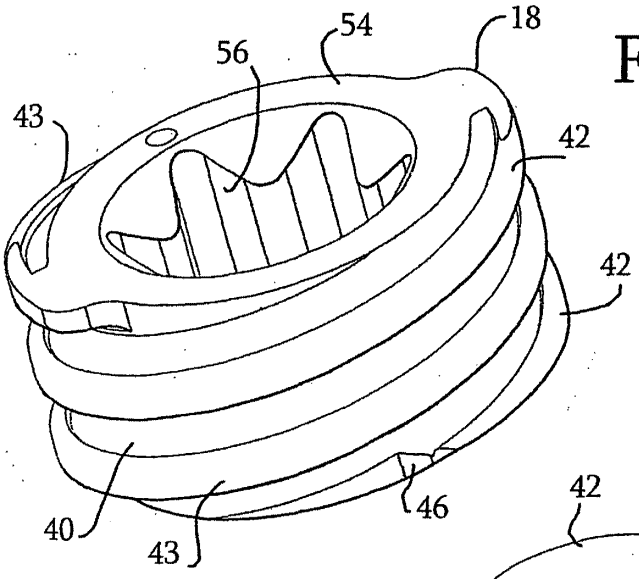



Fig. 2.

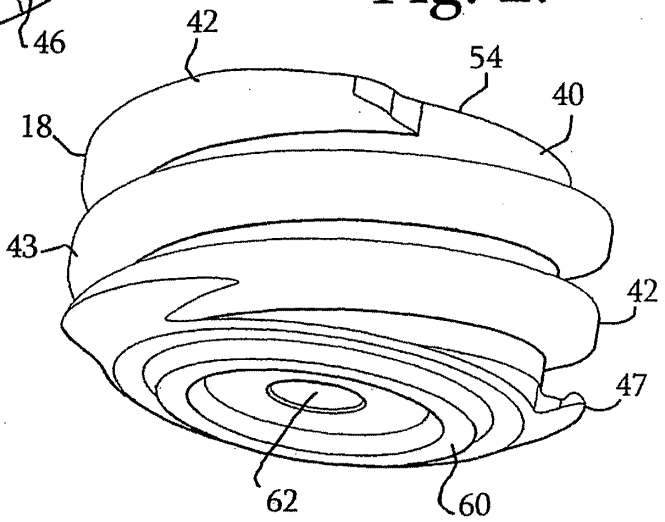
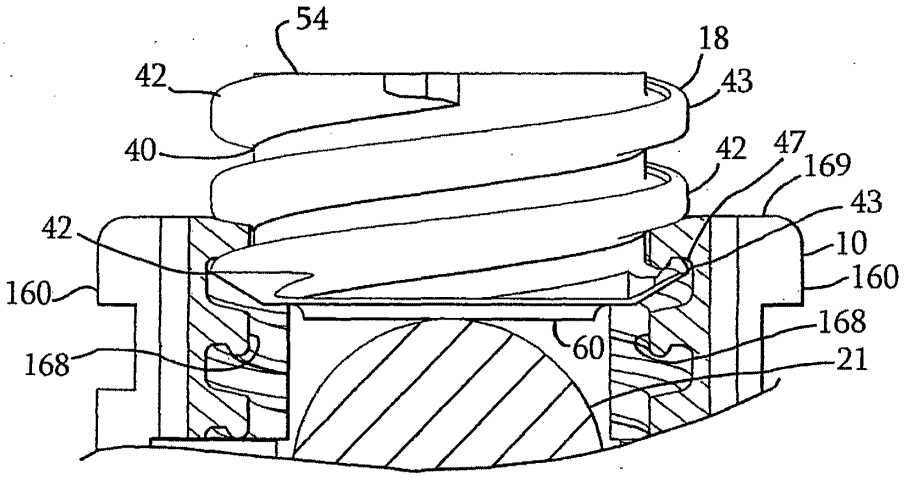



Fig. 3.



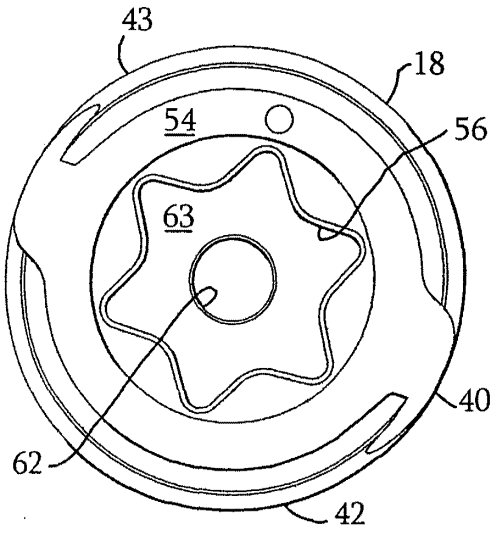



Fig. 4.

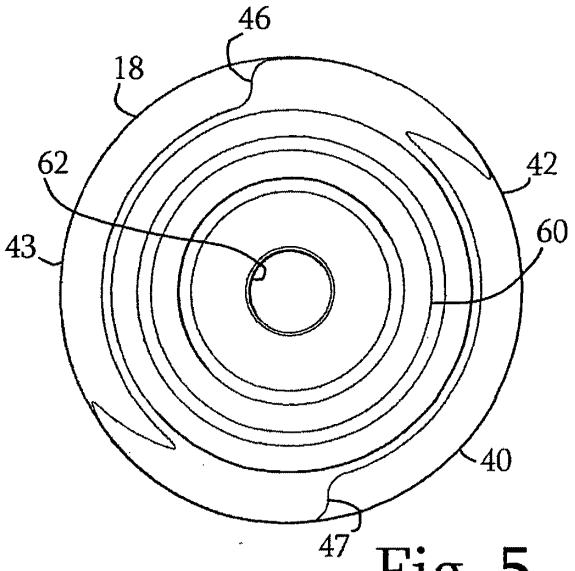



Fig. 5.

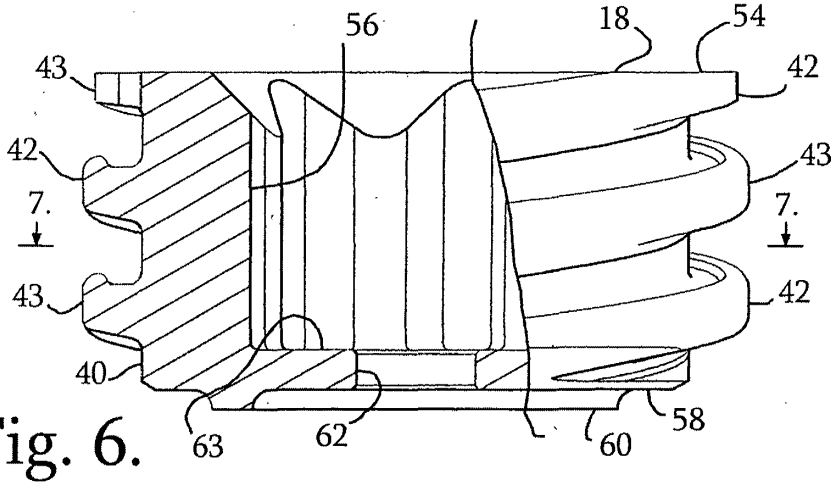



Fig. 6.

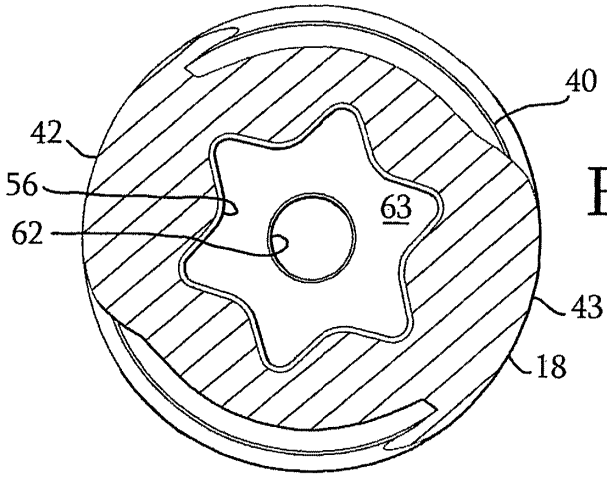



Fig. 7.

Fig. 8.

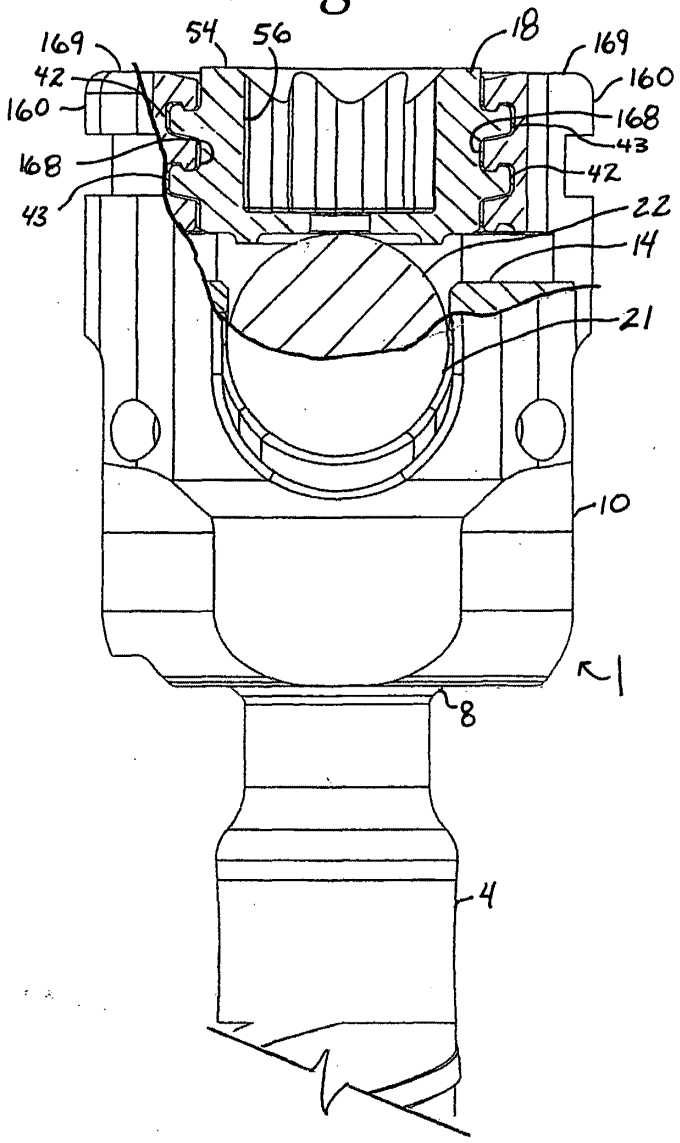


Fig. 9.

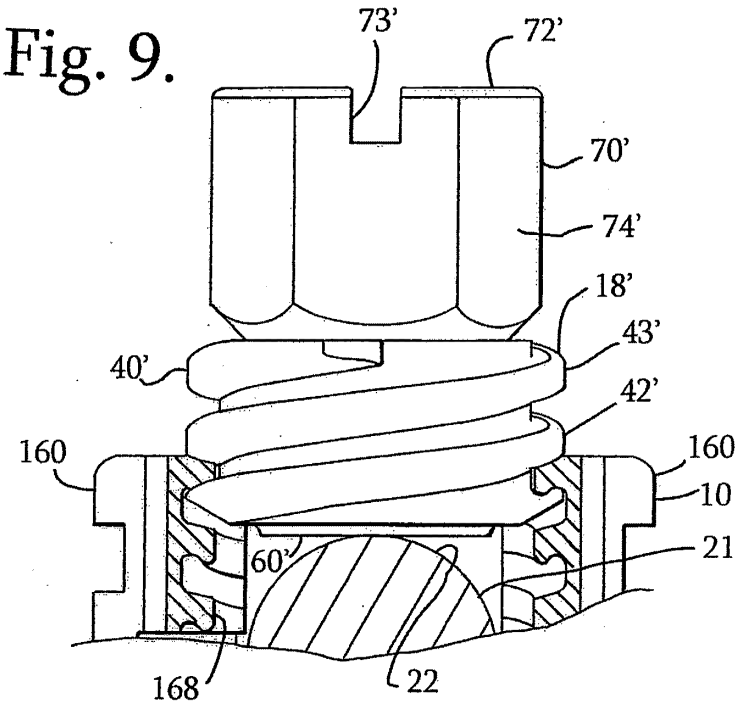

73'
72'
70'
74'
18'
43'
40'
42'
160
160
10
21
60'
168
22

Fig. 10.

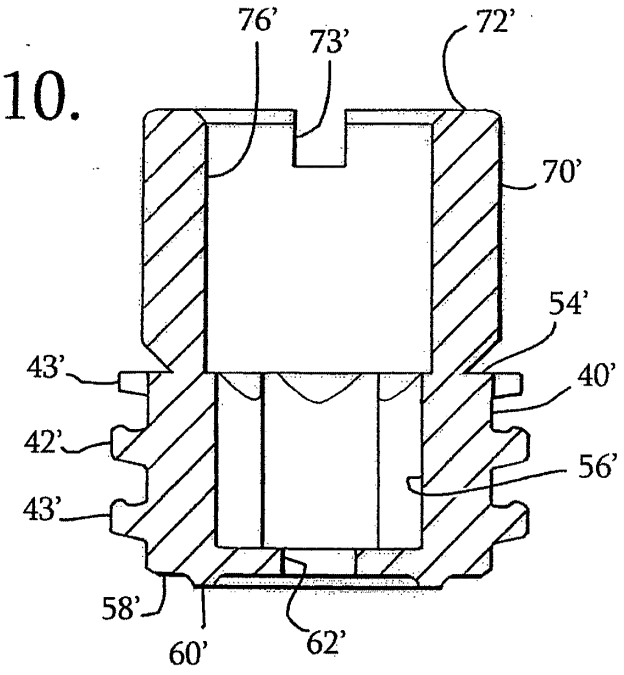

76'
73'
72'
70'
54'
43'
40'
42'
56'
43'
58'
60'
62'

Fig. 11.

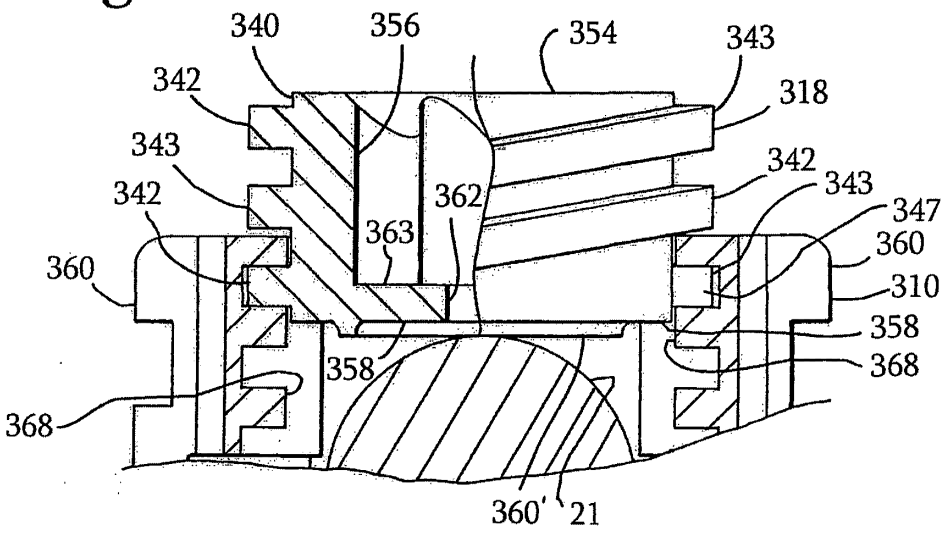
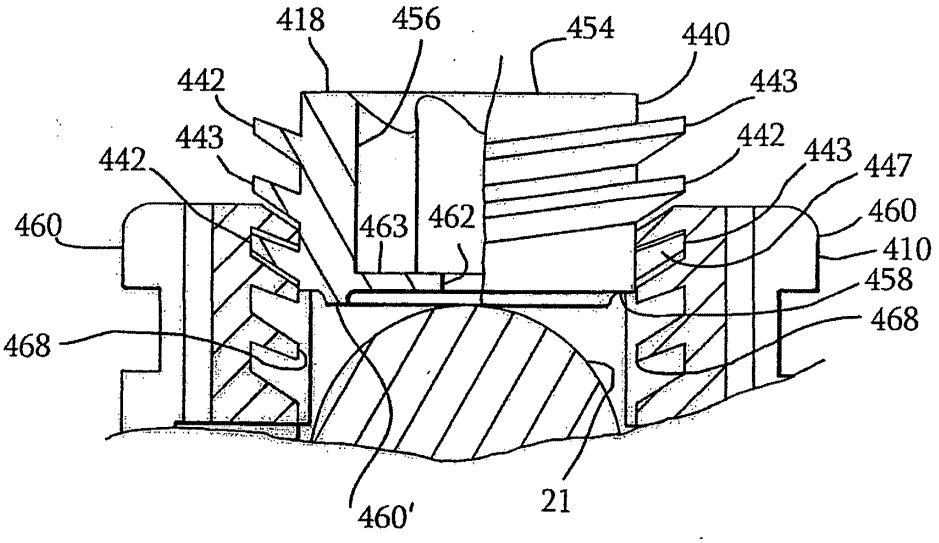

340
356
354
343
342
318
343
342
342
343
347
362
363
360
360
310
358
358
368
368
360'
21

Fig. 12.


418
456
454
440
442
443
443
442
442
443
447
460
463
462
460
410
458
468
468
460'
21

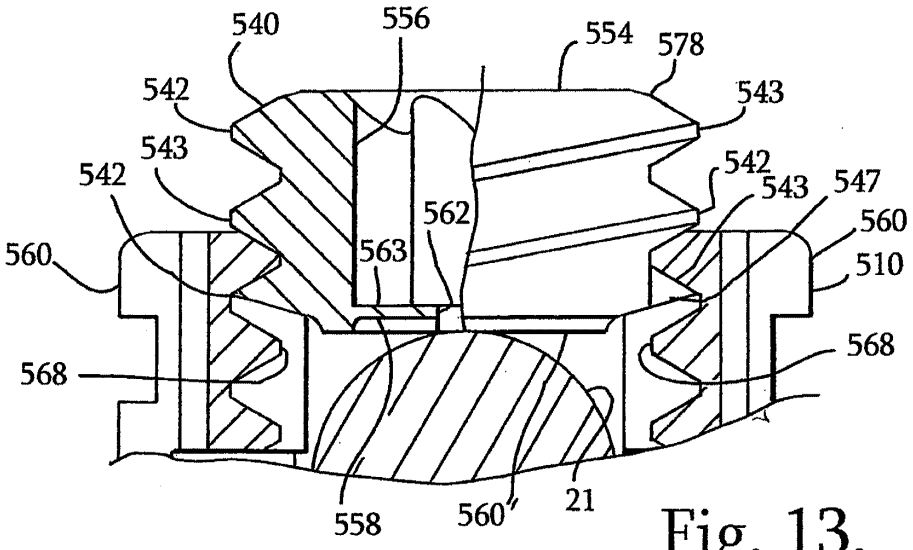

540
556
554
578
542
543
543
542
542
543
547
562
560
563
560
510
568
568
558
560'
21

Fig. 13.

Fig. 14.

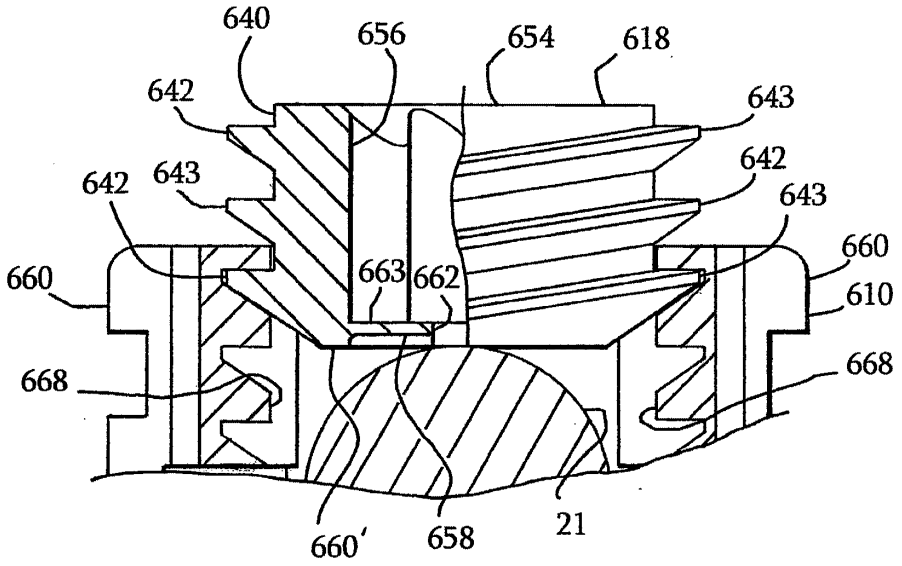
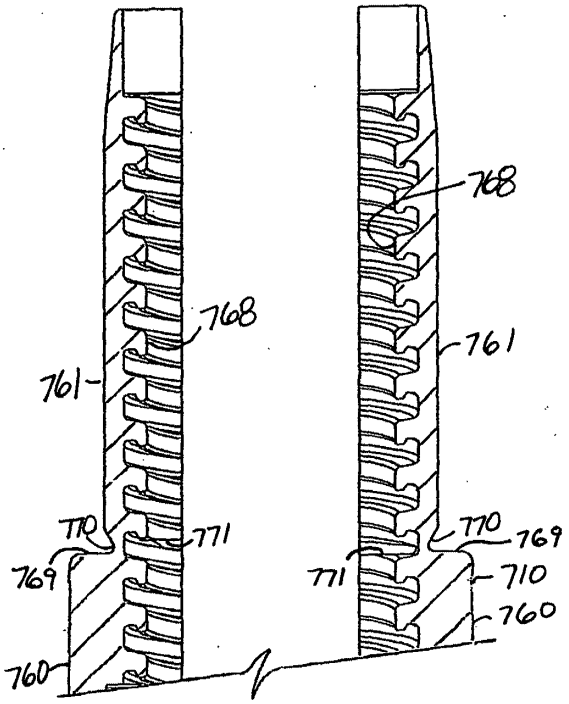

640
656
654
618
642
643
642
643
642
643
660
663
662
660
610
668
668
660'
658
21

Fig. 15.



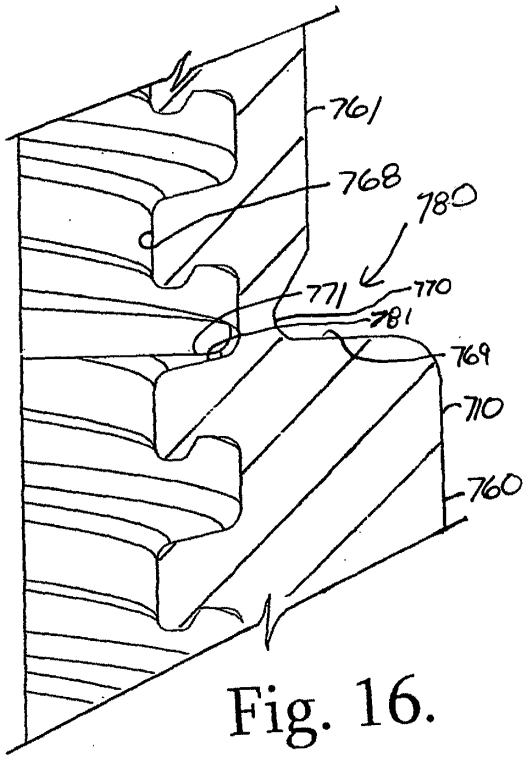
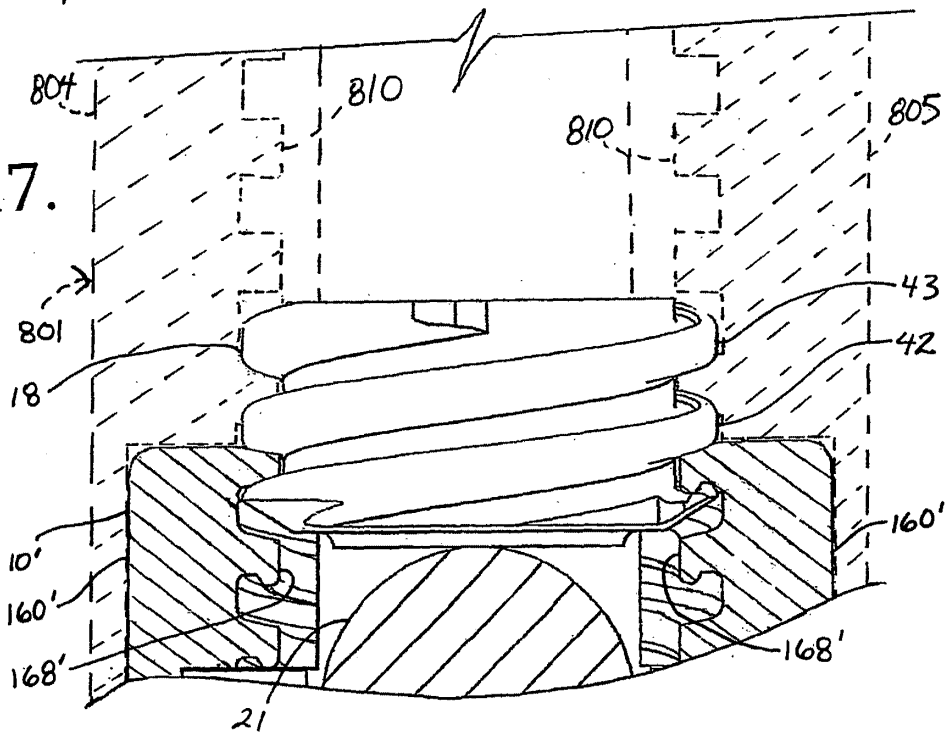
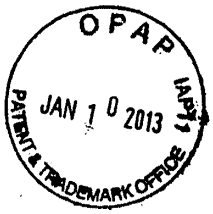




Fig. 16.

Fig. 17.



Express Mail EM626520557US




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:

**U. S. Patents**

| Patent No. | Date | Patentee |
|---|---|---|
| 8,236,035 | 08/07/2012 | Bedor |
| 8,236,032 | 08/07/2012 | Ramsay, et al. |
| 8,221,472 | 07/17/2012 | Peterson, et al. |
| 8,221,471 | 07/17/2012 | Kovach, et al. |
| 8,197,518 | 06/12/2012 | Hammill, Sr., et al. |



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 52 of 2152

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



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 53 of 2152

| | | |
|---|---|---|
| 8,043,340 | 10/25/11 | Law |
| 8,034,084 | 10/11/11 | Landry, et al. |
| 8,029,539 | 10/04/11 | Kirschman |
| 8,025,681 | 09/27/11 | Colleran, et al. |
| 8,021,397 | 09/20/11 | Farris, et al. |
| 8,016,866 | 09/13/11 | Warnick |
| 8,016,862 | 09/13/11 | Felix, et al. |
| 8,012,188 | 09/06/11 | Meltent, et al. |
| 8,012,186 | 09/06/11 | Pham, et al. |
| 8,012,183 | 09/06/11 | Alain |
| 8,002,806 | 08/23/11 | Justis |
| RE42,626 | 08/26/11 | Taylor, et al. |
| 7,988,711 | 08/02/11 | Errickson, et al. |
| 7,988,694 | 08/02/11 | Barrus, et al. |
| 7,985,248 | 07/26/11 | Walder, et al. |
| 7,985,242 | 07/26/11 | Forton, et al. |
| RE42,545 | 07/12/11 | Ralph, et al. |
| 7,972,364 | 07/05/11 | Biedermann, et al. |



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 54 of 2152

| | | |
|---|---|---|
| 7,819,902 | 10/26/10 | Abdelgany, et al. |
| 7,811,310 | 10/12/10 | Baker, et al. |
| 7,811,288 | 10/12/10 | Jones, et al. |
| 7,806,913 | 10/05/10 | Fanger, et al. |
| 7,794,480 | 09/14/10 | Gordon, et al. |
| 7,794,477 | 09/14/10 | Melkent, et al. |
| 7,789,900 | 09/07/10 | Levy, et al. |
| 7,785,354 | 08/31/10 | Biedermann, et al. |
| 7,785,351 | 08/31/10 | Gordon, et al. |
| 7,780,706 | 08/24/10 | Marino, et al. |
| 7,766,945 | 08/03/10 | Nilsson, et al. |
| 7,766,944 | 08/03/10 | Metz-Stavenhagen |
| 7,766,946 | 08/03/10 | Bailly |
| 7,766,943 | 08/03/10 | Fallin, et al. |
| 7,763,057 | 07/27/10 | Abdelgany, et al. |
| 7,758,618 | 07/20/10 | Walder, et al. |
| 7,749,258 | 07/06/10 | Biedermann, et al. |
| 7,731,749 | 06/08/10 | Biedermann, et al. |



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 55 of 2152

| | | |
|---|---|---|
| 7,731,736 | 06/08/10 | Guenther, et al. |
| 7,727,261 | 06/01/10 | Barker , et al. |
| 7,722,654 | 05/25/10 | Taylor, et al. |
| 7,722,652 | 05/25/10 | Justis, et al. |
| 7,722,651 | 05/25/10 | Kwak, et al. |
| 7,722,649 | 05/25/10 | Biedermann, et al. |
| 7,722,646 | 05/25/10 | Ralph, et al. |
| 7,717,943 | 05/18/10 | Kirschman |
| 7,717,942 | 05/18/10 | Schumacher |
| 7,717,941 | 05/18/10 | Petit |
| 7,713,288 | 05/11/10 | Timm, et al. |
| 7,704,271 | 04/27/10 | Abdou |
| 7,699,876 | 04/20/10 | Barry, et al. |
| 7,699,875 | 04/20/10 | Timm |
| 7,699,872 | 04/20/10 | Farris, et al. |
| 7,695,498 | 04/13/10 | Ritland |
| 7,695,497 | 04/13/10 | Cordaro, et al. |
| 7,691,132 | 04/06/10 | Landry, et al. |



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 56 of 2152

| | | |
|---|---|---|
| 7,691,131 | 04/06/10 | Graf |
| 7,691,129 | 04/06/10 | Felix |
| 7,686,835 | 03/30/10 | Warnick |
| 7,686,834 | 03/30/10 | Saint Martin |
| 7,686,833 | 03/30/10 | Muhanna, et al. |
| 7,682,377 | 03/23/10 | Konieczynski, et al. |
| 7,678,139 | 03/16/10 | Garamszegi, et al. |
| 7,678,136 | 03/16/10 | Doubler, et al. |
| 7,674,277 | 03/09/10 | Burd, et al. |
| 7,662,172 | 02/16/10 | Warnick |
| 7,658,739 | 02/09/10 | Shluzas |
| 7,648,522 | 01/19/10 | David |
| 7,645,294 | 01/12/10 | Kalfasetd |
| 7,641,674 | 01/05/10 | Young |
| 7,625,394 | 12/01/09 | Molz, IV, et al. |
| 7,621,941 | 11/24/09 | Schlapfer, et al. |
| 7,615,068 | 11/10/09 | Timm, et al. |
| 7,611,518 | 11/03/09 | Walder, et al. |



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 57 of 2152

| | | |
|---|---|---|
| 7,604,656 | 10/20/09 | Shluzas |
| 7,604,655 | 10/20/09 | Warnick |
| 7,601,166 | 10/13/09 | Biedermann, et al. |
| 7,591,839 | 09/22/09 | Biedermann, et al. |
| 7,588,593 | 09/15/09 | Aferzon |
| 7,588,588 | 09/12/09 | Spitler, et al. |
| 7,575,587 | 08/18/09 | Rezach, et al. |
| 7,588,575 | 08/15/09 | Colleran, et al. |
| 7,572,279 | 08/11/09 | Jackson |
| 7,572,280 | 08/11/09 | Dickinson, et al. |
| 7,569,061 | 08/04/09 | Colleran |
| 7,563,275 | 07/21/09 | Falahee, et al. |
| 7,563,264 | 07/21/09 | Landry, et al. |
| 7,559,943 | 07/14/09 | Mujwid |
| 7,530,992 | 05/12/09 | Biedermann, et al. |
| 7,527,640 | 05/05/09 | Ziolo, et al. |
| 7,524,323 | 04/28/09 | Malandain |
| 7,503,924 | 03/17/09 | Lee, et al. |



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 58 of 2152

| | | |
|---|---|---|
| 7,503,918 | 03/17/09 | Baccelli, et al. |
| 7,491,221 | 02/17/09 | David |
| 7,491,218 | 02/17/09 | Landry, et al. |
| 7,479,156 | 01/20/09 | Lourdel, et al. |
| 7,476,228 | 01/13/09 | Abdou |
| 7,445,627 | 11/04/08 | Hawkes, et al. |
| 7,329,258 | 02/12/08 | Studer |
| 7,306,606 | 12/11/07 | Sasing |
| 7,294,129 | 11/13/07 | Hawkins, et al. |
| 7,229,441 | 06/12/07 | Trieu, et al. |
| 7,207,992 | 04/24/07 | Ritland |
| 7,186,255 | 03/06/07 | Baynham, et al. |
| 7,137,985 | 11/21/06 | Jahng |
| 7,125,410 | 10/24/06 | Freudiger |
| 7,087,057 | 08/08/06 | Konieczynski, et al. |
| 7,029,475 | 04/18/06 | Panjabi |
| 7,018,379 | 03/28/06 | Drewry, et al. |
| 7,018,378 | 03/28/06 | Biedermann, et al. |



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 59 of 2152

| | | |
|---|---|---|
| RE39,035 | 03/21/06 | Finn, et al. |
| 7,008,424 | 03/07/06 | Teitelbaum |
| 6,991,632 | 01/31/06 | Ritland |
| 6,989,011 | 01/24/06 | Paul, et al. |
| 6,986,771 | 01/17/06 | Paul, et al. |
| 6,981,973 | 01/03/06 | McKinley |
| 6,979,334 | 12/27/05 | Dalton |
| 6,974,460 | 12/13/05 | Carbone, et al. |
| 6,966,910 | 11/22/05 | Ritland |
| 6,964,667 | 11/15/05 | Shaolian, et al. |
| 6,964,664 | 11/15/05 | Freid, et al. |
| 6,964,665 | 11/15/05 | Thomas, et al. |
| 6,958,065 | 10/25/05 | Ueyama, et al. |
| 6,955,677 | 10/18/05 | Dahners |
| 6,953,462 | 10/11/05 | Liebermann |
| 6,945,972 | 09/20/05 | Frigg, et al. |
| 6,932,820 | 08/23/05 | Osman |
| 6,932,817 | 08/23/05 | Baynham, et al. |
| 6,896,676 | 05/24/05 | Zubok, et al. |
| 6,872,208 | 03/29/05 | McBride, et al. |
| 6,869,432 | 03/22/05 | Schlapfer, et al. |
| 6,869,433 | 03/22/05 | Glascott |



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 60 of 2152

| | | |
|---|---|---|
| 6,858,031 | 02/22/05 | Morrison, et al. |
| 6,843,791 | 01/18/05 | Serhan |
| 6,840,940 | 01/11/05 | Ralph, et al. |
| 6,837,889 | 01/05 | Shluzas |
| 6,835,196 | 12/28/04 | Biedermann, et al. |
| 6,830,571 | 12/14/04 | Lenke, et al. |
| 6,827,719 | 12/07/04 | Ralph, et al. |
| 6,802,844 | 10/12/04 | Ferree |
| 6,790,209 | 09/14/04 | Beale, et al. |
| 6,783,527 | 08/31/04 | Drewry, et al. |
| 6,780,186 | 08/24/04 | Errico, et al. |
| 6,770,075 | 08/03/04 | Howland |
| 6,767,351 | 07/27/04 | Orbay, et al. |
| 6,761,723 | 07/13/04 | Buttermann, et al. |
| 6,755,836 | 06/29/04 | Lewis |
| 6,755,835 | 06/29/04 | Schultheiss, et al. |
| 6,755,829 | 06/29/04 | Bono, et al. |
| 6,746,449 | 06/08/04 | Jones, et al. |
| 6,740,086 | 05/25/04 | Richelsoph |
| 6,736,820 | 05/18/04 | Biedermann, et al. |
| 6,736,816 | 05/18/04 | Ritland |
| 6,733,502 | 05/11/04 | Altarac, et al. |



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 61 of 2152

| | | |
|---|---|---|
| 6,730,127 | 05/04/04 | Michelson |
| 6,730,093 | 05/04/04 | Saint Martin |
| 6,723,100 | 04/20/04 | Biedermann, et al. |
| 6,716,213 | 04/06/04 | Shitoto |
| 6,716,247 | 04/06/04 | Michelson |
| 6,716,214 | 04/06/04 | Jackson |
| 6,712,818 | 03/30/04 | Michelson |
| 6,706,045 | 03/16/04 | Lin, et al. |
| 6,699,249 | 03/02/04 | Schlapfer, et al. |
| 6,695,843 | 02/24/04 | Biedermann, et al. |
| 6,695,851 | 02/24/04 | Zdeblick, et al. |
| 6,695,843 | 02/24/04 | Biedermann, et al. |
| 6,689,134 | 02/10/04 | Ralph, et al. |
| 6,689,133 | 02/10/04 | Morrison, et al. |
| 6,682,530 | 01/27/04 | Dixon, et al. |
| 6,682,529 | 01/27/04 | Stahurski |
| 6,679,833 | 01/20/04 | Smith, et al. |
| 6,676,661 | 01/13/04 | Martin Benlloch, et al. |
| 6,673,073 | 01/06/04 | Schafer |
| 6,663,635 | 12/16/03 | Frigg, et al. |
| 6,663,632 | 12/16/03 | Frigg |



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 62 of 2152

| | | |
|---|---|---|
| 6,660,004 | 12/09/03 | Barker, et al. |
| 6,656,179 | 12/02/03 | Schaefer, et al. |
| 6,656,181 | 12/02/03 | Dixon, et al. |
| 6,652,765 | 11/25/03 | Beaty |
| 6,648,885 | 11/18/03 | Friesem |
| 6,648,887 | 11/18/03 | Ashman |
| 6,635,059 | 10/21/03 | Randall, et al. |
| 6,626,907 | 09/30/03 | Campbell, et al. |
| 6,626,908 | 09/30/03 | Cooper, et al. |
| 6,623,485 | 09/23/03 | Doubler, et al. |
| 6,613,050 | 09/02/03 | Wagner, et al. |
| 6,610,063 | 08/26/03 | Kumar, et al. |
| 6,595,992 | 07/22/03 | Wagner, et al. |
| 6,595,993 | 07/22/03 | Donno, et al. |
| 6,585,740 | 07/01/03 | Schlapfer, et al. |
| 6,582,436 | 06/24/03 | Schlapfer, et al. |
| 6,582,466 | 06/24/03 | Gauchet |
| 6,565,567 | 05/20/03 | Haider |
| 6,565,565 | 05/20/03 | Yuan, et al. |
| 6,562,040 | 05/13/03 | Wagner |
| 6,558,387 | 05/06/03 | Errico, et al. |
| 6,554,834 | 04/29/03 | Crozet, et al. |



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 63 of 2152

| | | |
|---|---|---|
| 6,554,832 | 04/29/03 | Shluzas |
| 6,554,831 | 04/29/03 | Rivard, et al. |
| 6,551,323 | 04/22/03 | Doubler, et al. |
| 6,551,320 | 04/22/03 | Liebermann |
| 6,547,790 | 04/15/03 | Harkey, III, et al. |
| 6,540,749 | 04/01/03 | Schafer, et al. |
| 6,533,786 | 03/18/03 | Needham, et al. |
| 6,530,929 | 03/11/03 | Justis, et al. |
| 6,527,804 | 03/04/03 | Gauchet, et al. |
| 6,520,962 | 02/18/03 | Taylor, et al. |
| 6,508,818 | 01/21/03 | Steiner, et al. |
| 6,488,681 | 12/03/02 | Martin, et al. |
| 6,485,494 | 11/26/02 | Haider |
| 6,485,492 | 11/26/02 | Halm, et al. |
| 6,485,491 | 11/02 | Farris, et al. |
| 6,471,705 | 10/29/02 | Biedermann, et al. |
| 6,471,703 | 10/29/02 | Ashman |
| 6,451,021 | 09/17/02 | Ralph, et al. |
| 6,440,137 | 08/27/02 | Horvath, et al. |
| 6,402,757 | 06/11/02 | Moore, et al. |
| 6,402,752 | 06/11/02 | Schaffler-Wachter, et al. |



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 64 of 2152

| | | |
|---|---|---|
| RE37,665 | 04/16/02 | Ralph, et al. |
| 6,368,321 | 04/09/02 | Jackson |
| 6,355,040 | 03/12/02 | Richelsoph, et al. |
| 6,309,391 | 10/30/01 | Crandall, et al. |
| 6,331,179 | 12/18/01 | Freid, et al. |
| 6,315,564 | 11/13/01 | Levisman |
| 6,309,391 | 10/01 | Crandall, et al. |
| 6,302,888 | 10/16/01 | Mellinger, et al. |
| 6,299,613 | 10/09/01 | Ogilvie, et al. |
| 6,296,643 | 10/02/01 | Hopf, et al. |
| 6,296,642 | 10/02/01 | Morrison, et al. |
| 6,287,308 | 09/11/01 | Betz, et al. |
| 6,287,311 | 09/11/01 | Sherman, et al. |
| 6,280,445 | 08/28/01 | Morrison, et al. |
| 6,280,442 | 08/28/01 | Barker, et al. |
| 6,273,888 | 08/14/01 | Justis |
| 6,267,765 | 07/01 | Taylor, et al. |
| 6,267,764 | 07/31/01 | Elberg |
| 6,254,602 | 07/03/01 | Justis |
| 6,254,146 | 07/03/01 | Church |
| 6,248,105 | 06/19/01 | Schlapfer, et al. |
| 6,241,730 | 06/01 | Alby |



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 65 of 2152

| | | |
|---|---|---|
| 6,235,034 | 05/22/01 | Bray |
| RE37,161 | 05/01/01 | Michelson, et al. |
| 6,224,598 | 05/01 | Jackson |
| 6,224,596 | 05/01/01 | Jackson |
| 6,187,005 | 02/13/01 | Brace, et al. |
| 6,183,472 | 02/06/01 | Lutz |
| 6,146,383 | 11/14/00 | Studer, et al. |
| 6,143,032 | 11/07/00 | Schafer, et al. |
| 6,136,002 | 10/24/00 | Shih, et al. |
| 6,132,434 | 10/17/00 | Sherman, et al. |
| 6,132,432 | 10/17/00 | Richelsoph |
| 6,132,431 | 10/17/00 | Nilsson, et al. |
| 6,117,137 | 09/12/00 | Halm, et al. |
| 6,113,601 | 09/05/00 | Tatar |
| 6,110,172 | 08/29/00 | Jackson |
| 6,102,913 | 08/15/00 | Jackson |
| 6,099,528 | 08/08/00 | Saurat |
| 6,090,111 | 07/18/00 | Nichols |
| 6,090,110 | 07/18/00 | Metz-Stavenhagen |
| 6,086,588 | 07/11/00 | Ameil, et al. |
| 6,077,262 | 06/20/00 | Schlapfer et al. |
| 6,074,391 | 06/13/00 | Metz-Stavenhagen et |



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 66 of 2152

| | | |
|---|---|---|
| | | al. |
| 6,063,090 | 05/16/00 | Schlapfer |
| 6,059,786 | 05/09/00 | Jackson |
| 6,053,917 | 04/25/00 | Sherman, et al. |
| 6,022,350 | 02/08/00 | Ganem |
| 6,019,759 | 02/01/00 | Rogozinski |
| 6,010,503 | 01/04/00 | Richelsoph, et al. |
| 6,004,349 | 12/21/99 | Jackson |
| 6,001,098 | 12/14/99 | Metz-Stavenhagen, et al. |
| 5,964,760 | 10/12/99 | Richelsoph |
| 5,961,517 | 10/05/99 | Biedermann, et al. |
| 5,954,725 | 09/21/99 | Sherman, et al. |
| 5,951,553 | 09/14/99 | Betz |
| 5,944,465 | 08/31/99 | Janitzki |
| RE36,221 | 06/01/99 | Breard, et al. |
| 5,891,145 | 04/06/99 | Morrison, et al. |
| 5,885,286 | 03/23/99 | Sherman, et al. |
| 5,882,350 | 03/16/99 | Ralph, et al. |
| 5,879,351 | 03/09/99 | Viart |
| 5,879,350 | 03/09/99 | Sherman, et al. |
| 5,876,402 | 03/02/99 | Errico, et al. |



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 67 of 2152

| | | |
|---|---|---|
| 5,863,293 | 01/26/99 | Richelsoph |
| 5,817,094 | 10/06/98 | Errico, et al. |
| 5,800,547 | 09/01/98 | Schafer, et al. |
| 5,800,435 | 09/01/98 | Errico, et al. |
| 5,797,911 | 08/25/98 | Sherman, et al. |
| 5,782,833 | 07/21/98 | Haider |
| 5,752,957 | 05/19/98 | Ralph, et al. |
| 5,741,254 | 04/21/98 | Henry, et al. |
| 5,738,685 | 04/14/98 | Halm, et al. |
| 5,733,286 | 03/31/98 | Errico, et al. |
| 5,728,098 | 03/17/98 | Sherman, et al. |
| 5,725,528 | 03/10/98 | Errico, et al. |
| 5,725,527 | 03/10/98 | Biedermann, et al. |
| 5,723,013 | 03/03/98 | Jeanson, et al. |
| 5,716,356 | 02/10/98 | Biedermann, et al. |
| 5,713,898 | 02/03/98 | Stucker, et al. |
| 5,711,709 | 01/27/98 | McCoy |
| 5,697,929 | 12/16/97 | Mellinger |
| 5,690,630 | 11/25/97 | Errico, et al. |
| 5,683,392 | 11/04/97 | Richelsoph |
| 5,683,390 | 11/04/97 | Metz-Stavenhagen, et al. |



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 68 of 2152

| | | |
|---|---|---|
| 5,681,319 | 10/28/97 | Biedermann, et al. |
| 5,676,703 | 10/14/97 | Gelbard |
| 5,672,176 | 09/30/97 | Biedermann, et al. |
| 5,672,175 | 09/30/97 | Martin |
| 5,669,911 | 09/23/97 | Errico et al. |
| 5,669,909 | 09/23/97 | Zdeblick, et al. |
| 5,662,653 | 09/02/97 | Songer, et al. |
| 5,662,652 | 09/02/97 | Schafer, et al. |
| 5,647,873 | 07/15/97 | Errico, et al. |
| 5,643,261 | 07/01/97 | Schafer, et al. |
| 5,643,260 | 07/01/97 | Doherty |
| 5,641,256 | 06/24/97 | Gundy |
| 5,630,817 | 05/20/97 | Rokegem |
| 5,628,740 | 05/13/97 | Mullane |
| 5,611,800 | 03/18/97 | Davis, e tal. |
| 5,607,428 | 03/04/97 | Lin |
| 5,607,426 | 03/04/97 | Ralph, et al. |
| 5,607,425 | 03/04/97 | Rogozinski |
| 5,607,304 | 03/04/97 | Bailey, et al. |
| 5,601,553 | 02/11/97 | Trebing et al. |
| 5,591,166 | 01/07/97 | Bernhardt, et al. |
| 5,586,984 | 12/24/96 | Errico, et al. |



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 69 of 2152

| | | |
|---|---|---|
| 5,584,834 | 12/17/96 | Errico, et al. |
| 5,569,251 | 10/29/96 | Baker, et al. |
| 5,569,247 | 10/29/96 | Morrison |
| 5,562,663 | 10/08/96 | Wisnewski, et al. |
| 5,562,660 | 10/08/96 | Grob |
| 5,554,157 | 09/10/96 | Errico, et al. |
| 5,549,607 | 08/27/96 | Olson et al. |
| 5,545,165 | 08/13/96 | Biedermann, et al. |
| 5,540,688 | 07/30/96 | Navas |
| 5,496,321 | 05/05/96 | Puno |
| 5,507,745 | 04/16/96 | Logroscino, et al. |
| 5,505,731 | 04/09/96 | Tornier |
| 5,499,892 | 03/19/96 | Reed |
| 5,496,321 | 03/05/96 | Puno, et al. |
| 5,490,750 | 02/13/96 | Gundy |
| 5,489,307 | 02/06/96 | Kuslich, et al. |
| 5,487,742 | 01/30/96 | Cotrel |
| 5,480,401 | 01/02/96 | Navas |
| 5,476,464 | 12/19/95 | Metz-Stevenhagen et al. |
| 5,476,462 | 12/19/95 | Allard, et al. |
| 5,474,555 | 12/12/95 | Puno, et al. |



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 70 of 2152

| | | |
|---|---|---|
| 5,468,241 | 11/21/95 | Metz-Stavenhagen, et al. |
| 5,466,237 | 11/14/95 | Byrd, III, et al. |
| 5,443,467 | 08/22/95 | Biedermann et al. |
| 5,429,639 | 07/04/95 | Judet |
| 5,427,418 | 06/27/95 | Watts |
| 5,423,816 | 06/13/95 | Lin |
| 5,415,661 | 05/16/95 | Holmes |
| 5,395,371 | 03/07/95 | Miller, et al. |
| 5,385,583 | 01/31/95 | Cotrel |
| 5,375,823 | 12/27/94 | Navas |
| 5,360,431 | 11/01/94 | Puno, et al. |
| 5,358,289 | 10/25/94 | Banker, et al. |
| 5,346,493 | 09/13/94 | Stahurski, et al. |
| 5,321,901 | 06/21/94 | Kelly |
| 5,312,404 | 05/17/94 | Asher et al. |
| 5,306,275 | 04/26/94 | Bryan |
| 5,282,863 | 02/01/94 | Burton |
| 5,275,601 | 01/04/94 | Gogolewski, et al. |
| 5,261,912 | 11/16/93 | Frigg |
| 5,261,907 | 11/16/93 | Vignaud, et al. |
| 5,257,993 | 11/02/93 | Asher, et al. |



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 71 of 2152

| | | |
|---|---|---|
| 5,217,497 | 06/08/93 | Mehdian |
| 5,207,678 | 05/04/93 | Harms, et al. |
| 5,180,393 | 01/19/93 | Commarmond |
| 5,176,680 | 01/05/93 | Vignaud, et al. |
| 5,176,678 | 01/93 | Tsou |
| 5,176,483 | 01/05/93 | Baumann, et al. |
| 5,154,719 | 10/13/92 | Cotrel |
| 5,147,363 | 07/15/92 | Harle |
| 5,129,388 | 07/14/92 | Vignaud, et al. |
| 5,102,412 | 04/07/92 | Rogozinski |
| 5,092,635 | 03/03/92 | DeLange, et al. |
| 5,067,955 | 11/26/91 | Cotrel |
| 5,034,011 | 07/23/91 | Howland |
| 5,022,791 | 06/11/91 | Isler |
| 5,005,562 | 04/09/91 | Cotrel |
| 4,950,269 | 08/21/90 | Gaines, Jr. |
| 4,946,458 | 08/07/90 | Harms, et al. |
| 4,887,596 | 12/19/89 | Sherman |
| 4,836,196 | 06/06/89 | Park, et al. |
| 4,748,260 | 05/31/88 | Marlett |
| 4,743,260 | 05/10/88 | Burton |



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 72 of 2152

| | | |
|---|---|---|
| 4,707,001 | 11/17/87 | Johnson |
| 4,703,954 | 11/03/87 | Ortloff, et al. |
| 4,653,486 | 03/31/87 | Coker |
| 4,600,224 | 07/15/86 | Blose |
| 4,448,191 | 05/15/84 | Rodnyansky, et al. |
| 4,484,570 | 11/27/84 | Sutter,et al. |
| 4,373,754 | 02/15/83 | Bollfrass,et al. |
| 4,041,939 | 08/16/77 | Hall |
| 3,640,416 | 02/08/72 | Temple |
| 3,604,487 | 09/14/71 | Gilbert |
| 3,236,275 | 02/22/66 | Smith |
| 2,243,717 | 05/27/41 | Moreira |
| 7,582,107 | 09/01/2009 | Trail, et al. |
| 7,008,228 | 03/07/2006 | Bjorn, et al. |
| 6,726,689 | 04/27/2004 | Jackson |
| 6,968,966 | 11/29/2005 | Gregory |
| 4,771,905 | 09/20/1998 | Perne, et al. |
| 7,878,351 | 01/01/2011 | Falzoni, et al. |

**U.S. Published Applications**

| Publication No. | Date | Patentee |
|---|---|---|
| 2011/0257690 | 10/20/11 | Rezach |



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 73 of 2152

| | | |
|---|---|---|
| 2011/0257689 | 10/20/11 | Fiechter, et al. |
| 2011/0257687 | 10/20/11 | Trieu, et al. |
| 2011/0251644 | 10/13/11 | Hestad, et al. |
| 2011/0230917 | 09/22/11 | Carson, et al. |
| 2011/0208251 | 08/25/11 | Hammill, Sr., et al. |
| 2011/0202095 | 08/18/11 | Semler, et al. |
| 2011/0196427 | 08/11/11 | Trautwein, et al. |
| 2011/0190826 | 08/04/11 | Ogilvie, et al. |
| 2011/0190823 | 08/04/11 | Bergeron, et al. |
| 2011/0190822 | 08/04/11 | Spitler, et al. |
| 2011/0184471 | 07/28/11 | Foley, et al. |
| 2011/0178558 | 07/21/11 | Barry |
| 2011/0172715 | 07/14/11 | Pond, Jr., et al. |
| 2011/0166606 | 07/07/11 | Stihl, et al. |
| 2010/0262196 | 10/14/10 | Barrus, et al. |
| 2010/0256682 | 10/07/10 | Fallin, et al. |
| 2010/0256681 | 10/07/10 | Hammer, et al. |
| 2010/0249856 | 09/30/10 | Iott, et al. |
| 2010/0249846 | 09/30/10 | Simonson |
| 2010/0241170 | 09/23/2010 | Cammisa, et al. |
| 2010/0234891 | 09/16/10 | Freeman, et al. |
| 2010/0228293 | 09/09/10 | Courtney, et al. |
| 2010/0222822 | 09/02/10 | Farris, et al. |



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 74 of 2152

| | | |
|---|---|---|
| 2010/0204735 | 08/12/10 | Gepharl, et al. |
| 2010/0198272 | 08/05/10 | Keyer, et al. |
| 2010/0198270 | 08/05/10 | Barker, et al. |
| 2010/0198269 | 08/05/10 | Taylor, et al. |
| 2010/0191290 | 07/29/10 | Felix |
| 2010/0185247 | 07/22/10 | Richelsoph |
| 2010/0179603 | 07/15/10 | Warnick |
| 2010/0174322 | 07/08/10 | Abdelgany, et al. |
| 2010/0168801 | 07/01/10 | Biedermann, et al. |
| 2010/0168800 | 07/01/10 | Biedermann, et al. |
| 2010/0168796 | 07/01/10 | Eliasen, et al. |
| 2010/0160980 | 06/24/10 | Walsh, et al. |
| 2010/0160974 | 06/24/10 | Viker |
| 2010/0160965 | 06/24/10 | Viker |
| 2010/0152788 | 06/17/10 | Warnick |
| 2010/0152787 | 06/17/10 | Walsh, et al. |
| 2010/0152785 | 06/17/10 | Forton, et al. |
| 2010/0152776 | 06/10/10 | Keyer, et al. |
| 2010/0145390 | 06/10/10 | McCarthy, et al. |
| 2010/0137920 | 06/03/10 | Hammill, Sr., et al. |
| 2010/0137918 | 06/03/10 | Wilcox, et al. |
| 2010/0131018 | 05/27/10 | Konieczynski, et al. |
| 2010/0131017 | 05/27/10 | Farris, et al. |



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 75 of 2152

| | | |
|---|---|---|
| 2010/0125302 | 05/20/10 | Hammill, Sr., et al. |
| 2010/0114180 | 05/06/10 | Rock, et al. |
| 2010/0114171 | 05/06/10 | Boachie-Adjei, et al. |
| 2010/0114170 | 05/06/10 | Barrus, et al. |
| 2010/0106189 | 04/29/10 | Miller |
| 2010/0100137 | 04/22/10 | Justis, et al. |
| 2010/0100136 | 04/22/10 | Won, et al. |
| 2010/0094353 | 04/15/10 | Shim, et al. |
| 2010/0094352 | 04/15/10 | Iott, et al. |
| 2010/0094349 | 04/15/10 | Hammer, et al. |
| 2010/0094348 | 04/15/10 | Biedermann, et al. |
| 2010/0094343 | 04/15/10 | Pham, et al. |
| 2010/0094353 | 04/15/10 | Shim, et al. |
| 2010/0094352 | 04/15/10 | Iott, et al. |
| 2010/0094349 | 04/15/10 | Hammer, et al. |
| 2010/0094348 | 04/15/10 | Biedermann, et al. |
| 2010/0094345 | 04/15/10 | Saidha, et al. |
| 2010/0094343 | 04/15/10 | Pham, et al. |
| 2010/0087865 | 04/08/10 | Biedermann, et al. |
| 2010/0087861 | 04/08/10 | Lechmann, et al. |
| 2009/0082819 | 03/26/09 | Blain, et al. |
| 2009/0076552 | 03/19/09 | Tornier |



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 76 of 2152

| | | |
|---|---|---|
| 2010/0069969 | 03/18/10 | Ampuero, et al. |
| 2010/0069963 | 03/18/10 | Eckman |
| 2010/0063551 | 03/11/10 | Richelsoph |
| 2010/0063550 | 03/11/10 | Felix, et al. |
| 2010/0063546 | 03/11/10 | Miller, et al. |
| 2010/0063545 | 03/11/10 | Richelsoph |
| 2010/0063553 | 03/11/10 | Warnick |
| 2010/0057126 | 03/04/10 | Hestad |
| 2010/0057125 | 03/04/10 | Viker |
| 2010/0049254 | 02/25/10 | Biedermann, et al. |
| 2010/0042155 | 02/18/10 | Biedermann, et al. |
| 2010/0036432 | 02/11/10 | Ely |
| 2010/0036422 | 02/11/10 | Flynn, et al. |
| 2010/0036420 | 02/11/10 | Kalfas, et al. |
| 2010/0036417 | 02/11/10 | James, et al. |
| 2010/0030283 | 02/04/10 | King, et al. |
| 2010/0030271 | 02/04/10 | Winslow, et al. |
| 2010/0030224 | 02/04/10 | Winslow, et al. |
| 2010/0023061 | 01/28/10 | Randol, et al. |
| 2010/0016898 | 01/21/10 | Shluzas |
| 2010/0016898 | 01/21/10 | Shluzas |
| 2010/0010540 | 01/14/10 | Park |
| 2010/0004692 | 01/07/10 | Biedermann, et al. |



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 77 of 2152

| | | |
|---|---|---|
| 2009/0326587 | 12/31/09 | Matthis, et al. |
| 2009/0326582 | 12/31/09 | Songer, et al. |
| 2009/0312804 | 12/17/09 | Gamache, et al. |
| 2009/0306720 | 12/10/09 | Doubler, et al. |
| 2009/0306719 | 12/10/09 | Meyer, III, et al. |
| 2009/0299415 | 12/03/09 | Pimenta |
| 2009/0287253 | 11/19/09 | Felix, et al. |
| 2009/0281573 | 11/12/09 | Biedermann, et al. |
| 2009/0281572 | 11/12/09 | White |
| 2009/0281571 | 11/12/09 | Weaver, et al. |
| 2009/0270917 | 10/29/09 | Boehm |
| 2009/0270916 | 10/29/09 | Ramsay, et al. |
| 2009/0264933 | 10/22/09 | Carls, et al. |
| 2009/0264896 | 10/22/09 | Biedermann, et al. |
| 2009/0259254 | 10/15/09 | Pisharodi |
| 2009/0254125 | 10/08/09 | Predick |
| 2009/0248088 | 10/01/09 | Biedermann |
| 2009/0248075 | 10/01/09 | Ogilvie, et al. |
| 2009/0248030 | 10/01/09 | Butler, et al. |
| 2009/0216280 | 08/27/09 | Hutchinson |
| 2009/0204155 | 08/13/09 | Aschmann |
| 2009/0198291 | 08/06/09 | Kevin, et al. |
| 2009/0198289 | 08/06/09 | Manderson |



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 78 of 2152

| | | |
|---|---|---|
| 2009/0198280 | 08/06/09 | Spratt, et al. |
| 2009/0192551 | 07/30/09 | Cianfrani, et al. |
| 2009/0192548 | 07/30/09 | Jeon, et al. |
| 2009/0182380 | 07/16/09 | Abdelgany |
| 2009/0163963 | 06/25/09 | Berrevoets |
| 2009/0163961 | 06/25/09 | Kirschman |
| 2009/0163956 | 06/25/09 | Biedermann, et al. |
| 2009/0163955 | 06/25/09 | Moumene, et al. |
| 2009/0149887 | 06/11/09 | Schlaepfer, et al. |
| 2009/0143829 | 06/04/09 | Shluzas |
| 2009/0143827 | 06/04/09 | Levy, et al. |
| 2009/0138052 | 05/28/09 | Biedermann, et al. |
| 2009/0138044 | 05/28/09 | Bergeron, et al. |
| 2009/0131983 | 05/21/09 | Biedermann |
| 2009/0118772 | 05/07/09 | Diederich, et al. |
| 2009/0105770 | 04/23/09 | Lei, et al. |
| 2009/0105769 | 04/23/09 | Rock, et al. |
| 2009/0093843 | 04/09/09 | Lemoine, et al. |
| 2009/0088807 | 04/02/09 | Castaneda, et al. |
| 2009/0088799 | 04/02/09 | Yeh |
| 2009/0082812 | 03/26/09 | Lewis |
| 2009/0082819 | 03/26/09 | Blain, et al. |
| 2009/0082815 | 03/26/09 | Zylber, et al. |



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 79 of 2152

| | | |
|---|---|---|
| 2009/0082809 | 03/26/09 | Nguyen, et al. |
| 2009/0076552 | 03/19/09 | Tornier |
| 2009/0076550 | 03/19/09 | Bernhardt, Jr., et al. |
| 2009/0069852 | 03/12/09 | Farris, et al. |
| 2009/0069849 | 03/12/09 | Oh, et al. |
| 2009/0069853 | 03/12/09 | Schumacher |
| 2009/0062914 | 03/05/09 | Marino |
| 2009/0062867 | 03/05/09 | Schumacher |
| 2009/0062865 | 03/05/09 | Schumacher |
| 2009/0062860 | 03/05/09 | Frasier, et al. |
| 2009/0036934 | 02/05/09 | Biedermann, et al. |
| 2009/0036932 | 02/05/09 | Rouyer, et al. |
| 2009/0036929 | 02/05/09 | Reglos, et al. |
| 2009/0030457 | 01/29/09 | Janowski, et al. |
| 2009/0024169 | 01/22/09 | Triplet, et al. |
| 2009/0018591 | 01/15/09 | Hawkes, et al. |
| 2009/0012567 | 01/08/09 | Biedermann, et al. |
| 2009/0005814 | 01/01/09 | Miller, et al. |
| 2009/0005813 | 01/01/09 | Crall, et al. |
| 2009/0005787 | 01/01/09 | Crall, et al. |
| 2008/0312701 | 12/18/08 | Butters, et al. |
| 2008/0312696 | 12/18/08 | Butters, et al. |



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 80 of 2152

| | | |
|---|---|---|
| 2008/0312692 | 12/18/08 | Brennan, et al. |
| 2008/0312655 | 12/18/08 | Kirschman, et al. |
| 2008/0306539 | 12/11/08 | Cain, et al. |
| 2008/0306533 | 12/11/08 | Winslow, et al. |
| 2008/0306528 | 12/11/08 | Winslow, et al. |
| 2008/0288002 | 11/20/08 | Crall, et al. |
| 2008/0287994 | 11/20/08 | Perez-Curet, et al. |
| 2008/0269809 | 10/30/08 | Garamszegi |
| 2008/0269742 | 10/30/08 | Levy, et al. |
| 2008/0262556 | 10/23/08 | Jacofsky, et al. |
| 2008/0262548 | 10/23/08 | Lange, et al. |
| 2008/0249570 | 10/09/08 | Carson, et al. |
| 2008/0249576 | 10/09/08 | Hawkes, et al. |
| 2008/0234759 | 09/25/08 | Marino |
| 2008/0234756 | 09/25/08 | Sutcliffe, et al. |
| 2008/0234734 | 09/25/08 | Walder, et al. |
| 2008/0228229 | 09/18/08 | Walder, et al. |
| 2008/0215095 | 09/04/08 | Biedermann, et al. |
| 2008/0195159 | 08/14/08 | Kloss, et al. |
| 2008/0200956 | 08/21/08 | Beckwith, et al. |
| 2008/0183223 | 07/31/08 | Jeon, et al. |
| 2008/0183215 | 07/31/08 | Altarac, et al. |
| 2008/0177332 | 07/24/08 | Reiley, et al. |



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 81 of 2152

| | | |
|---|---|---|
| 2008/0177322 | 07/24/08 | Davis, et al. |
| 2008/0177321 | 07/24/08 | Drewry, et al. |
| 2008/0161863 | 07/03/08 | Arnold, et al. |
| 2008/0161859 | 07/03/08 | Nilsson |
| 2008/0154315 | 06/26/08 | Jackson |
| 2008/0140075 | 06/12/08 | Ensign, et al. |
| 2008/0119858 | 05/22/08 | Potash |
| 2008/0108992 | 05/08/08 | Barry, et al. |
| 2008/0097457 | 04/24/08 | Warnick |
| 2008/0097441 | 04/24/08 | Hayes, et al. |
| 2008/0086132 | 04/10/08 | Biedermann, et al. |
| 2008/0086131 | 04/10/08 | Daly, et al. |
| 2008/0077139 | 03/27/08 | Landry, et al. |
| 2008/0071274 | 03/20/08 | Ensign |
| 2008/0071273 | 03/20/08 | Hawkes, et al. |
| 2008/0065079 | 03/13/08 | Bruneau, et al. |
| 2008/0065077 | 03/13/08 | Ferree |
| 2008/0065075 | 03/13/08 | Dant |
| 2008/0065073 | 03/13/08 | Perriello, et al. |
| 2008/0065071 | 03/13/08 | Park |
| 2008/0058812 | 03/06/08 | Zehnder |
| 2008/0051787 | 02/28/08 | Remington, et al. |
| 2008/0045951 | 02/21/08 | Fanger, et al. |



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 82 of 2152

| | | |
|---|---|---|
| 2008/0039843 | 02/14/08 | Abdou |
| 2008/0033435 | 02/07/08 | Studer, et al. |
| 2008/0021466 | 01/24/08 | Shadduck, et al. |
| 2008/0021465 | 01/24/08 | Shadduck, et al. |
| 2008/0021464 | 01/24/08 | Morin, et al. |
| 2008/0021462 | 01/24/08 | Trieu |
| 2008/0021459 | 01/24/08 | Lim |
| 2008/0021458 | 01/24/08 | Lim |
| 2007/0288012 | 12/13/07 | Colleran, et al. |
| 2007/0288011 | 12/13/07 | Logan |
| 2007/0288009 | 12/13/07 | Brown, et al. |
| 2007/0288008 | 12/13/07 | Park |
| 2007/0276380 | 11/29/07 | Jahng, et al. |
| 2007/0270843 | 11/22/07 | Matthis, et al. |
| 2007/0270838 | 11/22/07 | Bruneau, et al. |
| 2007/0270837 | 11/22/07 | Eckhardt, et al. |
| 2007/0270814 | 11/22/07 | Lim, et al. |
| 2007/0124249 | 11/01/07 | Lim, et al. |
| 2007/0233095 | 10/04/07 | Schlaepfer |
| 2007/0233094 | 10/04/07 | Colleran, et al. |
| 2007/0233092 | 10/04/07 | Falahee |
| 2007/0233087 | 10/04/07 | Schlapfer |
| 2007/0233085 | 10/04/07 | Biedermann, et al. |



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 83 of 2152

| | | |
|---|---|---|
| 2007/0233075 | 10/04/07 | Dawson |
| 2007/0233073 | 10/04/07 | Wisnewski, et al. |
| 2007/0233064 | 10/04/07 | Holt |
| 2007/0225710 | 09/27/07 | Jahng, et al. |
| 2007/0225708 | 09/27/07 | Biedermann, et al. |
| 2007/0213720 | 09/13/07 | Gordon, et al. |
| 2007/0191846 | 08/16/07 | Bruneau, et al. |
| 2007/0191841 | 08/16/07 | Justis, et al. |
| 2007/0173832 | 07/26/07 | Tebbe, et al. |
| 2007/0173822 | 07/26/07 | Bruneau, et al. |
| 2007/0173818 | 07/26/07 | Hestad, et al. |
| 2007/0161997 | 07/12/07 | Thramann, et al. |
| 2007/0161991 | 07/12/07 | Altarac, et al. |
| 2007/0135815 | 06/14/07 | Gerbec, et al. |
| 2007/0129729 | 06/07/07 | Petit, et al. |
| 2007/0123871 | 05/31/07 | Jahng |
| 2007/0123866 | 05/31/07 | Gerbec, et al. |
| 2007/0123865 | 05/31/07 | Schlapfer, et al. |
| 2007/0123864 | 05/31/07 | Walder, et al. |
| 2007/0118119 | 05/24/07 | Hestad |
| 2007/0118122 | 05/24/07 | Butler, et al. |
| 2007/0100341 | 05/03/07 | Reglos, et al. |
| 2007/0093815 | 04/26/07 | Callahan, II, et al. |
| 2007/0093814 | 04/26/07 | Callahan, II, et al. |



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 84 of 2152

| | | |
|---|---|---|
| 2007/0093813 | 04/26/07 | Callahan, II, et al. |
| 2007/0088359 | 04/19/07 | Woods, et al. |
| 2007/0078461 | 04/05/07 | Shluzas |
| 2007/0073293 | 03/29/07 | Martz |
| 2007/0073289 | 03/29/07 | Kwak |
| 2007/0055247 | 03/08/07 | Jahng |
| 2007/0055244 | 03/08/07 | Jackson |
| 2007/0055236 | 03/08/07 | Hudgins |
| 2007/0049936 | 03/01/07 | Colleran |
| 2007/0043356 | 02/22/07 | Timm |
| 200/0016193 | 01/18/07 | Ritland |
| 2007/0016190 | 01/18/07 | Martinez |
| 2007/0005137 | 01/04/07 | Kwak |
| 2007/0005063 | 01/04/07 | Bruneau |
| 2007/0005062 | 01/04/07 | Lange |
| 2006/0293663 | 12/28/06 | Walkenhorst |
| 2006/0293657 | 12/28/06 | Hartmann |
| 2006/0282080 | 12/14/06 | Albert |
| 2006/0282079 | 12/14/06 | Labrom |
| 2006/0282078 | 12/14/06 | Labrom |
| 2006/0282077 | 12/14/06 | Labrom |
| 2006/0282076 | 12/14/06 | Labrom |
| 2006/0282075 | 12/14/06 | Labrom |
| 2006/0276789 | 12/07/06 | Jackson |



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 85 of 2152

| | | |
|---|---|---|
| 2006/0264940 | 11/23/06 | Hartmannt |
| 2006/0264937 | 11/23/06 | White |
| 2006/0264935 | 11/23/06 | White |
| 2006/0247779 | 11/02/06 | Gordon |
| 2006/0247637 | 11/02/06 | Colleran |
| 2006/0247635 | 11/02/06 | Gordon |
| 2006/0247633 | 11/02/06 | Winslow |
| 2006/0247632 | 11/02/06 | Winslow |
| 2006/0241771 | 10/26/06 | Gordon |
| 2006/0241769 | 10/26/06 | Gordon |
| 2006/0229613 | 10/12/06 | Timm |
| 2006/0229609 | 10/12/06 | Wang |
| 2006/0229608 | 10/12/06 | Foster |
| 2006/0229612 | 10/12/06 | Rothman |
| 2006/0217716 | 09/28/06 | Baker, et al. |
| 2006/0212033 | 09/12/06 | Rothman |
| 2006/0200130 | 09/07/06 | Hawkins |
| 2006/0195093 | 08/31/06 | Jahng |
| 2006/0195090 | 08/31/06 | Suddaby |
| 2006/0189985 | 08/24/06 | Lewis |
| 2006/0189984 | 08/24/06 | Fallin |
| 2006/0189983 | 08/24/06 | Fallin |
| 2006/0184180 | 08/17/06 | Augostino |
| 2006/0184171 | 08/17/06 | Biedermann |



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 86 of 2152

| | | |
|---|---|---|
| 2006/0166535 | 07/27/06 | Brumfield, et al. |
| 2006/0276789 | 07/12/06 | Jackson |
| 2006/0149229 | 07/06/06 | Kwak |
| 2006/0149228 | 07/06/06 | Schlapfer |
| 2006/0142760 | 06/29/06 | McDonnell |
| 2006/0142758 | 06/29/06 | Petit |
| 2006/0129239 | 06/15/06 | Kwak |
| 2006/0122599 | 06/08/06 | Drewry |
| 2006/0106381 | 05/18/06 | Ferree |
| 2006/0085069 | 04/20/06 | Kim |
| 2006/0084991 | 04/20/06 | Borgstrom |
| 2006/0084983 | 04/20/06 | Kim |
| 2006/0084988 | 04/20/06 | Kim |
| 2006/0084987 | 04/20/06 | Kim |
| 2006/0084985 | 04/20/06 | Kim |
| 2006/0084984 | 04/20/06 | Kim |
| 2006/0084983 | 04/20/06 | Kim |
| 2006/0084982 | 04/20/06 | Kim |
| 2006/0079898 | 04/13/06 | Ainsworth |
| 2006/0079896 | 04/13/06 | Kwak |
| 2006/0069390 | Frigg | 03/30/06 |
| 2006/0064092 | 03/23/06 | Howland |
| 2006/0064091 | 03/23/06 | Ludwig, et al. |
| 2006/0064090 | 03/23/06 | Park |



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 87 of 2152

| | | |
|---|---|---|
| 2006/0058790 | 03/16/00 | Carl, et al. |
| 2006/0058788 | 03/16/06 | Hammer, et al. |
| 2006/0052786 | 03/09/06 | Dant, et al. |
| 2006/0052784 | 03/09/06 | Dant, et al. |
| 2006/0052783 | 03/09/06 | Dant, et al. |
| 2006/0052780 | 03/09/06 | Errico, et al. |
| 2006/0041259 | 02/23/06 | Paul, et al. |
| 2006/0036252 | 02/16/06 | Baynham, et al. |
| 2006/0036242 | 02/16/06 | Nilsson, et al. |
| 2006/0036324 | 02/16/06 | Sachs, et al. |
| 2006/0036323 | 02/16/06 | Carl, et al. |
| 2006/0036259 | 02/16/06 | Carl, et al. |
| 2006/0036256 | 02/16/06 | Carl, et al. |
| 2006/0036246 | 02/16/06 | Carl, et al. |
| 2006/0036244 | 02/16/06 | Spitler, et al. |
| 2006/0036240 | 02/16/06 | Colleran, et al. |
| 2006/0025770 | 02/02/06 | Schlapfer, et al. |
| 2006/0025767 | 02/02/06 | Khalili |
| 2006/0025768 | 02/02/06 | Iott, et al. |
| 2006/0015104 | 01/19/06 | Dalton |
| 2006/0015099 | 01/19/06 | Cannon, et al. |
| 2006/0009769 | 01/12/06 | Liebermann |
| 2006/0009770 | 01/12/06 | Speirs, et al. |
| 2006/0009846 | 01/12/06 | Trieu, et al. |



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 88 of 2152

| | | |
|---|---|---|
| 2006/0009768 | 01/12/06 | Ritland |
| 2006/0009767 | 01/12/06 | Kiester |
| 2006/0004359 | 01/05/06 | Kramer, et al. |
| 2006/0004357 | 01/05/06 | Lee, et al. |
| 2006/0004363 | 01/05/06 | Brockmeyer, et al. |
| 2006/0004360 | 01/05/06 | Kramer, et al. |
| 2005/0288669 | 12/29/05 | Abdou |
| 2005/0288671 | 12/29/05 | Yuan, et al. |
| 2005/0288673 | 12/29/05 | Catbagan, et al. |
| 2005/0288672 | 12/29/05 | Ferree |
| 2005/0288670 | 12/29/05 | Panjabi, et al. |
| 2005/0283244 | 12/22/05 | Gordon, et al. |
| 2005/0283238 | 12/22/05 | Reiley |
| 2005/0283152 | 12/22/05 | Lindemann, et al. |
| 2005/0283157 | 12/22/05 | Coates, et al. |
| 2005/0277925 | 12/15/05 | Mujwid |
| 2005/0277928 | 12/15/05 | Boschert |
| 2005/0277919 | 12/15/05 | Slivka, et al. |
| 2005/0277927 | 12/15/05 | Guenther, et al. |
| 2005/0277923 | 12/15/05 | Sweeney |
| 2005/0277922 | 12/15/05 | Trieu, et al. |
| 2005/0273101 | 12/08/05 | Schumacher |
| 2005/0273099 | 12/08/05 | Baccelli, et al. |
| 2005/0267474 | 12/01/05 | Dalton |



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 89 of 2152

| | | |
|---|---|---|
| 2005/0267471 | 12/01/05 | Biedermann, et al. |
| 2005/0267470 | 12/01/05 | McBride |
| 2005/0261687 | 11/24/05 | Garamszegi, et al. |
| 2005/0261685 | 11/24/05 | Fortin, et al. |
| 2005/0251141 | 11/10/05 | Frigg, et al. |
| 2005/0251137 | 11/10/05 | Ball |
| 2005/0251140 | 11/10/05 | Shaolian, et al. |
| 2005/0245930 | 11/03/05 | Timm, et al. |
| 2005/0240183 | 10/27/05 | Vaughan |
| 2005/0240181 | 10/27/05 | Boomer, et al. |
| 2005/0234450 | 10/20/05 | Barker |
| 2005/0234452 | 10/20/05 | Malandain |
| 2005/0234454 | 10/20/05 | Chin |
| 2005/0234456 | 10/20/05 | Malandain |
| 2005/0234451 | 10/20/05 | Markworth |
| 2005/0234453 | 10/20/05 | Shaolian, et al. |
| 2005/0228501 | 10/13/05 | Miller, et al. |
| 2005/0216003 | 09/29/05 | Beidermann, et al. |
| 2005/0216001 | 09/29/05 | David |
| 2005/0203516 | 09/15/05 | Biedermann, et al. |
| 2005/0203519 | 09/15/05 | Harms, et al. |
| 2005/0203518 | 09/15/05 | Biedermann, et al. |
| 2005/0203517 | 09/15/05 | Jahng, et al. |
| 2005/0203514 | 09/15/05 | Jahng, et al. |



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 90 of 2152

| | | |
|---|---|---|
| 2005/0203513 | 09/15/05 | Jahng, et al. |
| 2005/0203511 | 09/15/05 | Wilson-MacDonald, et al. |
| 2005/0192580 | 09/01/05 | Dalton |
| 2005/0187555 | 08/25/05 | Beidermann, et al. |
| 2005/0187548 | 08/25/05 | Butler, et al. |
| 2005/0182401 | 08/18/05 | Timm, et al. |
| 2005/0177157 | 08/11/05 | Jahng |
| 2005/0171540 | 08/04/05 | Lim, et al. |
| 2005/0171543 | 08/04/05 | Timm, et al. |
| 2005/0165400 | 07/28/05 | Fernandez |
| 2005/0165396 | 07/28/05 | Fortin, et al. |
| 2005/0159750 | 07/21/05 | Doherty |
| 2005/0154391 | 07/14/05 | Doherty, et al. |
| 2005/0154389 | 07/14/05 | Selover, et al. |
| 2005/0154390 | 07/14/05 | Biedermann, et al. |
| 2005/0149023 | 07/07/05 | Ritland |
| 2005/0149020 | 07/07/05 | Jahng |
| 2005/0143823 | 06/30/05 | Boyd, et al. |
| 2005/0143737 | 06/30/05 | Pafford, et al. |
| 2005/0137597 | 06/23/05 | Butler, et al. |
| 2005/0131404 | 06/16/05 | Mazda, et al. |
| 2005/0131413 | 06/16/05 | O'Driscoll, et al. |
| 2005/0131407 | 06/16/05 | Sicvol, et al. |



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 91 of 2152

| | | |
|---|---|---|
| 2005/0124991 | 06/09/05 | Jahng |
| 2005/0113927 | 05/26/05 | Malek |
| 2005/0107788 | 05/19/05 | Beaurain, et al. |
| 2005/0096652 | 05/05/05 | Burton |
| 2005/0085816 | 04/21/05 | Michelson |
| 2005/0085815 | 04/21/05 | Harms, et al. |
| 2005/0080415 | 04/14/05 | Keyer, et al. |
| 2005/0070899 | 03/31/05 | Doubler, et al. |
| 2005/0065516 | 03/24/05 | Jahng |
| 2005/0065515 | 03/24/05 | Jahng |
| 2005/0055026 | 03/10/05 | Biedermann, et al. |
| 2005/0049708 | 03/03/05 | Atkinson, et al. |
| 2005/0038432 | 02/17/05 | Shaolian, et al. |
| 2005/0033298 | 02/10/05 | Hawkes, et al. |
| 2005/0027296 | 02/03/05 | Thramann, et al. |
| 2004/0267264 | 12/30/04 | Konieczynski, et al. |
| 2004/0260283 | 12/23/04 | Wu et al. |
| 2004/0249380 | 12/09/04 | Glascott |
| 2004/0236329 | 11/25/04 | Panjabi |
| 2004/0236328 | 11/25/04 | Paul, et al. |
| 2004/0236327 | 11/25/04 | Paul, et al. |
| 2004/0225289 | 11/11/04 | Biedermann, et al. |
| 2004/0236330 | 11/25/04 | Purcell, et al. |
| 2004/0210216 | 10/21/04 | Farris, et al. |



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 92 of 2152

| | | |
|---|---|---|
| 2004/0176766 | 09/09/04 | Shluzas |
| 2004/0186473 | 09/23/04 | Cournoyer, et al. |
| 2004/0172022 | 09/02/04 | Landry, et al. |
| 2004/0158247 | 08/12/04 | Sitiso, et al. |
| 2004/0147929 | 07/29/04 | Biedermann, et al. |
| 2004/0147928 | 07/29/04 | Landry, et al. |
| 2004/0143265 | 07/22/04 | Landry, et al. |
| 2004/0138662 | 07/15/04 | Landry, et al. |
| 2004/0116929 | 06/17/04 | Barker, et al. |
| 2004/0097933 | 05/20/04 | Lourdel, et al. |
| 2004/0092934 | 05/13/04 | Howland |
| 2004/0087952 | 05/06/04 | Borgstrom, et al. |
| 2004/0087949 | 05/06/04 | Bono, et al. |
| 2004/0078082 | 04/22/04 | Lange |
| 2004/0073215 | 04/15/04 | Carli |
| 2004/0049190 | 03/11/04 | Biedermann, et al. |
| 2004/0049189 | 03/11/04 | Le Couedic, et al. |
| 2004/0006342 | 01/08/04 | Altarac, et al. |
| 2004/0002708 | 01/01/04 | Ritland |
| 2003/0220643 | 11/27/03 | Ferree |
| 2003/0220642 | 11/27/03 | Freudiger |
| 2003/0216735 | 11/20/03 | Altarac, et al. |
| 2003/0208204 | 11/06/03 | Bailey, et al. |
| 2003/0199873 | 10/23/03 | Richelsoph |



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 93 of 2152

| | | |
|---|---|---|
| 2003/0191470 | 10/09/03 | Ritland |
| 2003/0176862 | 09/18/03 | Taylor, et al. |
| 2003/0171749 | 09/11/03 | Le Couedic, et al. |
| 2003/0163133 | 08/28/03 | Altarac, et al. |
| 2003/0149432 | 08/07/03 | Frigg, et al. |
| 2003/0125741 | 07/03/03 | Biedermann, et al. |
| 2003/0114852 | 06/19/03 | Biedermann, et al. |
| 2003/0109880 | 06/12/03 | Shirado, et al. |
| 2003/0105460 | 06/05/03 | Crandall, et al. |
| 2003/0100896 | 05/29/03 | Biedermann, et al. |
| 2003/0093078 | 05/15/03 | Ritland |
| 2003/0083657 | 05/01/03 | Drewry, et al. |
| 2003/0073996 | 04/17/03 | Doubler, et al. |
| 2003/0023243 | 01/30/03 | Biedermann, et al. |
| 2002/0193795 | 12/19/02 | Gertzbein, et al. |
| 2002/0173789 | 11/21/02 | Howland |
| 2002/0143341 | 10/03/02 | Biedermann, et al. |
| 2002/0203511 | 09/15/02 | Wilson-MacDonald, et al. |
| 2002/0111626 | 08/15/02 | Ralph, et al. |
| 2002/0082602 | 06/27/02 | Biedermann, et al. |
| 2002/0058942 | 05/02 | Biedermann, et al. |
| 2002/0045898 | 04/18/02 | Freid, et al. |
| 2002/0035366 | 03/21/02 | Walder, et al. |



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 94 of 2152

| | | |
|---|---|---|
| 2002/0013586 | 01/31/02 | Justis, et al. |
| 2002/0007184 | 01/17/02 | Ogilvie, et al. |
| 2001/0037111 | 11/01/01 | Dixon, et al. |
| 2001/0029375 | 10/11/01 | Betz |
| 2001/0010000 | 07/26/01 | Gertzbein |
| 2001/0001119 | 05/01 | Lombardo |



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 95 of 2152

**Foreign Patents**

| | | |
|---|---|---|
| WO2012/075827 | 06/14/2012 | JW Hangjun, et al. |
| WO2012/088890 | 07/05/2012 | Li, Lei, et al. |
| EP2380513 | 10/26/11 | Biedermann, et al. |
| WO2010/017631 | 02/18/10 | Duplessis, et al. |
| FR2925288 | 06/26/09 | Timoteo |
| WO2009/015100 | 01/29/09 | Keyer, et al. |
| EP 1925263 | 05/28/08 | Matthis, et al. |
| WO2008/088731 | 07/24/08 | Hawkins |
| WO2006/045094 | 04/27/06 | Kim |
| WO2006/028537 | 03/16/06 | Thramann, et al. |
| EP 1634537 | 03/15/06 | Errico, et al. |
| WO2006/017616 | 02/16/06 | Doubler, et al. |
| WO2006/012088 | 02/02/06 | Kingsley |
| WO2005/099400 | 10/27/05 | Iott, et al. |
| WO2005/104969 | 11/10/05 | Schlapfer, et al. |
| WO2005/082262 | 09/09/05 | Sournac, et al. |
| WO2005/072632 | 08/11/05 | Sournac, et al. |
| EP1579816 | 09/28/05 | Harms, et al. |
| EP1570795 | 09/07/05 | Harms, et al. |
| WO2005/065375 | 07/21/05 | Pafford, et al. |
| WO2005/065374 | 07/21/05 | Boyd, et al. |
| WO2005/020829 | 03/10/05 | Renaud, et al. |
| EP1570795 | 02/17/05 | Harms, et al. |



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 96 of 2152

| | | |
|---|---|---|
| WO2005/000136 | 01/06/05 | Clement, et al. |
| WO2005/000137 | 01/06/05 | Clement, et al. |
| WO2004/107997 | 12/16/04 | Bette, et al. |
| WO2004/089245 | 10/21/04 | Mueller |
| FR 2865378 | 10/22/04 | Sournac, et al. |
| WO2004/075778 | 09/10/04 | Ritland |
| WO2004/041100 | 05/21/04 | Landry, et al. |
| FR 2857850 | 04/01/04 | Clement, et al. |
| DE10236691 | 02/26/04 | Biedermann |
| FR 2865377 | 01/27/04 | Clement, et al. |
| FR 2865375 | 01/27/04 | Sournac, et al. |
| FR 2865373 | 01/27/04 | Sournac, et al. |
| WO03/068088 | 08/21/03 | Altarac, et al. |
| FR 2856578 | 06/27/03 | Clement, et al. |
| GB2382304 | 05/28/03 | Sengupta |
| WO2003/026523 | 04/03/03 | Ritland |
| WO2002/102259 | 12/27/02 | Sengupta, et al. |
| WO02/054966 | 07/18/02 | Glascott |
| EP1210914 | 06/05/02 | Marquez Alvarez |
| FR 2814936 | 04/12/02 | Fortin |
| EP 1190678 | 03/27/02 | Bono, et al. |
| GB 2365345 | 02/20/02 | Cooper, et al. |
| EP 1 121 902 | 08/08/01 | Schaffler, et al. |
| WO2001/45576 | 06/28/01 | Mulholland, et al. |



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 97 of 2152

| | | |
|---|---|---|
| DE 19951145 | 05/31/01 | Schafer, et al. |
| FR2799949 | 04/27/01 | Benazza |
| WO 01/10317 | 02/15/01 | Marquez-Alverez |
| FR 2796545 | 01/26/01 | Saint Martin, et al. |
| JP2000325358 | 03/27/00 | Hitodo |
| DE 29810798 | 12/02/99 | Schafer, et al. |
| DE 29903342 | 06/02/99 | Grzibek |
| EP0885598 | 12/98 | Metz-Stavenhagen |
| JP10277070 | 10/20/98 | Sano |
| DE29806563 | 07/30/98 | Hauck |
| WO9641582 | 12/27/96 | Thierry |
| DE 19509331 | 9/26/96 | Harms, et al. |
| DE 195 07 141 | 09/12/96 | Gleich, et al. |
| FR 2729291 | 07/19/96 | Gennari |
| G 92 02 745.8 | 04/30/92 | Hauck, et al. |
| DE 4425392 | 11/02/95 | Schafer, et al. |
| FR2718946 | 10/27/95 | Soprane |
| EP0677277 | 10/18/95 | Moreau, et al. |
| FR2717370 | 09/22/95 | Moreau, et al. |
| EP0669109 | 08/30/95 | Baumgartner |
| EP0667127 | 08/16/95 | Sanders |
| WO 95/01132 | 01/12/95 | Schlapfer, et al. |
| WO 94/26191 | 11/24/94 | Schafer, et al. |
| DE4239716 | 08/04/94 | Winter, et al. |
| WO 94/10927 | 5/26/94 | Hopf |



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 98 of 2152

Copies of foreign references are enclosed. Where foreign references are in a foreign language, either a translation is provided (which may or may not be certified) or the importance of the references can be found in the drawings.

**Other Documents**

*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-



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 99 of 2152

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

*Spine*, Lipcott, Williams & Wilkins, Inc. Vol. 24, No. 15, p.1495

Brochure of Tyco/Healthcare/Surgical Dynamics on Spiral Radius 90D, Publication Date: September, 2001, pgs. 1-8

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



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 100 of 2152

OPAP
JAN 10 2013
PATENT & TRADEMARK OFFICE

EXPRESS MAIL EM626520557US

PTO/SB/08A (04-03)
Approved for use through 04/30/2003. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

| 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 | 1 | of | 50 | Attorney Docket Number | 11,433 |

**U. S. PATENT DOCUMENTS**

| Examiner Initials* | Cite No.[1] | Document Number<br>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-7,572,279 | 08/11/2009 | Jackson | |
| | | US-7,479,156 | 01/20/2009 | Lourdel, et al. | |
| | | US-7,476,228 | 01/13/2009 | Abdou | |
| | | US-7,445,627 | 11/04/2008 | Hawkes, et al. | |
| | | US-7,491,218 | 02/17/2009 | Landry, et al. | |
| | | US-7,491,221 | 02/17/2009 | David | |
| | | US-7,503,924 | 03/17/2009 | Lee, et al. | |
| | | US-7,503,918 | 03/17/2009 | Baccelli, et al. | |
| | | US-7,530,992 | 05/12/2009 | Biedermann, et al. | |
| | | US-7,527,640 | 05/05/2009 | Ziolo, et al. | |
| | | US-7,524,323 | 04/28/2009 | Malandain | |
| | | US-7,559,943 | 07/14/2009 | Mjuwid | |
| | | US-7,563,264 | 07/21/2009 | Landry, et al. | |
| | | US-7,563,275 | 07/21/2009 | Falahee, et al. | |

**FOREIGN PATENT DOCUMENTS**

| Examiner Initials | Cite No.[1] | Foreign Patent Document<br>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] |
|---|---|---|---|---|---|---|
| | | WO2009/015100 | 01/29/2009 | Keyer, et al. | | |
| | | WO95/01132 | 01/12/1995 | Schlapfer, et al. | | |
| | | FR2,925,288 | 06/26/2009 | Timoteo | | |
| | | WO01/10317 | 02/15/2001 | Marquez-Alverez | | |
| | | EP1210914 | 06/05/2002 | Marquez Alverez | | |

| Examiner Signature | | Date Considered | |
|---|---|---|---|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[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.

This collection of information is required by 37 CFR 1.97 and 1.98. 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 2 hours 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, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, Washington, DC 20231.**

*If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.*

PTO/SB/08A (04-03)
Approved for use through 04/30/2003. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

| 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 | 2 | of | 50 | Attorney Docket Number | 11,433 |

| U. S. PATENT DOCUMENTS | | | | | |
|---|---|---|---|---|---|
| Examiner Initials* | Cite No.[7] | Document Number<br>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-7,569,061 | 08/04/2009 | Colleran | |
| | | US-7,572,280 | 08/11/2009 | Dickinson, et al. | |
| | | US-7,575,587 | 08/18/2009 | Rezach, et al. | |
| | | US-7,588,575 | 08/15/2009 | Colleran, et al. | |
| | | US-7,588,588 | 09/12/2009 | Spitler, et al. | |
| | | US-7,588,593 | 09/15/2009 | Aferzon | |
| | | US-7,591,839 | 09/22/2009 | Biedermann, et al. | |
| | | US-7,601,166 | 10/13/2009 | Biedermann, et al. | |
| | | US-7,604,656 | 10/20/2009 | Shluzas | |
| | | US-7,611,518 | 11/03/2009 | Walder, et al. | |
| | | US-7,615,068 | 11/10/2009 | Timm, et al. | |
| | | US-7,621,941 | 11/24/2009 | Schlapfer, et al. | |
| | | US-7,625,394 | 12/01/2009 | Molz, IV, et al. | |

| FOREIGN PATENT DOCUMENTS | | | | | | |
|---|---|---|---|---|---|---|
| Examiner Initials | Cite No.[1] | Foreign Patent Document<br>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] |
| | | EP2380513 | 10/26/11 | Biedermann, et al. | | |
| | | DE29903342 | 06/02/99 | Grzibek | | |
| | | | | | | |
| | | | | | | |

| Examiner Signature | | Date Considered | |
|---|---|---|---|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[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.
This collection of information is required by 37 CFR 1.97 and 1.98. 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 2 hours 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, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, Washington, DC 20231.**
*If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.*

PTO/SB/08A (04-03)
Approved for use through 04/30/2003. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

| 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 | 3 | of | 50 | Attorney Docket Number | 11,433 |

**U. S. PATENT DOCUMENTS**

| Examiner Initials* | Cite No.[7] | Document Number<br>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-7,641,674 | 01/05/2010 | Young | |
| | | US-7,645,294 | 01/12/1010 | Kalfasetd | |
| | | US-7,648,522 | 01/19/2010 | David | |
| | | US-2009/0018591 | 01/15/2009 | Hawkes, et al. | |
| | | US-2009/0012567 | 01/08/2009 | Biedermann, et al. | |
| | | US-2009/0005814 | 01/01/2009 | Miller, et al. | |
| | | US-2009/0005813 | 01/01/2009 | Crall, e tal. | |
| | | US-2009/0005787 | 01/01/2009 | Crall, et al. | |
| | | US-2008/0312701 | 12/18/2008 | Batters, et al. | |
| | | US-2008/0312696 | 12/18/2008 | Battlers, et al. | |
| | | US-2008/0312692 | 12/18/2008 | Brennan, et al. | |
| | | US-2008/0312655 | 12/18/2008 | Kirschman, et al. | |
| | | US-2008/0154315 | 06/26/2008 | Jackson | |
| | | US-2009/0024169 | 01/22/2009 | Triplett, et al. | |

**FOREIGN PATENT DOCUMENTS**

| Examiner Initials | Cite No.[1] | Foreign Patent Document<br>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] |
|---|---|---|---|---|---|---|
| | | WO2012/088890 | 07/05/2012 | Li, Lei, et al. | | |
| | | WO2012/075827 | 06/14/2012 | Jin, Hangjun, et al. | | |
| | | | | | | |
| | | | | | | |

| Examiner Signature | | Date Considered | |
|---|---|---|---|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[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.
This collection of information is required by 37 CFR 1.97 and 1.98. 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 2 hours 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, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, Washington, DC 20231.**
*If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.*

PTO/SB/08A (04-03)
Approved for use through 04/30/2003. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

| 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 | 4 | of | 50 | Docket No. | 11,433 |

**U. S. PATENT DOCUMENTS**

| Examiner Initials* | Cite No.[7] | Document Number<br>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-2008/0200956 | 08/21/2008 | Beckwith, et al. | |
| | | US-2008/0215095 | 09/04/2008 | Biedermann, et al. | |
| | | US-2008/0228229 | 09/18/2008 | Walder, et al. | |
| | | US-2008/0234734 | 09/25/2008 | Walder, et al. | |
| | | US-2008/0234756 | 09/25/2008 | Sutcliffe, et al. | |
| | | US-2008/0234759 | 09/25/2008 | Marino | |
| | | US-2008/0249570 | 10/09/2008 | Carson, et al. | |
| | | US-2008/0262548 | 10/23/2008 | Lange, et al. | |
| | | US-2008/0262556 | 10/23/2008 | Jacofsky, et al. | |
| | | US-2008/0269742 | 10/30/2008 | Levy, et al. | |
| | | US-2008/0269809 | 10/30/2008 | Garamszegi | |
| | | US-2008/0287994 | 11/20/2008 | Perez-Cruet, et al. | |
| | | US-2008/0288002 | 11/20/2008 | Crall, et al. | |

**FOREIGN PATENT DOCUMENTS**

| Examiner Initials | Cite No.[1] | Foreign Patent Document<br>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 | |
|---|---|---|---|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[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.

This collection of information is required by 37 CFR 1.97 and 1.98. 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 2 hours 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, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, Washington, DC 20231.**
*If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.*

PTO/SB/08A (04-03)
Approved for use through 04/30/2003. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

| 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 | 5 | 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-2008/0306528 | 12/11/2008 | Winslow, et al. | |
| | | US-2008/0306533 | 12/11/2008 | Winslow, et al. | |
| | | US-2008/0306539 | 12/11/2008 | Cain, et al. | |
| | | US-2006/0166535 | 07/27/2006 | Brumfiled, et al. | |
| | | US-2006/0276789 | 12/07/2006 | Jackson | |
| | | US-2007/0055244 | 03/08/2007 | Jackson | |
| | | US-2009/0030457 | 01/29/2009 | Janowski, et al. | |
| | | US-2009/0036929 | 02/05/2009 | Reglos, et al. | |
| | | US-2009/0036932 | 02/05/2009 | Rouyer, et al. | |
| | | US-2009/0036934 | 02/05/2009 | Biedermann, et al. | |
| | | US-2009/0062860 | 03/05/2009 | Fraiser, et al. | |
| | | US-2009/0062865 | 03/05/2009 | Schumacher | |
| | | US-2009/0062867 | 03/05/2009 | Schumacher | |

**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 | |
|---|---|---|---|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[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.
This collection of information is required by 37 CFR 1.97 and 1.98. 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 2 hours 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, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, Washington, DC 20231.**
*If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.*

PTO/SB/08A (04-03)
Approved for use through 04/30/2003. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

| 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 | 6 | 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-2009/0062914 | 03/05/2009 | Marino | |
| | | US-2009/0069853 | 03/12/2009 | Schumacher | |
| | | US-2009/0069849 | 03/12/2009 | Oh, et al. | |
| | | US-2009/0069852 | 03/12/2009 | Farris, et al. | |
| | | US-2006/0217716 | 09/28/2006 | Baker, et al. | |
| | | US-2009/0076550 | 03/19/2009 | Bernhardt, Jr., et al. | |
| | | US-2009/0076552 | 03/19/2009 | Tornier | |
| | | US-2009/0082809 | 03/26/2009 | Nguyen, et al. | |
| | | US-2009/0082815 | 03/26/2009 | Zylber, et al. | |
| | | US-2009/0082819 | 03/26/2009 | Blain, et al. | |
| | | US-2009/0088799 | 04/02/2009 | Yeh | |
| | | US-2009/0088807 | 04/02/2009 | Castaneda, et al. | |
| | | US-2009/0082812 | 03/26/2009 | Lewis | |

**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 | |
|---|---|---|---|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[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.
This collection of information is required by 37 CFR 1.97 and 1.98. 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 2 hours 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, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, Washington, DC 20231.**
*If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.*

PTO/SB/08A (04-03)
Approved for use through 04/30/2003. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

| 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 | 7 | 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-2009/0005813 | 01/01/2009 | Crall, et al. | |
| | | US-2009/0093843 | 04/09/2009 | Lemoine, et al. | |
| | | US-2009/0105769 | 04/23/2009 | Rock, et al. | |
| | | US-2009/0105770 | 04/23/2009 | Berrevoets, et al. | |
| | | US-2009/0105771 | 04/23/2009 | Lei, et al. | |
| | | US-2009/0118772 | 05/07/2009 | Diederich, et al. | |
| | | US-2009/0131983 | 05/21/2009 | Biedermann | |
| | | US-2009/0138044 | 05/28/2009 | Bergeron, et al. | |
| | | US-2009/0138052 | 05/28/2009 | Biedermann, et al. | |
| | | US-2009/0143827 | 06/04/2009 | Levy, et al. | |
| | | US-2009/0143829 | 06/04/2009 | Shluzas | |
| | | US-2009/0149887 | 06/11/2009 | Schlaepfer, et al. | |
| | | US-2009/0163955 | 06/25/2009 | Moumene, et al. | |

**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 | |
|---|---|---|---|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[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.
This collection of information is required by 37 CFR 1.97 and 1.98. 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 2 hours 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, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, Washington, DC 20231.**
*If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.*

PTO/SB/08A (04-03)
Approved for use through 04/30/2003. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

| 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 | 8 | of | 50 | Attorney Docket Number | 11,433 |

**U. S. PATENT DOCUMENTS**

| Examiner Initials* | Cite No.[7] | Document Number<br>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-2009/0163956 | 06/25/2009 | Biedermann, et al. | |
| | | US-2009/0163961 | 06/25/2009 | Kirschman | |
| | | US-2009/0163963 | 06/25/2009 | Berrevoets | |
| | | US-2009/0182380 | 07/16/2009 | Abdelgany | |
| | | US-2009/0192548 | 07/30/2009 | Jeon, et al. | |
| | | US-2009/0192551 | 07/30/2009 | Cianfrani, et al. | |
| | | US-2009/0198280 | 08/06/2009 | Spratt, et al. | |
| | | US-2009/0198289 | 08/06/2009 | Manderson | |
| | | US-2009/0198291 | 08/06/2009 | Kevin, et al. | |
| | | US-2009/0204155 | 08/13/2009 | Aschmann | |
| | | US-2009/0216280 | 08/27/2009 | Hutchinson | |
| | | US-2009/0248030 | 10/01/2009 | Butler, et al. | |
| | | US-2009/0248075 | 10/01/2009 | Ogilvie, et al. | |

**FOREIGN PATENT DOCUMENTS**

| Examiner Initials | Cite No.[1] | Foreign Patent Document<br>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 | |
|---|---|---|---|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[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.
This collection of information is required by 37 CFR 1.97 and 1.98. 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 2 hours 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, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, Washington, DC 20231.**
*If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.*

PTO/SB/08A (04-03)
Approved for use through 04/30/2003. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

| 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 | 9 | 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-2009/0248088 | 10/01/2009 | Biedermann | |
| | | US-2009/0254125 | 10/08/2009 | Predick | |
| | | US-2009/0259254 | 10/15/2009 | Pisharodi | |
| | | US-2009/0264896 | 10/22/2009 | Biedermann, et al. | |
| | | US-2009/0264933 | 10/22/2009 | Carls, et al. | |
| | | US-2009/0270916 | 10/29/2009 | Ramsay, et al. | |
| | | US-2009/0270917 | 10/29/2009 | Boehm | |
| | | US-2009/0281571 | 11/12/2009 | Weaver, et al. | |
| | | US-2009/0281572 | 11/12/2009 | White | |
| | | US-2009/0281573 | 11/12/2009 | Biedermann,e t al. | |
| | | US-2009/0287253 | 11/19/2009 | Felix, et al. | |
| | | US-2009/0299415 | 12/03/2009 | Pimenta | |
| | | US-2009/0306719 | 12/10/2009 | Meyer, III, et al. | |

**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 | |
|---|---|---|---|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[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.
This collection of information is required by 37 CFR 1.97 and 1.98. 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 2 hours 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, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, Washington, DC 20231.**
*If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.*

PTO/SB/08A (04-03)
Approved for use through 04/30/2003. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

| 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 | 10 | of | 50 | Attorney Docket Number | 11,433 |

**U. S. PATENT DOCUMENTS**

| Examiner Initials* | Cite No.[7] | Document Number<br>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-2009/0306720 | 12/10/2009 | Doubler, et al. | |
| | | US-2009/0312804 | 12/17/2009 | Gamache, et al. | |
| | | US-2009/0326582 | 12/31/2009 | Songer, et al. | |
| | | US-2009/0326587 | 12/31/2009 | Matthis, et al. | |
| | | US-2010/0004692 | 01/07/2010 | Biedermann,e t al. | |
| | | US-2010/0010540 | 01/14/2010 | Park | |
| | | US-2010/0016898 | 01/21/2010 | Shluzas | |
| | | US-2006/0276789 | 07/12/2006 | Jackson | |
| | | US- | | | |
| | | US- | | | |
| | | US- | | | |
| | | US- | | | |
| | | US- | | | |

**FOREIGN PATENT DOCUMENTS**

| Examiner Initials | Cite No.[1] | Foreign Patent Document<br>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 | |
|---|---|---|---|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[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.
This collection of information is required by 37 CFR 1.97 and 1.98. 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 2 hours 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, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, Washington, DC 20231.**
*If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.*

PTO/SB/08A (04-03)
Approved for use through 04/30/2003. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

| 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 | 11 | of | 50 | Attorney Docket Number | 11,433 |

**U. S. PATENT DOCUMENTS**

| Examiner Initials* | Cite No.[7] | Document Number<br>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-7,445,627 | 11/04/08 | Hawkes, et al. | |
| | | US-7,018,379 | 03/28/06 | Drewry, et al. | |
| | | US-7,018,378 | 03/28/06 | Biedermann, et al. | |
| | | US-RE39,035 | 03/21/06 | Finn, et al. | |
| | | US-6,981,973 | 01/03/06 | McKinley | |
| | | US-6,979,334 | 12/27/05 | Dalton | |
| | | US-6,974,460 | 12/13/05 | Carbone, et al. | |
| | | US-6,964,664 | 11/15/05 | Freid, et al. | |
| | | US-6,964,665 | 11/15/05 | Thomas, et al. | |
| | | US-6,958,065 | 10/25/05 | Ueyama, et al. | |
| | | US-6,955,677 | 10/18/05 | Dahners | |
| | | US-6,953,462 | 10/11/05 | Liebermann | |
| | | US-6,945,972 | 09/20/05 | Frigg, et al. | |
| | | US-6,932,817 | 08/23/05 | Baynham, et al. | |

**FOREIGN PATENT DOCUMENTS**

| Examiner Initials | Cite No.[1] | Foreign Patent Document<br>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] |
|---|---|---|---|---|---|---|
| | | WO2006/028537 | 03/16/06 | Thramann, et al. | | |
| | | EP 1634537 | 03/15/06 | Errico, et al. | | |
| | | WO2006/017616 | 02/16/06 | Doubler, et al. | | |
| | | WO2006/012088 | 02/02/06 | Kingsley | | |
| | | WO2005/099400 | 10/27/05 | Iott, et al. | | |

| Examiner Signature | | Date Considered | |
|---|---|---|---|

PTO/SB/08A (04-03)

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[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.
This collection of information is required by 37 CFR 1.97 and 1.98. 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 2 hours 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, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, Washington, DC 20231.**
*If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.*

Approved for use through 04/30/2003. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

| 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 | 12 | of | 50 | Attorney Docket Number | 11,433 |

**U. S. PATENT DOCUMENTS**

| Examiner Initials* | Cite No.[7] | Document Number<br>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-6,872,208 | 03/29/05 | McBride, et al. | |
| | | US-6,869,432 | 03/22/05 | Schlapfer, et al. | |
| | | US-6,869,433 | 03/22/05 | Glascott | |
| | | US-6,858,031 | 02/22/05 | Morrison, et al. | |
| | | US-6,843,791 | 01/18/05 | Serhan | |
| | | US-6,840,940 | 01/11/05 | Ralph, et al. | |
| | | US-6,835,196 | 12/28/04 | Biedermann, et al. | |
| | | US-6,830,571 | 12/14/04 | Lenke, et al. | |
| | | US-6,827,719 | 12/07/04 | Ralph, et al. | |
| | | US-6,790,209 | 09/14/04 | Beale, et al. | |
| | | US-6,780,186 | 08/24/04 | Errico, et al. | |
| | | US-6,770,075 | 08/03/04 | Howland | |
| | | US-6,767,351 | 07/27/04 | Orbay, et al. | |

**FOREIGN PATENT DOCUMENTS**

| Examiner Initials | Cite No.[1] | Foreign Patent Document<br>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] |
|---|---|---|---|---|---|---|
| | | WO2005/082262 | 09/09/05 | Sournac, et al. | | |
| | | WO2005/072632 | 08/11/05 | Sournac, et al. | | |
| | | EP1579816 | 09/28/05 | Harms, et al. | | |
| | | EP1570795 | 09/07/05 | Harms, et al. | | |
| | | WO2005/020829 | 03/10/05 | Renaud, et al. | | |
| | | WO2005/000136 | 01/06/05 | Clement, et al. | | |

| Examiner Signature | | Date Considered | |
|---|---|---|---|



*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[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.
This collection of information is required by 37 CFR 1.97 and 1.98. 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 2 hours 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, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, Washington, DC 20231.**
*If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.*

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

| 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 | 13 | of | 50 | Attorney Docket Number | 11,433 |

**U. S. PATENT DOCUMENTS**

| Examiner Initials* | Cite No.[7] | Document Number<br>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-6,761,723 | 07/13/04 | Buttermann, et al. | |
| | | US-6,755,836 | 06/29/04 | Lewis | |
| | | US-6,755,835 | 06/29/04 | Schultheiss, et al. | |
| | | US-6,755,829 | 06/29/04 | Bono, et al. | |
| | | US-6,746,449 | 06/08/04 | Jones, et al. | |
| | | US-6,740,086 | 05/25/04 | Richelsoph | |
| | | US-6,736,820 | 05/18/04 | Biedermann, et al. | |
| | | US-6,736,816 | 05/18/04 | Ritland | |
| | | US-6,733,502 | 05/11/04 | Altarac, et al. | |
| | | US-6,730,127 | 05/04/04 | Michelson | |
| | | US-6,730,093 | 05/04/04 | Saint Martin | |
| | | US-6,723,100 | 04/20/04 | Biedermann, et al. | |
| | | US-6,716,213 | 04/06/04 | Shitoto | |

**FOREIGN PATENT DOCUMENTS**

| Examiner Initials | Cite No.[1] | Foreign Patent Document<br>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] |
|---|---|---|---|---|---|---|
| | | WO2005/000137 | 01/06/05 | Clement, et al. | | |
| | | WO2004/107997 | 12/16/04 | Bette, et al. | | |
| | | 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. | | |

| Examiner Signature | | Date Considered | |
|---|---|---|---|



*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[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.
This collection of information is required by 37 CFR 1.97 and 1.98. 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 2 hours 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, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, Washington, DC 20231.**
*If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.*

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

| 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 | 14 | of | 50 | Attorney Docket Number | 11,433 |

**U. S. PATENT DOCUMENTS**

| Examiner Initials* | Cite No.[7] | Document Number<br>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-6,716,247 | 04/06/04 | Michelson | |
| | | US-6,716,214 | 04/06/04 | Jackson | |
| | | US-6,712,818 | 03/30/04 | Michelson | |
| | | US-6,706,045 | 03/16/04 | Lin, et al. | |
| | | US-6,699,249 | 03/02/04 | Schlapfer, et al. | |
| | | US-6,695,843 | 02/24/04 | Biedermann, et al. | |
| | | US-6,695,851 | 02/24/04 | Zdeblick, et al. | |
| | | US-6,695,843 | 02/24/04 | Biedermann, et al. | |
| | | US-6,689,134 | 02/10/04 | Ralph, et al. | |
| | | US-6,689,133 | 02/10/04 | Morrison, et al. | |
| | | US-6,682,529 | 01/27/04 | Stahurski | |
| | | US-6,679,833 | 01/20/04 | Smith, e tal. | |
| | | US-6,676,661 | 01/13/04 | Martin Benlloch, et al. | |

**FOREIGN PATENT DOCUMENTS**

| Examiner Initials | Cite No.[1] | Foreign Patent Document<br>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] |
|---|---|---|---|---|---|---|
| | | FR2865377 | 01/27/04 | Clement, et al. | | |
| | | FR2865375 | 01/27/04 | Sournac, et al. | | |
| | | FR2865373 | 01/27/04 | Sournac, et al. | | |
| | | WO03/068088 | 08/21/03 | Altarac, et al. | | |
| | | FR2856578 | 06/27/03 | Clement, et al. | | |
| | | WO02/054966 | 07/18/02 | Glascott | | |

| Examiner Signature | | Date Considered | |
|---|---|---|---|

PTO/SB/08A (04-03)
Approved for use through 04/30/2003. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[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.
This collection of information is required by 37 CFR 1.97 and 1.98. 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 2 hours 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, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, Washington, DC 20231.**
*If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.*

| 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 | 15 | 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-6,673,073 | 01/06/04 | Schafer | |
| | | US-6,663,635 | 12/16/03 | Frigg, et al. | |
| | | US-6,663,632 | 12/16/03 | Frigg | |
| | | US-6,660,004 | 12/09/03 | Barker, et al. | |
| | | US-6,656,179 | 12/02/03 | Schaefer, et al. | |
| | | US-6,656,181 | 12/02/03 | Dixon, et al. | |
| | | US-6,648,885 | 11/18/03 | Friesem | |
| | | US-6,648,887 | 11/18/03 | Ashman | |
| | | US-6,635,059 | 10/21/03 | Randall, et al. | |
| | | US-6,626,907 | 09/30/03 | Campbell, et al. | |
| | | US-6,626,908 | 09/30/03 | Cooper, et al. | |
| | | US-6,623,485 | 09/23/03 | Doubler, et al. | |
| | | US-6,613,050 | 09/02/03 | Wagner, et al. | |

**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] |
|---|---|---|---|---|---|---|
| | | EP1190678 | 03/27/02 | Bono, et al. | | |
| | | GB2365345 | 02/20/02 | Cooper, et al. | | |
| | | EP1121902 | 08/08/01 | Schaffler, et al. | | |
| | | FR2796545 | 01/26/01 | Saint Martin, et al. | | |
| | | DE19507141 | 09/12/96 | Gleich, et al. | | |
| | | FR2729291 | 07/19/96 | Gennari | | |
| | | G9202745.8 | 04/30/92 | Hauck, et al. | | |

| Examiner Signature | | Date Considered | |
|---|---|---|---|

Approved for use through 04/30/2003. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[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.
This collection of information is required by 37 CFR 1.97 and 1.98. 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 2 hours 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, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, Washington, DC 20231.**
*If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-91001 and select option 2.*

| 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 | 16 | 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-6,610,063 | 08/26/03 | Kumar, et al. | |
| | | US-6,595,992 | 07/22/03 | Wagner, et al. | |
| | | US-6,595,993 | 07/22/03 | Donno, et al. | |
| | | US-6,585,740 | 07/01/03 | Schlapfer, et al. | |
| | | US-6,582,436 | 06/24/03 | Schlapfer, et al. | |
| | | US-6,582,466 | 06/24/03 | Gauchet | |
| | | US-6,565,567 | 05/20/03 | Haider | |
| | | US-6,565,565 | 05/20/03 | Yuan, et al. | |
| | | US-6,562,040 | 05/13/03 | Wagner | |
| | | US-6,558,387 | 05/06/03 | Errico, et al. | |
| | | US-6,554,834 | 04/29/03 | Crozet, et al. | |
| | | US-6,554,832 | 04/29/03 | Shluzas | |
| | | US-6,551,320 | 04/22/03 | Liebermann | |
| | | US-6,547,790 | 04/15/03 | Harkey, III, et al. | |
| | | US-6,533,786 | 03/18/03 | Needham, et al. | |
| | | US-6,530,929 | 03/11/03 | Jusis, et al. | |
| | | US-6,527,804 | 03/04/03 | Gauchet, et al. | |
| | | US-6,520,962 | 02/18/03 | Taylor, et al. | |
| | | US-6,508,818 | 01/21/03 | Steiner, et al. | |

**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] |
|---|---|---|---|---|---|---|
| | | WO2008/088731 | 07/24/2008 | Hawkins | | |
| | | EP1925263 | 05/28/2008 | Matthis, et al. | | |

| Examiner Signature | | Date Considered | |
|---|---|---|---|

PTO/SB/08A (04-03)

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[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.

This collection of information is required by 37 CFR 1.97 and 1.98. 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 2 hours 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, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, Washington, DC 20231.**

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 116 of 2152

Approved for use through 04/30/2003. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

| 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 | 17 | of | 50 | Attorney Docket Number | 11,433 |

| U. S. PATENT DOCUMENTS | | | | | |
|---|---|---|---|---|---|
| Examiner Initials* | Cite No.[7] | Document Number<br>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-6,488,681 | 12/03/02 | Martin, et al. | |
| | | US-6,485,494 | 11/26/02 | Haider | |
| | | US-6,471,705 | 10/29/02 | Biedermann, et al. | |
| | | US-6,471,703 | 10/29/02 | Ashman | |
| | | US-6,451,021 | 09/17/02 | Ralph, et al. | |
| | | US-6,440,137 | 08/27/02 | Horvath, et al. | |
| | | US-6,402,752 | 06/11/02 | Schaffler-Wachter, et al. | |
| | | US-RE37,665 | 04/16/02 | Ralph, et al. | |
| | | US-6,368,321 | 04/09/02 | Jackson | |
| | | US-6,355,040 | 03/12/02 | Richelsoph, et al. | |
| | | US-6,309,391 | 10/30/01 | Crandall, et al. | |
| | | US-6,331,179 | 12/18/01 | Freid, et al. | |
| | | US-6,302,888 | 10/16/01 | Mellinger, et al. | |
| | | US-6,287,308 | 09/11/01 | Betz, et al. | |
| | | US-6,287,311 | 09/11/01 | Sherman, et al. | |
| | | US-6,280,445 | 08/28/01 | Morrison, et al. | |
| | | US-6,280,442 | 08/28/01 | Barker, et al. | |
| | | US-6,273,888 | 08/14/01 | Justis | |
| | | US-6,254,602 | 07/03/01 | Justis | |

| FOREIGN PATENT DOCUMENTS | | | | | | |
|---|---|---|---|---|---|---|
| Examiner Initials | Cite No.[1] | Foreign Patent Document<br>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 | |
|---|---|---|---|



*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[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.
This collection of information is required by 37 CFR 1.97 and 1.98. 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 2 hours 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, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, Washington, DC 20231.**
*If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.*

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

| 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 | 18 | of | 50 | Attorney Docket Number | 11,433 |

**U. S. PATENT DOCUMENTS**

| Examiner Initials* | Cite No.[7] | Document Number<br>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-6,248,105 | 06/19/01 | Schlapfer, et al. | |
| | | US-RE37,161 | 05/01/01 | Michelson, et al. | |
| | | US-6,224,596 | 05/01/01 | Jackson | |
| | | US-6,187,005 | 02/13/01 | Brace, et al. | |
| | | US-6,183,472 | 02/06/01 | Lutz | |
| | | US-6,146,383 | 11/14/00 | Studer, et al. | |
| | | US-6,132,434 | 10/17/00 | Sherman, et al. | |
| | | US-6,132,432 | 10/17/00 | Richelsoph | |
| | | US-6,132,431 | 10/17/00 | Nilsson, et al. | |
| | | US-6,113,601 | 09/05/00 | Tatar | |
| | | US-6,110,172 | 08/29/00 | Jackson | |
| | | US-6,099,528 | 08/08/00 | Saurat | |
| | | US-6,090,111 | 07/18/00 | Nichols | |
| | | US-6,090,110 | 07/18/00 | Metz-Stavenhagen | |
| | | US-6,086,588 | 07/11/00 | Ameil, et al. | |
| | | US-6,077,262 | 06/20/00 | Schlapfer, et al. | |
| | | US-6,074,391 | 06/13/00 | Metz-Stavenhagen, et al. | |
| | | US-6,063,090 | 05/16/00 | Schlapfer | |
| | | US-6,053,917 | 04/25/00 | Sherman, et al. | |

**FOREIGN PATENT DOCUMENTS**

| Examiner Initials | Cite No.[1] | Foreign Patent Document<br>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 | |
|---|---|---|---|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[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.

This collection of information is required by 37 CFR 1.97 and 1.98. 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 2 hours 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, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: **Commissioner for Patents, Washington, DC 20231.**

PTO/SB/08A (04-03)
Approved for use through 04/30/2003. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

| 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 | 19 | of | 50 | Attorney Docket Number | 11,433 |

**U. S. PATENT DOCUMENTS**

| Examiner Initials* | Cite No.[7] | Document Number<br>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-6,022,350 | 02/08/00 | Ganem | |
| | | US-6,019,759 | 02/01/00 | Rogozinski | |
| | | US-6,010,503 | 01/04/00 | Richelsoph, et al. | |
| | | US-5,964,760 | 10/12/99 | Richelsoph | |
| | | US-5,961,517 | 10/05/99 | Biedermann, et al. | |
| | | US-5,954,725 | 09/21/99 | Sherman, et al. | |
| | | US-5,891,145 | 04/06/99 | Morrison, et al. | |
| | | US-5,885,286 | 03/23/99 | Sherman, et al. | |
| | | US-5,882,350 | 03/16/99 | Ralph, et al. | |
| | | US-5,879,351 | 03/09/99 | Viart | |
| | | US-5,879,350 | 03/09/99 | Sherman, et al. | |
| | | US-5,876,402 | 03/02/99 | Errico, et al. | |
| | | US-5,863,293 | 01/26/99 | Richelsoph | |
| | | US-5,817,094 | 10/06/98 | Errico, et al. | |
| | | US-5,800,435 | 09/01/98 | Errico, et al. | |
| | | US-5,797,911 | 08/25/98 | Sherman, et al. | |
| | | US-5,782,833 | 07/21/98 | Haider | |
| | | US-5,738,685 | 04/14/98 | Halm, et al. | |
| | | US-5,733,286 | 03/31/98 | Errico, et al. | |

**FOREIGN PATENT DOCUMENTS**

| Examiner Initials | Cite No.[1] | Foreign Patent Document<br>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 | |
|---|---|---|---|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[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.

This collection of information is required by 37 CFR 1.97 and 1.98. 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 2 hours 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, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, Washington, DC 20231.**
*If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.*

PTO/SB/08A (04-03)
Approved for use through 04/30/2003. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

| Substitute for form 1469/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 | 20 | of | 50 | Attorney Docket Number | 11,433 |

| U. S. PATENT DOCUMENTS | | | | | |
|---|---|---|---|---|---|
| Examiner Initials* | Cite No.[7] | Document Number<br>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-5,728,098 | 03/17/98 | Sherman, et al. | |
| | | US-5,725,528 | 03/10/98 | Errico, et al. | |
| | | US-5,716,356 | 02/10/98 | Biedermann, et al. | |
| | | US-5,690,630 | 11/25/97 | Errico, et al. | |
| | | US-5,681,319 | 10/28/97 | Biedermann, et al. | |
| | | US-5,672,176 | 09/30/97 | Biedermann, et al. | |
| | | US-5,669,911 | 09/23/97 | Errico, et al. | |
| | | US-5,647,873 | 07/15/97 | Errico, et al. | |
| | | US-7,186,255 | 03/06/2007 | Baynham, et al. | |
| | | US-5,607,426 | 03/04/97 | Ralph, et al. | |
| | | US-5,601,553 | 02/11/97 | Trebing, et al. | |
| | | US-5,591,166 | 01/07/97 | Bernhardt, et al. | |
| | | US-5,586,984 | 12/24/96 | Errico, et al. | |
| | | US-5,584,834 | 12/17/96 | Errico, et al. | |
| | | US-5,569,247 | 10/29/96 | Morrison | |
| | | US-5,554,157 | 09/10/96 | Errico, et al. | |
| | | US-5,496,321 | 03/05/96 | Puno, et al. | |
| | | US-5,476,464 | 12/19/95 | Metz-Stavenhagen, et al. | |
| | | US-5,476,462 | 12/19/95 | Allard, et al. | |
| | | US-5,474,555 | 12/12/95 | Puno, et al. | |

| FOREIGN PATENT DOCUMENTS | | | | | | |
|---|---|---|---|---|---|---|
| Examiner Initials | Cite No.[1] | Foreign Patent Document<br>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 | |
|---|---|---|---|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[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.

This collection of information is required by 37 CFR 1.97 and 1.98. 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 2 hours 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, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, Washington, DC 20231.**
*If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.*

PTO/SB/08A (04-03)
Approved for use through 04/30/2003. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449/PTO

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

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

Sheet 21 of 50

**U. S. PATENT DOCUMENTS**

| Examiner Initials* | Cite No.[7] | Document Number<br>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-5,466,237 | 11/14/95 | Byrd, III, et al. | |
| | | US-5,443,467 | 08/22/95 | Biedermann, et al. | |
| | | US-5,429,639 | 07/04/95 | Judet | |
| | | US-5,395,371 | 03/07/95 | Miller, et al. | |
| | | US-5,360,431 | 11/01/94 | Puno, et al. | |
| | | US-5,312,404 | 05/17/94 | Asher, et al. | |
| | | US-5,261,912 | 11/16/93 | Frigg | |
| | | US-5,207,678 | 05/04/93 | Harms, et al. | |
| | | US-5,129,388 | 07/14/92 | Vignaud, et al. | |
| | | US-4,946,458 | 08/07/90 | Harms, et al. | |
| | | US-2006/0058788 | 03/16/06 | Hammer, et al. | |
| | | US-2006/0052786 | 03/09/06 | Dant, et al. | |
| | | US-2006/0052784 | 03/09/06 | Dant, et al. | |
| | | US-2006/0052783 | 03/09/06 | Dant, et al. | |
| | | US-2006/0036252 | 02/16/06 | Baynham, et al. | |
| | | US-2006/0036242 | 02/16/06 | Nilsson, et al. | |
| | | US-2006/0025770 | 02/02/06 | Schlapfer, et al. | |
| | | US-2006/0025767 | 02/02/06 | Khalili | |
| | | US-2006/0025768 | 02/02/06 | Iott, et al. | |

**FOREIGN PATENT DOCUMENTS**

| Examiner Initials | Cite No.[1] | Foreign Patent Document<br>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 | |
|---|---|---|---|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[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.

This collection of information is required by 37 CFR 1.97 and 1.98. 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 2 hours 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, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, Washington, DC 20231.**
*If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.*

PTO/SB/08A (04-03)
Approved for use through 04/30/2003. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

| 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 | 22 | of | 50 | Attorney Docket Number | 11,433 |

**U. S. PATENT DOCUMENTS**

| Examiner Initials* | Cite No.[7] | Document Number<br>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-2006/0015104 | 01/16/06 | Dalton | |
| | | US-2006/0009769 | 01/12/06 | Liebermann | |
| | | US-2006/0009770 | 01/12/06 | Speirs, et al. | |
| | | US-2006/0004359 | 01/05/06 | Kramer, et al. | |
| | | US-2006/0004357 | 01/05/06 | Lee, et al. | |
| | | US-2006/0004363 | 01/05/06 | Brockmeyer, et al. | |
| | | US-2006/0004360 | 01/05/06 | Kramer, et al. | |
| | | US-2005/0288669 | 12/29/05 | Abdou | |
| | | US-2005/0288671 | 12/29/05 | Yuan, et al. | |
| | | US-2005/0288673 | 12/29/05 | Catbagan, et al. | |
| | | US-2005/0283238 | 12/22/05 | Reiley | |
| | | US-2005/0283152 | 12/22/05 | Lindemann, et al. | |
| | | US-2005/0283157 | 12/22/05 | Coates, et al. | |
| | | US-2005/0277925 | 12/15/05 | Mujwid | |
| | | US-2005/0277928 | 12/15/05 | Boschert | |
| | | US-2005/0277919 | 12/15/05 | Slivka, et al. | |
| | | US-2005/0273101 | 12/08/05 | Schumacher | |
| | | US-2005/0273099 | 12/08/05 | Baccelli, et al. | |
| | | US-2005/0267474 | 12/01/05 | Dalton | |

**FOREIGN PATENT DOCUMENTS**

| Examiner Initials | Cite No.[1] | Foreign Patent Document<br>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 | |
|---|---|---|---|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[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.

This collection of information is required by 37 CFR 1.97 and 1.98. 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 2 hours 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, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, Washington, DC 20231.**
*If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.*

PTO/SB/08A (04-03)
Approved for use through 04/30/2003. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

| 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 | 23 | of | 50 | Attorney Docket Number | 11,433 |

**U. S. PATENT DOCUMENTS**

| Examiner Initials* | Cite No.[7] | Document Number<br>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-2005/0261687 | 11/24/05 | Garamszegi, et al. | |
| | | US-2005/0251141 | 11/10/05 | Frigg, et al. | |
| | | US-2005/0251137 | 11/10/05 | Ball | |
| | | US-2005/0240183 | 10/27/05 | Vaughan | |
| | | US-2005/0240181 | 10/27/05 | Boomer, et al. | |
| | | US-2005/0234450 | 10/20/05 | Barker | |
| | | US-2005/0234452 | 10/20/05 | Malandain | |
| | | US-2005/0234451 | 10/20/05 | Markworth | |
| | | US-2005/0228501 | 10/13/05 | Miller, et al. | |
| | | US-2005/0216003 | 09/29/05 | Beidermann, et al. | |
| | | US-2005/0203516 | 09/15/05 | Biedermann, et al. | |
| | | US-2005/0192580 | 09/01/05 | Dalton | |
| | | US-2005/0187555 | 08/25/05 | Beidermann, et al. | |
| | | US-2005/0187548 | 08/25/05 | Butler, et al. | |
| | | US-2005/0171540 | 08/04/05 | Lim, et al. | |
| | | US-2005/0165400 | 07/28/05 | Fernandez | |
| | | US-2005/0159750 | 07/21/05 | Doherty | |
| | | US-2005/0154391 | 07/14/05 | Doherty, et al. | |
| | | US-2005/0154389 | 07/14/05 | Selover, et al. | |

**FOREIGN PATENT DOCUMENTS**

| Examiner Initials | Cite No.[1] | Foreign Patent Document<br>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 | |
|---|---|---|---|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[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.
This collection of information is required by 37 CFR 1.97 and 1.98. 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 2 hours 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, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, Washington, DC 20231.**
*If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.*

PTO/SB/08A (04-03)
Approved for use through 04/30/2003. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

| 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 | 24 | 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-2005/0149023 | 07/07/05 | Ritland | |
| | | US-2005/0131404 | 06/16/05 | Mazda, et al. | |
| | | US-2005/0131413 | 06/16/05 | O'Driscoll, et al. | |
| | | US-2005/0113927 | 05/26/05 | Malek | |
| | | US-2005/0107788 | 05/19/05 | Beaurain, et al. | |
| | | US-2005/0080415 | 04/14/05 | Keyer, et al. | |
| | | US-2005/0070899 | 03/31/05 | Doubler, et al. | |
| | | US-2005/0055026 | 03/10/05 | Biedermann, et al. | |
| | | US-2005/0027296 | 02/03/05 | Thramann, et al. | |
| | | US-2004/0267264 | 12/30/04 | Konieczynski, et al. | |
| | | US-2004/0249380 | 12/09/04 | Glascott | |
| | | US-2004/0225289 | 11/11/04 | Biedermann, et al. | |
| | | US-2004/0236330 | 11/25/04 | Purcell, et al. | |
| | | US-2004/0210216 | 10/21/04 | Farris, et al. | |
| | | US-2004/0176766 | 09/09/04 | Shluzas | |
| | | US-2004/0186473 | 09/23/04 | Cournoyer, et al. | |
| | | US-2004/0172022 | 09/02/04 | Landry, et al. | |
| | | US-2004/0158247 | 08/12/04 | Sitiso, et al. | |
| | | US-2004/0147929 | 07/29/04 | Biedermann, et al. | |

**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 | |
|---|---|---|---|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[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.

This collection of information is required by 37 CFR 1.97 and 1.98. 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 2 hours 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, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, Washington, DC 20231.**
*If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.*

PTO/SB/08A (04-03)
Approved for use through 04/30/2003. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

| 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 | 25 | of | 50 | Attorney Docket Number | 11,433 |

**U. S. PATENT DOCUMENTS**

| Examiner Initials* | Cite No.[7] | Document Number<br>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-2004/0143265 | 07/22/04 | Landry, et al. | |
| | | US-2004/0138662 | 07/15/04 | Landry, et al. | |
| | | US-2004/0116929 | 06/17/04 | Barker, et al. | |
| | | US-2004/0097933 | 05/20/04 | Lourdel, et al. | |
| | | US-2004/0092934 | 05/13/04 | Howland | |
| | | US-2004/0006342 | 01/08/04 | Altarac, et al. | |
| | | US-2003/0216735 | 11/20/03 | Altarac, et al. | |
| | | US-2003/0208204 | 11/06/03 | Bailey, et al. | |
| | | US-2003/0199873 | 10/23/03 | Richelsoph | |
| | | US-2003/0176862 | 09/18/03 | Taylor, et al. | |
| | | US-2003/0163133 | 08/28/03 | Altarac, et al. | |
| | | US-2003/0149432 | 08/07/03 | Frigg, et al. | |
| | | US-2003/0125741 | 07/03/03 | Biedermann, et al. | |
| | | US-2003/0105460 | 06/05/03 | Crandall, et al. | |
| | | US-2003/0100896 | 05/29/03 | Biedermann, et al. | |
| | | US-2003/0093078 | 05/15/03 | Ritland | |
| | | US-2003/0073996 | 04/17/03 | Doubler, et al. | |
| | | US-2003/0023243 | 01/30/03 | Biedermann, et al. | |
| | | US-2002/0193795 | 12/19/02 | Gertzbein, et al. | |

**FOREIGN PATENT DOCUMENTS**

| Examiner Initials | Cite No.[1] | Foreign Patent Document<br>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 | |
|---|---|---|---|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[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.

This collection of information is required by 37 CFR 1.97 and 1.98. 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 2 hours 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, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, Washington, DC 20231.**
*If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.*

PTO/SB/08A (04-03)
Approved for use through 04/30/2003. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

| 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 | 26 | of | 50 | Attorney Docket Number | 11,433 |

| U. S. PATENT DOCUMENTS | | | | | |
|---|---|---|---|---|---|
| Examiner Initials* | Cite No.[7] | Document Number<br>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-2002/0173789 | 11/21/02 | Howland | |
| | | US-2002/0143341 | 10/03/02 | Biedermann, et al. | |
| | | US-2002/0203511 | 09/15/02 | Wilson-MacDonald, et al. | |
| | | US-2002/0111626 | 08/15/02 | Ralph, et al. | |
| | | US-2002/0082602 | 06/27/02 | Biedermann, et al. | |
| | | US-2002/0045898 | 04/18/02 | Freid, et al. | |
| | | US-2002/0035366 | 03/21/02 | Walder, et al. | |
| | | US-2001/0001119 | 05/10/01 | Lombardo | |
| | | US-2006/0106383 | 05/18/06 | Biedermann, eta l. | |
| | | US-2006/0084995 | 04/20/06 | Biedermann, et al. | |
| | | US-2007/0073291 | 03/29/07 | Cordaro, et al. | |
| | | US-2007/0078460 | 04/05/07 | Frigg, et al. | |
| | | US-2007/0083199 | 04/12/07 | Baccelli | |

| FOREIGN PATENT DOCUMENTS | | | | | | |
|---|---|---|---|---|---|---|
| Examiner Initials | Cite No.[1] | Foreign Patent Document<br>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] |
| | | WO2006/005198 | 01/19/06 | Schlapfer | | |
| | | WO2007/0130835 | 11/15/07 | Dewey, et al. | | |
| | | WO2007/130840 | 11/15/07 | Moore | | |
| | | WO2007/130941 | 11/15/07 | Wisnewski | | |
| | | WO2007/124222 | 11/01/07 | Malandain, et al. | | |
| | | WO2006/119241 | 11/09/06 | Dickinson, et al. | | |
| | | WO2007/118045 | 10/18/07 | Melkent, et al. | | |
| Examiner Signature | | | Date Considered | | | |

PTO/SB/08A (04-03)

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[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.
This collection of information is required by 37 CFR 1.97 and 1.98. 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 2 hours 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, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, Washington, DC 20231.**

Approved for use through 04/30/2003. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

| 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 | 27 | of | 50 | Attorney Docket Number | 11,433 |

| U. S. PATENT DOCUMENTS | | | | | |
|---|---|---|---|---|---|
| Examiner Initials* | Cite No.[7] | Document Number<br>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-2007/0088357 | 04/19/07 | Johnson, et al. | |
| | | US-2007/0093817 | 04/26/07 | Barrus, et al. | |
| | | US-2007/0093818 | 04/26/07 | Biedermann, et al. | |
| | | US-2007/0093819 | 04/26/07 | Albert | |
| | | US-2007/0093826 | 04/26/07 | Hawkes, et al. | |
| | | US-2007/0093827 | 04/26/07 | Warnick | |
| | | US-2007/0093831 | 04/26/07 | Abdelgany, et al. | |
| | | US-2007/0055242 | 03/08/07 | Bailly | |
| | | US-2006/0235389 | 10/19/06 | Albert, et al. | |
| | | US-2006/0235392 | 10/19/06 | Hammer, et al. | |
| | | US-2006/0235393 | 10/19/06 | Bono, et al. | |
| | | US-2006/0241593 | 10/26/06 | Sherman, et al. | |
| | | US-2006/0241595 | 10/26/06 | Molz, IV., et al. | |
| | | US-2006/0241599 | 10/26/06 | Konieczcnski, et al. | |
| | | US-2006/0241600 | 10/26/06 | Ensign, et al. | |
| | | US-2006/0247631 | 11/02/06 | Ahn, et al. | |
| | | US-2006/0247624 | 11/02/06 | Banouskou, et al. | |
| | | US-2006/0247636 | 11/02/06 | Yuan, et al. | |

| FOREIGN PATENT DOCUMENTS | | | | | | |
|---|---|---|---|---|---|---|
| Examiner Initials | Cite No.[1] | Foreign Patent Document<br>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 | |
|---|---|---|---|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[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.
This collection of information is required by 37 CFR 1.97 and 1.98. 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 2 hours 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, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, Washington, DC 20231.**
*If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.*

PTO/SB/08A (04-03)
Approved for use through 04/30/2003. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

| 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 | 28 | of | 50 | Attorney Docket Number | 11,433 |

| U. S. PATENT DOCUMENTS | | | | | |
|---|---|---|---|---|---|
| Examiner Initials* | Cite No.[7] | Document Number<br>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-2006/0264933 | 11/23/06 | Baker, et al. | |
| | | US-2006/0264936 | 11/23/06 | Partin et al. | |
| | | US-2006/0276787 | 12/07/06 | Zubok, et al. | |
| | | US-2006/0276791 | 12/07/06 | Shluzas | |
| | | US-2006/0276792 | 12/07/06 | Ensign, eta l. | |
| | | US-2006/0282074 | 12/14/06 | Renaud, et al. | |
| | | US-2006/0293659 | 12/28/06 | Alvarez | |
| | | US-2006/0293666 | 12/28/06 | Matthis, et al. | |
| | | US-2006/0293665 | 12/28/06 | Shluzas | |
| | | US-2006/0247779 | 11/02/06 | Gordon, et al. | |
| | | US-2007/0016188 | 01/18/07 | Boehm, Jr., et al. | |
| | | US-2007/0049933 | 03/01/07 | Ahn, et al. | |
| | | US-2007/0043364 | 02/22/07 | Cawley, et al. | |
| | | US-2007/0043359 | 02/22/07 | Altarac, et al. | |
| | | US-2007/0043358 | 02/22/07 | Molz, IV., et al. | |
| | | US-2007/0043357 | 02/22/07 | Kirschman | |

| FOREIGN PATENT DOCUMENTS | | | | | | |
|---|---|---|---|---|---|---|
| Examiner Initials | Cite No.[1] | Foreign Patent Document<br>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 | |
|---|---|---|---|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[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.
This collection of information is required by 37 CFR 1.97 and 1.98. 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 2 hours 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, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, Washington, DC 20231.**

PTO/SB/08A (04-03)
Approved for use through 04/30/2003. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

| 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 | 29 | of | 50 | Attorney Docket Number | 11,433 |

**U. S. PATENT DOCUMENTS**

| Examiner Initials* | Cite No.[7] | Document Number<br>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-2007/0016198 | 01/18/07 | Boehm, Jr., et al. | |
| | | US-2007/0021750 | 01/25/07 | Shluzas, et al. | |
| | | US-2007/0043355 | 02/22/07 | Bette, et al. | |
| | | US-2007/0055235 | 03/08/07 | Janowski, et al. | |
| | | US-2007/0055238 | 03/08/07 | Biedermann, et al. | |
| | | US-2007/0055239 | 03/08/07 | Sweeney, et al. | |
| | | US-2007/0055240 | 03/08/07 | Matthis, et a902 | |
| | | US-2007/0055241 | 03/08/07 | Matthis, et al. | |
| | | US-2007/0073291 | 03/29/07 | Cordaro, et al. | |
| | | US-2006/0106380 | 05/18/06 | Colleran, et al. | |
| | | US-2006/0095037 | 05/04/06 | Jones, et al. | |
| | | US-2006/0089644 | 04/27/06 | Felix | |
| | | US-2006/0089643 | 04/27/06 | Mujwid | |
| | | US-2006/0084993 | 04/20/06 | Landry, et al. | |
| | | US-2006/0084989 | 04/20/06 | Dickinson, et al. | |
| | | US-2006/0084981 | 04/20/06 | Shluzas | |
| | | US-2006/0079899 | 04/13/06 | Ritland | |
| | | US-2006/0079895 | 04/13/06 | McLeer | |

**FOREIGN PATENT DOCUMENTS**

| Examiner Initials | Cite No.[1] | Foreign Patent Document<br>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 | |
|---|---|---|---|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[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.
This collection of information is required by 37 CFR 1.97 and 1.98. 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 2 hours 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, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, Washington, DC 20231.**
*If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.*

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

| 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 | 30 | of | 50 | Attorney Docket Number | 11,433 |

| U. S. PATENT DOCUMENTS | | | | | |
|---|---|---|---|---|---|
| Examiner Initials* | Cite No.[7] | Document Number<br>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-2006/0079894 | 04/13/06 | Colleran, et al. | |
| | | US-2006/0074419 | 04/06/06 | Taylor, et al. | |
| | | US-2006/0212034 | 09/21/06 | Triplett, et al. | |
| | | US-2006/0229614 | 10/12/06 | Foley, et al. | |
| | | US-2006/0229615 | 10/12/06 | Abdou | |
| | | US-2006/0200123 | 09/07/06 | Mueller | |
| | | US-2006/0200149 | 09/07/06 | Hoy, et al. | |
| | | US-2006/0200131 | 09/07/06 | Chao, et al. | |
| | | US-2006/0195198 | 08/31/06 | Schumacher | |
| | | US-2006/0173456 | 08/03/06 | Hawkes, et al. | |
| | | US-2006/0173454 | 08/03/06 | Spitler, et ak, | |
| | | US-2006/0167455 | 07/27/06 | Clement, et al. | |
| | | US-2006/0161152 | 07/20/06 | Ensign, et al. | |
| | | US-2006/0155278 | 07/13/06 | Warnick | |
| | | US-2006/0155277 | 07/13/06 | Metz-Stavenhagen | |
| | | US-2006/0149244 | 07/06/06 | Amrein, et al. | |
| | | US-2006/0149241 | 07/06/06 | Richelsoph, et al. | |
| | | US-2006/0149232 | 07/06/06 | Sasing | |

| FOREIGN PATENT DOCUMENTS | | | | | | |
|---|---|---|---|---|---|---|
| Examiner Initials | Cite No.[1] | Foreign Patent Document<br>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 | |
|---|---|---|---|



*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[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.
This collection of information is required by 37 CFR 1.97 and 1.98. 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 2 hours 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, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, Washington, DC 20231.**

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

| 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 | 31 | of | 50 | Attorney Docket Number | 11,433 |

| U. S. PATENT DOCUMENTS | | | | | |
|---|---|---|---|---|---|
| Examiner Initials* | Cite No.[7] | Document Number<br>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-2006/0142761 | 06/29/06 | Landry, eta l. | |
| | | US-2006/0129149 | 06/15/06 | Iott, et al. | |
| | | US-2006/0129147 | 06/15/06 | Biedermann, et al. | |
| | | US-2006/0116677 | 06/01/06 | Burd, et al. | |
| | | US-2007/0260243 | 11/08/07 | Biedermann | |
| | | US-2007/0100341 | 05/03/07 | Reglos, et al. | |
| | | US-2007/0118117 | 05/24/07 | Altarac, et al. | |
| | | US-2007/0118118 | 05/24/07 | Kwak, et al. | |
| | | US-2007/0118123 | 05/24/07 | Strausbaugh, et al. | |
| | | US-2007/0118124 | 05/24/07 | Biedermann, et al. | |
| | | US-2007/0123862 | 05/31/07 | Warnick | |
| | | US-2007/0123864 | 05/31/07 | Walder, et al. | |
| | | US-2007/0123867 | 05/31/07 | Kirschman | |
| | | US-2007/0161986 | 07/12/07 | Levy | |
| | | US-2007/0161994 | 07/12/07 | Lowrey, et al. | |
| | | US-2007/0161995 | 07/12/07 | Trautwein, et al. | |
| | | US-2007/0161996 | 07/12/07 | Biedermann, et al. | |
| | | US-2007/0161999 | 07/12/07 | Biedermann, et al. | |

| FOREIGN PATENT DOCUMENTS | | | | | | |
|---|---|---|---|---|---|---|
| Examiner Initials | Cite No.[1] | Foreign Patent Document<br>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 | |
|---|---|---|---|

PTO/SB/08A (04-03)
Approved for use through 04/30/2003. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[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.
This collection of information is required by 37 CFR 1.97 and 1.98. 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 2 hours 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, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, Washington, DC 20231.**
*If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.*

| 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 | 32 | of | 50 | Attorney Docket Number | 11,433 |

**U. S. PATENT DOCUMENTS**

| Examiner Initials* | Cite No.[7] | Document Number<br>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-2007/0167948 | 07/19/07 | Abdou | |
| | | US-2007/0167949 | 07/19/07 | Altarac, et al. | |
| | | US-2007/0123870 | 05/31/07 | Jeon, et al. | |
| | | US-2007/0173819 | 07/26/07 | Sandlin | |
| | | US-2007/0173820 | 07/26/07 | Trieu | |
| | | US-2007/0173828 | 07/26/07 | Firkins, et al. | |
| | | US-2007/0191839 | 08/16/07 | Justis, et al. | |
| | | US-2007/0198014 | 08/23/07 | Graf, et al. | |
| | | US-2007/0208344 | 09/06/07 | Young | |
| | | US-2007/0225707 | 09/27/07 | Wisnewski, eta l. | |
| | | US-2007/0225711 | 09/27/07 | Ensign | |
| | | US-2007/0233078 | 10/04/07 | Justis, et al. | |
| | | US-2007/0233080 | 10/04/07 | Na, et al. | |
| | | US-2007/0233086 | 10/04/07 | Harms, et al. | |
| | | US-2007/0233087 | 10/04/07 | Schlapfer | |
| | | US-2007/0250061 | 10/25/07 | Chin, et al. | |
| | | US-2005/0260058 | 11/2005 | Casagne, III | |
| | | US-2005/0096654 | 05/2005 | Lin | |

**FOREIGN PATENT DOCUMENTS**

| Examiner Initials | Cite No.[1] | Foreign Patent Document<br>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 | |
|---|---|---|---|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[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.

This collection of information is required by 37 CFR 1.97 and 1.98. 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 2 hours 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, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, Washington, DC 20231.**

PTO/SB/08A (04-03)
Approved for use through 04/30/2003. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

| 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 | 33 | 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-2006/0217716 | 09/2006 | Baker, et al. | |
| | | US-2003/0153911 | 08/2003 | Shluzas | |
| | | US-2002/0072751 | 06/2002 | Jackson | |
| | | US-2002/0133159 | 09/2002 | Jackson | |
| | | US-2003/0023240 | 01/2003 | Amrein, et al. | |
| | | US-7,211,086 | 05/01/07 | Biedermann, et al. | |
| | | US-7,186,255 | 03/06/07 | Baynham, et al. | |
| | | US-7,121,755 | 10/17/06 | Schlapfer, et al. | |
| | | US-7,125,426 | 10/24/06 | Moumene, et al. | |
| | | US-7,128,743 | 10/31/06 | Metz-Stavenhagen | |
| | | US-7,141,051 | 11/28/06 | Janowski, et al. | |
| | | US-7,144,396 | 12/05/06 | Shluzas | |
| | | US-7,163,538 | 1/16/07 | Altarac, et al. | |
| | | US-7,163,539 | 1/16/07 | Abdelgany, et al. | |
| | | US-7,166,108 | 1/23/07 | Mazda, et al. | |
| | | US-7,090,674 | 8/15/06 | Doubler, et al. | |
| | | US-7,087,057 | 08/08/06 | Konieczynski, et al. | |
| | | US-7,066,937 | 06/27/06 | Shluzas | |

**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 | |
|---|---|---|---|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[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.
This collection of information is required by 37 CFR 1.97 and 1.98. 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 2 hours 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, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, Washington, DC 20231.**

| 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 | 34 | 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-7,081,116 | 07/25/06 | Carly | |
| | | US-RE39,089 | 05/02/06 | Ralph, et al. | |
| | | US-7,022,122 | 04/04/06 | Amrein, et al. | |
| | | US-7,083,621 | 08/01/06 | Shaolian, et al. | |
| | | US-7,066,937 | 06/27/06 | Shluzas | |
| | | US-7,211,087 | 05/01/07 | Young | |
| | | US-7,223,268 | 05/29/07 | Biedermann | |
| | | US-7,264,621 | 09/04/07 | Coates, et al. | |
| | | US-7,270,665 | 09/18/07 | Morrison, et al. | |
| | | US-7,291,151 | 11/06/07 | Alvarez | |
| | | US-7,291,153 | 11/06/07 | Glascott | |
| | | US-7,294,128 | 11/13/07 | Alleyne, et al. | |
| | | US-7,294,129 | 11/13/07 | Hawkins, et al. | |
| | | US-2,346,346 | 04/11/1944 | Anderson | |
| | | US-4,759,672 | 07/1988 | Nilsen, et al. | |
| | | US-2,813,450 | 11/1957 | Dzus | |
| | | US-2,362,999 | 11/1944 | Elmer | |
| | | US-7,066,062 | 06/2006 | Flesher | |

**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 | |
|---|---|---|---|



*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[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.
This collection of information is required by 37 CFR 1.97 and 1.98. 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 2 hours 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, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, Washington, DC 20231.**

Approved for use through 04/30/2003. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

| 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 | 35 | of | 50 | Attorney Docket Number | 11,433 |

**U. S. PATENT DOCUMENTS**

| Examiner Initials* | Cite No.[7] | Document Number<br>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-5,019,080 | 05/1991 | Hemer | |
| | | US-4,033,139 | 07/1977 | Frederick | |
| | | US-6,186,718 | 02/2001 | Fogard | |
| | | US-6,214,012 | 04/2001 | Karpman, et al. | |
| | | US-2,531,892 | 11/1950 | Reese | |
| | | US-3,013,244 | 12/1961 | Rudy | |
| | | US-7,214,227 | 05/2007 | Colleran, et al. | |
| | | US-6,296,642 | 10/2001 | Morrison, et al. | |
| | | US-6,896,677 | 05/2005 | Lin | |
| | | US-5,938,663 | 08/1999 | Petreto | |
| | | US-5,873,878 | 02/1999 | Harms, et al. | |
| | | US-6,652,526 | 11/2003 | Arafiles | |
| | | US-6,296,642 | 10/2001 | Morrison, et al. | |
| | | US-6,371,957 | 04/2002 | Amrein, et al. | |
| | | US-4,790,297 | 12/1988 | Luque | |
| | | US-7,699,872 | 04/20/2010 | Farris, et al. | |
| | | US-7,699,875 | 04/20/2010 | Timm | |
| | | US-7,699,876 | 04/20/2010 | Barry, et al. | |
| | | US-7,704,271 | 04/27/2010 | Abdou | |
| | | US-7,713,288 | 05/11/2010 | Timm, et al. | |
| | | US-7,717,941 | 05/18/2010 | Petit | |
| | | US-7,717,942 | 05/18/2010 | Schumacher | |
| | | US-7,717,943 | 05/18/2010 | Kirschman | |

| Examiner Signature | | Date Considered | |
|---|---|---|---|

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[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.
This collection of information is required by 37 CFR 1.97 and 1.98. 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 2 hours 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, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, Washington, DC 20231.**
If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

| 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 | 36 | of | 50 | Attorney Docket Number | 11,433 |

**U. S. PATENT DOCUMENTS**

| Examiner Initials* | Cite No.[6] | Document Number<br>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-7,294,128 | 11/13/2007 | Alleyne, et al. | |
| | | US-7,294,127 | 11/13/2007 | Hawkins, et al. | |
| | | US-7,306,603 | 12/11/2007 | Boehm, Jr., et al. | |
| | | US-7,306,604 | 12/11/2007 | Carli | |
| | | US-7,306,606 | 12/11/2007 | Sasing | |
| | | US-7,314,467 | 01/01/2008 | Howland | |
| | | US-7,316,684 | 01/08/2008 | Baccelli, et al. | |
| | | US-7,322,979 | 01/29/2008 | Crandall, et al. | |
| | | US-7,335,201 | 02/26/2008 | Doubler, et al. | |
| | | US-7,335,202 | 02/26/2008 | Matthis, et al. | |
| | | US-7,338,490 | 03/04/2008 | Ogilvie, et al. | |
| | | US-7,338,4911 | 03/04/2008 | Baker, et al. | |
| | | US-2007/0270806 | 11/22/2007 | Foley, et al. | |
| | | US-2007/0270807 | 11/22/2007 | Armstrong, et al. | |
| | | US-2007/0270810 | 11/22/2007 | Sanders | |
| | | US-2007/0270813 | 11/22/2007 | Garamszegi | |
| | | US-2007/0270815 | 11/22/2007 | Johnson, et al. | |

**FOREIGN PATENT DOCUMENTS**

| Examiner Initials | Cite No.[1] | Foreign Patent Document<br>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 | |
|---|---|---|---|



*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[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.
This collection of information is required by 37 CFR 1.97 and 1.98. 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 2 hours 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, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, Washington, DC 20231.**

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

| 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 | 37 | of | 50 | Attorney Docket Number | 11,433 |

**U. S. PATENT DOCUMENTS**

| Examiner Initials* | Cite No.[7] | Document Number<br>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-2007/0270830 | 11/22/2007 | Morrison | |
| | | US-2007/0270831 | 11/22/2007 | Dewey, et al. | |
| | | US-2007/0270832 | 11/22/2007 | Moore | |
| | | US-2007/0270835 | 11/22/2007 | Wisnewski | |
| | | US-2007/0270839 | 11/22/2007 | Jeon, et al. | |
| | | US-2007/0288004 | 12/13/2007 | Alvarez | |
| | | US-2008/0009862 | 01/10/2008 | Hoffman | |
| | | US-2008/0009864 | 01/10/2008 | Forton, et al. | |
| | | US-2008/0015578 | 01/17/2008 | Erickson, et al. | |
| | | US-2008/0015579 | 01/17/2008 | Whipple | |
| | | US-2008/0015580 | 01/17/2008 | Chao | |
| | | US-2008/0015584 | 01/17/2008 | Richelsoph | |
| | | US-2008/0015586 | 01/17/2008 | Krishna, et al. | |
| | | US-7,722,646 | 05/25/2010 | Ralph, et al. | |
| | | US-7,722,649 | 05/25/2010 | Biedermann, et al. | |
| | | US-7,722,651 | 05/25/2010 | Kwak, et al. | |
| | | US-7,722,652 | 05/25/2010 | Justis, et al. | |
| | | US-7,722,654 | 05/25/2010 | Taylor, et al. | |
| | | US-7,727,261 | 06/01/2010 | Barker, et al. | |
| | | US-7,731,736 | 06/08/2010 | Guenther, et al. | |
| | | US-7,731,749 | 06/08/2010 | Biedermann, et al. | |
| | | US-7,749,258 | 07/06/2010 | Biedermann, et al. | |
| | | US-7,758,618 | 07/20/2010 | Walder, et al. | |
| | | US-2010/0094343 | 04/15/2010 | Pham, et al. | |

| Examiner Signature | | Date Considered | |
|---|---|---|---|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[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.

This collection of information is required by 37 CFR 1.97 and 1.98. 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 2 hours 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, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, Washington, DC 20231.**

PTO/SB/08A (04-03)
Approved for use through 04/30/2003. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

| 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 | 38 | of | 50 | Attorney Docket Number | 11,433 |

| U. S. PATENT DOCUMENTS | | | | | |
|---|---|---|---|---|---|
| Examiner Initials* | Cite No.[6] | Document Number<br>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-2008/0021454 | 01/24/2008 | Chao, et al. | |
| | | US-2008/0021455 | 01/24/2008 | Chao, et al. | |
| | | US-2008/0021462 | 01/24/2008 | Trieu | |
| | | US-2008/0021464 | 01/24/2008 | Morin, et al. | |
| | | US-2008/0021473 | 01/24/2008 | Butler, et al. | |
| | | US-2008/0027432 | 01/31/2008 | Strauss, et al. | |
| | | US-2008/0039838 | 02/14/2008 | Landry, et al. | |
| | | US-2008/0039843 | 02/14/2008 | Abdou | |
| | | US-2008/0045951 | 02/21/2008 | Fanger, et al. | |
| | | US-2008/0045955 | 02/21/2008 | Berrevoets, et al. | |
| | | US-2008/0045957 | 02/21/2008 | Landry, et al. | |
| | | US-2008/0051780 | 02/28/2008 | Vaidya, et al. | |
| | | US-2008/0058811 | 03/06/2008 | Alleyne, et al. | |
| | | US-2010/0094348 | 04/15/2010 | Biedermann, et al. | |
| | | US-2010/0094349 | 04/15/2010 | Hammer, et al. | |
| | | US-2010/0094352 | 04/15/2010 | Iott, et al. | |
| | | US-2010/0094353 | 04/15/2010 | Shim, et al. | |
| | | US-2010/0100136 | 04/22/2010 | Won, et al. | |
| | | US-2010/0100137 | 04/22/2010 | Justis, et al. | |
| | | US-2010/0106189 | 04/29/2010 | Miller | |
| | | US-2010/0114170 | 05/06/2010 | Barrus, et al. | |
| | | US-2010/0114171 | 05/06/2010 | Boachie-Adjei, et al. | |
| | | US-2010/0114180 | 05/06/2010 | Rock, et al. | |

| Examiner Signature | | Date Considered | |
|---|---|---|---|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[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.
This collection of information is required by 37 CFR 1.97 and 1.98. 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 2 hours 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, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, Washington, DC 20231.**

PTO/SB/08A (04-03)
Approved for use through 04/30/2003. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

| 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 | 39 | of | 50 | Attorney Docket Number | 11,433 |

**U. S. PATENT DOCUMENTS**

| Examiner Initials* | Cite No.[9] | 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-2008/0058812 | 03/06/2008 | Zehnder | |
| | | US-2008/0065073 | 03/13/2008 | Perriello, et al. | |
| | | US-2008/0065077 | 03/13/2008 | Ferree | |
| | | US-2008/0071273 | 03/20/2008 | Hawkes, et al. | |
| | | US-2008/0071277 | 03/20/2008 | Warnick | |
| | | US-2008/0071274 | 03/20/2008 | Enisgn | |
| | | US-2008/0065075 | 03/13/2008 | Dant | |
| | | US-2008/0077139 | 03/27/2008 | Landry, et al. | |
| | | US-2008/0086131 | 04/10/2008 | Daly, eta l. | |
| | | US-2008/0086132 | 04/10/2008 | Biedermann, eta l. | |
| | | US-2008/0097441 | 04/24/2008 | Hayes, et al. | |
| | | US-2008/0097457 | 04/24/2008 | Warnick | |
| | | US-2008/0108992 | 05/08/2008 | Barry, et al. | |
| | | US-2008/0119858 | 05/22/2008 | Potash | |
| | | US-2008/0140075 | 06/12/2008 | Ensign, et al. | |
| | | US-2010/0125302 | 05/20/2010 | Hammill, Sr., et al. | |
| | | US-2010/0131017 | 05/27/2010 | Farris, et al. | |
| | | US-2010/0131018 | 05/27/2010 | Konieczynski, et al. | |
| | | US-2010/0137918 | 06/03/2010 | Wilcox, et al. | |
| | | US-2010/0137920 | 06/03/2010 | Hammill, Sr., et al. | |
| | | US-2010/0145390 | 06/10/2010 | McCarthy, et al. | |
| | | US-2010/0152776 | 06/10/2010 | Keyer, et al. | |
| | | US-2010/0152785 | 06/17/2010 | Forton, et al. | |

| Examiner Signature | | Date Considered | |
|---|---|---|---|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[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.
This collection of information is required by 37 CFR 1.97 and 1.98. 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 2 hours 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, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, Washington, DC 20231.**
If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

| 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 | 40 | of | 50 | Attorney Docket Number | 11,433 |

| **U. S. PATENT DOCUMENTS** | | | | | |
|---|---|---|---|---|---|
| Examiner Initials* | Cite No.[10] | Document Number<br>Number-Kind Code [2] (if known) | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | | US-2008/0161859 | 07/03/2008 | Nilsson | |
| | | US-2008/0161863 | 07/03/2008 | Arnold, et al. | |
| | | US-2008/0177321 | 07/24/2008 | Drewry, et al. | |
| | | US-2008/0177322 | 07/24/2008 | Davis, et al. | |
| | | US-2008/0183215 | 07/31/2008 | Altarac, et al. | |
| | | US-2008/0183223 | 07/31/2008 | Jeon, et al. | |
| | | US-2008/0195159 | 08/14/2008 | Kloss, et al. | |
| | | US-2008/0200956 | 08/21/2008 | Beckwith, et al. | |
| | | US-2008/0177332 | 07/24/2008 | Reiley, et al. | |
| | | US-2008-0200956 | 08/21/2008 | Beckwith, et al. | |
| | | US-2008/0215095 | 09/04/2008 | Biedermann, et al. | |
| | | US-2008-0228229 | 09/18/2008 | Walder, et al. | |
| | | US-2008/0234734 | 09/24/2008 | Walder, et al. | |
| | | US-2008/0234756 | 09/25/2008 | Sutcliffe, et al. | |
| | | US-2008/0234759 | 09/25/2008 | Marino | |
| | | US-2010/0152787 | 06/17/2010 | Walsh, et al. | |
| | | US-2010/0152788 | 06/17/2010 | Warnick | |
| | | US-2010/0160965 | 06/24/2010 | Viker | |
| | | US-2010/0160974 | 06/24/2010 | Viker | |
| | | US-2010/0160980 | 06/24/2010 | Walsh, et al. | |
| | | US-2010/0168796 | 07/01/2010 | Eliasen, et al. | |

| Examiner Signature | | Date Considered | |
|---|---|---|---|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[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.
This collection of information is required by 37 CFR 1.97 and 1.98. 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 2 hours 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, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, Washington, DC 20231.**
*If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2*

PTO/SB/08A (04-03)
Approved for use through 04/30/2003. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

| Substitute for form 1449/PTO | | | | *Complete if Known* | |
|---|---|---|---|---|---|
| **INFORMATION DISCLOSURE STATEMENT BY APPLICANT** (Use as many sheets as necessary) | | | | Application Number | |
| | | | | Filing Date | |
| | | | | 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.[11] | 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. | |
| | | US-2008/0262548 | 10/23/2008 | Lange, et al. | |
| | | US-2008/0262556 | 10/23/2008 | Jacofsky, et al. | |
| | | US-2008/0269742 | 10/30/2008 | Levy, et al. | |
| | | US-2008/0269809 | 10/30/2008 | Garamszegi | |
| | | US-2008/0287994 | 11/20/2008 | Perez-Cruet, et al. | |
| | | US-2008/0288002 | 11/20/2008 | Crall, et al. | |
| | | US-2008/0306528 | 12/11/2008 | Winslow, et al. | |
| | | US-2008/0306533 | 12/11/2008 | Winslow, et al. | |
| | | US-2008/0306539 | 12/11/2008 | Cain, et al. | |
| | | US-2006/0166535 | 07/27/2006 | Brumfield, et al. | |
| | | US-2006/0276789 | 12/07/2006 | Jackson | |
| | | US-2007/0055244 | 03/08/2007 | Jackson | |
| | | US-2010/0168800 | 07/01/2010 | Biedermann, et al. | |
| | | US-2010/0168801 | 07/01/2010 | Biedermann, et al. | |
| | | US-2010/0174322 | 07/08/2010 | Abdelgany, et al. | |
| | | US-2010/0179603 | 07/15/2010 | Warnick | |
| | | US-2010/0063553 | 03/11/2010 | Warnick | |
| | | US-2008/0249576 | 10/09/2008 | Wawkes, et al. | |
| | | US-5,683,392 | 11/04/1997 | Richelsoph | |
| | | US-7,604,655 | 10/20/2009 | Warnick | |

| Examiner Signature | | Date Considered | |
|---|---|---|---|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[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.
This collection of information is required by 37 CFR 1.97 and 1.98. 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 2 hours 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, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, Washington, DC 20231.**

PTO/SB/08A (04-03)
Approved for use through 04/30/2003. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

| 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 | 42 | of | 50 | Attorney Docket Number | 11,433 |

**U. S. PATENT DOCUMENTS**

| Examiner Initials* | Cite No.[12] | Document Number<br>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-7,695,498 | 04/13/2010 | Ritland | |
| | | US-7,695,497 | 04/13/2010 | Cordaro, et al. | |
| | | US-7,691,132 | 04/06/2010 | Landry, et al. | |
| | | US-7,691,131 | 04/06/2010 | Graf | |
| | | US-7,691,129 | 04/06/2010 | Felix | |
| | | US-7,686,835 | 03/30/2010 | Warnick | |
| | | US-7,686,834 | 03/30/2010 | Saint Martin | |
| | | US-7,686,833 | 03/30/2010 | Muhanna, et al. | |
| | | US-7,682,377 | 03/23/2010 | Konieczynski, et al. | |
| | | US-7,678,139 | 03/16/2010 | Garamszegi, et al. | |
| | | US-7,678,136 | 03/16/2010 | Doubler, et al. | |
| | | US-7,674,277 | 03/09/2010 | Burd, et al. | |
| | | US-2010/0094353 | 04/15/2010 | Shim, et al. | |
| | | US-2010/0094352 | 04/15/2010 | Iott, et al. | |
| | | US-2010/0094349 | 04/15/2010 | Hammer, et al. | |
| | | US-2010/0094348 | 04/15/2010 | Biedermann, et al. | |
| | | US-2010/0094345 | 04/15/2010 | Saidha, et al. | |
| | | US-2010/0094343 | 04/15/2010 | Pham, et al. | |
| | | US-2010/0087865 | 04/08/2010 | Biedermann, et al. | |
| | | US-2010/0087861 | 04/08/2010 | Lechmann, et al. | |
| | | US-7,087,057 | 08/08/2006 | Konieczynski, et al. | |
| | | US-2006/0217716 | 09/28/2006 | Baker, et al. | |

| Examiner Signature | | Date Considered | |
|---|---|---|---|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[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.
This collection of information is required by 37 CFR 1.97 and 1.98. 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 2 hours 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, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, Washington, DC 20231.**

PTO/SB/08A (04-03)
Approved for use through 04/30/2003. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449/PTO

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

| Sheet | 43 | of | 50 |
|---|---|---|---|

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

**U. S. PATENT DOCUMENTS**

| Examiner Initials* | Cite No.[13] | Document Number<br>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-2009/0082819 | 03/26/2009 | Blain, et al. | |
| | | US-2009/0076552 | 03/19/2009 | Tornier | |
| | | US-2010/0069969 | 03/18/2010 | Ampuero, et al. | |
| | | US-2010/0069963 | 03/18/2010 | Eckman | |
| | | US-2010/0063551 | 03/11/2010 | Richelsoph | |
| | | US-2010/0063550 | 03/11/2010 | Felix, et al. | |
| | | US-2010/0063546 | 03/11/2010 | Miller, et al. | |
| | | US-2010/0063545 | 03/11/2010 | Richelsoph | |
| | | US-2010/0057126 | 03/04/2010 | Hestad | |
| | | US-2010/0057125 | 03/04/2010 | Viker | |
| | | US- | | | |
| | | US- | | | |
| | | US- | | | |

**FOREIGN PATENT DOCUMENTS**

| Examiner Initials | Cite No.[1] | Foreign Patent Document<br>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 | |
|---|---|---|---|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[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.
This collection of information is required by 37 CFR 1.97 and 1.98. 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 2 hours 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, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, Washington, DC 20231.**
*If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.*

PTO/SB/08A (04-03)
Approved for use through 04/30/2003. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

| 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 | 44 | of | 50 | Attorney Docket Number | 11,433 |

**U. S. PATENT DOCUMENTS**

| Examiner Initials* | Cite No.[7] | Document Number<br>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-7,819,902 | 10/26/10 | Abdelgany, et al. | |
| | | US-7,811,310 | 10/12/10 | Baker, et al. | |
| | | US-7,811,288 | 10/12/10 | Jones, et al. | |
| | | US-7,806,913 | 10/05/10 | Fanger, et al. | |
| | | US-7,794,480 | 09/14/10 | Gordon, et al. | |
| | | US-7,794,477 | 09/14/10 | Melkent, et al. | |
| | | US-7,789,900 | 09/07/10 | Levy, et al. | |
| | | US-7,785,354 | 08/31/10 | Biedermann, et al. | |
| | | US-7,785,351 | 08/31/10 | Gordon,e t al. | |
| | | US-7,780,706 | 08/24/10 | Marino, et al. | |
| | | US-7,766,945 | 08/03/10 | Nilsson, et al. | |
| | | US-7,766,944 | 08/03/10 | Metz-Stavenhagen | |
| | | US-7,766,946 | 08/03/10 | Bailly | |
| | | US-7,766,943 | 08/03/10 | Fallin, et al. | |
| | | US-7,763,057 | 07/27/10 | Abdelgany, et al. | |
| | | US-8,021,097 | 09/20/11 | Farris, et al. | |

**FOREIGN PATENT DOCUMENTS**

| Examiner Initials | Cite No.[1] | Foreign Patent Document<br>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 | |
|---|---|---|---|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[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.
This collection of information is required by 37 CFR 1.97 and 1.98. 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 2 hours 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, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, Washington, DC 20231.**
*If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.*

PTO/SB/08A (04-03)
Approved for use through 04/30/2003. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

| 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 | 45 | of | 50 | Attorney Docket Number | 11,433 |

**U. S. PATENT DOCUMENTS**

| Examiner Initials* | Cite No.[7] | Document Number<br>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-2010/0262196 | 10/14/10 | Barrus, et al. | |
| | | US-2010/0256682 | 10/07/10 | Fallin, et al. | |
| | | US-2010/0256681 | 10/07/10 | Hammer, et al. | |
| | | US-2010/0249856 | 09/30/10 | Iott, et al. | |
| | | US-2010/0249846 | 09/30/10 | Simonson | |
| | | US-2010/0241170 | 09/23/10 | Cammisa, et al. | |
| | | US-2010/0234891 | 09/16/10 | Freeman, et al. | |
| | | US-2010/0228293 | 09/09/10 | Courtney, et al. | |
| | | US-2010/0222822 | 09/02/10 | Farris, et al. | |
| | | US-2010/0204735 | 08/12/10 | Gephart, et al. | |
| | | US-2010/0198272 | 08/05/10 | Keyer, et al. | |
| | | US-2010/0198270 | 08/05/10 | Barker, et al. | |
| | | US-2010/0198269 | 08/05/10 | Taylor, et al. | |
| | | US-2010/0191290 | 07/29/10 | Felix | |
| | | US-2010/0185247 | 07/22/10 | Richelsoph | |
| | | US-7,572,279 | 08/11/2009 | Jackson | |
| | | US-7,186,255 | 03/06/2007 | Baynham, et al. | |
| | | US-2008/0154315 | 06/26/2008 | Jackson | |

**FOREIGN PATENT DOCUMENTS**

| Examiner Initials | Cite No.[1] | Foreign Patent Document<br>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 | |
|---|---|---|---|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[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.

This collection of information is required by 37 CFR 1.97 and 1.98. 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 2 hours 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, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, Washington, DC 20231.**
*If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.*

PTO/SB/08A (04-03)
Approved for use through 04/30/2003. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449/PTO

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 46 of 50

| *Complete if Known* | |
|---|---|
| Application Number | |
| Filing Date | |
| First Named Inventor | Roger P. Jackson |
| Art Unit | |
| Examiner Name | |
| 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-7,972,364 | 07/05/11 | Biedermann, et al. | |
| | | US-RE42,545 | 07/12/11 | Ralph, et al. | |
| | | US-7,985,242 | 07/26/11 | Forton, et al. | |
| | | US-7,985,248 | 07/26/11 | Walder, et al. | |
| | | US-7,988,694 | 08/02/11 | Barrus, et al. | |
| | | US-7,988,711 | 08/02/11 | Errickson, et al. | |
| | | US-RE42,626 | 08/16/11 | Taylor, et al. | |
| | | US-8,022,806 | 08/23/11 | Justis | |
| | | US-8,012,183 | 09/06/11 | Alain | |
| | | US-8,012,186 | 09/06/11 | Pham, et al. | |
| | | US-8,012,188 | 09/06/11 | Meltent, et al. | |
| | | US-8,016,862 | 09/13/11 | Felix, et al. | |
| | | US-8,016,866 | 09/13/11 | Warnick | |
| | | US-8,021,397 | 09/20/11 | Farris, et al. | |
| | | US-8,025,681 | 09/27/11 | Colleran, et al. | |
| | | US-8,029,539 | 01/04/11 | Kirschman | |
| | | 8,034,084 | 10/11/11 | Landry, et al. | |
| | | 8,043,340 | 10/25/11 | Law | |
| | | US-2011/0166606 | 07/07/11 | Stihl, et al. | |
| | | US-2011/0172715 | 07/14/11 | Pond, Jr., et al. | |

**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 | |
|---|---|---|---|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[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.

This collection of information is required by 37 CFR 1.97 and 1.98. 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 2 hours 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, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, Washington, DC 20231.**

PTO/SB/08A (04-03)
Approved for use through 04/30/2003. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449/PTO

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

| | | | | | |
|---|---|---|---|---|---|
| | 47 | of | 50 | | |

| *Complete if Known* | |
|---|---|
| Application Number | |
| Filing Date | |
| First Named Inventor | |
| Art Unit | |
| Examiner Name | |
| Attorney Docket Number | 11,433 |

**U. S. PATENT DOCUMENTS**

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

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[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.

This collection of information is required by 37 CFR 1.97 and 1.98. 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 2 hours 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, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, Washington, DC 20231.**

*If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.*

PTO/SB/08A (04-03)
Approved for use through 04/30/2003. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

| Substitute for form 1449/PTO<br>**INFORMATION DISCLOSURE STATEMENT BY APPLICANT**<br>(Use as many sheets as necessary) | | | | *Complete if Known* | |
|---|---|---|---|---|---|
| | | | | Application Number | |
| | | | | Filing Date | |
| | | | | 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<br>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. | |

**FOREIGN PATENT DOCUMENTS**

| Examiner Initials | Cite No.[1] | Foreign Patent Document<br>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 | | | |

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[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.
This collection of information is required by 37 CFR 1.97 and 1.98. 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 2 hours 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, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, Washington, DC 20231.**

PTO/SB/08A (04-03)
Approved for use through 04/30/2003. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

| 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 | 49 | of | 50 | Attorney Docket Number | 11,433 |

**U. S. PATENT DOCUMENTS**

| Examiner Initials* | Cite No.[7] | Document Number<br>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- | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |

**FOREIGN PATENT DOCUMENTS**

| Examiner Initials | Cite No.[1] | Foreign Patent Document<br>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 | |
|---|---|---|---|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[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.

This collection of information is required by 37 CFR 1.97 and 1.98. 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 2 hours 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, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, Washington, DC 20231.**

PTO/SB/08B (04-03)
Approved for use through 04/30/2003. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

| Substitute for form 1449/PTO | | | | *Complete if Known* | |
|---|---|---|---|---|---|
| **INFORMATION DISCLOSURE STATEMENT BY APPLICANT** (Use as many sheets as necessary) | | | | Application Number | |
| | | | | 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 | |

| Examiner Signature | | Date Considered | |
|---|---|---|---|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[1] Applicant's unique citation designation number (optional). [2] Applicant is to place a check mark here if English language Translation is attached.
This collection of information is required by 37 CFR 1.97 and 1.98. 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 2 hours 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, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, Washington, DC 20231.**
*If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.*

OPAP
JAN 10 2013
IAP11
PATENT & TRADEMARK OFFICE

PTO/AIA/01 (06-12)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

# 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.**

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

PTO/AIA/01 (06-12)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

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

Signature: _____

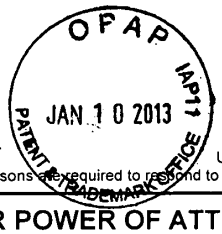
Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

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.**

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

Doc Code: PA..

Document Description: Power of Attorney




PTO/AIA/82A (07-12)
Approved for use through 11/30/2014. OMB 0651-0035
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

## TRANSMITTAL FOR POWER OF ATTORNEY TO ONE OR MORE REGISTERED PRACTITIONERS

NOTE: This form is to be submitted with the Power of Attorney by Applicant form (PTO/AIA/82B or equivalent) to identify the application to which the Power of Attorney is directed, in accordance with 37 CFR 1.5. If the Power of Attorney by Applicant form is not accompanied by this transmittal form or an equivalent, the Power of Attorney will not be recognized in the application.

| | |
|---|---|
| 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.

■ *Total of 3 forms are submitted.

This collection of information is required by 37 CFR 1.31, 1.32 and 1.33. 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 3 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.*

Doc Code: PA..

Document Description: Power of Attorney

PTO/AIA/82B(07-12)
Approved for use through 11/30/2014. OMB 0651-0035
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

OPAP JAN 10 2013 PATENT & TRADEMARK OFFICE JAP11

# POWER OF ATTORNEY BY APPLICANT

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):

27456

OR

☐ I hereby appoint Practitioner(s) named below 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):

| Name | Registration Number | Name | Registration Number |
|---|---|---|---|
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |

Please recognize or change the correspondence address for the application identified in the attached transmittal letter to:

☒ The address associated with the above-mentioned Customer Number.

OR

☐ 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 | | 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.

This collection of information is required by 37 CFR 1.31, 1.32 and 1.33. 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 3 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.*

OPAP JAN 10 2013 PATENT & TRADEMARK OFFICE

Doc Code: PA..

Document Description: Power of Attorney

PTO/AIA/82B(07-12)
Approved for use through 11/30/2014. OMB 0651-0035
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

# POWER OF ATTORNEY BY APPLICANT

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):

27456

OR

☐ I hereby appoint Practitioner(s) named below 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):

| Name | Registration Number | Name | Registration Number |
|---|---|---|---|
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |

Please recognize or change the correspondence address for the application identified in the attached transmittal letter to:

☒ The address associated with the above-mentioned Customer Number.

OR

☐ 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 | | | |

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.

This collection of information is required by 37 CFR 1.31, 1.32 and 1.33. 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 3 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.*

PATENT APPLICATION SERIAL NO._____

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE
FEE RECORD SHEET

01/14/2013 CNGUYEN2 00000032 13694849

| | | |
|---|---|---|
| 01 | FC:2011 | 195.00 OP |
| 02 | FC:2090 | 200.00 OP |
| 03 | FC:2111 | 310.00 OP |
| 04 | FC:2311 | 125.00 OP |
| 05 | FC:2201 | 125.00 OP |
| 06 | FC:2202 | 62.00 OP |

PTO-1556
(5/87)

*U.S. Government Printing Office: 2002- 489-267/69033

(19) Bundesrepublik Deutschland
Deutsches Patent- und Markenamt

(10) **DE 102 36 691 A1** 2004.02.26

(12) # Offenlegungsschrift

(21) Aktenzeichen: **102 36 691.8**
(22) Anmeldetag: **09.08.2002**
(43) Offenlegungstag: **26.02.2004**

(51) Int Cl.[7]: **A61B 17/70**

(71) Anmelder:
**Biedermann Motech GmbH, 78054 Villingen-Schwenningen, DE**

(74) Vertreter:
**Prüfer und Kollegen, 81545 München**

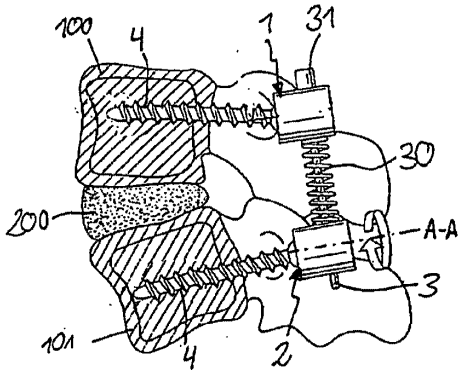
(72) Erfinder:
**Biedermann, Lutz, 78048 Villingen-Schwenningen, DE; Jeszensky, Dezsö, Dr., St. Gallen, CH**

Prüfungsantrag gemäß § 44 PatG ist gestellt.

**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.




Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 157 of 2152

## 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



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 158 of 2152

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-



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 159 of 2152

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.



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 160 of 2152

**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



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 161 of 2152

**Anhängende Zeichnungen**

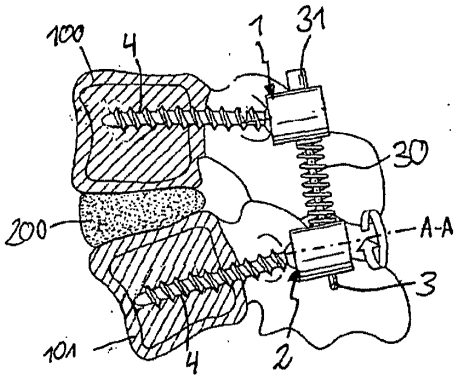



Fig.1

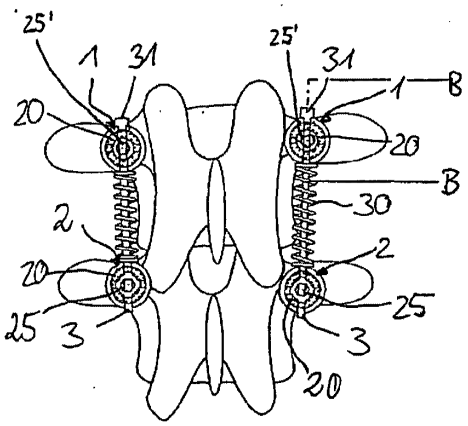



Fig.2

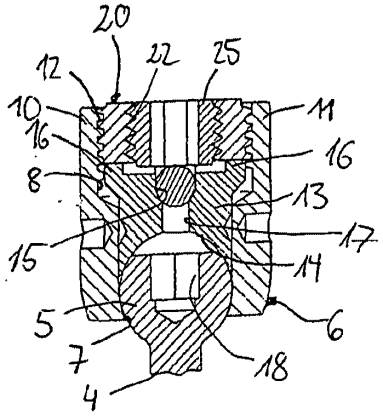



Fig.3

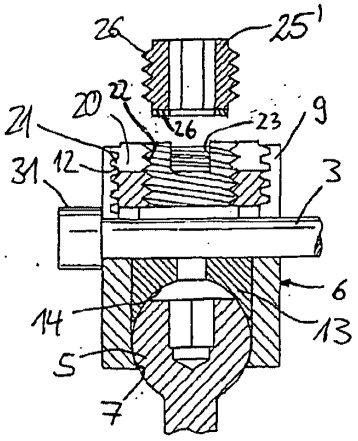



Fig.4



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 162 of 2152

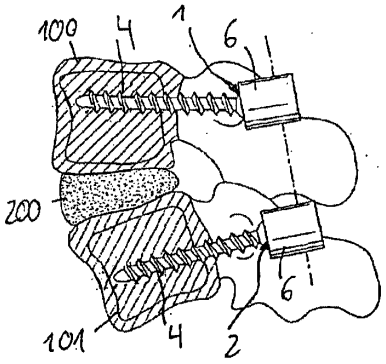



Fig.5

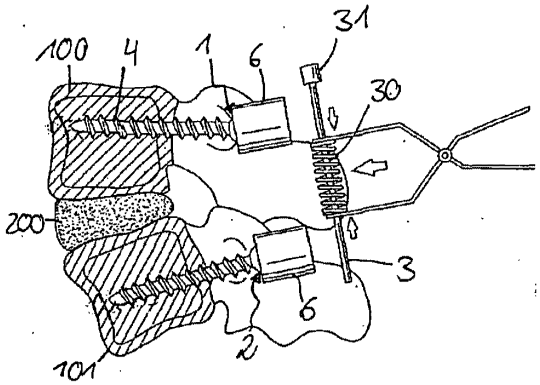



Fig.6

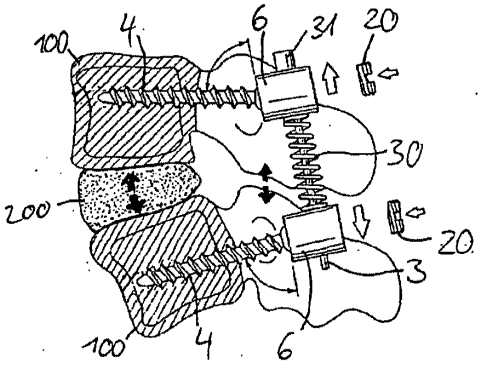



Fig.7

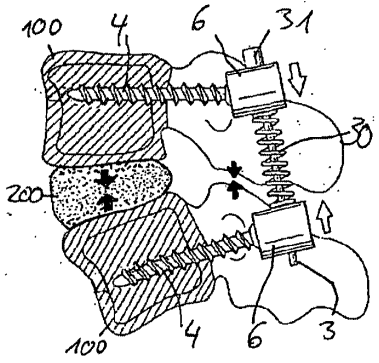



Fig.8



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 163 of 2152

(19) RÉPUBLIQUE FRANÇAISE

INSTITUT NATIONAL
DE LA PROPRIÉTÉ INDUSTRIELLE

PARIS

(11) N° de publication : **2 865 377**
(à n'utiliser que pour les commandes de reproduction)

(21) N° d'enregistrement national : **04 00747**

(51) Int Cl[7] : **A 61 B 17/70**

# (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 Société anonyme* — FR.

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

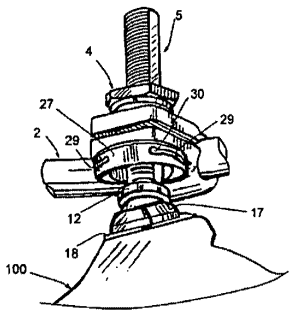
(73) **Titulaire(s) :**

(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 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.




FR 2 865 377 - A1

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 164 of 2152

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.

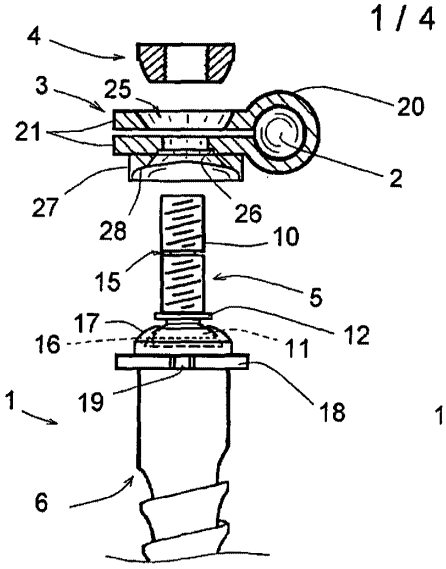



FIG. 1

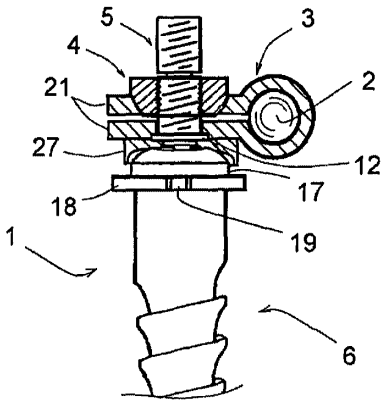



FIG. 2

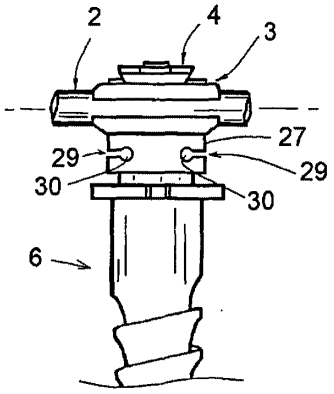



FIG. 3

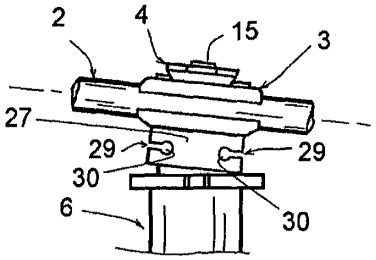



FIG. 4

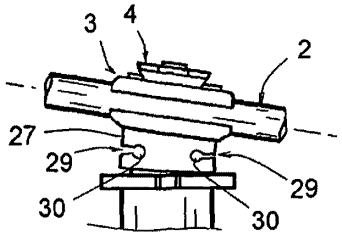



FIG. 5

FIG. 6

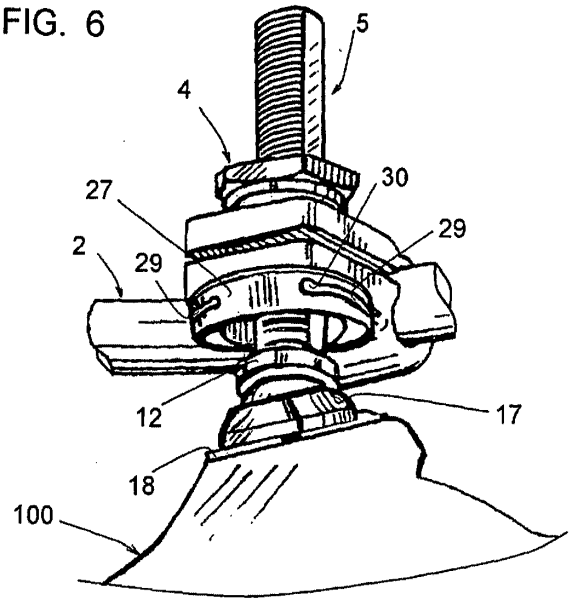
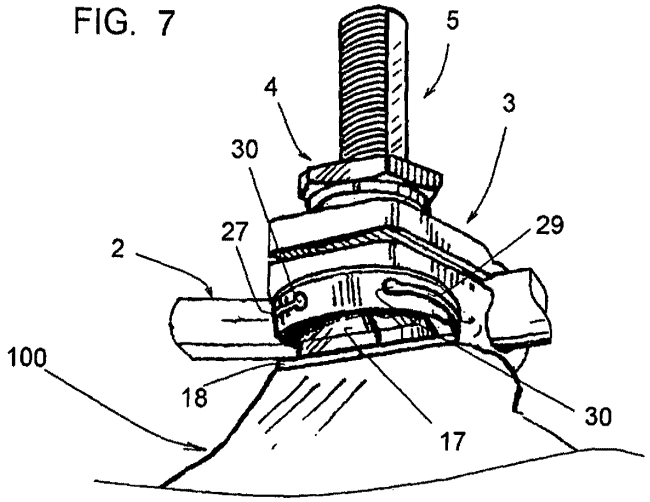



FIG. 7



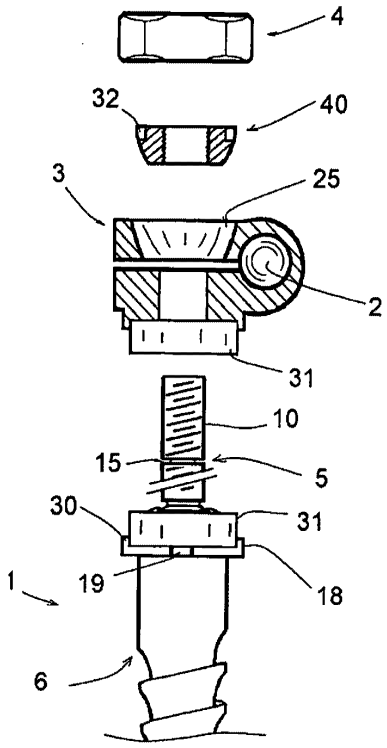



FIG. 8

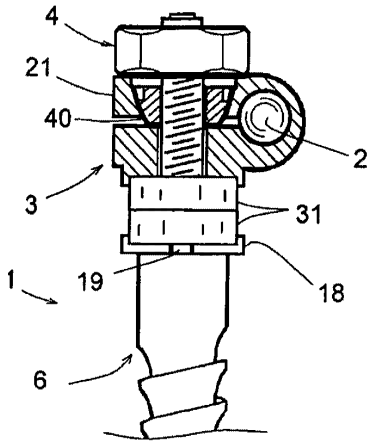



FIG. 9

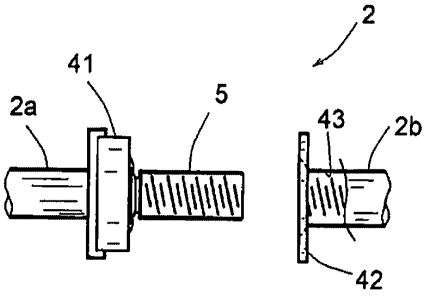



FIG. 10

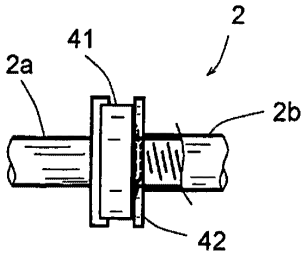



FIG. 11

FIG. 12

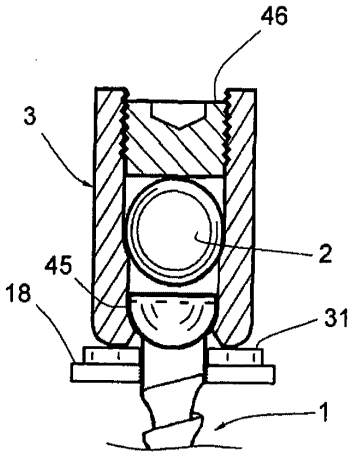
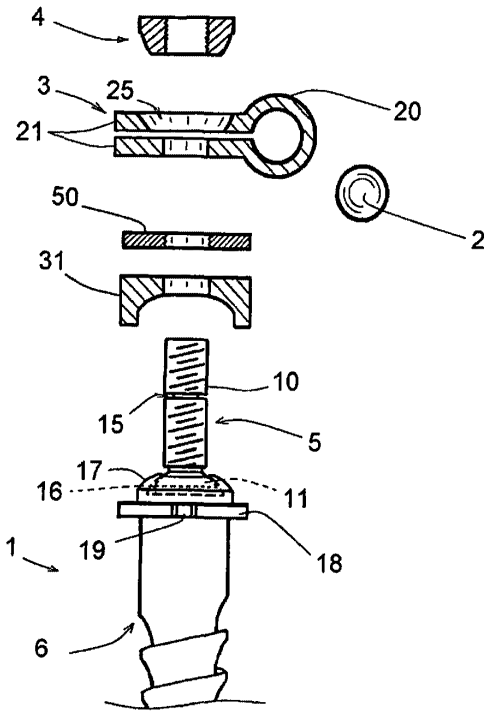



FIG. 13



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)<br>* colonne 3, ligne 6 - ligne 10; figures 1-3 *<br>* colonne 3, ligne 55 - colonne 44, ligne 15 *<br>----- | 1,3,4,7, 8 | A61B17/70 |
| Y | US 5 735 851 A (ERRICO J.P. ET AL)<br>7 avril 1998 (1998-04-07)<br>* figure 10a *<br>----- | 1,3,4,9 | |
| Y | FR 2 697 742 A (BIOMAT)<br>13 mai 1994 (1994-05-13)<br>* page 11, ligne 14 - page 12, ligne 9; figure 1 *<br>* page 8, ligne 22 - page 9, ligne 7 *<br>----- | 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 |
| | | | AT | 82484 T | 15-12-1992 |
| | | | 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 |
| | | | JP | 62277954 A | 02-12-1987 |
| | | | KR | 9506929 B1 | 26-06-1995 |
| | | | US | 4946458 A | 07-08-1990 |
| US 5735851 | A | 07-04-1998 | AU | 731811 B2 | 05-04-2001 |
| | | | AU | 4673197 A | 05-05-1998 |
| | | | CA | 2268152 A1 | 16-04-1998 |
| | | | EP | 0949887 A1 | 20-10-1999 |
| | | | JP | 2002515792 T | 28-05-2002 |
| | | | KR | 2000048988 A | 25-07-2000 |
| | | | WO | 9815233 A1 | 16-04-1998 |
| | | | US | 5800435 A | 01-09-1998 |
| FR 2697742 | A | 13-05-1994 | FR | 2697742 A1 | 13-05-1994 |
| | | | AT | 146064 T | 15-12-1996 |
| | | | CA | 2109457 A1 | 07-05-1994 |
| | | | DE | 69306536 D1 | 23-01-1997 |
| | | | DE | 69306536 T2 | 28-05-1997 |
| | | | EP | 0596788 A1 | 11-05-1994 |
| | | | ES | 2096249 T3 | 01-03-1997 |
| | | | GR | 3022754 T3 | 30-06-1997 |
| | | | JP | 2666683 B2 | 22-10-1997 |
| | | | JP | 6165789 A | 14-06-1994 |
| | | | 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
DE LA PROPRIÉTÉ INDUSTRIELLE

PARIS

(11) N° de publication : **2 865 375**
(à n'utiliser que pour les commandes de reproduction)

(21) N° d'enregistrement national : **04 00745**

(51) Int Cl[7] : **A 61 B 17/70**

# (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.

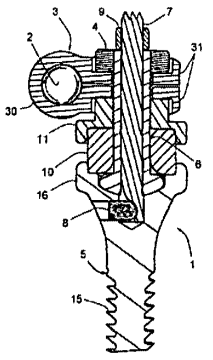
(73) **Titulaire(s)** :

(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).




FR 2 865 375 - A1

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 185 of 2152

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).

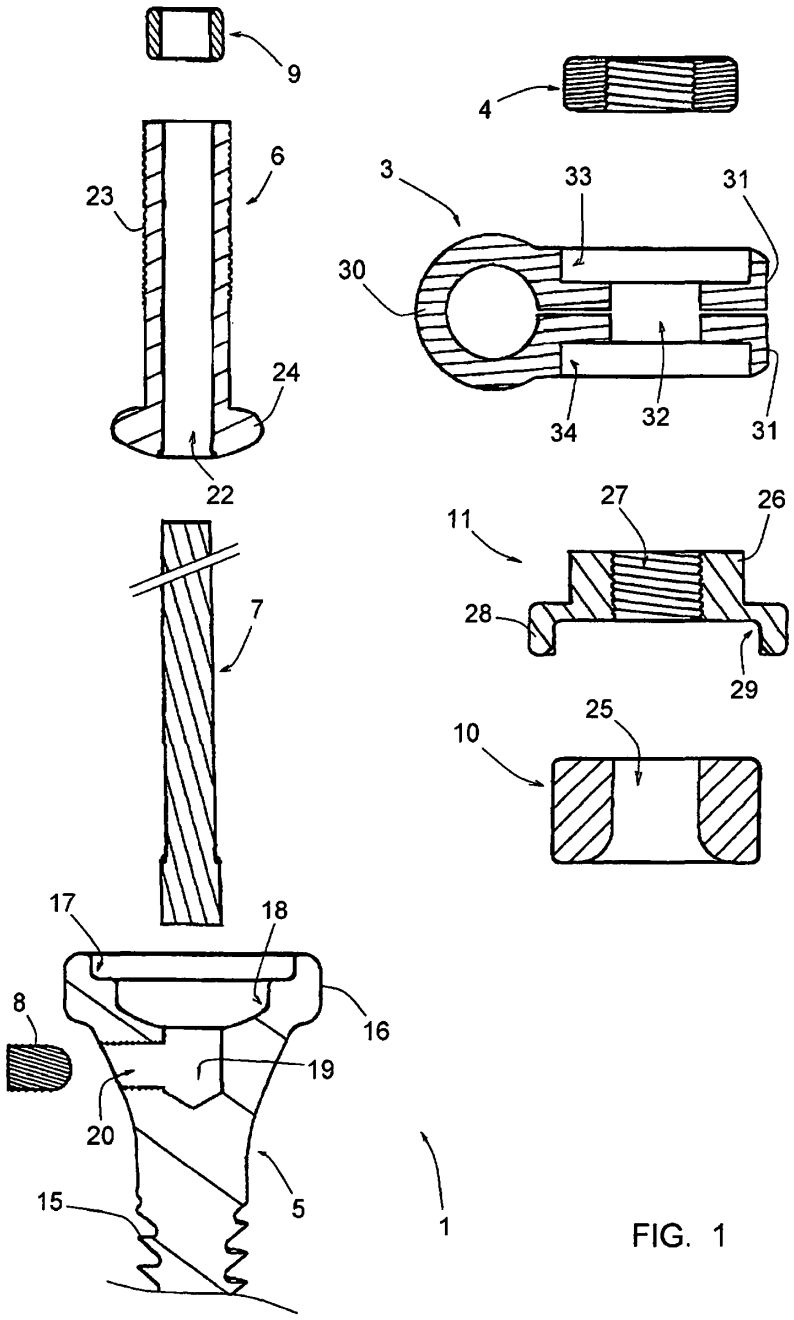
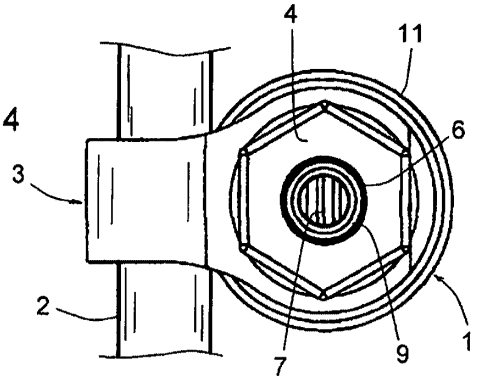

9
4
6
23
3
33
31
30
24
34
32
31
22
27
26
11
28
29
7
25
10
17
18
8
16
19
20
5
15
1

FIG. 1

FIG. 4



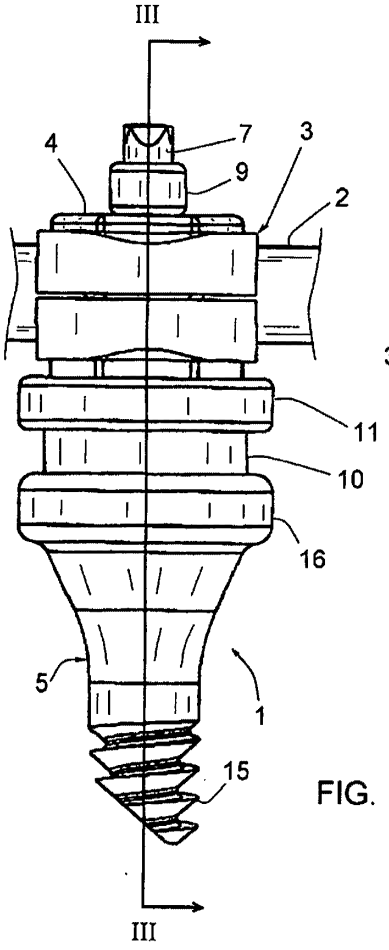




FIG. 2

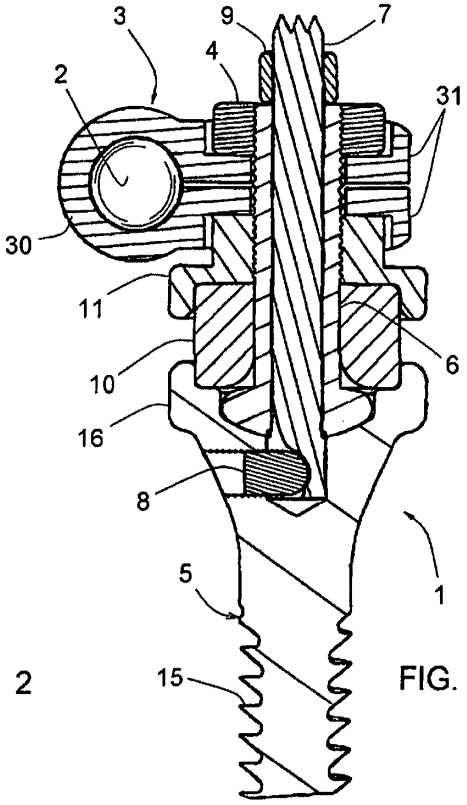



FIG. 3

RÉPUBLIQUE FRANÇAISE

2865375

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 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

EPO FORM 1503 12.99 (P04C14)

**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.
Les dits membres sont contenus au fichier informatique de l'Office européen des brevets à la date du 06-09-2004
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 5882350 | A | 16-03-1999 | US | 5669911 A | 23-09-1997 |
| | | | US | 5520690 A | 28-05-1996 |
| | | | US | RE37665 E1 | 16-04-2002 |
| | | | AT | 250393 T | 15-10-2003 |
| | | | AU | 714659 B2 | 06-01-2000 |
| | | | AU | 5539796 A | 30-10-1996 |
| | | | CA | 2216955 A1 | 17-10-1996 |
| | | | DE | 69630117 D1 | 30-10-2003 |
| | | | DE | 69630117 T2 | 09-06-2004 |
| | | | EP | 1364623 A1 | 26-11-2003 |
| | | | EP | 0828459 A1 | 18-03-1998 |
| | | | JP | 3497865 B2 | 16-02-2004 |
| | | | JP | 11503351 T | 26-03-1999 |
| | | | US | 2002045899 A1 | 18-04-2002 |
| | | | WO | 9632071 A1 | 17-10-1996 |
| | | | US | 5531746 A | 02-07-1996 |
| | | | US | 5643265 A | 01-07-1997 |
| | | | US | 5647873 A | 15-07-1997 |
| | | | US | 5607426 A | 04-03-1997 |
| | | | US | 5876402 A | 02-03-1999 |
| | | | US | 5725588 A | 10-03-1998 |
| | | | US | 5690630 A | 25-11-1997 |
| | | | US | 5817094 A | 06-10-1998 |
| WO 0015125 | A | 23-03-2000 | AU | 751174 B2 | 08-08-2002 |
| | | | AU | 5404799 A | 03-04-2000 |
| | | | CA | 2343327 A1 | 23-03-2000 |
| | | | WO | 0015125 A1 | 23-03-2000 |
| | | | EP | 1109502 A1 | 27-06-2001 |
| | | | JP | 2002524188 T | 06-08-2002 |
| | | | US | 6187005 B1 | 13-02-2001 |
| | | | ZA | 200100673 A | 28-08-2001 |
| WO 03068088 | A | 21-08-2003 | US | 2004006342 A1 | 08-01-2004 |
| | | | US | 2003163133 A1 | 28-08-2003 |
| | | | WO | 03068088 A1 | 21-08-2003 |
| FR 2735011 | A | 13-12-1996 | FR | 2735011 A1 | 13-12-1996 |

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
DE LA PROPRIÉTÉ INDUSTRIELLE

PARIS

(11) N° de publication : **2 865 373**
(à n'utiliser que pour les commandes de reproduction)

(21) N° d'enregistrement national : **04 00743**

(51) Int Cl[7] : **A 61 B 17/70**

# (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.

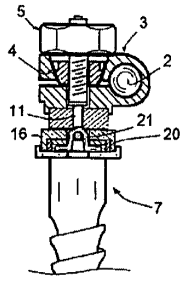
(73) **Titulaire(s) :**

(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.




FR 2 865 373 - A1

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 200 of 2152

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.

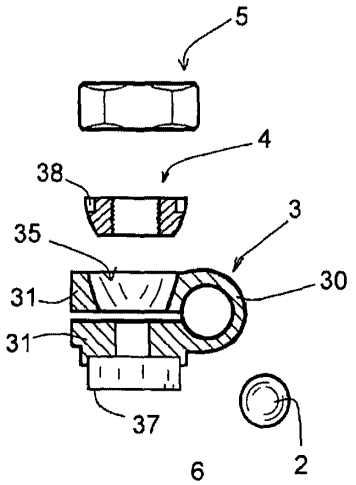
6 – Matériel selon la revendication 4 ou la revendication 5, caractérisé en ce que ladite pièce intermédiaire est conformée de manière à être retenue entre les deux parties transversales rigides grâce à la forme que présentent ces parties transversales rigides.

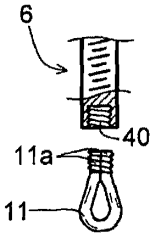
7 – Matériel selon l'une des revendications 1 à 6, caractérisé en ce que ledit organe d'ancrage (1) de type "polyaxial" comprend au moins une pièce (16, 37) ou une partie de pièce à structure élastiquement déformable, placée, après montage, entre ladite pièce de connexion (6, 3) et ladite pièce de base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

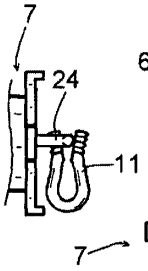
8 – Matériel selon la revendication 7, caractérisé en ce que ladite pièce de base (7) comprend une pièce (16) à structure élastiquement déformable et ladite pièce de connexion (3) comporte une autre pièce (37) à structure élastiquement déformable, ces deux pièces (16, 37) venant porter l'une contre l'autre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



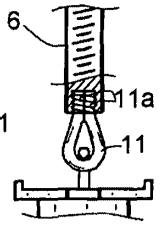
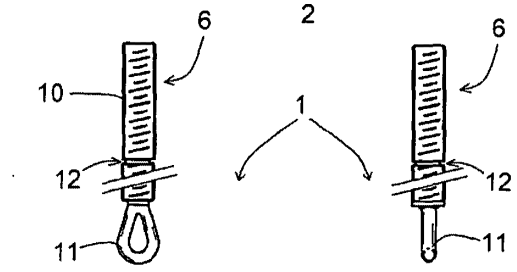
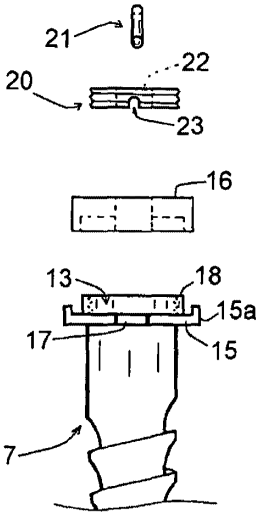
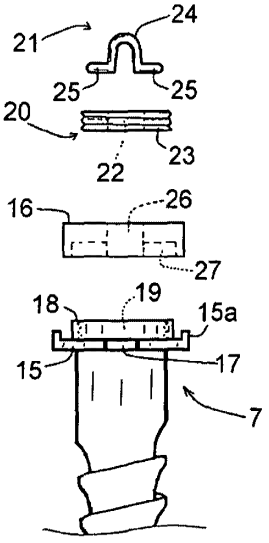




FIG. 4 FIG. 5 FIG. 6



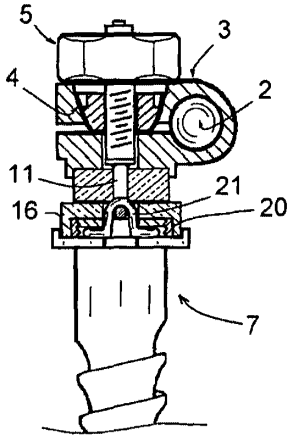




FIG. 1 FIG. 2 FIG. 3

RÉPUBLIQUE FRANÇAISE

2865373

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 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 | |
| A | FR 2 735 011 A (MECANURGIE SA SOC) 13 décembre 1996 (1996-12-13) * abrégé; figure 1 * | 1,7,8 | |
| 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
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

2

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 |
| | | | EP | 1257218 A1 | 20-11-2002 |
| | | | JP | 2003522589 T | 29-07-2003 |
| | | | WO | 0160271 A1 | 23-08-2001 |
| | | | US | 2001034521 A1 | 25-10-2001 |
| FR 2735011 | A | 13-12-1996 | FR | 2735011 A1 | 13-12-1996 |
| EP 0582857 | A | 16-02-1994 | CA | 2103775 A1 | 13-02-1994 |
| | | | DE | 59305375 D1 | 20-03-1997 |
| | | | EP | 0582857 A1 | 16-02-1994 |
| | | | ES | 2099326 T3 | 16-05-1997 |
| | | | JP | 2579884 B2 | 12-02-1997 |
| | | | JP | 6154258 A | 03-06-1994 |
| | | | US | 6325802 B1 | 04-12-2001 |
| | | | US | 2001034522 A1 | 25-10-2001 |

EPO FORM P0465

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

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
21 August 2003 (21.08.2003)

PCT

(10) International Publication Number
WO 03/068088 A1

(51) International Patent Classification[7]: A61B 17/70

(21) International Application Number: PCT/US03/04040

(22) International Filing Date: 11 February 2003 (11.02.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

| | | |
|---|---|---|
| 60/356,996 | 13 February 2002 (13.02.2002) | US |
| 10/360,145 | 7 February 2003 (07.02.2003) | US |
| 10/361,195 | 7 February 2003 (07.02.2003) | US |

(71) Applicant: **CROSS MEDICAL PRODUCTS, INC.** [US/US]; 181 Technology Drive, Irvine, CA 92618 (US).

(72) Inventors: **ALTARAC, Moti**; 89 Velissimo Drive, Aliso Viejo, CA 92656 (US). **MELLINGER, Philip, A.**; 83 Danwood, Ladera Ranch, CA 92694 (US).

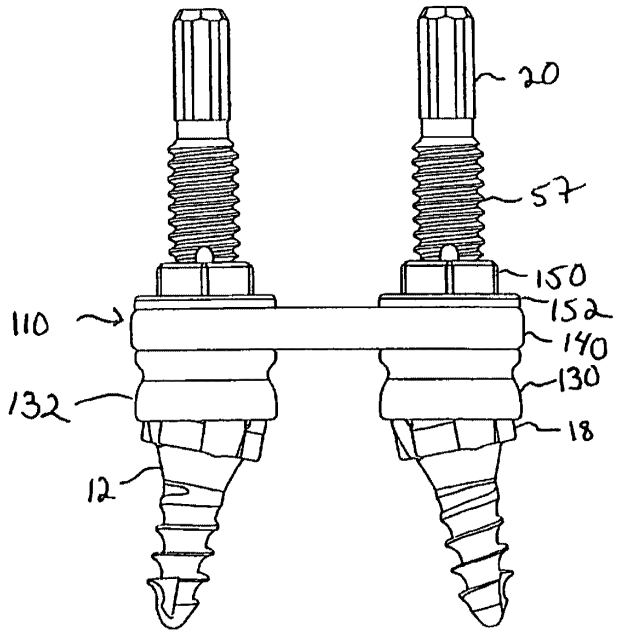
(74) Agents: **SHUNK, Laura, F.** et al.; HUDAK SHUNK & FARINE CO. LPA, Suite 307, 2020 Front Street, Cuyahoga Falls, OH 44221 (US).

(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZM, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

*[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.

WO 03/068088 A1

**Published:**
— *with international search report*

*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

# 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.

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.

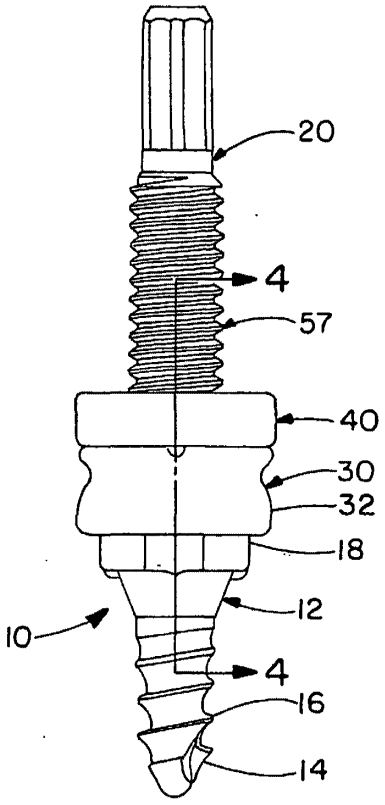

20
4
57
40
30
32
18
12
10
4
16
14

FIG.-1

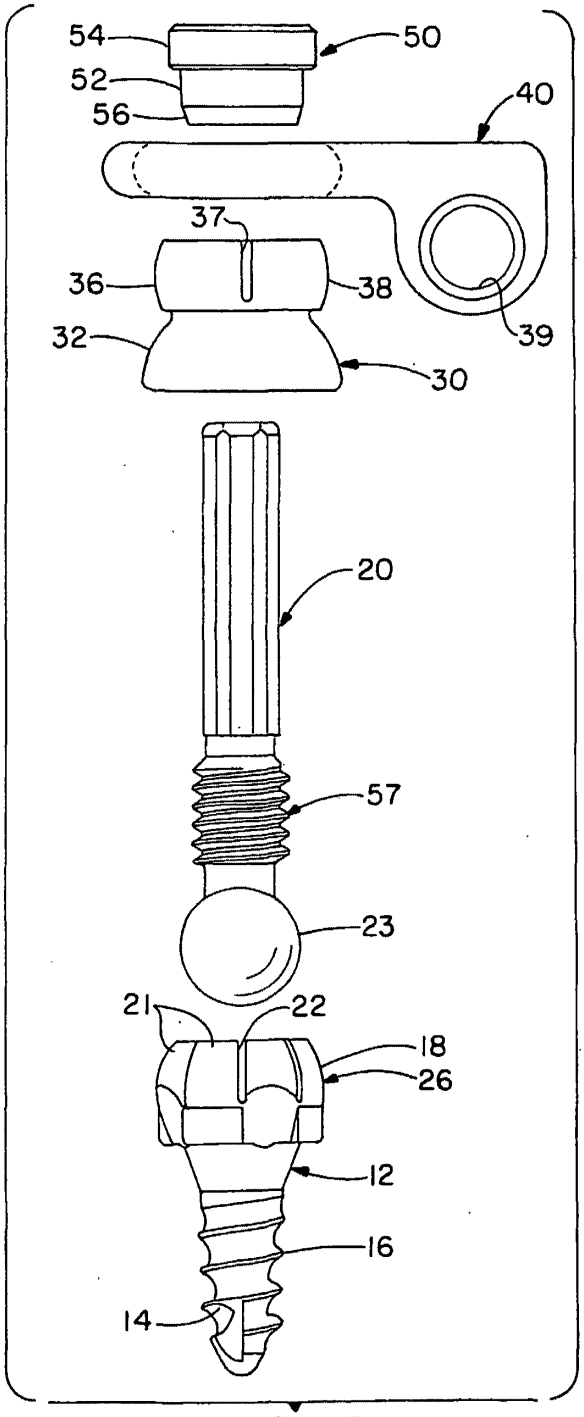
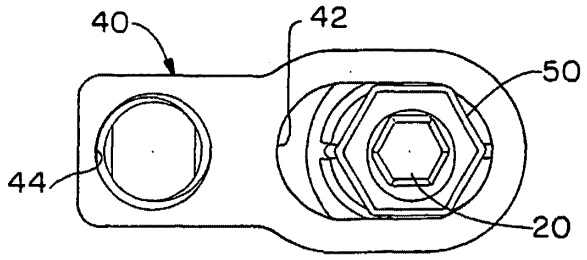

54
50
52
40
56
37
36
38
39
32
30
20
57
23
21
22
18
26
12
16
14

FIG.-2

FIG.-3



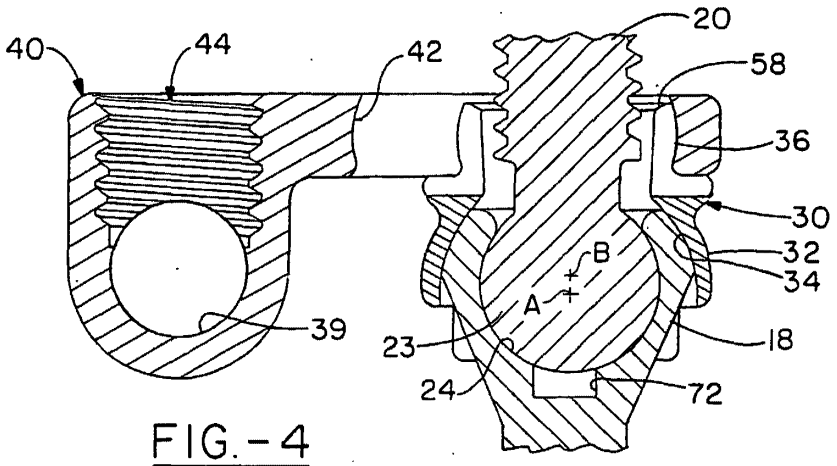




FIG.-4

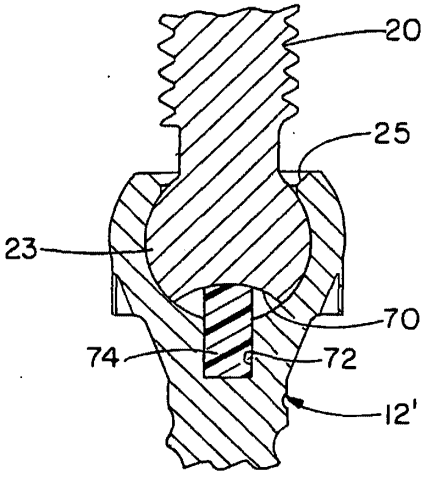



FIG.-5

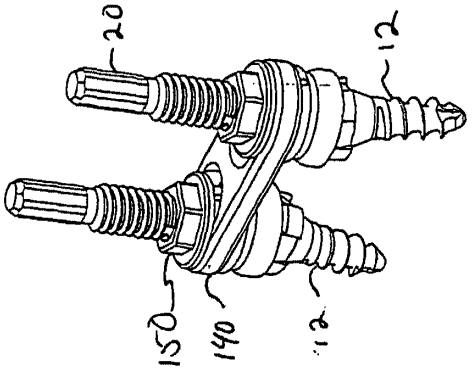



FIG 6

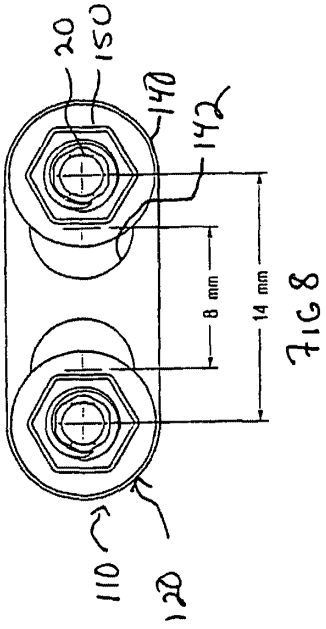



FIG 8

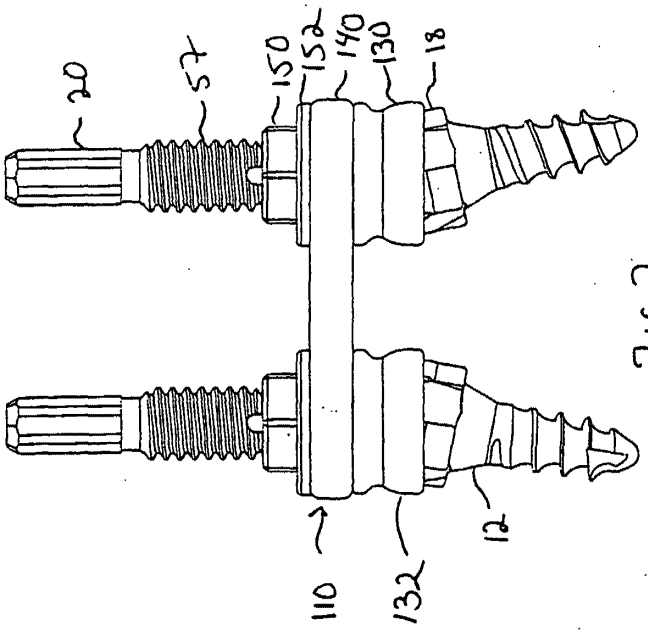



FIG 7

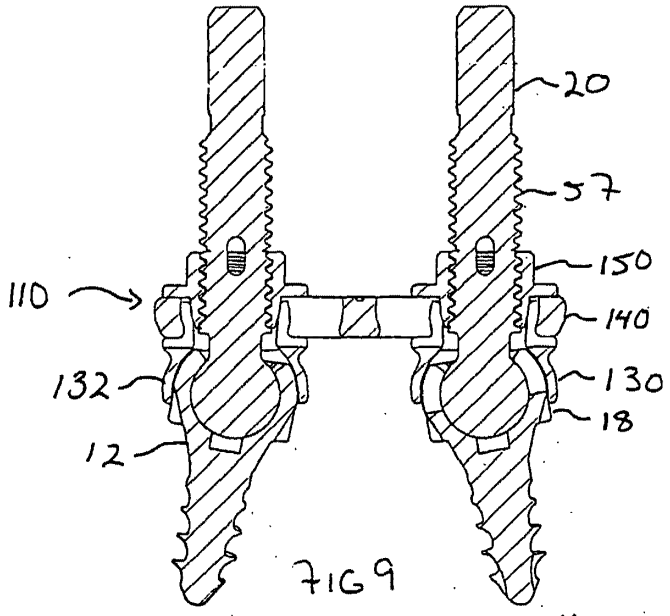



FIG 9

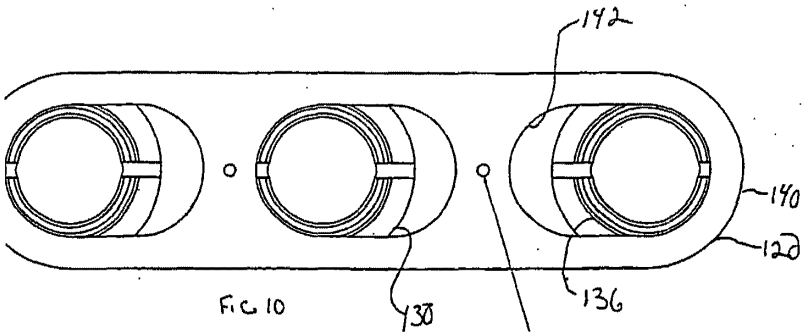



FIG 10

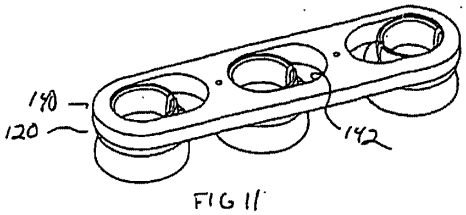



FIG 11

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

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

'E' earlier document but published on or after the international filing date

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

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

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

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

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

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

'&' document member of the same patent family

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

| Name and mailing address of the ISA | Authorized officer |
|---|---|
| European Patent Office, P.B. 5818 Patentlaan 2<br>NL - 2280 HV Rijswijk<br>Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,<br>Fax: (+31-70) 340-3016 | Macaire, S |

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

INTERNATIONAL SEARCH REPORT

Int. ...nal 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 |
|---|---|---|---|
| US 6050997 A | 18-04-2000 | CA 2361117 A1 | 27-07-2000 |
| | | EP 1152705 A1 | 14-11-2001 |
| | | WO 0042930 A1 | 27-07-2000 |
| EP 1090595 A | 11-04-2001 | US 6554834 B1 | 29-04-2003 |
| | | AU 5947900 A | 12-04-2001 |
| | | CA 2321803 A1 | 07-04-2001 |
| | | EP 1090595 A2 | 11-04-2001 |
| | | JP 2001140919 A | 22-05-2001 |
| DE 19807827 A | 26-11-1998 | DE 19807827 A1 | 26-11-1998 |
| | | EP 0861636 A2 | 02-09-1998 |
| WO 0015125 A | 23-03-2000 | AU 751174 B2 | 08-08-2002 |
| | | AU 5404799 A | 03-04-2000 |
| | | CA 2343327 A1 | 23-03-2000 |
| | | WO 0015125 A1 | 23-03-2000 |
| | | EP 1109502 A1 | 27-06-2001 |
| | | JP 2002524188 T | 06-08-2002 |
| | | US 6187005 B1 | 13-02-2001 |
| WO 0122893 A | 05-04-2001 | AU 1493301 A | 30-04-2001 |
| | | WO 0122893 A1 | 05-04-2001 |
| | | US 2001001119 A1 | 10-05-2001 |

Form PCT/ISA/210 (patent family annex) (July 1992)

(19) RÉPUBLIQUE FRANÇAISE

INSTITUT NATIONAL
DE LA PROPRIÉTÉ INDUSTRIELLE

PARIS

(11) N° de publication : **2 856 578**
(à n'utiliser que pour les commandes de reproduction)

(21) N° d'enregistrement national : **03 07776**

(51) Int Cl⁷ : **A 61 B 17/70**

# (12) DEMANDE DE BREVET D'INVENTION A1

(22) **Date de dépôt :** 27.06.03.

(30) **Priorité :**

(43) **Date de mise à la disposition du public de la demande :** 31.12.04 Bulletin 04/53.

(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.

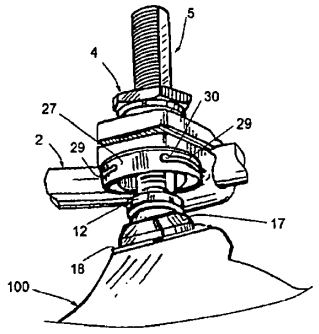
(73) **Titulaire(s) :**

(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 "poly-axial".

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.




FR 2 856 578 - A1

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 234 of 2152

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.

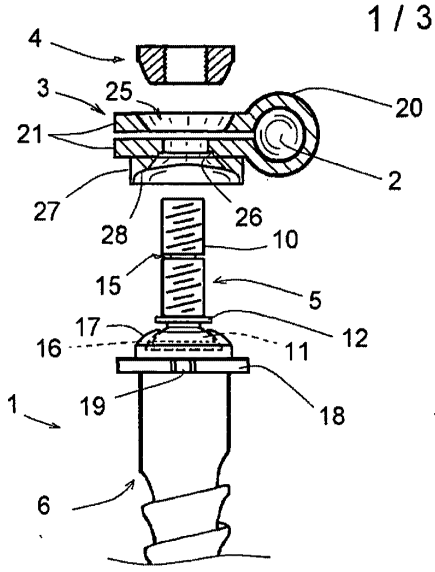



FIG. 1

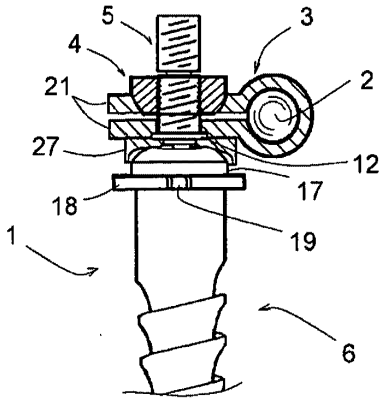



FIG. 2

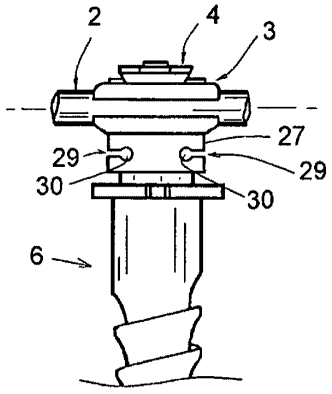



FIG. 3

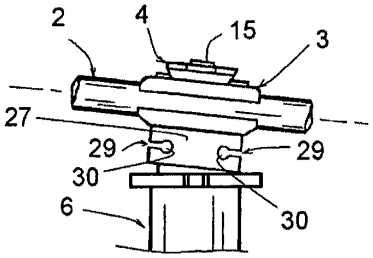



FIG. 4

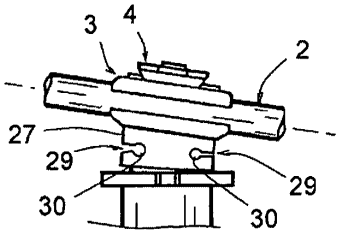



FIG. 5

FIG. 6

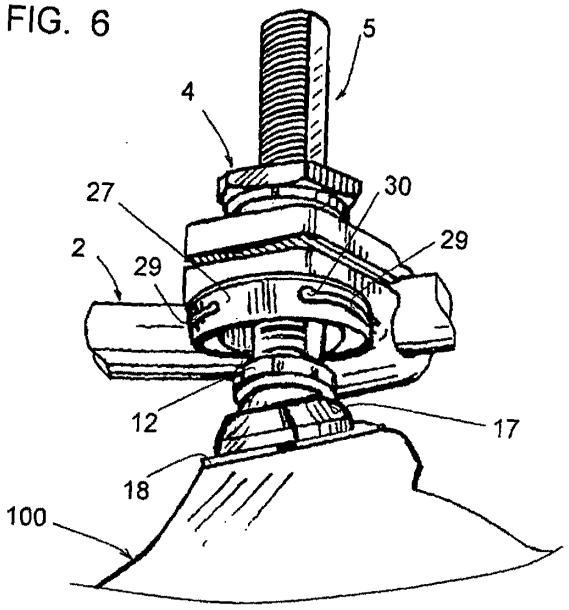
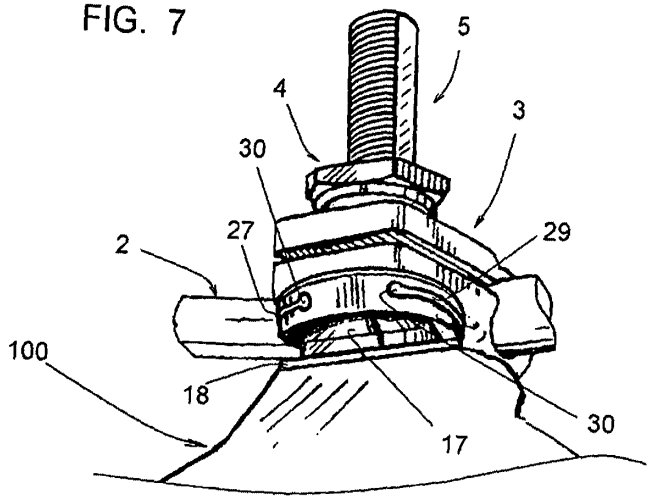



FIG. 7



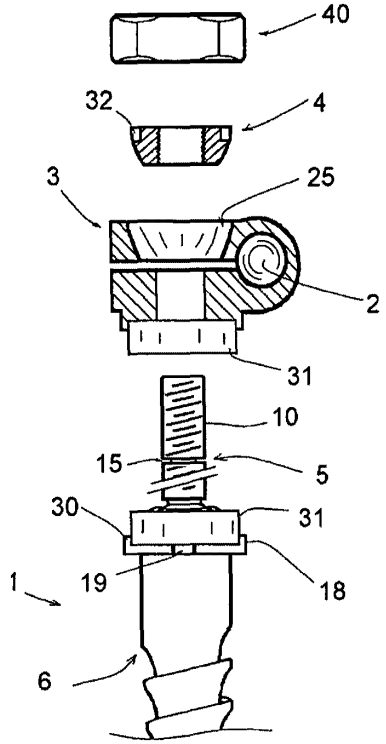



FIG. 8

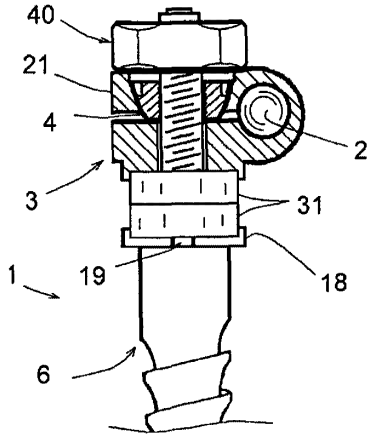



FIG. 9

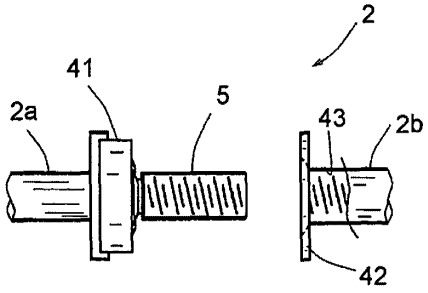



FIG. 10

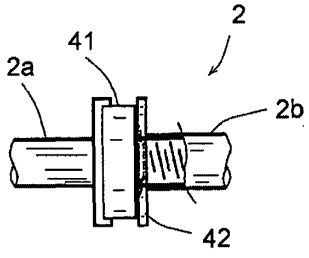



FIG. 11

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 |
| Y | US 5 735 851 A (ERRICO J.P. ET AL) 7 avril 1998 (1998-04-07) * figure 10a * | 1,2,10 | |
| 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 : particullèrement 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

4

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 |
|---|---|---|---|---|---|
| EP 0242708 | A | 28-10-1987 | DE | 3614101 C1 | 22-10-1987 |
| | | | AT | 82484 T | 15-12-1992 |
| | | | 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 |
| | | | JP | 62277954 A | 02-12-1987 |
| | | | KR | 9506929 B1 | 26-06-1995 |
| | | | US | 4946458 A | 07-08-1990 |
| US 5735851 | A | 07-04-1998 | AU | 731811 B2 | 05-04-2001 |
| | | | AU | 4673197 A | 05-05-1998 |
| | | | CA | 2268152 A1 | 16-04-1998 |
| | | | EP | 0949887 A1 | 20-10-1999 |
| | | | JP | 2002515792 T | 28-05-2002 |
| | | | KR | 2000048988 A | 25-07-2000 |
| | | | WO | 9815233 A1 | 16-04-1998 |
| | | | US | 5800435 A | 01-09-1998 |
| FR 2697742 | A | 13-05-1994 | FR | 2697742 A1 | 13-05-1994 |
| | | | AT | 146064 T | 15-12-1996 |
| | | | CA | 2109457 A1 | 07-05-1994 |
| | | | DE | 69306536 D1 | 23-01-1997 |
| | | | DE | 69306536 T2 | 28-05-1997 |
| | | | EP | 0596788 A1 | 11-05-1994 |
| | | | ES | 2096249 T3 | 01-03-1997 |
| | | | GR | 3022754 T3 | 30-06-1997 |
| | | | JP | 2666683 B2 | 22-10-1997 |
| | | | JP | 6165789 A | 14-06-1994 |
| | | | 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

(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

(71) Applicant(s)
Dilip Kumar Sengupta
101 Delaunays Road, Crumpsall,
MANCHESTER, M8 4RE, United Kingdom

(72) Inventor(s)
Dilip Kumar Sengupta

(74) Agent and/or Address for Service
Forrester Ketley & Co
Chamberlain House, Paradise Place,
BIRMINGHAM, B3 3HP, United Kingdom

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

(52) UK CL (Edition V )
A5R RX7

(56) Documents Cited
GB 2269753 A
EP 0669109 A
WO 2002/102259 A2
WO 2001/045576 A1
US 5733284 A
US 5423816 A
US 5180393 A

(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.

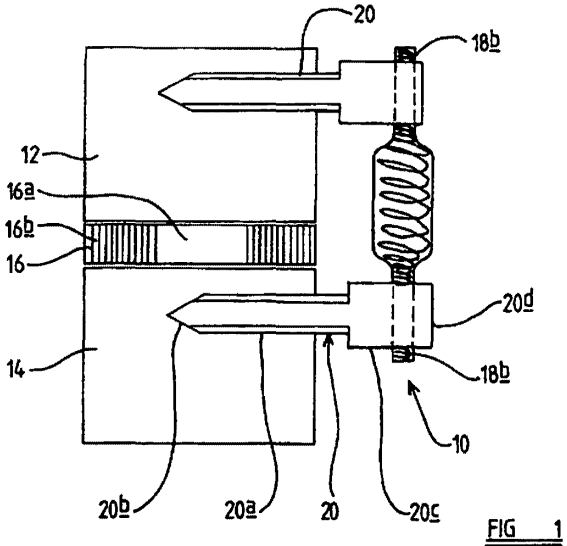



FIG 1

GB 2 382 304 A

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 253 of 2152

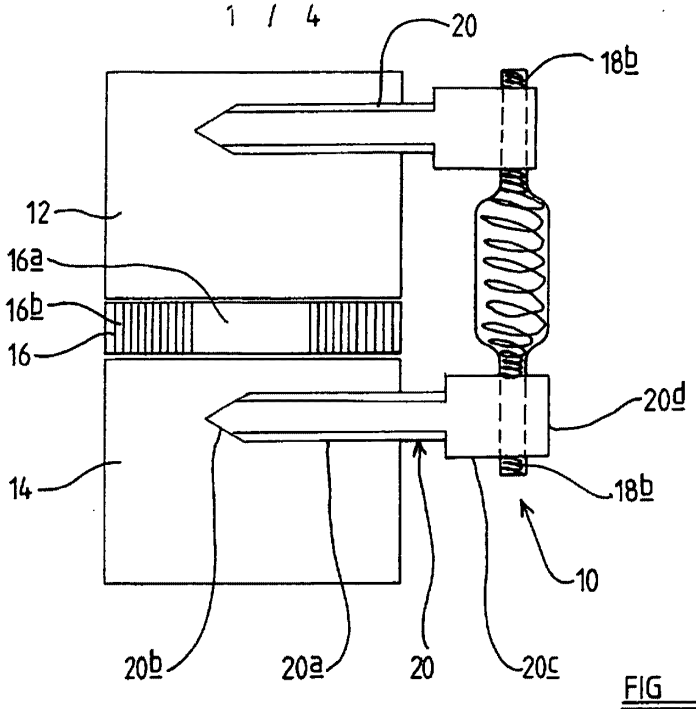



FIG 1

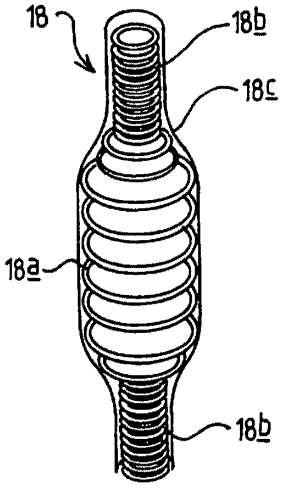



FIG 2a

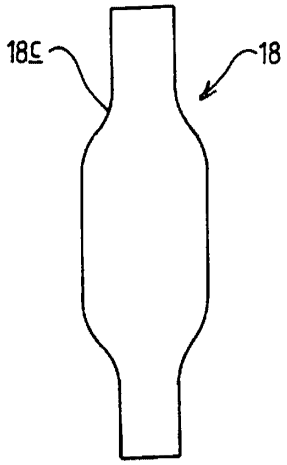



FIG 2b

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 254 of 2152

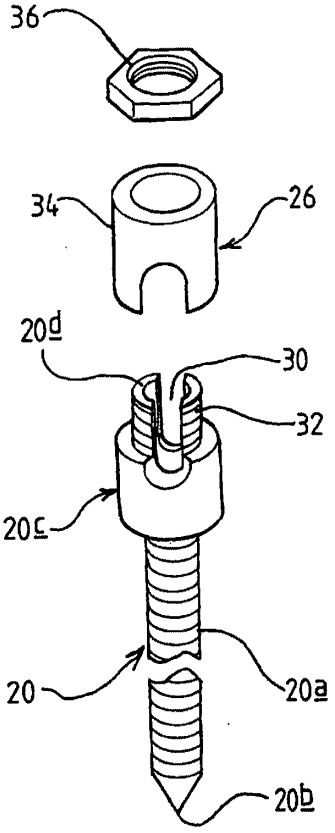



FIG 3a

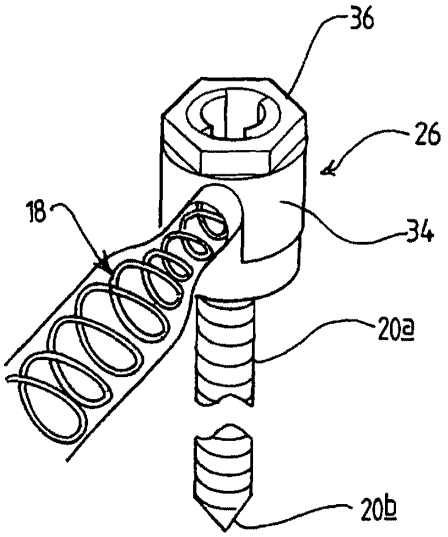



FIG 3b

FIG 4a

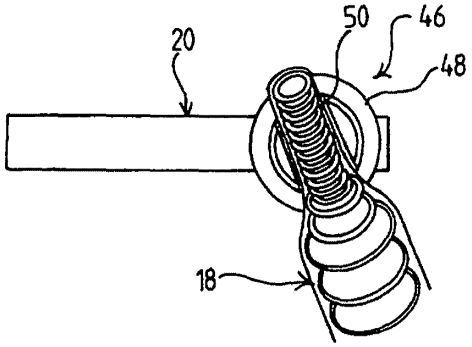
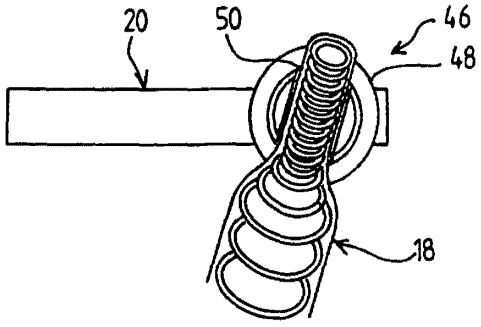



FIG 4b




Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 255 of 2152

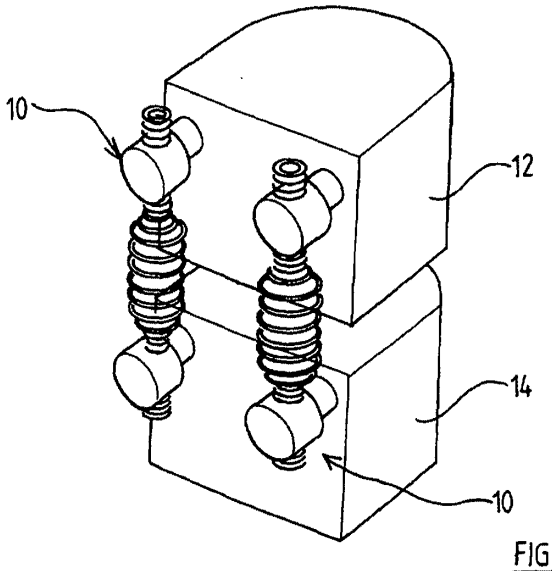



FIG 5

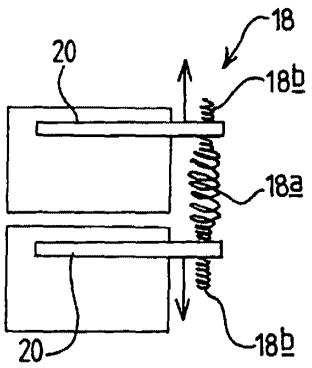



FIG 6a

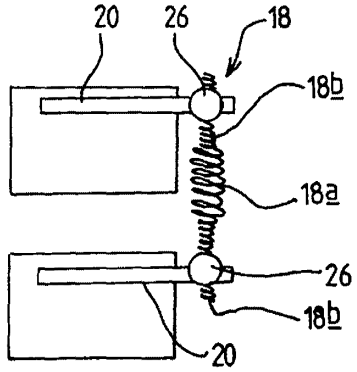



FIG 6b

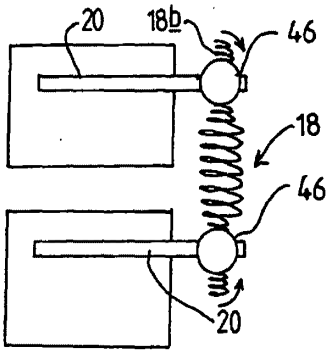



FIG 7a

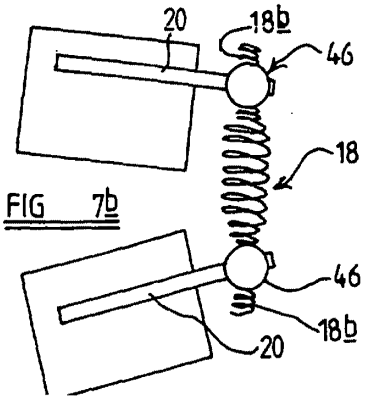



FIG 7b

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 256 of 2152

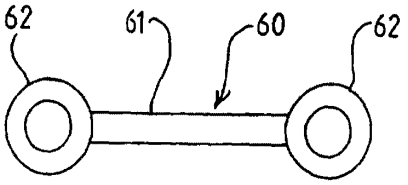



FIG 8a

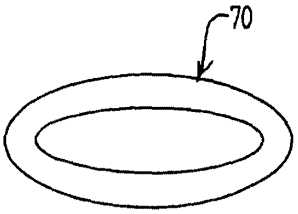



FIG 8b

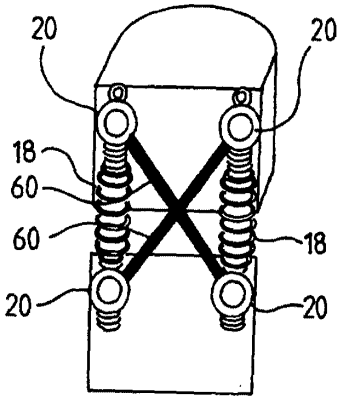



FIG 9

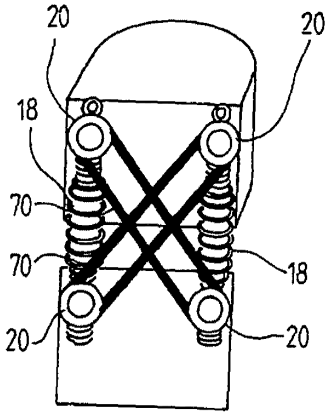



FIG 10

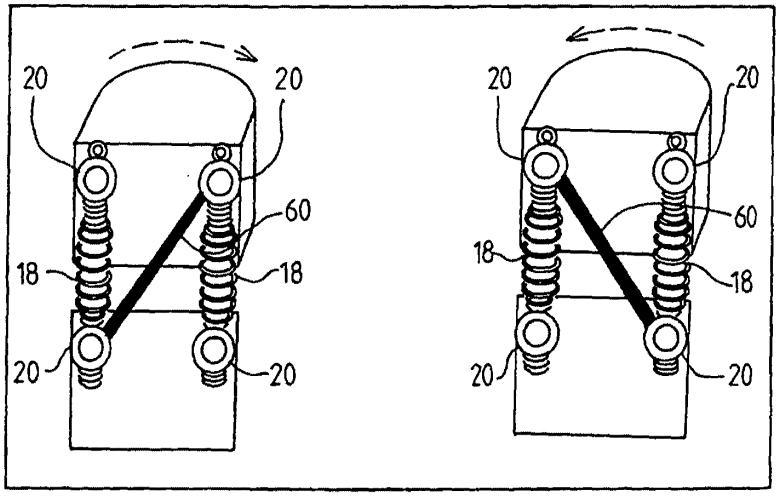



FIG 11

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 260 of 2152

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;

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.

The Patent Office
PATENTS • DESIGNS • COPYRIGHT • TRADE MARKS
INVESTOR IN PEOPLE

| | | | |
|---|---|---|---|
| **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 |

Categories:

| | | | |
|---|---|---|---|
| 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. |
| & | Member of the same patent family | E | Patent document published on or after, but with priority date earlier than, the filing date of this application. |

**Field of Search:**

Search of GB, EP, WO & US patent documents classified in the following areas of the UKC[V]:

A5R

Worldwide search of patent documents classified in the following areas of the IPC[7]:

A61B

The following online and other databases have been used in the preparation of this search report:

EPODOC, WPI, PAJ

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
3 April 2003 (03.04.2003)

PCT

(10) International Publication Number
WO 03/026523 A1

(51) International Patent Classification[7]: A61B 17/70

(21) International Application Number: PCT/US02/31201

(22) International Filing Date:
30 September 2002 (30.09.2002)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/325,809 28 September 2001 (28.09.2001) US

(71) Applicant and
(72) Inventor: **RITLAND, Stephen** [US/US]; 1150 N. San Francisco Street, Flagstaff, AZ 86001 (US).

(74) Agents: **YASKANIN, Mark, L.** et al.; Sheridan Ross P.C., Suite 1200, 1560 Broadway, Denver, CO 80202-5141 (US).

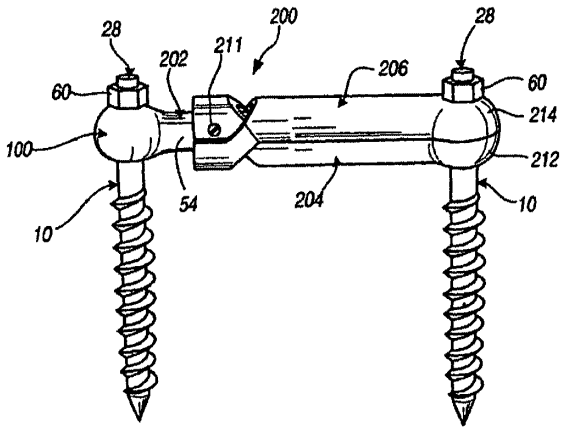
(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

**Published:**
— *with international search report*
— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

(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

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

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 276 of 2152

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.

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 278 of 2152

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

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 281 of 2152

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;

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;

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;

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 284 of 2152

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 287 of 2152

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.

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.

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

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.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 293 of 2152

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

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 296 of 2152

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

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

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 301 of 2152

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 304 of 2152

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 307 of 2152

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.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 308 of 2152

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.

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

(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.

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.

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.

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 317 of 2152

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:

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.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 319 of 2152

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.

5

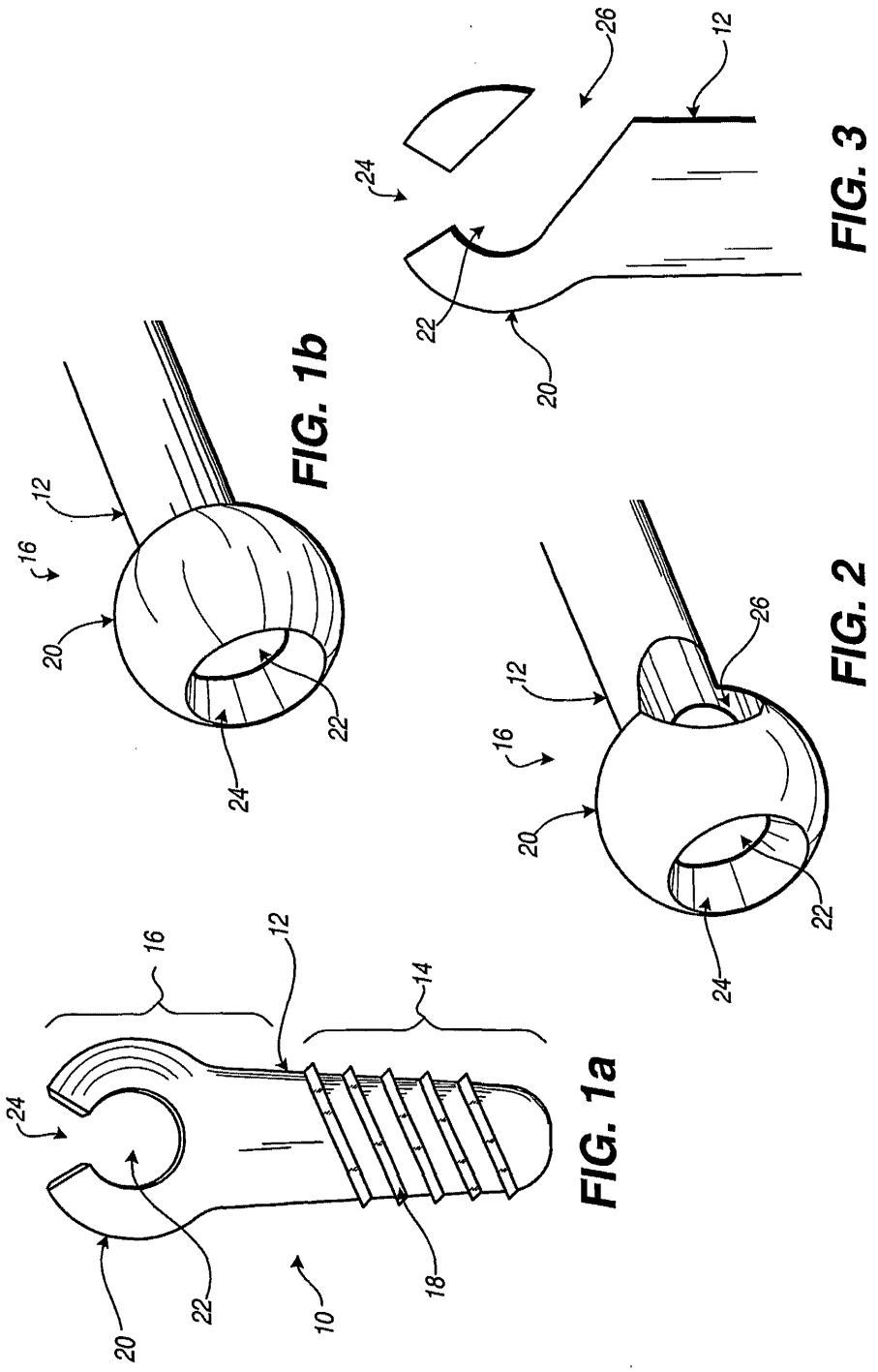



FIG. 1a




FIG. 1b




FIG. 3




FIG. 2

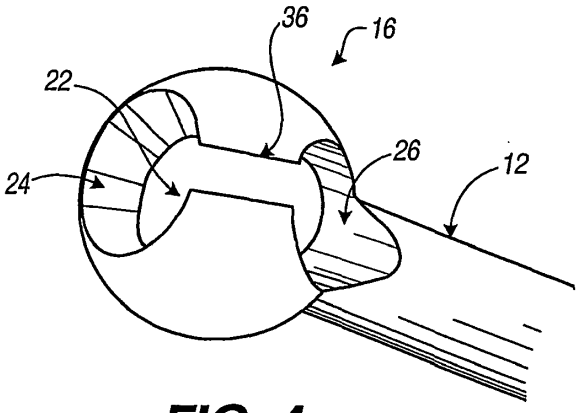



FIG. 4

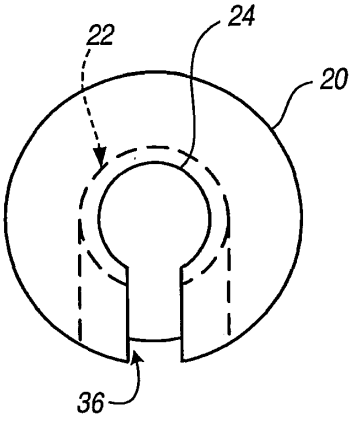



FIG. 5

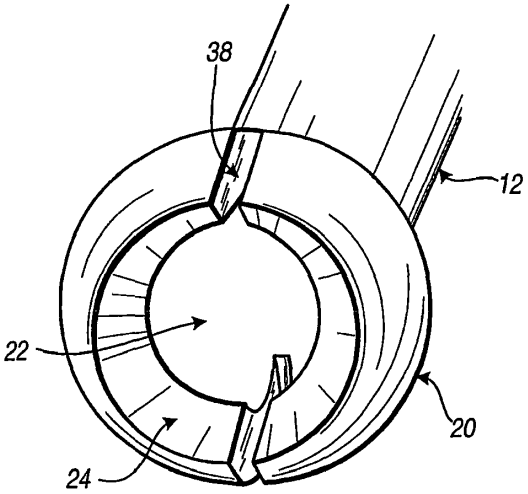



FIG. 6

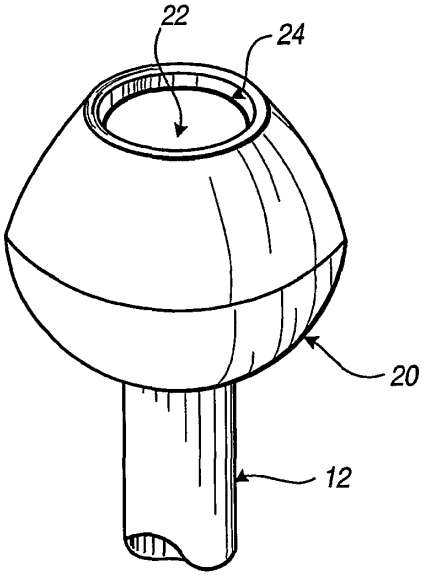



FIG. 7

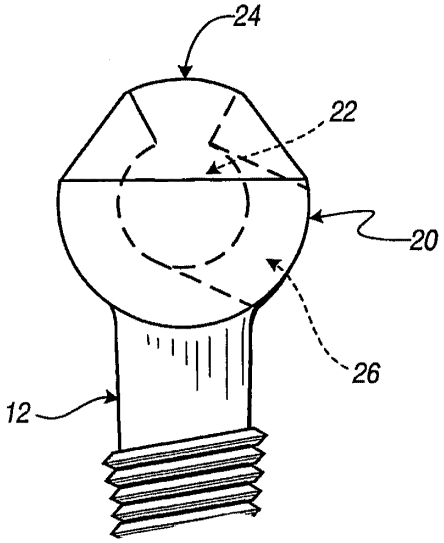



FIG. 8

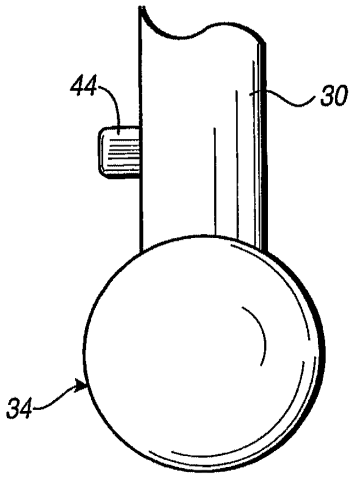



FIG. 9a

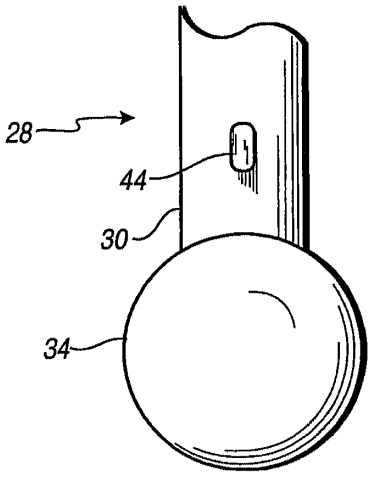



FIG. 9b

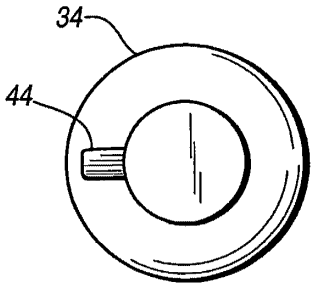



FIG. 9c

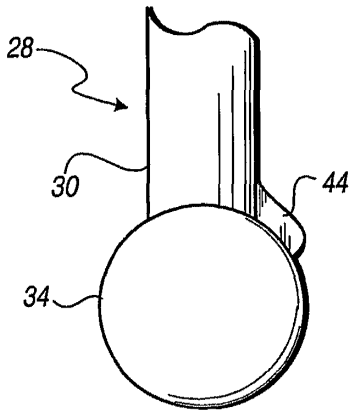



FIG. 10a

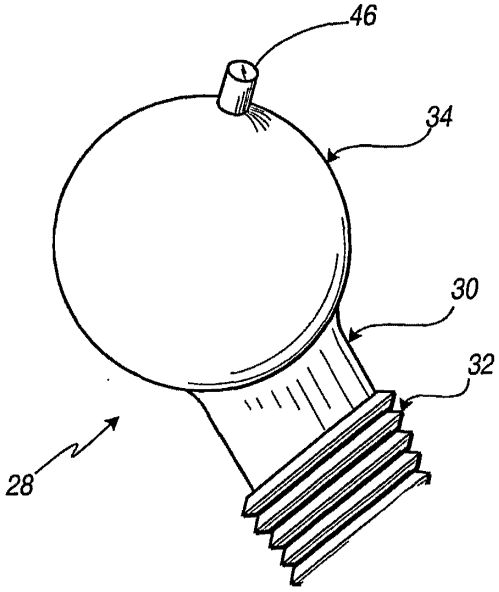



FIG. 11

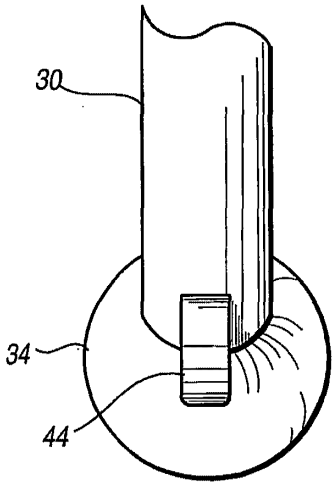



FIG. 10b

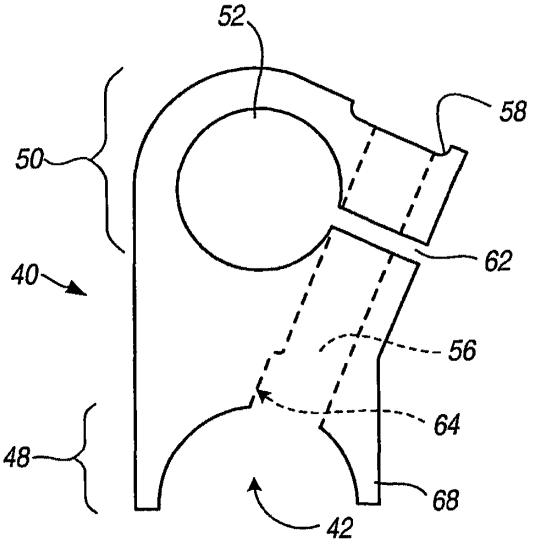



FIG. 12

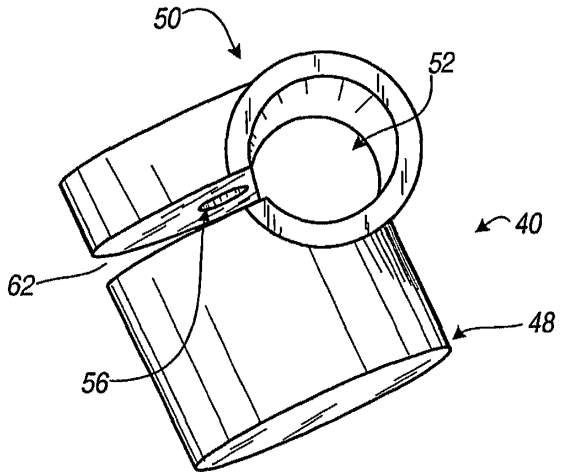



FIG. 13

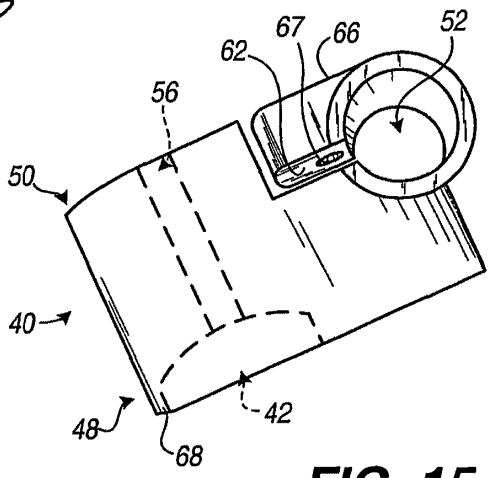



FIG. 15

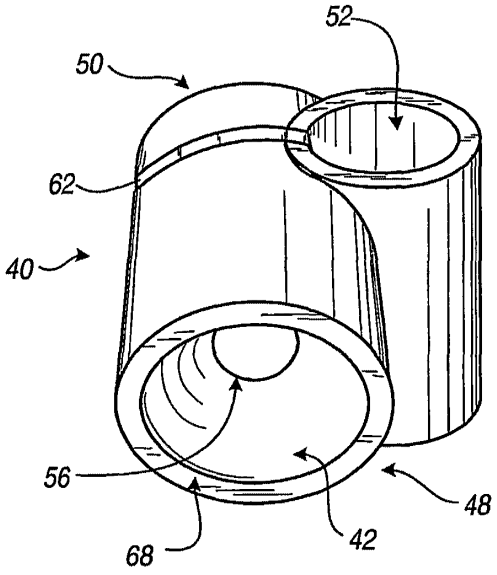



FIG. 14

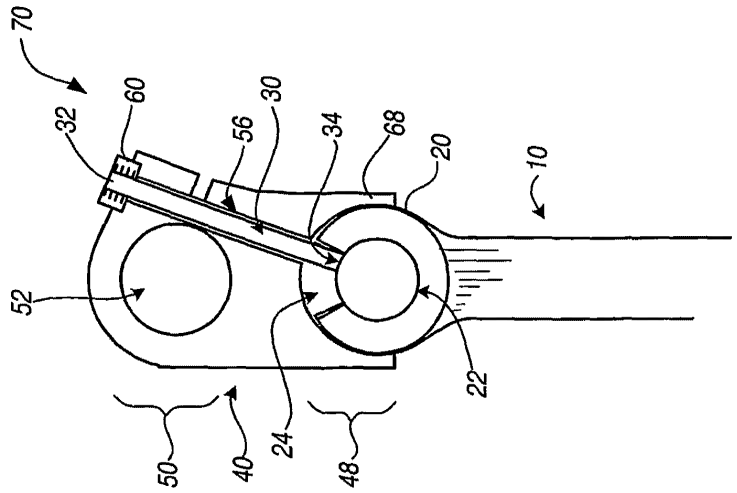



FIG. 17

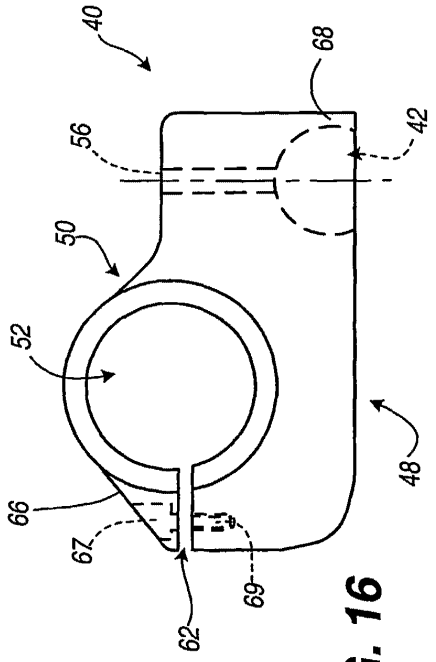



FIG. 16

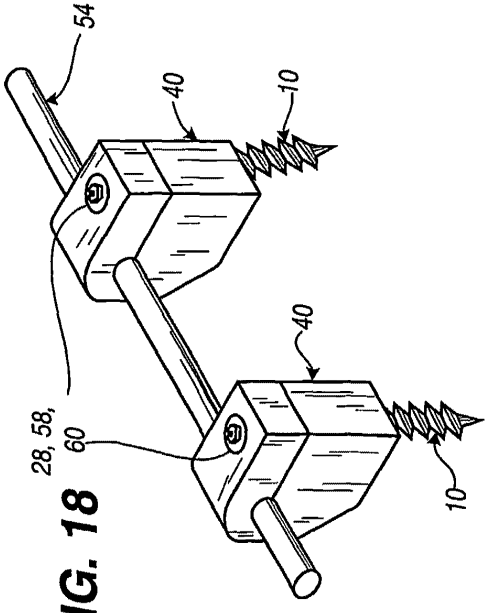



FIG. 18

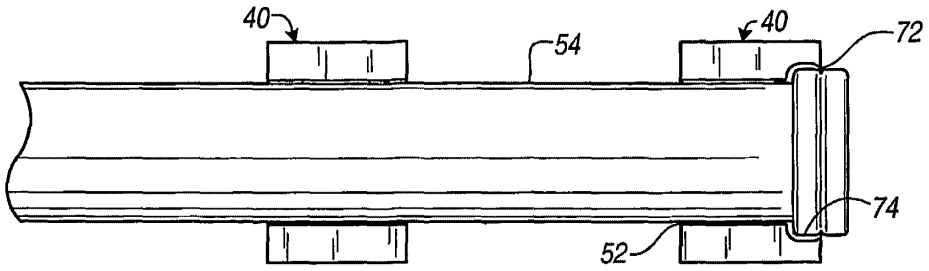



FIG. 19a

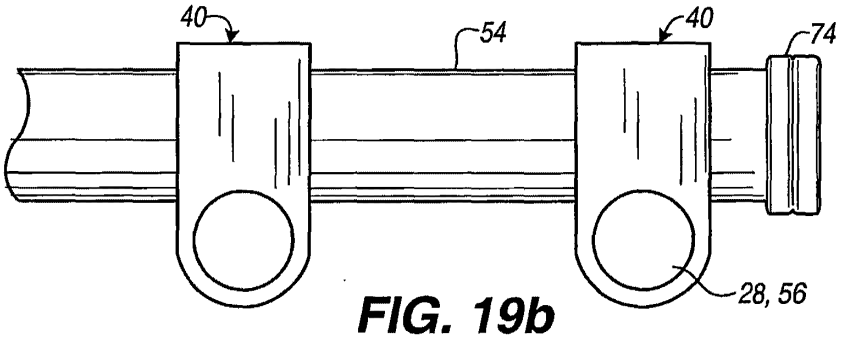



FIG. 19b

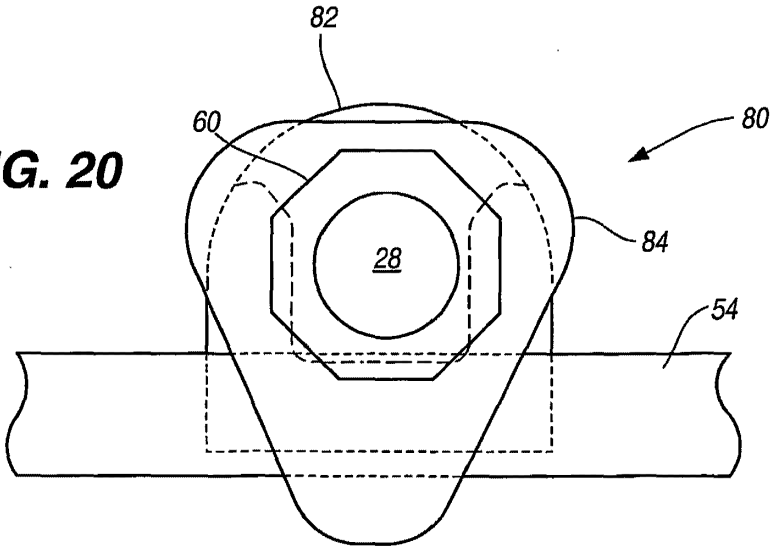



FIG. 20

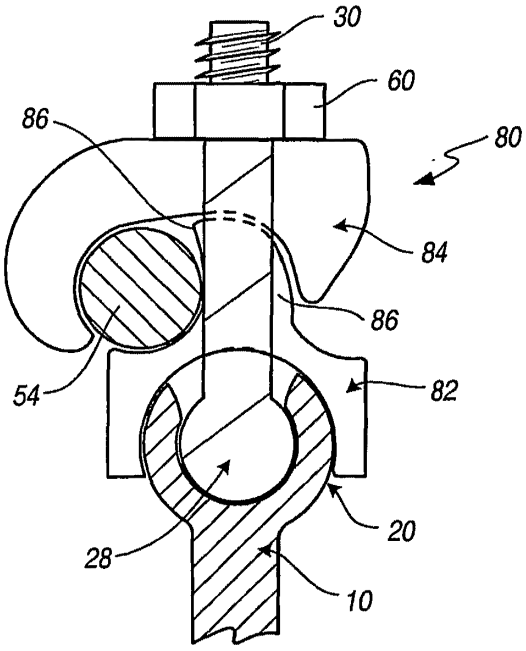



FIG. 21

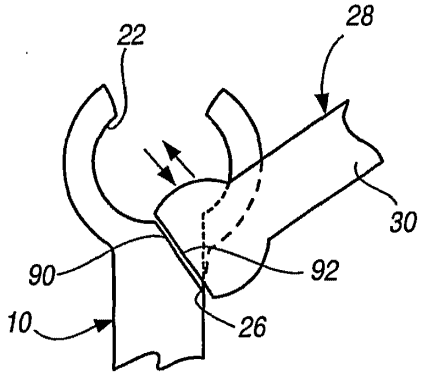



FIG. 22

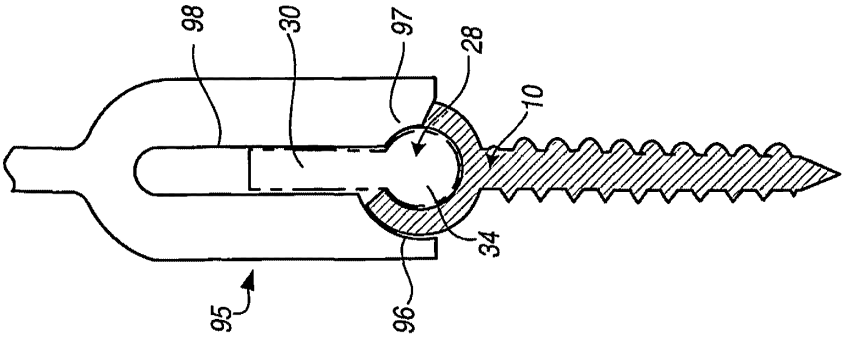



FIG. 24

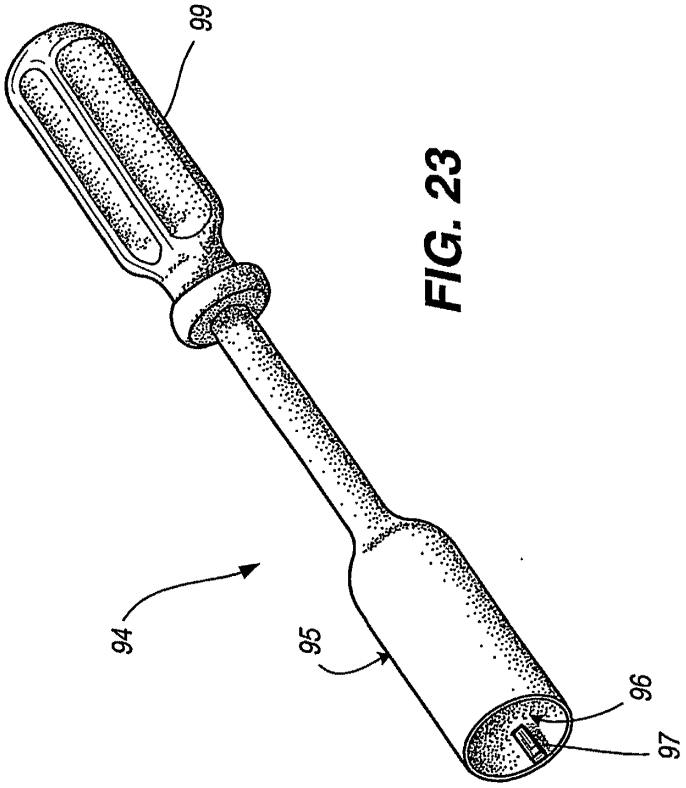



FIG. 23

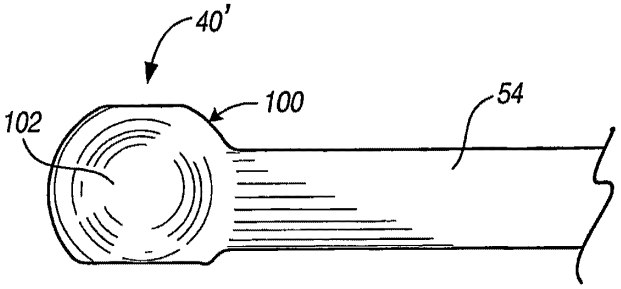



FIG. 25

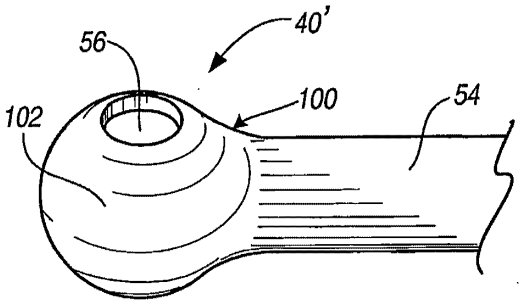



FIG. 26

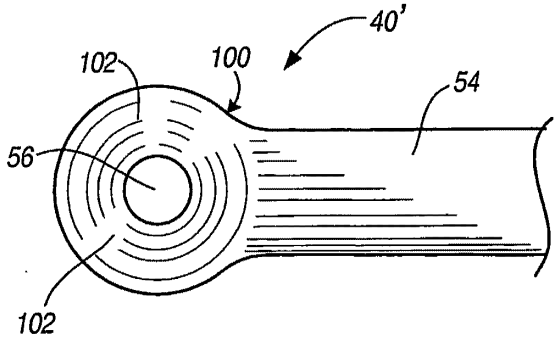



FIG. 27

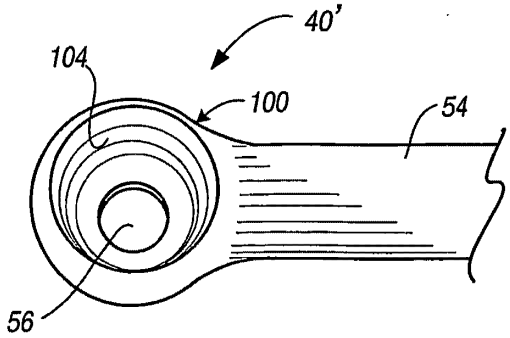



FIG. 28

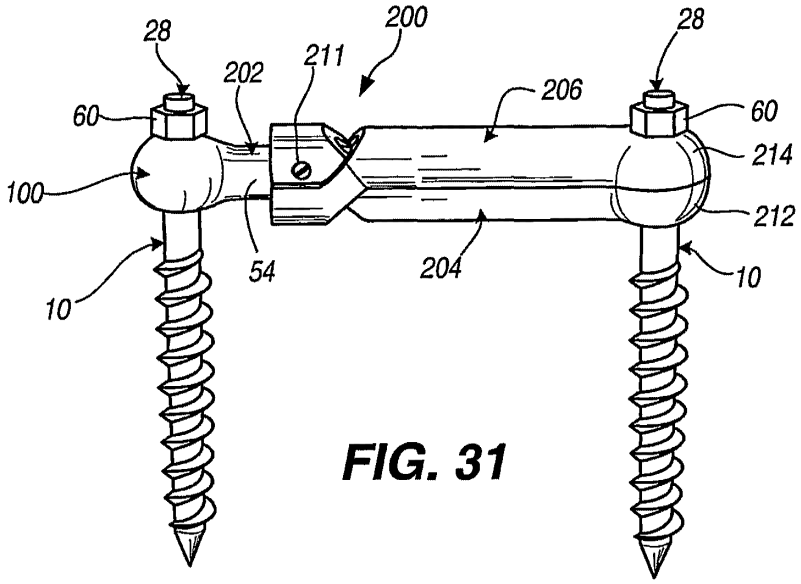



FIG. 31

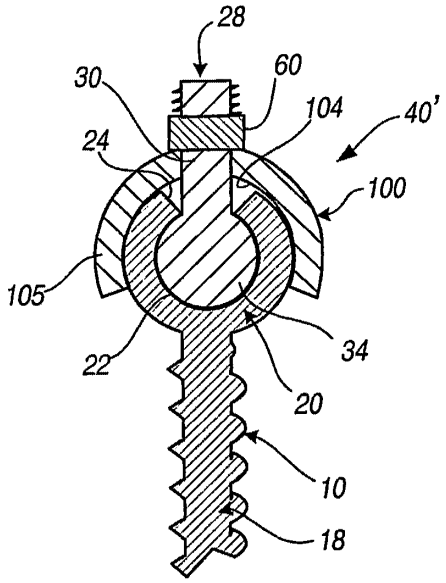



FIG. 30

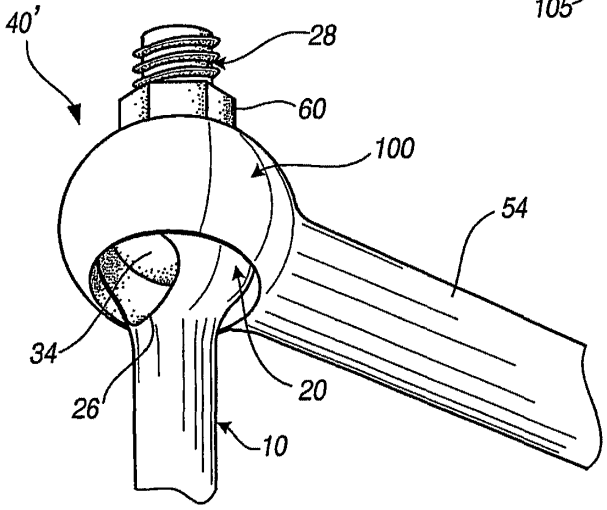



FIG. 29

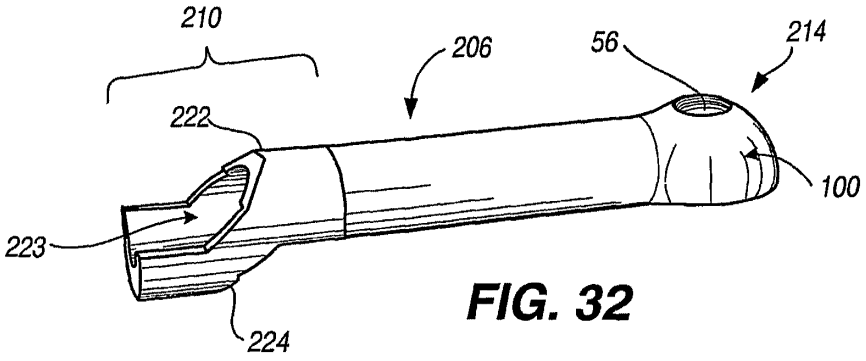



FIG. 32

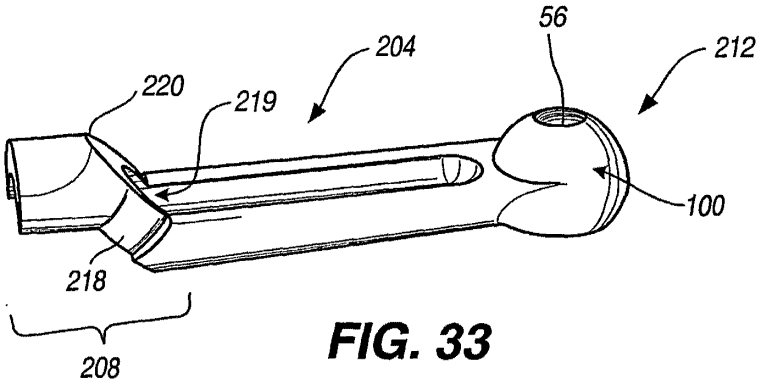



FIG. 33

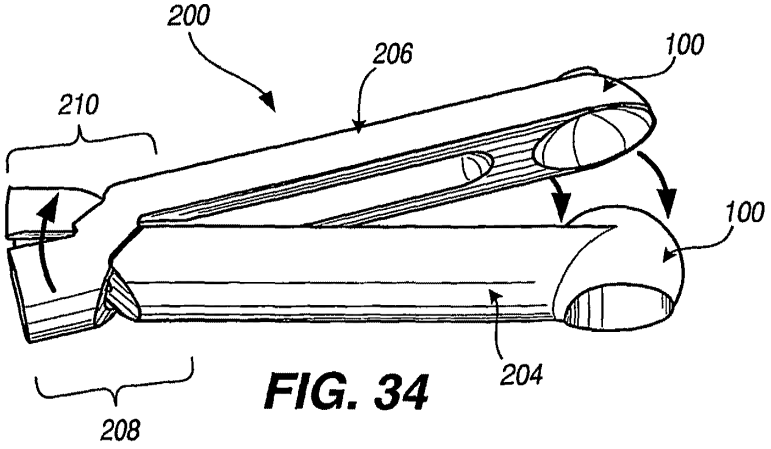



FIG. 34

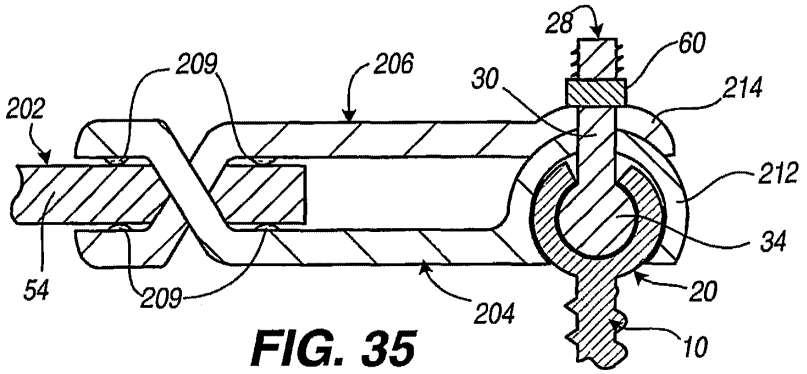



FIG. 35

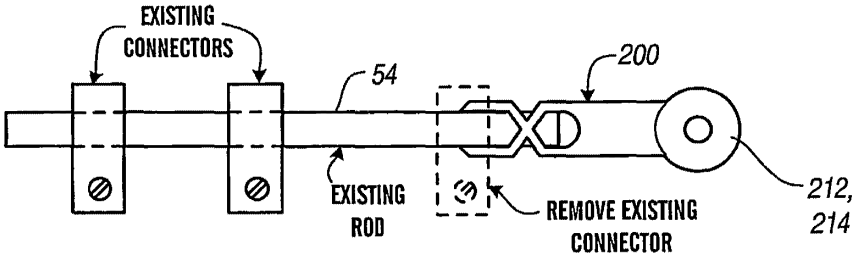



FIG. 36

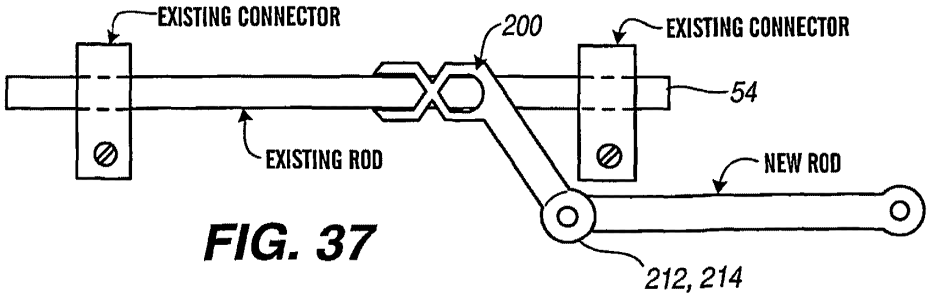
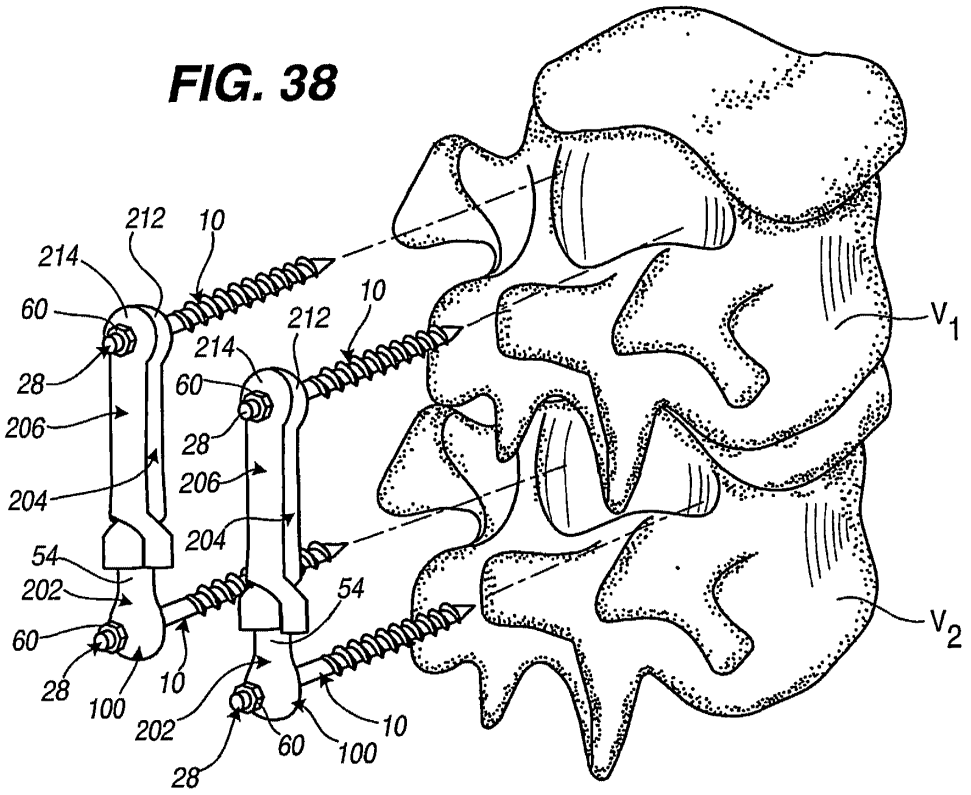



FIG. 37

FIG. 38


212
10
214
60
28
206
204
54
202
60
28
100
10
202
28
214
212
10
60
28
206
204
54
202
60
28
100
10
10
60
100
V1
V2

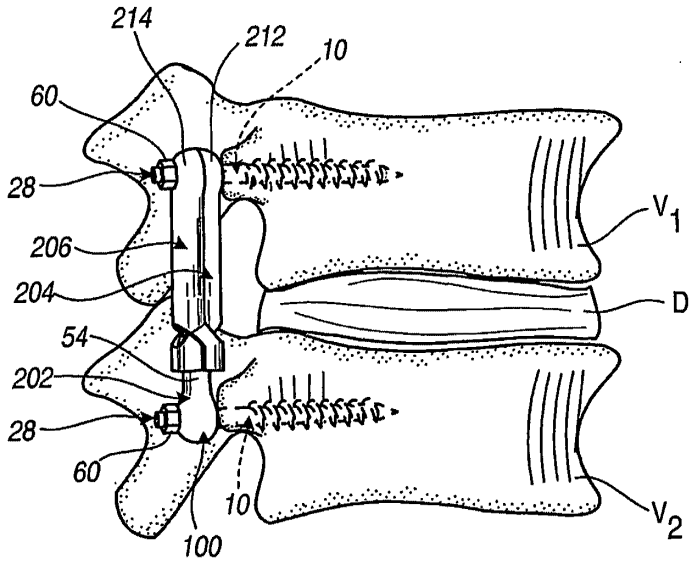
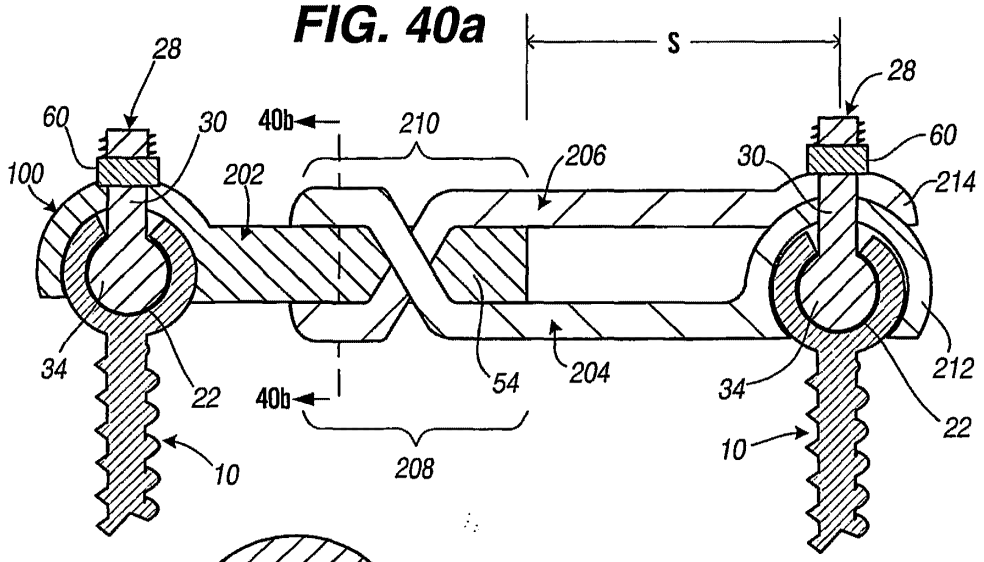

214
212
10
60
28
206
204
54
202
28
60
100
10
V1
D
V2

FIG. 39

FIG. 40a



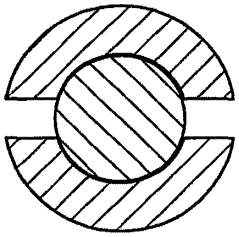



FIG. 40b

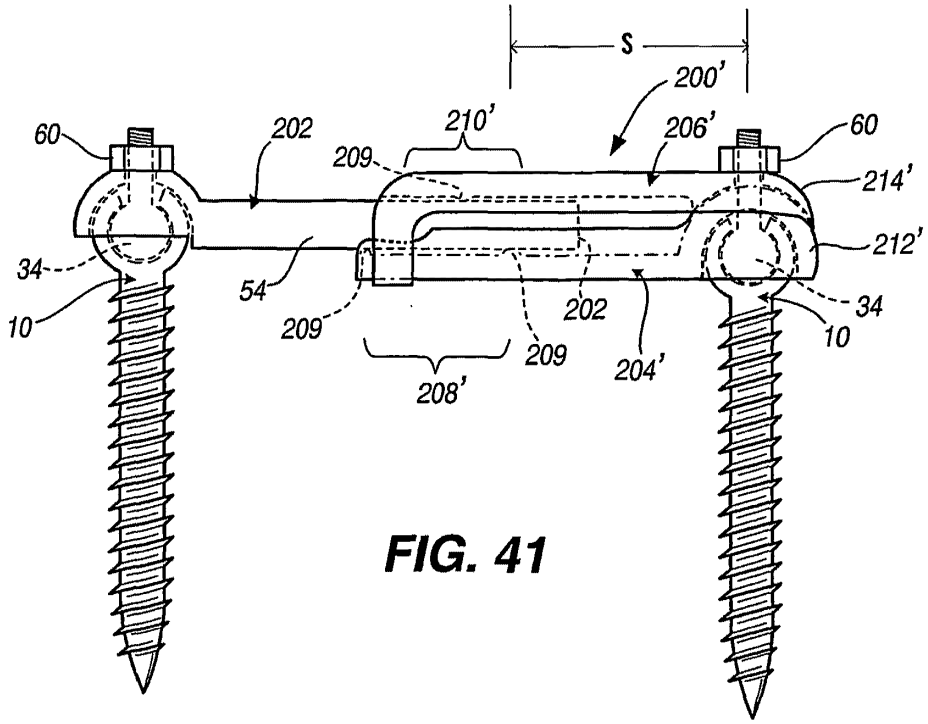



FIG. 41

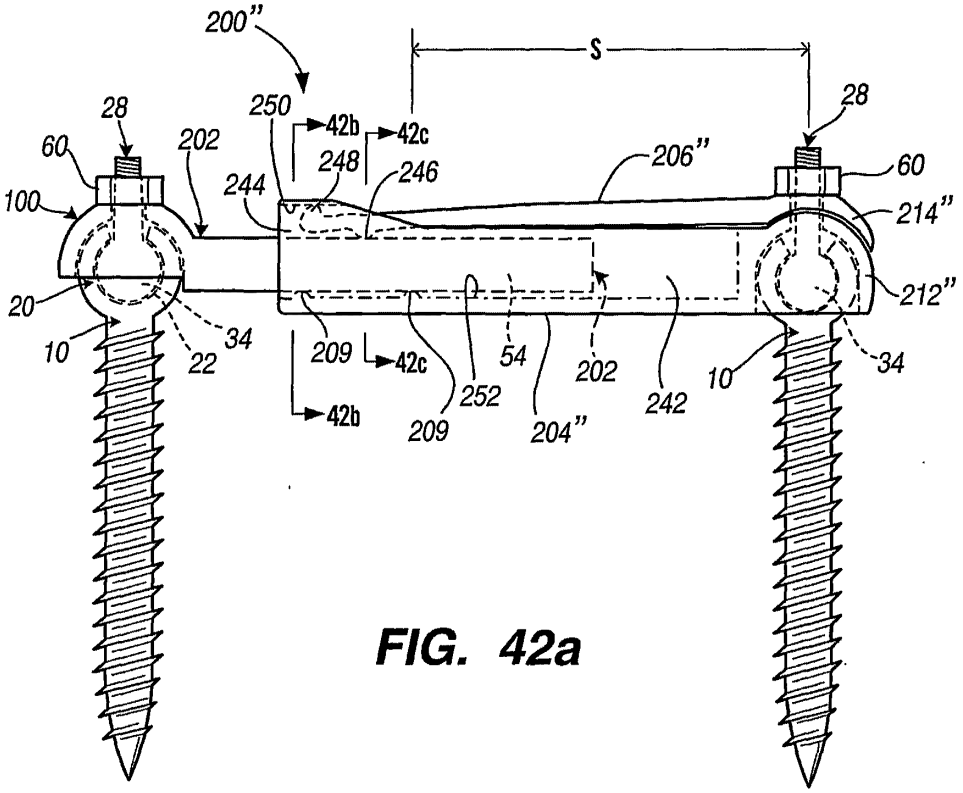



FIG. 42a

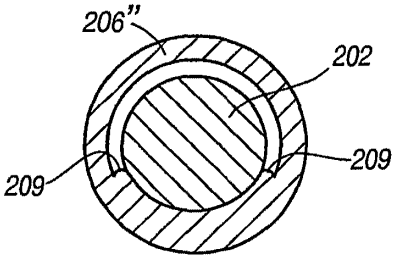



FIG. 42b

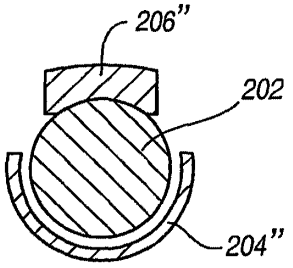



FIG. 42c

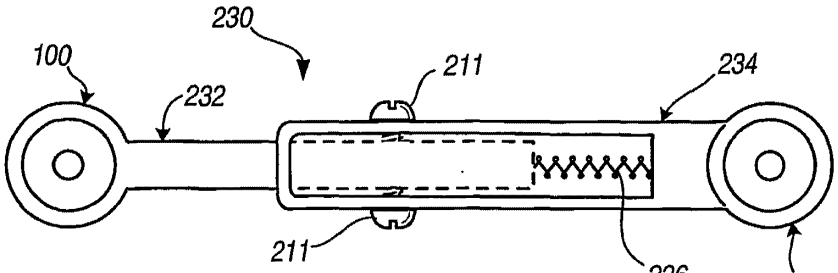



FIG. 43

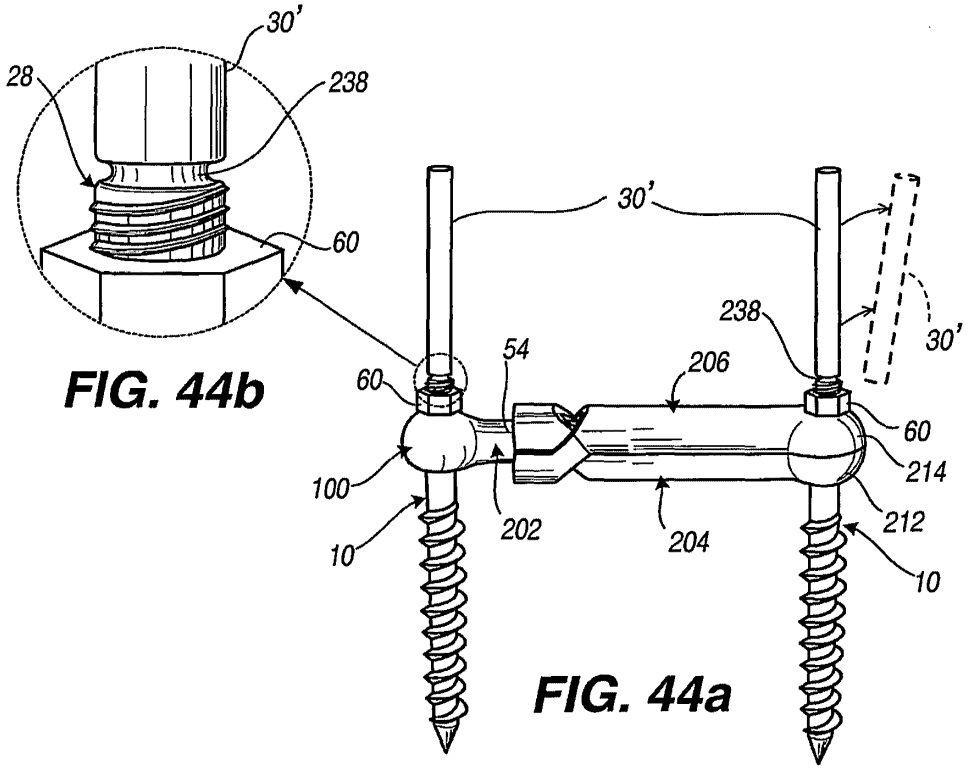



FIG. 44b

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 |
| "E" | earlier document published on or after the international filing date | "Y" | document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art |
| "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) | "&" | document member of the same patent family |
| "O" | document referring to an oral disclosure, use, exhibition or other means | | |
| "P" | document published prior to the international filing date but later than the priority date claimed | | |

| | |
|---|---|
| Date of the actual completion of the international search<br>23 JANUARY 2003 | Date of mailing of the international search report<br>19 FEB 2003 |
| Name and mailing address of the ISA/US<br>Commissioner of Patents and Trademarks<br>Box PCT<br>Washington, D.C. 20231<br>Facsimile No. (703) 305-3230 | Authorized officer<br>DAVID O. REIP<br>Telephone No. (703) 308-0858 |

Form PCT/ISA/210 (second sheet) (July 1998)★

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 339 of 2152

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
27 December 2002 (27.12.2002)

PCT

(10) International Publication Number
WO 02/102259 A2

(51) International Patent Classification[7]: A61B 17/70

(21) International Application Number: PCT/GB02/02709

(22) International Filing Date: 17 June 2002 (17.06.2002)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
0114783.4 16 June 2001 (16.06.2001) GB

(71) Applicants and
(72) Inventors: **SENGUPTA, Dilip, Kumar** [GB/GB]; 101 Delaunays Road, Crumpsall, Manchester M8 4RE (GB). **MULHOLLAND, Robert, Charles** [GB/GB]; 39 Private Road, Sherwood, Nottingham NG5 4DD (GB).

(74) Agent: **FORRESTER KETLEY & CO**; Chamberlain House, Paradise Place, Birmingham B3 3HP (GB).

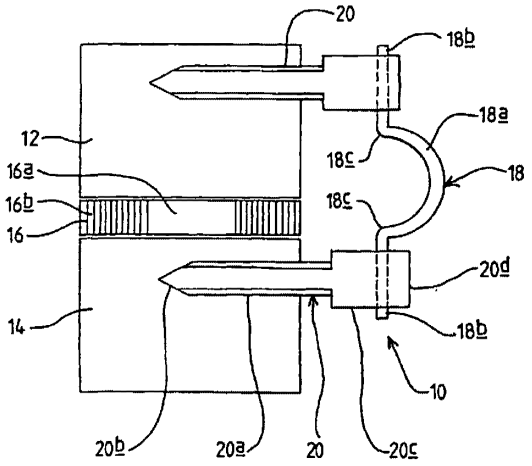
(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZM, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

**Published:**
— *without international search report and to be republished upon receipt of that report*

*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

(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.

WO 02/102259 A2

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 340 of 2152

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.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 341 of 2152

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.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 342 of 2152

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.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 343 of 2152

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;

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.

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 346 of 2152

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 348 of 2152

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.

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 350 of 2152

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.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 351 of 2152

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.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 352 of 2152

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.

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.

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.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 355 of 2152

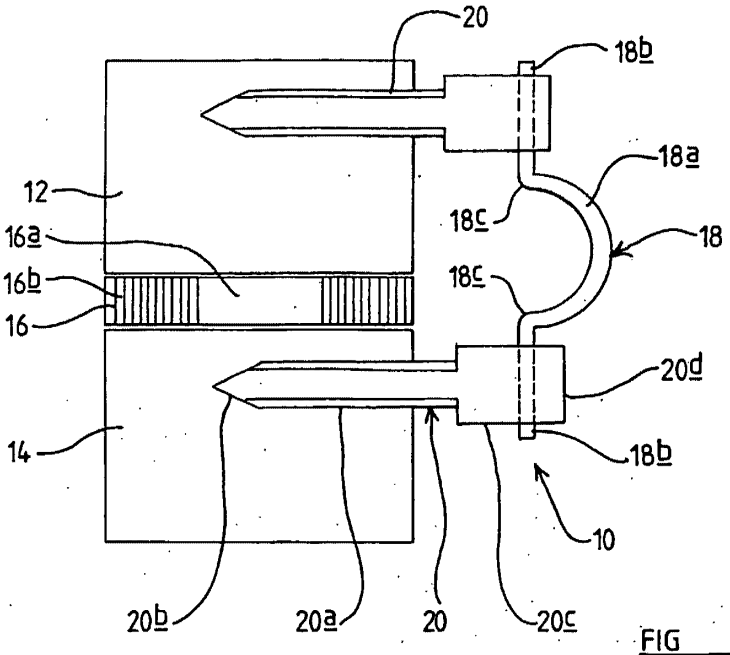



FIG 1

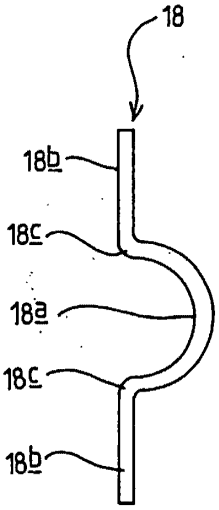



FIG 2a

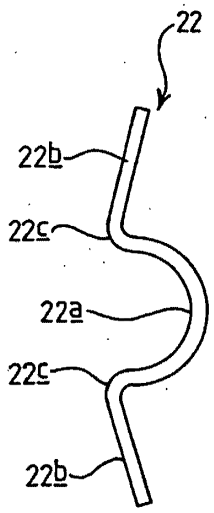



FIG 2b

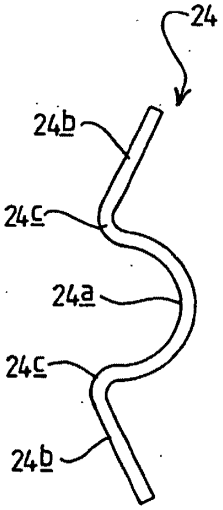



FIG 2c

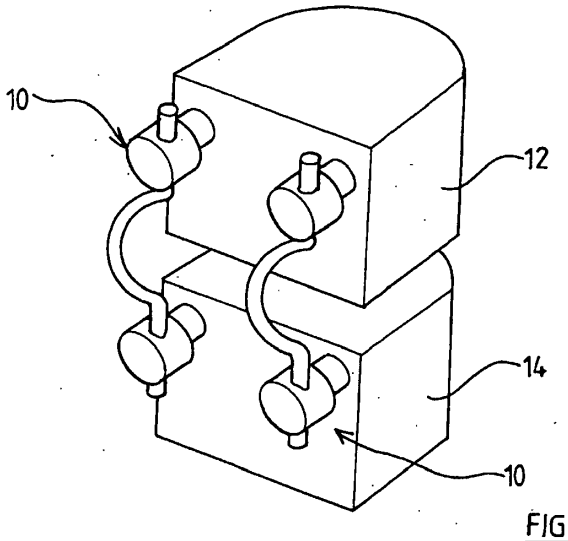



FIG 3

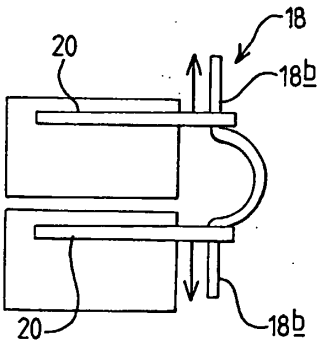



FIG 4a

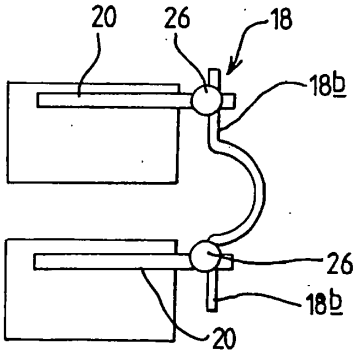



FIG 4b

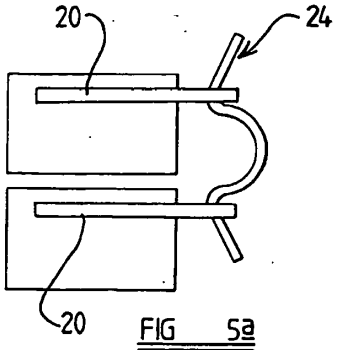



FIG 5a

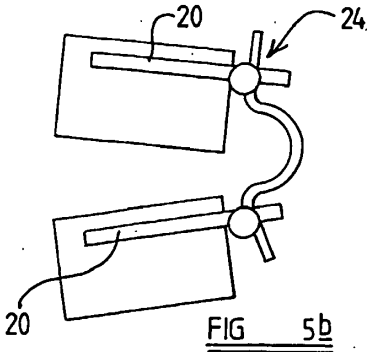



FIG 5b

FIG 6a

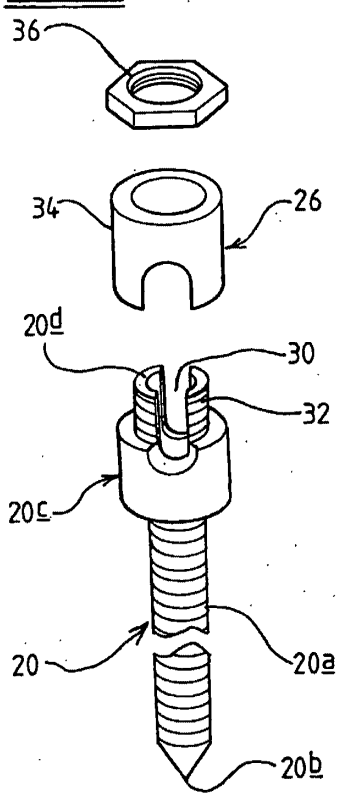
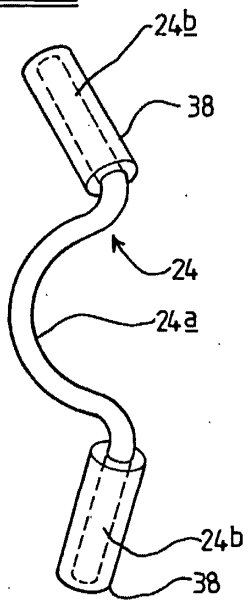



FIG 6b



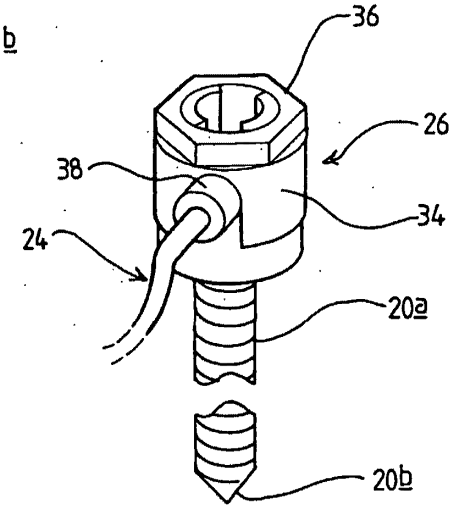




FIG 6c

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 358 of 2152

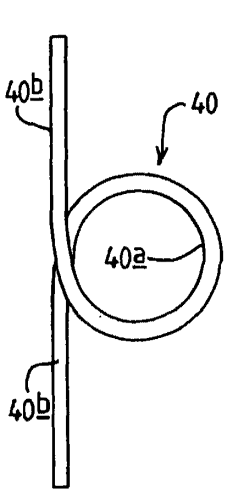



FIG 7a

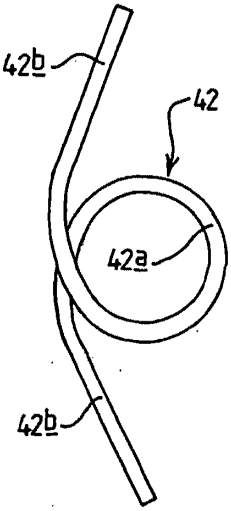



FIG 7b

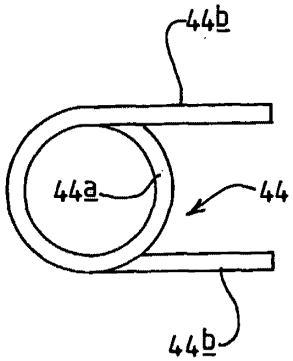



FIG 7c

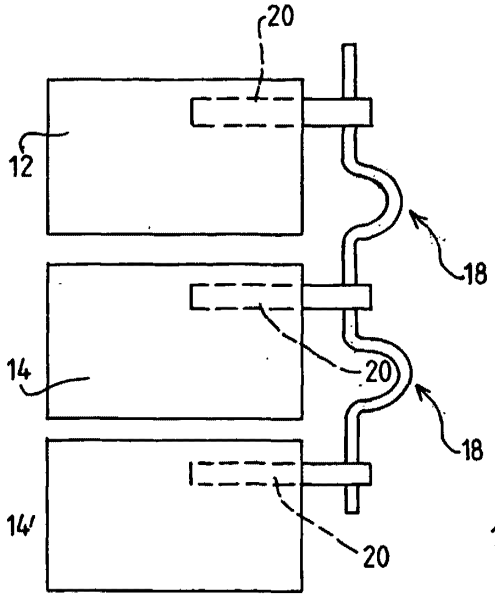



FIG 8

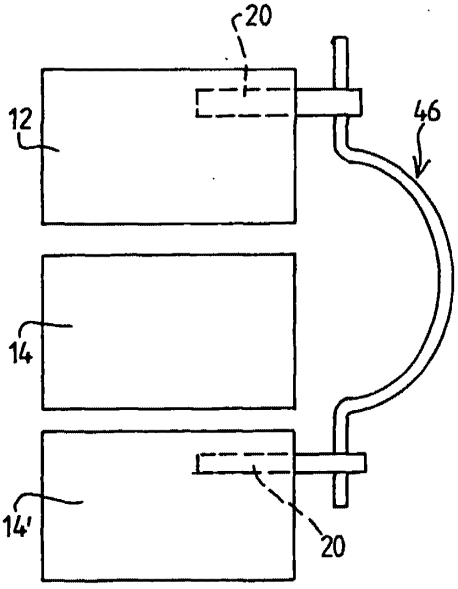



FIG 9

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
18 July 2002 (18.07.2002)

PCT

(10) International Publication Number
WO 02/054966 A2

(51) International Patent Classification[7]: A61B 17/70

(21) International Application Number: PCT/US02/00814

(22) International Filing Date: 11 January 2002 (11.01.2002)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/261,129 12 January 2001 (12.01.2001) US

(71) Applicant: DEPUY ACROMED, INC. [US/US]; 325 Paramount Drive, Raynhan, MA 02767-0350 (US).

(72) Inventor: GLASCOTT, Craig; 6612 Pineview Court, Boston Heights, OH 44236 (US).

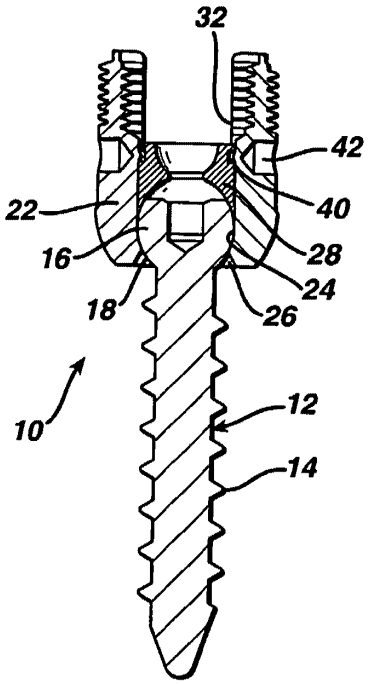
(74) Agents: JOHNSON, Philip, S. et al.; Johnson & Johnson, One Johnson & Johnson Plaza, New Brunswick, NJ 08933-7003 (US).

(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent

*[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.

WO 02/054966 A2

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

**Published:**

— *without international search report and to be republished upon receipt of that report*

*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

# Polyaxial Screw 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.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 365 of 2152

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.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 367 of 2152

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;

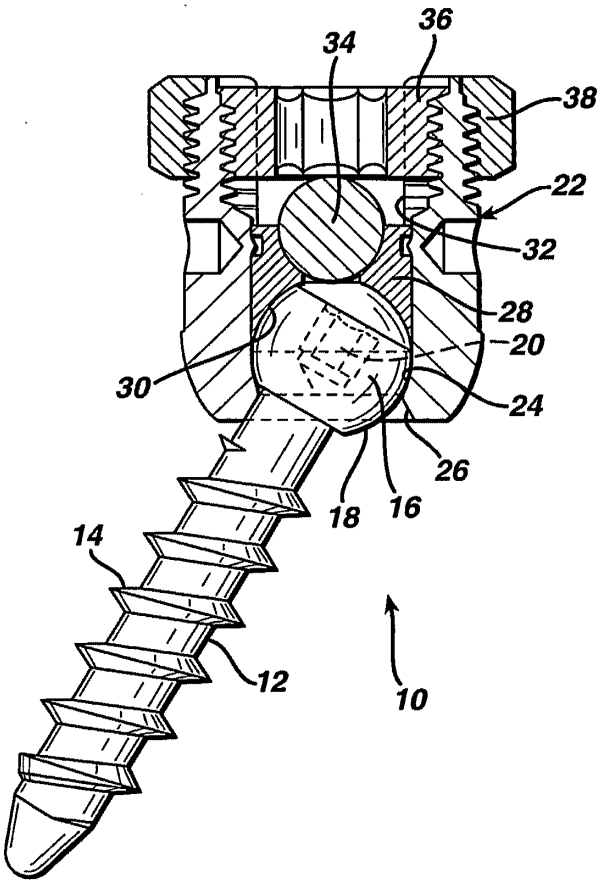
wherein the receiver comprises a body having an aperture therethrough for receiving the shank and having the concave portion located at the aperture;

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






Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 370 of 2152

FIG. 2

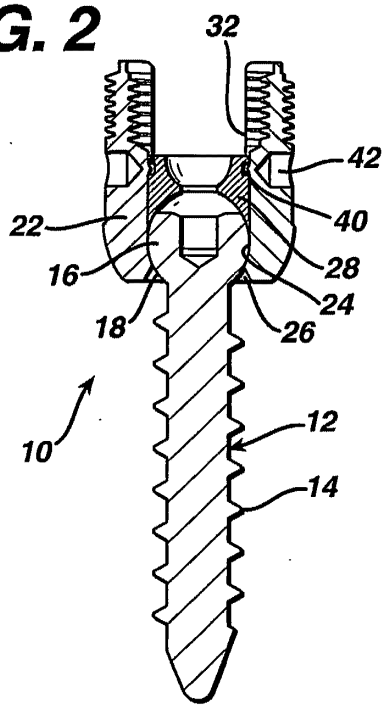
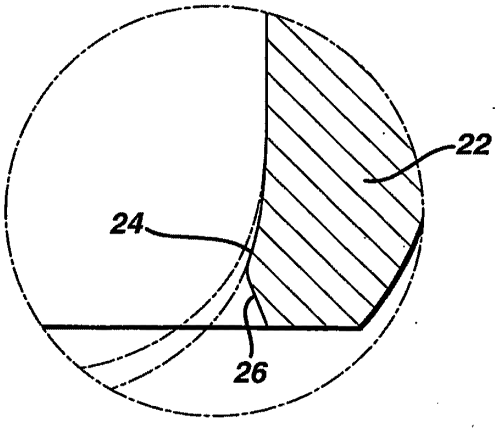



FIG. 3






Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 371 of 2152

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

(11) EP 1 210 914 A1

# (12) EUROPEAN PATENT APPLICATION

published in accordance with Art. 158(3) EPC

(43) Date of publication:
**05.06.2002 Bulletin 2002/23**

(21) Application number: **00951549.5**

(22) Date of filing: **04.08.2000**

(51) Int Cl.[7]: **A61B 17/70**

(86) International application number:
**PCT/ES00/00310**

(87) International publication number:
**WO 01/10317 (15.02.2001 Gazette 2001/07)**

(84) Designated Contracting States:
**AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU MC NL PT SE**
Designated Extension States:
**AL LT LV MK RO SI**

(30) Priority: **05.08.1999 ES 9901798**

(71) Applicant: **TRAIBER, S.A.**
**43206 Reus (ES)**

(72) Inventor: **MARQUEZ ALVAREZ, Luis,**
**Poligono Mas de Les Animes**
**43206 Reus (ES)**

(74) Representative: **Carpintero Lopez, Francisco**
**HERRERO & ASOCIADOS, S.L.**
**Alcalá, 35**
**28014 Madrid (ES)**

## (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).

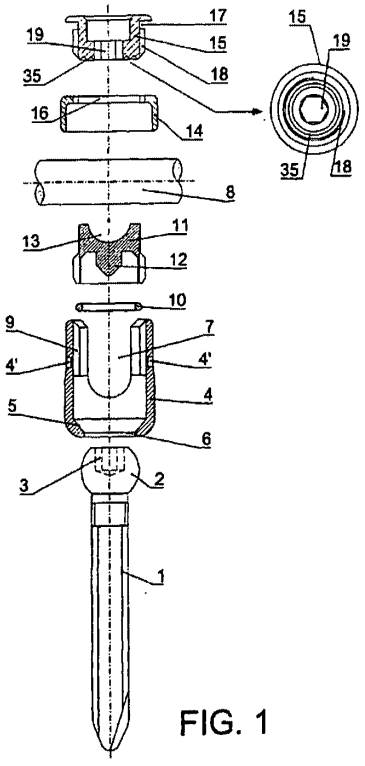



FIG. 1

EP 1 210 914 A1

Printed by Jouve, 75001 PARIS (FR)

## 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.



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 373 of 2152

**[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.



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 374 of 2152

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



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 375 of 2152

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-



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 376 of 2152

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,



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 377 of 2152

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.



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 378 of 2152

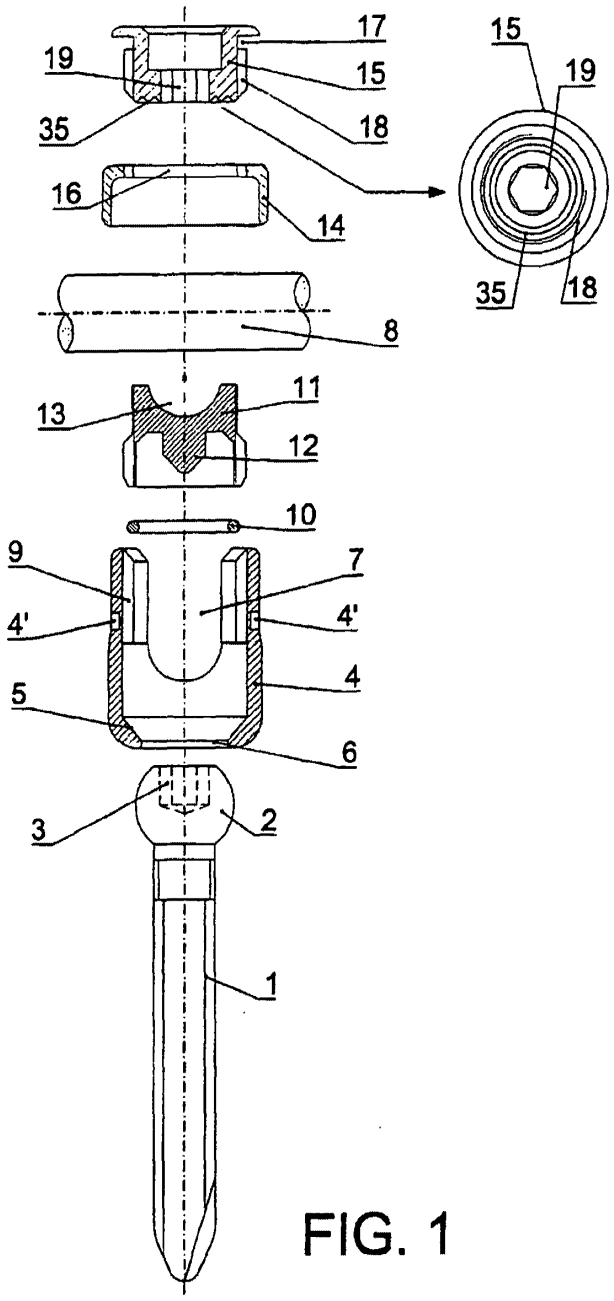



FIG. 1



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 379 of 2152

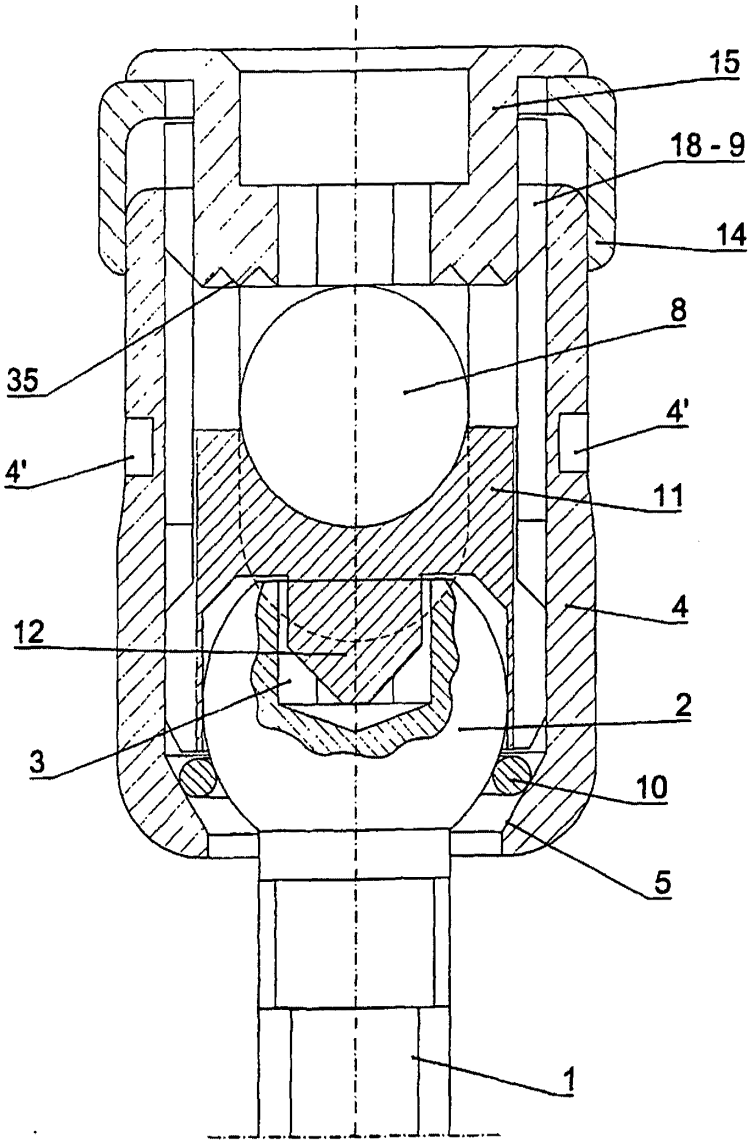



FIG. 2



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 380 of 2152

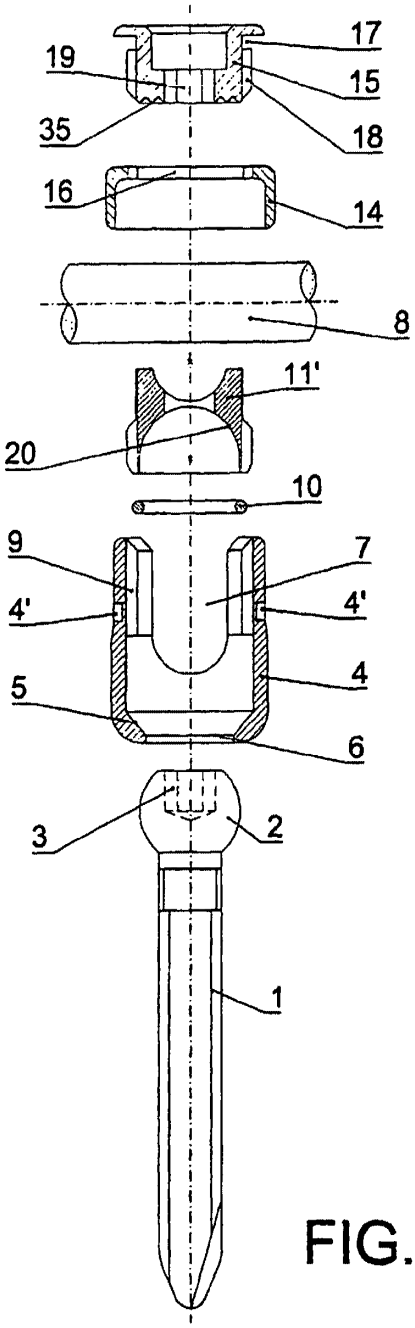



FIG. 3



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 381 of 2152

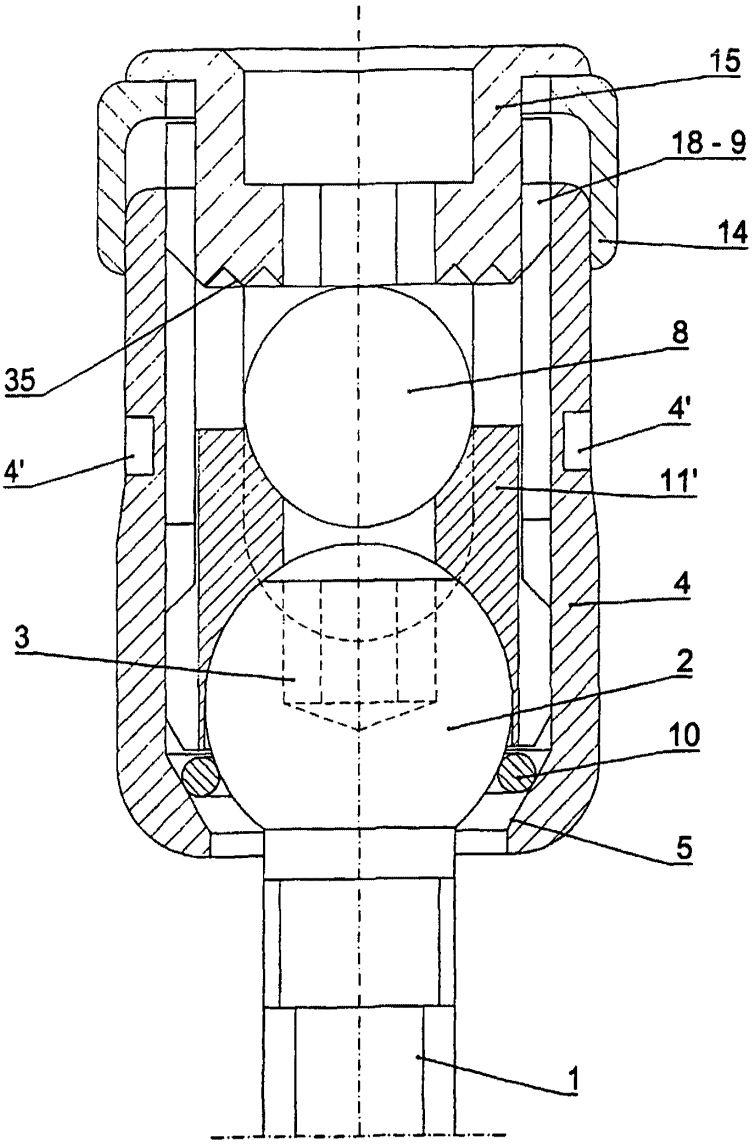



FIG. 4



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 382 of 2152

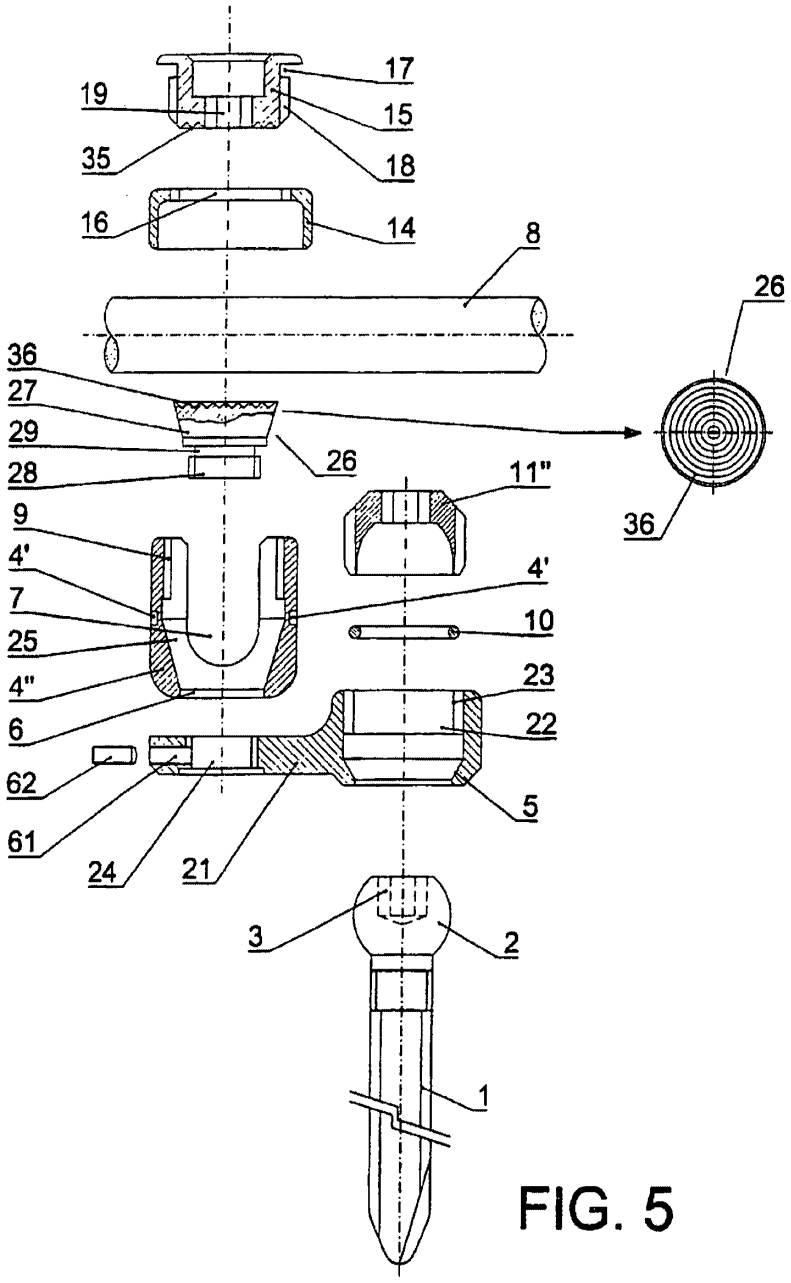



FIG. 5



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 383 of 2152

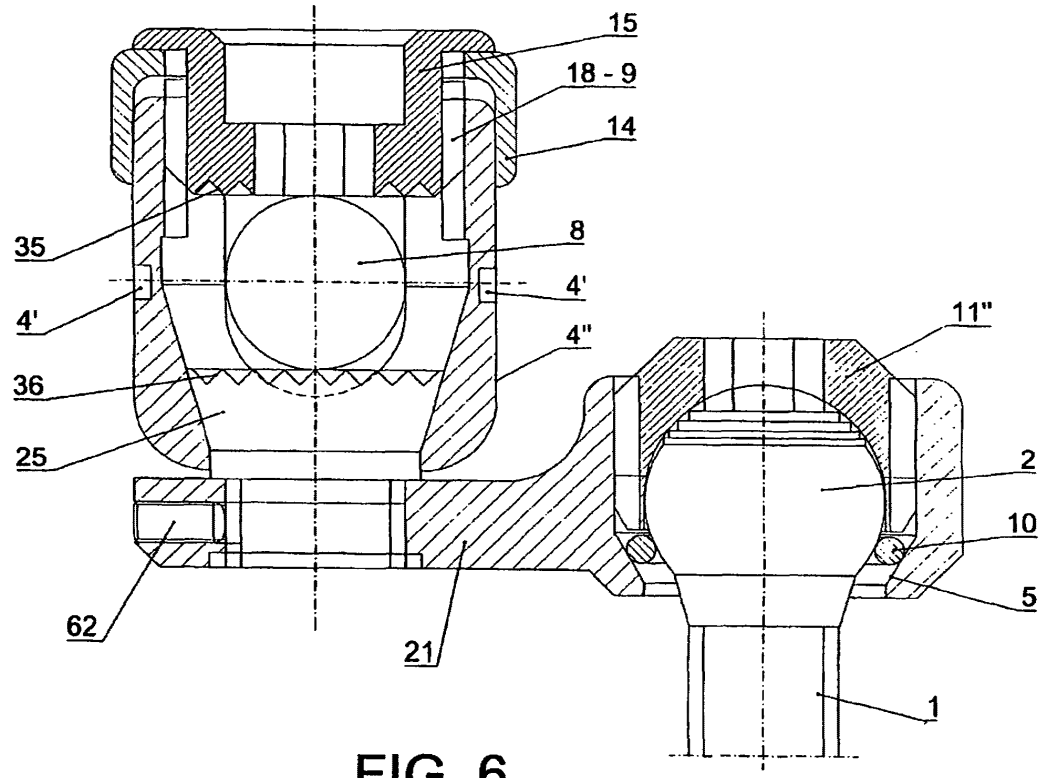



FIG. 6

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 384 of 2152

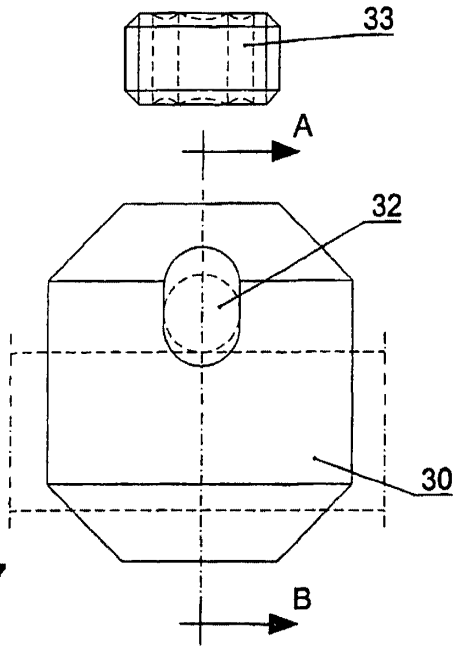
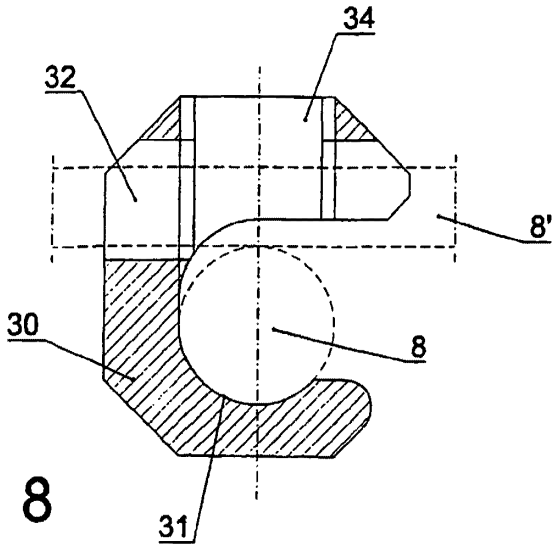



FIG. 7




A-B

FIG. 8



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 385 of 2152

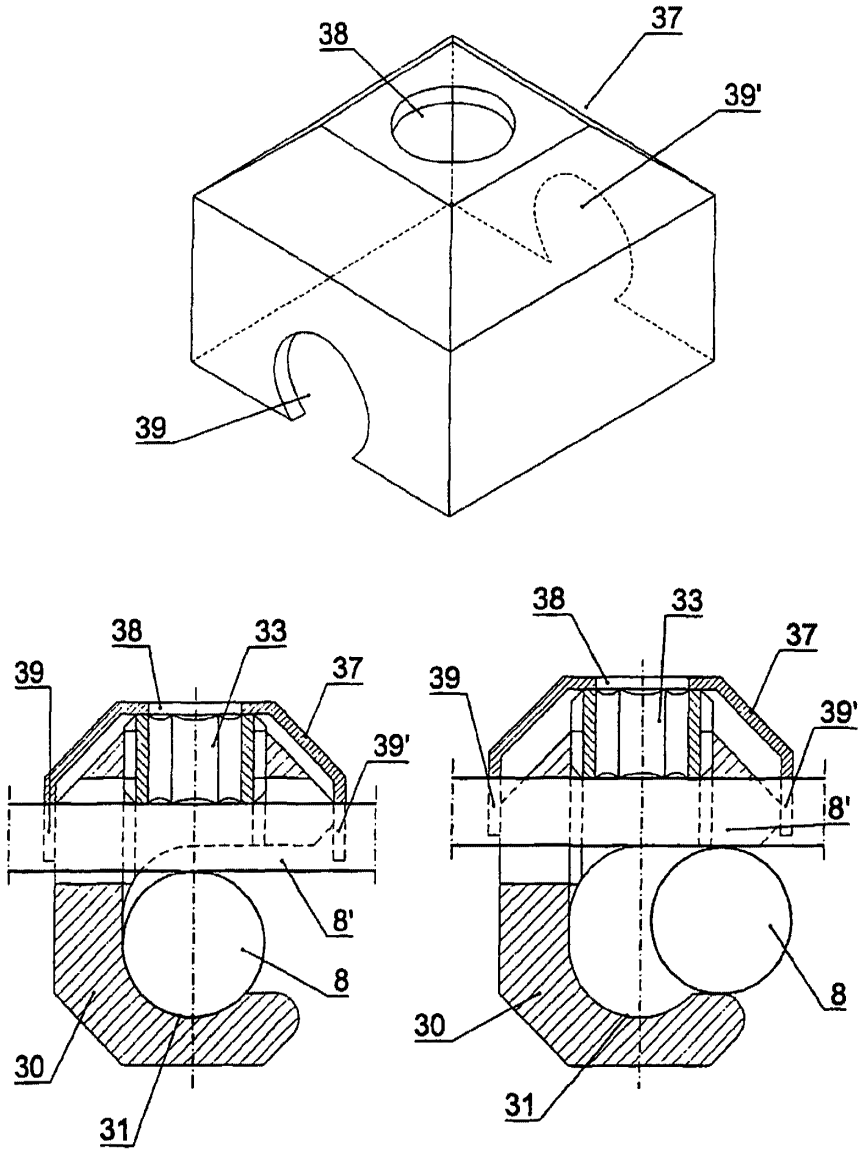



FIG. 9



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 386 of 2152

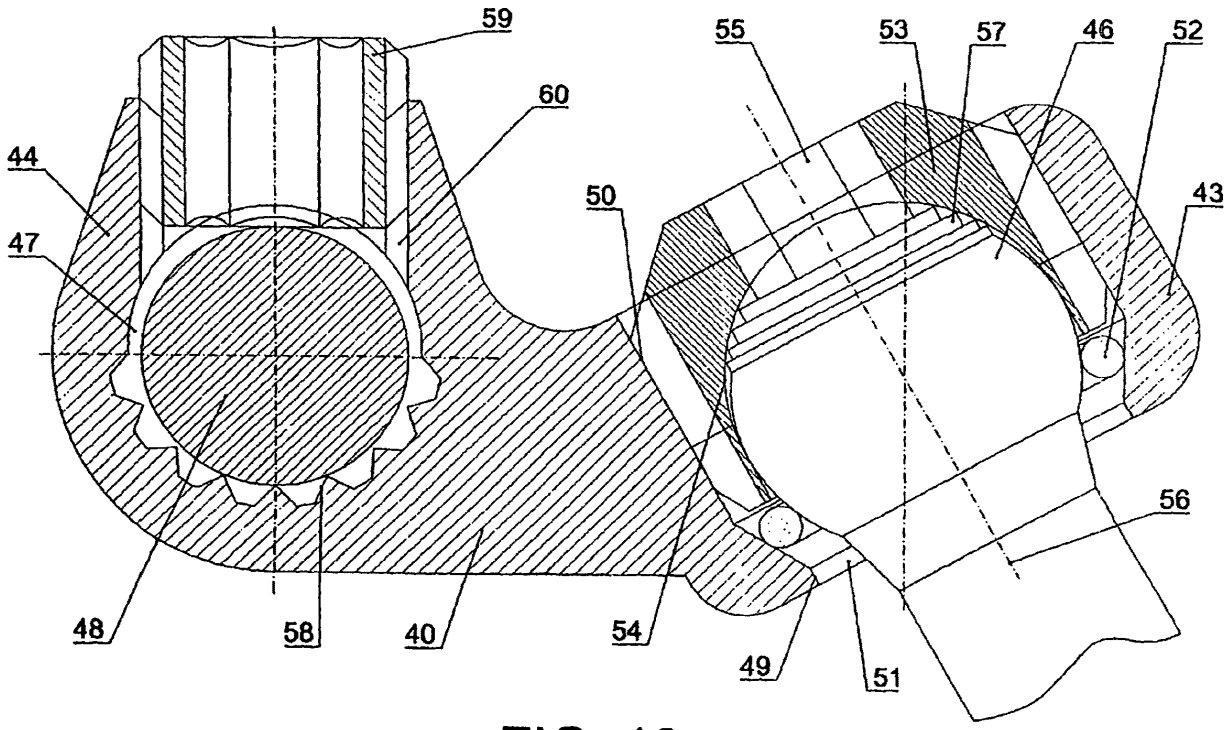



FIG. 10

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 387 of 2152

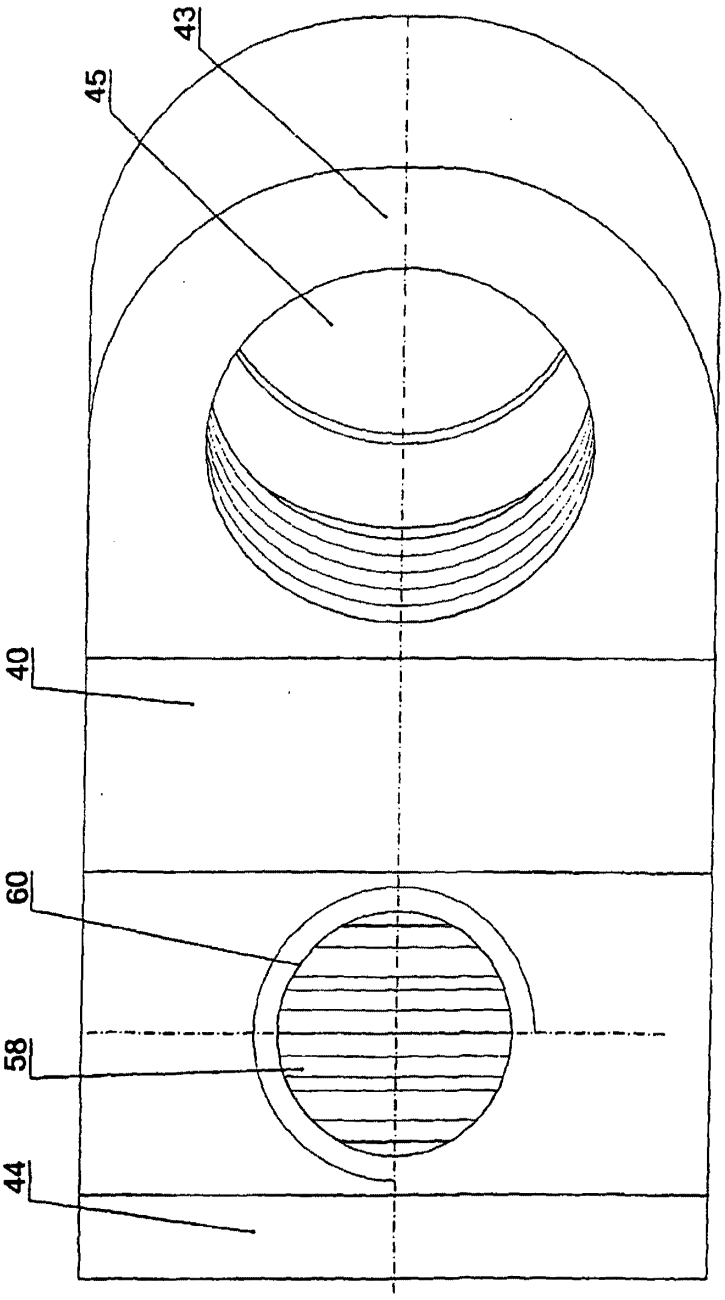



FIG. 11



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 388 of 2152

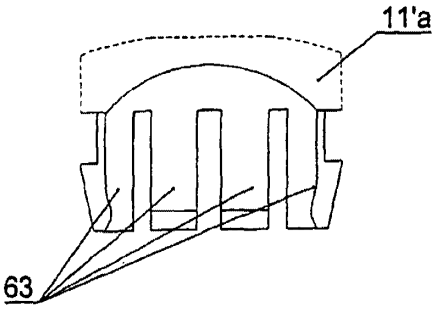



FIG. 12

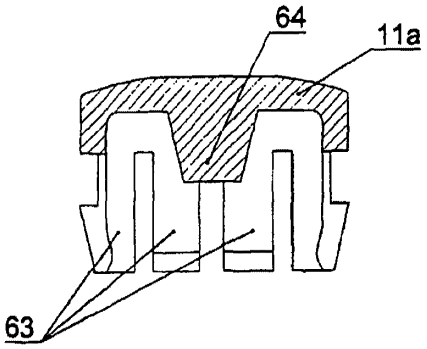



FIG. 13

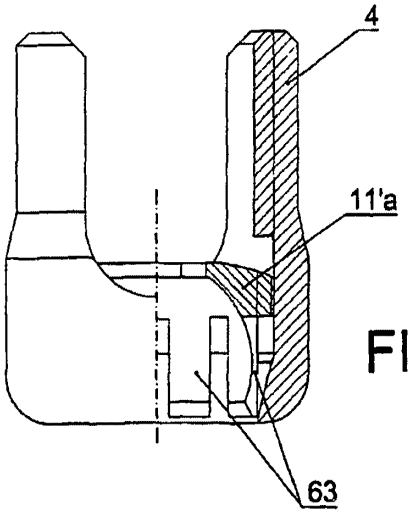



FIG. 14



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 389 of 2152

## INTERNATIONAL SEARCH REPORT

International application No.
PCT/ ES 00/00310

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61B 17/70

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 practicable, search terms used)

CIBEPAT, EPODOC, WPI, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| A | DE 19720782 A1 (SPARIN & RÖHL & HENSELER) 19 November 1998 (19.11.98), see the whole document | 1-3,6-9 |
| A | WO 9834554 A (SDGI HOLDINGS) 13 August 1998 (13.08.98), see the whole document | 1-3,6,9 |
| A | US5681319 A (BIEDERMANN)28 October 1997 (28.10.97), see the whole document | 1-3,6,9 |
| A | WO 9844859 A1 (DIMSO) 15 October 1998 (15.10.98), see the whole document | 4,5 |
| A | US 5899903 A (COTREL) 04 May 1999 (04.05.99), see the whole document | 7 |
| A | US 5733285 A (ERRICO ET AL) 31 March 1998 (31.03.98), see the whole document | 15 |

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

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

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 20 October 2000(20.10.00) | 08 November 2000(08.11.00) |
| Name and mailing address of the ISA/ S.P.T.O<br>Facsimile No. | Authorized officer<br>Telephone No. |

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



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 390 of 2152

**INTERNATIONAL SEARCH REPORT**
Information on patent family members

International Application No
PCT/ ES 00/00310

| Patent document cited in search report | Publication date | Patent familiy member(s) | Publication date |
|---|---|---|---|
| DE 19720782 A1 | 19.11.1998 | WO 9852482 A1 | 26.11.1998 |
| | | ZA 9804064 A | 24.02.1999 |
| | | AU 3022397 A | 11.12.1998 |
| | | EP 0984730 A1 | 15.03.2000 |
| | | CN 1254266 A | 24.05.2000 |
| WO 9834554 A1 | 13.08.1998 | AU 6157698 A | 26.08.1998 |
| | | US 5885286 A | 23.03.1999 |
| | | EP 0986338 A1 | 22.03.2000 |
| US 5681319 A | 28.10.1997 | DE 19507141 A1 | 12.09.1996 |
| WO 9844859 A1 | 15.10.1998 | FR 2761590 A1 | 09.10.1998 |
| | | AU 7338098 A | 30.10.1998 |
| | | EP 0971639 A1 | 19.01.2000 |
| US 5899903 A | 04.05.1999 | WO 9525473 A1 | 28.09.1995 |
| | | AU 1859795 A | 09.10.1995 |
| | | EP 0750477A1,B1 | 02.01.1997 |
| | | JP 9506283 T | 24.06.1997 |
| | | DE 69506850 E | 04.02.1999 |
| US 5733285 A | 31.03.1998 | NONE | |

Form PCT/ISA/210 (patent family annex) (July 1992)



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 391 of 2152

## INFORME DE BÚSQUEDA INTERNACIONAL

Solicitud internacional nº PCT/ ES 00/00310

A. CLASIFICACIÓN DEL OBJETO DE LA SOLICITUD

CIP[7] A61B 17/70
De acuerdo con la Clasificación Internacional de Patentes (CIP) o según la clasificación nacional y la CIP.

B. SECTORES COMPRENDIDOS POR LA BÚSQUEDA

Documentación mínima consultada (sistema de clasificación, seguido de los símbolos de clasificación)

CIP[7] A61B

Otra documentación consultada, además de la documentación mínima, en la medida en que tales documentos formen parte de los sectores comprendidos por la búsqueda

Bases de datos electrónicas consultadas durante la búsqueda internacional (nombre de la base de datos y, si es posible, términos de búsqueda utilizados)

CIBEPAT, EPODOC, WPI, PAJ

C. DOCUMENTOS CONSIDERADOS RELEVANTES

| Categoría* | Documentos citados, con indicación, si procede, de las partes relevantes | Relevante para las reivindicaciones nº |
|---|---|---|
| A | DE 19720782 A1 (SPARIN & RÖHL & HENSELER) 19.11.1998, todo el documento | 1-3,6-9 |
| A | WO 9834554 A (SDGI HOLDINGS) 13.08.1998, todo el documento | 1-3,6,9 |
| A | US5681319 A (BIEDERMANN) 28.10.1997, todo el documento | 1-3,6,9 |
| A | WO 9844859 A1 (DIMSO) 15.10.1998, todo el documento | 4,5 |
| A | US 5899903 A (COTREL) 04.05.1999, todo el documento | 7 |
| A | US 5733285 A (ERRICO ET AL) 31.03.1998,todo el documento | 15 |

☐ En la continuación del recuadro C se relacionan otros documentos ☒ Los documentos de familia de patentes se indican en el anexo

* Categorías especiales de documentos citados:

"A" documento que define el estado general de la técnica no considerado como particularmente relevante.

"E" solicitud de patente o patente anterior pero publicada en la fecha de presentación internacional o en fecha posterior.

"L" documento que puede plantear dudas sobre una reivindicación de prioridad o que se cita para determinar la fecha de publicación de otra cita o por una razón especial (como la indicada).

"O" documento que se refiere a una divulgación oral, a una utilización, a una exposición o a cualquier otro medio.

"P" documento publicado antes de la fecha de presentación internacional pero con posterioridad a la fecha de prioridad reivindicada.

"T" documento ulterior publicado con posterioridad a la fecha de presentación internacional o de prioridad que no pertenece al estado de la técnica pertinente pero que se cita por permitir la comprensión del principio o teoría que constituye la base de la invención.

"X" documento particularmente relevante; la invención reivindicada no puede considerarse nueva o que implique una actividad inventiva por referencia al documento aisladamente considerado.

"Y" documento particularmente relevante; la invención reivindicada no puede considerarse que implique una actividad inventiva cuando el documento se asocia a otro u otros documentos de la misma naturaleza, cuya combinación resulta evidente para un experto en la materia.

"&" documento que forma parte de la misma familia de patentes.

| Fecha en que se ha concluido efectivamente la búsqueda internacional. 20 Octubre 2000 (20.10.2000) | Fecha de expedición del informe de búsqueda internacional 08 NOV 2000 08. 11. 00 |
|---|---|
| Nombre y dirección postal de la Administración encargada de la búsqueda internacional O.E.P.M. C/Panamá 1, 28071 Madrid, España. nº de fax +34 91 3495304 | Funcionario autorizado F. JAVIER HAERING nº de teléfono + 34 91 3495473 |

Formulario PCT/ISA/210 (segunda hoja) (julio 1998)



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 392 of 2152

**INFORME DE BÚSQUEDA INTERNACIONAL**
Información relativa a miembros de familias de patentes

Solicitud internacional nº
PCT/ ES 00/00310

| Documento de patente citado en el informe de búsqueda | Fecha de publicación | Miembro(s) de la familia de patentes | Fecha de publicación |
|---|---|---|---|
| DE 19720782 A1 | 19.11.1998 | WO 9852482 A1 | 26.11.1998 |
| | | ZA 9804064 A | 24.02.1999 |
| | | AU 3022397 A | 11.12.1998 |
| | | EP 0984730 A1 | 15.03.2000 |
| | | CN 1254266 A | 24.05.2000 |
| WO 9834554 A1 | 13.08.1998 | AU 6157698 A | 26.08.1998 |
| | | US 5885286 A | 23.03.1999 |
| | | EP 0986338 A1 | 22.03.2000 |
| US 5681319 A | 28.10.1997 | DE 19507141 A1 | 12.09.1996 |
| WO 9844859 A1 | 15.10.1998 | FR 2761590 A1 | 09.10.1998 |
| | | AU 7338098 A | 30.10.1998 |
| | | EP 0971639 A1 | 19.01.2000 |
| US 5899903 A | 04.05.1999 | WO 9525473 A1 | 28.09.1995 |
| | | AU 1859795 A | 09.10.1995 |
| | | EP 0750477A1,B1 | 02.01.1997 |
| | | JP 9506283 T | 24.06.1997 |
| | | DE 69506850 E | 04.02.1999 |
| US 5733285 A | 31.03.1998 | NINGUNO | |

Formulario PCT/ISA/210 (anexo-familias de patentes) (julio 1998)



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 393 of 2152

(19) RÉPUBLIQUE FRANÇAISE

INSTITUT NATIONAL
DE LA PROPRIÉTÉ INDUSTRIELLE

PARIS

(11) N° de publication : **2 814 936**
(à n'utiliser que pour les commandes de reproduction)

(21) N° d'enregistrement national : **00 12998**

(51) Int Cl[7] : **A 61 B 17/70**

# (12) DEMANDE DE BREVET D'INVENTION A1

(22) **Date de dépôt :** 11.10.00.

(30) **Priorité :**

(43) **Date de mise à la disposition du public de la demande :** 12.04.02 Bulletin 02/15.

(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) :** *FORTIN FREDERIC* — FR.

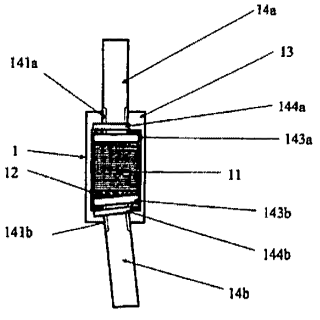
(72) **Inventeur(s) :** FORTIN FREDERIC, ROBIN JOHANN et DAUDE GERARD.

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

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

## (54) DISPOSITIF DE LIAISON VERTEBRALE SOUPLE ET MONOBLOC FONCTIONNANT DE MANIERE MULTIDIRECTIONNELLE.

(57) Dispositif de liaison vertébrale (1) comprenant:
un noyau central (11) constitué d'un réseau de fibres élastiques en matériau souple pouvant travailler en compression.
Une structure fibreuse (12) qui participe avec le noyau (11) aux caractéristiques mécaniques qui doivent satisfaire les modes de travaux requis pour le dispositif 1:
des moyens de fixation tels que par exemple: deux tiges filetées rigides (14 a et b) qui comprennent à leurs extrémités deux filetages (141 a et b) sur lesquels viennent se visser deux écrous (143 a et b) et s'enfiler deux rondelles (144 a et b)
un enrobage (13) constitué de préférence par une résine qui en se polymérisant vient lier l'ensemble des moyens en assurant toutes les fonctions désirées: tenue mécanique rigidité relative souplesse, bonne cohésion, étanchéité dudit dispositif (1) qui peut se déformer élastiquement de manière multidirectionnelle en satisfaisant à tous les modes de travail, ledit dispositif (1) grâce à la mise en place des précédents moyens étant capable d'amortir les sollicitations mécaniques, en ne bloquant aucun degré de liberté.




FR 2 814 936 - A1

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 394 of 2152

# DISPOSITIF DE LIAISON VERTEBRALE SOUPLE ET MONOBLOC FONCTIONNANT DE MANIERE MULTIDIRECTIONNELLE

---

## DOMAINE DE L'INVENTION

L'invention concerne un dispositif de liaison vertébrale postérieure monobloc qui stabilise les vertèbres dans toutes les directions et amortit toutes les sollicitations mécaniques en ne bloquant aucun degré de liberté. Ce dispositif va présenter des avantages fonctionnels qui vont apparaître au cours de la description

## ART ANTERIEUR :

On connait de nombreux systèmes de fixations vertébrales postérieures rigidifiant un certain nombre de vertèbres en les privant de toute mobilité pour permettre ainsi d'encaisser toutes les contraintes mécaniques. Cependant, la première vertèbre adjacente à ce bloc rigide garde toute sa mobilité et cette discontinuité brutale entre le bloc rigide et cette vertèbre libre engendre très souvent une hypersollicitation des éléments de liaison. Il s'en suit une accélération de la dégénérescence de ce niveau.

Ce problème n'a été que très partiellement résolu par des systèmes semi-rigides conçus pour créer une rigidité intermédiaire entre les vertèbres mobiles et les vertèbres fixes. Ces systèmes présentent les inconvénients suivants :

-soient ils travaillent en traction excluant toute action en flexion et compression. C'est le cas de tous les dispositifs basés sur les ligaments artificiels. Ces systèmes sont peu élastiques et laissent à l'appréciation de l'opérateur le soin de régler la tension rendant ainsi aléatoire les caractéristiques mécaniques dans les deux modes de fonctionnement possibles.

-soient ils travaillent en compression avec une butée en traction, l'assistance en flexion et en torsion étant exclu.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 395 of 2152

Quoiqu'il en soit: aucun des dispositifs connus ne résout entièrement le problème posé, à savoir: amortir toutes les sollicitations mécaniques auquelles une vertèbre mobile peut être soumise en ne bloquant aucun degré de liberté.

Nous allons citer comme antériorité la plus proche : le brevet EP 0576 379 A1 qui présente un amortisseur qui semble s'approcher le plus près tout au moins du point de vue du schéma général de la présente invention ; la revendication 1 du présent brevet protège "*un amortisseur uniaxial travaillant uniquement en compression tout en jouant le rôle d'une butée qui s'oppose à tout déplacement du piston au delà d'une valeur déterminée.....*

Dans ce cas l'aspect fonctionnement multidirectionnel de la présente invention ne figure pas dans l'antériorité , de plus la limitation exponentielle du déplacement résolue par l'antériorité , est un problème qui n'a rien à voir avec celui que veut résoudre la présente invention.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 396 of 2152

## DESCRIPTION

Les dessins servant la compréhension de l'invention sont les suivants:

La figure 1 de la planche 1/3 présente un schéma du dispositif en coupe verticale avec l'ensemble de ses moyens

Les figures 2 et 3 et 3bis de la planche 1/3 ( vues en coupe longitudinales et transversales) présentent une variante du dispositif avec une structure fibreuse différente

La figure 4 de la planche 2/3 montre une implantation du présent dispositif sur une colonne vertébrale .

La figure 5 de la planche 2/3 montre un type de fixation possible du dispositif sur deux vertèbres pas forcément voisines.

La figure 6 de la planche 3/3 montre une gamme de dispositifs envisageables pour divers cas.

Le dispositif de liaison 1 doit pouvoir offrir une tenue mécanique suffisante en restant du point de vue des contraintes subies, dans le domaine élastique en amortissant et en résistant à tous les modes de travail connus ( traction ,compression ,flexion ,torsion et cisaillement ). Ledit dispositif 1 comprend:

Un noyau central 11 constitué d'un réseau de fibres élastiques pouvant travailler en compression.

Ses caractéristiques mécaniques et physiques sont préalablement déterminées avant fabrication et mise en place. Il est adaptable au cas par cas .

Une structure fibreuse 12 qui participe avec le noyau 11 aux caractéristiques mécaniques qui doivent satisfaire les modes de travaux requis pour le dispositif 1.

Des moyens de fixation tels que par exemple :deux tiges rigides 14 ( a et b) qui comprennent à leurs extrémités deux filetages 141(a et b) sur lesquels viennent se visser deux écrous 143( a et b) et s'enfiler deux rondelles 144 (a et b),à pans coupés.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 397 of 2152

Ces précédents moyens 141,143,144 viennent pincer la structure fibreuse 12 en assurant une tenue mécanique en flexion et traction.

Un enrobage 13 constitué de préférence par une résine qui en se polymérisant vient lier l'ensemble des moyens, en assurant toutes les fonctions désirées , notamment : tenue mécanique, rigidité relative, souplesse , amortissement , bonne cohésion, et étanchéité avec absence de dégradation dans le temps de l'ensemble du dispositif. Le dispositif 1 ainsi constitué va donc pouvoir se positionner pour fonctionner de manière multidirectionnelle, par le type de conception adopté vérifié par des essais, et grâce à la nature des matériaux qui le constituent.

Les matériaux du dispositif 1 répondant aux fonctionnalités précédemment décrites sont **pour** :

le noyau central 11: un réseau de fibres textiles tridimensionnelles , offrant des caractéristiques de souplesse et d'amortissement ,renforcées ensuite par l'imprégnation d'une résine qui en se polymérisant assure de bonnes caractéristiques en compression.

la structure fibreuse 12 : un textile dont le réseau de fibre est de préférence au départ bidirectionnel ,et dont la forme peut être cylindrique adaptable à toutes les formes imposées présentant à ses extrémités deux têtes symétriques que l'on peut enfiler sur les tiges 14(a et b) pour les rabattre et les bloquer ensuite entre les écrous et les rondelles:143 ,144 .(figures 2, 2bis et 3)

les tiges filetées 14 et les écrous et rondelles 143 et 144 : un matériau rigide (composite ou métallique) .Il faut noter que les tiges filetées ne sont pas forcément coaxiales ,et peuvent se raccorder à tout système de fixation vertébral postérieur ou antérieur rigide. La rondelle présente au moins un pan coupé de forme adaptée pour que ce dernier puisse se positionner en évitant un déchirement de l'enrobage 13 et déchaussement possible des tiges quand le dispostif 1 travaille en flexion.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 398 of 2152

le moyen d'enrobage 13: une résine qui de préférence est de nature polyuréthane biocompatible, facile à mettre en oeuvre, moulable, éventuellement usinable pour adaptation et dont les variétés de caractéristiques desdites résines permettent de résoudre toutes les fonctionnalités désirées.

L'application industrielle reste bien ciblée , a savoir : la résolution du problème de la dégénérescence par l'implantation du dispositif 1 ; il n'en reste pas moins que ce dispositif amortisseur monobloc peut fonctionner dans toutes les directions peut avoir des dimensions et formes multiples ainsi que des caractéristiques mécaniques variées grâce à la combinaison de tous les constituants. C'est ainsi que la figure 6 de la planche 3/3 représente une gamme possible de dispositifs conçus comme il vient d'être décrit.

Dans certains cas, des composants comme le noyau central 11 ,la structure fibreuse 12 les écrous ou les rondelles peuvent être supprimés au sein du dispositif 1. Ainsi une multitude de combinaisons possibles permettra à l'opérateur de sélectionner un dispositif précis qui aura la réponse mécanique et la forme appropriées au cas à traiter.Ces dispositifs 1a, 1b, 1c, 1d, 1e, 1f, 1g, 1h, 1i, dont chacun dépendra des caractéristiques à respecter (par exemple: tenue mécanique, forme, encombrement, étanchéité...) possédera après fabrication et rangement dans un présentoir une fiche signalétique correspondant à un numéro donné,et l'opérateur pourra ainsi choisir le dispositif adapté,qui lui convient pour l'implantation.

Le dispositif 1 se fixe de manière classique sur des vertèbres qui peuvent être voisines ou distantes grâce à un système de fixation composé le plus souvent de vis pédiculaires et d'un système de blocage de la tige sur ladite vis (figure 5) .

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 399 of 2152

# REVENDICATIONS

1- Dispositif de liaison vertébrale monobloc(1) caractérisé en ce qu'il comprend :

un noyau central (11) constitué d'un réseau de fibres élastiques pouvant travailler en compression.

une structure fibreuse(12) qui participe avec le noyau 11 aux caractéristiques mécaniques qui doivent satisfaire les modes de travaux requis pour le dispositif (1)

des moyens de fixation tels que par exemple :deux tiges rigides (14 a et b) qui comprennent à leurs extrémités deux filetages (141 a et b) sur lesquels viennent se visser deux écrous (143 a et b) et s'enfiler deux rondelles ( 144 a et b),qui peuvent présenter au moins un pan coupé, ces précédents moyens (141), (143),( 144), venant pincer la structure fibreuse (12) assurant une tenue mécanique en flexion et traction

un enrobage (13) constitué de préférence par une résine qui en se polymérisant vient lier l'ensemble des moyens en assurant toutes les fonctions désirées: tenue mécanique rigidité relative souplesse , bonne cohésion , étanchéité dudit dispositif (1) qui une fois constitué va pouvoir se déformer élastiquement de manière multidirectionelle en satisfaisant à tous les modes de travail qui puissent exister, ledit dispositif (1)grâce à la mise en place des précédents moyens étant capable d'amortir les sollicitations mécaniques ,en ne bloquant aucun degré de liberté .

2- Dispositif de liaison vertébrale monobloc (1) selon la reven-dication 1 caractérisé en ce que son noyau (11) est constitué d'un réseau de fibres textiles ,tridimensionnelles, ayant au départ des caractéristiques de souplesse et d'amortissement admettant l'imprégnation d'une résine, qui en se polymérisant va donner audit noyau(11) de bonnes caractéristiques de tenue en compression.

3- Dispositif de liaison vertébrale monobloc (1) selon la revendication 1 caractérisé en ce que la structure fibreuse (12) est un textile dont le réseau de fibre est bidirectionnel ,et dont la géométrie présente à ses extrémités deux têtes symétriques que l'on peut enfiler sur des tiges (14a et b) pour les rabattre et les bloquer ensuite entre les écrous et les rondelles (143) ,(144 ).

4- Dispositif de liaison vertébrale monobloc (1) selon l'une des précédentes revendications caractérisé en ce qu'il comporte un moyen d'enrobage (13) constitué d'une résine dont la nature est de préférence en polyuréthane biocompatible, et non dégradable dans le temps facile à mette en oeuvre , moulable , éventuellement usinable après moulage pour adaptation et dont les variétés de caractéristiques desdites résines permettent de résoudre toutes les fonctionnalités désirées

5-Dispositif de liaison vertébrale monobloc (1) selon la revendication 1 caractérisé en ce que les rondelles (143 et 144) présentent au moins un pan coupé qui permet le positionnement de ladite rondelle en évitant un déchirement de l'enrobage(13) et le déchaussement possible des tiges (14a et b)

# PLANCHE 1/3

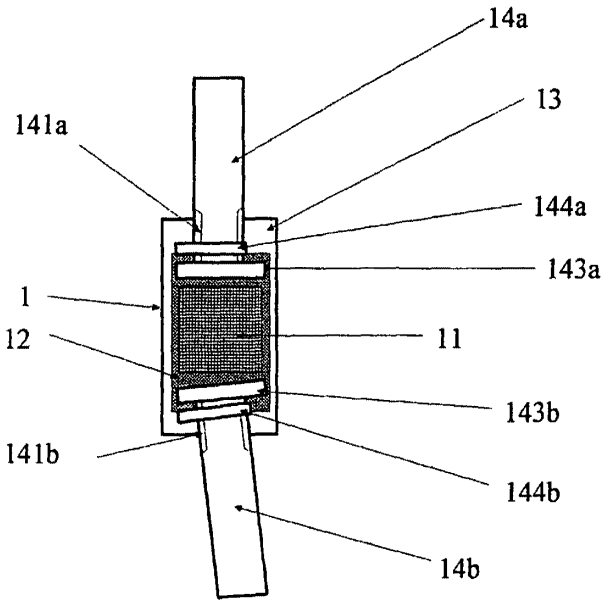



Figure 1

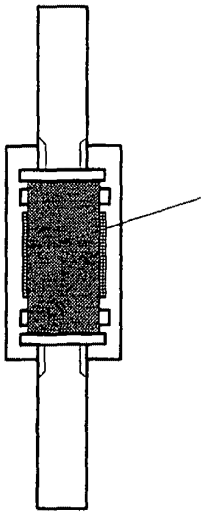


Figure 2

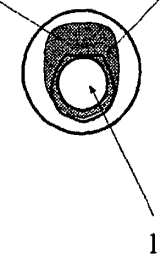



Figure 3

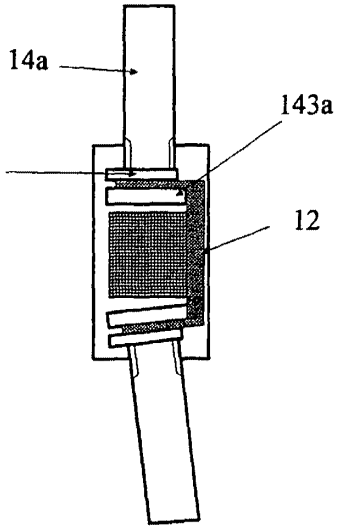



Figure 3bis

# PLANCHE 2/3

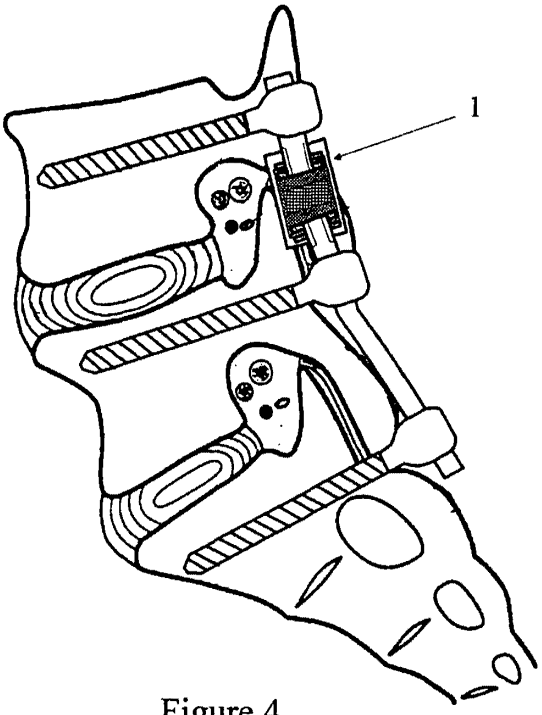



Figure 4

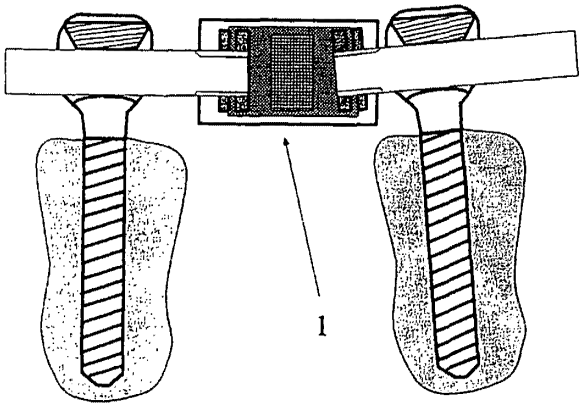



Figure 5

# PLANCHE 3/3

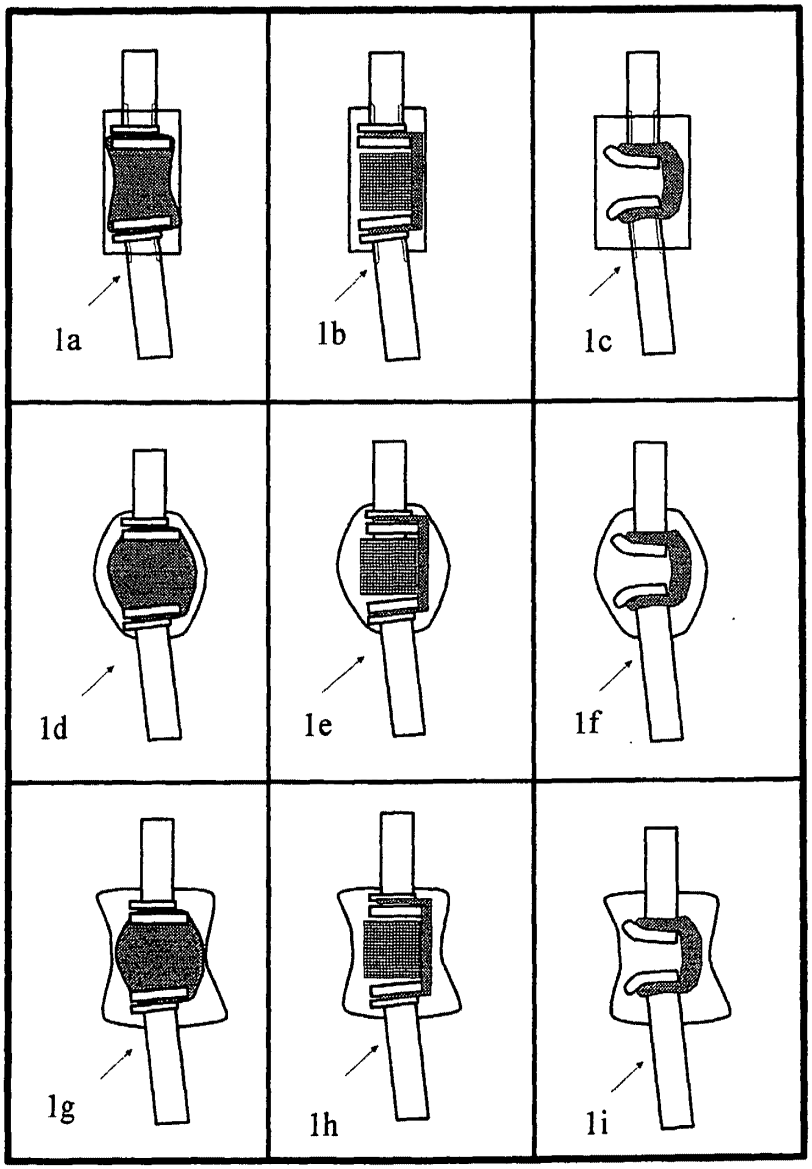



Figure 6

RÉPUBLIQUE FRANÇAISE

INPI
INSTITUT NATIONAL DE LA PROPRIETE INDUSTRIELLE

2814936

N° d'enregistrement national

FA 595972
FR 0012998

# RAPPORT DE RECHERCHE PRÉLIMINAIRE

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

| 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 | EP 0 677 277 A (P.MOREAU ET J.F.ELBERG) 18 octobre 1995 (1995-10-18) * abrégé; figure 7 * | 1 | A61B17/70 |
| A | FR 2 717 675 A (J.TAYLOR) 29 septembre 1995 (1995-09-29) * abrégé; figure 3 * * page 3, ligne 22 - ligne 28 * * page 4, ligne 25 - ligne 27 * * page 6, ligne 6 - ligne 12 * | 1,4 | |
| A | EP 0 317 972 A (ASAHI KOGAKU KOGYO) 31 mai 1989 (1989-05-31) * abrégé; figure 1 * * colonne 3, ligne 42 - ligne 51 * | 1,4 | |
| A | FR 2 755 844 A (STRYKER FRANCE ET J.F.ELBERG) 22 mai 1998 (1998-05-22) * abrégé; figure 1 * * page 2, ligne 28 - page 3, ligne 8 * | 1 | |
| | | | DOMAINES TECHNIQUES RECHERCHÉS (Int.CL.7) |
| A | FR 2 774 581 A (DIMSO ET J.F.ELBERG) 13 août 1999 (1999-08-13) * abrégé; figures 2,9 * * page 2, ligne 24 - ligne 26 * | 1 | A61B |

1

| Date d'achèvement de la recherche | Examinateur |
|---|---|
| 13 juin 2001 | Nice, P |

EPO FORM 1503 12.99 (P04C14)

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

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

(11) EP 1 190 678 A2

# (12) EUROPEAN PATENT APPLICATION

(43) Date of publication:
**27.03.2002 Bulletin 2002/13**

(51) Int Cl.7: **A61B 17/70**

(21) Application number: **01308038.7**

(22) Date of filing: **21.09.2001**

(84) Designated Contracting States:
**AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU MC NL PT SE TR**
Designated Extension States:
**AL LT LV MK RO SI**

(30) Priority: **22.09.2000 US 667937**

(71) Applicant: **DePuy AcroMed, Inc.**
**Raynham, MA 02767-0350 (US)**

(72) Inventors:
- **Bono, Frank Scott**
  **Rehoboth, Massachusetts 02769 (US)**
- **Ross, George Joseph**
  **Rehoboth, Massachusetts 02769 (US)**
- **Sicvol, Christopher Werner**
  **Boston, Massachusetts 02118 (US)**
- **Burgess, Ian**
  **Barrington, Rhode Island 02806 (US)**

(74) Representative: **Mercer, Christopher Paul et al**
**Carpmaels & Ransford**
**43, Bloomsbury Square**
**London WC1A 2RA (GB)**

## (54) Lock cap anchor assembly for orthopaedic fixation

(57) An assembly such as an anchor screw, bone plate, offset hook, post, transverse connector or other spinal anchor for anchoring to bone and clamping a linkage such as a rod, wire cable or the like. The assembly has a top member (33,53,153) with an open slot (34) to receive the linkage, and a twist-lock closure cap (40,60,140) to close the open end, capturing the linkage in the slot. One closure cap fits over and around the top member, with a set of segmented protrusions (46a,46b, 46c,46d,146) that extend through a corresponding set of protruding flange segments (36a,36b,36c,36d,158) spaced about the circumference of the top member. The cap is configured to rotate and lock against the top member like a flange-locking bayonet mount when turned through a limited degree of rotation. Slots (62a,62b) may be provided through the face of the closure cap allowing reduction tabs (55) to project through the cap, and the locking cap may be adapted to a range of screw, eye, hook, post, connector and other anchor assemblies to securely clamp the linkage by use of a rotation tool disposed along an access path aligned with the axis of the screw, thus requiring no lateral clearance along the longitudinal direction of the linkage element. Locking is effected by a set screw that passes (42) through the cap and tightens against the linkage to firmly immobilize it in the anchor assembly.

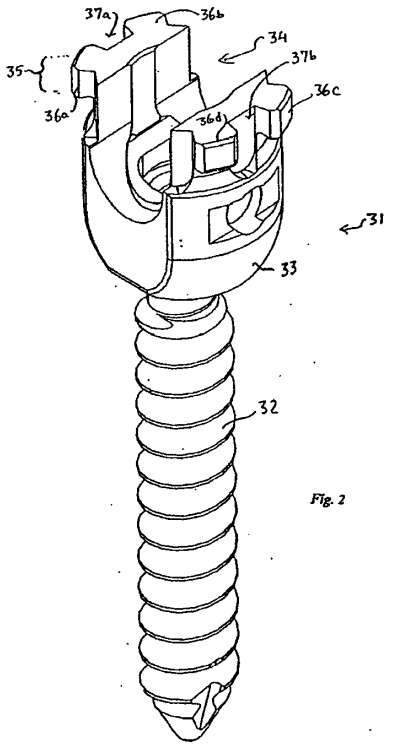



Fig. 2

EP 1 190 678 A2

Printed by Jouve, 75001 PARIS (FR)

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 406 of 2152

## Description

BACKGROUND

**[0001]** The present invention relates to orthopedic fastening systems and to mechanisms for securing and locking a linking or stabilizing element, such as a rod, to a bone screw having a slotted head that receives the rod therein. It also relates to structures or anchor assemblies having such a slotted or open head for receiving a rod, wherein the slotted portion extends from a hook, plate, bracket or positioning arm.

**[0002]** A number of such structures are known. Thus, for example, the widely used Harms T-plate used for stabilizing the cervical vertebrae has a projecting slotted bolt adapted to receive a rod or cable through the slot and clamp down by screwing a nut along the bolt to bear down against the rod. Several patents show holding structures for a fixation rod that are incorporated in the head of a screw, as in U.S. Patent 5,672,176, or into a small offset plate which itself may be fastened to the bone, as shown in published International Application WO96/28105. Other systems involve hooks, transverse rod connectors, or tandem connectors. Various tools have been provided for these systems to enable the surgeon to bend and shape the rod to a desired contour *in situ*, to position the rod in the slot of a bolt or head, and to secure the rod in position.

**[0003]** Because the rod is the stabilizing member which provides a precise contour, spacing or connection between one or more vertebrae, bones or bone fragments, alignment is quite critical, and the ability to pass the rod through two or more connecting assemblies requires various actions to form and shape the rod, or align the receiving structures at defined positions or path before final clamping is effected. This may involve positioning and removing the rod several times to check and adjust the degree of alignment. Thus, it is generally desirable to have a closure or secure locking mechanism that may be effected with simple installation steps.

**[0004]** One generally accepted locking mechanism simply involves an internally threaded locking nut that may be tightened down along the axis of the screw or slotted shaft, using a tool such as a socket wrench. Another commercial device employs a bayonet-mount cap that captures or is captured by the screw head, as in United States Patents 5,346,493 and 5,257,993. Another system utilizes a cap element with a dovetail or dovetail channel that slides over the rod to close the top of the slot and wedge the rod firmly in position. This latter construction involves no rotation of threaded members, but has the disadvantage that a certain amount of unobstructed lateral space along the rod adjacent to the connection point is necessary for the sliding installation of the closure cap. Furthermore, the cap inserts or sliding wedge closures, while they eliminate the need for awkward screwing or rotational motion during installation, cannot be used with some existing reduction screws, translation hooks or other common hardware having lengthy protruding guide members, reduction tabs or the like. Moreover, the wedge/cap closures are a specialized component that may require the user to switch entirely over to a proprietary line of orthopaedic hardware if he is to utilize the full range of hook, tab, plate and screw fixation points that may be required in spinal surgery.

**[0005]** Accordingly, it would be desirable to provide a closure cap for a bone screw or similar anchor assembly to secure a fixation linkage such as a rod or cable.

**[0006]** It would further be desirable to provide a rod-securing closure mechanism for a screw or anchor that installs simply by a partial turn.

**[0007]** It would further be desirable to provide a rod-securing closure mechanism for a screw or anchor that requires minimal lateral clearance along the rod for its installation.

**[0008]** It would further be desirable to provide a rod securing cap or closure mechanism adaptable to diverse reduction screws.

SUMMARY OF THE INVENTION

**[0009]** One or more of these and other desirable traits are achieved in accordance with the present invention by a fixation assembly wherein a closure cap fits over an opening to close a rod-receiving slot of a fixation screw, hook, post or other anchor assembly, and captures the rod therein. A set screw threads through the cap and tightens against the rod to further clamp it in the assembly. In one embodiment, the closure cap extends over and around the head of the rod-receiving assembly, which may, for example include a slotted shaft, post or head, and the cap is adapted to lock together therewith by limited rotation. This may be accomplished in one embodiment construction by arranging the cap to have a set of sector rim protrusions positioned to fit through a corresponding set of protruding bosses or partial flange segments located on the head, and to rotate into opposition therewith for securing the cap onto the top of the fixation screw. The protrusions or flange segments are angled, along the radial direction, so that they bear against each other and jam when rotated, thus cannot slip out of engagement. The opposed segments tighten and lock the cap against the head when the cap is rotated through a partial turn of about twenty-three degrees of arc, like a flange-locking bayonet mount. The cap may have a rim that extends over the outside of the bolt head to engage external flange segments on the head. In a preferred embodiment, the mating portions may located internally in the head, with flange segments projecting radially inward from the perimeter, and the cap fitting between segments in the head of the bolt and locking with a twist-in motion to capture a rod in the opening. A hold-down set screw threads through a central opening in the cap and tightens down against the rod to clamp the rod firmly in place. The closing and



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 407 of 2152

clamping may each be effected by a driver tool that operates along the axis of the assembly and requires little or no side clearance to rotate either the cap or the set screw. In the case of the external, twist-on cap, the limited degree of rotation allows the cap to also include slots through the cap to accommodate reduction tabs extending upwardly from the underlying screw or anchor member. The quick-twist closure cap assemblies of the invention may be adapted to a wide range of screw, hook, eye, plate, connector and other anchor assemblies for rod, cable and other linking elements.

## BRIEF DESCRIPTION OF THE DRAWINGS

**[0010]** These and other features of the invention will be understood more fully from the description below of representative embodiments thereof taken in conjunction with illustrative drawings, wherein

Figures 1A-1C schematically illustrate various spinal fixation rod anchor assemblies of the prior art;
Figure 2 shows on embodiment of an anchor screw of the present invention;
Figures 3 and 3A-3C show views of a closure cap utilized with the anchor screw of Figure 2 in accordance with the present invention;
Figure 4 shows a second embodiment of an anchor member and closure cap of the invention;
Figure 4A is a perspective view from below of the cap of Figure 4;
Figure 4B illustrates details of the anchor member of Figure 4;
Figure 5 shows a third embodiment of an anchor member and closure cap of the invention;
Figures 6A, 6B and 6C illustrate the cap and head structure, respectively, of embodiment of Figure 5 in greater detail; and
Figures 7A, 7B and 7C illustrate cap, head and assembled structure, respectively, of another internal twist cap embodiment.

## DETAILED DESCRIPTION

**[0011]** The invention and its range of embodiments will be better understood following a brief description of prior art, illustrating approaches to one- and two- part anchor assemblies, as well as certain common constructions.

**[0012]** Figures 1A-1C illustrate prior art anchor mechanisms for securing a fixation rod as used in spinal fixation. Figure 1A illustrates an anchor screw, while Figure 1B shows an offset tab having a slotted post for receiving the rod and Figure 1C shows a combined system in which anchor screws secure rod-shaped offset elements that, in turn, each terminate in an end that grips a common fixation rod. In the anchor screw of Figure 1A, a screw 1 with a rounded head 2 carries a slotted top member 3 into which a rod 5 shown in phantom is clamped by screwing down a threaded press ring or set screw 6. The press ring 6 is turned by engagement along its central portion e.g., by an Allen wrench, and has external threads 6a which fit corresponding internal threads 3a of the top member 3. A separate body 7 fills the space between the inner wall of the top 3 and the ball head 2 of the screw 1, so that when the rod is pressed down by the member 6, the screw head is firmly gripped and all parts are rigidly held together. An external nut 8 threads over the outside of the top to further strengthen and lock the assembly. For this prior art anchor member, the screw 1, the press member 6 and the nut 8 may all be installed with a straight tool, such as an Allen wrench or socket wrench, inserted directly along the axis of the screw.

**[0013]** Figure 1B shows another anchor assembly 15 for receiving a fixation rod 5. In this assembly, an offset tab construction having a body 15a that is anchored by a conventional bone screw 10 and including a slotted post (not numbered) for receiving the rod, is closed by a cap nut 17 which carries a pressure member 18 centrally thereon to press down against the rod 5 as the nut is tightened. In each of these two constructions, the member 6 or 17 for clamping down against the rod 5 installs by rotational movement.

**[0014]** Another prior art anchor assembly is illustrated in Figure 1C. In this article, a slotted body 21 or 22 is carried either on a bone screw (not visible in the Figure) or on a short length of offset rod 22a. In both cases, the slotted body 21 or 22 receives a rod and clamps it tightly. In this assembly the slotted head member 21 or 22 has angled or dovetailed walls at its upper portion, and a correspondingly shaped sliding cap member 23 is pressed along the dovetail into the upper region, sliding along the axis of the slot to close the slot and wedge firmly against the rod passing therethrough. As noted above, this construction has a disadvantage that a lateral clearance along the length of the rod is necessary for movement of the closure member 23 into position. Other constructions are shown in U.S. Patents Nos. 5,346,493, 5,257,993 and elsewhere.

**[0015]** Thus, the art includes both one-piece, and many-piece anchor assemblies, and these may look like screws, or may be specialized elements that are themselves to be anchored by another assembly. As described further below, the present invention provides a closing and fixing mechanism of enhanced utility, with a structure adaptable to much of this broad range of hooks, screws, connector assemblies and other orthopaedic anchor hardware involving one or more rod, cable, wire or other linking elements.

**[0016]** Figure 2 illustrates a first embodiment of an anchor screw assembly 31 of the present invention. As shown, the anchor screw assembly 31 includes a screw 32 and a top member 33 which may be integral with the screw or, like the prior art construction of Figure 1A, may be a separate head member that secures to the proximal end of the screw 32. The top member 33 includes a slot



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 408 of 2152

indicated generally by 34 for receiving a rod, and contains at its uppermost region 35, a plurality of segmented or partial flange members 36a, 36b, 36c, 36d which extend radially outward from its perimeter and have respective slots or spaces 37a, 37b therebetween. As further shown in Figure 2, each of the flange segments 36a, 36b..36d has a lower surface 38, as best seen in the end views of flange segments 36a and 36c, that engages a closure cap 40 (Figures 3A-3C). While not shown, one or more of the flange segments or cap may include a notch, detent or catch or a jamming feature, to prevent rotation in the opposite sense.

**[0017]** The anchor screw or hook 31 of Figure 2 is used in conjunction with a closure cap 40 which is shown in an upward-facing view, from below, in Figure 3C. The cap 40 fits over and around the upper portion 35 of the slotted, rod receiving top member. As shown Figure 3, the cap 40 includes a body 41 having a central threaded bore 42 extending therethrough and a pair of dependent side members 43a, 43b on opposed peripheral sides thereof which extend downward on opposed sides surrounding the outer circumference of the top member 33. Each of the side members 43a, 43b carries mating inwardly directed protrusions 46a, 46b, and 46c, 46d, respectively, which are spaced apart and positioned to correspond to the segmented flange members 36a-36d of the screw head. In particular, the protrusions 46a to 46d are positioned below the main body of the cap 41 by an amount corresponding to the maximum thickness of the flange segments 36a to 36d, and are rotationally offset so as to pass down through the gaps between segments and rotate into gripping engagement around the segments by a partial rotation of the cap 40 about the screw head assembly or top member 33, in the manner of a bayonet mounted lid closure. This secures the cap 40 on the top member closing the slot to prevent movement of the rod or cable from the head along the axial direction of the screw 32. A set screw (not shown) threaded through the aperture 42 is then tightened to clamp firmly down against the rod, cable or other linkage captured in the slot 34 (Figure 2).

**[0018]** Advantageously, with the foregoing construction, the anchor screw 31 and the closure assembly 40 as well as the set screw (not illustrated) all install by simple rotational movement of a tool that extends directly along the axis of the screw. Moreover, as illustrated, the initial locking of the cap on the head assembly is effected by a small rotational movement, substantially less than one-half turn, which corresponds approximately to the length of the lower surface 38 of one flange segment, or about 20[] of rotational movement. Thus a very slight movement is sufficient to capture the rod 5 (Figures 1A-1C) within the slot 34 during initial setup or fitting of the fixation rod.

**[0019]** This twist-lock flanged anchoring assembly with a cap structure of the present invention is readily adapted to diverse other fixation screws of known design, and thus in various alternative embodiments and adaptations may carry forward the advantages of those other designs. Thus, for example, the locking cap assembly of Figures 2-3 of the invention may be adapted to an anchor assembly such as a reduction screw, anchor screw, or hook in which the anchor member possesses protruding reduction tabs that extend upwardly from the head of the anchoring assembly.

**[0020]** Such an embodiment 50 is shown in Figure 4. In this embodiment, the head 53 of the anchor assembly has a pair of reduction tabs 55 extending upwardly from the sides of the slot. In this case, the invention contemplates a closure cap 60 with a rim-engaging securing structure similar to that of cap 40 for engagement by a small rotational motion, but the cap structure further includes a pair of arcuate slots 62a, 62b located in its central region and sized for passage of the reduction tabs 55 or other protruding head structure therethrough. Each of the slots 62a, 62b extends past the edges of the tabs 55, permitting sufficient rotation of the cap to lock the cap in position. The structure of the cap itself strengthens or supports both the surrounding wall of the rod receiving slot, and the thin-walled tabs 55 which rise therefrom, while leaving the central on-axis region above the cap entirely unobstructed for insertion, for example, of a set screw along an axial direction, and permitting line-of-sight access by a driver for installation.

**[0021]** In any of the foregoing constructions, the rod-receiving head assembly or top member 33, 53 may be integral with the anchor screw 35, 52 or may be constituted by a separate slotted head member that fits about the top of the screw to grip the rod or other connecting linkage. Thus, the invention applies to diverse anchors, hooks, monoaxial screws, transverse connections or tandem connections, slotted connectors or the like.

**[0022]** Figure 4 illustrates this aspect of the invention for a reduction tab embodiment of which the head is separate from the screw. As shown, the anchor screw assembly 50 has a screw body 52 with an enlarged head 54 which may, for example, have an Allen or other female socket formed therein (not shown) for applying torque along the axis of the screw to insert the screw in bone. A slotted top member 53 having a tapered interior bore is first fitted over the head 54, receiving the screw body from above, capturing the enlarged ball head 54 of the screw therein. A compressed member (not shown) which may be similar to element 7 of Figure 1A, may be provided to create a binding fit, and this element may be fixed in place, for example, by swaging at opposed surface relief drillings 53a, or it may fit by simple compression. The provision of top member 53 as a separate head structure that is loosely fixed to, but originally decoupled from, the screw 52 in this manner allows the slot angle to be set at a later stage of installation, while avoiding the risk of losing separate small components.

**[0023]** The cap 60 of this embodiment, which is shown in a perspective view from below in Figure 4A, is similar to that of the first described embodiment, but includes arcuate slots 62a, 62b to accommodate the projecting



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 409 of 2152

reduction tabs. In each case, the cap member having a dependent locking rim that grips the outside of the slotted top and closes the slot by a partial rotation, provides a simple and unobstructed procedure for closing the head of the anchor and capturing the rod, cable or other linkage in the anchor assembly and clamping the linkage while fixing the orientation.

**[0024]** In each of the foregoing illustrated embodiments, the cap extends radially beyond the outer radius of the anchor screw head assembly, and has a rim that extends to a greater diameter, and slides between the segmented flange bosses 36 to rotate into a captured position which closes the slot and captures the rod or other linkage within the head of the anchor assembly. A radial slant "RS" may be provided on one or more faces of the opposed locking members as shown in the detail Figure 4B to assure that they cannot slip radially outward under pressure.

**[0025]** In further embodiments, the invention contemplates a twist-on cap member which fits within the head of the anchor assembly rather than extending over and locking on the outside of the head.

**[0026]** Figure 5 illustrates one embodiment 100 of such a twist-in anchor closing mechanism. As shown, the anchor assembly 100 has a screw portion 152 for anchoring in bone, and a head portion 153 for receiving the rod, cable or other linkage. A closure cap 140 closes the slotted end of head 153. As in the previously described embodiments, the screw and head may be separate assemblies, in which case the upper portion of the screw preferably has a ball end as described above that allows the head to pivot about the axis of the screw and achieve a further degree of freedom in angular orientation before clamping down. As with the earlier described embodiments, the cap or closure portion 140 may have a central bore 145 which is internally threaded to accommodate a set screw to further clamp the rod in the slot; however, to simplify the drawing, threads are omitted from Figure 5.

**[0027]** The internal closure cap 140 has a plurality of radially protruding flange segments 146, of which one is visible in the Figure, and the cap is pushed downwardly on the head so the respective inward and outward directed segments pass between each other, in a manner similar to the above-described embodiments. Thus, the segments 146 fit between corresponding, inwardly protruding segments 158 of the head 153 and lock thereagainst by a small rotation of the cap 140.

**[0028]** Figures 6A and 6B illustrate the structure of the twist-in cap 140 and the slotted head 153 in greater detail.

**[0029]** Figure 6A shows the closure cap 140, and Figure 6B shows the head assembly 153, of an internal closure locking cap of Figure 5. As shown, the head assembly 153 of the anchor screw has a plurality of internally projecting bosses 158 and the closure cap 140 has corresponding outwardly projecting bosses 146. Respective bosses 146, 158 are dimensioned such that the cap 140 may be pushed downwardly between spaces of corresponding bosses to position the upper surface 149 of the cap bosses below the lower surface 159 of the retaining head bosses 158. As shown in Figure 6A and 6B, these mating contact surfaces are angled or sloped downwardly toward the center so that when the cap 140 is rotated to place opposed bosses in an engagement with each other, the cap exerts a net inwardly directed force on the head to prevent spreading of the retaining slot. The contours of the sloped ends are relatively sharply defined, effectively forming a circumferential ridge 149a, 159a and groove 149b, 159b on each of the respective components (Figure 6C). The ridge of one part fits in the groove of the other, so that the closure is centered and grips over a substantial contact area.

**[0030]** As best seen in Figures 5 and 6A, the twist-in cap has opposed edge flats 144 which may provide a contact or engagement surface for a tool such as a wrench used for turning the cap upon installation. Each of the flats 144 has a corner to prevent over-rotation of the cap, so that upon insertion it rotates to exactly position the respective bosses 146, 158 opposite each other as the anchor assembly is closed. The set screw is then tightened to secure the fixation linkage captured in the slot.

**[0031]** Figures 7A-7C illustrate another embodiment of a twist-in closure cap and spinal anchor assembly, having an anchor screw, a slotted head and a twist-in closure cap. As in the previously described embodiments, the screw and head may be separate assemblies, e.g., to achieve freedom in angular orientation before clamping down. The head and cap structure similarly may be adapted to spinal anchor assemblies of other types, such as transverse connectors, anchor plates and other link-receiving hardware. As with the earlier described embodiments, the cap may have a central bore which is internally threaded to accommodate a clamping set screw to lock and immobilize the linkage once it has been captured in the slot; however, to simplify the drawing, threads are omitted from Figures 7A and 7C.

**[0032]** In this embodiment, the radially protruding bosses or flange segments 146 of the cap, and the inwardly protruding bosses 158 of the head are arranged so the respective inward and outward directed segments pass between each other, when the cap is pushed downwardly into the head, in a manner similar to the above-described embodiments. Thus, the segments 146 fit between corresponding, inwardly protruding segments 158 of the head and lock thereagainst by a small rotation of the cap. In addition, the twist-lock mechanism may be configured to exert enhanced contact force in a detent region when the clamp screw is tightened down.

**[0033]** As shown in Figures 7A-C, this is achieved in a presently preferred embodiment by providing lower and upper contact faces 159, 149 on the segments 158, 146 of the head and cap, respectively, that slope downward toward the center so that when the set screw is



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 410 of 2152

tightened the upward force on the cap draws the segments 158 inward and upward. A vertically-oriented protruding ridge 158a and mating groove 146a are formed on the head and cap, on or directly above the corresponding flange region of each, so that the ridge 158a on the head is urged inwardly against the groove surface of the cap. This effectively locks the rotational detent to prevent any rotational movement of the cap once the set screw is tightened.

**[0034]** As further seen in Figures 7A and 7C, the twist-in cap has a protruding stop face 164 that contacts the head and prevents over-rotation of the cap when it is turned to close the head. Thus, upon insertion the cap rotates (clockwise as shown) to position the bosses 146, 158 exactly opposite each other as the anchor assembly is closed. The set screw is then tightened to secure the fixation linkage captured in the slot.

**[0035]** The invention being thus disclosed and illustrative embodiments depicted herein, further variations and modifications of the invention will occur to those skilled in the art. All such variations and modifications are considered to be within the scope of the invention, as defined by the claims appended hereto and equivalents thereof.

**Claims**

1. An anchor assembly for securing a fixation rod, such assembly comprising

   a spinal anchor assembly having a screw axis and a head member with a slot and an open distal end adapted for passage of a linking element such as a rod or cable therethrough and a cap for closing the open end

   wherein the head member comprises an upwardly extending body having at least a partial flange portion extending about a perimeter of said head member, and

   wherein the cap includes a cover having a plurality of spaced apart radially extending rim protrusions adapted for passing through the partial flange portion when the cover is moved along the screw axis and rotating into engagement with the partial flange portion of the head member so as to close the open end and thereby capture the linking member in the slot,

   said cap further having a centrally-placed clamping member for tightening down to further clamp the captured linking member.

2. The assembly of claim 1, wherein the head member includes a pair of reduction tabs extending upwardly therefrom, and said cap includes a corresponding pair of circumferentially oriented slots configured for passage of the reduction tabs therethrough so as to allow relative rotation of the head member and the cap.

3. The assembly of claim 1 or claim 2, wherein the clamping member includes a clamping screw that passes centrally through the cap for locking the linking member in position.

4. The assembly of any one of claims 1 to 3, wherein the partial flange portion of the head member extends externally of the perimeter, and said cap rim protrusions project inwardly from a dependent circumferential body.

5. The assembly of any one of claims 1 to 3, wherein the partial flange portion of the head member extends internally of the perimeter, and said cap fits within the head member.

6. An anchor assembly for securing a linkage such as a rod or cable, wherein the anchor assembly comprises

   an anchor element configured for attachment to a bone, and having a protruding top member including an open slot for passing the linkage therethrough, and

   a cap for closing the open slot of the top member

   wherein the top member and the cap are adapted to twist-lock together by a partial rotation to cover the slot so as to capture the linkage, and the cap further includes a clamping member for tightening down to secure the linkage.

7. The anchor assembly of claim 6, wherein the top member and cap twist-lock together by engagement of respective flange segments on said top member and said cap.

8. The anchor assembly of claim 7, wherein at least some of the flange segments are sloped along a radial direction.

9. The anchor assembly of any one of claims 6 to 8, wherein the clamping member includes a locking bolt threaded in the cap.

10. The anchor assembly of any one of claims 6 to 9, wherein the top member includes a surface forming a circumferential ridge for centering the cap.

11. The anchor assembly of any one of claims 6 to 9, wherein the top member includes reduction tabs, and the cap includes slots for passage of the reduction tabs therethrough and sized to permit said partial rotation of the cap relative to the top member.

12. The anchor assembly of any one of claims 6 to 9, wherein the top member includes radially inwardly



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 411 of 2152

protruding capture protrusions, and the cap is a twist-in-cap.

13. The anchor assembly of any one of claims 6 to 12, wherein the anchor element is a monoaxial screw, a polyaxial screw, a hook, a transverse connector, an offset connector, a slotted connector, a wire or cable anchor or an anchor for the connection of multiple longitudinal members.

14. A spinal anchor assembly for securing a linking element such as a fixation rod or cable, wherein the anchor assembly includes a head with an open slot for receiving the linking element, the head being adapted to anchor to bone, and said assembly further includes a cap for closing the head to capture the linking element in the slot, said head and said cap each having respective sets of radially-protruding segments positioned such that the respective sets pass between each other as the cap is moved along an axis of the anchor assembly, and lock against each other as the cap is rotated about said axis through a partial rotation.

15. The anchor assembly of claim 14, wherein said radially-protruding segments have a radially sloping lower surface to prevent disengagement.

16. The anchor assembly of claim 14 or claim 15, wherein said cap is an internal twist-in-cap.

17. The anchor assembly of any one of claims 14 to 16, wherein said cap extends radially outside the head.

18. The assembly of any one of claims 1 to 17 for use in securing an elongated linking element such as a rod, wire or cable to a bone.



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 412 of 2152

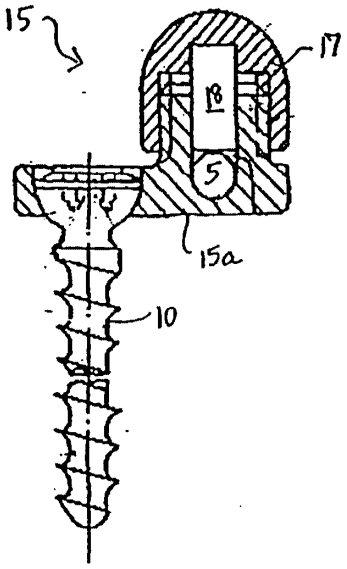



*FIG. 1B*
*( PRIOR ART)*

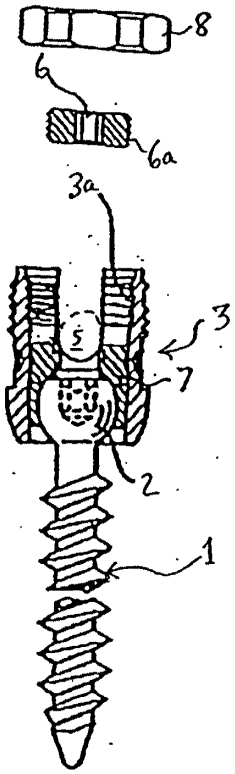



*FIG. 1A*
*(PRIOR ART)*




*FIG. 1C*
*(PRIOR ART)*



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 413 of 2152

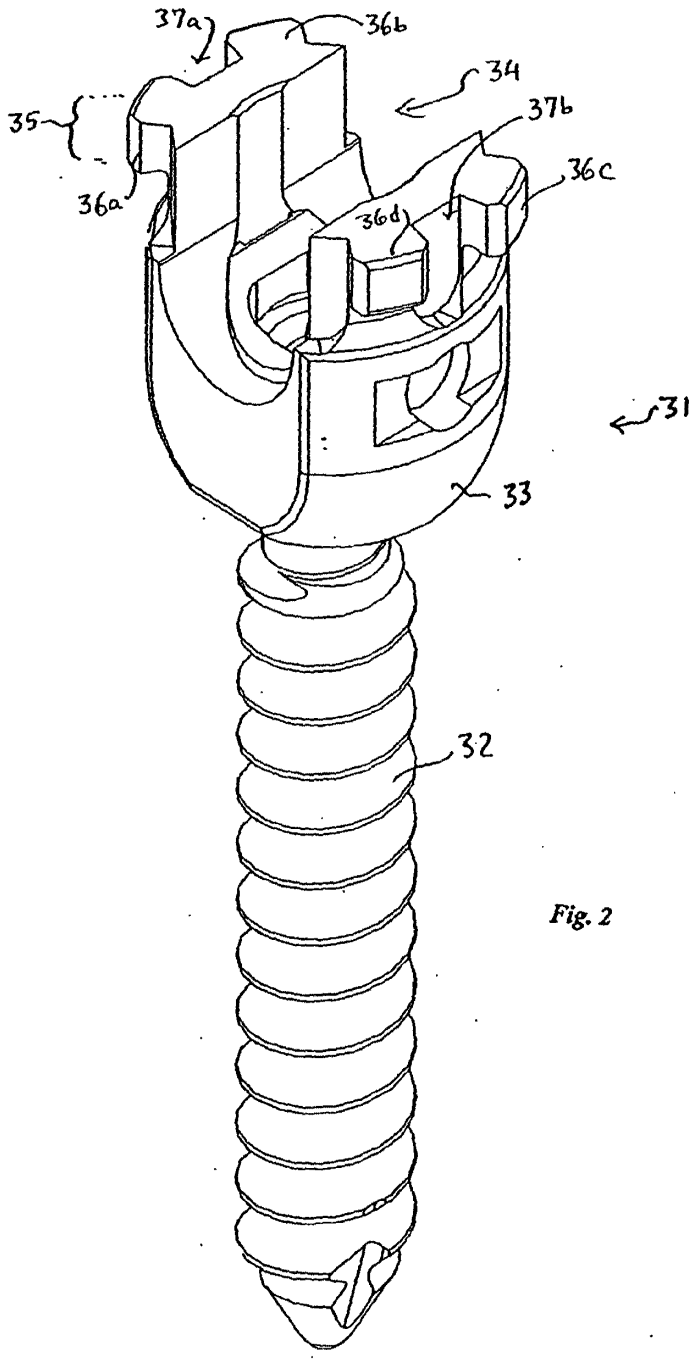



*Fig. 2*



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 414 of 2152

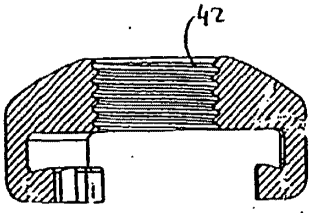



Fig. 3A

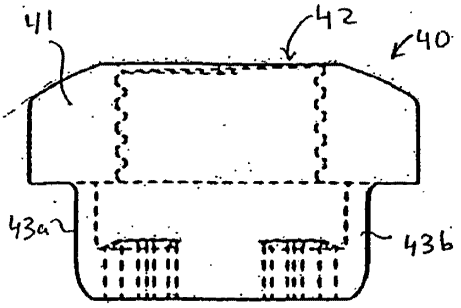



Fig. 3

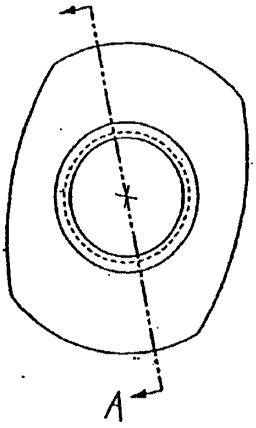



Fig. 3B

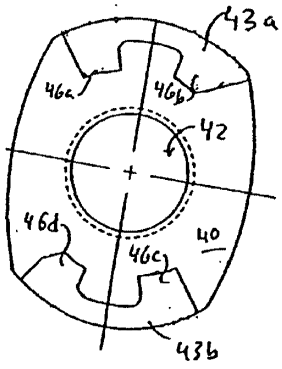



Fig. 3C



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 415 of 2152

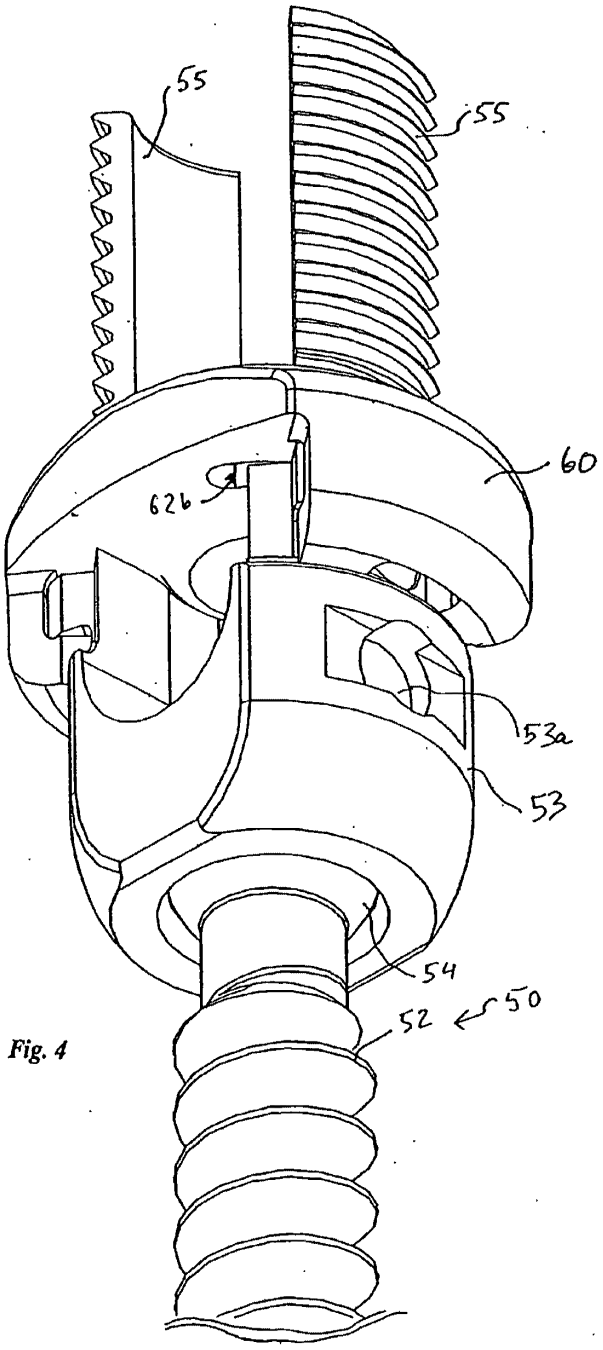



*Fig. 4*



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 416 of 2152

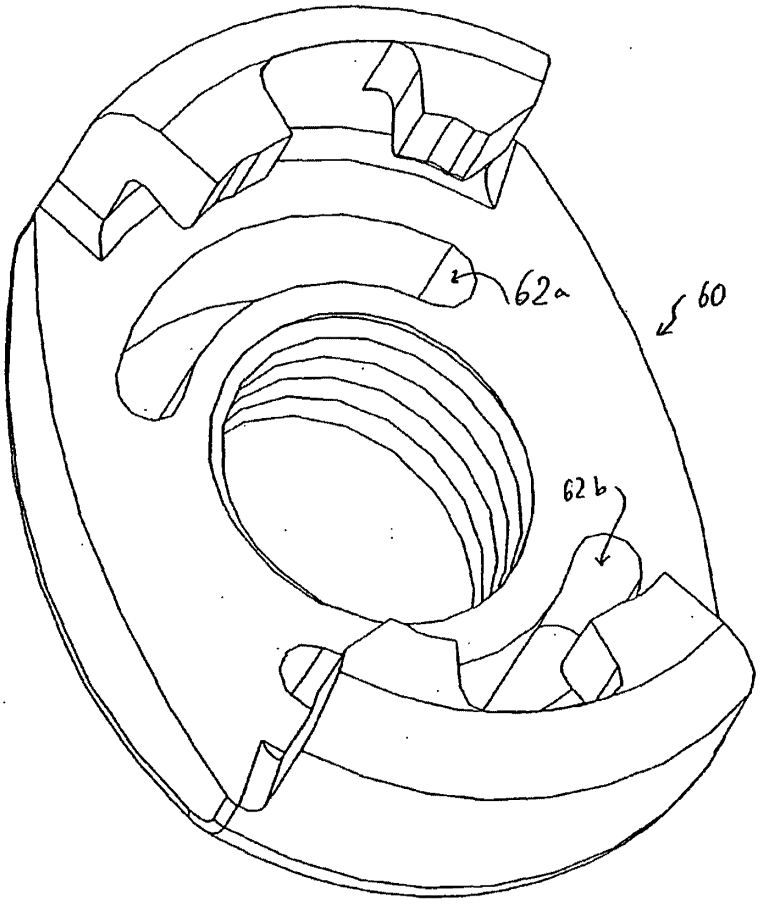



*Fig. 4A*



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 417 of 2152

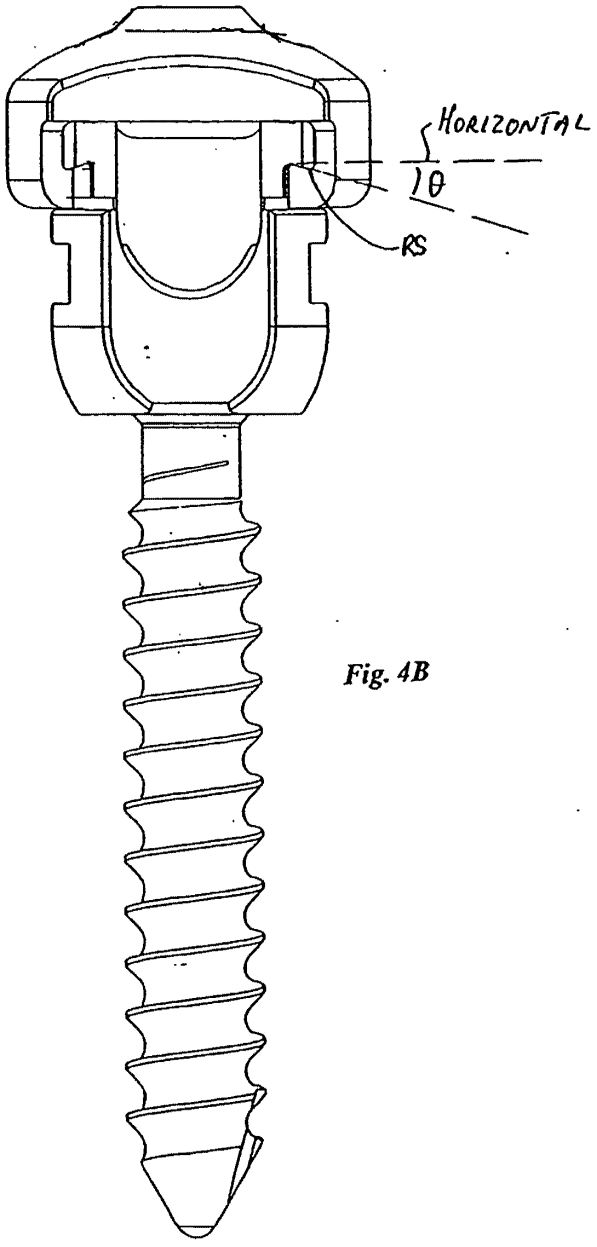



*Fig. 4B*



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 418 of 2152

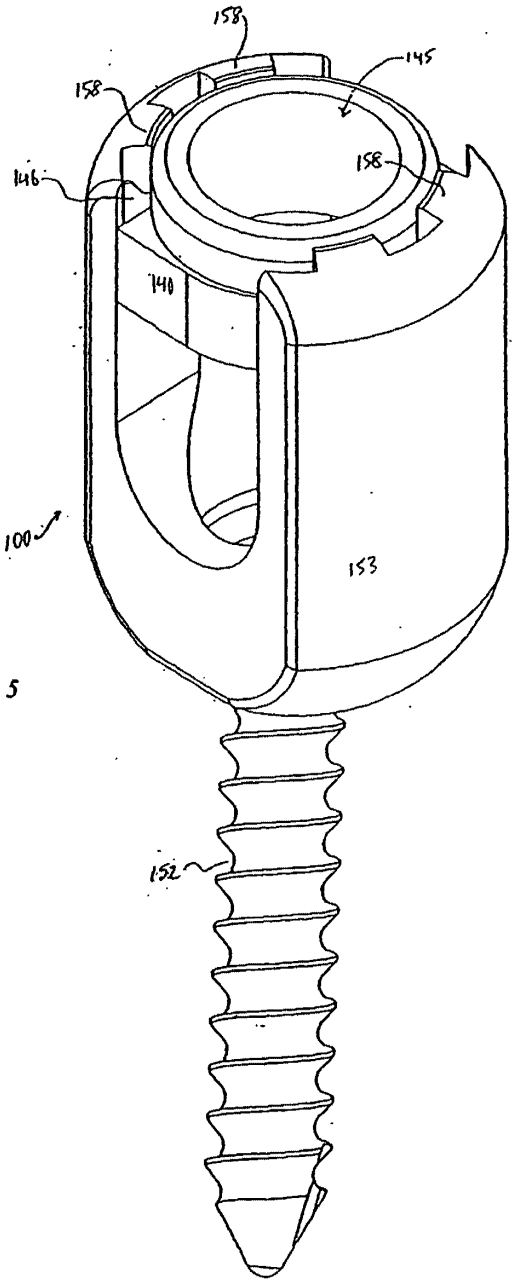



*Fig. 5*



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 419 of 2152

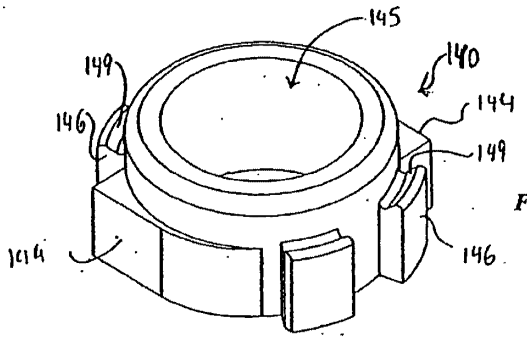



*Fig. 6A*

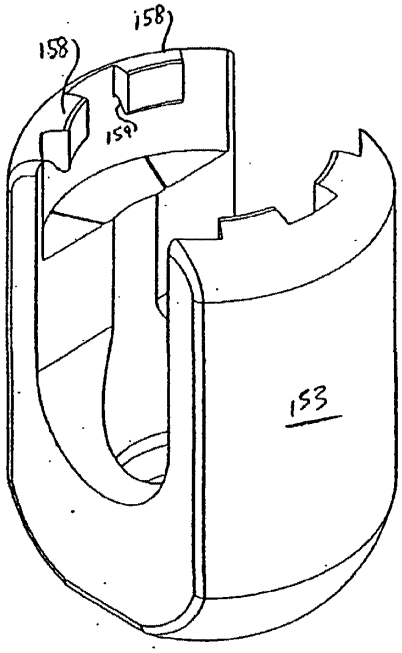



*Fig. 6B*

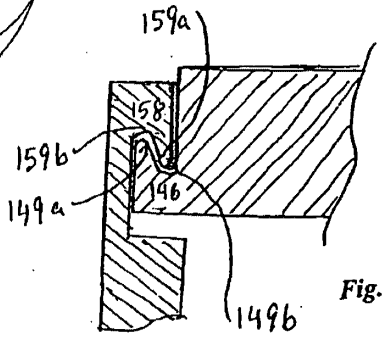



*Fig. 6C*



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 420 of 2152

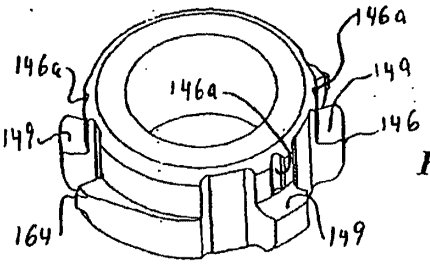



FIG. 7A

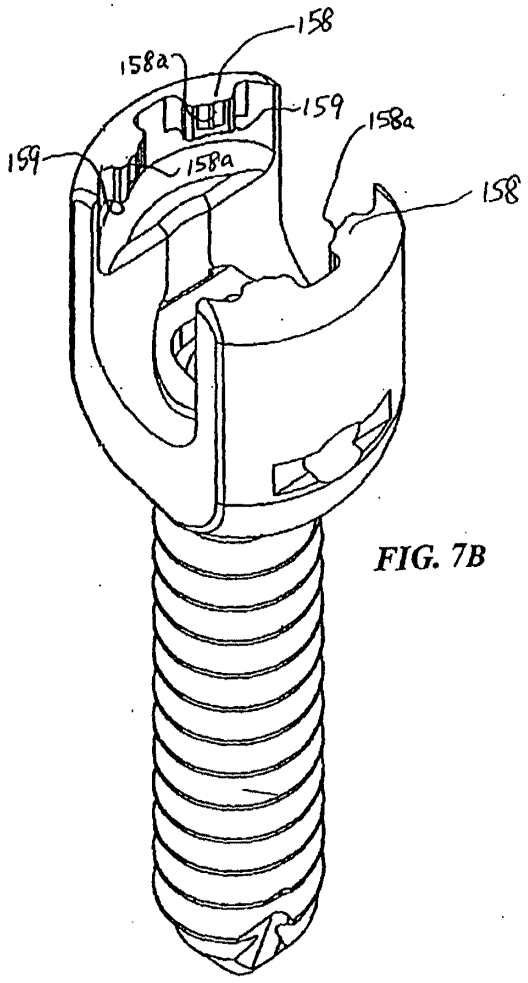



FIG. 7B



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 421 of 2152

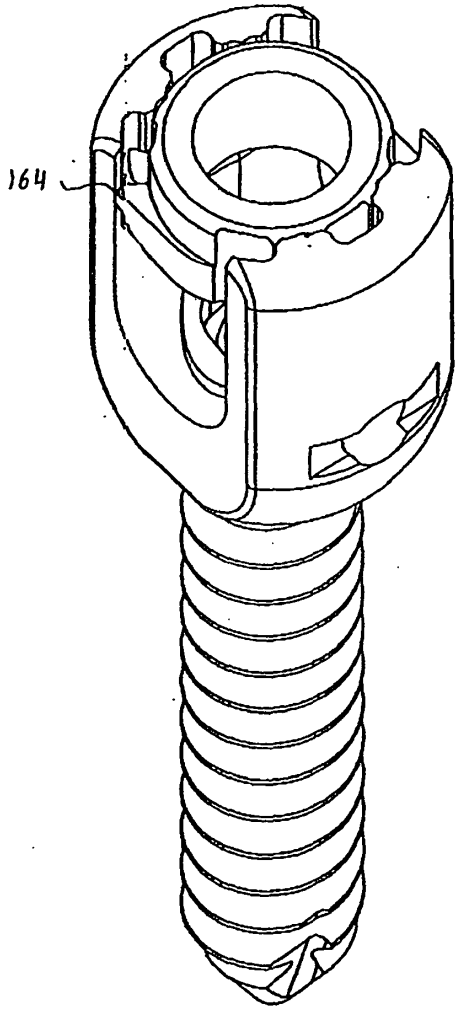



*FIG. 7C*



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 422 of 2152

(12) UK Patent Application (19) GB (11) 2 365 345 (13) A

(43) Date of A Publication 20.02.2002

(21) Application No 0109464.8

(22) Date of Filing 18.04.2001

(30) Priority Data
(31) 0017924 (32) 22.07.2000 (33) GB
(31) 0108270 (32) 03.04.2001

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

(52) UK CL (Edition T )
A5R RFB RX7

(56) Documents Cited
WO 98/27884 A1 WO 01/22893 A1
US 5797911 A US 5681319 A

(58) Field of Search
UK CL (Edition S ) A5R RFB
INT CL[7] A61B 17/70
ONLINE:EPODOC, WPI, JAPIO

(71) Applicant(s)
Corin Limited
(Incorporated in the United Kingdom)
The Corinium Centre, Cirencester, Gloucestershire, GL7 1YJ, United Kingdom

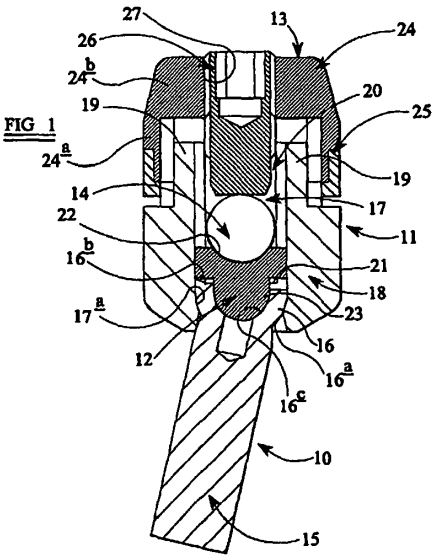
(72) Inventor(s)
Derek Redvers Cooper
Simon Nicholas Collins
Ian James Emslie
David Mark Fletcher

(74) Agent and/or Address for Service
A R Davies & Co
27 Imperial Square, CHELTENHAM, Gloucestershire, GL50 1RQ, United Kingdom

(54) Abstract Title
**A pedicle attachment assembly**

(57) The pedicle attachment assembly comprises a pedicle attachment device 10 having a head 16. A polyaxial housing 11 has a through bore 17 comprising a base portion 18 and two posts 19 upstanding from the base portion, the posts defining therebetween a slot 20 for receiving a rod 14. A saddle-shaped element 12 is disposable in the slot and has a part cylindrical recess 22 in an upper surface for engagement in use with the rod. The saddle-shaped element has a convex lower portion 23 for engagement in a complimentary concave recess 16c in an upper surface of the head of the attachment device. The lower surface of the head of the attachment device 16a and the lower end of the through bore 17a in the housing have complementary part spherical surfaces for engagement with one another. A cap assembly 13 is provided for clamping the rod in the housing.

FIG 1




GB 2 365 345 A

At least one drawing originally filed was informal and the print reproduced here is taken from a later filed formal copy.

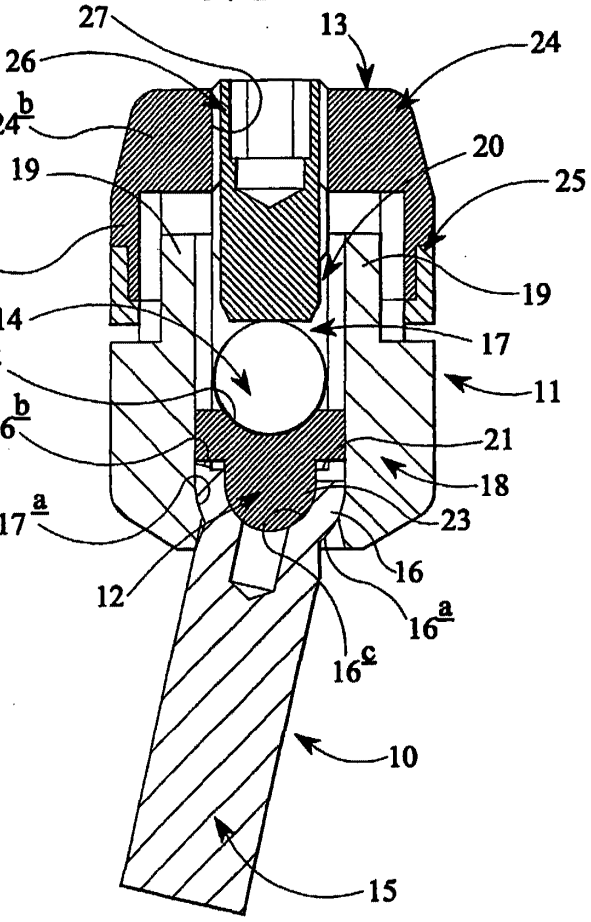

27
13
24
26
24b
20
19
25
24a
19
14
17
22
11
16b
21
18
17a
23
16
12
16a
16c
10
15

FIG 1

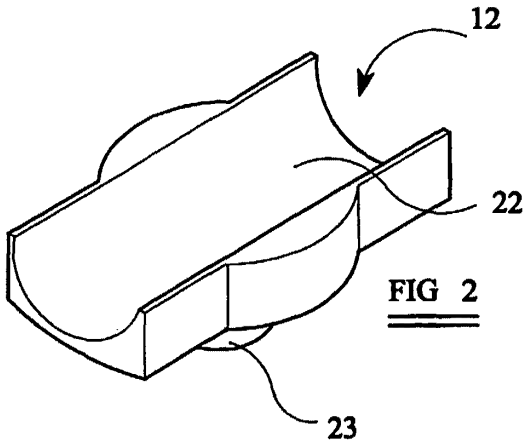

12
22
23

FIG 2

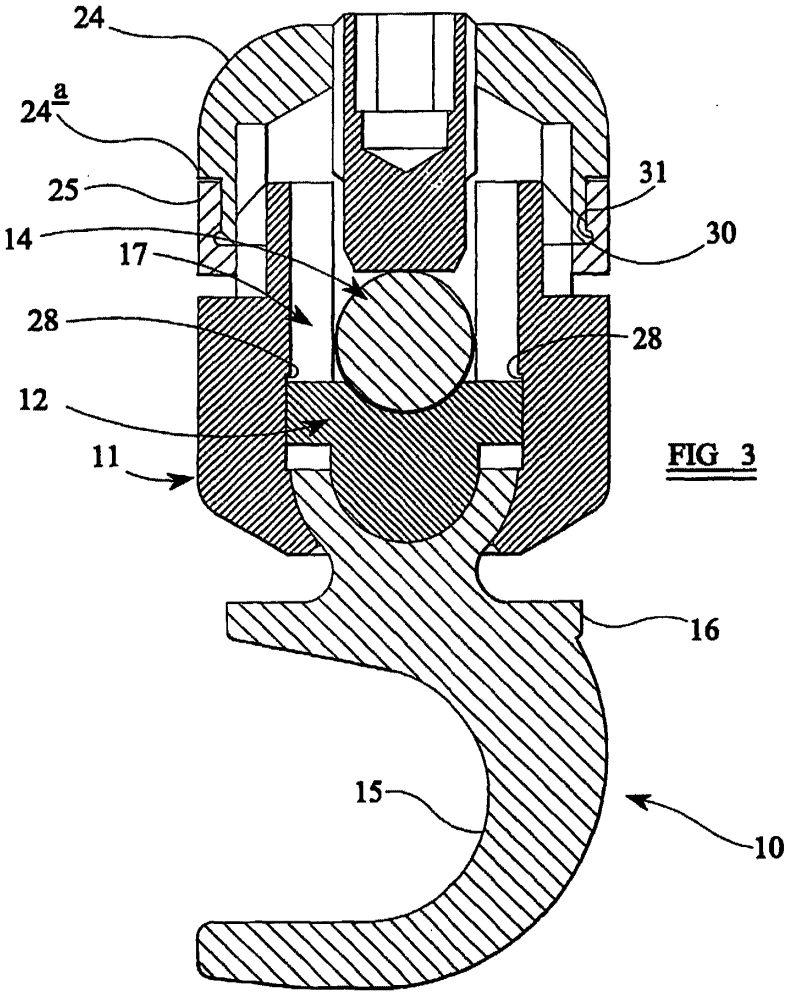



FIG 3

# A PEDICLE ATTACHMENT ASSEMBLY

This invention relates to a pedicle attachment assembly for use in conjunction with a rod for immobilising bone segments, particularly in the spine, so as to allow the segments to fuse together.

To achieve bone fusion or arthrodesis a stable environment has to be created. The pedicle attachment and rod assembly immobilises the bony junction so that bone graft of bone substitute material which is placed across the junction can consolidate. This consolidation process takes place during the healing process and creates a bony bridge or solid fusion mass across and between the bony junction. The process of arthrodesis has been well documented in the field of batch mechanics and traumatology.

According to a first aspect of the present invention there is provided a pedicle attachment assembly comprising a pedicle attachment device having a head, a polyaxial housing having a through bore and comprising a base portion and two posts upstanding from the base portion, the posts defining therebetween a slot for receiving a rod, a saddle-shaped element disposed or disposable in the slot and having a part cylindrical recess in an upper surface for engagement in use with the rod, the head of the attachment device and the lower end of the through bore having interengageable first portions and the head of the attachment device and the saddle-shaped element have interengageable second portions, the first portions and the second portions being shaped to allow the attachment device to pivot relative to the housing and the saddle-shaped element, and a cap assembly for use in clamping the rod in the housing.

Preferred and/or optional features of the first aspect of the invention are set out in claims 2 to 11.

According to a second aspect of the invention there is provided a pedicle screw assembly comprising a pedicle screw having a threaded stem and a head of larger diameter than the stem, a polyaxial housing having a through bore and comprising a base portion and two posts upstanding from the base portion, the posts defining therebetween a slot for receiving a rod, a saddle-shaped element disposed or disposable in the slot and having a part cylindrical recess in an upper surface for engagement in use with the rod, the lower surface of the head of the screw and the lower end of the through bore in the housing having complementary part spherical or substantially part spherical surfaces for engagement with one another, and a cap assembly for in use clamping the rod in the housing, the cap assembly comprising a cap having an internally threaded skirt portion for threadably engaging external threads provided on the two posts and a top portion having an internally threaded aperture, and a set screw engageable in the internally threaded aperture so that diametrically opposed regions of the lower edge of the cap and the set screw in use provide three point clamping between the rod and the cap assembly.

A preferred or optional feature of the second aspect of the invention is set out in claim 13.

The invention will now be more particularly described, by way of example, with reference to the accompanying drawings, in which:

Figure 1 is a sectional view through one embodiment of a pedicle attachment assembly according to the present invention,

Figure 2 is a perspective view of the saddle-shaped element of the pedicle attachment assembly shown in Figure 1, and

Figure 3 is a sectional view through another embodiment of a pedicle attachment assembly according to the present invention.

Referring to Figures 1 and 2 of the drawings, the pedicle attachment assembly shown therein is intended to be secured to bone segments of a patient's spine and comprises a pedicle attachment device in the form of a screw 10, a polyaxial housing 11, a saddle-shaped element 12 and a cap assembly 13. Figure 1 also shows a rod 14 which is clamped to two or more pedicle screw assemblies secured to different bone segments of the spine to immobilise the segments and allow the segments to fuse together. The assembly is typically formed of titanium.

The pedicle screw 10 comprises a threaded stem 15 and a head 16 having a diameter larger than the stem.

The polyaxial housing 11 has a through bore 17 and comprises a base portion 18 and two posts 19 upstanding from the base portion, the posts 19 defining therebetween a slot 20 for receiving the rod 14. The base of the slot 20 is indicated by the reference numeral 21.

The through bore 17 has a diameter, apart from at its lowermost end, sufficient to allow the stem 15 and head 16 of the pedicle screw 10 to pass therethrough. However, the lowermost end 17a of the through bore 17 is of part spherical shape and the diameter of the opening at the lowermost end of the through bore is sufficient to allow the stem 15 but not the head 16 of the pedicle screw to pass therethrough.

The lower surface 16a of the head 16 of the screw 10 is of part spherical shape so as to be complementary with the shape of the lowermost end 17a of the

through bore. This enables the screw 10 to tilt in any direction with respect to the housing 11.

The saddle-shaped element 12 is disposed in the slot 20 of the housing and extends across the entire width of the housing 11 and into the gaps between adjacent free side edges of the posts 19. This ensures that the saddle-shaped element 12 cannot be angularly displaced relative to the housing 11.

The saddle-shaped element 12 has a part cylindrical recess 22 in its upper surface, the recess 22 extending the longitudinal extent of the element 12, for engagement with the rod 14. By virtue of the fact that the saddle-shaped element 12 cannot be angularly displaced within the housing 11, the part cylindrical recess 22 is always correctly orientated to engage with the rod 14. The saddle-shaped element 12 has a convex and preferably a part spherical lower portion 23 for engagement in a complementary concave and preferably part spherical recess 16c in the head 16 of the screw 10. This enables the screw 10 to pivot with respect to the housing 11 and the saddle-shaped element 12 without vertical displacement of the saddle-shaped element 12 relative to the screw head 16 particularly where the lower portion 23 and recess 16c are part spherical. As an alternative to the above arrangement, the saddle-shaped element may have a concave and preferably a part spherical recess for engagement with a complementary convex and preferably part spherical portion on the head of the screw.

The posts 19 have a stepped external diameter and the smaller diameter ends are uppermost and are externally threaded.

The cap assembly 13 comprises a cap, having a main portion 24 and a collar 25, and a set screw 26. The main portion 24 of the cap comprises a skirt portion 24a

and a top portion 24b. The skirt portion 24a is internally threaded for threadable engagement with the external threads on the upper parts of the posts 19. The upper portion 24b of the cap has a central internally threaded aperture 27 threadably engageable with an external thread on the set screw 26.

The collar 25 is of stepped internal diameter, the lower end being of smaller diameter than the upper end and corresponding in diameter to the internal diameter of the skirt portion of the cap. The collar is a push fit over an externally stepped lower portion of the cap and serves to provide, when in use contacting the rod 14, a stationary or substantially stationary downwardly directed clamping force onto the rod 14 as the main portion 24 of the cap assembly 13 is being tightened.

In use, the screw 10 is fitted in the housing 11 and the screw is then screwed into the bone. In order to enable this to be done, the head of the screw 10 may be provided with cross slots which are engaged by a screwdriver portion of a special tool. A sleeve on the tool engages the external thread on the posts 19 thus pulling the screwdriver portion and screw together and rigidly locking the screw 10 and housing 11 together in the same axis during implantation. Once the screwdriver has been released, the housing 11 will be left free to articulate on the screw head.

The saddle-shaped element 12 is then placed in the slot 20 between the posts 19 of the housing 11. The rod 14 is then placed in the slot 20 to come into contact with the part cylindrical recess 22 in the upper surface of the saddle-shaped element 12. The cap assembly 13 is then screwed down onto the posts 19 and finally the set screw 26 is screwed into the aperture 27. Diametrically opposed regions of the lower edge of the collar 25, together with the set screw 26, provide three point clamping between the rod 14 and the cap assembly 13.

A pedicle screw assembly as described above reduces the need for accurate contouring of the rod 14.

Referring now to Figure 3 of the drawings, the pedicle attachment device comprises a hook 10 comprising a hook-shaped portion 15' (instead of a threaded stem) and a head 16'. In most other respects the attachment assembly is identical to the attachment assembly of Figures 1 and 2. However, the saddle-shaped element 12 is held captive relative to the housing 11 by providing a slight inwards step 28 in the bore 17 above the saddle-shaped element 12. Also, the collar 25 is held captive with the main portion 24 of the cap by providing the outer surface of the skirt portion 24a of the cap with a circumferentially extending lip 30 which is received in an annular groove 31 in the inner surface of the collar 25. These two modifications could also be made to the embodiment shown in Figures 1 and 2 to make the saddle-shaped element of that embodiment captive relative to the housing and to make the collar captive with the main portion of the cap.

The above embodiments are given by way of example only and various modifications will be apparent to persons skilled in the art without departing from the scope of the invention as defined in the appended claims.

## CLAIMS

1. A pedicle attachment assembly comprising a pedicle attachment device having a head, a polyaxial housing having a through bore and comprising a base portion and two posts upstanding from the base portion, the posts defining therebetween a slot for receiving a rod, a saddle-shaped element disposed or disposable in the slot and having a part cylindrical recess in an upper surface for engagement in use with the rod, the head of the attachment device and the lower end of the through bore having interengageable first portions and the head of the attachment device and the saddle-shaped element have interengageable second portions, the first portions and the second portions being shaped to allow the attachment device to pivot relative to the housing and the saddle-shaped element, and a cap assembly for use in clamping the rod in the housing.

2. A pedicle attachment assembly as claimed in claim 1, wherein the saddle-shaped element has a convex (or concave) lower portion for engagement with a complementary concave (or convex) portion in (or on) the upper surface of the head of the attachment device.

3. A pedicle attachment assembly as claimed in claim 2, wherein the lower portion of the saddle-shaped element and the upper surface of the head of the attachment device are of complementary part spherical or substantially part spherical shape.

4. A pedicle attachment assembly as claimed in any one of the preceding claims, wherein the lower surface of the head of the attachment device and the lower end of the through bore in the housing have complementary part spherical or substantially part spherical surfaces for engagement with one another.

5. A pedicle attachment assembly as claimed in any one of the preceding claims, wherein the saddle-shaped element extends across the entire width of the polyaxial housing and into the gaps between adjacent free side edges of the posts.

6. A pedicle attachment assembly as claimed in any one of the preceding claims, wherein the saddle-shaped element is held captive relative to the polyaxial housing.

7. A pedicle attachment assembly as claimed in any one of the preceding claims, wherein the cap assembly comprises a cap having an internally threaded skirt portion for threadably engaging external threads provided on the two posts and a top portion having an internally threaded aperture, and a set screw engageable in the internally threaded aperture so that diametrically opposed regions of the lower edge of the cap and the set screw in use provide three point clamping between the rod and the cap assembly.

8. A pedicle attachment assembly as claimed in claim 7, wherein the cap comprises a main portion including the top portion and an internally threaded part of the skirt portion and an internally stepped collar for fitting or fitted over the skirt portion.

9. A pedicle attachment assembly as claimed in claim 7 or claim 8, wherein the collar is held captive relative to the main portion of the cap.

10. A pedicle attachment assembly as claimed in any one of the preceding claims, wherein the attachment device is a screw having a threaded stem and a head of larger diameter than the stem.

11. A pedicle attachment assembly as claimed in any one of claims 1 to 9, wherein the attachment device comprises a hook having a head.

12. A pedicle screw assembly comprising a pedicle screw having a threaded stem and a head of larger diameter than the stem, a polyaxial housing having a through bore and comprising a base portion and two posts upstanding from the base portion, the posts defining therebetween a slot for receiving a rod, a saddle-shaped element disposed or disposable in the slot and having a part cylindrical recess in an upper surface for engagement in use with the rod, the lower surface of the head of the screw and the lower end of the through bore in the housing having complementary part spherical or substantially part spherical surfaces for engagement with one another, and a cap assembly for in use clamping the rod in the housing, the cap assembly comprising a cap having an internally threaded skirt portion for threadably engaging external threads provided on the two posts and a top portion having an internally threaded aperture, and a set screw engageable in the internally threaded aperture so that diametrically opposed regions of the lower edge of the cap and the set screw in use provide three point clamping between the rod and the cap assembly.

13. A pedicle screw assembly as claimed in claim 12, wherein the cap comprises a main portion including the top portion and an internally threaded part of the skirt portion and an internally stepped collar for fitting over the skirt portion.

14. A pedicle attachment assembly substantially as hereinbefore described with reference to Figure 1 and 2, or Figure 3, of the accompanying drawings.

**Amendments to the claims have been filed as follows**

CLAIMS

1. A pedicle attachment assembly comprising a pedicle attachment device having a head, a polyaxial housing having a through bore and comprising a base portion and two posts upstanding from the base portion, the posts defining therebetween a slot for receiving a rod, a saddle-shaped element disposed or disposable in the slot and having a part cylindrical recess in an upper surface for engagement in use with the rod, the lower surface of the head of the attachment device and the lower end of the through bore having complementary part spherical or substantially part spherical surfaces, the head of the attachment device having a part spherical or substantially part spherical recess and the lower portion of the saddle-shaped element being part spherical or substantially part spherical for engagement in the recess in the head of the attachment device so as to allow the attachment device to pivot relative to the housing and the saddle-shaped element, and a cap assembly for use in clamping the rod in the housing.

2. A pedicle attachment assembly as claimed in any one of the preceding claims, wherein the saddle-shaped element extends across the entire width of the polyaxial housing and into the gaps between adjacent free side edges of the posts.

3. A pedicle attachment assembly as claimed in claim 1 or claim 2, wherein the saddle-shaped element is held captive relative to the polyaxial housing.

4. A pedicle attachment assembly as claimed in any one of the preceding claims, wherein the cap assembly comprises a cap having an internally threaded skirt portion for threadably engaging external threads provided on the two posts and a top portion having an internally threaded aperture, and a set screw engageable in the internally threaded aperture so that diametrically opposed regions of the lower edge of

the cap and the set screw in use provide three point clamping between the rod and the cap assembly.

5. A pedicle attachment assembly as claimed in claim 4, wherein the cap comprises a main portion including the top portion and an internally threaded part of the skirt portion and an internally stepped collar for fitting or fitted over the skirt portion.

6. A pedicle attachment assembly as claimed in claim 4 or claim 5, wherein the collar is held captive relative to the main portion of the cap.

7. A pedicle attachment assembly as claimed in any one of the preceding claims, wherein the attachment device is a screw having a threaded stem and a head of larger diameter than the stem.

8. A pedicle attachment assembly as claimed in any one of claims 1 to 6, wherein the attachment device comprises a hook having a head.

9. A pedicle attachment assembly substantially as hereinbefore described with reference to Figure 1 and 2, or Figure 3, of the accompanying drawings.

**Application No:** GB 0109464.8 **Examiner:** Jason Bellia
**Claims searched:** 1-11 & 14 in part **Date of search:** 18 October 2001

## Patents Act 1977
## Search Report under Section 17

**Databases searched:**

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK Cl (Ed.S): A5R (RFB)

Int Cl (Ed.7): A61B 17/70

Other: ONLINE:EPODOC, WPI, JAPIO

**Documents considered to be relevant:**

| Category | Identity of document and relevant passage | | Relevant to claims |
|---|---|---|---|
| X | WO 01/22893 A1 | (BLACKSTONE MEDICAL) See page 9 line 18-22, Figures 1 & 2 | 1-4, 6 & 10 |
| X | WO 98/27884 A1 | (HAIDER) See Figures 2-5 | 1-4 & 10 |
| X | US 5 797 911 | (SHERMAN *et la*) See Figure 2 and column 6 line 28-43 | 1-4 |
| X | US 5 681 319 | (BIEDERMANN *et al*) See column 3 line 57 - column 4 line 2 | 1-4 & 10 |

| | | | |
|---|---|---|---|
| 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. |
| & | Member of the same patent family | E | Patent document published on or after, but with priority date earlier than, the filing date of this application. |



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 437 of 2152

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

(11) EP 1 121 902 A2

# (12) EUROPÄISCHE PATENTANMELDUNG

(43) Veröffentlichungstag:
**08.08.2001 Patentblatt 2001/32**

(51) Int Cl.7: **A61B 17/70**

(21) Anmeldenummer: **01100933.9**

(22) Anmeldetag: **17.01.2001**

(84) Benannte Vertragsstaaten:
**AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU MC NL PT SE TR**
Benannte Erstreckungsstaaten:
**AL LT LV MK RO SI**

(30) Priorität: **07.02.2000 DE 10005385**

(71) Anmelder: **Ulrich GmbH & Co. KG**
**89081 Ulm (DE)**

(72) Erfinder:
- **Schäffler-Wachter, Martin**
  **89231 Neu-Ulm (DE)**
- **Schönhöffer, Helmut**
  **89155 Erbach (DE)**

(74) Vertreter: **Hentrich, Swen Dipl.-Phys. Dr. et al**
**Postfach 17 67**
**89007 Ulm (DE)**

## (54) Pedikelschraube

(57) Die Erfindung betrifft eine Pedikelschraube für Implantate zur Korrektur und Stabilisierung der Wirbelsäule. Diese Pedikelschraube besitzt ein an dem axialen Ende eines Gewindeschafts (3) angeordnetes Kopfteil (5), an dem ein Bügelteil (7) anschließbar ist, das eine Aufnahme für einen am Kopfteil (5) fixierbaren Stab (2) aufweist. Das Kopfteil (5) ist durch ein Rundstück (4) und eine drehbar auf dem Rundstück (4) gelagerten Kappe (6) gebildet. Das Bügelteil (7) ist durch eine in axialer Richtung erfolgende Steckbewegung in einem Rastsitz an der Kappe (6) fixierbar.

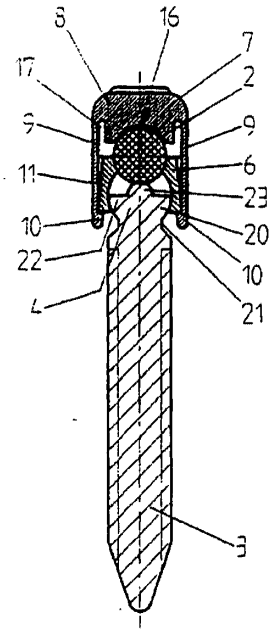



Fig. 3

EP 1 121 902 A2

Printed by Jouve, 75001 PARIS (FR)

## Beschreibung

**[0001]** Die Erfindung betrifft eine Pedikelschraube für Implantate zur Korrektur und Stabilisierung der Wirbelsäule, mit einem an dem axialen Ende eines Gewindeschafts angeordneten Kopfteil, an dem ein Bügelteil anschließbar ist, das eine Aufnahme für einen am Kopfteil fixierbaren Stab aufweist.

**[0002]** Derartige Pedikelschrauben sind beispielsweise aus der DE 41 07 480 A1 bekannt. Bei diesen bekannten Pedikelschrauben übergreift das Bügelteil das Kopfteil mit seitlichen Schenkelteilen, in denen parallel zur Längsrichtung des Stabes verlaufende, einseitig offene Nuten ausgebildet sind, in die am Kopfteil vorgesehene und entsprechend verlaufende Leisten formschlüssig eingreifen, wobei zur Vermeidung von Abspreizungen die Leisten und Nuten an ihren aneinanderliegenden Schenkelteilen schwalbenschwanzartige Hinterschneidungen aufweisen. Diese Pedikelschrauben haben sich in der Praxis gut bewährt, da es mit diesen möglich ist, eine stabile und dauerhafte Fixierung der Lage des Stabes zu ermöglichen. Allerdings ist für die Plazierung und gegenseitige Fixierung von der Pedikelschraube und dem Stab während der Operation relativ viel Raum erforderlich, wobei es infolge der Krümmung der Wirbelsäule und der geneigt zur Längsachse der Wirbelkörper eingesetzten Pedikelschrauben möglich ist, daß die bereits plazierten Pedikelschrauben die Plazierung der Pedikelschrauben am unmittelbar benachbarten Wirbel behindern oder sogar verhindern.

**[0003]** Der Erfindung liegt daher die Aufgabe zugrunde, eine Pedikelschraube der eingangs genannten Art so auszubilden, daß der Raumbedarf für die Plazierung und Justierung der Pedikelschraube während der Operation verringert ist.

**[0004]** Diese Aufgabe wird nach der Erfindung bei einer Pedikelschraube der eingangs genannten Art dadurch gelöst, daß das Kopfteil durch ein Rundstück und eine drehbar auf dem Rundstück gelagerten Kappe gebildet ist, und daß das Bügelteil durch eine in axialer Richtung erfolgende Steckbewegung in einem Rastsitz an der Kappe fixierbar ist.

**[0005]** Die Erfindung bietet den Vorteil, daß nach dem Plazieren der Pedikelschrauben in dem Wirbelkörper und der Positionierung des Stabes die weiteren erforderlichen Maßnahmen des Operateurs nur in der Längsrichtung des Gewindeschaftes durchgeführt werden müssen, also gegenüber dem Raum der ohnehin für das Einschrauben der Pedikelschrauben benötigt wird, kein zusätzlicher Raum erforderlich ist. Dabei ist eine individuelle Anpassung an den Verlauf des in der Regel gekrümmten Stabes möglich, da neben der geeigneten Wahl der Drehlage des Gewindeschaftes der Pedikelschraube mit dem Kopfteil zusätzlich die Kappe um das Rundstück verdreht werden kann.

**[0006]** Die so gegebene Verdrehbarkeit unterliegt den geringsten Einschränkungen, wenn das Rundstück als Halbkugel mit senkrecht zu dem Gewindeschaft orientierter, zum freien Ende weisender Planfläche ausgebildet ist.

**[0007]** Ist zusätzlich auf der Planfläche eine Kalotte mit gegenüber der Halbkugel geringeren Durchmessers angeordnet, besteht die Möglichkeit, den Stab an einem Auflagepunkt unmittelbar durch das Rundstück abzustützen, wobei die Drehbarkeit infolge des kleinen Durchmessers der Kalotte für den Stab relativ zum Rundstück nicht beeinträchtigt ist.

**[0008]** Nach einer besonders bevorzugten Ausführungsform der Erfindung ist vorgesehen, daß das Bügelteil U-förmig mit einer Grundplatte und zwei Seitenschenkeln gebildet ist, an deren freien Enden Rastnasen ausgebildet sind, die zur Ausbildung des Rastsitzes bei der Steckbewegung an dem Kappe einhaken.

**[0009]** Um eine ungewollte Verdrehung der Kappe zu verhindern, besteht die Möglichkeit, Mittel zur Blockade der Drehbarkeit von der Kappe auf dem Rundstück vorzusehen. Diese sind zweckmäßigerweise so gestaltet, daß die einander zugewandten Oberflächen von dem Rundstück und der Kappe eine Oberflächenprofilierung aufweisen, und daß in der Grundplatte des Bügelteils eine Gewindebohrung ausgebildet ist für eine der Fixierung des Stabes dienende Sicherungsschraube. Sobald beim Einschrauben der Sicherungsschraube diese an dem Stab zu Anlage kommt, wird der Stab gegen das Rundstück gepreßt, während die Sicherungsschraube sich an dem Stab abstützt und damit auch das Bügelteil gegen die Kappe verspannt, die somit gleichfalls an der dem Stab gegenüberliegenden Seite an das Rundstück gepreßt wird, was mit der geeigneten Oberflächenprofilierung ausgenutzt wird, die Drehbarkeit zu beschränken.

**[0010]** Um einen genau definierten Sitz des Bügelteiles auf der Kappe dauerhaft zu gewährleisten, ist die Pedikelschraube so gestaltet, daß an der Kappe Endplatten mit jeweils einem in axialer Richtung verlaufenden Führungssteg angeordnet sind, und daß jeder Seitenschenkel eine Führungsnut für den Führunssteg aufweist. Alternativ besteht zum Erreichen dieses Zieles natürlich auch die Möglichkeit, daß die Führungsstege und die Führungsnuten an den Endplatten und den Seitenschenkeln miteinander vertauscht sind.

**[0011]** Zur Vermeidung einer Aufspreizung der Seitenschenkel bei in axialer Richtung auf das Bügelteil einwirkenden Kräften ist vorgesehen, daß die Rastnasen die freien Kanten der Endplatten hintergreifen.

**[0012]** Im Hinblick auf eine möglichst großflächig verteilte Krafteinleitung ist es günstig, wenn die Kappe eine Rinne als Auflager für den Stab aufweist. Dabei ist zur unmittelbaren Übertragung von auf den Stab einwirkenden Kräfte auf die Pedikelschraube bzw die Kalotte in der Rinne eine Öffnung ausgebildet.

**[0013]** Um den Stab in Umfangsrichtung möglichst weit umfassen zu können, ist in der Grundplatte des Bügelteils eine Rinne ausgebildet.

**[0014]** Das Aufstecken des Bügelteils auf die Kappe, zu dem eine leichte Aufspreizung der Seitenschenkel



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 439 of 2152

erforderlich ist, wird dadurch erleichtert, daß zwischen der Grundplatte und den Seitenschenkeln eine Nut ausgebildet ist.

**[0015]** Die erfindungsgemäße Pedikelschraube ist weiterhin so gestaltet, daß das Kopfteil an einer Verjüngung des Gewindeschafts angesetzt ist. Dies bietet den Vorteil, daß die Kappe über einen größeren Winkelbereich auf dem Rundstück verstellt werden kann, ohne daß die Kappe an dem Gewindeschaft zur Anlage kommt.

**[0016]** Im folgenden wird die Erfindung an einem in der Zeichnung dargestellten Ausführungsbeispiel näher erläutert; es zeigen:

**Fig. 1** eine perspektivische Darstellung der erfindungsgemäßen Pedikelschraube mit einem am Kopfteil fixierten Stab,

Fig. 2 eine Seitenansicht der Pedikelschraube,

Fig. 3 der Schnitt III-III aus Fig. 2,

Fig. 4 eine Draufsicht auf die Pedikelschraube aus Fig. 2,

Fig. 5 eine Seitenansicht des Gewindeschaftes mit dem Kopfteil,

Fig. 6 eine perspektivische Darstellung der auf das Rundstück aufgesetzten Kappe,

Fig. 7 eine weitere perspektivische Darstellung der Pedikelschraube aus Fig. 6 aus einem anderen Blickwinkel,

Fig. 8 der Schnitt VIII-VIII aus Fig. 7,

Fig. 9 der Schnitt IX-IX aus Fig. 7

Fig. 10 eine der Fig. 9 entsprechende Darstellung mit einer gegenüber Fig. 9 verdrehten Kappe, und

Fig. 11 eine perspektivischen Darstellung des U-förmigen Bügelteils.

**[0017]** Die in der Fig. 1 dargestellte Pedikelschraube 1 wird benutzt im Zusammenhang mit Implantaten, die der Korrektur und Stabilisierung der Wirbelsäule dienen und die dazu einen an der Wirbelsäule entlanggeführten Stab 2 verwenden. Die Pedikelschraube 1 besteht aus einem Gewindeschaft 3, an dessen einem axialen Ende ein durch ein Rundstück 4 und eine Kappe 6 gebildetes Kopfteil 5 angeordnet ist. Dabei ist das Rundstück 4 als Halbkugel 20 ausgebildet, deren Planfläche 22 senkrecht zu dem Gewindeschaft 3 orientiert ist und nach außen weist. Auf der Planfläche 22 der Halbkugel 20 ist eine Kalotte 23 angeordnet, deren Durchmesser kleiner als der der Halbkugel 20 ist. Aus diesem Aufbau ergibt sich, daß die Kappe 6 polyaxial um das Rundstück 4 verdrehbar und eine gute Anpassungsmöglichkeit an die Lage des an der Wirbelsäule entlanggeführten Stabes 2 gegeben ist (Fig. 3,8,10).

**[0018]** Die auf dem Rundstück 4 angeordnete Kappe 6 wird von einem U-förmigen Bügelteil 7 übergriffen, das eine Aufnahme für den Stab 2 bereitstellt. Das Bügelteil 7 besteht aus einer Grundplatte 8 und zwei Seitenschenkeln 9, an deren freien Enden Rastnasen 10 ausgebildet sind. Zur Fixierung des Bügelteils 7 wird dieses durch eine ausschließlich in axialer Richtung erfolgende Steckbewegung auf die Kappe 6 aufgesteckt, wobei die Rastnasen 10 an den Kanten von der Kappe 6 zugeordneten Endplatten 11 in einem Rastsitz einhaken. Um eine lagerichtige Verbindung des Bügelteils 7 mit der Kappe 6 zu gewährleisten, sowie um ein Verschieben des Bügelteiles 7 in Längsrichtung des Stabes 2 zu vermeiden, sind an den Endplatten 11 Führungsstege 12 ausgebildet, die mit einer Führungsnut 13 zusammenwirken, die an den Seitenschenkeln 9 des Bügelteils 7 ausgebildet sind. Nach einer selber nicht in der Zeichnung dargestellten Ausführungsform ist es selbstverständlich auch möglich, daß die Führungsstege 12 und die Führungsnuten 13 an den Endplatten 11 und den Seitenschenkeln 9 miteinander vertauscht sind.

**[0019]** Eine in der Grundplatte 8 des Bügelteils 7 angeordnete Gewindebohrung 18 dient zur Aufnahme einer Sicherungsschraube 19, mit der der Stab 2 gegen Verschiebungen in seiner Längsrichtung gesichert werden kann. Diese Sicherungsschraube 19 verspannt im Zusammenwirken mit den Rastnasen 10 auch das Bügelteil 7 gegenüber der Kappe 6, was weiterhin dazu ausgenutzt wird, um die Kappe 6 gegen die Halbkugel 20 zu pressen. Wenn nach einer Ausführungsform die einander zugewandten Oberflächen von dem Rundstück 4 und der Kappe 6 eine Oberflächenprofilierung aufweisen, wirkt dies als Mittel zur Blockade der Drehbarkeit von der Kappe 6 und dem Rundstück 4, wobei die Gestaltung der Oberflächenprofilierung die Möglichkeit offenläßt, die Drehbarkeit vollständig, hinsichtlich mehrerer Achsen oder nur hinsichtlich einer Achse zu unterbinden.

**[0020]** Wie insbesondere aus Fig. 7 ersichtlich ist, weist die Kappe 6 eine Rinne 14 als Auflager für den Stab 2 auf. Die Umfassung des Stabes 2 durch die Pedikelschraube 1 wird durch eine in der Grundplatte 8 des Bügelteils 7 ausgebildete Rinne 16 komplettiert.

**[0021]** Aus den Fig. 1, 3 und 11 ist ersichtlich, daß am Bügelteil 7 zwischen der Grundplatte 8 und den Seitenschenkeln 9 eine Nut 17 ausgebildet ist, die das Aufspreizen des Bügelteil 7 beim Aufsteckvorgang erleichtert. Ein unerwünschtes Aufspreizen nach dem Aufstekken des Bügelteils 7 wird dadurch verhindert, daß die Rastnasen 10 die freien Kanten der Endplatten 11 hintergreifen.

**[0022]** Aus der Zeichnung, insbesondere den Fig. 5 bis 10 ist weiterhin ersichtlich, daß das Kopfteil 5 an ei-



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 440 of 2152

ner Verjüngung 21 des Gewindeschaftes 3 angesetzt ist, der Drehwinkel der Kappe 6 also nicht frühzeitig durch dessen Anlage an dem Gewindeschaft 3 begrenzt ist.

**Patentansprüche**

1. Pedikelschraube für Implantate zur Korrektur und Stabilisierung der Wirbelsäule, mit einem an dem axialen Ende eines Gewindeschafts (3) angeordneten Kopfteil (5), an dem ein Bügelteil (7) anschließbar ist, das eine Aufnahme für einen am Kopfteil (5) fixierbaren Stab (2) aufweist, dadurch gekennzeichnet, daß das Kopfteil (5) durch ein Rundstück (4) und eine drehbar auf dem Rundstück (4) gelagerten Kappe (6) gebildet ist, und daß das Bügelteil (7) durch eine in axialer Richtung erfolgende Steckbewegung in einem Rastsitz an der Kappe (6) fixierbar ist.

2. Pedikelschraube nach Anspruch 1, dadurch gekennzeichnet, daß das Rundstück (4) als Halbkugel (20) mit senkrecht zu dem Gewindeschaft (3) orientierter, zum freien Ende weisender Planfläche (22) ausgebildet ist.

3. Pedikelschraube nach Anspruch 2, dadurch gekennzeichnet, daß auf der Planfläche (22) eine Kalotte (23) mit gegenüber der Halbkugel (20) geringeren Durchmessers angeordnet ist.

4. Pedikelschraube nach einem der Ansprüche 1 bis 3, dadurch gekennzeichnet, daß das Bügelteil (7) U-förmig mit einer Grundplatte (8) und zwei Seitenschenkeln (9) gebildet ist, an deren freien Enden Rastnasen (10) ausgebildet sind, die zur Ausbildung des Rastsitzes bei der Steckbewegung an der Kappe (6) einhaken.

5. Pedikelschraube nach einem der Ansprüche 1 bis 4, dadurch gekennzeichnet, daß Mittel zur Blockade der Drehbarkeit der Kappe (6) auf dem Rundstück (4) vorgesehen sind.

6. Pedikelschraube nach einem Anspruch 5, dadurch gekennzeichnet, daß die einander zugewandten Oberflächen von dem Rundstück (4) und dem Kappe (6) eine Oberflächenprofilierung aufweisen, und daß in der Grundplatte (8) des Bügelteils (7) eine Gewindebohrung (18) ausgebildet ist für eine der Fixierung des Stabes (2) dienende Sicherungsschraube (19) .

7. Pedikelschraube nach einem der Ansprüche 1 bis 6, dadurch gekennzeichnet, daß an der Kappe (6) Endplatten (10) mit jeweils einem in axialer Richtung verlaufenden Führungssteg (12) angeordnet sind, und daß jeder Seitenschenkel (9) eine Führungsnut (13) für den Führungssteg (12) aufweist.

8. Pedikelschraube nach Anspruch 7, dadurch gekennzeichnet, daß die Führungsstege (12) und die Führungsnuten (13) an den Endplatten (10) und den Seitenschenkeln (9) miteinander vertauscht sind.

9. Pedikelschraube nach einem der Ansprüche 4 bis 8, dadurch gekennzeichnet, daß die Rastnasen (10) die freien Kanten der Endplatten (10) hintergreifen.

10. Pedikelschraube nach einem der Ansprüche 1 bis 9, dadurch gekennzeichnet, daß die Kappe (6) eine Rinne (14) als Auflager für den Stab (2) aufweist.

11. Pedikelschraube nach Anspruch 10, dadurch gekennzeichnet, daß in der Rinne (14) eine Öffnung (15) ausgebildet ist.

12. Pedikelschraube nach einem der Ansprüche 4 bis 11, dadurch gekennzeichnet, daß in der Grundplatte (8) des Bügelteils (7) eine Rinne (16) ausgebildet ist.

13. Pedikelschraube nach einem der Ansprüche 2 bis 12, dadurch gekennzeichnet, daß zwischen der Grundplatte (8) und den Seitenschenkeln (9) eine Nut (17) ausgebildet ist.

14. Pedikelschraube nach einem der Ansprüche 1 bis 13, dadurch gekennzeichnet, daß das Kopfteil (5) an einer Verjüngung (21) des Gewindeschafts (3) angesetzt ist.



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 441 of 2152

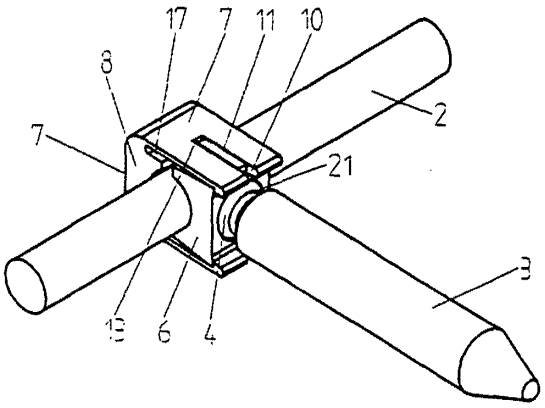



Fig. 1



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 442 of 2152

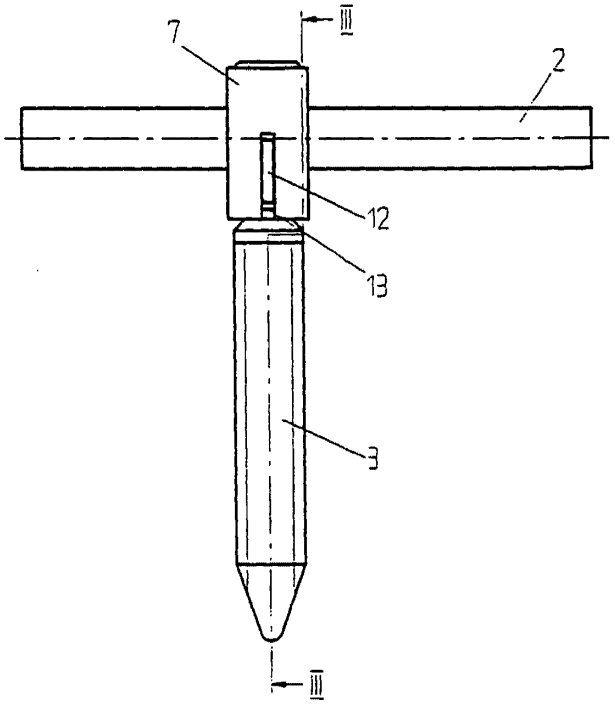



Fig. 2



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 443 of 2152

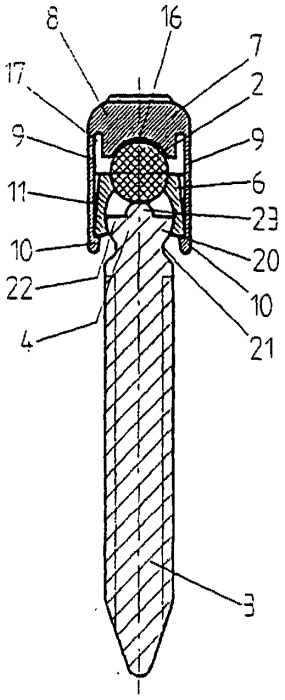



Fig. 3



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 444 of 2152

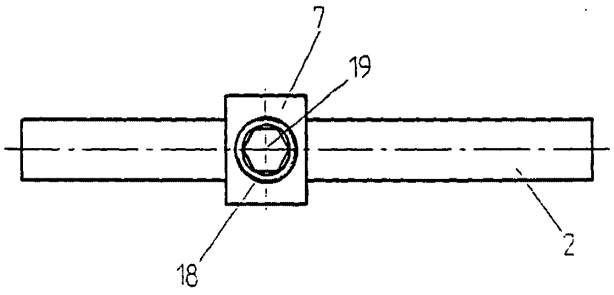



Fig. 4



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 445 of 2152

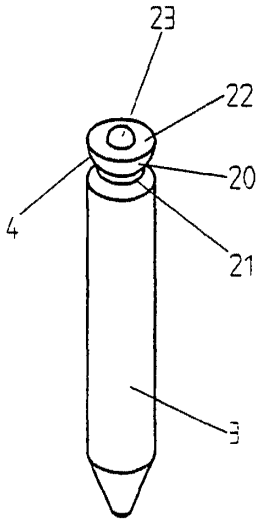



Fig. 5



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 446 of 2152

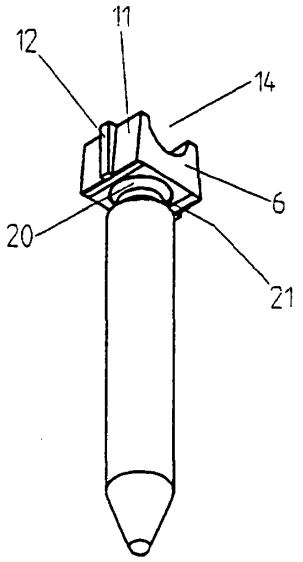



Fig. 6



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 447 of 2152

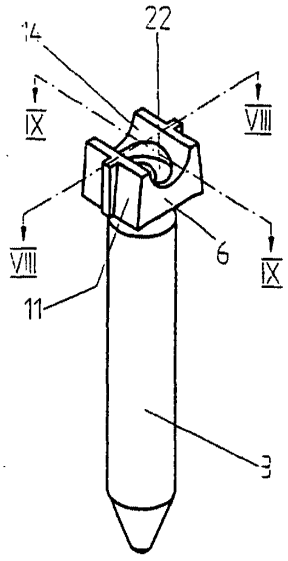



Fig. 7



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 448 of 2152

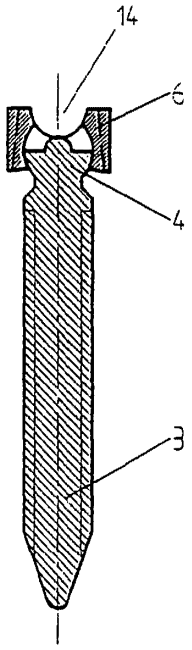



Fig. 8



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 449 of 2152

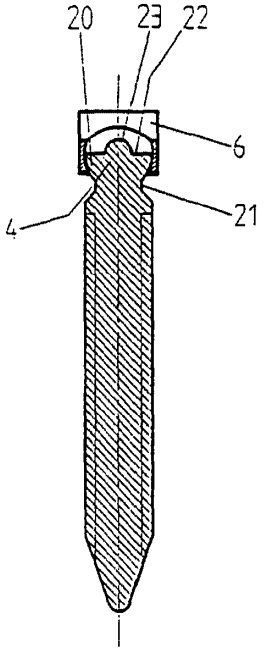



Fig. 9



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 450 of 2152

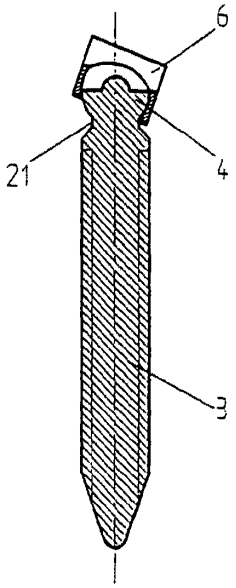



Fig. 10



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 451 of 2152

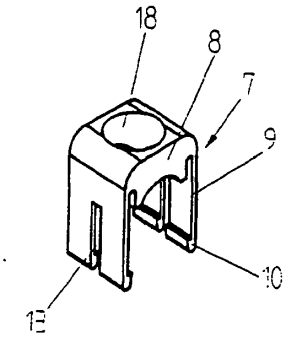



Fig. 11



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 452 of 2152

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
28 June 2001 (28.06.2001)

PCT

(10) International Publication Number
WO 01/45576 A1

(51) International Patent Classification[7]: A61B 17/70

(21) International Application Number: PCT/CH99/00612

(22) International Filing Date:
20 December 1999 (20.12.1999)

(25) Filing Language: English

(26) Publication Language: English

(71) Applicant *(for all designated States except CA, US)*: **SYNTHES AG CHUR** [CH/CH]; Grabenstrasse 15, CH-7002 Chur (CH).

(71) Applicant *(for CA only)*: **SYNTHES (U.S.A.)** [US/US]; 1690 Russell Road, P.O. Box 1766, Paoli, PA 19301-1222 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **MULHOLLAND, Robert, C.** [GB/GB]; 39 Private Road, Sherwood, Nottingham NG5 4DD (GB). **SENGUPTA, Dilip, K.** [IN/GB]; Queen's Medical Centre, Nottingham NG7 2UH (GB).

(74) Agent: **LUSUARDI, Werther**; Dr. Lusuardi AG, Kreuzbühlstrasse 8, CH-8008 Zürich (CH).

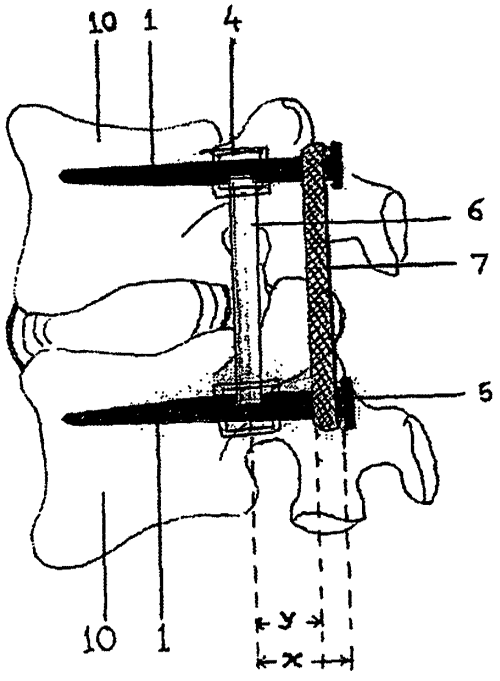
(81) Designated States *(national)*: AU, BR, CA, JP, MX, NZ, US, ZA.

(84) Designated States *(regional)*: European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

**Published:**
— *With international search report.*

*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

(54) Title: DEVICE FOR THE STABILISATION OF TWO ADJACENT VERTERBRAL BODIES OF THE SPINE




(57) Abstract: The assembly is used for the stabilisation of two adjacent vertebral bodies (10) of the spine. It comprises two pedicle screws (1), having a threaded shaft (2) with a tapering first end (3) for introduction into the vertebral bodies (10) and a head portion (4) with a second end (5). It further comprises a flexible longitudinal fulcrum (6) with two portions (8), which can be disposed transversely to said pedicle screws (1), and fixed with its end portions (8) to the head portions (4) of said two pedicle screws (1) at a distance x from said second end. The assembly further comprises an elastic ligament (7) which can be disposed transversely to said two pedicle screws (1) and fixed to the head portions (4) of said two pedicle screws (1) at a distance y<x from the end portion of the fulcrum (8). By introduction of a fulcrum, lying close to the axis of flexion and extension of the spinal motion segment, the posteriorly placed ligament distracts the whole disc, and the fulcrum istself becomes a load-bearing structure. This reduces the load over the disc, and makes it an even distribution of load across the end-plate throughout the range of movement of the motion segment, that is allowed by the implant.

WO 01/45576 A1

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 453 of 2152

**Device for the stabilisation of two adjacent vertebral bodies of the spine**

This invention concerns a device in accordance with the pre-characterising portion of Claim 1.

The human spine consists of blocks of bony vertebra with intervening blocks of soft-tissue, the intervertebral discs. These functional elements allow the spine to be flexible, and to transfer load evenly over the lower vertebra, despite variation in the position of the upper vertebra, They function as a fluid filled bag between each vertebra. However, with disc degeneration, they become anisotropic and transmit load irregularly over the endplate and this irregular loading pattern in different positions of the spine is associated with back pain.

Conventional treatment of this disorder is to fuse the two vertebrae together. This method of treatment is not attended by a high level of success. This is in part related to the stiff segment created by the fusion operation, which produces problems to the adjacent spinal segments above and below. The ideal solution would be one that allows normal load transmission and also allows movement as achieved with artificial joints elsewhere in the human body. However, the artificial disc prostheses, which have been proposed so far, have not to date produced any better results than fusion. This is in part because insertion of an artificial disc involves major surgery, and there is the difficulty in accurately placing the device to ensure that the segmental movement of the facet joints remains normal.

There are two further devices described in the treatemnt of low back pain, known as "soft-stabilisation" in which pedicle screws are placed in the vertebrae, and a stretchable ligament is attached behind, at their head portions. In both the devices, the restraining

ligaments are well behind the axis of flexion/extension. In one of these systems (Dyesys-Sulzer), whilst excessive lordosis is prevented by a cylinder embracing the ligament, the actual distraction of the posterior disc space can only be achieved by producing flexion of the segment. It is known that a kyphotic segment in the lumbar spine can produce back pain.

In the other of these systems (Graf ligament), distraction of the anterior disc space and creation of physiological lordosis is accompanied by compression of the posterior part of the disc. This results in narrowing of the diameter of the exit foramen of the nerve root, and also increases load transfer to the posterior part of the disc. It is known that increased load transfer by the posterior annulus can produce annular tear. Neither system addresses therefore the important aims of producing uniform disc distraction and the creating a normal loading pattern across the end-plate of the vertebrae.

The invention as claimed, aims at solving the problems described above.

The present invention provides a device as defined in Claim 1. By introduction of a fulcrum, lying close to the axis of flexion and extension of the spinal motion segment, the posteriorly placed ligament distracts the whole disc, and the fulcrum itself becomes a load-bearing structure. This reduces the load over the disc, and makes it an even distribution of load across the end-plate throughout the range of movement of the motion segment, that is allowed by the implant.

Clinically the ligament is applied to the assembly under tension and the fulcrum under compression at the resting position of the spine. The screws are introduced posteriorly through the pedicles on either side, so that there is an assembly of screws, fulcrums and ligaments on right and left side in the posterior aspect of the vertebrae to be stabilised. the same system can also be extended over more than one motion segment, if necessary.

The fulcrum lies closer to the axis of movement of flexion-extension of the lumbar spine. When the assembly is introduced into the spine, it allows movement of the spine in

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 455 of 2152

flexion-extension, as well as in other directions. During flexion-extension, the range of movement of the fulcrum is less than that of the ligament, since the former lies closer to the axis of the movement.

The ligament actually elongates during flexion and recoils during extension. During flexion, the fulcrum bends, and also to some extent, compresses itself. These movements are reversed in extension. The two ends of the fulcrum, being tightly fixed to the pedicle screws, prevent any movement between the pedicle screws and the fulcrum at their junction.

The pedicle screws will preferably be made up of titanium and with diameters of 5, 6, 7, and 8 mm. The pedicle screw has a head portion and a threaded shaft portion. The length of the threaded shaft portion of the screw is preferably between 35 and 55 mm, with 5 mm increments. The length of the head portion is preferably of different sizes, e.g. 20, 30 and 40mm.

The distance x is preferably in the range of 10 – 20 mm and the distance y is preferably in the range of 7 to 17 mm (Fig. 1).

The fulcrum should (at least partially) be compressible in the longitudinal direction. In a preferred embodiment the fulcrum consists of a longitudinal main body of which at least its middle portion consists of a flexible material and two end portions consisting of a rigid material (e.g. the same as that of the pedicle screws) . The two end portions can be designed as a sleeve over the main body.
The main body of said fulcrum is preferably made of a flexible polymer, e.g. a high-density polyethylene (HDP) with a modulus of elasticity between 17'000 to 28'000 $kg/cm^2$ or a poly tetra-fluoro ethylene (PTFE) with modulus of elasticity between 3000 to 6500 $kg/cm^2$. The outer diameter at the metallic ends of the fulcrum is preferably between 5, 6, or 7 mm. The flexibility of the fulcrum will depend on the design and the diameter as well.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 456 of 2152

The fulcrum is preferably covered with a fabric sleeve. This has the advantage that it can resist the wear resulting from friction of the relatively soft material of the fulcrum against the bone and the soft tissues around, in the spine.
Preferably the fulcrum is drum-shaped in order to prevent buckling during bending.

Preferably the head portions of the pedicle screws are provided with a fixation mechanism for accommodating and fixing an end portion of the fulcrum.
The head portion of the pedicle screw is provided with a smooth seat for receiving the ligament , a groove for receiving the end portion of the fulcrum , and a threaded portion for receiving a locking nut .
In a preferred embodiment the assembly has a fastening mechanism to tighten the end portion of the fulcrum to the head of the pedicle screws. The fastening mechanism preferably comprises of a sleeve which can be passed over the end portion of the fulcrum, after the latter is seated into the groove in the head portion of the pedicle screw .

In a further preferred embodiment the assembly comprises of a locking nut which can be tightened over the corresponding threaded part in the head of the pedicle screw , fastening the sleeve and the end portion of the fulcrum to the head of the pedicle screw.

In a further preferred embodiment the ligament has the shape of a closed loop, which can be passed over the second end of the pedicle screw, to sit on the smooth part of the head portion of the pedicle screw. It may further comprise a cap nut which can be screwed into the second end of the pedicle screw to retain the ligament in place.

The ligament is preferably made up with braided polyester. The diameter of the cross section of the ligament can vary between 3 and 7 mm. The breaking strength should be between 2000 N and 5000 N load, depending on the diameter of the ligament, and rate of loading. The strain will be between 10 and 30 % under physiological loading.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 457 of 2152

**In the drawings:**

Fig. 1 Shows a schematic representation of a longitudinal section through the assembly according to the invention;

Fig. 2a shows a side view of the fulcrum, attached to a pedicle screw in the assembly according to the invention;

Fig. 2b shows the pedicle screw, the fastening mechanism of the fulcrum to it, and the cap nut, before they are assembled together;

Fig. 2c shows the profile of the pedicle screw and the sleeve of the festening mechanism;

Fig. 3 shows the assembly of the pedicle screw, the fulcrum, and the ligament together for one side of the spinal segment; and

Fig. 4 shows the assembly applied to one spinal motion segment, shown in a plastic model of the lumbar spine, from a posterior oblique view.

The assembly as shown in Fig. 1 is used for the stabilisation of two adjacent vertebral bodies 10 of the spine. It comprises two pedicle screws 1, having a threaded shaft 2 with a tapering first end 3 for introduction into the vertebral bodies 10 and a head portion 4 with a second end 5 which are shown in more detail in Figs. 2b and 2c.

The pedicle screw is made up of titanium and its diameter is 7 mm (which may vary between 5 and 8 mm). The length of the threaded portion of the pedicle screw is 45 mm (which may vary between 35 and 55 mm, with 5 mm increments). The length of the head portion up to its said second end is 30 mm (which may vary between 20 and 40 mm).

As shown in Fig. 2a, a flexible longitudinal fulcrum 6 with two end portions 8, can be disposed transversely to the pedicle screws 1, and fixed with its end portions 8 to the head portion 4 of the two pedicle screws 1, at a distance of 15 mm (which may vary between 10 and 20 mm) from the said second end 5 as shown in Fig. 1. The main body 9 of the fulcrum 6 consists of a flexible material, similar to 'high density polyethylene' (HDP) with a modulus of elasticity of 22'500 kg/cm$^2$ (which may vary between 17'000 and 28'000 kg/cm$^2$ or 'poly tetra-fluoro ethylene (PTFE) with a modulus of elasticity of 4'750 kg/cm$^2$ (which may vary between 3'000 amd 4'500 kg/cm$^2$). The two end portions 8 consist of a metallic sleeve, between 15 and 20 mm long, over the flexible material of the fulcrum. The outer diameter of these metallic end portions 8 are 6 mm (which may vary between 5 and 8 mm). The fulcrum 6 is drum shaped, with larger diameter in its middle compared to the ends. The fulcrum is at least partially compressible in the longitudinal direction.

As shown in Figs. 3 and 4, the ligament 7 has teh shape of a loop, which can be passed over the second end 5 of the pedicle screw, to sit on the smooth part 12 of the head portion 4 of the pedicle screw. The diameter of the cross section of the ligament is 5 mm (which may vary between 3 and 7 mm) and its breaking strength is 3'500 N load in tension (which may vary between 2'000 and 4'500 N). The strain of the ligament is 20 % under physiological loading.

The elastic ligament 7 made up of braided polyester. The ligament 7 is disposed transversely to the said pedicle screws 1, and fixed to the head portions 4 of the pedicle screws 1 at a distance of 12 mm (whihc may vary between 7 and 17 mm) from the groove 14 for the fulcrum in the nead of the pedicle screw.

Alternatively the ligament may consist of a single length flexible cord, which is made up with an outer layer of braided polyester, and an inner core of stretchable material like Dyneema (which is registered trademark of DSM High Performance Fibres B.V., Netherlands) or similar. The single length version (as opposed to the above described

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 459 of 2152

loop version) of the ligament has metal sleeves at its ends for fastening it to the second end (5) of the pedicle screws.

As shown in Fig. 2c the head portions 4 of the pedicle screws 1 are provided with a fixation mechanism 12,14,16 for accommodating and fixing an end portion 8 of the fulcrum 6. The head portion 4 of the pedicle screw 1 is provided with a smooth seat 12 at its free and for receiving the ligament 7 (Fig. 1), a groove 14 for receiving an end portion 8 of the fulcrum 6, and a threaded portion 16 locate between the groove 14 and the smooth seat 12 for receiving a locking nut 11.

As shown in Fig. 2 c the head portion 4 of the pedicle screws 1 consists of three segments 12,14,16 for accommodation and fixation of the end portions 8 of the fulcrum 6. These are , a smooth seat 12 at its free and for receiving teh ligament 7, a groove 14 for receiving the end portion 8 of the fulcrum 6, and a threaded portion 16, located between the smooth seat and the groove, for receiving the locking nut 11.

As shown in Fig, 2a the end portion 8 of the fulcrum 6 is fastened to the head portion 4 of the pedicle screw with a sleeve 17 and a nut 11. The fastening mechanism 13 is shown in more detail in Fig. 2b. It comprises a sleeve 17 which can be passed over the end portions 8 of the fulcrum 6 after the latter is seated into the grooved 14 in the head portion 4 of the pedicle screw. It further comprises a locking nut 11, which can be tightened over the corresponding threaded portion 16 in the head portion 4 of the pedicle screw, fastening the sleeve 17 and teh end portion 8 of the fulcrum, to the pedicle screw. Finally a cap nut 15 can be screwed into the second end 5 of the pedicle screw, to retain the ligament in place.

In Fig. 3 the completed assembly is represented with the fulcrum 6 fixed to the two pedicle screws 1 and the ligament 7 wound and secured on the head portions 4 of the pedicle screws 1.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 460 of 2152

In Fig. 4 two pairs of assemblies are shown implanted in the spine model. On the right hand assembly only the fulcrum 6 has been fixed to the head portion 4 of the pedicle screws 1, whereas on the left hand assembly (having a different type of fulcrum) the ligament 7 has also been applied thereto.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 461 of 2152

Claims

1. Assembly for the stabilisation of two adjacent vertebral bodies (10) of the spine comprising of two pedicle screws (1), having a threaded shaft (2) with a tapering first end (3) for introduction into the vertebral bodies (10) and a head portion (4) with a second end (5), characterized by

(A) a flexible longitudinal fulcrum (6) with two portions (8), which can be disposed transversely to said pedicle screws (1), and fixed with its end portions (8) to the head portions (4) of said two pedicle screws (1) at a distance x from said second end; and

(B) an elastic ligament (7) which can be disposed transversely to said two pedicle screws (1) and fixed to the head portions (4) of said two pedicle screws (1) at a distance $y < x$ from the end portion of the fulcrum (8).

2. Assembly according to claim 1, characterized in that said fulcrum (6) ist at least partially compressible in the longitudinal direction.

3. Assembly according to claim 1 or 2, characterized in that said distance x is in the range of 10 – 20 mm.

4. Assembly according to one of the claims 1 to 3, characterized in that said distance y is in the range of 7 to 17 mm.

5. Assembly according to one of the claims 1 to 4, characterized in that said fulcrum (6) comprises

A) a longitudinal main body (9) of which at least its middle portion consists of a flexible material ; and

B) two end portions (8) consisting of a rigid material.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 462 of 2152

6. Assembly according to claim 5, characterized in that said two end portions (8) are designed as a sleeve over said main body (9).

7. Assembly according to claim 5, characterized in that said main body (9) of said fulcrum (6) is either a high-density polyethylene (HDP) with a modulus of elasticity between 17'000 to 28'000 kg/cm$^2$ or a poly tetra-fluoro ethylene (PTFE) with modulous of elasticity between 3000 to 6500 kg/cm$^2$

8. Assembly according to one of the claims 1 to 7, characterized in that said fulcrum (6) is covered with a fabric sleeve.

9. Assembly according to one of the claims 1 to 8, characterized in that said fulcrum (6) is drum-shaped.

10. Assembly according to one of the claims 1 to 9, characterized in that said head portions (4) of said pedicle screws (1) are provided with a fixation mechanism (12,14,16) for accommodating and fixing an end portion (8) of the fulcrum(6).

11. Assembly according to one of the claims 1 to 10, characterized in that said head portion (4) of said pedicle screw (1) is provided with a smooth seat (12) for receiving said ligament (7), a groove (14) for receiving said end portion (8) of the fulcrum (6), and a threaded portion (16) for receiving a locking nut (11).

12. Assembly according to one of the claims 1 to 11, characterized in that said head (4) is provided with a fastening mechanism (13) for tightening said end portion (8) of the fulcrum (6).

13. Assembly according to one of the claims 11 or 12, characterized in that said fastening mechanism (13) comprises a sleeve (17) which can be passed over the end portion (8) of the fulcrum (6), after the latter is seated into said groove (14) in the head portion (4) of said pedicle screw (1).

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 463 of 2152

14. Assembly according to claim 13, characterized in that it comprises a locking nut (11) which can be tightened over the corresponding threaded part (16) in the head (4) of the pedicle screw (1), fastening the sleeve (17) and the head end (8) and the fulcrum to the pedicle screw(1).

15. Assembly according to one of the claims 1 to 14, characterized in that said ligament (7) has the shape of a closed loop, which can be passed over the second end (5) of the pedicle screw, to sit on the smooth part (12) of the head portion (4) of the pedicle screw.

16. Assembly according to one of the claims 1 to 15, characterized in that said ligament (7) is made up with braided polyester.

17. Assembly according to one of the claims 1 to 16, characterized in that it comprises a cap nut (15) which can be screwed into the second end of the pedicle screw (1) to retain the ligament (7) in place.

18. Assembly according to one of the claims 1 to 17, characterized in that said ligament (7 )consists of a single length flexible cord, which preferebly is made up with an outer layer of braided polyester, and an inner core of stretchable material.

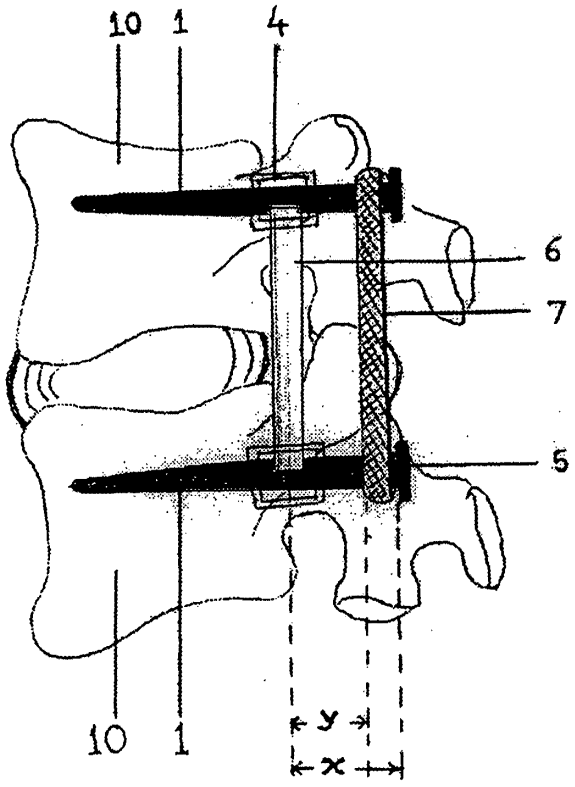



FIG. 1

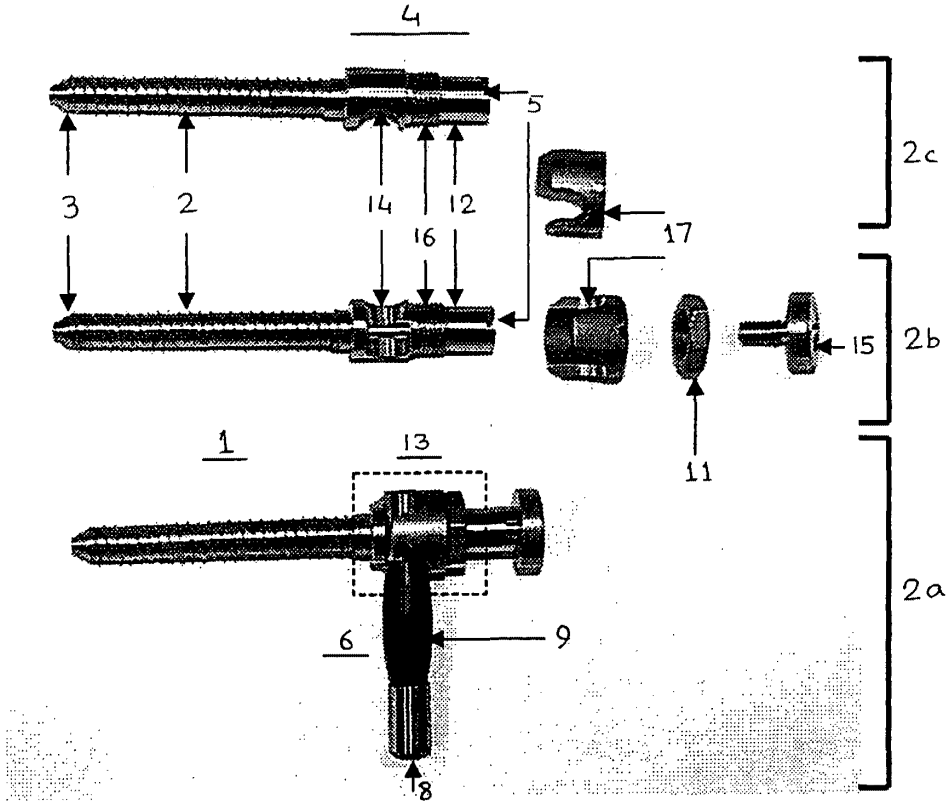



FIG 2 a, b, c

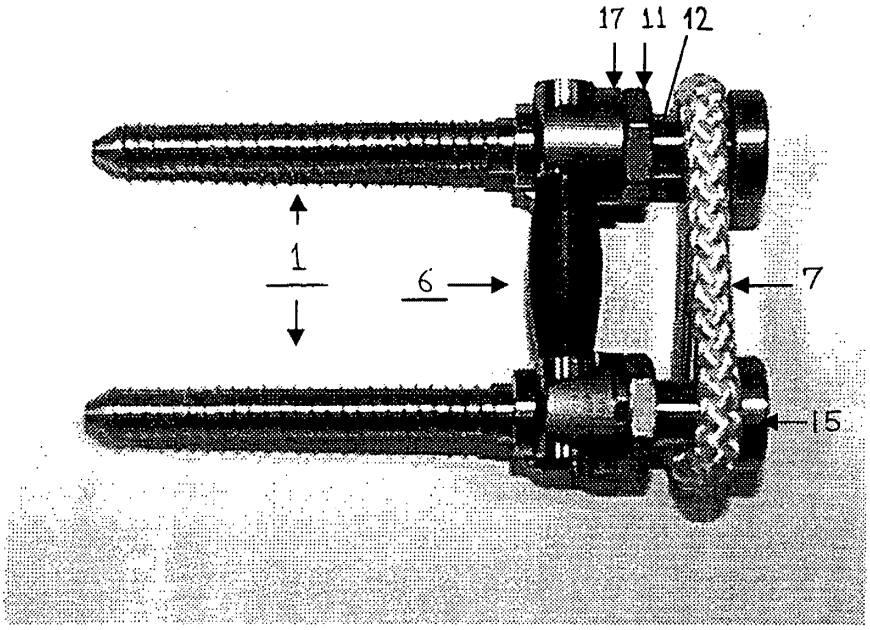



FIG. 3

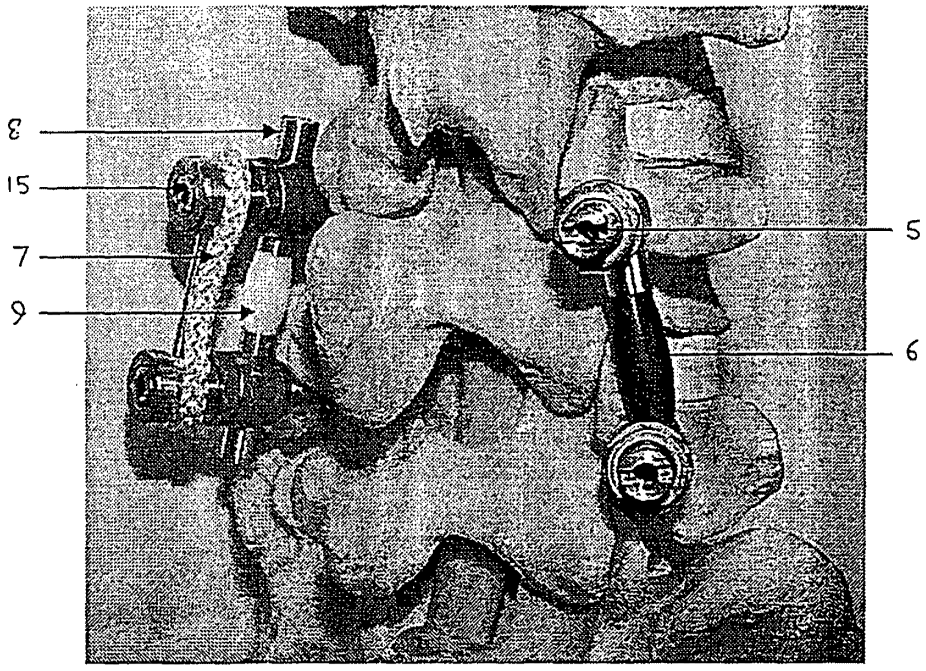



FIG. 4

# INTERNATIONAL SEARCH REPORT

Int. ·ional Application No
PCT/CH 99/00612

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 | DE 91 12 466 U (HOWMEDICA)<br>5 December 1991 (1991-12-05)<br>the whole document | 1 |
| A | DE 38 07 335 A (ORTHOPLANT ENDOPROTHETIK)<br>14 September 1989 (1989-09-14)<br>the whole document | 1 |
| A | EP 0 669 109 A (PROTEK AG ;SULZER MEDIZINALTECHNIK AG (CH))<br>30 August 1995 (1995-08-30)<br>the whole document | 1,2,5,6,<br>9,10,12 |
| A | FR 2 715 057 A (BREARD FRANCIS HENRI)<br>21 July 1995 (1995-07-21)<br>the whole document | 1 |

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

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

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

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

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

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

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

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

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

"&" document member of the same patent family

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 21 August 2000 | 25/08/2000 |

| Name and mailing address of the ISA | Authorized officer |
|---|---|
| European Patent Office, P.B. 5818 Patentlaan 2<br>NL – 2280 HV Rijswijk<br>Tel. (+31–70) 340–2040, Tx. 31 651 epo nl,<br>Fax: (+31–70) 340–3016 | Verelst, P |

1

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

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/CH 99/00612

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
|---|---|---|---|
| DE 9112466 U | 05-12-1991 | IT 1255529 B | 09-11-1995 |
| DE 3807335 A | 14-09-1989 | NONE | |
| EP 0669109 A | 30-08-1995 | AT 180402 T | 15-06-1999 |
| | | DE 59408313 D | 01-07-1999 |
| | | ES 2133517 T | 16-09-1999 |
| | | JP 7255741 A | 09-10-1995 |
| FR 2715057 A | 21-07-1995 | AT 181810 T | 15-07-1999 |
| | | AU 2599695 A | 01-08-1995 |
| | | CA 2155760 A | 20-07-1995 |
| | | DE 69419407 D | 12-08-1999 |
| | | DE 69419407 T | 13-04-2000 |
| | | EP 0689401 A | 03-01-1996 |
| | | ES 2133538 T | 16-09-1999 |
| | | WO 9519149 A | 20-07-1995 |



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 470 of 2152

(19) BUNDESREPUBLIK DEUTSCHLAND

DEUTSCHES PATENT- UND MARKENAMT

(12) **Offenlegungsschrift**

(10) **DE 199 51 145 A 1**

(51) Int. Cl.[7]: **A 61 B 17/68**

(21) Aktenzeichen: 199 51 145.4
(22) Anmeldetag: 23. 10. 1999
(43) Offenlegungstag: 31. 5. 2001

(71) Anmelder:
SCHÄFER micomed GmbH, 73035 Göppingen, DE

(74) Vertreter:
Dreiss, Fuhlendorf, Steimle & Becker, 70188 Stuttgart

(72) Erfinder:
Schäfer, Bernd, Oberägeri, CH

(56) Entgegenhaltungen:

| | |
|---|---|
| DE | 41 10 002 C1 |
| DE | 39 42 429 A1 |
| DE | 39 16 198 A1 |
| DE | 91 04 027 U1 |
| DE | 90 04 240 U1 |
| US | 55 62 663 |
| US | 49 50 269 |
| EP | 05 28 706 A1 |
| EP | 04 65 158 A2 |
| EP | 04 43 894 A1 |
| EP | 04 43 892 A1 |
| EP | 03 48 272 A1 |
| EP | 03 46 521 A1 |
| WO | 94 26 191 A1 |

**Die folgenden Angaben sind den vom Anmelder eingereichten Unterlagen entnommen**

Prüfungsantrag gem. § 44 PatG ist gestellt

(54) Osteosynthesevorrichtung

(57) Bei einer Osteosynthesevorrichtung mit einer Knochenschraube, insbesondere einer Pedikelschraube, mit einem eine Nut aufweisenden Gabelkopf und einem in der Nut des Gabelkopfes gelagerten Korrekturstab wird eine geringe Bauhöhe dadurch erreicht, dass der Korrekturstab mittels eines Rastdeckels an der Knochenschraube fixiert ist.

DE 199 51 145 A 1



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 471 of 2152

## Beschreibung

Die Erfindung betrifft eine Osteosynthesevorrichtung mit einer Knochenschraube, insbesondere einer Pedikelschraube, mit einem eine Nut aufweisenden Gabelkopf und einem in der Nut des Gabelkopfes gelagerten Korrekturstab, wobei der Grund der Nut des Gabelkopfes mit mehreren parallel zueinander liegenden Kerben versehen ist.

Derartige Osteosynthesevorrichtungen sind in einer Vielzahl bekannt (DE-Gbm 90 04 240, DE-Gbm 91 04 027, EP-A-346 521, DE-A 39 42 429, EP-A-443 894, EP-A-348 272, EP-A-465 158, EP-A-528 706, EP-A-443 892, DE-A 39 16 198, DE-C 41 10 002, WO-A-9426191). Aus diesen Druckschriften sind unterschiedliche Knochenschrauben mit Gabelköpfen bekannt, in die ein Korrekturstab eingelegt und fixiert werden kann. Dabei kommt es hauptsächlich auf eine rutschfreie Verankerung des Korrekturstabes an der Knochenschraube an. Nur eine rutsch- und verdrehsichere Fixierung des Korrekturstabes an der Knochenschraube gewährleistet eine optimale Übertragung von Zug- und Druckkräften auf die einzelnen zu korrigierenden und fixierenden Knochen sowie die Übertragung von Dreh- und Biegemomenten.

In der Regel wird eine gute Fixierung dadurch erzielt, dass in den Gabelkopf eine Fixierschraube derart eingeschraubt wird, dass diese auf den eingelegten Korrekturstab drückt. Es hat sich jedoch gezeigt, dass aufgrund der auftretenden hohen Kräfte und Momente, ein Aufbiegen des Gabelkopfes nicht auszuschließen ist, so dass sich die Fixierung des Korrekturstabes lösen kann. Außerdem bietet eine derartige Klemmfixierung keine ausreichende Sicherheit gegen ein Verdrehen des Korrekturstabes um die eigene Achse.

Bei einem klemmenden Osteosyntheseimplantat (EP-A-528 706) wird auf den in den Gabelkopf der Knochenschraube eingelegten Korrekturstab eine Fixierplatte aufgelegt, der einerseits die Aufgabe hat, dass die beiden Schenkel des Gabelkopfes nicht auseinandergepresst werden, andererseits an seinem auf dem Korrekturstab aufliegenden Abschnitt Längsnuten aufweist, die in Längsnuten des Korrekturstabes eingreifen. Hierdurch wird zwar eine erhöhte Sicherheit gegen ein Verdrehen des Korrekturstabes im Gabelkopf erzielt, jedoch muss das gesamte am Korrekturstab wirkende Drehmoment über die Andruckplatte, eine Fixierschraube und die beiden Schenkel des Gabelkopfes auf die Knochenschraube übertragen werden. Bei hohen Drehmomenten besteht immer noch die Gefahr, dass der Gabelkopf verformt und dadurch die Fixierung des Korrekturstabes gelockert wird.

Aus der WO-A-9426191 ist eine Knochenschraube bekannt, bei der auf die beiden Schenkel des Gabelkopfes nach dem Einlegen des Korrekturstabes eine Hutmutter aufgeschraubt wird. Hierdurch wird eine optimale Fixierung erreicht.

Der Erfindung liegt daher die Aufgabe zugrunde, eine Osteosynthesevorrichtung der eingangs genannten Art derart weiterzubilden, dass der Korrekturstab sicher gegen ein Verdrehen an der Knochenschraube festlegbar ist ohne dass eine aufzuschraubende Hutmutter oder eine einzuschraubende Fixierschraube verwendet werden muss. Außerdem soll die Bauhöhe der Schaube oberhalb des Korrekturstabes verringert werden.

Diese Aufgabe wird mit einer Osteosynthesevorrichtung der eingangs genannten Art erfindungsgemäß dadurch gelöst, dass der Korrekturstab mittels eines Rastdeckels an der Knochenschraube fixiert ist.

Die am Nutgrund des Gabelkopfes, d. h. am Grund der Nut, in die der Korrekturstab eingelegt wird, vorgesehenen Kerben erlauben bekanntermaßen einerseits eine verdrehsichere Befestigung des Korrekturstabes an der Knochenschraube, andererseits eine direkte Kraftübertragung vom Korrekturstab auf den Schaft der Knochenschraube. Wird ein Korrekturstab mit einer glatten Oberfläche in den Gabelkopf eingelegt, dann graben sich die Kerben in die Oberfläche des Korrekturstabes ein und fixieren diesen auf diese Weise. Ist der Korrekturstab als Gewindestange ausgebildet, dann graben sich die Kerben in das Gewinde der Gewindestange ein. Vorteilhaft verlaufen die Kerben als Längskerben in Richtung der Achse des Korrekturstabes. Bei anderen Ausführungsformen können die Kerben auch diagonal oder quer verlaufen.

Die erfindungsgemäße Ausgestaltung der Knochenschraube hat den Vorteil, dass die Kraftübertragung vom Korrekturstab auf den Schaft der Knochenschraube nicht über Halteelemente, Schrauben oder die beiden Schenkel des Gabelkopfes erfolgt, sondern direkt vom Stab auf den Schaft. Auf diese Weise können wesentlich höhere Kräfte und Momente übertragen werden bzw. wird die Kraft bzw. das Moment mit höherer Sicherheit gegen Verrutschen bzw. Durchrutschen übertragen.

Vorteilhaft ist der Korrekturstab mit Längsnuten versehen, wobei die Längsnuten zu den Längskerben korrespondieren und insbesondere in Achsrichtung verlaufen. Bei dieser Ausführungsform greifen die Längsnuten beim Einlegen des Korrekturstabes in die Nut des Gabelkopfes in die Längskerben und stellen eine formschlüssige Verbindung zwischen dem Korrekturstab und der Knochenschraube her. Dabei können sowohl der Korrekturstab als auch der Gabelkopf aus einem harten formbeständigen Material bestehen. Hartes bzw. zähes Material ist insbesondere bei der Übertragung hoher Kräfte und Momente empfehlenswert.

Ein problemloses Einlegen und anschließendes Entfernen des Korrekturstabes in die Nut des Gabelkopfes wird dadurch erzielt, dass die Längskerben in Richtung der Achse der Knochenschraube hinterschnittsfrei ausgebildet sind. Da die Längskerben keine Hinterschnitte aufweisen, kann der Korrekturstab auch nach einer Verformung beim Einpressen in die Längskerben problemlos wieder aus der Nut des Gabelkopfes entfernt werden, ohne dass er sich in den Längskerben festkrallt.

Bevorzugt sind die Kerben am Rand des Gabelkopfes vorgesehen. Dies hat den Vorteil, dass aufgrund der kürzeren Längskerben wesentlich höhere Druckkräfte beim Anpressen des Korrekturstabes erzielt werden können, so dass sich die Kerben bei einem glatten Korrekturstab wesentlich besser in dessen Oberfläche eingraben können. Außerdem wird durch den höheren Anpressdruck die Haltekraft sowohl bei glatten als auch bei genuteten Korrekturstäben erhöht.

Der auf den Schraubenkopf, insbesondere auf die beiden Gabelschenkel aufzurastende Rastdeckel hat den wesentlichen Vorteil, dass keine Hutmutter aufgeschraubt oder Fixierschraube eingeschraubt werden muss. Die Schraubbewegungen werden überflüssig. Es ist nur noch eine Verpressung von Rastdeckel und Schraube bzw. Schraubenkopf erforderlich, was problemlos mit einem entsprechenden Werkzeug, z. B. einer Zange erfolgen kann.

Da die Fixierung des Korrekturstabes auf einfache Weise durch das Aufrasten des Rastdeckels erfolgt, bedarf es keiner Schraubbewegung zum Aufschrauben einer Kopf- bzw. Hutmutter und es bedarf somit auch keines Werkzeugs, mit dem die Mutter aufgeschraubt werden muss. Die Verwendung einer Zange ist zum einen wesentlich bequemer, zum anderen bedarf es hierfür weniger Platz. Außerdem kann der Zeitaufwand für die Operation verringert werden.

Bevorzugt sind der Rastdeckel mit ersten Rastelementen und die Knochenschraube mit zweiten Rastelement verse-

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 472 of 2152

hen. Über diese Rastelement werden die beiden Bauteile miteinander verbunden. Diese Rastelemente können in Form von Rastnasen, Rastaufnahmen, Schnappverbindungen, Hakenelementen oder dgl. ausgebildet sein. Dabei ist wichtig, dass die Rastelemente sich nicht selbsttätig voneinander lösen können.

Mit Vorzug ist der Rastdeckel mit Schenkeln versehen, die in Richtung auf die Knochenschraube weisen. Diese Schenkel umgreifen seitlich den in den Gabelkopf eingelegten Korrekturstab und halten diesen zusätzlich fest. Eine Fixierung des Rastdeckels an der Knochenschraube erfolgt dabei mittels Rastnasen, die an den freien Enden der Schenkel vorgesehen sind. Die Schenkel haben den Vorteil, dass sie eine federelastische Anordnung der Rastelemente bewirken. Dabei können die Schenkel des Rastdeckels die Schenkel des Gabelkopfes übergreifen, so dass diese von den Schenkeln des Rastdeckels abgestützt werden. Auch die Schenkel des Gabelkopfes können federelastisch ausgeführt sein. Unter federelastischer Ausführung wird die elastische Nachgiebigkeit im Bereich weniger µm verstanden.

Bei einem Ausführungsbeispiel ist vorgesehen, dass am Fuß des Gabelkopfes Rastaufnahmen für Rastnasen des Rastdeckels vorgesehen sind. Über diese Rastnasen, die in die Rastaufnahmen eingreifen, wird der Deckel an der Knochenschraube verrastet. Dabei übergreift der gesamte Rastdeckel mit seinen Schenkeln den Aufnahmebereich des Gabelkopfes der Knochenschraube und schließt diesen derart nach außen ab, dass der Korrekturstab spielfrei und unter Vorspannung in seiner Aufnahme gehalten wird.

Ein Ausführungsbeispiel sieht vor, dass die Schenkel des Gabelkopfes an ihrer Außenseite mit einer Auflaufschräge für den Rastdeckel bzw. für die Schenkel des Rastdeckels versehen sind. Wird der Rastdeckel auf den Gabelkopf aufgesetzt und in Richtung seiner Raststellung bewegt, dann laufen die Schenkel des Rastdeckels auf die Außenflächen der Schenkel des Gabelkopfes auf und biegen diese geringfügig aufeinander zu. An den freien Enden der Schenkel des Rastdeckels sind nach außen weisende Rastnasen vorgesehen, die in entsprechende Aufnahmen eingreifen. Ein sicherer Halt dieser Rastnasen in den Aufnahmen wird dadurch erzielt, dass die Schenkel des Rastdeckels von den Schenkeln des Gabelkopfes nach außen gedrängt werden.

Weiterhin besitzt der Rastdeckel gegenüber dem Gabelkopf eine Verdrehsicherung, die von einer in Richtung der Längsachse verlaufenden schlitzförmigen Öffnung geschaffen wird, in welche wenigstens ein Schenkel bzw. ein Abschnitt eines Schenkels des Gabelkopfes eingreift.

Weitere Vorteile, Merkmale und Einzelheiten der Erfindung ergeben sich aus der nachfolgenden Beschreibung, in der unter Bezugnahme auf die Zeichnung ein besonders bevorzugtes Ausführungsbeispiel im einzelnen dargestellt ist. Dabei können die in der Zeichnung dargestellten und in der Beschreibung erwähnten Merkmale jeweils einzeln für sich oder in beliebiger Kombination bei der Erfindung verwirklicht sein.

In der Zeichnung zeigen:

**Fig.** 1 eine schematische perspektivische Darstellung des oberen Endes einer Knochenschraube mit eingelegtem Korrekturstab und angesetztem Rastdeckel; und

**Fig.** 2 die Knochenschraube gemäß **Fig.** 1 mit aufgerastetem Rastdeckel.

In der **Fig.** 1 ist in perspektivischer Ansicht das obere Ende einer insgesamt mit 10 bezeichneten Knochenschraube dargestellt, wobei für die Erfindung lediglich der Gabelkopf **12** der Knochenschraube **10** wichtig ist. Dieser Gabelkopf **12** besitzt zwei Schenkel **14** und **16**, zwischen denen sich eine Nut **18** erstreckt. Der Grund **20** der Nut **18** ist mit mehreren Kerben **20** versehen, welche sich als Längskerben in Richtung der Längsachse eines Korrekturstabs **24** erstrecken. Dieser Korrekturstab **24** weist an seiner Außenfläche Längskerben **26** auf, so dass der Korrekturstab **24** verdrehsicher in die Längskerben **22** der Nut **18** eingesetzt werden kann.

Oberhalb des Gabelkopfes **12** ist in **Fig.** 1 ein Rastdeckel **28** dargestellt, der einen relativ dünnen Deckelboden **30** aufweist. Seitlich an den Deckelboden **30** schließen sich Schenkel **32** und **34** an, die in Richtung auf die Knochenschraube **10** nach unten abragen. Der Abstand der Schenkel **32** und **34** ist derart bemessen, dass sie zwischen sich die beiden Schenkel **14** und **16** bei eingelegtem Korrekturstab **24** aufnehmen können.

Am freien Ende der Schenkel **32** und **34** sind nach außen abragende Rastnasen **36** vorgesehen, die bei aufgerastetem Deckel **28** in Rastaufnahmen **38** eingreifen und, wie in **Fig.** 2 dargestellt, eine Verrastung bilden, mit der der Rastdeckel **28** an der Knochenschraube **10** gehalten wird.

In der **Fig.** 2 ist außerdem deutlich erkennbar, dass die Schenkel **14** und **16** an ihren Außenflächen eine Auflaufschräge **40** aufweisen, d. h. die Außenflächen der beiden Schenkel **14** und **16** laufen konisch aufeinander zu. Auf diese Auflaufschräge **40** wird der Rastdeckel **20** aufgeschoben, so dass die Schenkel **14** und **16** an der Innenfläche **42** des Rastdeckels **28** anliegen. Dabei werden die beiden Schenkel **14** und **16** geringfügig nach innen gedrückt, wodurch der Korrekturstab **24** spielfrei in der Nut **18** gehalten wird. Außerdem üben die Schenkel **14** und **16** eine Rückstellkraft auf die Schenkel **32** und **34** aus, so dass diese bzw. deren Rastnasen **36** in die Rastaufnahmen **38** hineingedrängt werden.

In **Fig.** 2 ist deutlich erkennbar, dass oberhalb des Korrekturstabes **24** lediglich der Rastdeckel **28** mit seinem Deckelboden **30** sich befindet, wodurch eine extrem geringe Bauhöhe erzielt wird.

Weiterhin ist in **Fig.** 1 erkennbar, dass der Rastdeckel **28** mit einem vertikalen Schlitz **44** versehen ist, in welchen ein Abschnitt des Schenkels **14** eingreift. Dieser Schlitz **44** dient als Verdrehsicherung und außerdem als Zentrierung beim Aufsetzen des Rastdeckels **28** auf die Knochenschraube **10**.

Sowohl die Schenkel **14** und **16** als auch die Schenkel **32** und **34** sind mit Einschnitten **50** und **52** versehen, wodurch jeweils eine Art Gelenek gebildet wird, um welches sich die Schenkel elastisch verformen lassen. Außerdem ist in **Fig.** 1 deutlich erkennbar, dass der die Rastaufnahme **38** aufweisende Vorsprung **54** in Umfangsrichtung um den Gabelkopf **12** gerundet ist.

Zum Aufrasten des Rastdeckels **28** bedarf es lediglich einer Zange, die unterhalb der Schultern **46** angreift und mit der der Rastdeckel **28** auf den Gabelkopf **12** aufgedrückt werden kann. Zum Entfernen des Rastdeckels **28** bedarf es eines anderen Werkzeugs, mit dem die beiden Schenkel **32** und **34** unterhalb der Vorsprünge **48** zusammengepresst werden. Die Verrastung von Rastnase **36** und Rastaufnahme **38** wird dadurch gelöst.

## Patentansprüche

1. Osteosynthesevorrichtung mit einer Knochenschraube (**10**), insbesondere einer Pedikelschraube, mit einem eine Nut (**18**) aufweisenden Gabelkopf (**12**) und einem in der Nut (**18**) des Gabelkopfes (**12**) gelagerten Korrekturstab (**24**), wobei der Grund (**20**) der Nut (**18**) des Gabelkopfes (**12**) mit mehreren parallel zueinander liegenden Kerben (**22**) versehen ist, **dadurch gekennzeichnet**, dass der Korrekturstab (**24**) mittels eines Rastdeckels (**28**) an der Knochenschraube (**10**) fixiert ist.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 473 of 2152

2. Osteosynthesevorrichtung nach Anspruch 1, dadurch gekennzeichnet, dass die Kerben (**22**) in Richtung der Achse des Korrekturstabes (**10**) verlaufen.

3. Osteosynthesevorrichtung nach einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, dass die Kerben (**22**) in Richtung der Achse der Knochenschraube (**10**) hinterschneidungsfrei ausgebildet sind.

4. Osteosynthesevorrichtung nach einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, dass die Kerben (**22**) am Nutrand des Gabelkopfes (**12**) vorgesehen sind.

5. Osteosynthesevorrichtung nach einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, dass der Korrekturstab (**24**) mit Längsnuten (**26**) versehen ist, wobei die Längsnuten (**26**) zu den Kerben (**22**) korrespondieren, und insbesondere in Achsrichtung verlaufen.

6. Osteosynthesevorrichtung nach einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, dass der Rastdeckel (**28**) mit ersten Rastelementen und die Knochenschraube (**10**) mit zweiten Rastelementen versehen sind.

7. Osteosynthesevorrichtung nach Anspruch 6, dadurch gekennzeichnet, dass die Rastelemente von Rastnasen (**36**) und Rastaufnahmen (**38**) gebildet werden.

8. Osteosynthesevorrichtung nach einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, dass der Rastdeckel (**28**) in Richtung auf die Knochenschraube (**10**) weisende Schenkel (**32, 34**) aufweist.

9. Osteosynthesevorrichtung nach Anspruch 8, dadurch gekennzeichnet, dass die freien Enden der Schenkel (**32, 34**) mit Rastelementen, insbesondere mit Rastnasen (**36**) versehen sind.

10. Osteosynthesevorrichtung nach Anspruch 8 oder 9, dadurch gekennzeichnet, dass die Schenkel (**32, 34**) des Rastdeckels (**28**) die Schenkel (**14, 16**) des Gabelkopfes (**12**) übergreifen.

11. Osteosynthesevorrichtung nach einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, dass am Fuß des Gabelkopfes (**12**) Rastaufnahmen (**38**) für Rastnasen (**36**) des Rastdeckels (**28**) vorgesehen sind.

12. Osteosynthesevorrichtung nach einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, dass der Rastdeckel (**28**) in der Raststellung auf dem Korrekturstab (**24**) aufliegt und diesen in den Kerben (**22**) festhält.

13. Osteosynthesevorrichtung nach einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, dass die Schenkel (**14, 16**) des Gabelkopfes (**12**) an ihrer Außenseite mit einer Auflaufschräge (**40**) für den Rastdeckel (**28**) bzw. für die Schenkel (**32, 34**) des Rastdeckels (**28**) versehen sind.

14. Osteosynthesevorrichtung nach einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, dass der Rastdeckel (**28**) und die Schenkel (**14, 16**) des Gabelkopfes (**12**) eine Verdrehsicherung bilden.

15. Osteosynthesevorrichtung nach Anspruch 14, dadurch gekennzeichnet, dass die Verdrehsicherung von wenigstens einem in Richtung der Längsachse der Knochenschraube (**10**) verlaufenden Schlitz (**44**) geschaffen wird, in den der bzw. die Schenkel (**14, 16**) des Gabelkopfes (**12**) ganz oder teilweise eingreifen.

Hierzu 2 Seite(n) Zeichnungen

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 474 of 2152

Nummer: DE 199 51 145 A1
Int. Cl.[7]: A 61 B 17/68
Offenlegungstag: 31. Mai 2001

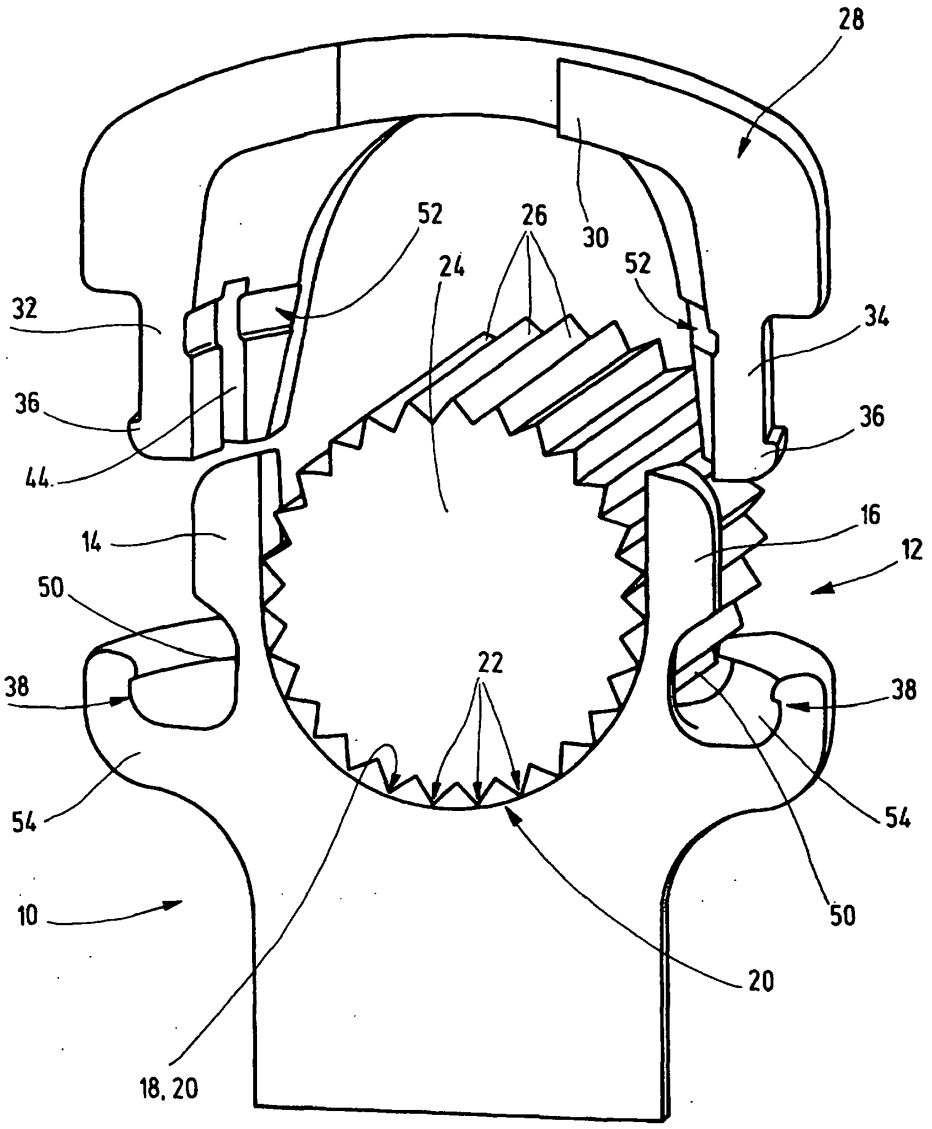



FIG. 1



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 475 of 2152

Nummer: DE 199 51 145 A1
Int. Cl.[7]: A 61 B 17/68
Offenlegungstag: 31. Mai 2001

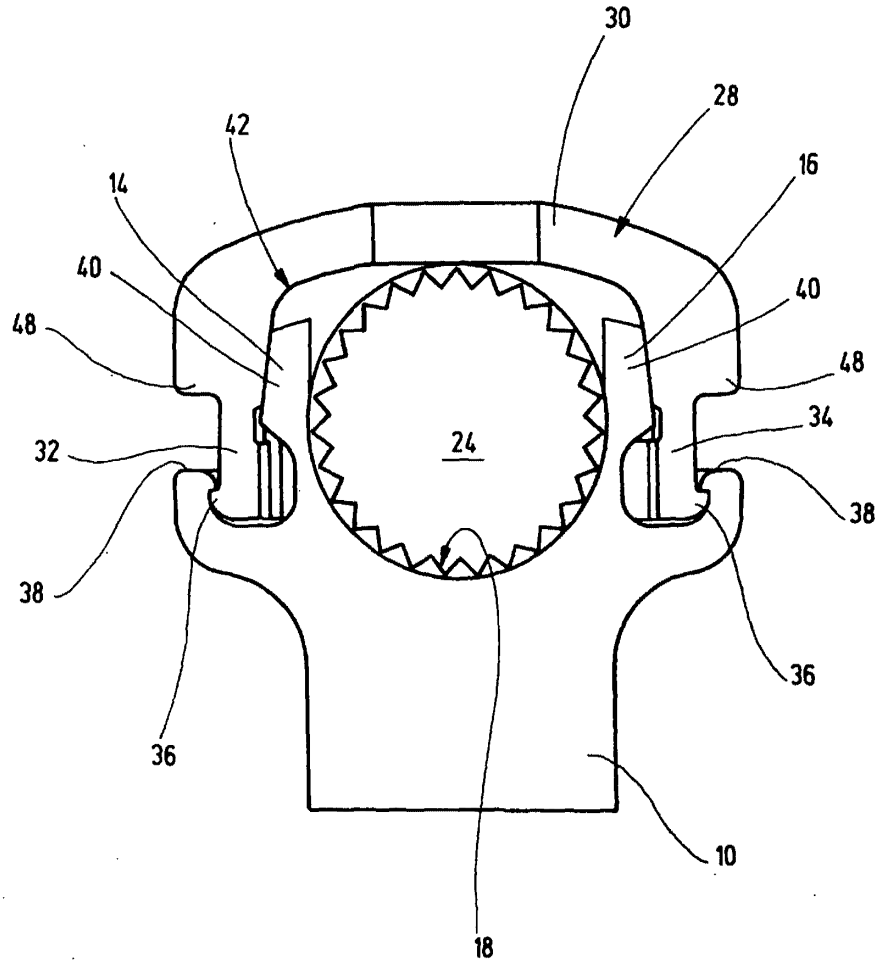



FIG. 2



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 476 of 2152

(19) RÉPUBLIQUE FRANÇAISE

INSTITUT NATIONAL
DE LA PROPRIÉTÉ INDUSTRIELLE

PARIS

(11) N° de publication : **2 799 949**
(à n'utiliser que pour les commandes de reproduction)

(21) N° d'enregistrement national : **99 13475**

(51) Int Cl[7] : **A 61 B 17/70**

# (12) DEMANDE DE BREVET D'INVENTION A1

(22) **Date de dépôt** : 22.10.99.

(30) **Priorité** :

(43) **Date de mise à la disposition du public de la demande** : 27.04.01 Bulletin 01/17.

(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)** : *BENAZZA ABDER* — FR, *GLOAGUEN HERVE* — FR et *PERSON HERVE* — FR.

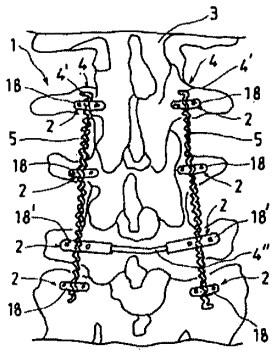
(72) **Inventeur(s)** : BENAZZA ABDER, GLOAGUEN HERVE et PERSON HERVE.

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

(74) **Mandataire(s)** : CABINET POUPON.

## (54) DISPOSITIF D'OSTHEOSYNTHESE RACHIDIENNE.

(57) La présente invention se rapporte à un dispositif (1) d'ostéosynthèse rachidienne du type comportant des éléments de fixation (2) destinés à être implantés partiellement dans certains segments du rachis (3) et des éléments de maintien (4) sensiblement longitudinaux (4') et éventuellement transversaux (4 '') destinés à maintenir lesdits segments du rachis (3) entre eux, chaque élément de maintien (4) coopérant avec au moins deux éléments de fixation (2), caractérisé en ce qu'au moins un élément de maintien (4) comporte au moins une partie souple constituée d'un ressort hélicoïdal (5) afin d'autoriser potentiellement les mouvements rachidiens originels d'inclinaison avant, d'inclinaison arrière, d'inclinaison latérale et de rotation.




FR 2 799 949 - A1

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 477 of 2152

La présente invention se rapporte au domaine des dispositifs d'ostéosynthèse rachidienne et plus particulièrement au domaine des dispositifs d'ostéosynthèse rachidienne installés par voie postérieure, du type comportant des éléments de fixation destinés à être implantés partiellement dans certains segments du rachis ainsi que des éléments de maintien longitudinaux et éventuellement transversaux, destinés à maintenir lesdits segments du rachis entre eux, chaque élément de maintien coopérant avec au moins deux éléments de fixation.

Le but de ce genre de dispositif est de permettre de rétablir au moins partiellement la statique de la colonne vertébrale lorsque des instabilités apparaissent.

Les indications chirurgicales nécessitant une telle installation sont essentiellement de type dégénératif.

Les dispositifs d'ostéosynthèse rachidienne se composent en général d'un ensemble de composants comprenant des éléments de fixation destinés à être vissés dans les pédicules des vertèbres, ainsi que des éléments de maintien rigides destinés à maintenir lesdits segments du rachis entre eux en prenant appui sur les éléments de fixation. Les éléments de maintien se présentent souvent sous la forme d'une paire de barres sensiblement longitudinales, rigides, entre lesquelles peuvent éventuellement être positionnés un ou plusieurs éléments de maintien transversaux rigides ou semi-rigides. Chaque élément de maintien transversal ou longitudinal coopère toujours avec au moins deux éléments de fixation.

Ces dispositifs cherchent ainsi à créer une arthrodèse, c'est à dire une fusion des segments du rachis concernés.

Ces dispositifs peuvent être installés, par exemple, entre la cinquième lombaire et le sacrum pour les dispositifs appelés L5 - S1. Ces dispositifs réduisent alors la mobilité de la colonne vertébrale des patients, essentiellement pour les mouvements d'inclinaison avant, d'inclinaison arrière, d'inclinaison latérale et de rotation du tronc.

L'inconvénient majeur de ces dispositifs réside dans le fait que les segments de la colonne vertébrale adjacents qui ne sont pas intégrés dans le dispositif d'ostéosynthèse, subissent alors des contraintes beaucoup plus importantes et se dégradent par conséquent plus vite car le dispositif d'ostéosynthèse étant très

rigide, les segments maintenus par le dispositif d'ostéosynthèse ne peuvent plus jouer leurs rôles d'amortisseurs.

L'art antérieur connaît des dispositifs d'ostéosynthèse rachidienne qui cherchent à diminuer les effets de l'ostéosynthèse sur les segments adjacents et en particulier, l'art antérieur connaît la demande de brevet internationale N° WO 98/22033 qui porte sur un système d'ostéosynthèse comprenant un élément de liaison transversal positionné entre les éléments de maintient longitudinaux et qui possèdent certaines qualités de déformation élastique.

Ce dispositif est destiné à être disposé sur le segment sus-jacent immédiatement supérieur au dispositif d'ostéosynthèse et propose finalement d'intégrer cet élément sus-jacent dans le dispositif d'ostéosynthèse.

L'inconvénient de ce dispositif réside dans le fait qu'il ne résout que partiellement les problèmes de répartitions de contraintes car ce problème se pose également avec les autres segments sus-jacents.

Une solution pourrait consister à installer un dispositif d'ostéosynthèse qui maintienne la majeure partie de la colonne vertébrale, mais les dispositifs existants ne sont que très partiellement souples et uniquement selon la direction transversale. Il est évident que la gêne alors procurée serait importante car, les mouvements d'inclinaison avant, d'inclinaison arrière, d'inclinaison latérale et de rotation du tronc seraient très limités par rapport à ceux originels.

La présente invention entend remédier aux inconvénients de l'art antérieur en proposant un dispositif d'ostéosynthèse du type décrit ci-dessus dans lequel chaque élément de maintien longitudinal et éventuellement transversal comporte au moins une partie souple constituée d'un ressort hélicoïdal afin d'autoriser potentiellement tous les mouvements rachidiens originels d'inclinaison avant, d'inclinaison arrière, d'inclinaison latérale, de rotation et de translation mutlidirectionnelle selon le plan horizontal.

Un but important de l'invention est de permettre de rétablir la statique lombaire tout en limitant l'arthrodèse et seul un élément de maintien ou un ensemble d'éléments de maintien constitués au moins partiellement d'un ressort hélicoïdal permet à la fois de maintenir le rachis en compression, en extension et en rotation.

Avantageusement, le dispositif d'ostéosynthèse selon l'invention est en mesure de se substituer complètement aux liaisons inter-segmentaires qui ne sont plus en mesure de remplir leur office de maintien, d'amortissement et d'articulation.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 479 of 2152

Avantageusement, le dispositif d'ostéosynthèse selon l'invention permet, en en réduisant l'amplitude et en les freinant, les mouvements de flexion, d'extension, d'inclinaison latérale droite et gauche, de rotation droite et gauche et de translation mutlidirectionnelle selon le plan horizontal entre deux vertèbres. Il permet ainsi de réduire les contraintes subies lors de ces différents mouvements par les moyens d'union naturels inter-vertébraux inclus dans le dispositif.

Avantageusement, le dispositif d'ostéosynthèse selon l'invention est en mesure de réaliser un système de protection des segments mobiles intervertébraux immédiatement sus-jacents en réduisant les contraintes qui pèsent sur eux et en ralentissant ainsi leurs dégénérescences naturelles.

Avantageusement également, grâce au dispositif selon l'invention, il n'est plus nécessaire que le chirurgien procède au cintrage des éléments de maintien longitudinaux afin de les adapter à la courbure de la colonne vertébrale du patient car la souplesse des ressorts hélicoïdaux est telle qu'elle leur permet de s'adapter naturellement à la morphologie de chaque patient.

Avantageusement également, chaque élément de maintien longitudinal ou transversal se compose soit d'un seul ressort hélicoïdal, éventuellement doublé, soit d'une succession de ressorts hélicoïdaux, éventuellement doublés, telle que chaque ressort hélicoïdal unique ou doublé corresponde à un espace entre deux segments du rachis à maintenir ensemble.

Chaque ressort hélicoïdal seul ou inclus dans une succession et éventuellement doublé, comporte à ses extrémités des embouts destinés, chacun, à coopérer avec un élément de fixation.

Grâce au dispositif selon l'invention, il est également possible d'imaginer que pour des applications thérapeutiques particulières, un ou plusieurs éléments de maintien transversaux, comportant au moins en partie des ressorts hélicoïdaux, soient disposés entre le pédicule droit d'une vertèbre et le pédicule gauche d'une vertèbre sus ou sous-jacente, ou inversement.

Le dispositif selon l'invention permet en outre de traiter facilement des pathologies particulières telles que la pathologie dégénérative appelée « spondylolysthésis » nécessitant d'opérer un rappel de vertèbres ou encore les pathologies scoliotiques. En effet, dans ce dernier cas, le dispositif selon l'invention peut être utilisé comme tuteur afin de stabiliser la colonne vertébrale.

On comprendra mieux l'invention à l'aide de la description faite ci-après d'un mode de mise en œuvre donné à titre d'exemple non limitatif, en référence aux figures annexées dans lesquelles :

- la figure 1 illustre une vue postérieure et partielle d'un rachis équipé d'un dispositif d'ostéosynthèse selon l'invention à élément de maintien longitudinal constitué d'un seul ressort hélicoïdal ;
- la figure 2 illustre une vue de profil d'un élément de fixation vis tulipe selon la figure 1 ;
- la figure 3 illustre une vue de profil d'un autre élément de fixation vis tulipe ;
- la figure 4 illustre une vue de profil d'un dispositif d'ostéosynthèse selon l'invention utilisé pour effectuer un rappel de vertèbre ;
- la figure 5 illustre une vue de profil d'un élément de fixation vis tulipe à double évidement en U pour ressort hélicoïdal doublé ;
- la figure 6 illustre une vue de profil d'un élément de maintien transversal tel que celui présenté figure 1 ;
- la figure 7 illustre une vue postérieure et partielle d'un rachis équipé d'un dispositif d'ostéosynthèse selon l'invention à éléments de maintien longitudinaux constitués d'une succession de ressorts hélicoïdaux à embouts cylindriques ;
- la figure 8 illustre une vue de profil et partielle d'un agencement de deux éléments de fixation et d'un élément de maintient selon la figure 7 ;
- la figure 9 illustre une vue de profil d'un élément de fixation vis tulipe à capuchon muni d'une cale de blocage libre selon la figure 7 ;
- la figure 10 illustre une vue de profil d'un élément de fixation vis tulipe à capuchon muni de deux cales de blocage libres, ladite vis tulipe comportant un double évidement en U pour ressort hélicoïdal doublé ;
- la figure 11 illustre une vue postérieure et partielle d'un rachis équipé d'un dispositif d'ostéosynthèse selon l'invention à éléments de maintien longitudinaux constitués d'une succession de ressorts hélicoïdaux à embouts en forme de plaques présentant des lumières ; et
- la figure 12 illustre une vue de face d'un élément de fixation selon la figure 11.

Le dispositif (1) d'ostéosynthèse rachidienne selon l'invention est du type comportant des éléments de fixation (2) destinés à être implantés partiellement dans certains segments du rachis (3) et des éléments de maintien (4) sensiblement longitudinaux (4'), souvent au nombre de deux, et éventuellement transversaux (4")

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 481 of 2152

destinés à maintenir lesdits segments du rachis (3) entre eux, chaque élément de maintien (4) coopérant avec au moins deux éléments de fixation (2).

Les éléments de fixation (2) sont, par exemple, des vis de fixation (8) appelées « vis pédiculaires » comportant une tige filetée destinée à être introduite dans les pédicules vertébraux lombaires ou thoraciques ou dans le sacrum, ainsi qu'une tête sur laquelle peut être maintenu, par différents moyens, un ou plusieurs éléments de maintien longitudinal et / ou transversal.

Le dispositif (1) d'ostéosynthèse rachidienne selon l'invention est caractérisé en ce qu'au moins un élément de maintien (4) comporte au moins une partie souple constituée d'un ressort hélicoïdal (5) afin d'autoriser potentiellement les mouvements rachidiens originels d'inclinaison avant, d'inclinaison arrière, d'inclinaison latérale et de rotation.

Selon l'invention, ce sont les ressorts hélicoïdaux (5) qui assurent le maintien entre les segments du rachis (3), et aucun autre élément rigide ou semi-rigide n'intervient.

Dans une première version de l'invention, illustrée figure 1, au moins un élément de maintien (4) et notamment de maintien longitudinal (4') se présente sous la forme d'un ressort hélicoïdal (5) unique.

Chaque liaison ressort hélicoïdal (5) / élément de fixation (2) peut alors être réalisée à l'aide d'un élément de fixation (2) se présentant sous la forme d'une vis tulipe (8') dont la tête comporte au moins un évidement (16) en U dans chacun desquels peut être positionné et maintenu au moins une partie du ressort hélicoïdal (5), chaque évidement (16) en U comportant à l'extrémité supérieure de ses parois latérales, au moins une tige filetée (17) permettant de retenir un palier de maintien (18) à l'aide d'un écrou (19). Le palier de maintien (18) a pour fonction de maintenir le ressort hélicoïdal dans l'évidement (16).

Dans le cas où le ressort hélicoïdal (5) n'est pas doublé, chaque évidement (16) en U peut comporter à l'extrémité supérieure de ses parois latérales, soit deux tiges filetées (17) permettant de retenir le palier de maintien (18) à l'aide de deux écrous (19), comme illustré figure 2, soit une seule tige filetée (17) permettant de retenir le palier de maintien (18) en forme de sabot à l'aide d'un seul écrou (19), comme illustré figure 3. Le principal avantage de cette dernière solution réside dans le fait que le dispositif d'ostéosynthèse rachidienne est alors plus simple à installer car il comporte moins d'écrous.

Dans une variante de la première version, les éléments de maintien (4) et notamment les éléments de maintien longitudinaux (4') sont réalisés chacun à l'aide de deux ressorts hélicoïdaux (5) disposés côte à côte.

Dans ce cas, chaque liaison ressort hélicoïdal (5) / élément de fixation (2) peut alors être réalisée à l'aide d'un élément de fixation (2) se présentant sous la forme d'une vis tulipe (8') dont la tête comporte deux évidements (16) en U, comme illustré figure 4, dans lesquels peuvent être positionnés et maintenus au moins une partie des ressorts hélicoïdaux (5).

Quelque soit le type de fixation de palier de maintien (18) et quelque soit le nombre de ressorts hélicoïdaux, il est possible de réaliser un ou plusieurs éléments de fixation rallongés (2') dont la longueur de la ou des tiges filetées (17') est plus importante, afin de permettre de réaliser un rappel de vertèbre, comme illustré figure 5.

Ainsi, le segment ou les segments de vertèbre qui comportent des éléments de fixation rallongés (2') subissent une traction selon la flèche F qui tend à les ramener au niveau des autres segments.

Dans cette première version de l'invention illustrée figure 1, il est possible de prévoir un élément de maintien transversal (4") réalisé à l'aide d'une tige d'union (20) présentant une courbure adaptée ou d'un ressort hélicoïdal, coulissant, dont les extrémités sont rectilignes et filetées, comme illustré figure 6. La liaison entre l'élément de maintien transversal (4") et les éléments de fixation (2) peut alors être réalisée à l'aide de paliers de maintien à fourreau (18') présentant chacun un fourreau (21) dans lequel peut être positionnée et maintenue une extrémité de l'élément de maintien transversal (4"). Pour adapter la longueur de l'élément de maintien transversal (4"), et pour parfaire le maintien, il est préférable de prévoir en outre des œillets de serrage (22), traversant de part en part les fourreaux (21) et les extrémités filetées de l'élément de maintien transversal (4").

Dans une deuxième version de l'invention, illustrée figure 7, chaque élément de maintien longitudinal (4') se compose d'une succession de ressorts hélicoïdaux (5), éventuellement doublés, chaque ressort hélicoïdal (5), ou double ressort hélicoïdal, correspondant à un espace entre deux segments du rachis (3) à maintenir ensemble.

Chaque ressort hélicoïdal (5) comporte alors, à ses extrémités, un embout (6), partie intégrante du ressort hélicoïdal (5) ou sertis à ce dernier et destiné à coopérer avec un élément de fixation (2).

La liaison embout (6)-élément de fixation (2) peut être de plusieurs types.

Une première solution consiste, par exemple, à réaliser lesdits embouts (6) sous la forme de cylindres (7), droits, comme illustré figure 8. Les cylindres (7) peuvent être réalisés soit en modifiant des parties du ou des ressorts hélicoïdaux (5) de façon à les rendre sensiblement rectilignes, soit en introduisant des éléments cylindriques sertis aux extrémités des ressorts hélicoïdaux (5).

Lesdits éléments de fixation (2) peuvent alors se présenter sous la forme de vis tulipes (8') dont les têtes comportent chacune au moins un évidement (16) en U, éventuellement doublé, dans chacun desquels peut être positionnée et maintenue au moins une partie dudit embout (6), les parois extérieures de l'évidement (16) ou de la pluralité d'évidements (16) étant filetées de manière à permettre de visser un capuchon (9) à cale(s) de blocage (10) libre(s), comme illustré figures 9 et 10.

Dans le cas où chaque élément maintien longitudinal (4') se compose d'une succession de ressorts hélicoïdaux (5) doublés, les vis tulipes (8') comportent alors deux évidements (16) en U, comme illustré figure 10, et le capuchon (9) comporte alors deux cales de blocage (10) libres.

Une deuxième solution consiste à réaliser lesdits embouts (6) sous la forme de plaques (11), par exemple serties aux extrémités des ressorts hélicoïdaux (5), chaque plaque (11) étant munie d'au moins une lumière (12), comme illustré figure 11.

Lesdits éléments de fixation (2) peuvent alors se présenter sous la forme de vis de fixation (8) munies d'au moins un pas de vis supérieur (13) dont le diamètre est inférieur à la largeur de ladite lumière (12), comme illustré figure 12, afin de permettre de régler l'espace nécessaire entre chaque élément du rachis qui doit être soutenu.

La plaque (11) est alors bloquée dans la lumière (12) à l'aide d'un écrou (15) et éventuellement d'une cale (14).

D'une manière générale, l'utilisation des embouts (6), sous forme de cylindres droits (7) ou de plaques (11) comportant des lumières (12), permet de simplifier considérablement l'ajustement du dispositif d'ostéosynthèse à la morphologie du patient.

Pour la fixation des éléments de maintien longitudinaux (4') sur le sacrum, il peut être prévu un embout (6') comportant deux trous.

Un dispositif de rappel de vertèbres pour le traitement du spondylolysthésis peut également être réalisé sur la base de cette deuxième solution.

Les ressorts hélicoïdaux (5) peuvent être réalisés, par exemple, en alliage de titane du type $Ta_6V_4$.

Le diamètre du fil utilisé pour réaliser les ressorts hélicoïdaux (5), non doublés, est de l'ordre de 2 à 3 millimètres et le diamètre total des ressorts hélicoïdaux (5) est de l'ordre de 8 millimètres.

Il apparaît que, grâce à ce genre d'alliage et grâce surtout à la structure souple du dispositif d'ostéosynthèse rachidienne, les frottements engendrés à l'intérieur du dispositif ne génèrent que peu de débris d'usure.

Pour empêcher que les écrous (15 ou 19) ne se dévissent, il peut être prévu des stries sous la base de ces écrous ainsi que sur la surface supérieure des plaques (11) ou des paliers de maintien (18).

Des écrous autobloquants peuvent également être utilisés.

## REVENDICATIONS

1- Dispositif (1) d'ostéosynthèse rachidienne, du type comportant des éléments de fixation (2) destinés à être implantés partiellement dans certains segments du rachis (3) et des éléments de maintien (4) sensiblement longitudinaux (4') et éventuellement transversaux (4") destinés à maintenir lesdits segments du rachis (3) entre eux, chaque élément de maintien (4) coopérant avec au moins deux éléments de fixation (2), caractérisé en ce qu'au moins un élément de maintien (4) comporte au moins une partie souple constituée d'un ressort hélicoïdal (5) afin d'autoriser potentiellement les mouvements rachidiens originels d'inclinaison avant, d'inclinaison arrière, d'inclinaison latérale et de rotation.

2- Dispositif (1) d'ostéosynthèse rachidienne selon la revendication 1, caractérisé en ce qu'au moins un élément de maintien (4) se présente sous la forme d'un seul ressort hélicoïdal (5).

3- Dispositif (1) d'ostéosynthèse rachidienne selon la revendication 1, caractérisé en ce qu'au moins un élément de maintien (4) se présente sous la forme de deux ressorts hélicoïdaux (5) disposés côte à côte.

4- Dispositif (1) d'ostéosynthèse rachidienne selon la revendication 1, caractérisé en ce que chaque élément de maintien longitudinal (4') se compose d'une succession de ressorts hélicoïdaux (5), éventuellement doublés, chaque ressort hélicoïdal (5), ou double ressort hélicoïdal, correspondant à un espace entre deux segments du rachis (3) à maintenir ensemble.

5- Dispositif (1) d'ostéosynthèse rachidienne selon l'une quelconque des revendications 1 à 4, caractérisé en ce que chaque ressort hélicoïdal (5) comporte à ses extrémités un embout (6) destiné à coopérer avec un élément de fixation (2).

6- Dispositif (1) d'ostéosynthèse rachidienne selon la revendication 5, caractérisé en ce que lesdits embouts (6) sont sertis à l'extrémité des ressorts hélicoïdaux (5).

7- Dispositif (1) d'ostéosynthèse rachidienne selon la revendication 5 ou la revendication 6, caractérisé en ce que lesdits embouts (6) se présentent sous la forme de cylindres (7) droits.

8- Dispositif (1) d'ostéosynthèse rachidienne selon l'une quelconque des revendications 5 à 7, caractérisé en ce que lesdits éléments de fixation (2) se présentent sous la forme de vis tulipes (8') dont les têtes comportent chacune au

moins un évidement (16) en U dans chacun desquels peut être positionnée et maintenue au moins une partie dudit embout (6), les parois extérieures de l'évidement (16) ou la pluralité d'évidements (16) étant filetées de manière à permettre de visser un capuchon (9) à cale(s) de blocage (10) libre(s).

9- Dispositif (1) d'ostéosynthèse rachidienne selon la revendication 5 ou la revendication 6, caractérisé en ce que lesdits embouts (6) se présentent sous la forme de plaques (11), chaque plaque (11) étant munie d'au moins une lumière (12).

10- Dispositif (1) d'ostéosynthèse rachidienne selon la revendication 9, caractérisé en ce que lesdits éléments de fixation (2) se présentent sous la forme de vis de fixation (8) munies d'au moins un pas de vis supérieur (13) dont le diamètre est inférieur à la largeur de ladite lumière (12), la plaque (11) étant bloquée dans la lumière (12) à l'aide d'un écrou (15).

11- Dispositif (1) d'ostéosynthèse rachidienne selon l'une quelconque des revendications 1 à 3, caractérisé en ce que lesdits éléments de fixation (2) se présentent sous la forme de vis tulipes (8') dont les têtes comportent chacune au moins un évidement (16) en U dans chacun desquels peut être positionné et maintenu au moins une partie du ressort hélicoïdal (5), chaque évidement (16) en U comportant à l'extrémité supérieure de ses parois latérales, au moins une tige filetée (17) permettant de retenir un palier de maintien (18) à l'aide d'un écrou (19).

12- Dispositif (1) d'ostéosynthèse rachidienne selon la revendication 11, caractérisé en ce qu'il comporte des paliers de maintien à fourreau (18') présentant chacun un fourreau (21) dans lequel peut être positionnée et maintenue une extrémité d'un élément de maintien transversal (4").

2799949

FIG. 1

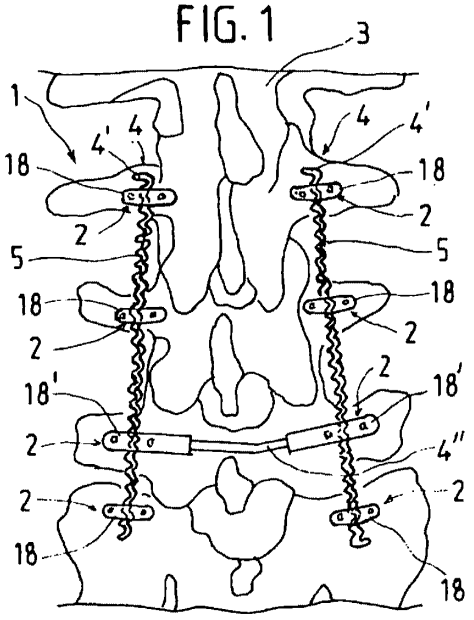


FIG. 2

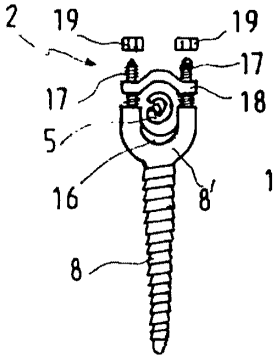


FIG. 3

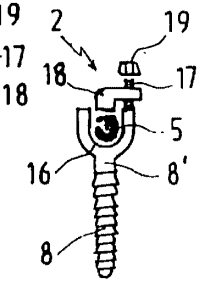


FIG. 4

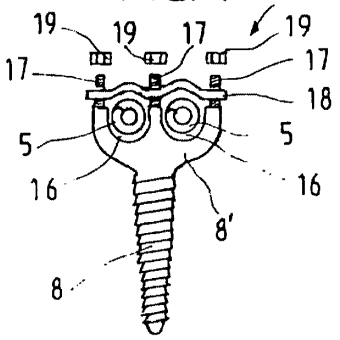
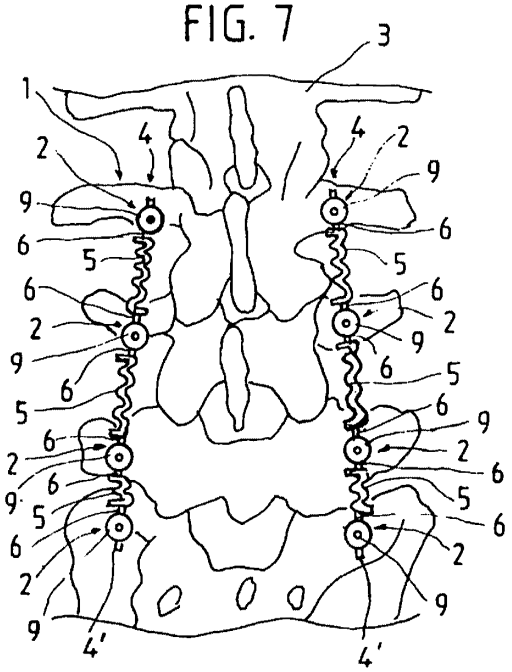


FIG. 7



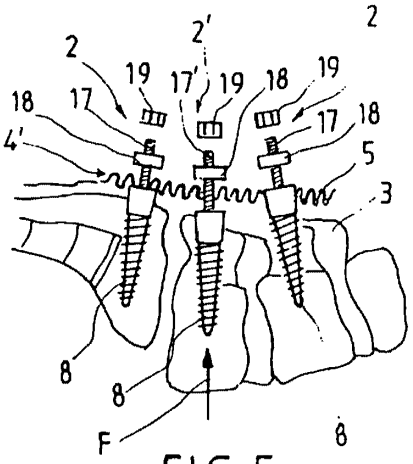


FIG. 5

2799949

FIG. 6

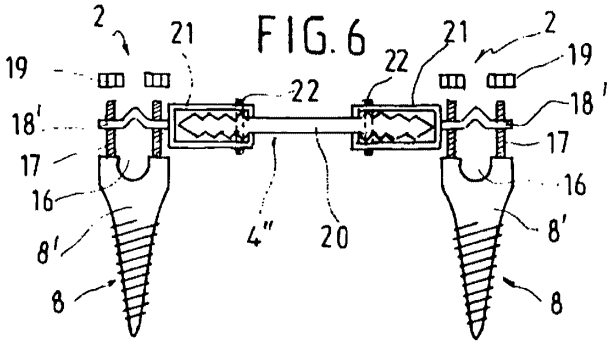



FIG. 9

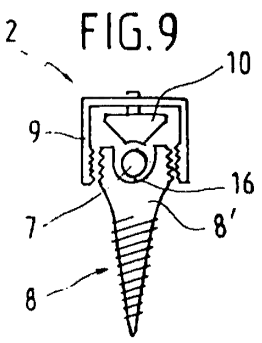



FIG. 8

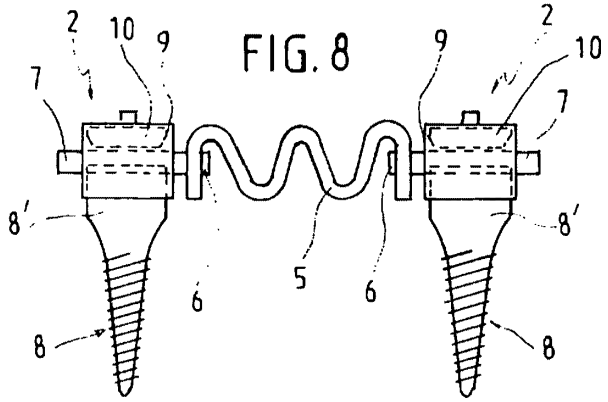



FIG. 10

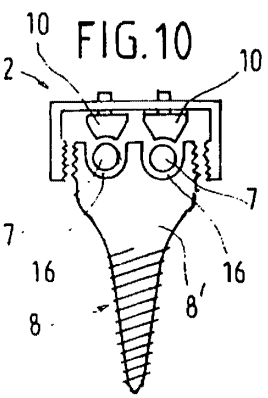



FIG. 11

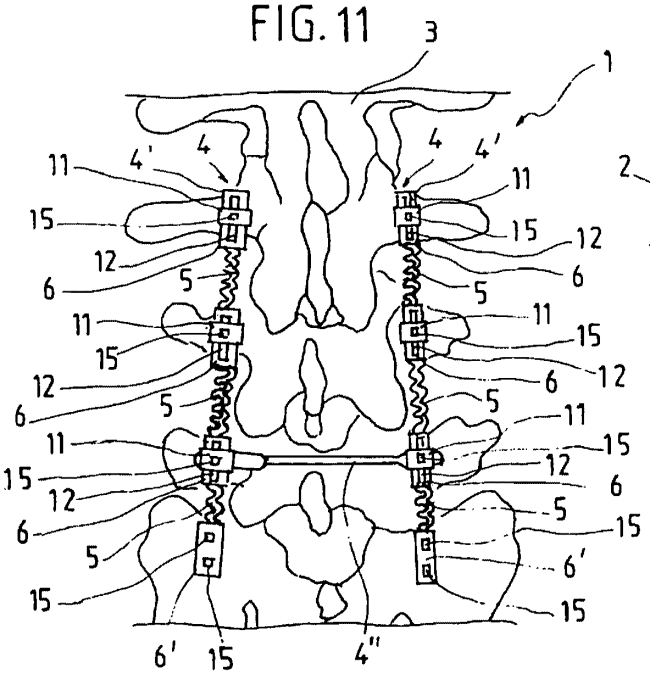
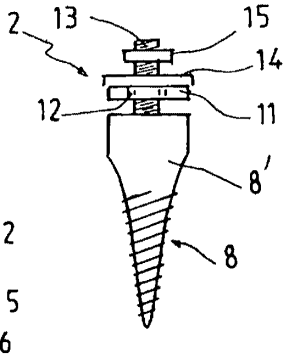



FIG. 12



RÉPUBLIQUE FRANÇAISE

INPI
INSTITUT NATIONAL DE LA PROPRIETE INDUSTRIELLE

2799949

N° d'enregistrement national

FA 579018
FR 9913475

# RAPPORT DE RECHERCHE PRÉLIMINAIRE

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

| 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 | FR 2 718 946 A (SOPRANE)<br>27 octobre 1995 (1995-10-27) | 1,2 | A61B17/70 |
| A | * page 2, ligne 12 - ligne 20; figure 1 *<br>* page 2, ligne 33 - page 3, ligne 7 * | 3 | |
| X | FR 2 717 370 A (P.MOREAU)<br>22 septembre 1995 (1995-09-22) | 1,2,4,5,<br>9,10 | |
| Y | * page 1, ligne 18 - ligne 22 *<br>* page 6, ligne 6 - ligne 23 *<br>* page 8, ligne 16 - ligne 18; figure 5 * | 7 | |
| Y | FR 2 728 158 A (J.F.ELBERG ET P.MOREAU)<br>21 juin 1996 (1996-06-21)<br>* page 6 * | 7 | |
| X | US 5 180 393 A (J.COMMARMOND)<br>19 janvier 1993 (1993-01-19)<br>* figure 5 * | 1,2,4,5 | |
| X | PATENT ABSTRACTS OF JAPAN<br>vol. 1999, no. 01,<br>29 janvier 1999 (1999-01-29)<br>& JP 10 277070 A (K.ITO ET S.SANO) | 1,2 | DOMAINES TECHNIQUES RECHERCHÉS (Int.Cl.7)<br>A61B |
| A | * abrégé; figures * | 3 | |
| A | FR 2 681 525 A (MEDICAL OP)<br>26 mars 1993 (1993-03-26)<br>* revendication 1; figures * | 1,2 | |
| A | US 5 667 508 A (T.J.ERRICO ET AL.)<br>16 septembre 1997 (1997-09-16)<br>* figure 4 * | 8 | |
| A | FR 2 719 759 A (C.KHALIFE ET S.KHALIFE)<br>17 novembre 1995 (1995-11-17)<br>* figure 2A * | 11 | |

| Date d'achèvement de la recherche | Examinateur |
|---|---|
| 11 juillet 2000 | 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

1

EPO FORM 1503 12.99 (P04C14)

(12) SOLICITUD INTERNACIONAL PUBLICADA EN VIRTUD DEL TRATADO DE COOPERACIÓN EN MATERIA DE PATENTES (PCT)

(19) Organización Mundial de la Propiedad Intelectual
Oficina internacional

(43) Fecha de publicación internacional
15 de Febrero de 2001 (15.02.2001)

PCT

(10) Número de Publicación Internacional
WO 01/10317 A1

(51) Clasificación Internacional de Patentes[7]: A61B 17/70

(21) Número de la solicitud internacional: PCT/ES00/00310

(22) Fecha de presentación internacional:
4 de Agosto de 2000 (04.08.2000)

(25) Idioma de presentación: español

(26) Idioma de publicación: español

(30) Datos relativos a la prioridad:
P 9901798 5 de Agosto de 1999 (05.08.1999) ES

(71) Solicitante *(para todos los Estados designados salvo US)*: **TRAIBER, S.A.** [ES/ES]; Polígono Ind. "Mas de Les Animes", Calle Joan Oliver, 13-17, E-43206 Reus (ES).

(72) Inventor; e

(75) Inventor/Solicitante *(para US solamente)*: **MARQUEZ ALVAREZ, Luis** [ES/ES]; Polígono Ind. "Mas de Les Animes", Calle Joan Oliver, 13-17, E-43206 Reus (ES).

(74) Mandatario: **CARPINTERO LOPEZ, Francisco**; Herrero & Asociados, S.L., Calle Alcalá, 35, E-28014 Madrid (ES).

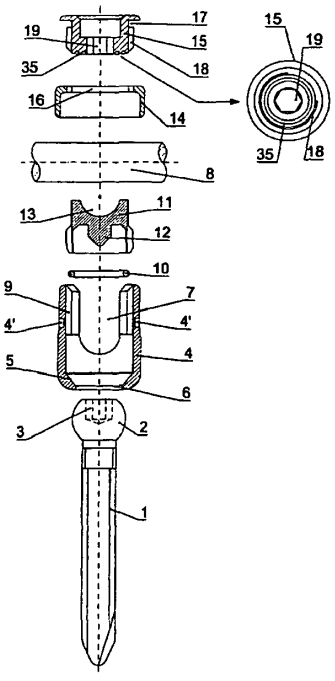
(81) Estados designados *(nacional)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

*[Continúa en la página siguiente]*

WO 01/10317 A1

(54) Title: INTERVERTEBRAL FIXING SYSTEM USED IN TREATMENTS OF THE SPINAL COLUMN

(54) Título: SISTEMA DE FIJACION INTERVERTEBRAL PARA TRATAMIENTOS DE COLUMNA




(57) **Abstract:** The screw (1) to be implanted in the bone comprises a substantially spherical head (2) which is provided with an axial blind hole (3) enabling the screwing into the bone with the use of an Allen type tool. A tulip (4) provided with an orifice (6) having a larger diameter than the head (2) collaborates with the latter; the orifice is framed by a truncated narrowing (5); an open washer (10) bears against said narrowing; due to the axial pressure of an internal pan (11), the washer is pinched to the lower zone of the head (2) of the screw thereby causing the fixing of the tulip to said screw; the tulip is provided with upper notches (7) intended to the implantation of the bar (8) linked between nails; the bar is secured definitely with the collaboration of a second pan (14) and a screwed plug (15) which is screwed onto the interior (9) of the tulip (4) and which generates the axial pressure necessary for pinching the washer (10) and for securing the bar (8).

(57) **Resumen:** El tornillo (1) de implantación en el hueso, incorpora una cabeza (2) sensiblemente esférica, provista de un orificio axial y ciego (3), que permite el atornillamiento al hueso con la colaboración de una llave "Allen", colaborando con la cabeza (2) del tornillo una tulipa (4) dotada de un orificio (6) de mayor diámetro que la cabeza (2), enmarcado por una estrangulación tronco-cónica (5) sobre la que apoya una arandela abierta (10) que, por la presión axial de una cazoleta interior (11), se estrangula sobre la zona inferior de la cabeza (2) del tornillo provocando la fijación de la tulipa a este último, tulipa que cuenta con escotaduras superiores (7) para implantación de la barra (8) de relación entre clavos, la cual queda definitivamente fijada con la colaboración de una segunda cazoleta (14) y un tapón roscado (15), que rosca sobre el interior (9) de la tulipa (4) y que genera la presión axial necesaria para la estrangulación de la arandela (10) y para la inmovilización de la barra (8).

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 491 of 2152

(84) **Estados designados** *(regional)*: patente ARIPO (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), patente euroasiática (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), patente europea (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), patente OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

**Publicada:**
— *Con informe de búsqueda internacional.*

*Para códigos de dos letras y otras abreviaturas, véase la sección "Guidance Notes on Codes and Abbreviations" que aparece al principio de cada número regular de la Gaceta del PCT.*

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 492 of 2152

# SISTEMA DE FIJACIÓN INTERVERTEBRAL PARA TRATAMIENTOS DE COLUMNA

## D E S C R I P C I Ó N

### OBJETO DE LA INVENCIÓN

La presente invención se refiere a un sistema de fijación intervertebral especialmente concebido para la inmovilización de dos o más vértebras, mediante la utilización de barras que, debidamente configuradas, se fijan a los huesos mediante clavos pediculares.

La invención es de aplicación en el ámbito de la medicina y, específicamente, en el ámbito de la cirugía ósea, permitiendo realizar indistintamente fijaciones fijas, móviles o con placa conectora que desplaza lateralmente la zona de fijación de la varilla con respecto a la zona del tornillo.

También es objeto de la invención asociar al citado sistema unos medios de fijación al hueso sacro, para conseguir la inmovilización de éste respecto a la zona próxima de la columna vertebral, es decir, con respecto a la zona lumbar de la misma, teniendo por objetivo dicho complemento el de conseguir una fijación sin tensiones, dado que el hueso sacro es un hueso de naturaleza más esponjosa que las vértebras y, consecuentemente, menos resistente que estas últimas.

### ANTECEDENTES DE LA INVENCIÓN

Uno de los sistemas utilizados para la

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 493 of 2152

inmovilización de dos o más huesos, consiste en implantar en los mismos respectivos clavos pediculares, dotados cada uno de ellos de una cabeza provista de medios para fijar a la misma una barra que actúa como puente de unión entre los diferentes clavos, de manera que al quedar cada uno de dichos clavos rígidamente unido a la barra común, los respectivos huesos quedan correspondientemente inmovilizados.

Dentro de este sistema de fijación ósea existen tres tipos, fijo, móvil y con placa conectora.

En el sistema fijo la barra queda dispuesta perpendicularmente al tornillo, de forma inamovible, en el segundo caso entre la barra y el tornillo se establece una unión rotular que permite variar la orientación de la barra con respecto al tornillo, y en el tercer tipo barra y tornillo se relacionan mediante una placa intermedia, que los distancia en sentido lateral, permitiendo un acusado desfase entre los elementos repetidamente citados.

La problemática que presenta este tipo de fijación se centra fundamentalmente en el hecho de que los medios de fijación de la barra al tornillo se mantienen de origen asociados a este último, lo que trae consigo dos inconvenientes, por un lado que dificultan la propia implantación del tornillo y por otro que merman la visión del médico a la hora de establecer una adecuada inserción del tornillo en el hueso.

**DESCRIPCIÓN DE LA INVENCIÓN**

El sistema de fijación intervertebral que la invención propone, utilizable con ligeras modificaciones tanto en fijaciones fijas y móviles como en sistemas provistos de placa conectora, resuelve de forma plenamente satisfactoria la problemática anteriormente expuesta, en los dos aspectos comentados, permitiendo que la implantación del tornillo se realice con independencia física del resto de las piezas que participan en el mismo, es decir en ausencia de los medios de fijación a la cabeza de tornillo clavo de la barra de relación entre tornillos, lo que supone que la implantación del mismo pueda realizarse en óptimas condiciones, tanto desde el punto de vista de manipulación como desde el punto de vista de visión.

Para ello y de forma más concreta el clavo que participa en el sistema que se preconiza, en su versión correspondiente a los sistemas fijo y móvil, está estructurado mediante la combinación funcional de: un tornillo con cabeza esférica ligeramente peraltada en su parte superior, destinado a insertarse en el hueso; una tulipa capacitada para recibir en su seno a la cabeza del tornillo, dotada de amplias escotaduras para asentamiento de la barra y de una embocadura estrangulada, de configuración tronco-cónica, que permitiendo el paso de la cabeza del tornillo provoca la retención de este último con la colaboración de una arandela abierta, que se estrangula al ser presionada axialmente sobre la citada embocadura tronco-cónica; una cazoleta de actuación axial sobre la citada arandela abierta y que es presionada en este sentido por la propia barra, una segunda cazoleta de apoyo y presión sobre la zona opuesta de la citada barra, y finalmente un tapón roscado, que se acopla a la embocadura de la

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 495 of 2152

tulipa y que es a través del que se realiza la definitiva fijación y apriete del conjunto. Dicho tapón está dotado en su parte inferior de un estriado circular.

De acuerdo con otra de las características de la invención, la cabeza del tornillo presenta un orificio axial, ciego y poligonal, que permite su implantación en el hueso con la colaboración de una llave "Allen", previamente a la implantación del resto de los mecanismos del clavo.

A partir de esta estructuración básica la cazoleta de incidencia sobre la arandela abierta podrá incorporar en su fondo un tetón prismático-poligonal, de acoplamiento en el orificio ciego de la cabeza, cuando se trate de un sistema fijo, o bien dicha cazoleta podrá presentar una superficie interna de forma semiesférica, para establecer un acoplamiento rotular sobre la cabeza del tornillo.

En el caso de utilizar el sistema de placa conectora, la placa en cuestión incorporará un alojamiento similar al de la tulipa, sensiblemente más corto y carente de escotaduras, en cuyo caso recibirá exclusivamente la cazoleta de estrangulación de la arandela abierta, que estará roscada, mientras que la cazoleta propiamente dicha se fijará al otro extremo de la placa conectora, recibiendo en su seno a un cono pseudomorse utilizable como medio de fijación a la placa conectora y como asiento para la barra, la cual quedará definitivamente fijada con la colaboración de una segunda cazoleta y un tapón roscado, como en el caso anterior.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 496 of 2152

El citado cono pseudomorse se prolonga en un corto cuello cilíndrico y roscado de implantación en la placa conectora, que tras dicha implantación se fija por medio de un pasador quedando solidario a la placa.

Con la estructura descrita colabora un dispositivo de unión transversal entre barras, consistente en una pieza dotada de un cajeado abierto lateralmente, formal y dimensionalmente adecuado para la implantación en su seno de una de las barras a unir, cajeado que se cruza con un orificio transversal de la propia pieza, rasgado y destinado a la implantación de la segunda barra, incorporando dicha pieza además un orificio roscado, que se abre perpendicularmente desde el exterior al citado orificio transversal y que está destinado a recibir a un tapón de apriete con el que se presiona una barra contra otra, una vez seleccionada la posición relativa entre las mismas.

De acuerdo con la estructura descrita se consigue que la implantación del tornillo resulte sumamente fácil y cómoda, con una perfecta visión para el médico de la zona de trabajo, que además asegura una óptima rigidez estructural para el conjunto, es decir una perfecta inmovilización de la varilla con respecto al tornillo, sin riesgo de que se produzcan movimientos no deseados de los elementos óseos a unir, con un esfuerzo mínimo por parte del médico, con un tiempo de intervención también mínimo, con la posibilidad además de rigidizar convenientemente entre sí las barras que participan en el sistema, tras el adecuado posicionamiento de las mismas, y todo ello con la particularidad de que las múltiples piezas que participan en el sistema, para conseguir la fijación de los diferentes elementos, son

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 497 of 2152

aportadas al médico en situación de premontaje, es decir convenientemente relacionadas entre sí, de manera que éste tan sólo debe efectuar las operaciones de apriete tras el adecuado posicionamiento u orientación de cada una de ellas.

En una variante de realización se prescinde de la arandela abierta que es presionada axialmente sobre la embocadura tronco-cónica de la tulipa, en cuyo caso la cazoleta de actuación axial sobre la arandela presenta su parte inferior con una forma cónica y seccionada en segmentos que se pueden deformar en el apriete para permitir previamente el paso de la cabeza esférica del tornillo y realizar seguidamente el clásico "clip" de pinzado y sujeción de tal cabeza, quedando este sujeto y solidario al sistema.

Asimismo, se ha previsto un complemento que permite la fijación de la correspondiente barra que relaciona el sacro con la vértebra o las vértebras lumbares, en ausencia de la más mínima tensión.

Más concretamente, la fijación al hueso sacro se basa en la utilización de una plantilla que, una vez fijada la barra a la zona lumbar de la columna, permite establecer el punto exacto en el que debe ser implantado el tornillo, así como la orientación del mismo, aunque la angulación de los tornillos del sacro no tienen porqué ser exacta puesto que debe adaptarse a la cabeza del tornillo para formar una rótula. Para ello se utiliza una placa conectora de configuración angular, adecuadamente conformada para absorber el ángulo que forma la columna en la zona de unión del sacro a las vértebras lumbares, contando dicha placa conectora en

uno de sus extremos con un orificio transversal para acoplamiento de la barra de fijación a la columna, orificio con su interior dentado para facilitar el agarre sobre dicha barra y que se cruza con un orificio roscado para implantación de un tornillo de apriete, preferentemente con cabeza tipo "Allen", mientras que en el otro extremo de la placa conectora se establecen los medios de fijación a la cabeza del tornillo.

Tales medios de fijación consisten en un alojamiento de embocadura estrangulada tronco-cónicamente, a través del que es susceptible de pasar libremente la cabeza del tornillo, de manera que éste pueda se implantado en el hueso previamente al acoplamiento de la placa conectora, estableciéndose en el interior del citado alojamiento, de pared lateral roscada, una arandela abierta cuyo diámetro, en situación de distensión, es superior tanto al diámetro de la cabeza del tornillo como al diámetro de la embocadura estrangulada del alojamiento, permitiendo también el paso a su través de la cabeza del tornillo, complementándose este conjunto con una cazoleta, exteriormente roscada, preferentemente dotada de medios para accionamiento con una llave tipo "Allen", cazoleta cuyo apriete provoca el desplazamiento axial de la arandela, con la consecuente estrangulación de la misma, sobre la cabeza del tornillo, y fijación de este último, presentando la cazoleta un alojamiento semiesférico, para asentamiento de la cabeza del tornillo, que permite un movimiento rotular entre estos elementos, previamente al definitivo apriete del conjunto.

La especial configuración de la placa conectora y de los medios de fijación tanto a la cabeza del

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 499 of 2152

tornillo como a la barra de relación con el resto de la columna vertebral, hacen que dicha fijación se produzca en ausencia de tensiones que pudieran dañar el sacro en la zona de implantación del tornillo.

**DESCRIPCIÓN DE LOS DIBUJOS**

Para complementar la descripción que se está realizando y con objeto de ayudar a una mejor comprensión de las características del invento, de acuerdo con un ejemplo preferente de realización práctica del mismo, se acompaña como parte integrante de dicha descripción, un juego de dibujos en donde con carácter ilustrativo y no limitativo, se ha representado lo siguiente:

La figura 1.- Muestra un despiece en perspectiva de un sistema de fijación intervertebral para tratamientos de columna realizado de acuerdo con el objeto de la presente invención, en la que alguno de los componentes del mismo aparecen diametralmente seccionados, de acuerdo con una primera realización en la que se trata de un sistema fijo.

La figura 2.- Muestra el mismo conjunto de la figura anterior debidamente montado y seccionado transversalmente.

Las figuras 3 y 4.- Muestran representaciones similares a las de las figuras 1 y 2, pero correspondientes a la realización del sistema móvil.

Las figuras 5 y 6.- Muestran representaciones

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 500 of 2152

también similares a las de las figuras 1 y 2, pero correspondientes al sistema que utiliza placa conectora.

La figura 7.- Muestra una vista en alzado lateral del dispositivo previsto para la unión transversal entre barras, que participa también en el sistema de la invención.

La figura 8.- Muestra un detalle en sección transversal del dispositivo de la figura anterior, según la línea de corte A - B de dicha figura.

La figura 9.- Muestra el dispositivo de unión transversal finalmente montado, junto con el elemento que mantiene todos los componentes unidos, que es representado en perspectiva independientemente.

La figura 10.- Muestra una vista en alzado lateral y en sección de la placa conectora que participa en el sistema de fijación al hueso sacro, sobre la que aparecen acopladas la cabeza del tornillo y la barra que puentea y rigidiza el sacro con otra u otras vértebras de la columna.

La figura 11.- Muestra una vista en planta de la citada placa conectora representada en la figura anterior, en este caso desprovista del tornillo de fijación al sacro y de la barra, incluso del tornillo de apriete de ésta última.

La figura 12.- Muestra una vista en alzado lateral de la cazoleta de presionado y sujecion de la cabeza del tornillo, en una variante de realización para sistema móvil.

La figura 13.- Muestra una vista en alzado lateral seccionado de la cazoleta de la figura anterior para sistema fijo.

La figura 14.- Muestra el montaje de la cazoleta de la figura 12 sobre la tulipa correspondiente que forma parte del sistema objeto de la invención.

**REALIZACIÓN PREFERENTE DE LA INVENCIÓN**

A la vista de estas figuras, y más concretamente de las figuras 1 y 2, puede observarse cómo en el sistema de fijación intervertebral para tratamientos de columna que la invención propone participa un tornillo (1), de inserción en el hueso, provisto de una cabeza (2), esférica, dotada de un orificio axial y ciego (3), de sección poligonal, para permitir su implantación en el hueso con la colaboración de una llave tipo "Allen". A la cabeza (2) del tornillo (1) está destinada a acoplarse una tulipa (4) provista en su extremidad proximal con respecto al tornillo de una estrangulación tronco-cónica (5), pero determinando tal estrangulación un orificio (6) que permite el paso de la cabeza (2) del tornillo, incorporando además dicha tulipa amplias escotaduras (7), alineadas diametralmente, que permiten la implantación de la barra (8) que constituye el verdadero nexo de unión entre vértebras, así como de un roscado interior (9) en la zona que enmarca a dichas escotaduras (7).

La tulipa (4) está destinada a recibir en su seno a una arandela abierta (10) cuyo diámetro, en situación de distensión, se aproxima al diámetro interno del

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 502 of 2152

sector inferior de la tulipa (4), destinada a estrangularse radialmente sobre la zona inferior de la cabeza (2) del tornillo (1), por el desplazamiento axial de una cazoleta (11), básicamente cilíndrica al igual que la tulipa (4), dotada de un frente circunferencial de apoyo sobre la arandela (10), dotada de un tetón axial (12), emergente de su fondo, acoplable en el orificio ciego (3) de la cabeza (2) del tornillo y a través del que se inmovilizan estos elementos y dotada de una cama superior (13) para asentamiento de la barra (8).

Así pues, la cama (13) de la cazoleta (11) está destinada a recibir el apoyo de la barra (8), y la presión axial que, a través de una segunda cazoleta (14), ejerce un tapón roscado (15) acoplable a la embocadura roscada (9) de la tulipa (4), cazoleta (14) provista en su base de un orificio roscado (16) que permite mantenerla permanentemente fijada al tapón (15), el cual cuenta a tal efecto con un cuello liso (17), retrasado con respecto a su propio sector roscado (18), donde la cazoleta (14) queda engatillada pero libre. Este tapón (15) presenta además la peculiaridad de incorporar un orificio axial y poligonal (19) que permite su accionamiento con la colaboración de una llave tipo "Allen" o similar, equivalente a la utilizada para la implantación del tornillo (1). Esta pieza (15) está dotada en su parte inferior de un estriado circular (35) a fin de mejorar y garantizar su agarre sobre la barra (8), la cual es a su vez estriada.

Volviendo a la pieza denominada tulipa (8), la misma está afectada de una pareja de rebajes laterales (4') que una vez introducida tal pieza (11) se

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 503 of 2152

repiquetean de forma tal que esta pieza o cazoleta (11) no podría salir ni girar, quedando posicionada para poder recibir la barra (8) sin problemas.

La estructura descrita se repite esencialmente cuando se trata de un sistema de fijación móvil, con la única salvedad de que en este caso la cazoleta (11'), equivalente a la cazoleta (11) del caso anterior, en lugar de incorporar el tetón axial (13) de esta última, incorpora una superficie interna (20) de configuración semiesférica y de curvatura acorde con la de la cabeza (2) del tornillo (1), para establecer un acoplamiento rotular entre estos elementos, que permita variar la situación fija del caso anterior, de perpendicular de la barra (8) con respecto al tornillo (1), pudiendo en este caso la citada barra adoptar la inclinación más apropiada con respecto a la dirección del tornillo.

Por otro lado y tal como se ha representado en las figuras 5 y 6, cuando se trate de un sistema provisto de placa conectora (21), dicha placa estará dotada de un alojamiento (22) similar al del sector inferior de la tulipa (4) de los casos anteriores, con la misma embocadura estrangulada tronco-cónicamente (5) e igualmente provista de una rosca (23), para acoplamiento de una cazoleta (11"), también similar a la cazoleta (11) del sistema fijo, con el mismo tetón axial (12) pero con una rosca exterior para su implantación en el receptáculo (22) de la placa (21), y más concretamente para la presión axial sobre la arandela abierta (10) que provoca la estrangulación de la misma sobre la cabeza (2) del tornillo (1).

En el otro sector de la placa conectora (21) se

establece un orificio roscado (24) para fijación a la misma de la tulipa (4"), que en este caso configura un alojamiento inferior (25) para un cono pseudomorse (26), con un sector tronco-cónico (27) y un cuello roscado (28), entre los que se define una garganta (29) destinada a la inmovilización del cono pseudomorse (26) a fin de garantizar que al ser presionado por la barra formará todo un cuerpo rígido, el cual se suministra al médico convenientemente acoplado a la tulipa (4"), con la extremidad libre de su cuello (28) remachada para impedir su desacoplamiento de dicha tulipa, pero con una cierta movilidad para poder orientar convenientemente la barra (8), realizando el médico la fijación definitiva con la colaboración de un tornillo prisionero (62) que juega en un orificio lateral (61) de la placa (21), abierto hacia el orificio (24), destinado a actuar sobre la citada garganta (29), y más concretamente a bloquear o inmovilizar definitivamente la tulipa (4") con respecto a la placa (21), constituyendo dicho cono (26) el asiento para la barra (8), que se fija igualmente con la colaboración de la cazoleta (14) y el tapón (15) roscado en el sector (8) de la citada tulipa (4').

Como complemento de la estructura descrita, en el sistema participa el dispositivo de unión transversal entre barras representado en las figuras 7 y 8, materializado en una pieza (30) provista de un cajeado o alojamiento (31) abierto lateralmente, de configuración cóncava, aproximadamente en "C", para acoplamiento y asentamiento de una de las barras (8) a unir, cruzándose este cajeado (31) con un orificio transversal (32), rasgado en el mismo sentido que el citado cajeado (31) y destinado a la recepción de la segunda barra (8'), realizándose la definitiva fijación

o bloqueo entre ambas barras, tras su adecuado posicionamiento relativo, con la colaboración de un tapón roscado (33) que se acopla en un orificio (34) así mismo roscado de la pieza (30) y que presiona la barra (8') contra la barra (8).

En la figura 9 se ha representado el dispositivo de unión transversal entre barras finalmente montado, donde interviene un sombrerete (37) que está formal y dimensionalmente capacitado para acoplarse a la parte superior de la pieza (30), con el objeto de impedir que esta pieza se separe de la barra (8') y de retener al tapón roscado (33), de modo que el dispositivo de unión transversal permanezca montado antes o después de su instalación respecto a las barras (8), con lo que se facilita considerablemente su manipulación.

Para ello, el sombrerete (37) dispone en su base superior de un orificio (38) a través del cual se da acceso al tapón (33) para que éste pueda ser roscado y, de respectivos orificios (39) y (39') para el paso de la barra (8') a su través y a través del orificio transversal (32). El sombrerete (37) mantiene unidos a la pieza (30), barra (8') y el tapón roscado (33), ya que la barra (8') tiene impedido su desplazamiento al estar insertada a través de dichos orificios, mientras que el sombrerete (37) retiene en su interior al tapón roscado (33), pero permite su desplazamiento axial respecto al orificio (34) para que éste pueda ejercer o liberar la presión sobre la barra (8).

Para impedir la salida de la pieza (30) y de los elementos solidarios a ella, por los extremos de la barra (8'), estos extremos se realizan expandidos o

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 506 of 2152

sobredimensionados, o bien se les añade cualquier elemento que aumente su diámetro, particularidad que no ha sido ilustrada en las figuras.

Sólo resta señalar por último que la cabeza (2) del tornillo (1) estará dotada, de estrías que aseguren la estabilización del conjunto, una vez efectuado el apriete del mismo, y que la barra (8) presentará su superficie grafilada, es decir, estriada, con la misma finalidad de colaborar en una perfecta estabilidad de la misma tras su fijación.

Como complemento del sistema descrito, se ha previsto un medio de fijación al hueso sacro, representado en las figuras 10 y 11, utilizando como elemento fundamental una placa conectora (40) materializada en un cuerpo en el que se establecen dos sectores extremos (43) y (44), el primero de ellos dotado de un alojamiento (45) para la cabeza (46) del tornillo de implantación en el sacro, y un segundo dotado de un orificio (47) para paso de la barra (48) destinada a relacionar y solidarizar el sacro a una o más de las vértebras de la columna, con la especial particularidad, como se desprende de la observación de la figura 9 de que los dos sectores (43) y (44) de la citada pieza forman un ángulo adecuado para compensar la angulación entre el sacro y el resto de la columna.

El alojamiento (45) para la cabeza del tornillo (46), básicamente cilíndrico, presenta una estrangulación tronco-cónica (49) en su extremo de adaptación al sacro, y un sector roscado (50) en su extremo opuesto, siendo la embocadura (51) definida por dicho estrechamiento tronco-cónico (49) de diámetro

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 507 of 2152

superior al de la cabeza esférica del tornillo (46), en orden a permitir la implantación de dicho tornillo en el sacro previamente al montaje sobre el mismo de la placa conectora (40), teniendo el plano tronco-cónico del estrechamiento (49) la finalidad específica de estrangular una arandela abierta (52), que asienta sobre el mismo, que en situación de distensión presenta también un diámetro superior al de la cabeza (46) del tornillo, con la misma finalidad de permitir el paso de dicha cabeza a su través, y que es desplazada axialmente con la colaboración de una cazoleta (53), que interiormente configura un alojamiento semiesférico peraltado (54), para permitir un movimiento rotular a la cabeza (46) del tornillo, y que está dotada de una rosca exterior para su fijación al sector roscado (50) del alojamiento (45), contando además en su base con un orificio poligonal (55) para accionamiento con una llave tipo "Allen", todo ello de manera que tras la implantación de la cabeza (46) del tornillo en el alojamiento (45), y tras la orientación adecuada de la placa conectora (40) con respecto al eje (56) de dicho tornillo, el apriete de la cazoleta (53) provoca el desplazamiento axial de la arandela (52), su estrangulación sobre el cuello del tornillo y el consecuente bloqueo del conjunto, bloqueo que se ve potenciado por la existencia en la cabeza (46) del tornillo de dientes anulares (57) que se "clavan" sobre la superficie del alojamiento (54) de la cazoleta (53).

Por otro lado, el orificio (47) para implantación y fijación de la barra (48) que relaciona la placa conectora solidarizada al sacro con la zona adyacente de la columna, presenta su superficie interna dotada de estrias (58) destinados a su vez a potenciar el agarre

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 508 of 2152

sobre dicha barra, concretamente cuando ésta es presionada en su alojamiento por un tornillo (59), preferentemente tipo "Allen", que rosca en un orificio (60) del sector (44) de la placa conectora (40), que se abre perpendicularmente hacia el orificio (47) de implantación de dicha barra.

En las figuras 12, 13 y 14 se muestra una variante de realización de la cazoleta (11) u (11'), cuando en el sistema se prescinde de la arandela abierta (10).

Concretamente, en ese caso la cazoleta (11a) es cónica en su parte inferior y está segmentada en porciones o segmentos (63) que permiten la deformación de la pieza al apretar y encontrarse la conicidad (5) de la tulipa (4), lo que permite la entrada de la cabeza esferica (2) del tornillo (3) y realiza el "clip" cuando se presiona dicha cazoleta (11a) contra la tulipa (4), haciendo que las conicidades actuen de manera tal que aprisionarán la cabeza esférica (2) del tornillo (3), quedando este sujeto y solidario al sistema.

Como ya se ha referido, la cazoleta (11a) es utilizable para el sistema fijo; mientras que la cazoleta (11'a) es utilizable para el sistema móvil, contando en este caso con el apendice central e interno (64), siendo por lo demás, incluida su función, igual a la cazoleta (11a).

El conjunto se entrega montado, de manera que para su desmontaje serán necesarias unas pinzas especiales, debiendo realizar primeramente el desapretado del conjunto y a través de la ranura de la

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 509 of 2152

tulipa (4) por la que asoma ligeramente la cazoleta, aprovechando los hilos de rosca, se clavará la pinza especial evitando que al traccionar el tornillo se mueva la cazoleta y se clave, para permitir la salida del tornillo.

## R E I V I N D I C A C I O N E S

1ª.- Sistema de fijación intervertebral para tratamientos de columna, en el que participan clavos pediculares de implantación en el hueso, a los que se fijan barras actuantes como medio de unión entre los diferentes clavos, para inmovilización relativa entre los respectivos huesos, sistema de fijación que puede ser fijo, móvil o asistido por una placa conectora, y previéndose un complemento para la fijación del hueso sacro, caracterizado porque el tornillo (1) incorpora una cabeza esférica (2) dotada de un orificio axial y ciego (3), de sección poligonal, colaborando con dicha cabeza una tulipa (4) dotada en su extremidad proximal con respecto al tornillo (1) de una embocadura (5) estrangulada tronco-cónicamente, determinante de un orificio (6) de mayor diámetro que el de la cabeza (2) del tornillo, estando dicha tulipa (4) destinada a alojar en su seno a una arandela abierta (10) y a una cazoleta (11) sobre la que ha de apoyar la barra (8) a fijar, de manera que el desplazamiento axial de dicha cazoleta (11) provoca la estrangulación de la arandela (10) sobre la zona inferior de la cabeza del tornillo (2) y el consecuente bloqueo de esta última con respecto a la tulipa, la cual se complementa con una segunda cazoleta (14), actuante sobre la zona exterior y correspondiente de la barra (8), presionada axialmente por un tapón (15) que se rosca en la embocadura así mismo roscada (9) de la tulipa (4), la cual cuenta con unos hendidos laterales (4') para impedir el giro y la salida de la cazoleta (11) una vez haya sido introducida en la tulipa (4).

2ª.- Sistema de fijación intervertebral para

tratamientos de columna, según reivindicación 1ª, caracterizado porque cuando dicho sistema es fijo, la cazoleta (11) incorpora un tetón interior (12), emergente axialmente de su base, de sección con la configuración del orificio ciego (3) de la cabeza (2) del tornillo, para la inmovilización relativa entre estos dos elementos.

3ª.- Sistema de fijación intervertebral para tratamientos de columna, según reivindicación 1ª, caracterizado porque cuando el sistema de fijación es móvil, la cazoleta (11') presenta una superficie interna (20) cóncava, de configuración semiesférica, que establece un acoplamiento rotular sobre la cabeza (2) del tornillo (1).

4ª.- Sistema de fijación intervertebral para tratamientos de columna, según reivindicación 1ª, caracterizado porque cuando se utiliza placa (21) conectora, dicha placa incorpora en uno de sus extremos un alojamiento (22) de características similares a la extremidad inferior de la tulipa (4), con la misma estrangulación tronco-cónica (5), pero con una rosca interior (23) para recepción de la cazoleta (11"), a su vez dotada de una rosca exterior y actuante como medio estrangulador de la arandela abierta (10) sobre la cabeza del tornillo, mientras que en el otro extremo de la placa conectora se establece un orificio roscado (24), para fijación de una tulipa (4"), provista en este caso de un alojamiento tronco-cónico (25) para un cono pseudomorse (26), provisto de un cuello roscado (28) de fijación al orificio (24) y sobre el que asienta la barra (8) que se fija igualmente con la colaboración de una cazoleta superior (14) y el complementario tapón

(15) de apriete axial.

5ª.- Sistema de fijación intervertebral para tratamientos de columna, según reivindicación 4ª, caracterizado porque entre el sector tronco-cónico (27) y el sector cilíndrico y roscado (28) del cono pseudomorse (26), se establece una garganta perimetral (29) que tras el montaje de dicho cono (26) en el orificio roscado (24) de la placa conectora (21), queda enfrentado a un orificio lateral (61) y también roscado de la citada placa (21), en el que juega un pasador (62) que inmoviliza definitivamente el cono (26) y la tulipa (4") a la placa base (21).

6ª.- Sistema de fijación intervertebral para tratamientos de columna, según reivindicaciones anteriores, caracterizado porque la parte inferior del tapón (15) está dotada de estrías para potenciar el agarre en situación de apriete, mientras que la barra (8) de relación entre clavos está grafilada con similar finalidad.

7ª.- Sistema de fijación intervertebral para tratamientos de columna, según reivindicaciones anteriores, caracterizado porque en el mismo participa además un dispositivo de unión transversal entre barras, materializado en una pieza (30) provista de un cajeado lateral (31), de perfil curvo-cóncavo, alargado transversalmente con respecto a su embocadura y destinado al acoplamiento en su seno de una de las barras (8) a unir, cruzándose dicho cajeado (31) con un orificio transversal (32), también rasgado en el mismo sentido, para implantación de la segunda barra (8'), a unir a la primera, incorporando la pieza (30) un

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 513 of 2152

orificio roscado (34), que resulta perpendicular tanto al cajeado (31) como al orificio (32) en el que juega un tapón roscado (33), para apriete de una barra (8') contra la otra barra (8) en el punto de cruce entre ellas, colaborando además un sombrerete (37) formal y dimensionalmente capacitado para acoplarse a la parte superior de la pieza (30), a la barra (8') y al tapón roscado (33) durante la implantación o retirada del dispositivo de unión transversal, pero permitiendo el desplazamiento axial del tapón roscado (33), para lo cual el sombrerete (37) dispone en su base superior de un orificio (38) que da acceso al tapón roscado (33), y de orificios (39 - 39') para el paso de la barra (8').

8ª- Sistema de fijación intervertebral para tratamientos de columna, según reivindicaciones anteriores, caracterizado porque las piezas componentes están preensambladas antes de su montaje definitivo.

9ª.- Sistema de fijación intervertebral para tratamientos de columna, según reivindicaciones anteriores, caracterizado porque el apriete del tapón (15) conlleva la fijación de la tulipa (4) contra el tornillo (1), quedando todo fijo formando un bloque.

10ª.- Sistema de fijación intervertebral para tratamientos de columna, según reivindicación 1ª, caracterizado porque la fijación inicial del tornillo (1) y de la tulipa (4), participa una arandela abierta (10) la cual está forzada en su apertura para permitir el paso de la cabeza del tornillo (1), cerrándose enérgicamente cuando la citada arandela supera el diámetro mayor de la cabeza del tornillo (1).

11ª.- Sistema de fijación intervertebral para tratamientos de columna, según reivindicación 7ª, caracterizado porque en los extremos de las barras (8') se realizan expandidos o se les adicionan elementos que aumenten el diámetro, para evitar la salida involuntaria de las mismas respecto de las piezas de unión (30).

12ª.- Sistema de fijación intervertebral para tratamientos de columna, según reivindicación 1ª, caracterizado porque el complemento para la fijación del hueso sacro se constituye a partir de una placa conectora (40) destinada a relacionar el tornillo (46) de implantación en el sacro con la correspondiente barra (48), adoptando dicha placa conectora una configuración angular, de manera que entre la zona (43) de implantación de la cabeza (46) del tornillo y la zona (44) de implantación de la barra (48), se establece un ángulo que compensa la angulación anatómica entre el sacro y la zona lumbar de la columna, estableciéndose en estas zonas extremas (43) y (44) de la placa conectora (40) los medios de fijación para la cabeza (46) del tornillo y para la barra (48).

13ª.- Sistema de fijación intervertebral para tratamientos de columna, según reivindicación 12ª, caracterizado porque la placa conectora (40) incorpora, como medio de fijación para la cabeza (43) del tornillo, un alojamiento (45) básicamente cilíndrico, con una embocadura estrangulada tronco-cónica (49) a nivel de su extremo de adaptación al sacro, de diámetro superior al de la cabeza esférica (46) del tornillo, sobre cuya superficie tronco-cónica (49) asienta una arandela abierta (52) que, en situación de distensión, presenta un diámetro superior al de la cabeza del tornillo, para

permitir el acoplamiento de la placa conectora al mismo tras la implantación de dicho tornillo en el sacro, y que se estrangula sobre el cuello de dicha cabeza por la acción de una cazoleta (53) provista de un alojamiento (54) de configuración semiesférica, determinante de un acoplamiento rotular para la cabeza del tornillo, cazoleta que rosca en la pared interna del alojamiento (45) y que cuenta con una cabeza (55) tipo "Allen" para su accionamiento durante la maniobra de apriete.

14ª.- Sistema de fijación intervertebral para tratamientos de columna, según reivindicaciones 12ª y 13ª, caracterizado porque la placa conectora (40) incorpora como medio de fijación para la barra (48) un orificio básicamente cilíndrico (47) a través del que se abre radialmente otro orificio (60), éste roscado, en el que juega un tornillo (59), preferentemente de tipo "Allen", que presiona la barra (48) contra la pared del orificio (47), pared dotada de medios angulares (58) que potencian el agarre de dicha barra (48).

15ª.- Sistema de fijación intervertebral para tratamientos de columna, según reivindicaciones 1 a 3 caracterizado porque se prescinde de la arandela abierta (10), en cuyo caso tanto la cazoleta (11a) para el sistema fijo como la cazoleta (11'a) para el sistema móvil, están divididas en fragmetos (63) capacitados de deformarse para permitir el paso de la cabeza (2) del tornillo (3) y posterior clipado de dicha cabeza para sujetar el tornillo y quedar este solidarizado al sistema.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 516 of 2152

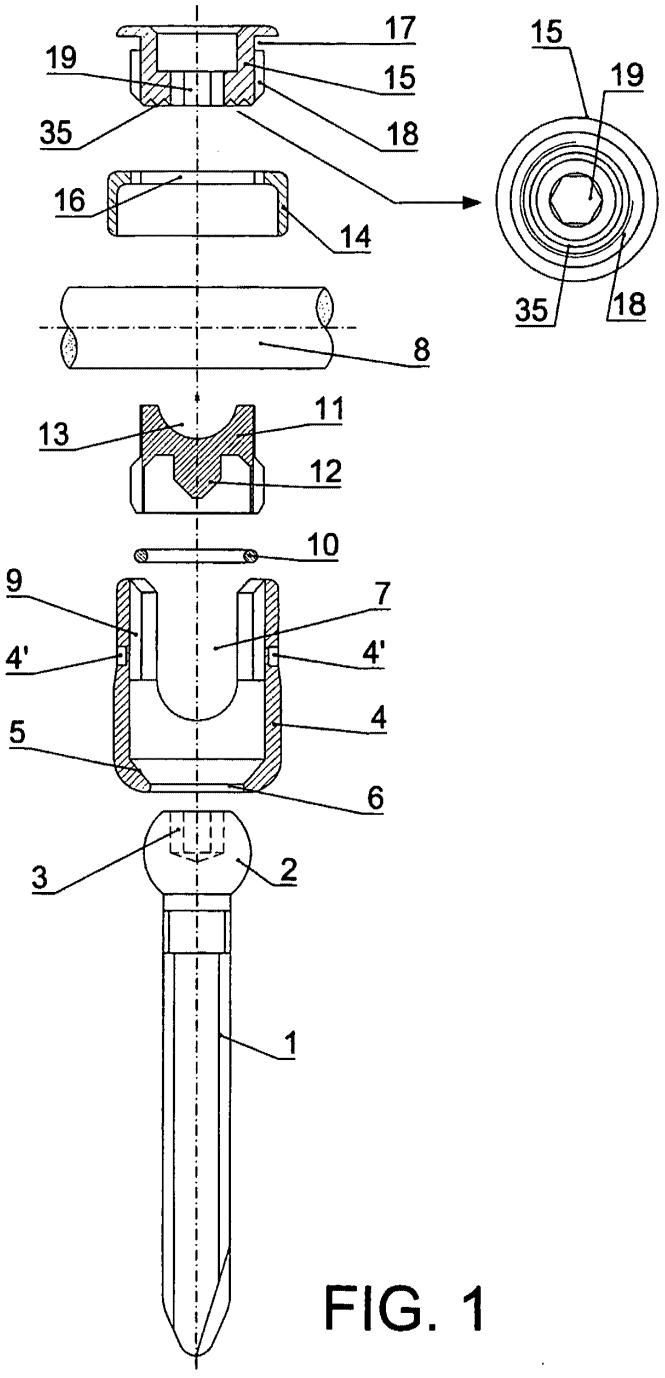



FIG. 1



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 517 of 2152

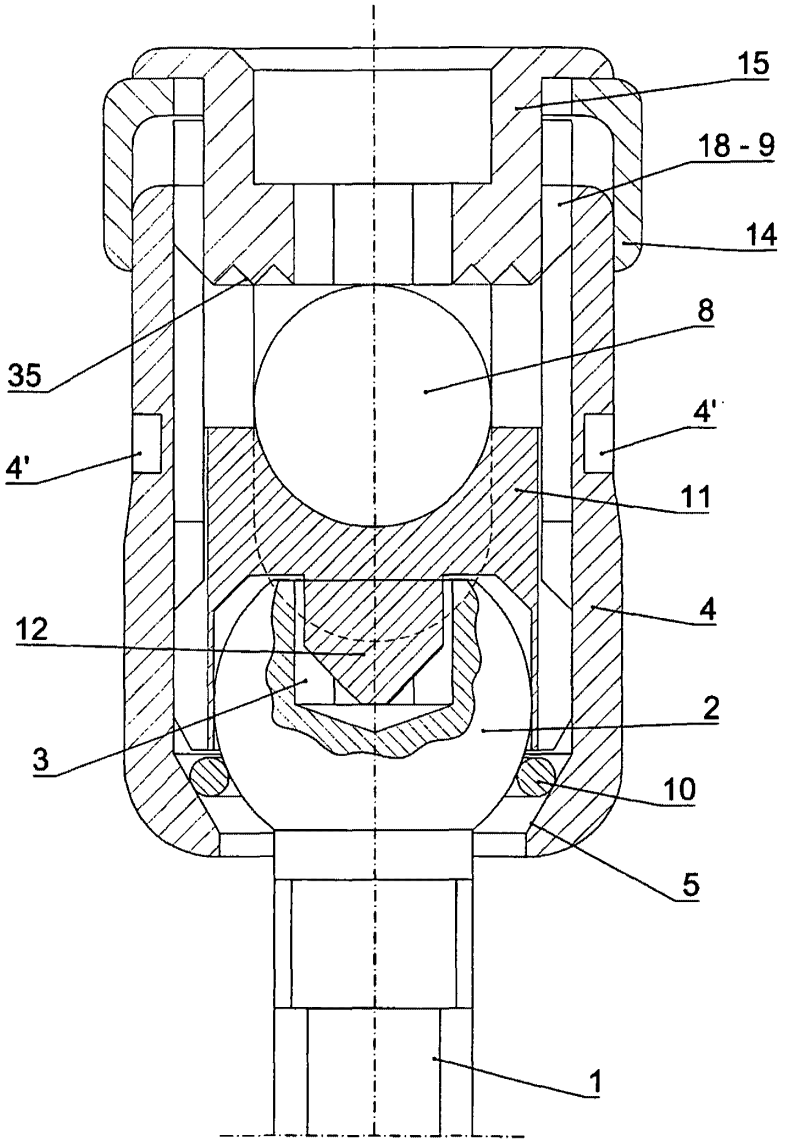



FIG. 2



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 518 of 2152

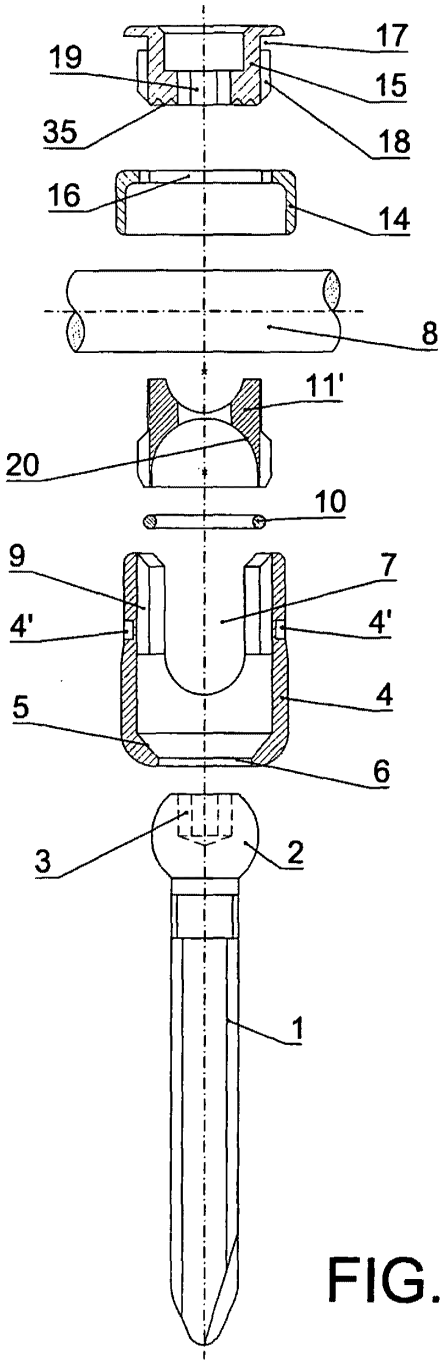



FIG. 3



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 519 of 2152

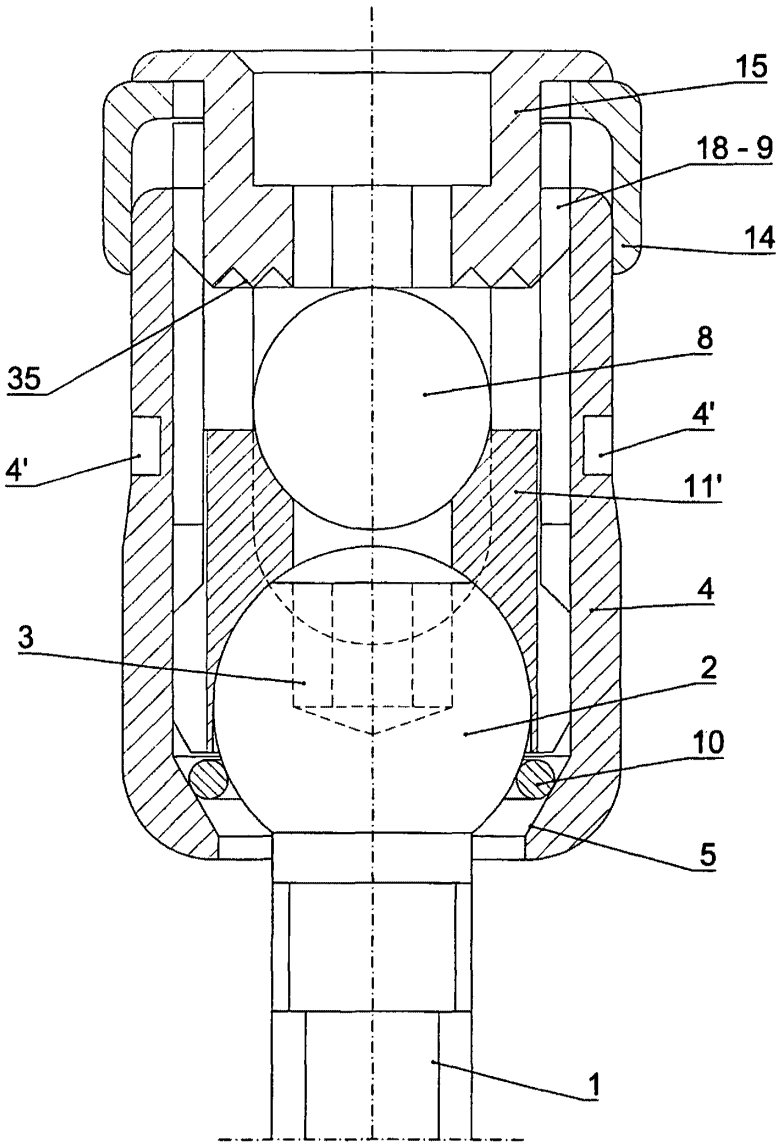



FIG. 4



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 520 of 2152

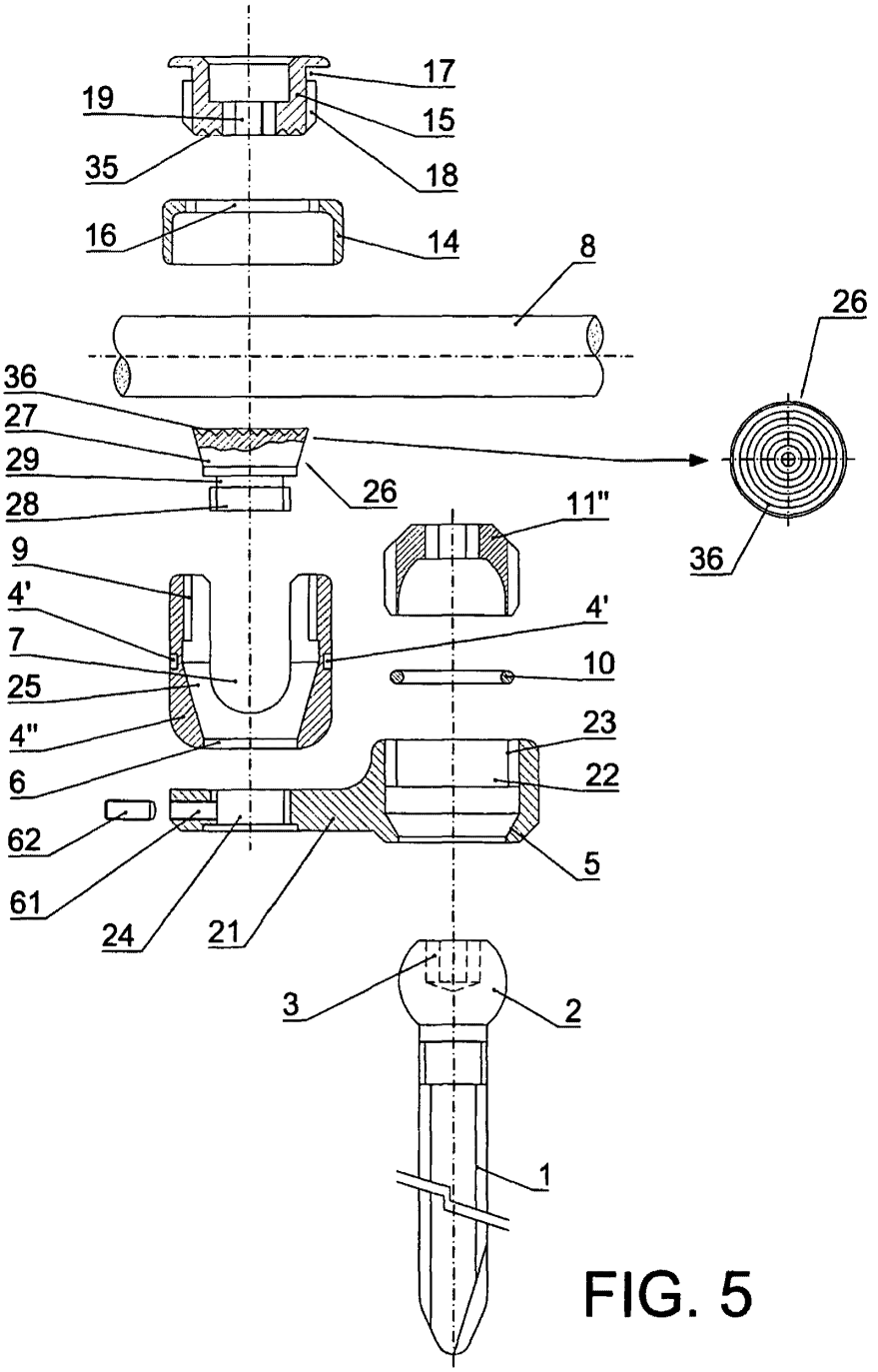



FIG. 5



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 521 of 2152

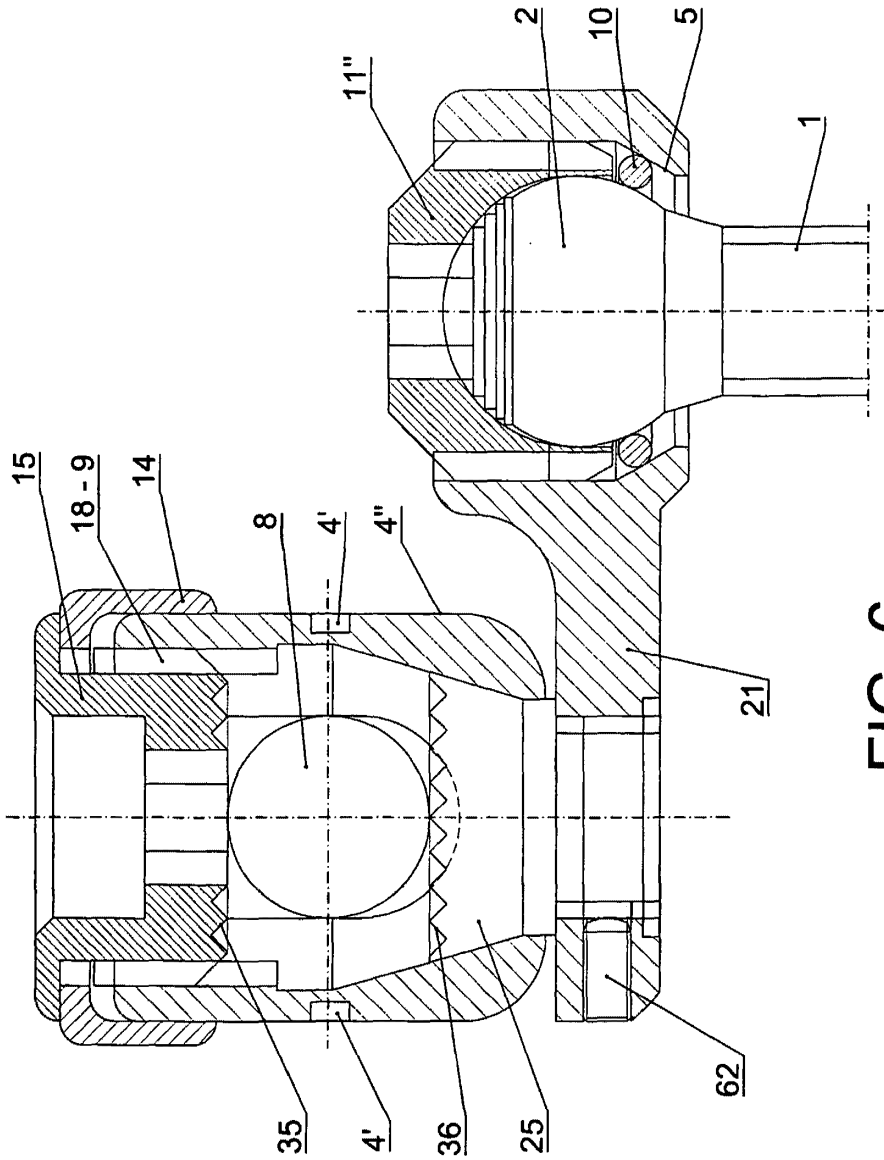



FIG. 6



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 522 of 2152

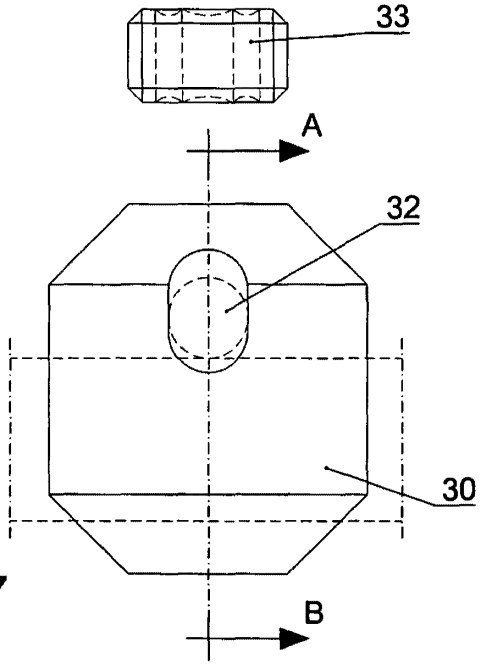
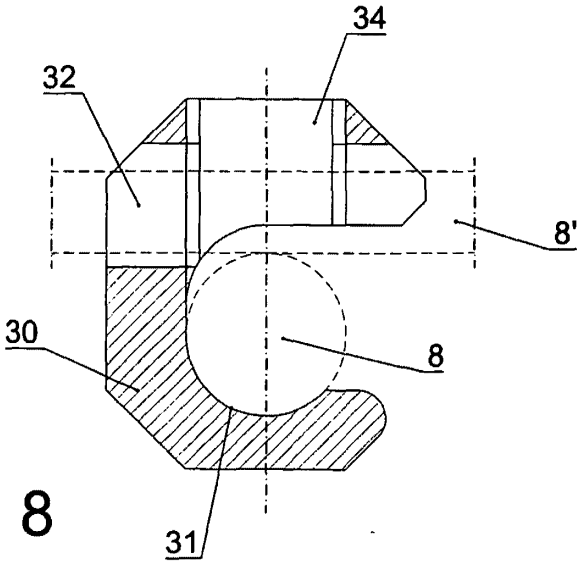



FIG. 7




A-B

FIG. 8



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 523 of 2152

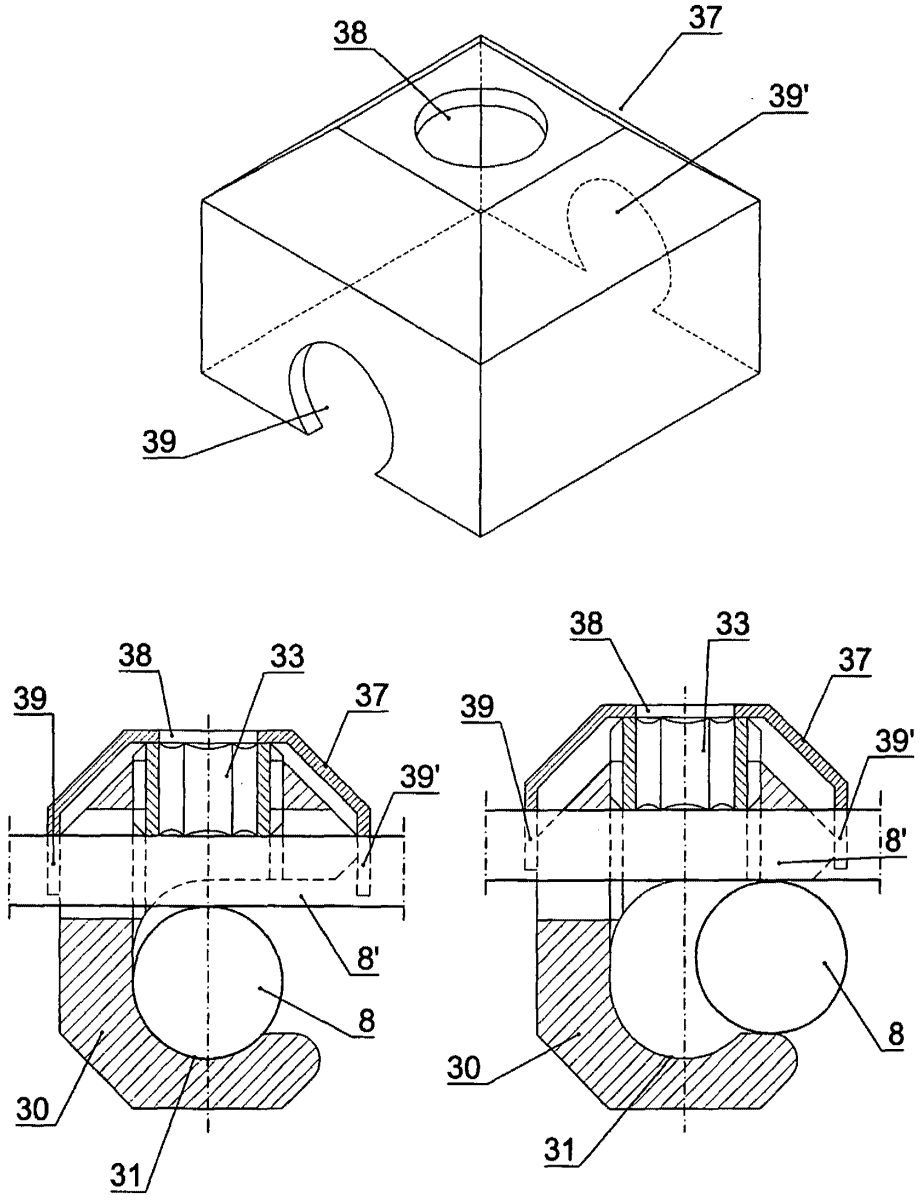



FIG. 9



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 524 of 2152

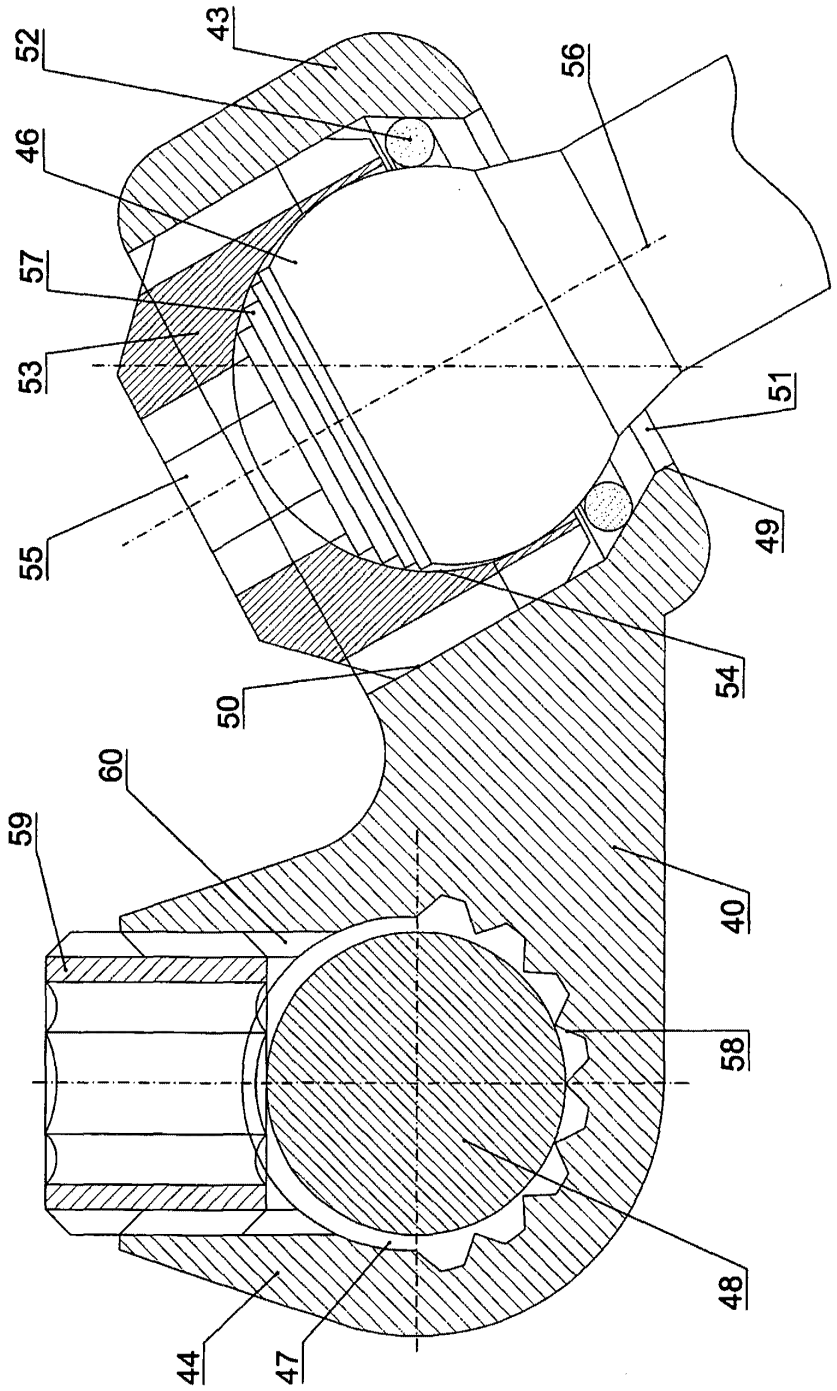



FIG. 10



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 525 of 2152

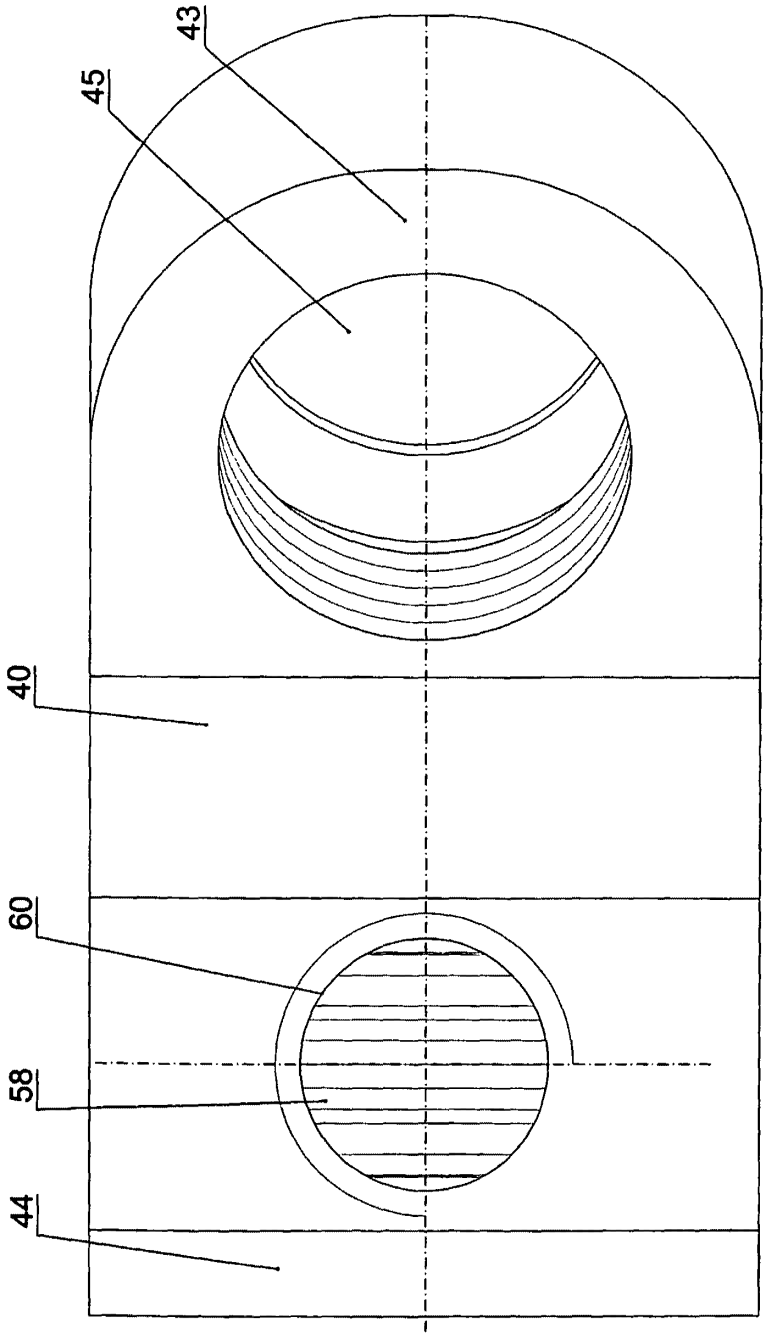



FIG. 11



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 526 of 2152

11/11

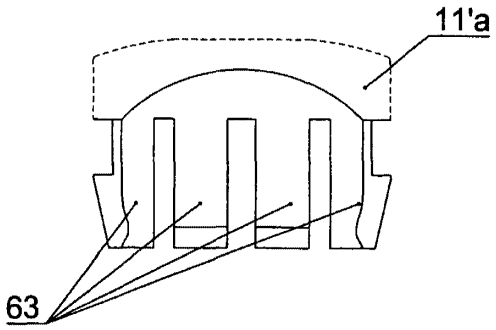



FIG. 12

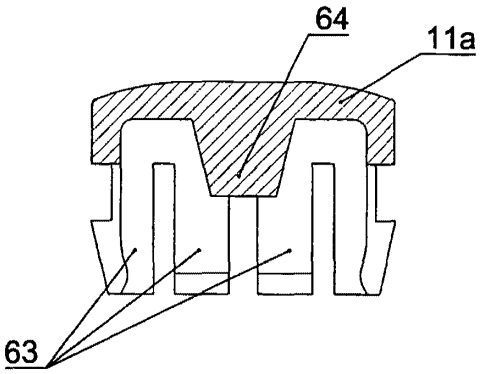



FIG. 13

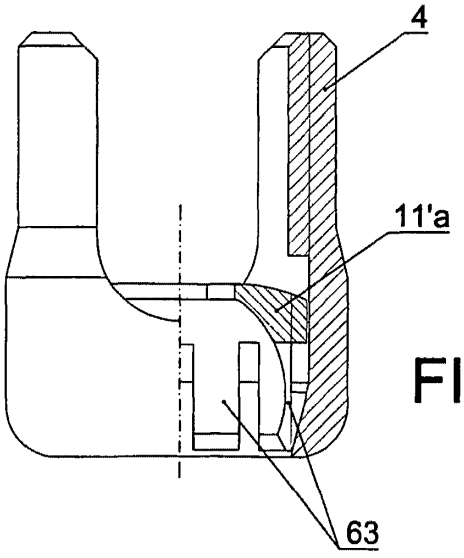



FIG. 14



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 527 of 2152

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/ ES 00/00310

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61B 17/70

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 practicable, search terms used)

CIBEPAT, EPODOC, WPI, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| A | DE 19720782 A1 (SPARIN & RÖHL & HENSELER) 19 November 1998 (19.11.98), see the whole document | 1-3,6-9 |
| A | WO 9834554 A (SDGI HOLDINGS) 13 August 1998 (13.08.98), see the whole document | 1-3,6,9 |
| A | US5681319 A (BIEDERMANN)28 October 1997 (28.10.97), see the whole document | 1-3,6,9 |
| A | WO 9844859 A1 (DIMSO) 15 October 1998 (15.10.98), see the whole document | 4,5 |
| A | US 5899903 A (COTREL) 04 May 1999 (04.05.99), see the whole document | 7 |
| A | US 5733285 A (ERRICO ET AL) 31 March 1998 (31.03.98), see the whole document | 15 |

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

* Special categories of cited documents:

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

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

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

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

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

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

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

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

"&" document member of the same patent family

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 20 October 2000(20.10.00) | 08 November 2000(08.11.00) |
| Name and mailing address of the ISA/ S.P.T.O<br>Facsimile No. | Authorized officer<br>Telephone No. |

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

## INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/ ES 00/00310

| Patent document cited in search report | Publication date | Patent familiy member(s) | Publication date |
|---|---|---|---|
| DE 19720782 A1 | 19.11.1998 | WO 9852482 A1 | 26.11.1998 |
| | | ZA 9804064 A | 24.02.1999 |
| | | AU 3022397 A | 11.12.1998 |
| | | EP 0984730 A1 | 15.03.2000 |
| | | CN 1254266 A | 24.05.2000 |
| WO 9834554 A1 | 13.08.1998 | AU 6157698 A | 26.08.1998 |
| | | US 5885286 A | 23.03.1999 |
| | | EP 0986338 A1 | 22.03.2000 |
| US 5681319 A | 28.10.1997 | DE 19507141 A1 | 12.09.1996 |
| WO 9844859 A1 | 15.10.1998 | FR 2761590 A1 | 09.10.1998 |
| | | AU 7338098 A | 30.10.1998 |
| | | EP 0971639 A1 | 19.01.2000 |
| US 5899903 A | 04.05.1999 | WO 9525473 A1 | 28.09.1995 |
| | | AU 1859795 A | 09.10.1995 |
| | | EP 0750477A1,B1 | 02.01.1997 |
| | | JP 9506283 T | 24.06.1997 |
| | | DE 69506850 E | 04.02.1999 |
| US 5733285 A | 31.03.1998 | NONE | |

Form PCT/ISA/210 (patent family annex) (July 1992)

## INFORME DE BÚSQUEDA INTERNACIONAL

Solicitud internacional nº
PCT/ ES 00/00310

A. CLASIFICACIÓN DEL OBJETO DE LA SOLICITUD

CIP[7] A61B 17/70
De acuerdo con la Clasificación Internacional de Patentes (CIP) o según la clasificación nacional y la CIP.

B. SECTORES COMPRENDIDOS POR LA BÚSQUEDA

Documentación mínima consultada (sistema de clasificación, seguido de los símbolos de clasificación)

CIP[7] A61B

Otra documentación consultada, además de la documentación mínima, en la medida en que tales documentos formen parte de los sectores comprendidos por la búsqueda

Bases de datos electrónicas consultadas durante la búsqueda internacional (nombre de la base de datos y, si es posible, términos de búsqueda utilizados)

CIBEPAT, EPODOC, WPI, PAJ

C. DOCUMENTOS CONSIDERADOS RELEVANTES

| Categoria* | Documentos citados, con indicación, si procede, de las partes relevantes | Relevante para las reivindicaciones nº |
|---|---|---|
| A | DE 19720782 A1 (SPARIN & RÖHL & HENSELER) 19.11.1998, todo el documento | 1-3,6-9 |
| A | WO 9834554 A (SDGI HOLDINGS) 13.08.1998, todo el documento | 1-3,6,9 |
| A | US5681319 A (BIEDERMANN) 28.10.1997, todo el documento | 1-3,6,9 |
| A | WO 9844859 A1 (DIMSO) 15.10.1998, todo el documento | 4,5 |
| A | US 5899903 A (COTREL) 04.05.1999, todo el documento | 7 |
| A | US 5733285 A (ERRICO ET AL) 31.03.1998,todo el documento | 15 |

☐ En la continuación del recuadro C se relacionan otros documentos ☒ Los documentos de familia de patentes se indican en el anexo

* Categorías especiales de documentos citados:

"A" documento que define el estado general de la técnica no considerado como particularmente relevante.

"E" solicitud de patente o patente anterior pero publicada en la fecha de presentación internacional o en fecha posterior.

"L" documento que puede plantear dudas sobre una reivindicación de prioridad o que se cita para determinar la fecha de publicación de otra cita o por una razón especial (como la indicada).

"O" documento que se refiere a una divulgación oral, a una utilización, a una exposición o a cualquier otro medio.

"P" documento publicado antes de la fecha de presentación internacional pero con posterioridad a la fecha de prioridad reivindicada.

"T" documento ulterior publicado con posterioridad a la fecha de presentación internacional o de prioridad que no pertenece al estado de la técnica pertinente pero que se cita por permitir la comprensión del principio o teoría que constituye la base de la invención.

"X" documento particularmente relevante; la invención reivindicada no puede considerarse nueva o que implique una actividad inventiva por referencia al documento aisladamente considerado.

"Y" documento particularmente relevante; la invención reivindicada no puede considerarse que implique una actividad inventiva cuando el documento se asocia a otro u otros documentos de la misma naturaleza, cuya combinación resulta evidente para un experto en la materia.

"&" documento que forma parte de la misma familia de patentes.

| Fecha en que se ha concluido efectivamente la búsqueda internacional. 20 Octubre 2000 (20.10.2000) | Fecha de expedición del informe de búsqueda internacional 08 NOV 2000 08. 11. 00 |
|---|---|
| Nombre y dirección postal de la Administración encargada de la búsqueda internacional O.E.P.M. C/Panamá 1, 28071 Madrid, España. nº de fax +34 91 3495304 | Funcionario autorizado F. JAVIER HAERING nº de teléfono + 34 91 3495473 |

Formulario PCT/ISA/210 (segunda hoja) (julio 1998)

**INFORME DE BÚSQUEDA INTERNACIONAL**
Información relativa a miembros de familias de patentes

Solicitud internacional nº
PCT/ ES 00/00310

| Documento de patente citado en el informe de búsqueda | Fecha de publicación | Miembro(s) de la familia de patentes | Fecha de publicación |
|---|---|---|---|
| DE 19720782 A1 | 19.11.1998 | WO 9852482 A1 | 26.11.1998 |
| | | ZA 9804064 A | 24.02.1999 |
| | | AU 3022397 A | 11.12.1998 |
| | | EP 0984730 A1 | 15.03.2000 |
| | | CN 1254266 A | 24.05.2000 |
| WO 9834554 A1 | 13.08.1998 | AU 6157698 A | 26.08.1998 |
| | | US 5885286 A | 23.03.1999 |
| | | EP 0986338 A1 | 22.03.2000 |
| US 5681319 A | 28.10.1997 | DE 19507141 A1 | 12.09.1996 |
| WO 9844859 A1 | 15.10.1998 | FR 2761590 A1 | 09.10.1998 |
| | | AU 7338098 A | 30.10.1998 |
| | | EP 0971639 A1 | 19.01.2000 |
| US 5899903 A | 04.05.1999 | WO 9525473 A1 | 28.09.1995 |
| | | AU 1859795 A | 09.10.1995 |
| | | EP 0750477A1,B1 | 02.01.1997 |
| | | JP 9506283 T | 24.06.1997 |
| | | DE 69506850 E | 04.02.1999 |
| US 5733285 A | 31.03.1998 | NINGUNO | |

Formulario PCT/ISA/210 (anexo-familias de patentes) (julio 1998)

(19) RÉPUBLIQUE FRANÇAISE

INSTITUT NATIONAL
DE LA PROPRIÉTÉ INDUSTRIELLE

PARIS

(11) N° de publication : **2 796 545**
(à n'utiliser que pour les commandes de reproduction)

(21) N° d'enregistrement national : **99 09524**

(51) Int Cl⁷ : **A 61 B 17/70**

# (12) DEMANDE DE BREVET D'INVENTION A1

(22) **Date de dépôt :** 22.07.99.

(30) **Priorité :**

(43) **Date de mise à la disposition du public de la demande :** 26.01.01 Bulletin 01/04.

(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) :** *DIMSO (DISTRIBUTION MEDICALE DU SUD-OUEST) Société anonyme* — FR.

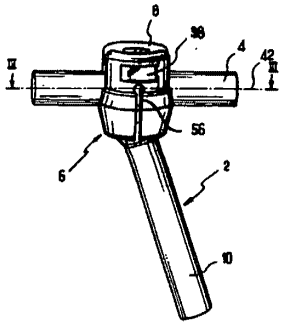
(72) **Inventeur(s) :** BACCELLI CHRISTIAN, CONCHY FREDERIC, GAUCHET FABIEN, LE COUEDIC REGIS, PASQUET DENIS, SAINT MARTIN PIERRE HENRI, TURNER DOMERGUE MICHELE et VIENNEY CECILE.

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

(74) **Mandataire(s) :** REGIMBEAU.

## (54) LIAISON POLY-AXIALE POUR SYSTEME D'OSTEOSYNTHESE, NOTAMMENT POUR LE RACHIS.

(57) Le système d'ostéosynthèse à liaison poly-axiale notamment pour le rachis, comprend un élément d'ancrage osseux 2 comportant une tête, un élément de liaison 4, un connecteur 6 présentant un premier logement déformable pour recevoir la tête et un deuxième logement pour recevoir l'élément de liaison, le système comprenant un moyen de serrage 8 de l'élément de liaison dans le deuxième logement, le connecteur étant agencé de sorte que, lorsque le moyen de serrage sollicite l'élément de liaison dans le deuxième logement, l'élément de liaison sollicite directement le connecteur pour déformer le premier logement et y bloquer la tête.




FR 2 796 545 - A1

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 532 of 2152

La présente invention concerne un système d'ostéosynthèse à liaison poly-axiale, notamment pour le rachis.

Dans le cadre de la chirurgie de la colonne vertébrale, par exemple, et notamment par voie d'approche postérieure, le praticien est souvent confronté au problème du mésalignement des organes d'ancrages ainsi que de l'interférence entre de tels organes sur deux vertèbres adjacentes. Ce problème a pour conséquence d'allonger le temps opératoire ou de ne pas permettre au praticien, dans les meilleures conditions qui soient, de réaliser l'intervention désirée. La source de ce problème est que l'élément de couplage entre l'organe de liaison des différentes vertèbres et l'organe d'ancrage dans la vertèbre est rigidement lié à cet organe d'ancrage.

Le document N° WO 97/02786 nous enseigne une liaison poly-axiale entre les éléments. L'organe d'ancrage comporte une tête semi-sphérique. L'élément de couplage comporte, en plus des moyens pour recevoir l'organe de liaison des différentes vertèbres, une chambre fendue de réception de la tête semi-sphérique dans sa partie inférieure. La surface externe de l'élément de couplage comporte un cône s'évasant vers l'extrémité inférieure. Un collier de serrage est apte à s'enfiler sur l'élément de couplage par sa partie supérieure pour venir s'appuyer sur la partie conique. Avant serrage, l'élément de couplage est libre de rotation par rapport à l'organe d'ancrage. Le blocage en position s'effectue lors du serrage de l'organe de liaison des différentes vertèbres. Ce dernier vient appuyer sur le collier de serrage qui referme dans le même temps la chambre de réception sur la tête semi-sphérique de l'organe d'ancrage.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 533 of 2152

La complexité du mécanisme de blocage en position, du fait de ses nombreuses pièces, oblige le praticien à effectuer des manipulations supplémentaires, ce qui a pour conséquence d'allonger les temps opératoires.

Un but de l'invention est de fournir un dispositif de liaison poly-axiale simple de mise en œuvre, pouvant être mis en place avec un nombre réduit d'opérations.

En vue de réaliser ce but, on prévoit, selon la présente invention, un système d'ostéosynthèse à liaison poly-axiale notamment pour le rachis, comprenant un élément d'ancrage osseux comportant une tête, un élément de liaison, un connecteur présentant un premier logement déformable pour recevoir la tête et une deuxième logement pour recevoir l'élément de liaison, et un moyen de serrage de l'élément de liaison dans le deuxième logement. Le connecteur est agencé de sorte que, lorsque le moyen de serrage sollicite l'élément de liaison dans le deuxième logement, l'élément de liaison sollicite directement le connecteur pour déformer le premier logement et y bloquer la tête.

Ainsi, le premier logement déformable se referme sur la tête. Cela permet de réduire le nombre de pièces, donc de simplifier la mise en œuvre du dispositif.

Avantageusement, le premier logement comporte une chambre à surface concave.

Avantageusement, la chambre à surface concave est complémentaire de tout ou partie de la surface convexe de la tête.

Avantageusement, le premier logement comporte au moins une cavité apte à recevoir en partie la tête.

Avantageusement, le connecteur comporte au moins une fente s'étendant dans le premier logement.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 534 of 2152

Ainsi, le premier logement pourra avoir une déformabilité élastique plus prononcée lors de l'introduction de la tête et lors du blocage en position du dispositif.

Avantageusement, la tête comporte une partie sphérique.

Avantageusement, le premier logement comporte une ouverture en « U » comprenant une axe et deux branches s'étendant à distance et en regard l'une de l'autre.

Avantageusement, la fente est perpendiculaires à l'axe de l'ouverture en " U ".

Avantageusement les branches de l'ouverture en " U " présentent un filetage.

Avantageusement, les moyens de serrage comportent un verrou apte à venir en prise entre les branches de l'ouverture en " U ".

Avantageusement, les moyens de serrage comportent une bride apte à venir autour des branches de l'ouverture en " U ".

Ainsi, lors du serrage du verrou, la bride empêche l'écartement des branches de l'ouverture en " U ".

Avantageusement, le filetage comporte une face sensiblement perpendiculaire à l'axe du filet et orientée suivant un sens de pénétration du moyen de serrage sur le connecteur.

Ainsi, lors du serrage, la face sensiblement perpendiculaire à l'axe du filet du verrou entrent en contact avec celle des branches de l'ouverture en « U ». La force de réaction ainsi provoquée est sensiblement parallèle à l'axe du filetage et on minimise la force de réaction radiale qui ferait, sinon, s'écarter les branches de l'ouverture en " U ".

D'autres caractéristiques et avantages de l'invention apparaîtront encore dans la description

suivante de trois modes de réalisation préférés donnés à titre d'exemples non limitatifs. Aux dessins annexés :

- la figure 1 est une vue partielle en perspective du système selon une première réalisation ;
- la figure 2 est une vue en perspective éclatée du système de la figure 1 ;
- la figure 3 est une vue en coupe du système selon le plan III-III de la figure 1 ;
- la figure 4 est une vue en perspective de dessus du connecteur selon la première réalisation ;
- la figure 5 est une vue en perspective de dessous du connecteur de la figure 4 ;
- la figure 6 est une vue en coupe du connecteur selon le plan VI-VI de la figure 4 ;
- la figure 6a est une vue schématique en coupe du filetage en sapin de Noël du connecteur de la figure 4 ;
- la figure 7 est une vue en perspective de dessous du connecteur selon une seconde réalisation ; et
- la figure 8 est une vue en perspective de dessous du connecteur selon une troisième réalisation.

Nous allons décrire un premier mode de réalisation de la présente invention en référence aux figures 1 à 6a.

Le système d'ostéosynthèse comprend au moins deux organes d'ancrage 2 vertébral, des moyens de liaison 4, tels qu'une tige, entre cet organe d'ancrage 2 et les autres organes d'ancrages (non représentés) du système d'ostéosynthèse, un connecteur 6 apte à venir s'adapter sur l'organe 2, et un verrou 8 apte à coopérer avec le connecteur 6.

L'organe d'ancrage vertébral 2, ici sous la forme d'une vis à os, comprend un corps fileté 10 cylindrique de section circulaire ayant un filetage à os (non

représenté). L'organe comporte aussi une tête 12 présentant une surface convexe 14, ici une surface de révolution autour de l'axe de la vis 16. La surface convexe comporte une partie latérale sphérique 18, une partie supérieure plane 22 perpendiculaire à l'axe de la vis, et un congé de raccordement 20 entre celles-ci. La tête 12 comporte des moyens de mise en œuvre 24 de la vis 2, ici sous la forme d'une empreinte 24 en creux ayant six pans et de forme hexagonale.

Le verrou a ici une forme générale de vis et comporte un filetage 26 apte à coopérer avec celui 28 présent sur le connecteur 6 décrit ci-après. Le verrou comporte aussi des moyens de mise en œuvre 30 ici sous la forme d'une empreinte 30 à six pans de forme hexagonale.

Le connecteur 6 est un élément de couplage entre la vis à os 2 et la tige 4 de liaison. Cet élément de couplage est de forme générale cylindrique à section circulaire. Il comporte une partie supérieure 6a pour la liaison avec la tige 4 et une partie inférieure 6b pour la liaison avec la vis à os 2.

Dans la partie supérieure 6a, l'élément de couplage 6 comprend une ouverture 32 en " U " ayant un axe 42 et délimitée par deux branches 34 s'étendant à distance et en regard l'une de l'autre. Ces deux branches 34 constituent deux secteurs d'un même cylindre à section circulaire formant l'élément de couplage 6. Les faces externes cylindriques 36 des branches 34 sont coaxiales et lisses. Elles peuvent comporter des moyens de préhension 38 par exemple sous forme d'une encoche à fond plat parallèle à l'axe 42 de l'ouverture en " U " 32 et situé sur chacune des branches 34. Les encoches 38 sont symétriques en miroir par rapport au plan médian de l'ouverture en « U » 32. Les faces internes cylindriques

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 537 of 2152

28 des branches sont coaxiales et filetées. Ce filetage est apte à coopérer avec celui du verrou 26. Les deux filetages 26 et 28 sont complémentaires et sont dits " en sapin de Noël ". Le filetage 28 présente une première face 80 sensiblement perpendiculaire à l'axe du filet, une seconde face 81 sensiblement parallèle à l'axe du filet délimitant le fond du filet, une troisième face 83 s'étendant en regard de la première face 80 et pouvant être inclinée en direction de l'axe par rapport à la direction de la première face 80, et une quatrième face 82 sensiblement parallèle à l'axe du filet délimitant la crête du filet. Le filetage 26 est sensiblement complémentaire du filetage 28. Ce filetage 26 présente une première face 90 parallèle et complémentaire de la face 80, une seconde face 91 sensiblement parallèle à l'axe du filet délimitant la crête du filet, une troisième face 93 sensiblement parallèle et complémentaire de la face 83, et une quatrième face 92 sensiblement parallèle à l'axe du filet délimitant le fond du filet. Lors du serrage, la face 90 du filetage 28 vient en contact avec la face 80 du filetage 26. La force de réaction Fr ainsi obtenue se décompose en une force normale Fn, parallèle à l'axe des file, et en une force transversale Fs de direction radiale. Cette force transversale Fs pourrait être responsable de l'écartement des branches 34 lors du serrage du verrou 8, mais la forme particulière, précitée, des filetages 26,28 permet de réduire la valeur de la force transversale Fs, et ainsi de réduire l'écartement des branches 34 au moment du serrage.

Dans un plan perpendiculaire à l'axe 42, le fond 40 de l'ouverture en " U " est semi-circulaire pour pouvoir recevoir la tige de liaison 4, avec un diamètre équivalent à celui de la tige de liaison 4. D'autre

part, le fond 40 présente une concavité dans le plan médian de l'ouverture 32 en « U » et ayant un centre de courbure situé du coté de la partie 6a du connecteur 6. Enfin, le fond 40 présente des extrémités 44 parallèles à l'axe 42, servant de siège de réception pour la tige de liaison 4.

Dans la partie inférieure 6b, le connecteur 6 comprend un logement 46 débouchant sur la face inférieure 48 en un orifice 50 d'insertion et débouchant dans le fond 40 de l'ouverture en « U » 32 en un orifice de communication 52. L'orifice d'insertion 50 de section circulaire permet l'introduction de la tête 12 de la vis à os 2 dans le logement 46. Le logement 46 comporte une chambre inférieure 54 en portion de sphère qui est apte à recevoir la tête 12 de la vis à os 2. La forme de la chambre inférieure 54 est complémentaire de la portion latérale sphérique 18 de la surface convexe 14 de la tête 12. Une fente 56 traverse diamétralement la partie inférieure 6b. La fente 56 est perpendiculaire à l'axe 42 de l'ouverture en « U » 32. Elle s'étend, vers le bas, jusqu'à la face inférieure 48 du connecteur 6 et, vers le haut, jusqu'à déboucher dans le fond 40 de l'ouverture en « U » 32. Ainsi la partie inférieure 6b est partagée en deux sous-parties 58 et 60 symétriques en miroir par rapport au plan médian de la fente 56. La fente 56 facilite le clipsage de la tête 12 dans l'élément de couplage 6 en facilitant la déformabilité de l'espace de réception 46.

Avant l'intervention, chaque connecteur 6 est prémonté par clipsage sur la tête 12 de la vis à os 2. La vis à os est mise en place sur le patient en utilisant les moyens de mise en œuvre 24 qu'un instrument atteint via l'orifice de communication 52. Une fois la vis 2 mise en place, le connecteur 6 est

libre de rotation par rapport à cette vis 2. Ceux-ci sont reliés l'un à l'autre par une liaison rotule formée par la tête 12 et la chambre inférieure 54. La tige 4 est mise en place dans l'ouverture en " U " 32 de manière à venir reposer sur les extrémités 44 du fond 40. Le verrou 8 est ensuite engagé entre les branches 34 de l'ouverture 32, les filetages 26 et 28 en prise l'un avec l'autre. Le verrou 8 est amené alors en appui contre la tige 4 et le praticien serre le verrou 8. Le verrou 8 appuie sur la tige 4. La tige 4 appuie sur les extrémités 44 du fond 40 qui se déforme alors grâce à la présence de la fente 56 perpendiculaire à l'axe 42 de l'ouverture 32 qui se referme en rapprochant les deux sous-parties 58 et 60 l'une de l'autre. Par conséquent, l'espace de réception 46 et la chambre 54 se referment sur la tête 12 de la vis à os 2, bloquant l'ensemble en position, immobilisant rigidement le connecteur sur la tête de la vis à os.

Dans le deuxième mode de réalisation illustré à la figure 7, les modifications par rapport au premier mode de réalisation concernent la partie inférieure du connecteur 106. Le logement 146 ne comporte plus de chambre sphérique mais est de forme cylindrique circulaire avec deux méplats 102 et 104. Le rayon de la partie circulaire 108 pourra être équivalent au rayon de la tête 12 de la vis à os 2. Les deux méplats 102 et 104 sont parallèles à la fente 56. Perpendiculairement à ces méplats 102 et 104, un trou 110 de section circulaire traverse diamétralement la partie inférieure de part en part au niveau des méplats, perpendiculairement à ceux-ci. Le diamètre de ce trou 110 est sensiblement équivalent à la largeur des méplats 102 et 104.

Lors du clipsage du connecteur 106 sur la tête 12 de la vis à os 2, la tête 12 vient se loger dans les trous 110 laissant libre la liaison rotule ainsi formée.

L'utilisation est identique à celle du premier mode de réalisation lors du serrage, la déformation de l'espace de réception 146, par le rapprochement des deux sous-parties 158 et 160 l'une vers l'autre, oblige les deux méplats 102 et 104 à se rapprocher l'un de l'autre, bloquant, de ce fait, la tête 12 de la vis à os 2 dans les trous 110.

Dans le troisième mode de réalisation illustré à la figure 8, les modifications par rapport au mode précédent concernent la partie inférieure du connecteur 206. Le logement 246 et la fente 256 sont confondus, la fente 256 ayant la largeur du logement 246. La largeur L de la fente 256 est inférieure au diamètre de la tête 12 de la vis à os 2. Comme dans le mode de réalisation précédent, un trou 210 de section circulaire traverse diamétralement, de manière perpendiculaire aux parois de la fente 256, la partie inférieure du connecteur 206 de part en part au niveau des méplats, perpendiculairement à ceux-ci. Le diamètre de ce trou 210 est inférieur à celui de la partie sphérique 18 de la surface convexe 14 de la tête 12.

Le clipsage s'effectue de la même manière : la tête 12 vient se loger dans les trous 210 laissant libre la liaison rotule ainsi formée.

L'utilisation est identique à celle du second mode de réalisation. Le blocage en position est similaire.

Bien entendu, on pourra apporter à l'invention de nombreuses modifications sans sortir du cadre de celle-ci.

Les organes d'ancrage pourraient être des crochets.

Le moyen de serrage pourra comporter une bague ou une bride apte à s'enfiler sur les branches de l'ouverture en " U " en remplacement du verrou ou en complément de ce dernier. Dans ce cas de complément, cette bride ou bague pourra être liée au verrou.

Le filet coopérant avec celui des branches pourra être sur la bride, les branches étant filetées sur leur face extérieure.

REVENDICATIONS

1. Système d'ostéosynthèse à liaison poly-axiale notamment pour le rachis, comprenant un élément d'ancrage osseux (2) comportant une tête (12), un élément de liaison (4), un connecteur (6;106;206) présentant un premier logement déformable (46;146;246) pour recevoir la tête et un deuxième logement (32) pour recevoir l'élément de liaison, le système comprenant un moyen de serrage (8) de l'élément de liaison dans le deuxième logement, caractérisé en ce que le connecteur est agencé de sorte que, lorsque le moyen de serrage sollicite l'élément de liaison dans le deuxième logement, l'élément de liaison sollicite directement le connecteur pour déformer le premier logement et y bloquer la tête.

2. Système selon la revendication 1 caractérisé en ce que le premier logement comporte une chambre (54) à surface concave.

3. Système selon la revendication 1 ou 2 caractérisé en ce que le premier logement comporte au moins une cavité (110;210) apte à recevoir en partie la tête (12).

4. Système selon l'une des revendications 1 à 3 caractérisé en ce que la tête comprend une partie sphérique (18).

5. Système selon l'une des revendications 1 à 4 caractérisé en ce que le connecteur comporte au moins

une fente (56;256) s'étendant dans le premier logement.

6. Système selon l'une des revendications 1 à 5 caractérisé en ce que le premier logement présente une ouverture en « U » comprenant un axe (42) et deux branches (34) s'étendant à distance et en regard l'une de l'autre.

7. Système selon les revendications 5 et 6 caractérisé en ce que la fente est perpendiculaires à l'axe (42) de l'ouverture en " U ".

8. Système selon la revendication 6 ou 7 caractérisé en ce que le moyen de serrage comportent un verrou (8) apte à venir en prise entre les branches de l'ouverture en " U ".

9. Système selon l'une des revendications 6 à 8 caractérisé en ce que le moyen de serrage comportent une bride apte à venir autour des branches de l'ouverture en " U ".

10. Système selon l'une des revendications 6 à 9 caractérisé en ce que les branches (34) de l'ouverture en " U " présentent un filetage (28).

11. Système selon la revendication 10 caractérisé en ce que le filetage (26,28) comporte une face (80) sensiblement perpendiculaire à l'axe du filet et orientée suivant un sens de pénétration du moyen de serrage sur le connecteur.

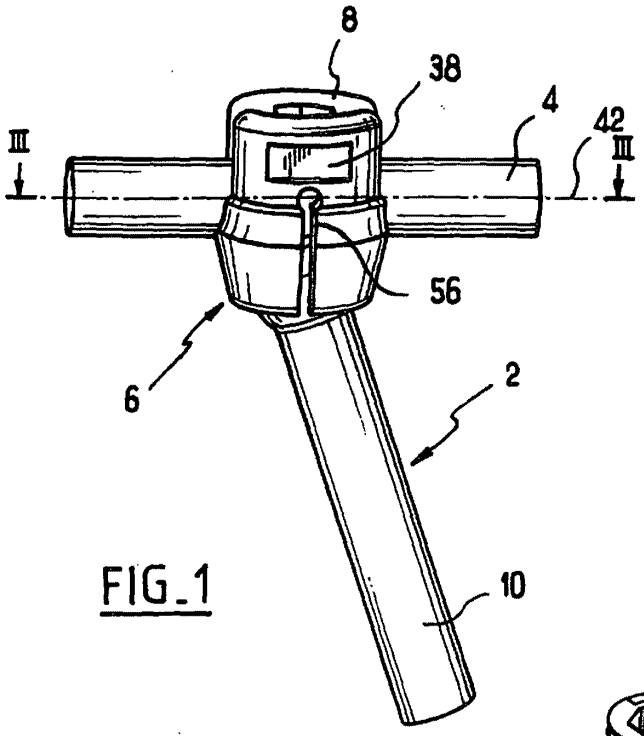



FIG_1

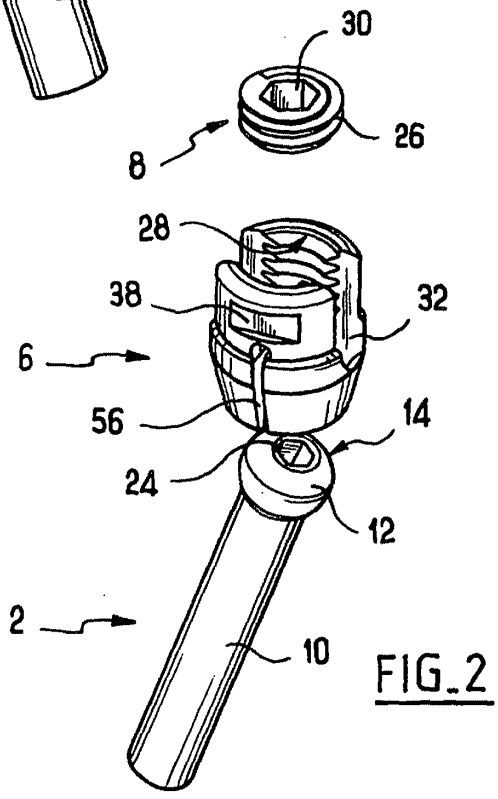



FIG_2

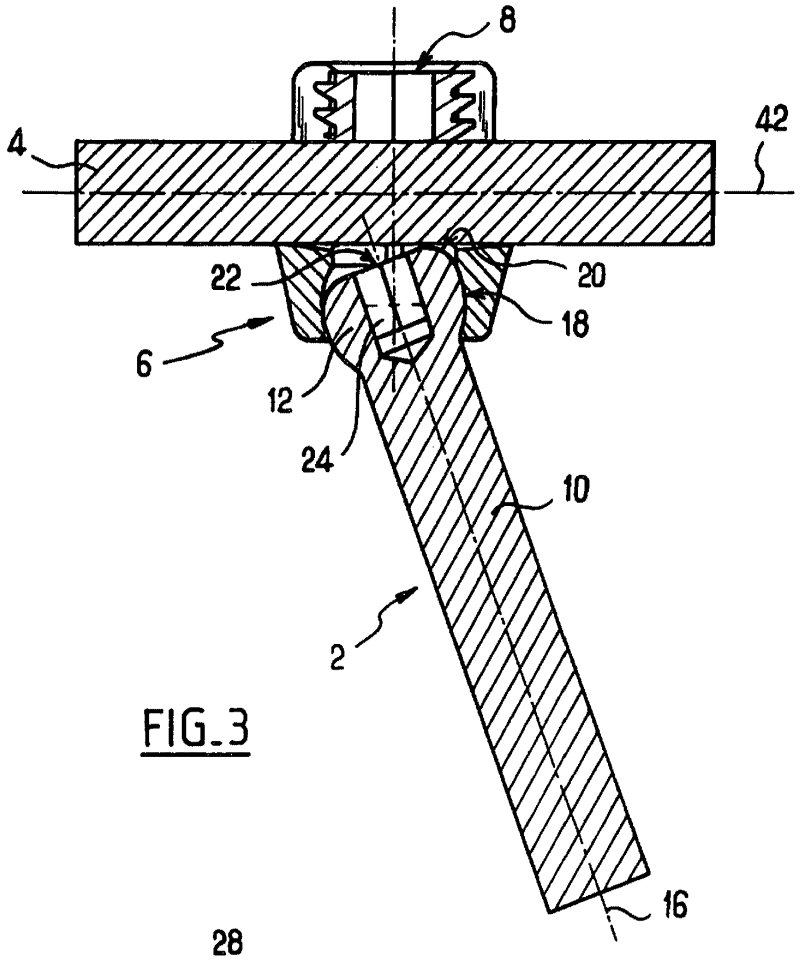



FIG.3

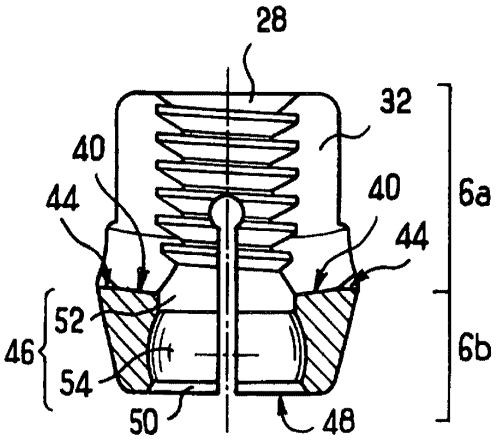



FIG.6

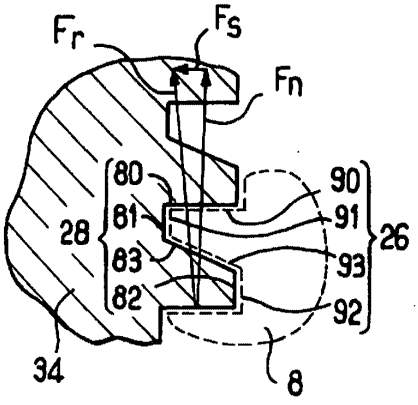



FIG.6a

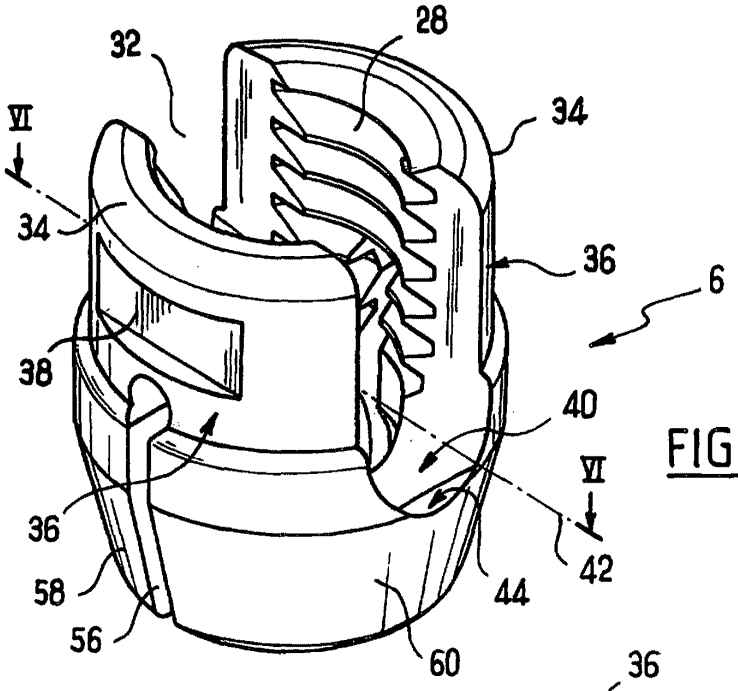

28
32
34
VI
34
36
6
38
40
VI
36
42
58
44
56
60

FIG.4

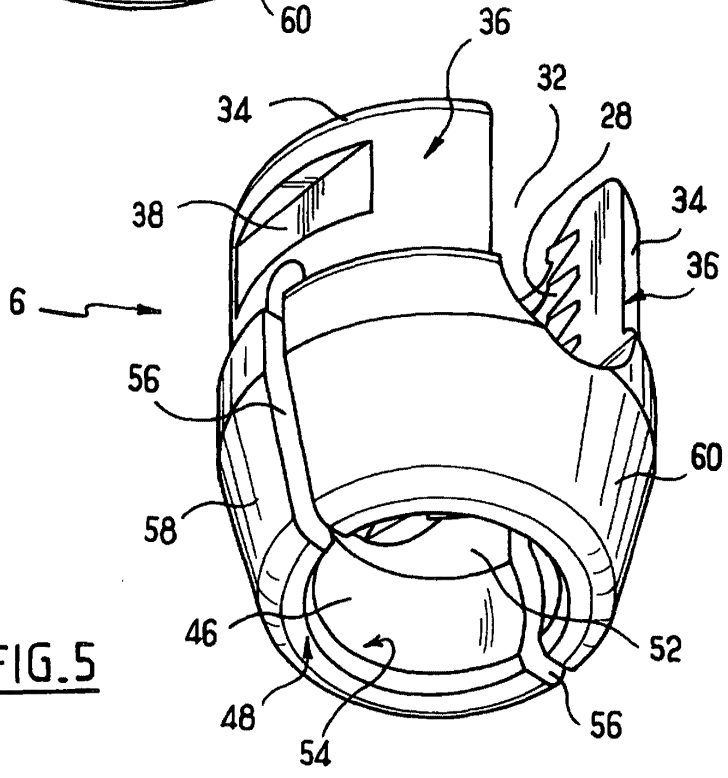

36
32
34
28
38
34
36
6
56
60
58
46
52
48
56
54

FIG.5

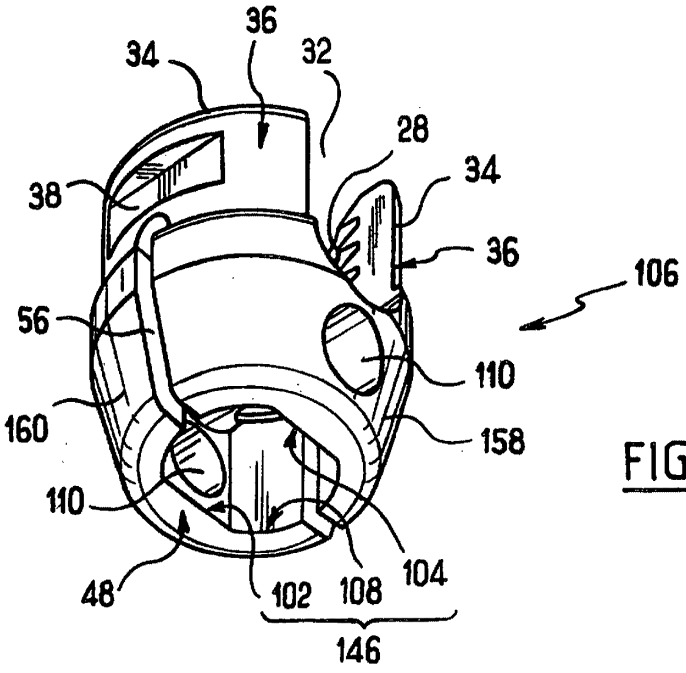

36
34
32
28
38
34
36
106
56
110
160
158
110
48
102
108
104
146

FIG_7

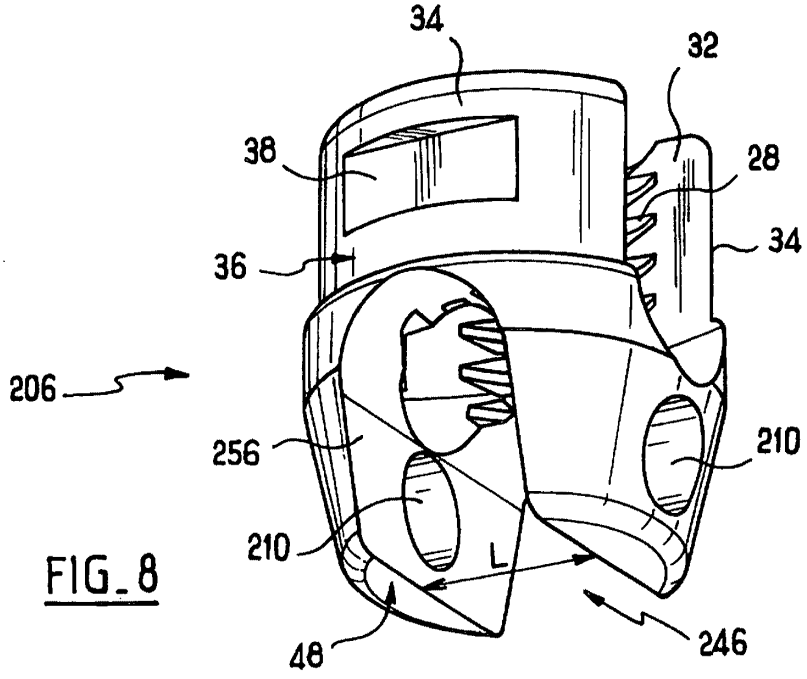

34
32
38
28
36
34
206
256
210
210
L
48
246

FIG_8

2796545

**REPUBLIQUE FRANÇAISE**

INSTITUT NATIONAL
de la
PROPRIETE INDUSTRIELLE

# RAPPORT DE RECHERCHE PRELIMINAIRE

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

N° d'enregistrement national
FA 575925
FR 9909524

| DOCUMENTS CONSIDERES COMME PERTINENTS | | Revendications concernées de la demande examinée |
|---|---|---|
| Catégorie | Citation du document avec indication, en cas de besoin, des parties pertinentes | |
| D,Y | WO 97 02786 A (FASTENETIX)<br>30 janvier 1997 (1997-01-30)<br>* page 3, ligne 30 - page 4, ligne 15 *<br>* page 14, ligne 28 - page 15, ligne 6 *<br>* figure 8B * | 1-11 |
| Y | FR 2 771 918 A (DIMSO)<br>11 juin 1999 (1999-06-11)<br>* page 1, ligne 3 - page 2, ligne 7 *<br>* page 7, ligne 13 - page 8, ligne 8 *<br>* figures 2,5,6 * | 1-11 |
| A | WO 98 32386 A (T.AMREIN ET M.HESS)<br>30 juillet 1998 (1998-07-30)<br>* abrégé *<br>* page 7, ligne 20 - page 8, ligne 6 *<br>* figures 1,2 * | 1-5 |
| A | DE 299 03 342 U (E.GRZIBEK)<br>2 juin 1999 (1999-06-02)<br>* page 1, ligne 15 - ligne 23 *<br>* revendications 1,5 *<br>* figures 6,9 * | 11 |

DOMAINES TECHNIQUES RECHERCHES (Int.CL.7)

A61B

| Date d'achèvement de la recherche | Examinateur |
|---|---|
| 7 avril 2000 | Nice, P |

CATEGORIE DES DOCUMENTS CITES

X : particulièrement pertinent à lui seul
Y : particulièrement pertinent en combinaison avec un autre document de la même catégorie
A : pertinent à l'encontre d'au moins une revendication ou arrière-plan technologique général
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 03.82 (P04C13)

1

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 549 of 2152

(19)日本国特許庁（ＪＰ）　(12)公開特許公報（Ａ）　(11)特許出願公開番号
特開2000－325358
（P2000－325358A）
(43)公開日　平成12年11月28日(2000.11.28)

| (51)Int.Cl.' | 識別記号 | ＦＩ | | ﾃｰﾏｺｰﾄﾞ(参考) |
|---|---|---|---|---|
| Ａ６１Ｂ　17/58 | ３１５ | Ａ６１Ｂ　17/58 | ３１５ | ４Ｃ０６０ |
| Ａ６１Ｆ　2/44 | | Ａ６１Ｆ　2/44 | | ４Ｃ０９７ |

審査請求　有　　請求項の数３　ＯＬ　（全４頁）

(21)出願番号　特願平11－135841

(22)出願日　平成11年５月17日(1999.5.17)

(71)出願人　395014275
株式会社ロバート・リード商会
東京都北区西ヶ原１丁目27番３号　古河ガーデンマンション1102号

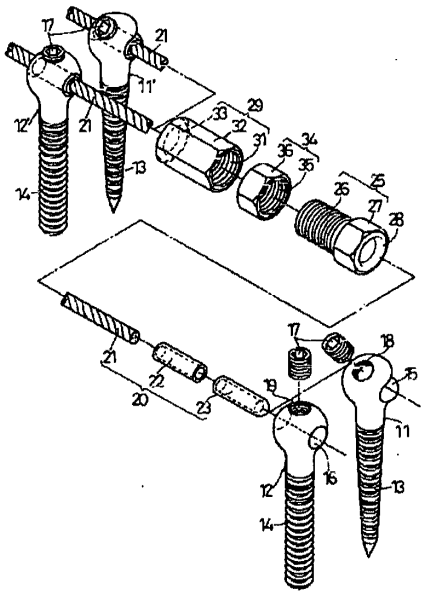
(72)発明者　一青　英雄
東京都北区西ケ原１丁目27番３号　古河ガーデンマンション1102号　株式会社ロバート・リード商会内

(74)代理人　100072039
弁理士　井澤　洵

Ｆターム(参考)　4C060 LL16
4C097 AA01 BB01 CC14 CC20 MM09

(54)【発明の名称】　ワイヤーロッドの固定装置

(57)【要約】
【目的】　可撓性を有するワイヤーロッドを完全に固定する。
【構成】　外面におねじ部２６を有し、ワイヤーロッド２０に嵌めたときに一端部で一方のインプラント１１、１２の側面に当接可能なほぼ筒状の第１部材２５と、第１部材２５のおねじ部２６と螺合可能なめねじ部３１を有し、ワイヤーロッド２０に嵌めたのちおねじ部２６にめねじ部３１を螺合させた状態で他方のインプラント１１′、１２′の側面に当接可能なほぼ筒状の第２部材２９と、第１部材２５のおねじ部２６に螺合して第２部材２９の端面に接し、第１、第２両部材２５、２９の緩み止めとなるロック部材３４とから成るワイヤーロッドの固定装置。




Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 550 of 2152

【特許請求の範囲】
【請求項１】　骨に植設される複数のインプラントを連絡するワイヤーロッドの固定のための装置であって、外面におねじ部が形成され、ワイヤーロッドに嵌装したときに一端部で一方のインプラントの側面に当接可能な、所要の長さを有するほぼ筒状の第１部材と、上記第１部材のおねじ部と螺合可能なめねじ部が内面に形成され、ワイヤーロッドに嵌装しておねじ部とめねじ部とを螺合させた状態で他方のインプラントの側面に当接可能な、所要の長さを有するほぼ筒状の第２部材と、第１部材のおねじ部に螺合可能でありかつその状態で第２部材の端面に接して第１、第２両部材の緩み止めとなるロック部材とからなることを特徴とするワイヤーロッドの固定装置。
【請求項２】　インプラントの側面を凸状の球面形とし、他方、第１部材及び第２部材の端面を凹状の円形とすることにより、隙き間のない接触を可能とした請求項１記載のワイヤーロッドの固定装置。
【請求項３】　ワイヤーロッドは、ワイヤー構造を持つロッド本体と、そこに嵌め合わせるパイプ及び端部キャップとを有する請求項１記載のワイヤーロッドの固定装置。
【発明の詳細な説明】
【０００１】
【発明の属する技術分野】本発明は、骨に植設される複数のインプラントを連絡するワイヤーロッドの固定のための装置に関するものである。
【０００２】
【従来の技術】例えば損傷や病変の生じた複数の椎体にインプラントを植設し、各インプラントをロッドを用いて結合し、各椎体を一定の位置関係に保つことが行なわれる。上記ロッドとして従来は文字通り棒状の部材が使用されてきた。しかしこれを取り付けるには、困難な曲げ加工を手術中に行わねばならず、手間取ったり、或いは無理な力を加えて骨にひびを入れたりするというような問題があった。
【０００３】そこで本発明者はワイヤーを上記ロッドとして使用することに着目し、開発を進めるとともに、成果の一部については既に出願をした。このワイヤーロッドは自由に曲げられ、どのような角度にも設定できるため手術をし易い上、悪影響がないという特徴がある。しかしながら、完全な固定のためにはワイヤーの可撓性が不利となる。
【０００４】
【発明が解決しようとする課題】本発明は前記の点に着目してなされたものであり、その課題は、可撓性を有するワイヤーロッドの完全な固定の実現を図ることである。
【０００５】
【課題を解決するための手段】前記の課題等を解決するため本発明は、外面におねじ部が形成され、ワイヤーロッドに嵌装したときに一端部で一方のインプラントの側面に当接可能な、所要の長さを有するほぼ筒状の第１部材と、上記第１部材のおねじ部と螺合可能なめねじ部が内面に形成され、ワイヤーロッドに嵌装しておねじ部とめねじ部とを螺合させた状態で他方のインプラントの側面に当接可能な、所要の長さを有するほぼ筒状の第２部材と、第１部材のおねじ部に螺合可能でありかつその状態で第２部材の端面に接して第１、第２両部材の緩み止めとなるロック部材とによってワイヤーロッドの固定装置を構成するという手段を講じたものである。
【０００６】
【発明の実施の形態】本発明に係るワイヤーロッドの固定装置は、骨に植設される複数のインプラントを連絡するワイヤーロッドを剛性の在来のロッドと同様の状態に固定するものである。ワイヤーロッドは可撓性を有し、インプラントのロッド受け部に、在来のロッドと同様に受け支えられ、かつ止めねじにより締め着けられる。止めねじによる締め付け力を受け止めるために、ワイヤーにパイプ及びキャップを嵌めることができる。
【０００７】インプラントは、骨にねじ込むためのスクリュー（ねじ）構造を持ち、その外方端部にロッド受け部が通常は設けられる。ロッド受け部はインプラントのねじ軸方向とは交叉する方向を向いており、ワイヤーロッドはそこへ載置ないしは差し込みによって配置される。つまりロッド受け部が溝のように開いた構造の場合には、ワイヤーロッドを載せるように置くことができるが、貫通孔のように両端以外は閉じた構造の場合には、ワイヤーロッドを差し込むこととなる。
【０００８】このようなワイヤーロッドの固定のための装置は、ほぼ筒状の第１部材と、第２部材及びロック部材とから成る。第１部材と第２部材とは一体となって、隣接したインプラントの間に介在する。
【０００９】第１部材は、外面におねじ部が形成され、ワイヤーロッドに嵌装したときに一端部で一方のインプラントの側面に当接可能なほぼ筒状の部材である。第１部材は次に述べる第２部材と一体化して、隣接したインプラントの間に介在するために必要な長さを有する。
【００１０】上記第２部材は、第１部材のおねじ部と螺合可能なめねじ部を内面に形成したほぼ筒状の部材である。第２部材はワイヤーロッドに嵌装してそのめねじ部と第１部材のおねじ部とを螺合させた状態で、他方のインプラントの側面に当接可能な所要の長さを有する。
【００１１】ロック部材は上記第１部材のおねじ部に螺合可能であり、かつ螺合した状態で第２部材の端面に接して、第１、第２両部材の緩み止めとなる。このロック部材はロックナットに相当する。
【００１２】ワイヤーロッドは可撓性を有する点に特徴があり、インプラントの両側でワイヤーロッドを曲げた場合、第１部材と第２部材が隣接インプラントの側面に

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 551 of 2152

隙き間なく面接触可能になるとは限らない。そこでインプラントの側面を凸状の球面形とし、他方、第１部材及び第２部材の端面を凹状の円形ないしは球面形として面接触可能な条件を与えることができる。なお、インプラントのワイヤーロッドを受け支えるロッド受け部と、前述したスクリューとは部材として１個のものである必要はなく、２部品以上からなる構造であっても良い。

【００１３】

【実施例】以下図面を参照して本発明をより詳細に説明する。２種を例示したインプラント１１、１２、１１′、１２′は、下部がおねじ部１３、１４となっており、上端部がロッド受け部１５、１６となっている１個の部材から成る。一方のロッド受け部１５は溝状構造のものであり、もう一方のロッド受け部１６は貫通孔構造のものである。なお尖端を有しないおねじ部１４をもつものは神経を刺激することがより少ない等の特徴を有するので、適用部位に応じて使い分ける。

【００１４】ロッド受け部１５、１６に配置されるワイヤーロッド２０の止めねじ１７による締め着けのためにねじ込み孔１８、１９が形成されている。またロッド受け部１５、１６が設けられたインプラント１１、１２の外方端部は球状に形成され、ロッド受け部１５、１６の位置はその球の直径方向と一致する（図２参照）。

【００１５】ワイヤーロッド２０は、ワイヤー構造を持つロッド本体２１と、そこに嵌め合わせるパイプ２２及び端部キャップ２３とを有する。例示のロッド本体２１はステンレス鋼線の撚り線構造を持つ。パイプ２２及び端部キャップ２３は止めねじ１７を受け止めることによりねじ締めを確実にするもので、ロッド本体２１に嵌め合わせたのちかしめ変形により一体化される。

【００１６】例示の第１部材２５は外周面のほぼ全体に形成されたおねじ部２６を有し、一端部には多角形等のスパナ掛け部２７を有する全体として筒形のものである。外方のスパナ掛け部２７の側の端面２８は一方のインプラント１１、１２の球状端部と密に接触可能なように凹状の円形に形成されている。例示の第２部材２９は内周面に上記おねじ部２６と螺合可能なめねじ部３１を有し、外周面には多角形等のスパナ掛け部３２を有する全体として筒形のものである。同じく外方端となる側の端面３３は他方のインプラント１１′、１２′の球状端部と密に接触可能なように凹状の円形に形成されている。

【００１７】これらの第１、第２両部材２５、２９はそのおねじ部２６とめねじ部３１とで螺合一体化して、伸縮可能な１種の介在物若しくはスペーサとなり、隣接するインプラント１１、１２の側面において球面同士で接触可能である（図４参照）。この状態を維持してワイヤーロッドの固定を完全にするために、ロック部材３４が組み合わされる。ロック部材３４は、内面に前記おねじ部２６と螺合可能なめねじ部３５、外面にスパナ掛け部３６を有する。

【００１８】各図中、３７はロッド受け部１５、１６の端部開口の拡がり部であり、可撓性を有するワイヤーロッド２０の曲がりに対応するために設けられている。

【００１９】このような本装置は、椎体Ｖの各々に植設された複数のインプラント１２…を連絡するワイヤーロッド２０に取り付けて、各インプラントの位置に合わせて曲げられたワイヤーロッド２０を剛性物と化す。各インプラント１２…間において本装置は第１部材２５と第２部材２９との間隔を最適の寸法とした状態とした上でロック部材３４により最終固定され、その結果椎体の位置関係が概ね一定に保たれる（図５参照）。

【００２０】

【発明の効果】本発明は以上の如く構成されかつ作用するものであるから、可撓性を有するワイヤーロッドによる曲げ変形容易という恩恵を享受しながら、その所要の形態を維持するために、完全にワイヤーロッドを固定し、所期の目的を達成することができるという効果を奏する。

【図面の簡単な説明】

【図１】本発明に係るワイヤーロッドの固定装置の１実施例を示す分解斜視図。

【図２】（ａ）インプラントの横断面図。

（ｂ）インプラントの縦断面図。

（ｃ）インプラントの側面図。

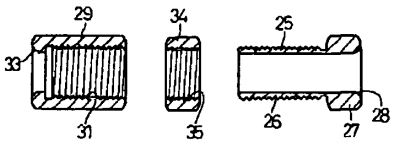
【図３】本装置の縦断面図。

【図４】（ａ）本装置をインプラントへ取り付けた１例を示す平面図。

（ｂ）本装置をインプラントへ取り付けた１例を示す側面図。

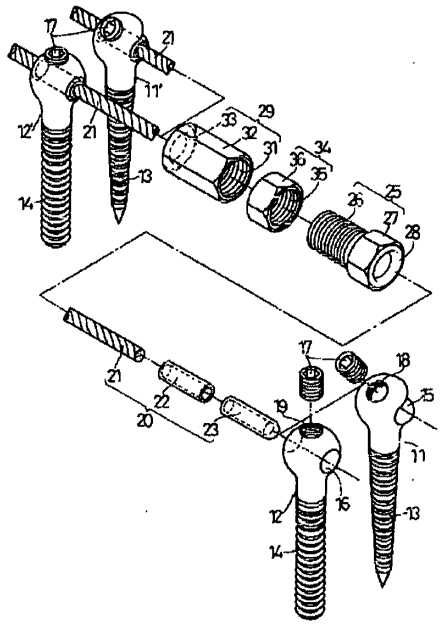
【図５】本装置の使用状態を示す斜視図。

【図３】

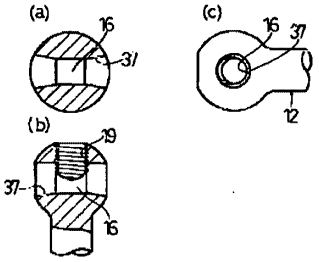



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 552 of 2152

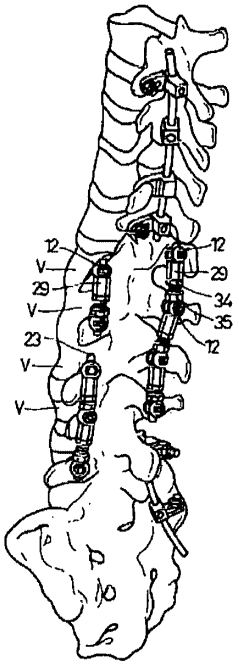
【図1】



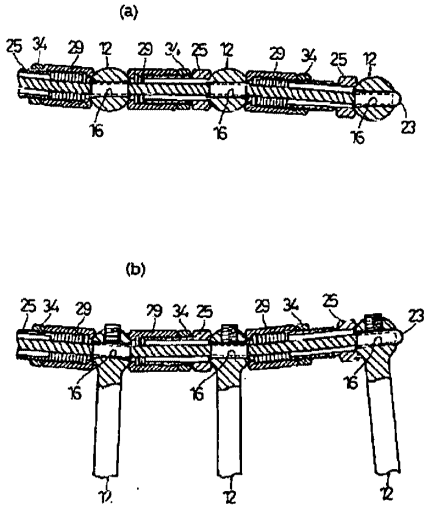
【図2】



【図5】



【図4】



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 553 of 2152

(19) BUNDESREPUBLIK DEUTSCHLAND

DEUTSCHES PATENT- UND MARKENAMT

(12) **Gebrauchsmusterschrift**

(10) **DE 298 10 798 U 1**

(51) Int. Cl.[6]:
**A 61 B 17/58**
A 61 B 17/68

(21) Aktenzeichen: 298 10 798.8
(22) Anmeldetag: 17. 6. 98
(47) Eintragungstag: 28. 10. 99
(43) Bekanntmachung im Patentblatt: 2. 12. 99

DE 298 10 798 U 1

(73) Inhaber:
SCHÄFER micomed GmbH, 73035 Göppingen, DE

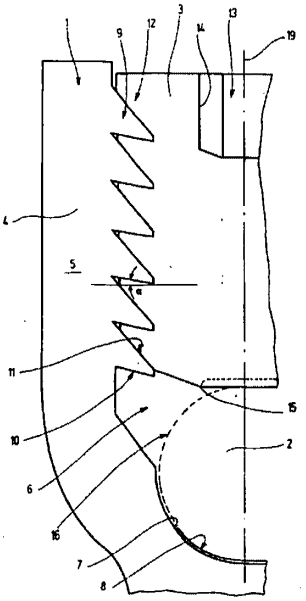
(74) Vertreter:
Dreiss, Fuhlendorf, Steimle & Becker, 70188 Stuttgart

(56) Recherchenergebnisse nach § 7 Abs. 2 GbmG:

| | |
|---|---|
| DE | 39 16 198 A1 |
| DE | 298 06 563 U1 |
| DE | 94 03 231 U1 |
| DE | 90 06 568 U1 |
| DE | 89 15 443 U1 |
| DE | 692 06 318 T2 |
| EP | 05 72 790 A1 |

(54) Osteosynthesevorrichtung

(57) Osteosynthesevorrichtung mit einer Knochenschraube (1) mit einem eine Nut (6) aufweisenden Gabelkopf (4) und einem in die Nut (6) des Gabelkopfes (4) einzulegenden Stützstab (2), der ein Oberflächenprofil aufweist, der Gabelkopf (4) im Nutgrund (7) eine Oberflächenprofilierung (8) aufweist und der Gabelkopf (4) mit einer den Stützstab (2) fixierenden Madenschraube (3) versehen ist, wobei die Oberflächenprofilierung (8) des Nutgrundes (7) die Halterung des Stützstabes (2) in der Nut (6) ermöglichende Mittel aufweist und die Innenseiten der Schenkel (5) des Gabelkopfes (4) mit einem Abschnitt eines Innengewindes (9) versehen sind und das Innengewinde (9) nach Art eines Tannenbaumgewindes ausgebildet ist und eine dem Nutgrund (7) zugewandte Flanke (10) aufweist, die, ausgehend von der Achse (19) der Knochenschraube (1) in radialer Richtung gesehen, ansteigt.




DE 298 10 798 U 1



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 554 of 2152

17.06.98

F:\IJBDHF\DHFANM\3967091

Anmelder:
Firma
SCHÄFER micomed GmbH
Sparwieserweg 4

73035 Göppingen

Allgemeine Vollmacht: 3.4.5.Nr.1062/93AV

3967 091 16.06.1998
ste / neg

**Titel: Osteosynthesevorrichtung**

**Beschreibung**

Die Erfindung betrifft eine Osteosynthesevorrichtung mit einer Knochenschraube mit einem eine Nut aufweisenden Gabelkopf und einem in die Nut des Gabelkopfes einzulegenden Stützstab.

Aus der DE 43 16 542 C1 ist eine Knochenschraube bekannt geworden, mit der ein längsgenuteter Stab verdrehsicher fixiert werden kann. Hierfür weist die Knochenschraube einen Gabelkopf auf, in deren Nut der längsgenutete Stab eingelegt werden kann. Der Nutgrund ist mit Längsnuten versehen, welche eine formschlüssige Verbindung mit dem Stab herstellen. Zur Fixierung des Stabes wird auf den Gabelkopf eine Hutmutter aufgeschraubt und mit dieser der

Stab im Nutgrund festgeklemmt. Durch die verdrehsichere Festlegung des Stabes an der Knochenschraube können hohe Korrekturkräfte bzw. Haltekräfte übertragen werden.

Es hat sich nun gezeigt, dass die Hutmutter zwar den Vorteil aufweist, dass beim Fixieren des längsgenuteten Stabes im Gabelkopf die beiden Schenkel des Gabelkopfes nicht nach außen aufgebogen werden können, da sie von der Hutmutter umgriffen werden. Hierfür benötigt die Knochenschraube jedoch entsprechend viel Platz.

Der Erfindung liegt die Aufgabe zugrunde, eine Osteosynthevorrichtung der eingangs genannten Art derart weiterzubilden, dass sie einen geringeren Platzbedarf besitzt, den Stützstab im Gabelkopf jedoch gleichermaßen gut festhält.

Diese Aufgabe wird erfindungsgemäß mit einer Osteosynthesevorrichtung gelöst, wie sie in den Ansprüchen 1, 13 und 14 angegeben ist.

Die erfindungsgemäße Osteosynthesevorrichtung besitzt den wesentlichen Vorteil, dass der Stützstab nicht mittels einer Hutmutter sondern mittels einer Madenschraube im Gabelkopf festgehalten wird. Die Madenschraube besitzt ein Außengewinde und wird in ein Innengewinde des Gabelkopfes

eingeschraubt und drückt mit ihrem eingeschraubten Ende auf den Stützstab und hält diesen am Nutgrund fest. Um zu vermeiden, dass beim Einschrauben und Festziehen der Madenschraube im Gabelkopf die beiden Schenkel des Gabelkopfes aufgebogen werden weist das Innengewinde dieser Schenkel die Form eines Tannenbaumes auf, wobei die dem Nutgrund zugewandte Flanke des Gewindes von der Achse aus in radialer Richtung gesehen ansteigt. Die abzustützenden Kräfte, die von der Madenschraube auf den Gabelkopf übertragen werden, greifen an dieser in Richtung des Nutgrundes weisenden Flanke an. Da diese Flanke jedoch nach außen ansteigt wird der Gabelkopf nicht nach außen aufgebogen sondern die beiden Schenkel werden von der Madenschraube nach Art einer Schwalbenschwanzverbindung gehalten und eher nach innen gezogen.

Hierdurch wird der wesentliche Vorteil geschaffen, dass ohne die Verwendung einer Hutmutter oder eines anderen, die beiden Schenkel des Gabelkopfes umgreifenden Elements, die Schenkel selbst beim Einschrauben und Festziehen der Madenschraube nicht nach außen aufgebogen werden. Auf diese Weise können relativ hohe Kräfte von der Madenschraube auf den Stützstab übertragen werden.

Dieser Stützstab ist mit einer Oberflächenprofilierung versehen, die mit einer Profilierung des Nutgrundes des

Gabelkopfes korrespondiert. So können z.B. der Stützstab als Gewindestab ausgebildet sein und die Oberflächenprofilierung quer zur Längsachse des Korrekturstabs verlaufende Querrillen aufweisen. Dieser Gewindestab wird durch die Madenschraube optimal gegen axiale Verschiebung festgehalten.

Dabei korrespondieren vorteilhaft die Querrillen des Nutgrundes zum Gewinde des Korrekturstabes. Insbesondere weisen die Querrillen eine geringere Tiefe auf als das Gewinde des Korrekturstabes. Auf diese Weise wird eine optimale Verpressung und ggf. sogar eine plastische Verformung des Gewindestabes im Nutgrund erzielt. Außerdem weisen die Querrillen vorteilhaft eine dem Gewinde des Korrekturstabes entsprechende Steigung auf.

Eine andere Ausführungsform sieht vor, dass die Oberflächenprofilierung eine Riffelung ist. Mit einer derartigen Riffelung werden sowohl eine axiale Verschiebung als auch eine Verdrehung des Stützstabes verhindert.

Eine weitere Ausführungsform sieht vor, dass der Korrekturstab Umfangsnuten aufweist. Mittels dieser Umfangsnuten wird ebenfalls eine optimale Sicherheit gegen axiales Verschieben geschaffen.

Bei der erfindungsgemäßen Osteosynthesevorrichtung kann die dem Nutgrund zugewandte Flanke in radialer Richtung entweder linear, degressiv oder progressiv ansteigen. Je nach Einsatz und zu übertragender Kräfte wird die eine oder andere Form gewählt.

Dabei kann die Flanke in radialer Richtung gebogen, mit Absätzen oder mit Knicken versehen sein. Derartige, insbesondere diskrete Abstufungen haben den Vorteil, dass die Kräfte gezielt in das Gewinde des Gabelkopfes eingeleitet werden kann.

Eine weitere Ausführungsform sieht vor, dass wenigstens in einem Abschnitt des Gewindes der Steigungswinkel der einzelnen, vom Nutgrund zu den freien Enden der Schenkel des Gabelkopfes angeordneten Flanken gleich ist, abnimmt oder zunimmt.

Eine optimale Handhabung der Madenschraube wird dadurch erzielt, dass die Madenschraube an ihrem freien Ende einen Innensechskant aufweist, so dass sie mit einem Sechskantwerkzeug betätigbar ist.

Bei einer weiteren Variante der Erfindung ist vorgesehen, dass die Innenseiten der Schenkel des Gabelkopfes mit einem Abschnitt eines Innengewindes versehen sind und das

Innengewinde eine Flanke aufweist, die, ausgehend von der Achse der Knochenschraube in radialer Richtung gesehen, mit einer Hinterschneidung versehen ist. Eine derartige Hinterschneidung kann z.B. eine Stufe sein oder schwalbenschwanzartig ausgebildet sein.

Insbesondere ist die Madenschraube mit einem Außengewinde versehen, welches dem Innengewinde des Gabelkopfes entspricht.

Weitere Vorteile, Merkmale und Einzelheiten der Erfindung ergeben sich aus den Unteransprüchen sowie der nachfolgenden Beschreibung, in der unter Bezugnahme auf die Zeichnung besonders bevorzugte Ausführungsbeispiele im Einzelnen beschrieben sind. Dabei können die in der Zeichnung dargestellten und in den Ansprüchen sowie in der Beschreibung erwähnten Merkmale jeweils einzeln für sich oder in beliebiger Kombination erfindungswesentlich sein. In der Zeichnung zeigen:

Figur 1 einen Längsschnitt, teilweise abgebrochen, durch ein erstes Ausführungsbeispiel eines Gabelkopfes einer Knochenschraube mit eingelegtem Stützstab und eingeschraubter Madenschraube; und

Figur 2 einen Längsschnitt durch eine zweite Ausführungsform einer erfindungsgemäßen Knochenschraube.

Die Figur 1 zeigt ein erstes Ausführungsbeispiel der erfindungsgemäßen Osteosynthesevorrichtung mit einer Knochenschraube 1, einem lediglich andeutungsweise dargestellten Stützstab 2 sowie einer Madenschraube 3. Von der Knochenschraube ist lediglich der Gabelkopf 4 dargestellt, welcher in den Gewindeteil übergeht, welcher das in den Knochen einzuschraubende Gewinde aufweist.

Der Gabelkopf 4 weist zwei Schenkel 5 auf, von denen lediglich einer dargestellt ist. Die beiden Schenkel bilden eine Nut 6, welche einen Nutgrund 7 aufweist. Dieser Nutgrund 7 ist mit einer Oberflächenprofilierung 8 versehen. In der Nut 6 und auf der Oberflächenprofilierung 8 liegt der Stützstab 2 auf und wird von der Madenschraube 3 festgehalten. Diese Madenschraube 3 ist in den Gabelkopf 4 eingeschraubt. Hierfür weist der Schenkel 5 ein insgesamt mit 9 bezeichnetes Innengewinde auf. Dieses Innengewinde 9 weist die Form eines Tannenbaums auf, wobei sowohl die dem Nutgrund 7 zugewandte untere Flanke 10 als auch die obere Flanke 11 von der Achse 12 der Knochenschraube 1 in radialer Richtung gesehen ansteigen. Der Steigungswinkel $\alpha$ der unteren Flanke 10 ist also größer Null.

Die Madenschraube 3 weist ein insgesamt mit 12 bezeichnetes Außengewinde auf, welches zum Innengewinde 9 des Gabelkopfes 4 korrespondiert.

Am freien Ende besitzt die Madenschraube 3 eine Ausnehmung 13 mit einem Innensechskant 14, in welche ein Sechskant-Werkzeug eingesetzt und damit die Madenschraube 3 betätigt werden kann.

An ihrem dem Stützstab 2 zugewandten freien Ende besitzt die Madenschraube 3 eine Ringschneide 15, welche sich beim Festziehen der Madenschraube 3 in die Oberfläche des Stützstabe 2 eingräbt und dadurch den Stützstab 2 zusätzlich festhält. Die Oberflächenprofilierung 8 korrespondiert zum Oberflächenprofil 16 des Stützstabes 2. Besitzt der Stützstab 2 als Oberflächenprofil 16 Längsnuten, d.h. in Richtung der Längsachse des Stützstabes 2 verlaufende Nuten, dann ist die Oberflächenprofilierung 8 des Nutgrundes 9 ebenfalls in Form von Längsnuten ausgebildet. Ist der Stützstab 2 ein Gewindestab, dann weist die Oberflächenprofilierung 8 Quernuten mit einer Steigung auf, die der Gewindesteigung des Stützstabes 2 entspricht.

Beim Ausführungsbeispiel der Figur 2 besitzt der Gabelkopf 4 der Knochenschraube 1 ebenfalls ein Gewinde, welches

jedoch mit einer ebenen oberen Flanke 11 und einer stufenartig ausgebildeten unteren Flanke 10 versehen ist. Die Stufe der unteren Flanke 10 ist derart geformt, dass sie einen Hinterschnitt 17 bildet. Über diesen Hinterschnitt 17 wird verhindert, insbesondere über die Schulter 18, dass der Schenkel 5 beim Einschrauben der Madenschraube 3 radial nach außen gebogen wird. In radialer Richtung wird also zwischen Gabelkopf 4 und Madenschraube 3 ein Formschluss geschaffen. Über diesen Formschluss wird, wie bereits erwähnt, ein Ausweichen des Schenkels 5 verhindert.

**Schutzansprüche**

1. Osteosynthesevorrichtung mit einer Knochenschraube (1) mit einem eine Nut (6) aufweisenden Gabelkopf (4) und einem in die Nut (6) des Gabelkopfes (4) einzulegenden Stützstab (2), der ein Oberflächenprofil aufweist, der Gabelkopf (4) im Nutgrund (7) eine Oberflächenprofilierung (8) aufweist und der Gabelkopf (4) mit einer den Stützstab (2) fixierenden Madenschraube (3) versehen ist, wobei die Oberflächenprofilierung (8) des Nutgrundes (7) die Halterung des Stützstabes (2) in der Nut (6) ermöglichende Mittel aufweist und die Innenseiten der Schenkel (5) des Gabelkopfes (4) mit einem Abschnitt eines Innengewindes (9) versehen sind und das Innengewinde (9) nach Art eines Tannenbaumgewindes ausgebildet ist und eine dem Nutgrund (7) zugewandte Flanke (10) aufweist, die, ausgehend von der Achse (19) der Knochenschraube (1) in radialer Richtung gesehen, ansteigt.

2. Osteosynthesevorrichtung nach Anspruch 1, dadurch gekennzeichnet, dass die Flanke (10) radialer Richtung linear ansteigt.

3. Osteosynthesevorrichtung nach einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, dass die Flanke (10) in radialer Richtung gebogen ist.

4. Osteosynthesevorrichtung nach einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, dass wenigstens in einem Abschnitt des Gewindes der Steigungswinkel ($\alpha$) der einzelnen, zwischen dem Nutgrund (7) und den freien Enden der Schenkel (5) des Gabelkopfes (4) vorgesehenen Flanken (10) gleich ist, abnimmt oder zunimmt.

5. Osteosynthesevorrichtung nach einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, dass die Madenschraube (3) mit einem Innensechskant (14) betätigbar ist.

6. Osteosynthesevorrichtung nach einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, dass der Nutgrund (7) mit Längsrillen versehen ist.

7. Osteosynthesevorrichtung nach einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, dass der Stützstab (2) ein Gewindestab ist und die Oberflächenprofilierung (8) quer zur Längsachse des Stützstabes (2) verlaufende Querrillen aufweist.