8. Osteosynthesevorrichtung nach Anspruch 7, dadurch gekennzeichnet, dass die Querrillen zum Gewinde des Stützstabes (2) korrespondieren.

9. Osteosynthesevorrichtung nach Anspruch 8, dadurch gekennzeichnet, dass die Querrillen eine geringere Tiefe aufweisen als das Gewinde des Stützstabes (2).

10. Osteosynthesevorrichtung nach Anspruch 8 oder 9, dadurch gekennzeichnet, dass die Querrillen eine dem Gewinde des Stützstabes (2) entsprechende Steigung aufweisen.

11. Osteosynthesevorrichtung nach einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, dass die Oberflächenprofilierung (8) eine Riffelung ist.

12. Osteosynthesevorrichtung nach einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, dass der Stützstab (2) Umfangsnuten aufweist.

13. 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) eine Flanke (10) aufweist, die, ausgehend von der Achse (19) der Knochenschraube (1) in radialer Richtung gesehen, mit einer Hinterschneidung (17) versehen ist.

14. 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) und die Madenschraube (3) ausgehend von der Achse (19) der Knochenschraube (1) in radialer Richtung gesehen, formschlüssig miteinander verbunden sind.

15. Osteosynthesevorrichtung nach einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, dass die Madenschraube (3) ein dem Innengewinde (14) des Gabelkopfes (4) entsprechendes Aussengewinde (12) aufweist.

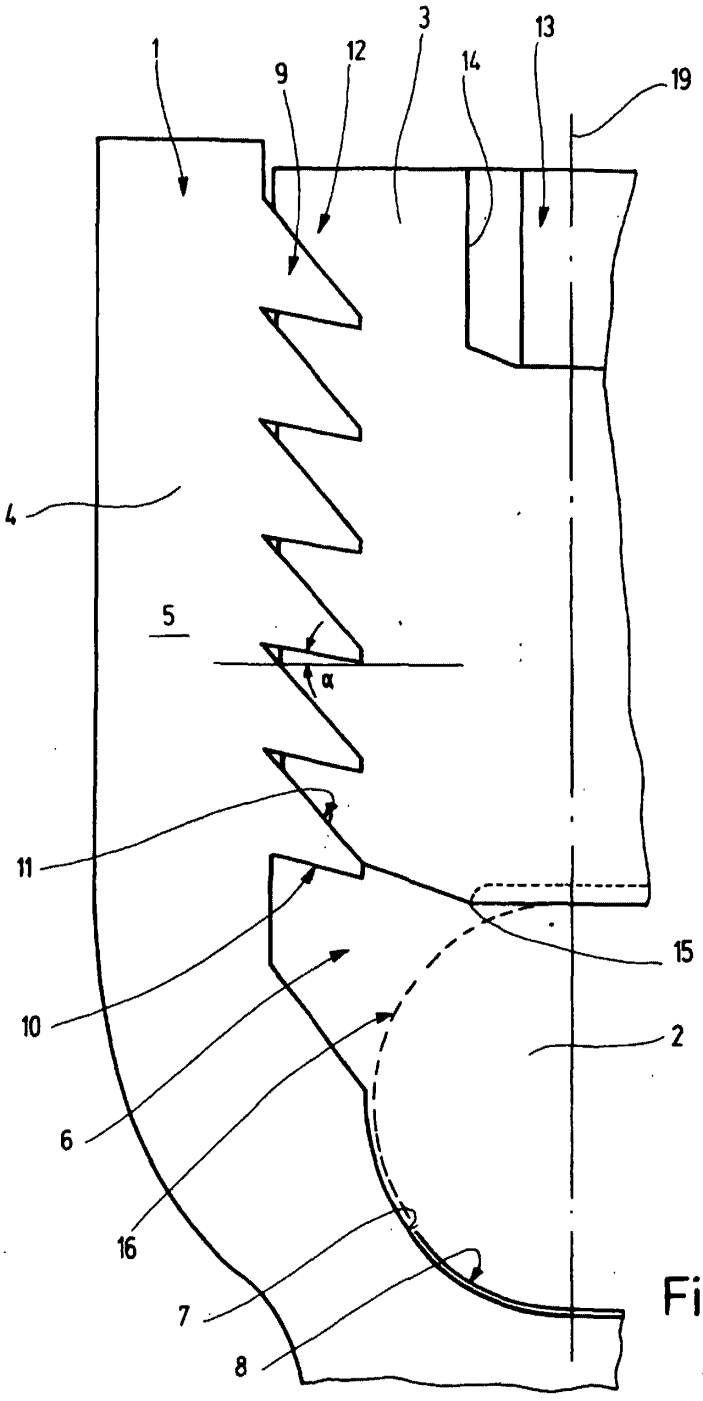


Fig. 1

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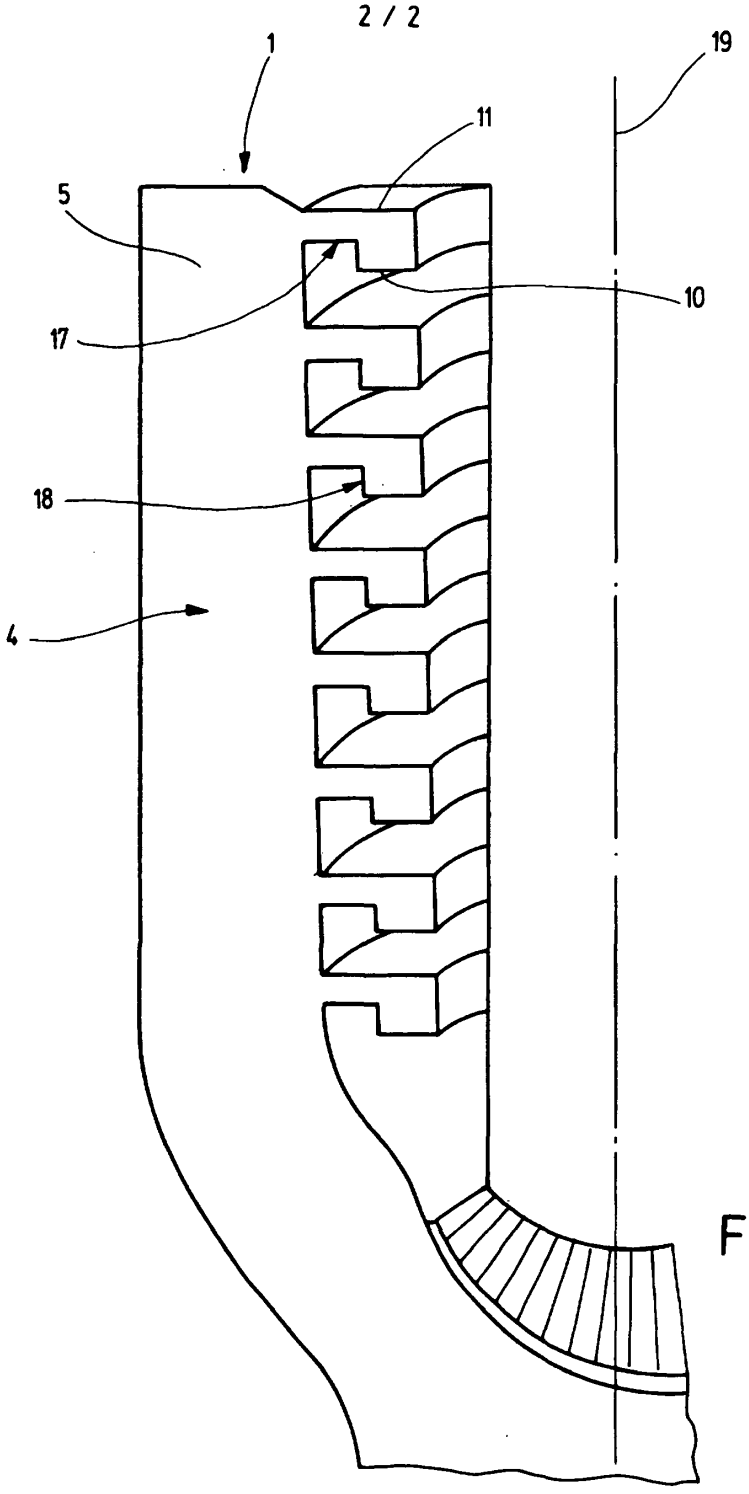


Fig. 2

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(71) Anmelder *(für alle Bestimmungsstaaten mit Ausnahme von CA, US)*: **SYNTHES AG CHUR** [CH/CH]; Grabenstrasse 15, CH-7002 Chur (CH).

(71) Anmelder *(nur für CA)*: **SYNTHES (U.S.A.)** [US/US]; 1690 Russell Road, P.O. Box 1766, Paoli, PA 19301-1222 (US).

(72) Erfinder; und

(75) Erfinder/Anmelder *(nur für US)*: **SCHLÄPFER, Fridolin** [CH/CH]; Bölchenstrasse 1, CH-4434 Hölstein (CH). **HESS, Martin** [CH/CH]; Schützenstrasse 2, CH-4434 Hölstein (CH).

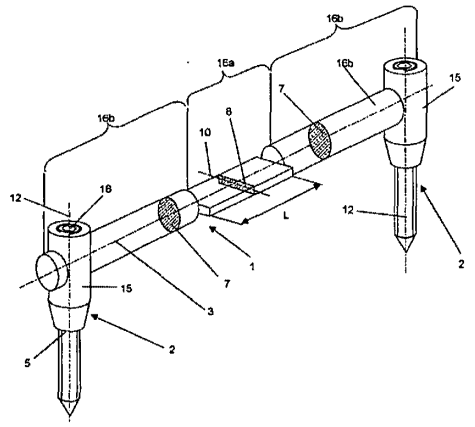
(74) Anwalt: **LUSUARDI, Werther**; Dr. Lusuardi AG, Kreuzbühlstrasse 8, CH-8008 Zürich (CH).

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[Fortsetzung auf der nächsten Seite]

(54) Title: DEVICE FOR DYNAMIC BONE STABILIZATION

(54) Bezeichnung: VORRICHTUNG ZUR DYNAMISCHEN STABILISIERUNG VON KNOCHEN



(57) Abstract: The invention concerns a device for dynamic stabilization of bones or bone fragments, in particular of vertebral bodies (4), and comprising: A) at least one longitudinal support (1) with longitudinal axis (3) and B) at least two bone anchoring means (2) respectively provided with a central axis (12) and an anchoring element (14) to be anchored on a bone. The invention is characterized in that C) each bone anchoring means (2) can be removably fixed on a longitudinal support (1) via a linking element equipped with clamping means (18). The longitudinal support (1) comprises in the axial direction D) a number ≥ 1 of flexible segments (16a) having a section surface (8) orthogonal to the longitudinal axis (3) and corresponding neither to a circle nor a regular polygon, and E) a number m = (n + 1) of practically rigid segments (16b) with any surface section, such that F) in total a number z ≥ (2n + 1) of axial segments (16a, 16b) is obtained.

(57) Zusammenfassung: Vorrichtung zur dynamischen Stabilisierung von Knochen oder Knochenfragmenten, insbesondere von Wirbelkörpern (4) mit A) mindestens einem eine Längsachse (3) aufweisenden longitudinalen Längsträger (1); und B) mindestens zwei Knochenverankerungsmitteln (2) mit je einer Zentralachse (12) und je einem zur Verankerung

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WO 2005/104969 A1

PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) **Bestimmungsstaaten** *(soweit nicht anders angegeben, für jede verfügbare regionale Schutzrechtsart)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), eurasisches (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), europäisches (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Veröffentlicht:
— *mit internationalem Recherchenbericht*

Zur Erklärung der Zweibuchstaben-Codes und der anderen Abkürzungen wird auf die Erklärungen ("Guidance Notes on Codes and Abbreviations") am Anfang jeder regulären Ausgabe der PCT-Gazette verwiesen.

an einem Knochen bestimmten Verankerungsteil (14), wobei C) jedes Knochenverankerungsmittel (2) mittels eines mit Spannmitteln (18) ausgestatteten Verbindungsteils (15) an einem Längsträger (1) lösbar befestigbar ist, wobei der mindestens eine Längsträger (1) in axialer Richtung D) eine Anzahl $n \geq 1$ flexible Segmente (16a) mit einer zur Längsachse (3) orthogonalen Querschnittsfläche (8) umfasst, welche weder einem Kreis noch einem regelmässigen Polygon entspricht, sowie E) eine Anzahl $m = (n + 1)$ von im wesentlichen steifen Segmente (16b) beliebiger Querschnittsfläche umfasst, so dass F) gesamthaft eine Anzahl $z \geq (2n + 1)$ von axialen Segmenten (16a; 16b) resultiert.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 572 of 2152

Vorrichtung zur dynamischen Stabilisierung von Knochen

Die Erfindung bezieht sich auf eine Vorrichtung zur dynamischen Stabilisierung von Knochen und Knochenfragmenten, insbesondere von Wirbelkörpern, gemäss dem Oberbegriff des Patentanspruchs 1.

Die Wirbelsäule ist das Zentrum eines komplexen Prozesses zur Austarierung von externen und internen Kräften und Momenten. Die Kräfte und Momente werden dabei durch die Muskeln balanciert mit der Wirbelsäule als Widerlager.

Die Wirbelsäule hat gleichzeitig eine formgebende Funktion (Biegen nach vorne und hinten, Ausdrehen, etc.) und spielt auch eine grosse Rolle bei der Dämpfung.

Bei der Stabilisierung von Segmenten der Wirbelsäule auf Grund von degenerativen Erkrankungen, Frakturen, Deformitäten etc. muss darauf geachtet werden, dass der Einfluss der Stabilisierung auf die Funktionen der Wirbelsäule möglichst minimal gehalten wird.

In Fällen, wo keine Korrekturkräfte notwendig sind, kann dies bewerkstelligt werden, indem die betroffenen Segmente nicht fusioniert sondern deren geschwächte Strukturen gezielt intern durch ein dynamisches, mit der Wirbelsäule verbundenes System gestützt werden. Dabei muss realisiert werden, dass im Gegensatz zur Bandscheibenendoprothese die betroffenen Strukturen nicht entfernt werden. Dementsprechend löst eine Wiederherstellung des physiologischen Bewegungsmusters je nach Degenerationsgrad nicht unbedingt das klinische Problem.

Hauptindikationen für ein dynamisches System sind Erkrankungen, Entzündungen und/oder Verletzungen im Bereich der Bandscheibe, des Bandapparates, der Fazettengelenke und/oder des subchondralen Knochens. In diesen Situationen ist es wichtig, dass

a) der Schmerz behoben und der Fortgang der Pathologie zumindest eingefroren werden,

b) eine den Metabolismus der Strukturen (Bandscheibe, Bänder, Fazettengelenke) unterstützende Restbewegung übrigbleibt.

Klinisch identifizierbare Schmerzzonen sind von posterior nach anterior gesehen die Fazettengelenke, der posteriore Annulus, und der subchondrale Knochen unterhalb der knöchernen Deckplatte des Wirbelkörpers. Die Schmerzen können rein mechanischer Natur sein oder durch aseptische Entzündungen (durch mechanische und/oder chemische Reizungen bewirkt) ausgelöst werden. Linderung der Schmerzen und Abheilung von Entzündungen bedingen eine Reduktion der Belastung und damit der Dehnung der betroffenen Strukturen.

Der AO Wirbelsäulen Fixateur externe (Systembeschreibung in „Fixateur externe", Autoren: B.G. Weber und F. Magerl, Springer-Verlag 1985, Seite 290 – 366) wird derzeit vor allem für diagnostische Zwecke eingesetzt. Auf Grund seiner Konfiguration ist er sehr steif in Schub und Rotation und flexibel in Flexion/Extension und Seitneigung. Durch die extrem posteriore Lage des Rahmens des Fixateur extern werden bei Flexion und Extension die Bandscheibe und die knöchernen Deckplatten der angrenzenden Wirbeln mehr oder weniger gleichmässig in Kompression belastet. Im Gegensatz dazu findet beim intakten Bewegungssegment ein Abrollen über den zentralen Nucleus statt. Dabei werden der posteriore und anteriore Teil des Annulus wechselseitig auf Zug und Druck belastet. Die grösste Belastung der knöchernen Deckplatten der angrenzenden Wirbeln tritt dabei im Bereich des Nucleus auf. Da das Nucleusmaterial eine gelartige Masse darstellt, wird die Masse bei Flexion und Extension hin- und hergewalkt und dabei gegen den Annulus gepresst. Wenn der Anulus Risse auf Grund eines degenerativen Prozesses oder eines traumatischen Vorfalles aufweist, dringt bei dieser Walkbewegung Nucleusmaterial in die Risse ein. Wenn das Nucleusmaterial dabei bis in den innervierten und vaskularisierten Aussenbereich des Annulus vordringt oder gar aus der Bandscheibe austritt und mit der entsprechenden Nervenwurzel in Kontakt kommt, können entzündliche Prozesse mit den entsprechenden Schmerzen ausgelöst werden. Das aus dem Zusammenspiel zwischen Fixateur externe und Bandscheibe entstandene Bewegungsmuster (bestehend aus einer mehr oder weniger vertikalen

Bewegung im Bereich der Bandscheibe) reduziert das Risiko, dass Nucleusmaterial in den Aussenbereich des Annulus gedrückt bzw. gepumpt wird.

Mit dem Ausschliessen der Walkbewegung bei Flexion und Extension werden durch den Fixateur extern gleichzeitig die knöchernen Deckplatten der angrenzenden Wirbel und damit der darunterliegende subchondrale Knochen entlastet. Diese Entlastung kann bei entzündlichen Veränderungen im subchondralen Knochen (beschrieben durch Modic Change 1) zu einer Reduktion der Schmerzen führen. Mit der Entlastung der Deckplatten sind auch die Voraussetzungen für eine Abheilung der Entzündung geschaffen.

Bei dehydriertem Nucleus fehlt der radiale Druck auf den Annulus mit dem Effekt, dass die bei Flexion und Extension entstehende hohe lokale Belastung des Annulus zu dessen Delamination führen kann. Durch den Fixateur externe wird, wie schon oben erwähnt, der bei Flexion und Extension entstehende Druck gleichmässig über die ganze Bandscheibe verteilt. Damit wird das Risiko einer Delamination des posterioren Annulus reduziert.

Die klinische Erfahrung mit dem diagnostisch eingesetzten AO Wirbelsäulen Fixateur externe zeigt, dass ein System, das steif in Rotation und Schub und flexibel in Flexion/Extension und Seitneigung ist, zu einer Reduktion der Beschwerden führen kann.

Da der AO Wirbelsäulen Fixateur externe nur für diagnostische Zwecke und damit nur kurzfristig eingesetzt wird, gibt die mit dem System gewonnene klinische Erfahrung keine Information, inwieweit mit einem System wie dem Fixateur externe der Metabolismus der Weichteilstrukturen aufrecht erhalten bleibt.

Das im Patent EP 0 669 109 B1 (Baumgartner) beschriebene System wird seit einigen Jahren klinisch erfolgreich eingesetzt. Durch die posteriore Lage der Längsträger entsteht eine ähnliche Situation im Bandscheibenbereich wie beim AO Wirbelsäulen Fixateur externe. Die mehrjährige klinische Erfahrung mit dem System deutet darauf hin, dass der Metabolismus der Weichteilstrukturen aufrecht erhalten bleibt.

Basierend auf der klinischen Erfahrung mit dem AO Wirbelsäulen Fixateur interne und dem im Patent EP 0 669 109 B1 (Baumgartner) beschriebenen System muss ein zur Stützung der Wirbelsäulenstrukturen eingesetztes System steif auf Rotation und Schub und flexibel auf Flexion und Extension sein, um einerseits die Beschwerden zu reduzieren und andererseits den Metabolismus der betroffenen Strukturen aufrecht zu erhalten, letzteres um die Voraussetzungen für biologisches Remodeling und Heilung zu schaffen. Ein solches System ist im Oberbegriff des Patentanspruchs 1 beschrieben.

Das im Patent EP 0 669 109 B1 (Baumgartner) beschriebene System verschiebt den Drehpunkt des Wirbelsäulensegmentes aus der Bandscheibe heraus nach posterior in den Bereich der Fazettengelenke. Auf Grund des zentral gelegenen Bandes weist das System eine im Vergleich zum AO Wirbelsäulen Fixateur externe reduzierte Rotations- und Schubsteifigkeit auf.

Neben der reduzierten Rotations- und Schubsteifigkeit hat das im Patent EP 0 669 109 B1 (Baumgartner) beschriebene System auch Nachteile in Bezug auf die Handhabung:

- Aufwendiges Auffädeln der Stützelemente auf das Band
- Zuschneiden der Stützelemente auf die gewünschte Länge. Dabei muss darauf geachtet werden, dass die Schnittflächen parallel zu den Seitenflächen der Knochenschrauben zu stehen kommen.
- Wenn die Knochenschrauben nach anterior divergierend eingebracht sind, ist es schwierig von posterior her die Stützelemente zwischen die Schraubenköpfe zu bringen.

Durch die zentrale Lage des Bandes federt das System nicht automatisch in die Ausgangslage zurück.

Kugelgelenkartige Verbindungen zwischen Pedikelschraube und Längsträger, wie sie zum Beispiel in den Patenten WO 94/00066 (Schläpfer) und PCT/CH02/00672 (Schläpfer) beschrieben werden, erlauben eine spannungsfreie Montage des Implantates mit anschliessender Blockierung aller Freiheitsgrade.

Um trotz der winkelstabilen Verbindung zwischen den Pedikelschrauben und dem Längsträger ein gewisses dynamisches Verhalten des Konstruktes zu gewährleisten, können entweder die beiden oberen (kranialen) Kugelverbindungen zwischen den oberen Pedikelschrauben und den Längsträgern lose gelassen oder die Längsträger selbst flexibel gestaltet werden.

Flexible Längsträger werden unter anderem in den Patenten DE 42 39 716 C1 (Winter), WO 95/27444 (Alby), WO 98/22033 (Elberg), WO 02/102259 A2 (Sengupta) und WO 93/20771 (Mazel) beschrieben. Die beiden erstgenannten Patente umfassen Systeme, die aus beweglichen Teilen bestehen. Bewegliche Teile haben den grossen Nachteil von Abrieb.

Die beiden Patente WO 98/22033 (Elberg) und WO 02/102259 A2 (Sengupta) beschreiben Systeme mit gebogenen, federnden Längsträgern. Beim erstgenannten Patent weist der Längsträger einen Anschlag auf, der die Biegung in einer Richtung beschränkt. Richtig ausgelegt, ermöglichen die in den beiden Patenten beschriebenen Systeme eine dynamische Stabilisierung der geschwächten Strukturen der Wirbelsäule.

Das Patent WO 93/20771 (Mazel) umschreibt ein System, das aus flexiblen Stäben besteht. Auch hier ist, wenn richtig ausgelegt, eine dynamische Stabilisierung der geschwächten Strukturen der Wirbelsäule möglich.

Der Erfindung liegt die Aufgabe zu Grunde, einen mit Knochenverankerungsmitteln verbindbaren Längsträger zu schaffen, der bei einer vorgegebenen Festigkeit, insbesondere Schubsteifigkeit eine maximale Flexibilität in Biegung aufweist.

Die Erfindung löst die gestellte Aufgabe mit einer Vorrichtung zur dynamischen Stabilisierung von Knochen und Knochenfragmenten, insbesondere von Wirbelkörpern, welche die Merkmale des Anspruchs 1 aufweist.

Weitere vorteilhafte Ausgestaltungen der Erfindung sind in den abhängigen Ansprüchen gekennzeichnet.

Die durch die Erfindung erreichten Vorteile gegenüber den bestehenden Systemen sind wie folgt:

- Maximale Biegeflexibilität bei vorgegebener Festigkeit
- Entkopplung von Schubsteifigkeit und Biegeflexibilität
- Eine Kombination mit den in den Patenten WO 94/00066 (Schläpfer) und PCT/CH02/00672 (Schläpfer) beschriebenen, dreidimensionalen Verbindungen zwischen Längsträger und Knochenverankerungsmittel ermöglicht eine spannungsfreie Montage des Längsträgers.

Wenn eine Fusion durchgeführt wird, muss das zur Stabilisierung verwendete System eine so grosse Steifigkeit aufweisen, dass die Bewegung im zu fusionierenden Bewegungssegment so klein ist, dass eine knöcherne Überbrückung der Wirbel stattfindet. Das zur Stabilisierung verwendete System ist mechanisch gesehen parallel zum zu fusionierende Wirbelsäulensegment geschaltet, d.h. je steifer das System ist, um so grösser ist der über das System geleitete Anteil der Wirbelsäulenbelastung. Dementsprechend stark muss das System ausgelegt werden.

Im Gegensatz dazu ist wie oben ausführlich dargelegt bei einer dynamischen Stabilisierung eines Wirbelsäulensegmentes Biegeflexibilität kombiniert mit Kompressions-, Rotations- und Schubsteifigkeit gefragt.

Bei der mechanischen Dimensionierung muss ein dynamisches Fixationssystem mit besagten Eigenschaften dementsprechend in Bezug auf Biegung auf eine Maximaldeformation und in Bezug auf Kompression, Schub und Rotation auf eine Maximallast dimensioniert werden. Die entsprechenden Bedingungen können mit der linearen Elastizitätstheorie angenähert werden.

Im Falle eines von posterior durch die Pedikel verankerten dynamischen Fixationssystems werden die Längsträger vorwiegend in Biegung belastet.

Dementsprechend können die oben dargelegten Bedingungen für die einzelnen als Biegebalken wirkenden Längsträger durch

a) die Differentialgleichung der elastischen Biegelinie der Balkenachse (Eulersche Elastika)

$$\frac{w(z)''}{(1 + w(z)'^2)^{3/2}} = \frac{M_b(z)}{E * I_y(z)} \qquad (1)$$

b) die Momentengleichung

$$M_b(z) = M_y + F_y * (l - z) - F_z * w(z) \qquad (2)$$

c) das Hooke'sche Gesetz

$$\sigma_b(x,z) = \frac{M_b(z)}{I_y(z)} * z \qquad (3)$$

d) und die Fliessbedingung nach Maxwell (von Mises) oder Tresca

$$\sigma_x^2 + \sigma_z^2 - \sigma_x * \sigma_z + 3 * \tau_{xz}^2 (x,z) \quad \text{von Mises} \qquad (4a)$$

$$\sigma_x^2 + \sigma_z^2 - \sigma_x * \sigma_z + 4 * \tau_{xz}^2 (x,z) \quad \text{Tresca} \qquad (4b)$$

beschrieben werden.

Bei Variierung der Dicke des Querschnittes und/oder der Materialsteifigkeit (mit oder ohne zusätzlicher Faserverstärkung wie z.B. Kohlefasern) entlang dem Längsträger wird es möglich, Biegeflexibilität mit Schubsteifigkeit zu kombinieren. Die Schubkräfte werden über die kranialen Pedikelschrauben auf das Konstrukt übertragen → die durch die Schubkräfte im Konstrukt bewirkte Biegebelastung nimmt linear von kranial (Null) nach kaudal (Maximum) zu. Im Gegensatz dazu bewirken in der sagittalen Ebene agierende Biegemomente eine homogene Biegebelastung über die ganze Länge des Konstruktes. Wenn nun die Längsträger des Konstruktes kaudal möglichst steif und

kranial möglichst flexibel gestaltet werden, kann das Konstrukt Schubkräfte aufnehmen, während es auf Biegung nach wie vor flexibel ist.

Die einzelnen Längsträger bestehen aus „z" seriell angeordneten Segmenten, wobei $z \geq 3$ ist. Der Uebergang zwischen den einzelnen Segmenten kann kontinuierlich verlaufen oder diskret (abrupt) sein.

Die einzelnen Segmente unterscheiden sich in der Grösse und Form des Querschnittes und/oder der Materialsteifigkeit. Innerhalb der Segmente selbst kann der Querschnitt wie auch die Materialsteifigkeit variieren.

Von den z Segmenten sind mindestens die Endsegmente im Vergleich zu den „n" dazwischen liegenden, flexiblen Segmenten in Biegung mindestens doppelt so steif.

Die „n" flexiblen Segmente mit $1 \leq n \leq z-2$ sind wie schon erwähnt derart ausgelegt, dass sie bei einer vorgegebenen Biegedeformation des Längsträgers nicht mechanisch versagen. Die besagte Biegedeformation des Längsträgers ist die Summe der in den einzelnen flexiblen Segmenten auftretenden Deformation.

Die Querschnittsflächen der n flexiblen Segmente können beispielsweise rechteckig, trapezförmig, rhombisch, dreieckig (aber nicht gleichseitig) , oval oder elliptisch sein.

In einer bevorzugten Ausführungsform sind die Querschnittsflächen mindestens eines der n flexiblen Segmente mit einer abgeflachten Querschnittsfläche rechteckig ausgebildet. Der Vorteil dieser Ausgestaltung liegt darin, dass mit einer rechteckigen Gestaltung des Querschnittes der flexiblen Segmente der Längsträger bei einer vorgegebenen Flexibilität eine optimale Festigkeit erreicht wird. Bei Variierung des Querschnittes von kaudal nach kranial (kaudal dick, kranial dünn), kann Biegeflexibilität mit Rotationssteifigkeit und Schubsteifigkeit kombiniert werden. Die anzustrebende, bei einer vorgegebenen Festigkeit maximale Flexibilität in Biegung wird nur durch eine rechteckige Gestaltung des Querschnittes des flexiblen Teils des Längsträgers erreicht. Eine rechteckige Gestaltung des Längsträgers bedingt eine dreidimensionale kugelige Verbindung zwischen Längsträger und Pedikelschraube wie sie zum Beispiel in den Patenten WO 94/00066 (Schläpfer) und PCT/CH02/00672 (Schläpfer) beschrieben ist.

Die z – n im wesentlichen steifen Segmente des Längsträgers sind vorzugsweise zylindrisch oder prismatisch ausgebildet, wobei deren zur Längsachse orthogonale Querschnittsfläche vorzugsweise radialsymmetrisch ausgestaltet sind. Der Längsträger umfasst axial aussenstehend je eines dieser z – n steifen Segmente, so dass der Längsträger mittels dieser aussenstehenden Segmente in den Verbindungsteilen unter verschiedenen – im Falle einer kreiszylindrischen Ausgestaltung dieser aussenstehenden steifen Segmente mit einem beliebigen - Drehwinkel relativ zur Längsachse verbindbar ist. Die Querschnittsfläche dieser z – n steifen Segmente, insbesondere der aussenstehenden steifen Segmente ist vorzugsweise kreisförmig.

Unter der Annahme, dass der Querschnitt und die Materialsteifigkeit des Segmentes über dessen Länge L konstant bleibt, gilt für n = 1 flexible Segmente:

Dicke $\leq \sigma_{zul} / E \times$ „freie Länge" $\times 2 / \text{tg}\, \alpha$

e $\leq \sigma_{zul} / E \times$ L $\times$ 28 für $\alpha = 4°$

wobei:

α .... Deformationswinkel des Längsträgers, zwischen 4° und 12° , vorzugsweise 8°

e .... senkrecht zur Biegeachse gemessene Dicke eines elastischen Segmentes

L .... Länge des elastischen Segmentes

σ_{zul} .... dynamische Biegefestigkeit des Materials (z.B. 48 N/mm^2 für Kunststoff bis 1400 N/mm^2 für Stahl)

E .... Elastizitätsmodul (28 N/mm^2 für Kunststoff bis 220'000 N/mm^2 für Stahl)

σ_{zul} / E: $0.5 \geq \sigma_{zul} / E \geq 0.005$

Vorzugsweise sind die n flexiblen Segmente mit Abmessungen innerhalb der folgenden Grenzen ausgestaltet:

- Breite b zwischen 8 mm und 15 mm, vorzugsweise zwischen 10 mm und 13 mm;
- Dicke e zwischen 0,5 mm und 3 mm, vozugsweise zwischen 0,9 und 1,1 mm; und
- Länge L zwischen 2 mm und 30 mm, vorzugsweise zwischen 5 mm und 15 mm.

Für n > 1 flexible Segmente gilt:

$e^i \leq \sigma^i_{zul} / E^i \times L^i \times 2 / \text{tg}\, \alpha^i$

wobei: $i = 1$ bis n

$\Sigma^{i=1 \text{ bis } n} \alpha^i = \alpha \quad 4° \leq \alpha \leq 12°$

Vorzugsweise sind die n flexiblen Segmente mit Abmessungen innerhalb der folgenden Grenzen ausgestaltet:

- Breite b zwischen 8 mm und 15 mm, vorzugsweise zwischen 10 mm und 13 mm;
- Dicke e zwischen 0,5 mm und 3 mm, vozugsweise zwischen 0,9 und 1,1 mm; und
- Länge L zwischen 2 mm und 30 mm, vorzugsweise zwischen 5 mm und 15 mm.

Der Längsträger wird vorzugsweise aus einem der folgenden Materialien hergestellt:

- aus hochfestem Titan;
- aus einer hochfesten Titanlegierung;
- aus hochfestem Stahl;
- aus einer Cobalt-Chrom Legierung;
- aus einem hochfesten, monokristallinen Material; oder
- aus einem durch hochfeste, monokristallinen Fasern verstärkten Material.

Die Erfindung und Weiterbildungen der Erfindung werden im folgenden anhand der teilweise schematischen Darstellungen mehrerer Ausführungsbeispiele noch näher erläutert.

Es zeigen:

Fig. 1 eine perspektivische Darstellung einer Ausführungsform der erfindungsgemässen Vorrichtung;

Fig. 2 eine zur Längsachse orthogonale Querschnittsfläche eines flexiblen Segmentes des Längsträgers in einer Ausführungsform der erfindungsgemässen Vorrichtung;

Fig. 3 einen Schnitt durch ein Knochenverankerungsmittel gemäss einer Ausführungsform der erfindungsgemässen Vorrichtung;

Fig. 4 eine Ansicht einer Ausführungsform der erfindungsgemässen Vorrichtung als Wirbelsäulenstabilisationsvorrichtung;

Fig. 5a eine schematische Darstellung eines mittels zweier Knochenverankerungsmitel an zwei benachbarten Wirbelkörpern befestigten Längsträgers gemäss einer Ausführungsform der erfindungsgemässen Vorrichtung;

Fig. 5b einen Ausschnitt aus einem flexiblen Segment eines Längsträgers gemäss einer Ausführungsform der erfindungsgemässen Vorrichtung; und

Fig. 6 eine Graphik zur vereinfachten Darstellung der Bruchkriterien für den Längsträger gemäss einer Ausführungsform der erfindungsgemässen Vorrichtung.

In Fig. 1 ist eine Ausführungsform dargestellt, welche zwei als Pedikelschrauben 5 mit integrierten Verbindungsteilen 15 ausgeführte Knochenverankerungsmittel 2 mit je einer Zentralachse 12 und einen Längsträger 1 mit einer Längsachse 3 umfasst. Der Längsträger 1 besteht aus gesamthaft z = 3 Segmenten 16, wobei die beiden axial aussenstehenden Segmente 16b steif sind und das eine Länge L aufweisende, flexible Segment 16a (n = 1) axial zwischen den zwei steifen Segmenten 16b angeordnet ist. Wie in Fig. 2 gezeigt weist das mittig angeordnete, flexible Segment 16a eine zur Längsachse 3 orthogonale rechteckige Querschnittsfläche 8 mit einer Breite b und einer Dicke e auf. Dabei ist die Breite b der rechteckförmigen Querschnittsfläche 8 quer zu der Längsachse 3 des Längsträgers 1 und quer zu den Zentralachsen 12 der Knochenverankerungsmittel 2 angeordnet. Das flexible Segment 16a ist durch seine Form bevorzugt bezüglich der mit einer zur langen Achse der rechteckförmigen Querschnittsfläche 8 zusammenfallenden oder parallelen Biegeachse 10 elastisch biegbar. Die Knochenverankerungsmittel 2 sind über die Verbindungsteile 15 mit den steifen, kreiszylindrisch ausgebildeten Segmenten 16b des Längsträgers 1 lösbar verbunden.

Die in Fig. 3 dargestellte Ausführungsform der Knochenverankerungsmittel 2 umfassen Pedikelschrauben 5, welche je ein in einen Pedikel eines Wirbelkörpers 4 (Fig. 4) einschraubbares Verankerungsteil 14 und je einen kugelförmigen Schraubenkopf 19 umfassen. Der kugelförmige Schraubenkopf 19 bildet die eine Komponente des Kugelgelenkes 17 durch das die Knochenverankerungsmittel 2 polyaxial schwenkbar mit dem Verbindungsteil 15 verbindbar ist.

Diese Pedikelschrauben 5 bestehen aus einem koaxialen Schraubenschaft 20 und einem oben an den Schraubenschaft angrenzenden, konzentrisch angeordneten kugelförmigen Schraubenkopf 19. Das Verbindungsteil 15 ist derart ausgebildet, dass der Längsträger 1 vor seiner Fixation am Knochenverankerungsmittel 2 in einen im Hohlkörper 36 angeordneten Kanal 21 eingelegt und anschliessend mittels der Spannmittel 18 im Kanal 21 fixiert wird. Der Kanal 21 durchdringt den Hohlkörper 36 quer zur Zentralachse 12 und ist am oberen Ende 22 des Hohlkörpers 36 offen.

Der Hohlkörper 36 umfasst ein die Zentralachse 12 schneidendes, oberes Ende 22, ein die Zentralachse 12 schneidendes, unteres Ende 23 und eine Kavität 24, welche hier den Hohlkörper 36 koaxial vom oberen Ende 22 bis zum unteren Ende 23 durchdringt. Die Kavität 24 besteht aus zwei axial hintereinander angeordneten Segmenten 25;26, wovon das obere Segment 25 eine koaxial zylindrische Bohrung umfasst, in welcher das radial elastisch deformierbare Klemmelement 27 axial verschiebbar gelagert ist, und das untere Segment 26 sich gegen des untere Ende 23 des Verbindungsteils 15 verjüngend konisch ausgebildet ist. Die Aussenwand 28 des Klemmelementes 27 ist zum Innenkonus 29 im unteren Segmentes 26 komplementär konisch ausgestaltet, so dass das Klemmelement 27 – wenn es in der Kavität 24 koaxial gegen das untere Ende 26 des Verbindungsteiles 15 gepresst wird – radial komprimiert wird. Ferner umfasst das Klemmelement 27 einen axial durchgehend offenen Hohlraum 30, welcher hier zum Schraubenkopf 19 komplementär sphärisch ausgebildet ist. Der Schraubenkopf 19 ist im dekomprimierten Zustand des Klemmelementes 27 vom unteren Ende 26 des Verbindungsteiles 15 in den Hohlraum 30 einschnappbar. Im komprimierten Zustand des Klemmelementes 27 wird der Schraubenkopf 19 im Hohlraum 30 blockiert. Wegen des sphärischen Ausgestaltung des Schraubenkopfes 19 und des Hohlraumes 30 ist das Knochenverankerungsmittel 2 relativ zum Verbindungsteil 15 polyaxial schwenkbar

und auch unter verschiedenen Winkeln zwischen der Zentralachse 12 des Knochenverankerungsmittels 2 und der Achse des Verbindungsteiles 15 blockierbar.

Die axiale Verschiebung des Klemmelementes 27 erfolgt hier mittels der als Spannschraube 31 ausgebildeten Spannmittel 18, welche in ein zu ihrem Gewinde komplementäres Innengewinde 32 im oberen Segment 25 der Kavität 24 einschraubbar ist. Das vordere Ende der Spannschraube 31 drückt beim Anziehen auf den in den Kanal 21 eingelegten Längsträger 1. Damit beim Anziehen der Spannmittel 18 neben dem Längsträger 1 auch der Schraubenkopf 19 im Verbindungsteil 15 fixierbar ist, ist zwischen dem Längsträger 1 und dem Klemmelement 27 ein ringförmiges Zwischenstück 33 angeordnet. Die Tiefe T des Kanals 21 so gross gewählt, dass der in den Kanal 21 eingelegte Längsträger 1 auf des obere Ende 34 des Zwischenstückes 33 drückt. Das untere Ende 35 des Zwischenstückes 33 liegt auf dem Klemmelement 27 auf. Beim Anziehen der Spannmittel 18 drückt dieses auf den Längsträger 1, wodurch das Zwischenstück 33 zusammen mit dem 21 angrenzenden Klemmelement 27 gegen das untere Ende 23 des Verbindungselementes 15 gepresst wird. Durch das innen konisch ausgebildete untere Segment 26 der Kavität 24 wird das konische Klemmelement 27 radial komprimiert und der Schraubenkopf 19 im Hohlraum 30 des Klemmelementes 27 blockiert.

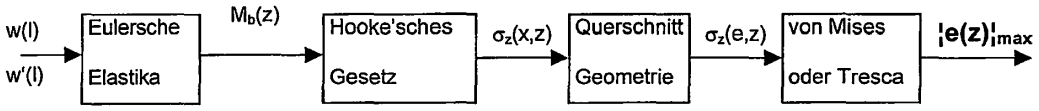
In Fig. 4 ist eine Anwendung des Längsträgers 1 innerhalb einer Wirbelsäulenstabilisationsvorrichtung dargestellt. Der Längsträger 1 hat $z = 7$ Segmente 16, wovon $n = 3$ flexible Segmente 16a und $z - n = 4$ steife Segmente 16b sind. Je ein steifes Segment 16b ist mit dem Verbindungsteil 15 eines Knochenverankerungsmittels 2 verbunden ist. Dabei ist je ein Knochenverankerungs-mittel 2 in einen Pedikel eines Wirbelkörpers 4 eingeschraubt.

Beschreibung des Implationsvorganges:

- Pedikelschrauben mit polyaxialen Köpfen eindrehen
- Abstand der Pedikelschrauben bestimmen
- Längsträger (vorgebogen) entsprechend den gemessenen Abständen auswählen
- Längsträger einbringen

- Polyaxiale Köpfe der Pedikelschrauben verschliessen
- Je nach Bedarf Komprimieren/Distrahieren der Pedikelschrauben
- Verbindung zwischen Pedikelschraube und Längsträger blockieren

Fig. 5a und 5b illustrieren den durch das nachfolgende Blockdiagramm beschriebenen Zusammenhang zwischen der Deformation des betroffenen Wirbelsäulensegmentes und der Geometrie der Längsträger.



$\mathbf{e(z)_{max}}$ repräsentiert die maximal mögliche Dicke der Längsträger, dass bei einer durch die Deformation der Längsträger erzeugte kraniale Bewegung kein Bruch der Längsträger auftritt.

w(l) und w'(l)=tgα sind von Funktionsröntgenbildern und/oder in vitro Tests bekannt.

Da w(l) und w'(l) vom Verhältnis der Steifigkeit des dynamischen Fixationssystems und des überbrückten Wirbelsäulensegmentes abhängt, kann $\mathbf{|e(z)|_{max}}$ genau genommen nur iterativ erarbeitet werden. Wenn aber die Biegesteifigkeit des überbrückten Wirbelsäulensegmentes als viel kleiner als die Biegesteifigkeit des überbrückten Wirbelsäulensegmentes angenommen werden kann (was der Fall ist), können w(l) und w'(l) direkt aus Funktionsröntgenbildern von Patienten gemessen werden, die mit einem funktionsähnlichen Fixationssystem versorgt wurden.

Zusammengefasst kann gesagt werden, dass bei der SoftFixation das Ziel nicht mehr eine Fusion sondern eine funktionelle Abstützung der Strukturen der überbrückten Wirbelsäulensegmente ist. In diesem Zusammenhang muss das Fixationssystem zu einem gewissen Grad mechanisch nachgiebig sein. Dementsprechend muss im

Gegensatz zu einer auf eine Fusion hinwirkenden Stabilisierung bei der SoftFixation das Fixationssystem nicht mehr auf eine maximale Belastung sondern auf eine maximale Deformation dimensioniert werden. Wie Figur 6 zeigt, ist ein flexibles System aber erst ab einer gewissen Flexibilität bruchsicher, d.h. das System muss so dimensioniert werden, dass bei einer vorgegebenen Deformation die kritische Flexibilität des Fixationssystems nicht unterschritten wird.

Die in Fig. 6 gezeigte Graphik ist eine vereinfachte Darstellung der Bruchkriterien für ein zur Stabilisierung eines Wirbelsäulensegmentes verwendeten Fixationssystems (oben rechts symbolisch dargestellt).

Die Graphik $\alpha_{kritisch}$ zeigt auf vereinfachte Art den Zusammenhang zwischen der Geometrie des Fixationsystems (symbolisiert durch den Durchmesser ϕ der Längsträger) und der maximalen Deformation (symbolisiert durch den Deformationswinkel $\alpha_{kritisch}$), die das System kompensieren kann, bevor es bricht.

Die Graphik zeigt auch, dass mit zunehmender Festigkeit und zunehmender Flexibilität des Materials sich der kritische Bereich nach rechts verschiebt.

Die Graphik $\alpha_{Belastung}$ ist die Kennlinie des Fixationssystems. Sie zeigt den Zusammenhang zwischen Geometrie (symbolisiert durch den Durchmesser ϕ der Längsträger) und Deformation des Fixationssystems (symbolisiert durch den Deformationswinkel α) für eine vorgegebene Wirbelsäulenbelastung (symbolisiert durch F) in Abhängigkeit der mechanischen Eigenschaften von Fixationssystem (symbolisiert durch Zugfestigkeit σ_0 und Elastizitätsmodul E) und Wirbelsäulensegment (symbolisiert durch die linear-elastisch Federkonstante k_s).

Solange die Kennlinie $\alpha_{Belastung}$ des Systems links von der Graphik $\alpha_{Belastung}$ liegt, ist das Fixationssystem nicht bruchgefährdet.

In der vorliegenden Figur überschneiden sich die Graphiken zweimal. Bei der Dimensionierung eines Fixationssystems bewegte man sich bis anhin im Bereich oberhalb des obern Schnittpunktes der beiden Graphiken.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 587 of 2152

Das Ziel der Stabilisierung mit einem Fixationssystem war die Fusion der überbrückten Segmente. Wie die Graphik zeigt, darf dabei die Steifigkeit des Systems (unter anderem gegeben durch den Durchmesser der Längsträger) einen bestimmten Wert nicht unterschreiten.

Bei der SoftFixation ist das Ziel nicht mehr eine Fusion, sondern eine funktionelle Abstützung der Strukturen der überbrückten Wirbelsäulensegmente. In diesem Zusammenhang muss das Fixationssystem zu einem gewissen Grad mechanisch nachgiebig sein. Dementsprechend muss im Gegensatz zu einer auf eine Fusion hinwirkenden Stabilisierung bei der SoftFixation das Fixationssystem nicht mehr auf eine maximale Belastung sondern auf eine maximale Deformation dimensioniert werden. Wie die vorliegende Graphik zeigt, ist ein flexibles System erst ab einer gewissen Flexibilität bruchsicher, d.h. das System muss so dimensioniert werden, dass bei einer vorgegebenen Deformation die kritische Flexibilität des Fixationssystems nicht unterschritten wird. Die Erfindung betrifft die Definition dieser Bedingung und deren diverse Realisierungsmöglichkeiten.

Patentansprüche

1. Vorrichtung zur dynamischen Stabilisierung von Knochen oder Knochenfragmenten, insbesondere von Wirbelkörpern (4) mit

A) mindestens einem eine Längsachse (3) aufweisenden longitudinalen Längsträger (1); und

B) mindestens zwei Knochenverankerungsmitteln (2) mit je einer Zentralachse (12) und je einem zur Verankerung an einem Knochen bestimmten Verankerungsteil (14), wobei

C) jedes Knochenverankerungsmittel (2) mittels eines mit Spannmitteln (18) ausgestatteten Verbindungsteils (15) an einem Längsträger (1) lösbar befestigbar ist,

dadurch gekennzeichnet, dass

der mindestens eine Längsträger (1) in axialer Richtung

D) eine Anzahl $n \geq 1$ flexible Segmente (16a) mit einer zur Längsachse (3) orthogonalen Querschnittsfläche (8) umfasst, welche weder einem Kreis noch einem regelmässigen Polygon entspricht, sowie

E) eine Anzahl $m = (n + 1)$ von im wesentlichen steifen Segmente (16b) beliebiger Querschnittsfläche umfasst, so dass

F) gesamthaft eine Anzahl $z \geq (2n + 1)$ von axialen Segmenten (16a; 16b) resultiert.

2. Vorrichtung nach Anspruch 1, dadurch gekennzeichnet, dass mindestens eines der flexiblen Segmente (16a) über die gesamte Länge eine konstante Querschnittsfläche (8) aufweist.

3. Vorrichtung nach Anspruch 1, dadurch gekennzeichnet, dass die Querschnittsfläche (8) sich bei mindestens einem der flexiblen Segmente (16a) entlang der Längsachse (3) verändert.

4. Vorrichtung nach Anspruch 3, dadurch gekennzeichnet, dass die Querschnittsfläche (8) sich kontinuierlich entlang der Längsachse (3) verändert.

5. Vorrichtung nach einem der Ansprüche 1 bis 4, dadurch gekennzeichnet, dass das Elastizitätsmodul des Materials mindestens eines der flexiblen Segmente (16a) über die gesamte Länge konstant ist.

6. Vorrichtung nach einem der Ansprüche 1 bis 4, dadurch gekennzeichnet, dass sich das Elastizitätsmodul des Materials mindestens eines der flexiblen Segmente (16a) entlang der Längsachse (3) verändert.

7. Vorrichtung nach Anspruch 6, dadurch gekennzeichnet, dass das Elastizitätsmodul des Materials sich kontinuierlich entlang der Längsachse (3) verändert.

8. Vorrichtung nach einem der Ansprüchen 1 bis 7, dadurch gekennzeichnet, dass die Dicken e_i der flexiblen Segmente (16a) so klein sind, dass

a) die Summe der Deformationen α^i der einzelnen flexiblen Segmenten (16a) eine Gesamtdeformation α des Längsträgers (3) zwischen 4° und 12°, vorzugsweise 8° ergibt, und

b) die in den Segmenten (16) resultierenden maximalen Biegespannungen die zulässige Biegespannung des Materials nicht überschreitet.

9. Vorrichtung nach Anspruch 8, dadurch gekennzeichnet, dass der Längsträger (1) aus einem flexiblen Segment (16a) besteht und die Querschnittsfläche (8) und das Elastizitätsmodul über die gesamte Länge des flexiblen Segmentes (16a) konstant bleibt.

10. Vorrichtung nach Anspruch 9, dadurch gekennzeichnet, dass das Verhältnis der Produkte „Dicke e des flexiblen Segmentes (16a) multipliziert mit dem Biegeelastizitätsmodul des Materials" und „Länge L des flexiblen Segmentes (16a) multipliziert mit der zulässigen Biegespannung des Materials" zwischen 9 und 28, vorzugsweise zwischen 12 und 15 beträgt.

11. Vorrichtung nach einem der Ansprüche 1 bis 10, dadurch gekennzeichnet, dass die Querschnittsfläche (8) mindestens eines der n flexiblen Segmente (16a) rechteckig ausgebildet sind.

12. Vorrichtung nach einem der Ansprüche 1 bis 11, dadurch gekennzeichnet, dass der Längsträger (1) axial aussenstehend je ein steifes Segment (16b) mit einer zur Längsachse (3) orthogonalen, radial symmetrischen Querschnittsfläche (7) umfasst.

13. Vorrichtung nach einem der Ansprüche 1 bis 12, dadurch gekennzeichnet, dass der Längsträger (1) m = (z – n) im wesentlichen steife Segmente (16b) mit einer zur Längsachse (3) orthogonalen, radialsymmetrischen Querschnittsfläche (7) umfasst.

14. Vorrichtung nach Anspruch 13, dadurch gekennzeichnet, dass die n flexiblen Segmente (16a) und die m im wesentlichen steifen Segmente (16b) alternierend angeordnet sind.

15. Vorrichtung nach einem der Ansprüche 1 bis 14, dadurch gekennzeichnet, dass mindestens eines der n flexiblen Segmente (16a) eine Querschnittsfläche (8) mit einer Breite b und einer Dicke e aufweist, wobei das Verhältnis e/b maximal zwischen 0,3 und 0,4 beträgt.

16. Vorrichtung nach einem der Ansprüche 1 bis 15, dadurch gekennzeichnet, dass mindestens eines der n flexiblen Segmente (16a) eine Querschnittsfläche (8) mit einer Breite b und einer Dicke e aufweist, wobei das Verhältnis e/b mindestens zwischen 0,05 und 0,1 beträgt.

17. Vorrichtung nach einem der Ansprüche 1 bis 16, dadurch gekennzeichnet, dass der Längsträger (1) einstückig ist.

18. Vorrichtung nach einem der Ansprüche 1 bis 16, dadurch gekennzeichnet, dass mindestens eines der n flexiblen Segmente (16a) mit den angrenzenden steifen Segmenten (16b) verbindbar ist.

19. Vorrichtung nach einem der Ansprüche 1 bis 18, dadurch gekennzeichnet, dass mindestens eines der n flexiblen Segmente (16a) aus einem biokompatiblen Kunststoff gefertigt ist.

20. Vorrichtung nach einem der Ansprüche 1 bis 18, dadurch gekennzeichnet, dass mindestens eines der n flexiblen Segmente (16a) aus einem hochfesten, monokristallinen Material besteht.

21. Vorrichtung nach einem der Ansprüche 1 bis 20, dadurch gekennzeichnet, dass mindestens eines der n flexiblen Segmente (16a) durch hochfeste, monokristalline Fasern verstärkt wird.

22. Vorrichtung nach einem der Ansprüche 1 bis 19, dadurch gekennzeichnet, dass mindestens eines der n flexiblen Segmente (16a) aus einem faserverstärkten, biokompatiblen Kunststoff besteht.

23. Vorrichtung nach einem der Ansprüche 1 bis 22, dadurch gekennzeichnet, dass mindestens ein Verbindungsteil (15) ein Kugelgelenk (17) zur polyaxial schwenkbaren Verbindung des Knochenverankerungsmittels (2) mit dem Längsträger (1) umfasst.

24. Vorrichtung nach einem der Ansprüche 1 bis 10 oder 12 bis 23, dadurch gekennzeichnet, dass die Querschnittsfläche (8) mindestens eines der n flexiblen Segmente (16a) oval ausgebildet ist.

25. Vorrichtung nach einem der Ansprüche 1 bis 24, dadurch gekennzeichnet, dass mindestens eines der n flexiblen Segmente (16a) hohl ist.

26. Vorrichtung nach Anspruch 25, dadurch gekennzeichnet, dass mindestens eines der n flexiblen Segmente (16a) eine sich axial erstreckende Bohrung aufweist.

27. Vorrichtung nach einem der Ansprüche 1 bis 26, dadurch gekennzeichnet, dass jedes der n flexiblen Segmente (16a) axial ein erstes und ein zweites, je an ein im wesentlichen steifes Segment (16b) angrenzendes Ende (37;38) aufweist und dass die Querschnittsfläche (8) mindestens eines der n flexiblen Segmente (16a) gegen mindestens eines der Enden (37;38) in mindestens einer Dimension zunimmt.

28. Vorrichtung nach Anspruch 27, dadurch gekennzeichnet, dass die Querschnittsfläche (8) mindestens eines der n flexiblen Segmente (16a) in mindestens einer Dimension linear zunimmt.

29. Vorrichtung nach Anspruch 27, dadurch gekennzeichnet, dass die Querschnittsfläche (8) mindestens eines der n flexiblen Segmente (16a) in mindestens einer Dimension progressiv zunimmt.

30. Vorrichtung nach einem der Ansprüche 1 bis 29, dadurch gekennzeichnet, dass der Längsträger (1) relativ zu den Knochenverankerungsmitteln (2) derart angeordnet ist, dass die maximale Abmessung der zur Längsachse (3) orthogonalen Querschnittsfläche (8) mindestens eines der n flexiblen Segmente (16a) quer zu den Zentralachsen (12) der Knochenverankerungsmittel (2) angeordnet ist.

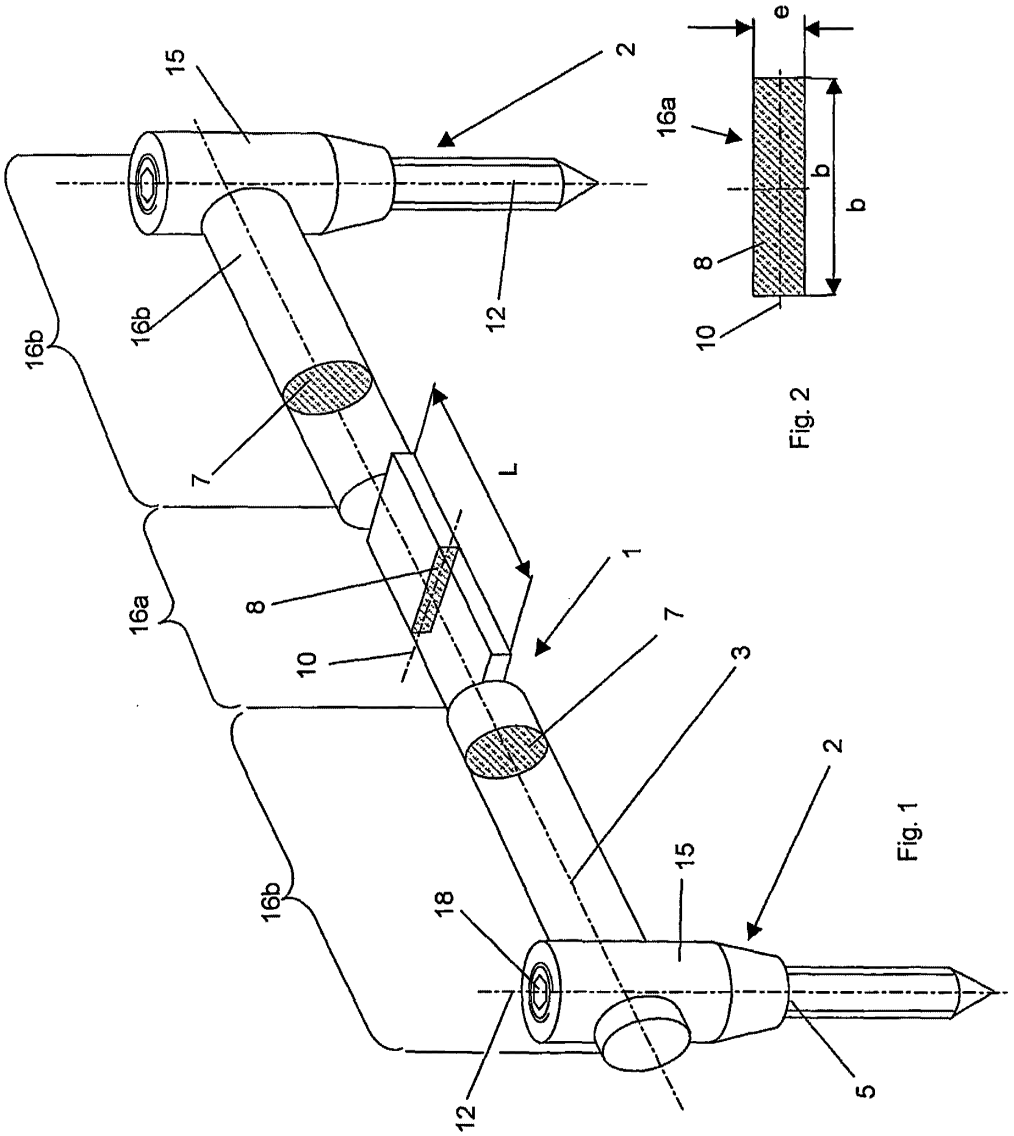


Fig. 1

Fig. 2

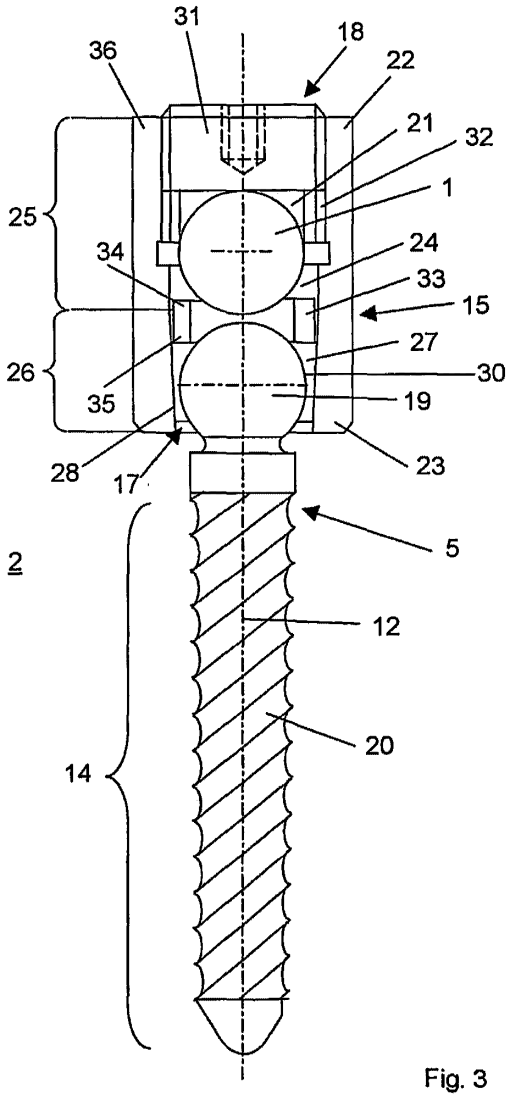


Fig. 3

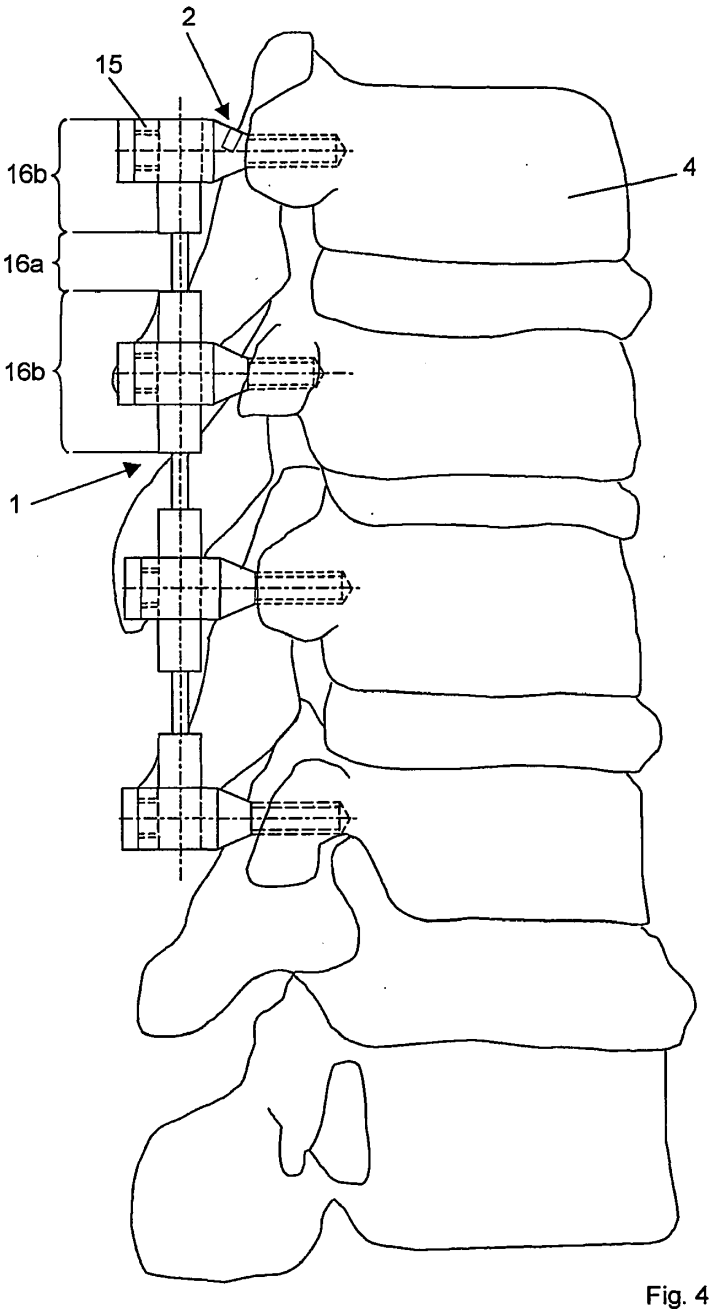


Fig. 4

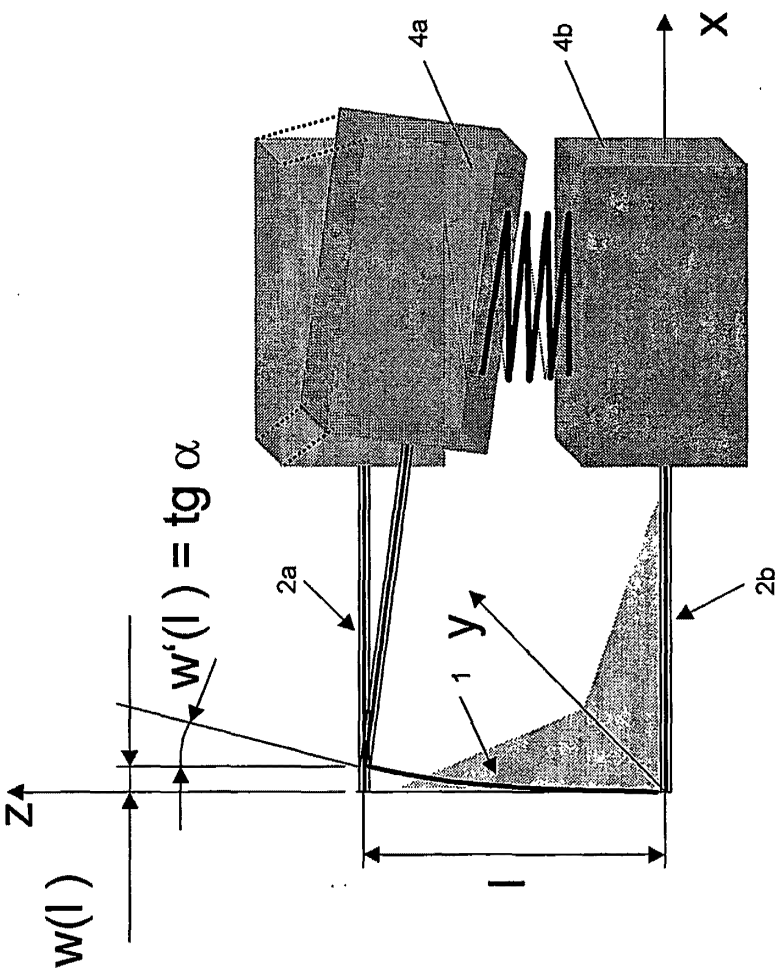


Fig. 5a

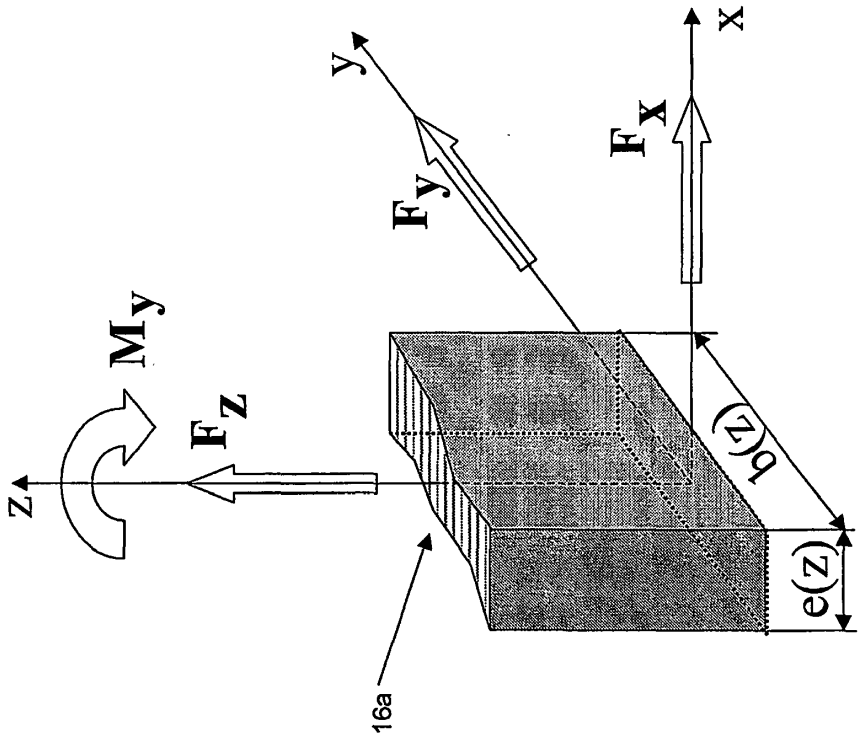


Fig. 5b

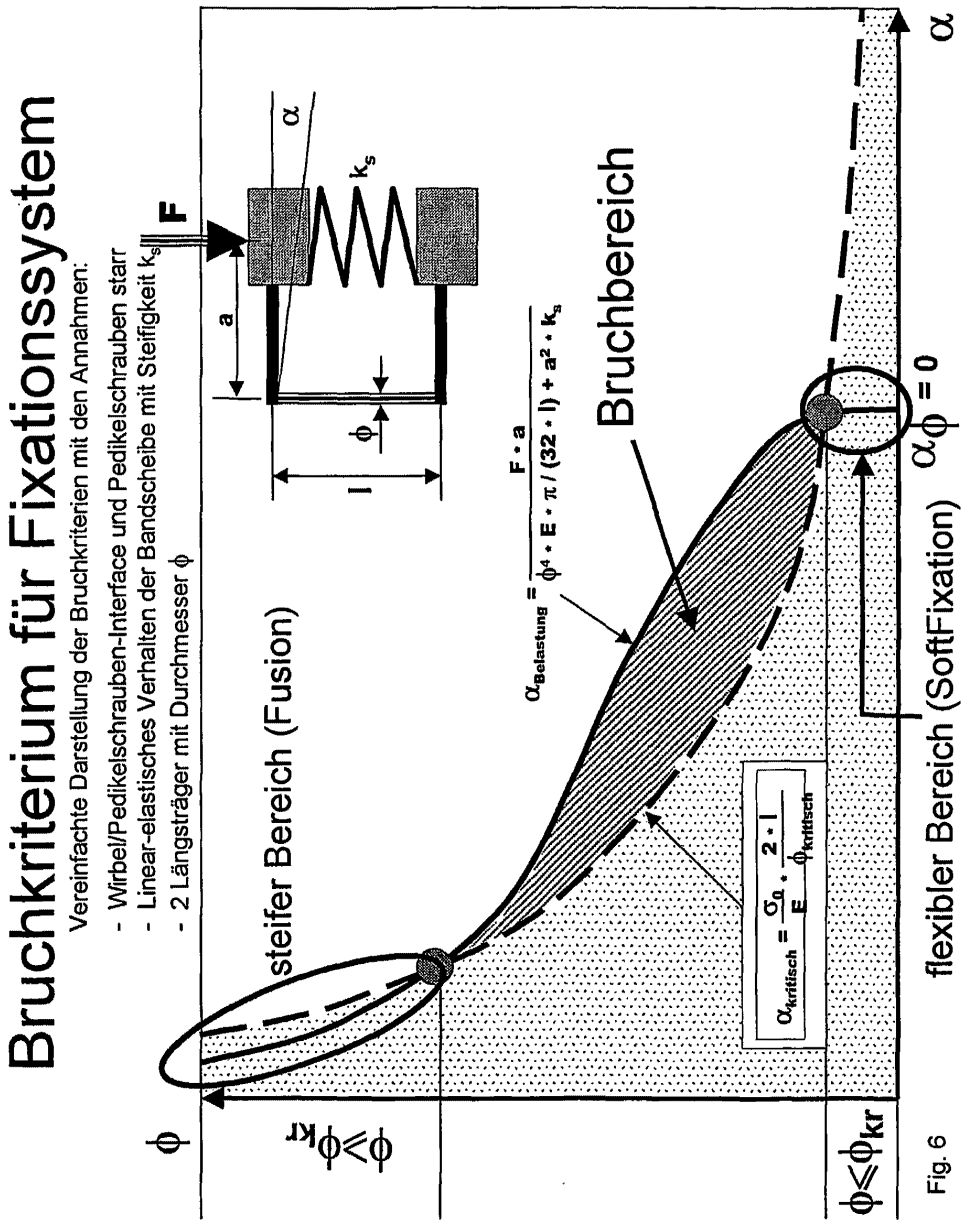

Bruchkriterium für Fixationssystem
Vereinfachte Darstellung der Bruchkriterien mit den Annahmen:
- Wirbel/Pedikelschrauben-Interface und Pedikelschrauben starr
- Linear-elastisches Verhalten der Bandscheibe mit Steifigkeit k_s
- 2 Längsträger mit Durchmesser ϕ
F
a
α
k_s
l
ϕ
steifer Bereich (Fusion)
Bruchbereich
$\alpha_{Belastung} = \frac{F \cdot a}{\phi^4 \cdot E \cdot \pi / (32 \cdot l) + a^2 \cdot k_s}$
$\alpha_{kritisch} = \frac{\sigma_n}{E} \cdot \frac{2 \cdot l}{\phi_{kritisch}}$
$\alpha\phi = 0$
flexibler Bereich (SoftFixation)
$\phi \geq \phi_{kr}$
$\phi \leq \phi_{kr}$

Fig. 6

INTERNATIONAL SEARCH REPORT

International Application No
PCT/CH2004/000257

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.
X	US 2003/191470 A1 (RITLAND STEPHEN) 9 October 2003 (2003-10-09)	1-5, 8-17, 19-24, 27-30
Y	paragraph '0044! - paragraph '0052!	18,25,26
X	US 2003/171749 A1 (LE COUEDIC REGIS ET AL) 11 September 2003 (2003-09-11) paragraph '0007! - paragraph '0010!	1
Y	US 2004/049189 A1 (LE COUEDIC REGIS ET AL) 11 March 2004 (2004-03-11) paragraph '0010! - paragraph '0032!	18
Y	FR 2 726 995 A1 (EUROS SA) 24 May 1996 (1996-05-24) page 4, line 7 - line 14	25,26

-/--

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

[X] Patent family members are listed in annex.

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
25 January 2005	04/02/2005

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

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/CH2004/000257

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 6 267 764 B1 (ELBERG JEAN-FRANCOIS) 31 July 2001 (2001-07-31) cited in the application column 3, line 55 - column 4, line 48	1-30

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/CH2004/000257

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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		AU 7990701 A	05-02-2002
		EP 1303224 A1	23-04-2003
		WO 0207621 A1	31-01-2002
US 2004049189 A1	11-03-2004	FR 2812186 A1	01-02-2002
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		AU 5125098 A	10-06-1998
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		DE 69721822 T2	08-04-2004
		DE 951246 T1	05-07-2001
		EP 0951246 A1	27-10-1999
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		JP 2001507957 T	19-06-2001
		KR 2000053281 A	25-08-2000

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 602 of 2152

INTERNATIONALER RECHERCHENBERICHT

Internationales Aktenzeichen
PCT/CH2004/000257

A. KLASSIFIZIERUNG DES ANMELDUNGSGEGENSTANDES
IPK 7 A61B17/70

Nach der Internationalen Patentklassifikation (IPK) oder nach der nationalen Klassifikation und der IPK

B. RECHERCHIERTE GEBIETE

Recherchierter Mindestprüfstoff (Klassifikationssystem und Klassifikationssymbole)
IPK 7 A61B

Recherchierte aber nicht zum Mindestprüfstoff gehörende Veröffentlichungen, soweit diese unter die recherchierten Gebiete fallen

Während der internationalen Recherche konsultierte elektronische Datenbank (Name der Datenbank und evtl. verwendete Suchbegriffe)
EPO-Internal

C. ALS WESENTLICH ANGESEHENE UNTERLAGEN

Kategorie°	Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile	Betr. Anspruch Nr.
X	US 2003/191470 A1 (RITLAND STEPHEN) 9. Oktober 2003 (2003-10-09)	1-5, 8-17, 19-24, 27-30
Y	Absatz '0044! - Absatz '0052!	18,25,26
X	US 2003/171749 A1 (LE COUEDIC REGIS ET AL) 11. September 2003 (2003-09-11) Absatz '0007! - Absatz '0010!	1
Y	US 2004/049189 A1 (LE COUEDIC REGIS ET AL) 11. März 2004 (2004-03-11) Absatz '0010! - Absatz '0032!	18
Y	FR 2 726 995 A1 (EUROS SA) 24. Mai 1996 (1996-05-24) Seite 4, Zeile 7 - Zeile 14	25,26

-/--

[X] Weitere Veröffentlichungen sind der Fortsetzung von Feld C zu entnehmen

[X] Siehe Anhang Patentfamilie

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"&" Veröffentlichung, die Mitglied derselben Patentfamilie ist

Datum des Abschlusses der internationalen Recherche	Absendedatum des internationalen Recherchenberichts
25. Januar 2005	04/02/2005

Name und Postanschrift der Internationalen Recherchenbehörde	Bevollmächtigter Bediensteter
Europäisches Patentamt, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Buchmann, G

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INTERNATIONALER RECHERCHENBERICHT

Internationales Aktenzeichen
PCT/CH2004/000257

C.(Fortsetzung) ALS WESENTLICH ANGESEHENE UNTERLAGEN

Kategorie°	Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile	Betr. Anspruch Nr.
A	US 6 267 764 B1 (ELBERG JEAN-FRANCOIS) 31. Juli 2001 (2001-07-31) in der Anmeldung erwähnt Spalte 3, Zeile 55 - Spalte 4, Zeile 48	1-30

Formblatt PCT/ISA/210 (Fortsetzung von Blatt 2) (Januar 2004)

INTERNATIONALER RECHERCHENBERICHT

Angaben zu Veröffentlichungen, die zur selben Patentfamilie gehören

Internationales Aktenzeichen
PCT/CH2004/000257

Im Recherchenbericht angeführtes Patentdokument		Datum der Veröffentlichung	Mitglied(er) der Patentfamilie		Datum der Veröffentlichung
US 2003191470	A1	09-10-2003	WO	2004089244 A2	21-10-2004
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			EP	1303224 A1	23-04-2003
			WO	0207621 A1	31-01-2002
US 2004049189	A1	11-03-2004	FR	2812186 A1	01-02-2002
			AU	7990801 A	05-02-2002
			EP	1303225 A1	23-04-2003
			WO	0207622 A1	31-01-2002
FR 2726995	A1	24-05-1996	WO	9615729 A1	30-05-1996
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			AT	239426 T	15-05-2003
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			AU	5125098 A	10-06-1998
			CA	2272140 A1	28-05-1998
			DE	69721822 D1	12-06-2003
			DE	69721822 T2	08-04-2004
			DE	951246 T1	05-07-2001
			EP	0951246 A1	27-10-1999
			ES	2149735 T1	16-11-2000
			WO	9822033 A1	28-05-1998
			HK	1023047 A1	08-04-2004
			JP	2001507957 T	19-06-2001
			KR	2000053281 A	25-08-2000

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 605 of 2152

(12) DEMANDE INTERNATIONALE PUBLIÉE EN VERTU DU TRAITÉ DE COOPÉRATION EN MATIÈRE DE BREVETS (PCT)

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(43) Date de la publication internationale
9 septembre 2005 (09.09.2005)

PCT

(10) Numéro de publication internationale
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(51) Classification internationale des brevets[7] : A61B 17/70

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PCT/FR2005/000173

(22) Date de dépôt international :
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(30) Données relatives à la priorité :
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60/554,415 19 mars 2004 (19.03.2004) US

(71) Déposant *(pour tous les États désignés sauf US)* : **MEDICREA INTERNATIONAL** [FR/FR]; 24 Porte du Grand Lyon, F-01700 NEYRON (FR).

(72) Inventeurs; et

(75) Inventeurs/Déposants *(pour US seulement)* : **SOURNAC, Denys** [FR/FR]; 345 Montée de Bellevue, F-01600 REYRIEUX (FR). **CAFFIERO, Jean-Philippe** [FR/FR]; 12 rue du Commandant Faurax, F-69006 LYON (FR). **CARLIER, François** [FR/FR]; Allée de Colveu, F-44352 GUERANDE (FR).

(74) Représentant commun : **MEDICREA INTERNATIONAL**; 24 Porte du Grand Lyon, F-01700 NEYRON (FR).

(81) États désignés *(sauf indication contraire, pour tout titre de protection nationale disponible)* : AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

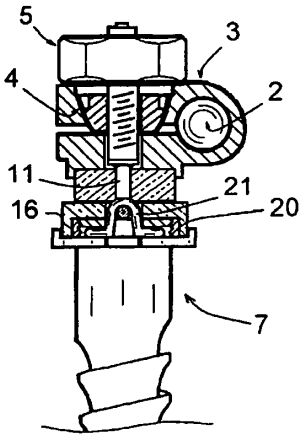
(84) États désignés *(sauf indication contraire, pour tout titre de protection régionale disponible)* : ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), eurasien (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), européen (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Publiée :
— *sans rapport de recherche internationale, sera republiée dès réception de ce rapport*

[Suite sur la page suivante]

(54) Title: VERTEBRAL OSTEOSYNTHESYS DEVICE

(54) Titre : MATERIEL D'OSTEOSYNTHESE VERTEBRALE



(57) Abstract: The inventive device comprises osseous anchoring elements, one or two connecting rods (2) which are connectable to said anchoring elements and fixable to vertebrae by means thereof and connecting means (6, 3) of the rod(s) (2) for fixing said rod(s) to the anchoring elements, at least one anchoring element being of a polyaxial type. According to the invention, each connecting part (6) and each base part (7) comprises a transversal passage and a rigid transversal element (11, 24) whose direction is substentially perpendicular to the direction of the passage. The rigid transversal element (11, 24) of the connecting part (6) or of the base part (7) is introducible into the transversal passage of the base part (7) or of the connecting part (6) and vice-versa in such a way that said rigid transversal elements (11, 24) are pivotable in said passages.

(57) Abrégé : Le matériel comprend des organes d'ancrage osseux, 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 moyens 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". Selon l'invention, ladite partie 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 la partie de connexion (6) ou de la pièce de base (7) étant engagée dans le passage transversal de la pièce de base (7) ou de la partie de connexion (6), et réciproquement, avec possibilité de pivotement de ces parties transversales rigides (11, 24) dans ces passages.

WO 2005/082262 A2

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 606 of 2152

En ce qui concerne les codes à deux lettres et autres abréviations, se référer aux "Notes explicatives relatives aux codes et abréviations" figurant au début de chaque numéro ordinaire de la Gazette du PCT.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 607 of 2152

MATERIEL D'OSTEOSYNTHESE VERTEBRALE

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 partie 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 partie 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 partie 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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 609 of 2152

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 moyens 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 partie 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 partie 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, une partie transversale rigide de la partie de connexion ou la pièce de base étant engagée dans le passage transversal de la pièce de base ou la partie de connexion, et réciproquement, avec possibilité de pivotement de ces parties transversales rigides dans ces passages.

La partie 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 "partie de connexion" doit être compris dans une acception très large : il peut en particulier s'agir d'un pion proximal fileté ou d'une partie de connexion en forme de "tulipe" tels que décrit plus haut ; il peut également s'agir d'une portion d'extrémité d'une tige de liaison.

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

Ce passage transversal et cette 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 partie de connexion et ladite pièce de base, cette pièce ou partie de pièce à structure élastiquement déformable permettant une mobilité de la partie 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 partie 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 partie 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 partie 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 partie de connexion par rapport à ladite pièce de base. Notamment, ladite partie 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.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 613 of 2152

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 partie 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 ;

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 616 of 2152

- en réalisant l'un des deux anneaux sous forme d'une chape recevant une goupille.

Le terme "partie 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, d'une partie de connexion en forme de "tulipe", présentant un logement dans lequel une tige de liaison 2 peut être engagée, ou encore de la portion d'extrémité d'une tige de liaison.

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 moyens 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 partie 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 partie 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 la partie de connexion (6) ou de la pièce de base (7) étant engagée dans le passage transversal de la pièce de base (7) ou de la partie de connexion (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) de la partie de connexion (6) ou de la pièce de base (7) sont réalisés en aménageant un anneau (11) sur la partie de connexion (6) et un anneau (24) sur la pièce de base (7), les deux anneaux (11, 24) de la partie de connexion (6) ou de la pièce de base (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).

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 618 of 2152

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.

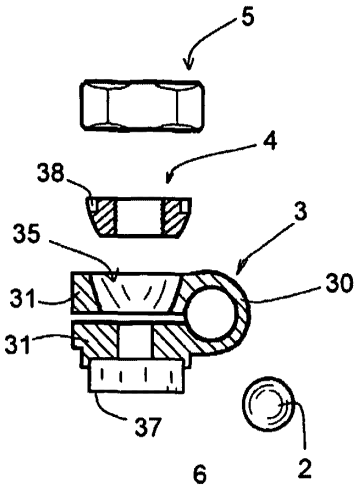
6 – Matériel selon la revendication 4 ou la revendication 5, caractérisé en ce que ladite pièce intermédiaire est conformée de manière à être retenue entre les deux parties transversales rigides grâce à la forme que présentent ces parties transversales rigides.

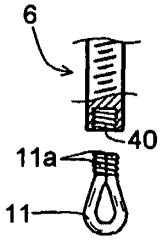
7 – Matériel selon l'une des revendications 1 à 6, caractérisé en ce que ledit organe d'ancrage (1) de type "polyaxial" comprend au moins une pièce (16, 37) ou une partie de pièce à structure élastiquement déformable, placée, après montage, entre ladite partie de connexion (6, 3) et ladite pièce de base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

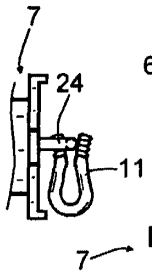
8 – Matériel selon la revendication 7, caractérisé en ce que ladite pièce de base (7) comprend une pièce (16) à structure élastiquement déformable et ladite partie de connexion (3) comporte une autre pièce (37) à structure élastiquement déformable, ces deux pièces (16, 37) venant porter l'une contre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

9 – Matériel selon l'une des revendications 1 à 6, caractérisé en ce que ladite partie 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 partie de connexion par rapport à ladite pièce de base.

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







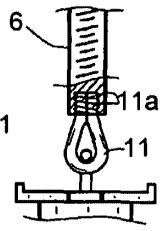
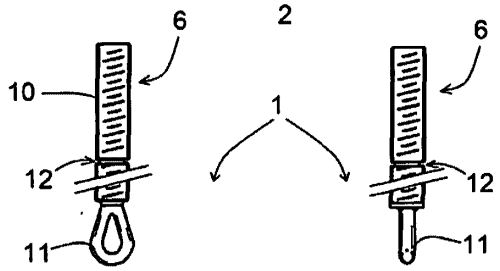
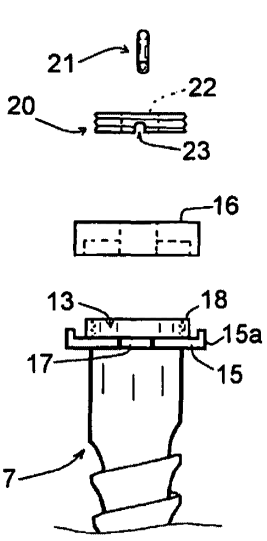
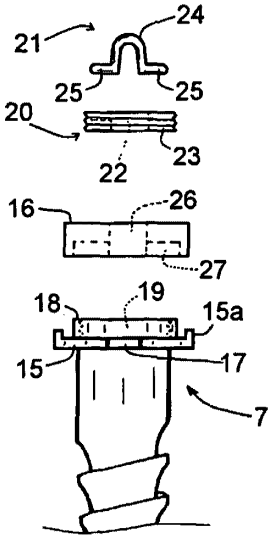


FIG. 4 FIG. 5 FIG. 6







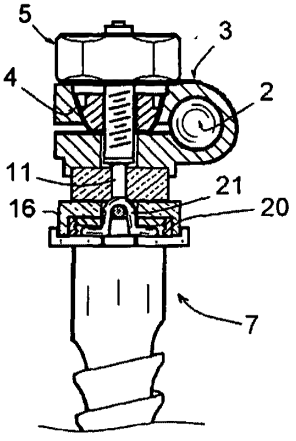


FIG. 1 FIG. 2 FIG. 3

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(71) Applicant *(for all designated States except US)*: **MEDICREA INTERNATIONAL** [FR/FR]; 24 Porte du Grand Lyon, F-01700 NEYRON (FR).

(72) Inventors; and

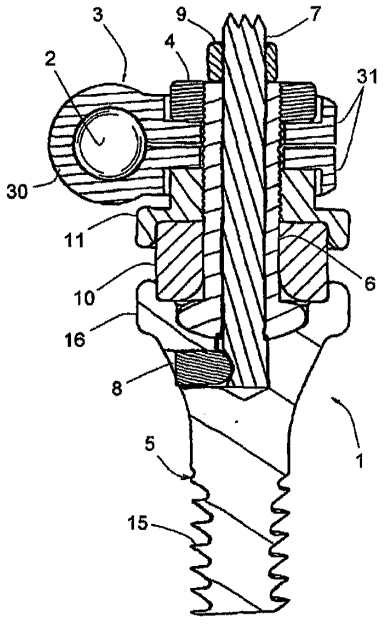
(75) Inventors/Applicants *(for US only)*: **SOURNAC, Denys** [FR/FR]; 345 Montée de Bellevue, F-01600 REYRIEUX (FR). **CAFFIERO, Jean-Philippe** [FR/FR]; 12 rue du Commandant Faurax, F-69006 LYON (FR). **CARLIER, François** [FR/FR]; Allée de Colveu, F-44352 GUERANDE (FR).

(74) Common Representative: **MEDICREA INTERNATIONAL**; 24 Porte du Grand Lyon, F-01700 NEYRON (FR).

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[Continued on next page]

(54) Title: VERTEBRAL OSTEOSYNTHESIS EQUIPMENT



(57) Abstract: This vertebral osteosynthesis equipment includes bony anchoring members, such as pedicular screws (1), one or two linking rods (2), intended to be connected to these anchoring members, and connection assemblies (6, 3) of this or these rods (2) to these anchoring members, at least one of these anchoring members (1) being of the "polyaxial" type, i.e. including a connection part (6) articulated with respect to a base portion (5) intended to be attached to the vertebrae. According to the invention, said "polyaxial" anchoring element (1) comprises a flexible junction portion (7) connecting said connection part (6) and said base portion (5), this flexible junction portion (7) providing the desirable joint of this connection part (6) with respect to the base portion (5).

WO 2005/072632 A1

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 621 of 2152

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Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 622 of 2152

VERTEBRAL OSTEOSYNTHESIS EQUIPMENT

The present invention concerns a vertebral osteosynthesis equipment.

A vertebral osteosynthesis equipment comprises generally bony anchoring members, such as pedicular screws, forceps or hooks, one or two linking rods, intended to be linked to these anchoring members, and connection parts of this or these linking rods to these anchoring members. The equipment may also contain crosslinks adjustable in length, which connect transversally two parallel linking rods to maintain these rods with respect to one another.

In a type of existing equipment, each anchoring element may include a proximal threaded stud whereon may be screwed a nut and each connection part may contain a rounded portion intended to surround a linking rod and two parallel wings drilled with holes. These wings are intended to be engaged on said proximal threaded stud and to be clamped, by means of this nut, against a bearing surface provided on the anchoring element, this clamping causing in turn the clamping of said rounded portion around the linking rod and thereby ensuring the longitudinal immobilisation of this rod with respect to the anchoring element.

In another type of existing equipment, each anchoring element may be "tulip-shaped", i.e. include a head wherein is provided a transversal passage for receiving a linking rod.

The anchoring members may be of "polyaxial" type, i.e. enable, before clamping, a joint of the connection part (proximal threaded stud or "tulip-shaped" head) with respect to the base portion of the anchoring element, intended to be inserted in the bone. This joint facilitates the assembly of the linking rods to the anchoring members.

In the existing "polyaxial" anchoring members, the joint is realised in the form of a ball joint with spherical portions, either by providing a sphere at the distal end of a threaded proximal stud and a cavity in said base portion, this cavity receiving the sphere of the stud and being closed at the proximal portion

to retain this sphere, or by providing a sphere at the proximal end of the base portion and a cavity corresponding to the bottom of the "tulip-shaped" head. The documents US 5,882,350 or WO 00/15125 illustrate such materials.

The shortcoming of this type of joint lies in enabling only limited bottoming of the connection part, taking into account the stop of this part against the base portion at the edge closing the cavity receiving the sphere. This limited bottoming may compromise in certain cases the placement of a rod on anchoring members. Moreover, the contact surface of the sphere with said edge is restricted and the clamping of the rod generates relatively significant axial tension on this edge, which is not optimal from a mechanic viewpoint. Besides, the repeated stresses inflicted to the equipment once implanted, resulting from the movements of the patient, generate repeated frictions of the sphere against said edge, which leads to an undesirable risk of diffusion of metal particles in the organism.

Besides, the existing vertebral osteosynthesis equipment is intended to immobilise two vertebrae with respect to one another, to eliminate any relative movement of these vertebrae, or to restore the adequate position of a vertebra with respect to the other. For the realisation of this immobilisation, this equipment is designed for a perfectly rigid assembly of the linking rods with the anchoring members.

This rigid assembly may however not be desirable in all cases. It leads in particular to the application of significant stresses to anchoring bony zones of said anchoring members, as well as to increased stresses at vertebral joints situated of both sides of the vertebral segment treated, which may lead to degenerescences of these joints. Besides, this rigid assembly is not adapted to the treatment of non-degenerative affections, notably to the treatment of scoliosis in younger patients.

The purpose of the present invention is to remedy all these shortcomings.

Its main object is hence to provide a vertebral osteosynthesis equipment comprising at least one polyaxial anchoring element, wherein the connection part has a significant bottoming with respect to the base portion of the anchoring element intended to be attached to the bone, and wherein the risk of diffusion of metal particles in the organism is significantly reduced with respect to an existing equipment.

Another object of the invention is to provide a vertebral osteosynthesis equipment enabling non-rigid assembly, possibly flexible assembly, of the linking rods with the anchoring members, with possible dampening effect of the movement of the mobile parts.

An additional object of the invention is to provide a vertebral osteosynthesis equipment enabling such non-rigid assembly, possibly flexible assembly, having a mobile portion whereof the localisation is close to the conditions of anatomic movements.

An additional object of the invention is to provide a vertebral osteosynthesis equipment having small space requirements in order to minimise the interventions necessary to realise the implantation.

The equipment concerned includes, in itself, bony anchoring members, such as pedicular screws, forceps or hooks, one or two linking rods, intended to be connected to these anchoring members, and connection assemblies of this or these rods to these anchoring members, at least one of these anchoring members being of the "polyaxial" type, i.e. including a connection assembly articulated with respect to a base portion intended to be attached to the bone.

According to the invention, said "polyaxial" anchoring element comprises a junction portion connecting a portion of said connection assembly and said base portion, this junction portion having a flexible structure providing the desirable joint of this connection assembly with respect to the base portion.

The joint of the connection assembly is thus not a ball joint with spherical portions, but provided by the single flexion of said junction portion. The

bottoming of the connection assembly may be quite significantly greater than that of a connection assembly of an existing anchoring element. Moreover, the axial tension imparted between the connection assembly and the base portion after assembly applies to the junction portion globally and not to a restricted surface of a portion of a joint, as according to the previous technique.

The absence of contact of portions of joint on restricted surfaces enables to reduce quite significantly, possibly to eliminate, the risk of diffusion of metal particles in the organism, and of wear of the material. There results the possibility of allowing flexibility of said junction portion after implantation, enabling thus non-rigid assembly, possibly flexible assembly, of the linking rods with the anchoring members.

The junction portion enables several degrees of multidirectional movements of said connection assembly with respect to the base portion, in translation as well as in pivoting motion.

Besides, the joint according to the invention is significantly less cumbersome than a joint according to the previous technique, which enables not only to minimise the interventions to realise for the implantation but also to localise this joint in order to come as close as possible to the conditions of anatomic movements.

According to a possibility, the junction portion is formed by a part distinct from the part of said connection assembly and of the base portion. The junction portion may then notably be composed of a rod of flexible material.

According to another possibility, the junction portion is composed of an extension of the base portion or of said part of the connection assembly, made flexible by an appropriate shape and/or by slots or recesses. This extension may for instance have a tubular structure and exhibit a helicoid slot, or may exhibit stepped radial recesses, preferably offset angularly.

The junction portion and the links of said part of said connection assembly and of said base portion may be designed so that said part of said

connection assembly and said base portion are never in contact with one another.

This absence of contact eliminates the risk of diffusion of metal particles in the organism.

Alternately, the junction portion is slightly stretchable longitudinally and means are provided to stretch this junction portion slightly longitudinally, enabling to space the surfaces away from one another whereas said part of said connection assembly and the base portion contact one another.

These surfaces of said part and of the base portion may be shaped to guide the movement of joint of this part with respect to the base portion. It may notably concern surfaces in portions of a sphere, respectively concave and convex, and provided coaxially to said junction portion.

These surfaces enable thus, when reducing vertebrae for osteosynthesis, to guide the movement of the part of said connection assembly with respect to the base portion in order not to subject the junction portion to excessive transversal stresses.

Along the same line, these same surfaces of the part of said connection assembly and of the base portion may be bordered by lateral bearing surfaces, enabling lateral wedging of said part with respect to the base portion.

Preferably, said anchoring element of "polyaxial" type comprises at least one part or a portion of part with elastically deformable structure, placed after assembly, between a part of the connection assembly and said base portion, this part or portion of part with elastically deformable structure enabling mobility of the connection assembly, and hence of the linking rod, with respect to the base portion, with a dampening effect.

Thus, in the equipment according to the invention, the connection assembly is not immobilised with respect to the base portion after assembly but may, relative to the elastic deformability of said part or portion of part, have a certain clearance with respect to the base portion in order to authorise limited movements of the vertebrae. The stresses imparted by the anchoring

element on the anchoring bony zones are thus notably reduced, as well as the risks of excessive stresses at vertebral joints situated on both sides of the vertebral segment treated.

The invention will be better understood, and other characteristics and advantages thereof, will appear with reference to the appended schematic drawing, representing, for non-limiting exemplification purposes, several possible embodiments of parts contained in the equipment affected.

Figure 1 is an axial sectional view of the different elements forming an anchoring element and a connection assembly contained in this equipment, according to a first embodiment;

Figure 2 is a lateral view of this anchoring element, of this connection assembly and of a linking rod, after assembly;

Figure 3 is a sectional view of these anchoring element, connection assembly and linking rod along the line III-III of Figure 2;

Figure 4 is a top view of these anchoring element, connection assembly and linking rod;

Figures 5 to 7 are perspective exploded, side and sectional views, respectively of the anchoring element, of the connection assembly and of the linking rod according to a second embodiment, along the line VII - VII of Figure 6;

Figures 8 to 10 are similar views of the anchoring element, of the connection assembly and of the linking rod according to a third embodiment, and

Figures 11 and 12 are views of the anchoring element, of the connection assembly and of the linking rod according to a fourth embodiment, respectively in perspective before assembly and as a sectional view along the axis of the anchoring element.

By simplification, the portions or elements described for the first embodiment, which can be found identically or similarly in the other

embodiments, will be designated by the same numeric references and will not described further.

Figures 2 to 4 represent a polyaxial pedicular screw 1, a rod 2 for linking several of these screws 1, a yoke 3 for connecting this rod 2 to one of these screws 1 and a nut 4 enabling to assemble the linking rod 2 to this screw 1.

As shown more particularly on Figure 1, the screw 1 comprises a base part 5 in the form of a screw, a proximal threaded stud 6, an elongated element 7, for joining the base part 5 and the stud 6, a screwable plug 8 for assembling the element 7 to the base part 5 and a crimpable ring 9 for assembling the element 7 to the stud 6. The screw 1 comprises also a part 10 with elastically deformable structure and a ring 11 bearing against this part 10.

The stud 6, the yoke 3, the nut 4, the part 10 and the ring 11 form a connection assembly of a linking rod 2 to a base portion 5.

The base part 5 is metallic, notably made of titanium, as well as the stud 6, the rod 2, the yoke 3, the nut 4, the plug 8, the crimpable ring 9 and the ring bearing 11. It comprises a threaded cylindrical portion 15 enabling its insertion in the pedicle of a vertebra, and a widened head 16 intended to bear against this pedicle.

This head 16 comprises a cylindrical upper cavity 17, liable to receive the part 10 with a shrink-fit, a cylindrical intermediate cavity 18 with concave spherical bottom, liable to receive the base of the stud 6, and a lower bore 19, liable to receive an end of the element 7, these cavities 17, 18 and bore 19 being coaxial to the axis of the base portion 5.

The head 16 also comprises a tapered transversal perforation 20, emerging in the bore 19. As appears on Figure 3, the plug 8 is intended to be screwed in the perforation 20 in order to clamp the element 7 in the bore 19 and thus ensure the assembly of this element 7 with the base portion 5.

The stud 6 comprises an axial bore 22 liable to be traversed by the element 7, a proximal thread 23 and a wider base 24 with convex spherical

distal face, whereas this base 24 may be received with a shrink-fit, but with possibility of movement, in the cavity 18.

The element 7 may notably be formed of braided polyester wires. After its engagement through the bore 22, this element 7 receives the ring 9, which is crimped thereon in order to maintain the base 24 in the cavity 18. The surplus portion of the element 7 is then cut beyond the ring 9.

The part 10 may notably be of silicon or of PMMA. It comprises an axial perforation 25 enabling its engagement on the stud 6, this bore 25 being flared at its lower portion to promote the bottoming of the stud 6 with respect to the base portion 5.

The bearing part 11 comprises an upper portion 26 drilled with a tapered bore 27 enabling to screw it on the stud 6 and a wider lower portion 28, delineating a lower cylindrical cavity 29 liable to receive the part 10 with a shrink-fit.

The part 10 is thus intended to be engaged on the stud 6 until it rests against the bottom of the cavity 17 and the part 11 is intended to be screwed on the stud 6 in order to clamp the part 10 therebetween and the base portion 5, independently of the clamping realised by the nut 4. The part 11 may be clamped in a controlled fashion, for instance by means of a torque wrench, according to the degree of dampening effect requested of the movement of the stud 5, relative to the characteristics of the patient (condition of the intervertebral disks, degree of vertebral instability, weight). The effect of this clamping is also to cause slight stretching of the element 7, which enables to move the convex face of the base 24 from the bottom concave of the cavity 18.

There results that the multidirectional movement of the stud 6 with respect to the base portion 5 is possible thanks to the sole flexibility of the element 7, according to a bottoming important, without any restricted bearing zone of the stud 6 against an edge of the base portion 5, and without any

substantial friction of the adjacent surfaces of the stud 6 and of the base portion 5.

The linking rod 2 is cylindrical and exhibits such rigidity that it enables to maintain several vertebras relative to one another. This rod 2 is however deformable in order to be shaped relative to the vertebral correction to be carried out.

The yoke 3 comprises a rounded portion 30 intended to surround the linking rod 2 and two parallel lateral wings 31 drilled with holes 32 for the engagement of the yoke 3 on the stud 6. These wings 31 are mutually distant so that, in a spaced apart position, the rod 2 may be inserted and may slide in the portion 30, and, in a closing-in position provided by clamping the nut 4, they clamp the portion 30 around the rod 2, immobilising said rod with respect to the yoke 3.

As shown on Figure 1, each wing 31 exhibits a cavity 33, 34 on its outer face, intended for receiving the nut 4 and the bearing ring 11, respectively.

In practice, the number of screw 1 necessary to the treatment to realise is implemented in the pedicles of the vertebras affected, then the yokes 3, with the rod 2 engaged in the portions 30, are placed on the studs 6.

The significant bottoming of the studs 6 enables to facilitate quite notably this placement of the yokes 3 on its studs 6. During this operation, while the vertebras are reduced towards their osteosynthesis position, the heads 16 of the base portions 15 maintain transversally the bases 24 of the studs 6 and eliminate thus any risk of applying to the elements 7 excessive transversal stresses.

The nuts 4 are then clamped to bring the branches 31 together and thus clamp the rods 2 in the portions 30 of the yokes 3.

Figures 5 to 7 represent another embodiment of the osteosynthesis equipment according to the invention, also including a base part 5, a proximal threaded stud 6, a yoke 3 and a nut 4.

In such a case, the base part 5 comprises a proximal tubular extension 40 wherein is provided a helicoid slot 41.

This extension 40 is also drilled with two transversal coaxial holes 42 and the stud 6 comprises a transversal hole 43 facing, during the assembly of the stud 6 and of the base portion 5, these holes 42, whereas the holes 42, 43 may then receive a pin 44 pushed therethrough.

The slot 41 enables to confer the extension 40 the required flexibility to enable the stud 6 to bottom with respect to the base portion 5 and to enable a non-rigid assembly of a linking rod 2 to a base portion 5.

The yoke 3 and the nut 4 may be identical to those described previously or, as is represented, the nut 4 may exhibit an outer peripheral face in portion of a sphere and the yoke 3 may exhibit an upper cavity 33 of corresponding shape, wherein the nut 4 is totally engaged after complete screwing, as shown on Figure 7.

Figures 8 to 10 represent another embodiment of the osteosynthesis equipment according to the invention, also including a base portion 5 with proximal tubular extension 40, a proximal threaded stud 6, a yoke 3 and a nut 4.

In such a case, the proximal tubular extension 40 comprises stepped radial recesses 45, whereas each recess is provided on slightly less than half the circumference of the extension 40 and is provided with an angular offset with respect to the recesses 45 of the adjacent stages. These recesses 45 enable to delineate spaces authorising transversal deformation of the extension 40 in an "accordion"-like fashion, conferring this extension 40 the required flexibility.

The assembly of the stud 6 to the extension 40 may be realised by means of a pin as described previously, or, as represented, by screwing and gluing a threaded base of the stud 6 in the bore of the extension 40, which is also tapered.

The proximal threaded stud 6 may contain an upper stud 46 for screwing an extension (not represented) enabling to facilitate the descent of the yoke 3 - linking rod 2 assembly on the stud 6 when implanting the equipment.

Figures 11 and 12 represent a "tulip"-type screw 1, i.e. whereof the head 50 is widened and exhibits a transversal housing 51 for receiving a linking rod 2. This head 50 exhibits an axial tapered bore 52 provided in facing walls delineated by the transversal housing 51 and receives a nut 4 for locking the linking rod 2 in the housing 51.

In such a case, the base of the head 50 also comprises stepped radial recesses 45, whereas each recess is provided on slightly less than half the circumference of the head 50 and is provided with an angular offset with respect to the recesses 45 of the adjacent stages. These recesses 45 enable, as described previously, to delineate spaces authorising transversal deformation of the head 50 in an "accordion"-like fashion, conferring this head 50 the required flexibility.

As appears from the foregoing, the invention provides a vertebral osteosynthesis equipment wherein a part 6, 50 of the connection assembly has a significant bottoming with respect to the base portion 5 of the anchoring element 1 intended to be attached to the bone and wherein the risk of diffusion of metal particles in the organism is significantly reduced with respect to an existing equipment.

This vertebral osteosynthesis equipment enables moreover non-rigid assembly, possibly flexible assembly, of the linking rods 2 with the anchoring members 1, with possible dampening effect of the movement of the mobile parts.

Besides, this equipment has a mobile portion whereof the localisation is close to conditions of anatomic movements, and has small space requirements in order to enable to minimise the interventions necessary to realise the implantation.

It goes without saying that the invention is not limited to the embodiment described above for exemplification purposes but it extends to all the embodiments covered by the claims appended thereto.

In particular, the expression "connection part" should be understood in a wide meaning: it may be a proximal threaded stud 6 or a connection part in the form of a "tulip", i.e. including a housing for receiving a linking rod.

Similarly, the expression "base portion" 5 should be understood as any structure enabling the attachment of the anchoring element 1 with one vertebra, notably in the form of pedicular screw, forceps or hook.

CLAIMS

1 – vertebral osteosynthesis equipment comprising bony anchoring members, such as pedicular screws (1), forceps or hooks, one or two linking rods (2), intended to be connected to these anchoring members, and connection assemblies (6, 3, 4, 10, 11 ; 40, 50, 4) of this or these rods (2) to these anchoring members, at least one of these anchoring members (1) being of the "polyaxial" type, i.e. including a connection assembly (6, 3, 4, 10, 11 ; 40, 50, 4) articulated with respect to a base portion (5) intended to be attached to the vertebra ;

Equipment characterized in that said "polyaxial" anchoring element (1) comprises a junction portion (7, 40) connecting a portion (6, 50) of said connection assembly (6, 3, 4, 10, 11 ; 40, 50, 4) and said base portion (5), this junction portion having a flexible structure providing the desirable joint of this connection assembly (6, 3, 4, 10, 11 ; 40, 50, 4) with respect to the base portion (5).

2 – Equipment according to claim 1, characterized in that the junction portion is formed by a part (7) distinct from the part (6, 50) of said connection assembly (6, 3, 4, 10, 11 ; 40, 50, 4) and of the base portion (5).

3 – Equipment according to claim 2, characterized in that the junction portion may then notably be composed of a rod (7) of flexible material.

4 – Equipment according to claim 1, characterized in that the junction portion is composed of an extension (40) of the base portion (5) or of said part (50) of the connection assembly, made flexible by an appropriate shape and/or by slots (41) or recesses (45).

5 – Equipment according to claim 4, characterized in that the extension (40) may for instance have a tubular structure and exhibit a helicoid slot (41), or may exhibit stepped radial recesses (45), preferably offset angularly.

6 – Equipment according to any claims 1 to 5, characterized in that the junction portion and the links of said part of said connection assembly and of

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 635 of 2152

said base portion may be designed so that said part of said connection assembly and said base portion are never in contact with one another.

7 – Equipment according to any claims 1 to 5, characterized in that the junction portion (7) is slightly stretchable longitudinally and means (6, 9, 3, 4, 10, 11) are provided to stretch this junction portion (7) slightly longitudinally, enabling to space the surfaces away from one another whereas said part (6) of said connection assembly and the said base portion (5) contact one another.

8 – Equipment according to any claims 1 to 7, characterized in that surfaces by which said part (6) of said connection assembly and the said base portion (5) contact one another, may be shaped to guide the movement of joint of this connection part (6) with respect to the base portion (5).

9 – Equipment according to claim 8, characterized in that said surfaces of the part (6) of said connection assembly and of the base portion (5) may be bordered by lateral bearing surfaces, enabling lateral wedging of said part (6) with respect to the base portion (5).

10 – Equipment according to any claims 1 to 9, characterized in that said anchoring element (1) of "polyaxial" type comprises at least one part or a portion of part (10) with elastically deformable structure, placed after assembly, between a part (11) of the connection assembly and said base portion (5), this part or portion of part (10) with elastically deformable structure enabling mobility of the connection assembly, and hence of the linking rod (2), with respect to the base portion (5), with a dampening effect.

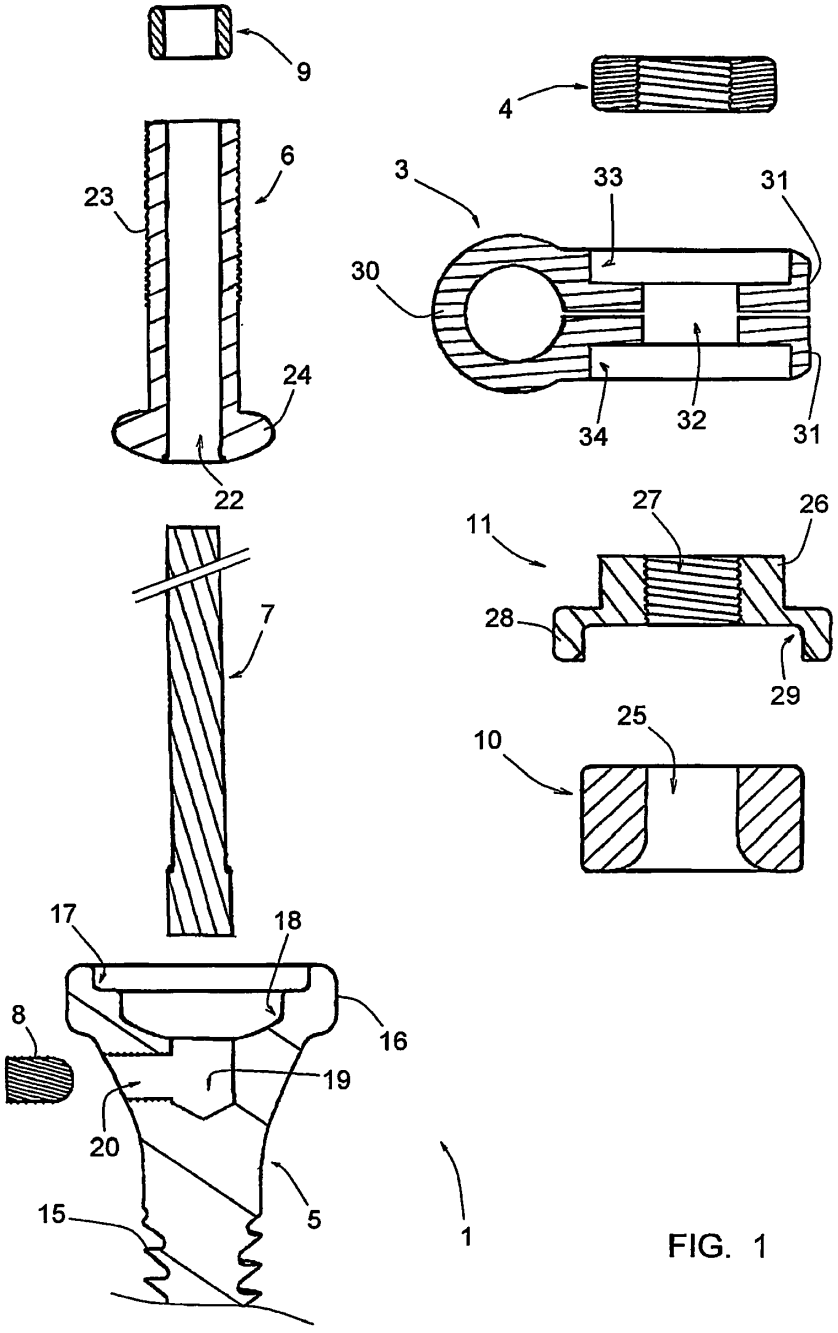
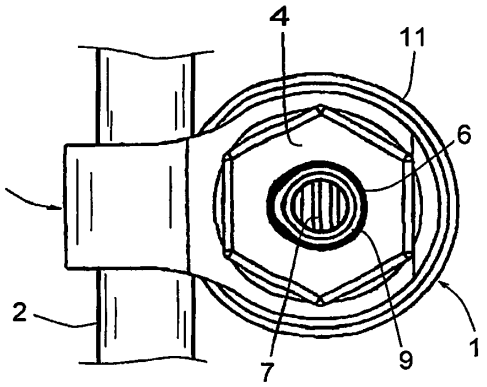

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FIG. 1

FIG. 4



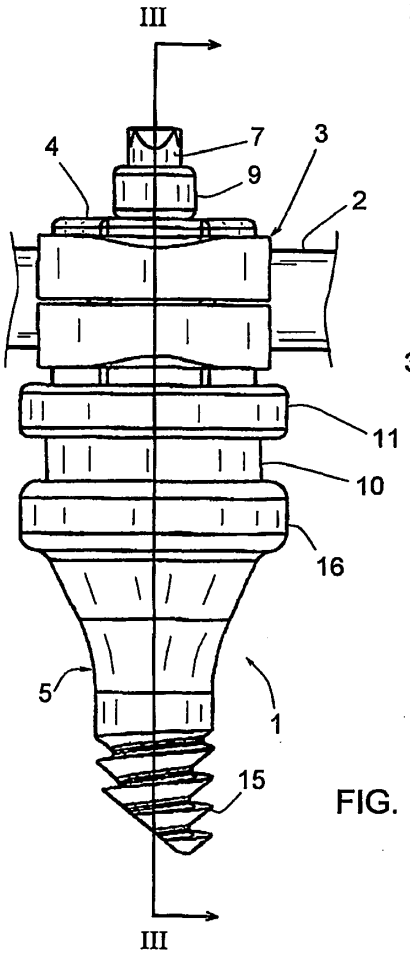


FIG. 2

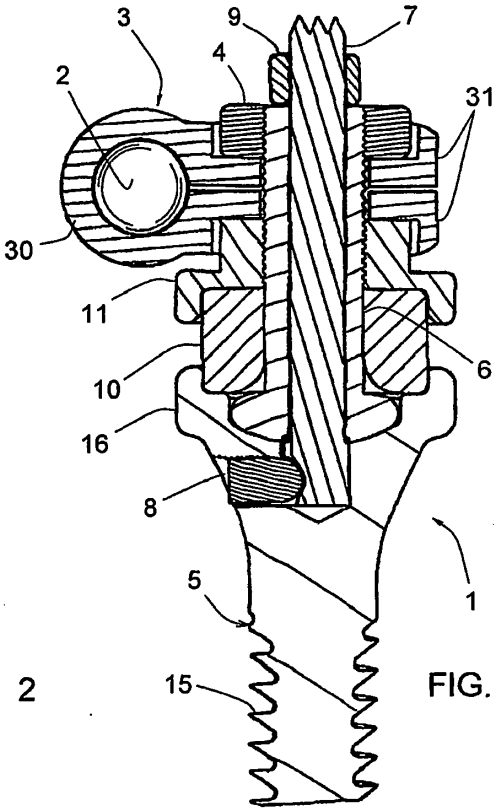


FIG. 3

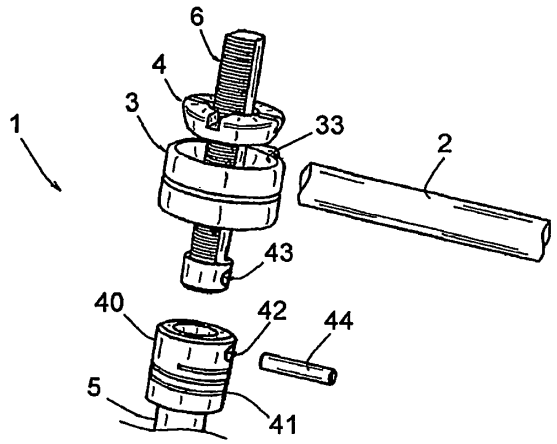


FIG. 5

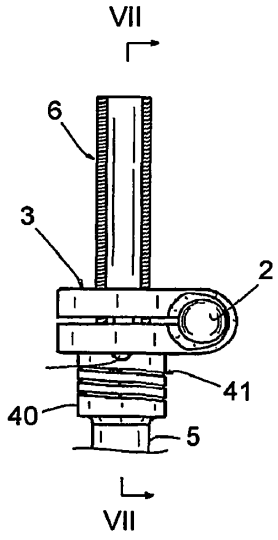


FIG. 6

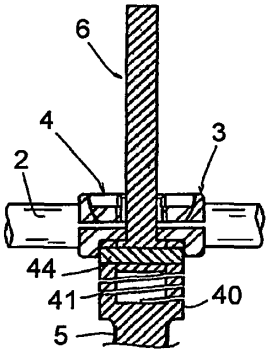


FIG. 7

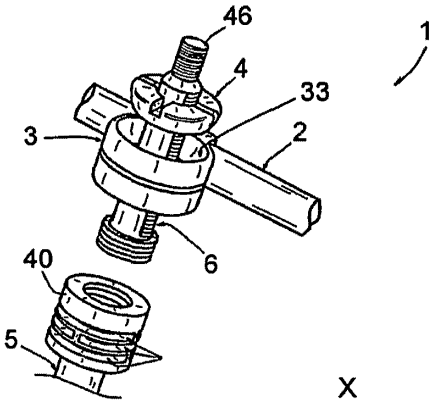


FIG. 8

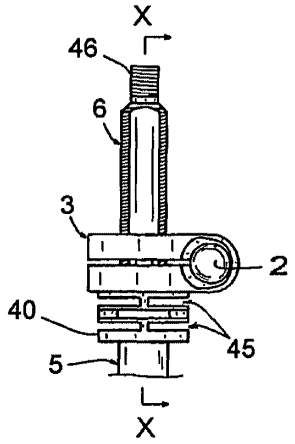


FIG. 9

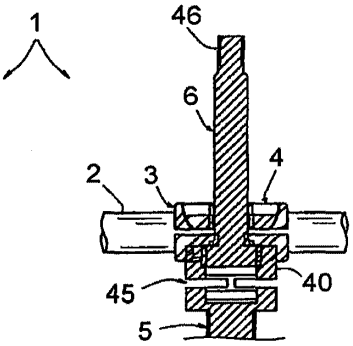


FIG. 10

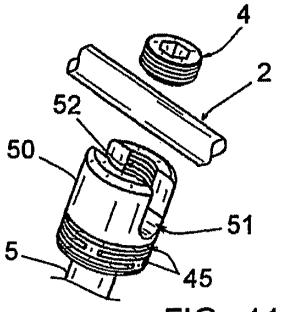


FIG. 11

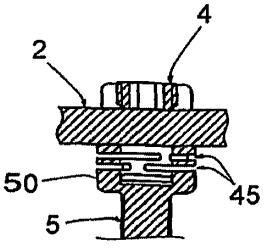


FIG. 12

INTERNATIONAL SEARCH REPORT

International Application No
PCT/IB2005/000341

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.
X	US 4 946 458 A (HARMS ET AL) 7 August 1990 (1990-08-07) column 3, line 4 - line 27; figures 1,2	1,2,6,10
Y		4,5,8,9
Y	WO 03/047441 A1 (MATHYS MEDIZINALTECHNIK AG; STUDER, ARMIN) 12 June 2003 (2003-06-12) figures 3-5	4,5
Y	WO 03/068088 A (CROSS MED PROD INC) 21 August 2003 (2003-08-21) page 5, line 3 - page 6, line 9; figures 1,2	8,9

-/--

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

[X] Patent family members are listed in annex.

° Special categories of cited documents :

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Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 643 of 2152

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Page 644 of 2152

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(71) Anmelder: **BIEDERMANN MOTECH GmbH**
78054 VS-Schwenningen (DE)

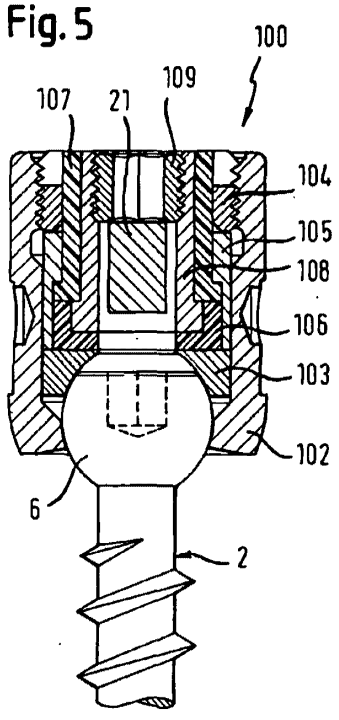
(72) Erfinder:
- **Harms, Jürgen**
  76227 Karlsruhe (DE)
- **Matthis, Wilfried**
  79367 Weisweil (DE)
- **Biedermann, Lutz**
  78048 VS-Villingen (DE)

(74) Vertreter: **Hofer, Dorothea et al**
Prüfer & Partner GbR
Patentanwälte
Harthauser Strasse 25 d
81545 München (DE)

(54) Verankerungselement und Einrichtung zur dynamischen Stabilisierung von Wirbeln bzw. Knochen

(57) Es wird ein Knochenverankerungselement (1, 1', 100, 415, 420) für eine Stabilisierungsvorrichtung (200) für Knochen bzw. Wirbel bereitgestellt, mit der ein Knochen bzw. Wirbel mit einem stabförmigen Element (21, 407) verbunden werden kann. Durch mindestens einen Rotationsfreiheitsgrad zwischen dem Stab und einem mit dem Knochen bzw. Wirbel fest verbundenen Verankerungselement (2, 4) kann die Übertragung von Drehmomenten (M) auf das Verankerungselement (2, 4) und damit das Lockern oder gar Lösen der festen Verankerung in dem Knochen bzw. Wirbel verhindert werden. Weiter wird eine Stabilisierungsvorrichtung (200) bereitgestellt, bei der solche Knochenverankerungselemente (1, 100, 415, 420) verwendet werden.

Fig. 5



EP 1 579 816 A1

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Beschreibung

[0001] Die Erfindung betrifft ein Verankerungselement und eine Stabilisierungseinrichtung zur dynamischen Stabilisierung von Wirbeln oder Knochen mit einem solchen Verankerungselement.

[0002] Zur Fixierung von Knochenfrakturen oder zur Stabilisierung der Wirbelsäule sind starre Fixations- und Stabilisierungseinrichtungen bekannt, die aus wenigstens zwei jeweils in einem Knochen bzw. Wirbel zu verankernden und über einen starren Stab miteinander verbundenen Knochenschrauben bestehen. Beispielsweise ist aus der EP 0 483 242 ein Verankerungselement nach dem Oberbegriff des Patentanspruchs 1 bekannt, das zusammen mit einem starren Stab für eine solche starre Stabilisierungseinrichtung verwendet wird. Starre Systeme werden dann eingesetzt, wenn eine Relativbewegung der zu stabilisierenden Knochenteile oder Wirbel zueinander nicht erwünscht ist, z.B. beim Vorhandensein von Frakturen oder anderen Fehlstellungen.

[0003] Aus der US 5,474,555 ist ein Knochenverankerungselement in Form einer Polyaxial-Knochenschraube mit einem Schraubenelement und einem Aufnahmeteil zur Verbindung mit einem Stab bekannt, bei der das im Knochen zu verankernde Schraubenelement mit dem Aufnahmeteil derart verbunden ist, dass eine begrenzte Bewegung zwischen dem Schraubenelement und dem Aufnahmeteil möglich ist. Die beschriebene Lösung erlaubt jedoch keine Stabilisierung mit einer kontrollierten Bewegungsmöglichkeit.

[0004] Bei bestimmten Indikationen, z.B. bei einer geschädigten Bandscheibe oder bei Vorhandensein einer künstlichen Bandscheibe ist eine Stabilisierungseinrichtung wünschenswert, die eine begrenzte Bewegung der zu stabilisierenden Wirbel ermöglicht. Eine derartige dynamische Stabilisierungseinrichtung ist beispielsweise aus der US 5,733,284 bekannt.

[0005] Bei den bekannten Stabilisierungsvorrichtungen, insbesondere den dynamischen, besteht die Gefahr, dass über den Stab ein Drehmoment auf das Verankerungselement ausgeübt wird. Dies kann dazu führen, dass es zu einem Lockern oder gar Lösen des Verankerungselementes im Knochen kommt.

[0006] In Fig. 9 ist das Zustandekommen eines Drehmomentes M um die Schraubenachse bei einer der Anmelderin bekannten dynamischen Stabilisierungseinrichtung 200 dargestellt. Bei der hier dargestellten Stabilisierungseinrichtung 200 sind zwei Knochenverankerungselemente 202, 202' über einen gekrümmten Stab 201 mit einer vorbestimmten Biege-Elastizität miteinander verbunden. Die Knochenverankerungselemente 202, 202' sind mit Knochenschrauben fest in zwei benachbarten Wirbeln (hier nicht dargestellt) verankert. In Fig. 9 ist der Fall dargestellt, dass die beiden Knochenverankerungselemente 202, 202' mit einer Kraft F zusammengedrückt werden. Durch die Kraft F wirkt ein Biegemoment auf den Stab, das zu einem Drehmoment M auf die Knochenverankerungselemente 202, 202' um die Schraubenachse führt. Entsprechend führt Auseinanderziehen der Knochenverankerungselemente mit einer Kraft F zu einem Drehmoment M in entgegengesetzter Richtung um die Schraubenachse.

[0007] Es ist Aufgabe der Erfindung, ein Verankerungselement und eine dynamischen Stabilisierungseinrichtung zur Stabilisierung und zur Bewegungsbegrenzung von benachbarten Wirbeln oder Knochen bereitzustellen, bei dem bzw. der ein Lockern oder Lösen des Verankerungselementes im Betrieb verhindert wird.

[0008] Die Aufgabe wird gelöst durch ein Verankerungselement nach Patentanspruch 1 und durch eine Stabilisierungsvorrichtung nach Patentanspruch 12.

[0009] Weiterbildungen der Erfindung sind in den Unteransprüchen angegeben.

[0010] Die Erfindung weist den Vorteil auf, dass durch eine drehbare Verbindung des im Knochen verankerten Abschnitts des Verankerungselementes relativ zu dem Stab ein Lockern oder Lösen des Verankerungselementes durch an dem Verankerungselement angreifende Drehmomente effektiv verhindert werden kann. Die Stabilisierungseinrichtung ist vorteilhaft anwendbar zur Entkoppelung der Schaftrotation von Kopf- bzw. Stabfixierung bei der dynamischen Stabilisierung von Wirbeln.

[0011] Weitere Merkmale und Zweckmäßigkeiten der Erfindung ergeben sich aus der Beschreibung von Ausführungsbeispielen anhand der Figuren.

[0012] Von den Figuren zeigen:

Fig. 1a	eine Explosionsdarstellung eines Verankerungselementes nach einer ersten Ausführungsform der Erfindung;
Fig. 1b	eine teilgeschnittene Ansicht des Verankerungselements nach der ersten Ausführungsform der Erfindung mit einem eingelegten Stab;
FIG. 2	eine perspektivische Ansicht eines Lagerteils, das bei der ersten Ausführungsform der Erfindung verwendet wird;
Fig. 3	Eine Abwandlung des Verankerungselementes nach der ersten Ausführungsform;
Fig. 4	eine Explosionsdarstellung eines Verankerungselementes nach einer zweiten Ausführungsform der Erfindung;
Fig. 5	eine teilgeschnittene Darstellung des Verankerungselementes nach der zweiten Ausführungsform der Erfindung;

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 646 of 2152

Fig. 6a eine Seitenansicht der Stabfassung des Verankerungselements nach der zweiten Ausführungsform mit eingelegtem Stab und mit noch nicht vollständig eingeschraubter Innenschraube;

Fig. 6b eine Schnittdarstellung der Stabfassung des Verankerungselements nach der zweiten Ausführungsform mit eingelegtem Stab und mit vollständig eingeschraubter Innenschraube;

Fig. 7a und 7b ein Verankerungselement nach der zweiten Ausführungsform der Erfindung in zwei verschiedenen Winkelstellungen des stabförmigen Elements relativ zum Aufnahmeteil;

Fig. 8a eine Explosionsdarstellung eines Verankerungselements nach einer dritten Ausführungsform der Erfindung;

Fig. 8b Knochenschraube mit drehbarer Verbindung zwischen Kopf und Verankerungsabschnitt die bei der dritten Ausführungsform der Erfindung verwendet wird;

Fig. 8c Abwandlung des Verankerungselementes aus Fig. 8a und 8b; und

Fig. 9 das Zustandekommen eines Drehmomentes auf eine Knochenschraube bei einer der Anmelderin bekannten dynamischen Stabilisierungsvorrichtung.;

Erste Ausführungsform

[0013] Wie in den Figuren 1a und 1b zu sehen ist, beinhaltet ein Verankerungselement 1 zum Verbinden eines Knochenteils oder eines Wirbels und eines Stabs 21 mit bevorzugt rechteckigem Querschnitt nach einer ersten Ausführungsform ein Schraubenelement 2, ein Aufnahmeteil 3, eine in das Aufnahmeteil einzuschraubenden Innenschraube 4 und ein Lagerteil 5.

[0014] Das Schraubenelement 2 weist einen Kopf 6 in der Form eines Kugelsegments und einen Gewindeschaft 7 zum Verankern in dem Knochen oder Wirbel auf. Auf der dem Gewindeschaft 7 abgewandten Seite ist der Kopf 6 des Schraubenelementes 2 abgeflacht und weist eine Ausnehmung 8 zum Ineingriffbringen eines Inbusschlüssels auf.

[0015] Das Aufnahmeteil 3 ist ein im wesentlichen zylinderförmiger Körper mit einem ersten Ende 9 und einem diesem gegenüberliegenden zweiten Ende 10. Koaxial zu seiner Hauptachse weist das Aufnahmeteil eine Bohrung 11 auf. Angrenzend an das erste Ende 9 ist zum Aufnehmen des Stabs 21 eine rechteckige Ausnehmung 12 vorgesehen, durch die zwei freie Schenkel 40, 41 gebildet sind. Die Breite der Ausnehmung ist dabei etwas größer als die Länge der schmalen Seite des Stabs, während die Tiefe der Ausnehmung größer als die Länge der breiten Seite des Stabs ist. Auf der Innenseite der Schenkel 40, 41 ist angrenzend an das erste Ende 9 in der Bohrung 11 ein Innengewinde 13 vorgesehen. In einem an das erste Ende angrenzenden ersten Abschnitt weist die Bohrung einen im wesentlichen konstanten Innendurchmesser auf, der größer als der Durchmesser des Kopfes 6 des Schraubenelementes 2 ist. An den ersten Abschnitt angrenzend weist das Aufnahmeteil 3 einen sich in Richtung von dem ersten Ende 9 zu dem zweiten Ende 10 hin derart verjüngenden Abschnitt auf, dass ein an das zweite Ende angrenzender sphärischer Sitz 14 ausgebildet ist. Die Öffnung 32 auf der Seite des zweiten Endes ist größer als der Durchmesser des Gewindeschaftes 7 des Schraubenelementes 2.

[0016] Das Lagerteil 5 weist einen zylindrischen Abschnitt mit flacher Stirnseite 15 auf. Der Durchmesser des zylindrischen Abschnittes ist so gewählt, dass im zusammengebauten Zustand dieser Abschnitt mit Presspassung in dem ersten Abschnitt des Aufnahmeteils 3 sitzt. Das Lagerteil 5 weist weiter einen an den zylindrischen Abschnitt angrenzenden kugelschalenförmigen Abschnitt 31 auf, dessen äußere Form an die Form des sphärischen Sitzes 14 angepasst ist. Im Inneren des Lagerteils 3 ist eine sphärische Ausnehmung 17 vorgesehen, die der Aufnahme des Kopfes 6 des Schraubenelementes 2 dient und an dessen sphärische Form angepasst ist. Der Innendurchmesser der Ausnehmung 17 ist, je nach gewünschter Schwergängigkeit der Dreh- und Schwenkbewegung des Schraubenelementes relativ zu dem Lagerteil, in einem Bereich von etwa gleich oder gerade etwas größer als der Durchmesser des Kopfes des Schraubenelementes. Von der flachen Stirnseite 15 ist eine in die Ausnehmung 17 einmündende Bohrung 18 mit einem Durchmesser vorgesehen, der das Durchführen eines Inbusschlüssels zum Festschrauben des Schraubenelementes 2 erlaubt, aber geringer ist als der Durchmesser des Kopfes 6 des Schraubenelementes 2. In dem kugelschalenförmigen Abschnitt ist eine in die Ausnehmung 17 einmündende koaxiale Bohrung 19 vorgesehen, deren Durchmesser kleiner als der Durchmesser des Kopfes 6 des Schraubenelementes 2, aber größer als der Durchmesser des Gewindeabschnittes 7 ist. Wie in Fig. 2 zu sehen weist das Lagerteil 5 in dem kugelschalenförmigen Abschnitt angrenzend an die der flachen Stirnseite gegenüberliegende Seite des Lagerteils Schlitze 20 auf, durch die die Elastizität des Lagerteils erhöht ist. Vorzugsweise ist das Lagerteil 5 aus einem körperverträglichen Kunststoff gefertigt, der gute Gleiteigenschaften aufweist. Be-

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 647 of 2152

vorzugt wird Polyethylen (PE) eingesetzt. Hierbei können verschiedene Vernetzungsgrade mit daraus resultierenden verschiedenen Molekulargewichten, wie z.B. LDPE und LLDPE mit Molekulargewichten von bis zu 50.000 g/mol, HDPE mit Molekulargewichten bis zu 200.000 g/mol oder UHMWP (Ultra-Height Molecular Weight Poly Ethylen) mit Molekulargewichten um 6.000.000 g/mol, verwendet werden. Bevorzugt wird für das Lagerteil aufgrund seines geringen Langzeitverschleißes UHMWP eingesetzt.

[0017] Die Innenschraube 4 weist eine koaxiale Ausnehmung 42 zum Ineingriffbringen eines Inbusschlüssels auf.

[0018] Im Betrieb wird zunächst der Kopf 6 des Schraubenelementes 2 in die Ausnehmung 17 des Lagerteils 5 eingebracht und dann das Schraubenelement 2 zusammen mit dem Lagerteil 5 in das Aufnahmeteil 3 eingeführt. Anschließend an diese Vormontage wird das Schraubenelement 2 in den Knochen bzw. Wirbel eingeschraubt. Danach wird das stabförmige Element 21 in das Aufnahmeteil 3 eingelegt, wodurch sich das Aufnahmeteil 3 selbst richtig zum stabförmigen Element 21 hin ausrichtet. Anschließend wird das stabförmige Element 21 durch die Innenschraube 4 relativ zu dem Aufnahmeteil 3 fixiert.

[0019] Auf die oben beschriebene Art und Weise wird eine Verbindung zwischen dem fest in den Knochen bzw. Wirbel eingeschraubten Schraubenelement 2 und dem stabförmigen Element 21 hergestellt, bei der der Kopf 6 des Schraubenelementes 2 in dem Lagerteil 5 in einem vorbestimmten Raumwinkelbereich drehbar gelagert ist. Dabei ist der Raumwinkelbereich einerseits durch den Durchmesser des Gewindeschaftes 7 und andererseits durch den Durchmesser der Öffnung 32 auf der Seite des zweiten Endes 10 des Aufnahmeteils 3 oder den Durchmesser der koaxialen Bohrung 19 in dem Aufnahmeteil 5 festgelegt. Je nachdem, wie der Durchmesser der sphärischen Ausnehmung 17 und der Durchmesser des Kopfes 6 zueinander gewählt werden, ist die Einstellung unterschiedlich starker Reibungskräfte zwischen Kopf und Lagerteil und somit die Einstellung der Kräfte möglich, die überwunden werden müssen, um den Kopf 6 des Schraubenelements 2 in der Ausnehmung 17 des Lagerteils 3 zu drehen bzw. zu schwenken.

[0020] In Fig. 3 ist eine Abwandlung 1' des Verankerungselementes 1 nach der ersten Ausführungsform dargestellt, bei der das Lagerteil 5' zweiteilig aus einem ersten Lagerelement 5a' und einem zweiten Lagerelement 5b' ausgebildet ist. Das zweiteilige Lagerteil 5' ist wie das Lagerteil 5, jedoch parallel zur Stirnseite in zwei Teile geschnitten ausgebildet. Durch die zweiteilige Form kann der Kopf 6 des Schraubenelementes 2 in die Ausnehmung 17' eingebracht werden, ohne die Öffnung 19' aufzuspreizen. Das Lagerteil 5' kann daher aus einem steifen Material ohne Schlitze ausgebildet sein.

Zweite Ausführungsform

[0021] In den Figuren 4 bis 7 ist ein Verankerungselement 100 nach einer zweiten Ausführungsform der Erfindung dargestellt. Elemente, die gleich denjenigen der ersten Ausführungsform sind, sind mit gleichen Bezugszeichen versehen.

[0022] Wie am besten in den Figuren 4 und 5 zu sehen ist, beinhaltet das Verankerungselement 100 nach der zweiten Ausführungsform ein Schraubenelement 2, ein Aufnahmeteil 102, ein Druckelement 103, einen ersten Ring 104, einen zweiten Ring 105, ein erstes Lagerteil 106, ein zweites Lagerteil 107, eine Stabfassung 108 und eine Innenschraube 109.

[0023] Das Schraubenelement 2 in dem Verankerungselement 100 nach der zweiten Ausführungsform ist identisch mit dem Schraubenelement 2 des Verankerungselements 1 nach der ersten Ausführungsform.

[0024] Das Aufnahmeteil 102 ist ein im wesentlichen zylindrischer Körper mit einem ersten Ende 112 und einem diesem gegenüberliegenden zweiten Ende 113. Eine koaxiale Bohrung 120 erstreckt sich von dem ersten Ende 112 bis zu dem zweiten Ende 113 des Aufnahmeteils 102. Angrenzend an das erste Ende 112 ist eine im wesentlichen U-förmige Ausnehmung 140 vorgesehen, wodurch zwei freie Schenkel 114 und 115 gebildet sind. Angrenzend an das erste Ende 112 ist auf der Innenseite der freien Schenkel 114 und 115 ein Innengewinde 122 vorgesehen. In einem an das erste Ende 112 des Aufnahmeteils 102 angrenzenden Abschnitt hat die Bohrung 120 einen im wesentlichen konstanten Durchmesser, der größer ist, als der Durchmesser des Kopfes 6 des Schraubenelementes 2. In einem sich an den ersten Abschnitt anschließenden und bis zum zweiten Ende des Aufnahmeteils 102 erstreckenden zweiten Abschnitt verjüngt sich die Bohrung 120 in Richtung des zweiten Endes 113. Angrenzend an das zweite Ende 113 ist ein sphärischer Abschnitt 121 gebildet, dessen Form an die Form des Kopfes 6 des Schraubenelementes 2 angepasst ist. Der Durchmesser der Bohrung in dem zweiten Abschnitt ist so gewählt, dass er angrenzend an das zweite Ende kleiner als der Durchmesser des Kopfes 6 des Schraubenelementes 2, aber größer als der Durchmesser des Gewindeschaftes 7 des Schraubenelementes 2 ist.

[0025] Der erste Ring 104 weist auf seiner Außenseite ein Außengewinde 123 auf, das mit dem Innengewinde 122 auf der Innenseite der freien Schenkel 114 und 115 des Aufnahmeteils 102 zusammenwirkt. An einer Stirnseite 146 des ersten Rings 104 sind sich in radialer Richtung erstreckende Ausnehmungen 124 vorgesehen, in die ein Werkzeug zum Einschrauben des ersten Rings 104 in das Aufnahmeteil 102 eingreifen kann.

[0026] Der zweite Ring 105 ist rohrförmig ausgebildet mit konstantem Außendurchmesser mit einem an ein erstes Ende 141 angrenzenden ersten Abschnitt mit einem ersten Innendurchmesser und mit einem an ein zweites Ende 142 angrenzenden zweiten Abschnitt mit

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 648 of 2152

einem zweiten Innendurchmesser, der größer ist als der Innendurchmesser des ersten Abschnitts, so dass dadurch eine Schulter 147 ausgebildet ist. Der Außendurchmesser des zweiten Ringes 105 ist über die gesamte Länge des Ringes konstant und etwas kleiner als der Durchmesser der Bohrung 120 in dem an das erste Ende 112 des Aufnahmeteils 102 angrenzenden Abschnitt, sodass der Ring 105 in die Bohrung 120 einschiebbar ist. An das erste Ende 141 angrenzend ist eine rechteckige Ausnehmung 143 vorgesehen, durch die zwei freie Schenkel 144, 145 gebildet sind. Die Breite der Ausnehmung 143 ist wie die Breite der U-förmigen Ausnehmung 140 des Aufnahmeteils 102 größer als die schmale Seite des rechteckigen Querschnittes des Stabes, sodass der in diese Ausnehmungen eingelegte Stab 21 in einem vorbestimmten Winkelbereich, bevorzugt etwa ±10°, hin und her geschwenkt werden kann.

[0027] Das Druckelement 103 hat im wesentlichen die Form eines flachen Zylinders mit einer sphärischen Ausnehmung 111 auf der dem Schraubenkopf zugewandten Seite, deren Form an die Form des Kopfes 6 des Schraubenelementes 2 angepasst ist, und mit einer in diese Ausnehmung 111 einmündenden koaxialen Bohrung 110 zum Hindurchführen eines Schraubendrehers versehen. Der Außendurchmesser des Druckelementes 103 ist etwas geringer als der Durchmesser der Bohrung 120 in dem Aufnahmeteil 102, sodass das Druckelement 103 in die Bohrung des Aufnahmeteils einschiebbar ist.

[0028] Der erste und der zweite Ring 104, 105 dienen zum Ausüben von Druck auf das Druckelement 103 und damit zum Fixieren des Kopfes 6 des Schraubenelementes 2 in dem sphärischen Abschnitt 121.

[0029] Das erste Lagerteil 106 hat die Form einer Kreisscheibe mit einer koaxialen Bohrung 135 zum Hindurchführen eines Schraubendrehers und mit einem in Umfangsrichtung verlaufenden ringförmigen Vorsprung 148, der im eingesetzten Zustand auf der dem Druckelement abgewandten Seite liegt. Der ringförmige Vorsprung weist zwei gegenüberliegende rechteckige Ausnehmungen 149 auf.

[0030] Das zweite Lagerteil 107 ist als ein rohrförmiger Abschnitt mit einem flanschartigen Ansatz 151 ausgebildet, wobei der Durchmesser des rohrförmigen Abschnittes geringer ist als der Durchmesser des ersten Lagerteils 106. Der äußere Durchmesser des flanschartigen Ansatzes 151 des zweiten Lagerteils 107 ist gleich dem Durchmesser des ersten Lagerteils 106. Angrenzend an die Seite mit dem flanschartigen Ansatz 151 sind zwei sich gegenüberliegende rechteckige Ausnehmungen 150 vorgesehen.

[0031] Das erste und das zweite Lagerteil 106, 107 sind im eingesetzten Zustand koaxial so angeordnet, dass der ringförmige Vorsprung 148 des ersten Lagerteils 106 an den flanschartigen Ansatz 151 des zweiten Lagerteils 107 angrenzt, wobei die rechteckigen Ausnehmungen 149, 150 in den beiden Lagerteilen 106, 107 jeweils aneinander ausgerichtet sind, sodass in dem durch die beiden Lagerteile 106, 107 gebildeten Lager zwei sich gegenüberliegende, in das Innere des Lagers mündende Öffnungen zum Aufnehmen des Stabes ausgebildet sind. In der Breite sind die durch die Ausnehmungen 149, 150 im zusammengesetzten Zustand ausgebildeten Öffnungen so ausgelegt, dass der durch diese Öffnungen eingelegte Stab 21 in einem vorbestimmten Winkelbereich, bevorzugt etwa ±10°, hin und her geschwenkt werden kann. Die Höhe der durch die Ausnehmungen 149, 150 im zusammengesetzten Zustand gebildeten Öffnungen ist etwas größer als die entsprechende Querschnittsseite des Stabs 21. Der Außendurchmesser des Lagers ist gerade so bemessen, dass eine Presspassung des Lagers in dem ersten und zweiten Klemmring möglich ist. Im zusammengebauten Zustand liegt der flanschartige Ansatz 151 an der Schulter 147 des zweiten Rings 105 an.

[0032] Das erste und das zweite Lagerteil 106, 107 sind vorzugsweise aus einem körperverträglichen Kunststoff gefertigt, der gute Gleiteigenschaften aufweist. Bevorzugt wird Polyethylen (PE) eingesetzt. Hierbei können verschiedene Vernetzungsgrade mit daraus resultierenden verschiedenen Molekulargewichten, wie z.B. LDPE und LLDPE mit Molekulargewichten von bis zu 50.000 g/mol, HDPE mit Molekulargewichten bis zu 200.000 g/mol oder UHMWP (Ultra-Height Molecular Weight Poly Ethylen) mit Molekulargewichten um 6.000.000 g/mol, verwendet werden. Bevorzugt wird für das Lagerteil aufgrund seines geringen Langzeitverschleißes UHMWP eingesetzt. Die übrigen Teile des Verankerungselementes sind bevorzugt aus einem körperverträglichen Material mit guten mechanischen Eigenschaften, wie z.B. Titan, gefertigt.

[0033] Wie aus den Figuren 5, 6a und 6b ersichtlich ist, ist die Stabfassung 108 als zylinderförmiger Körper mit einem ersten Ende 130 und einem zweiten Ende 131 ausgebildet. Von dem ersten Ende 130 ist bis zu dem zweiten Ende 131 eine durchgehende koaxiale Bohrung 132 vorgesehen. Angrenzend an das erste Ende 130 ist in der Bohrung 132 ein Innengewinde 155 vorgesehen, in das die Innenschraube 109 eingeschraubt werden kann. Der Außendurchmesser der Stabfassung 108 ist etwas geringer als der Innendurchmesser des zweiten Lagerteils 107. An seinem zweiten Ende 131 weist die Stabfassung 108 einen flanschartigen Ansatz 152 auf, dessen Außendurchmesser etwas geringer als der Innendurchmesser des ersten Lagerteils 106 ist. An den Seitenwänden der Stabfassung 108 sind zwei sich gegenüberliegende Öffnungen 133 mit rechteckigem Querschnitt vorgesehen. Die Breite B der Öffnung ist etwas größer als die Breite des Stabes. Die Höhe H der Öffnung ist größer als die Höhe des Stabes.

[0034] Die Innenschraube 109 weist ein Außengewinde 154 auf, das mit dem Innengewinde 155 der Stabfassung 108 zusammenwirkt. Eine koaxiale Bohrung 134 durch die Innenschraube 109 weist einen Querschnitt auf, der zum Ineingriffbringen mit einem Inbusschlüssel geeignet ist.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 649 of 2152

[0035] Wie aus den Figuren 6a und 6b ersichtlich ist, ist die axiale Länge des Innengewindeabschnitts 155 der Stabfassung 108 und die Höhe der Öffnungen 133 so gewählt, dass der Stab durch Festziehen der Innenschraube 109 von einer Position, in der er in der Öffnung verschiebbar ist, in eine Position, in der er gegen den unteren Rand 153 der Öffnung 133 gedrückt und so fixiert wird, verschiebbar ist.

[0036] Im Betrieb wird zum Vormontieren des Verankerungselements zuerst das Schraubenelement 2 mit dem Gewindeschaft 7 voran in das Aufnahmeteil 102 eingeführt, sodass der Kopf 6 an der sphärischen Fläche 121 anliegt. Im Anschluss daran wird von dem ersten Ende 112 des Aufnahmeteils 102 her in die koaxiale Bohrung 120 des Aufnahmeteils 102 zuerst das Druckelement 103 mit der sphärischen Ausnehmung 111 gegen den Kopf hin eingeführt, dann wird das erste Lagerteil 106 mit der koaxialen Bohrung voran in das Aufnahmeteil 102 eingeführt und anschließend wird die Stabfassung 108 mit zuvor leicht eingeschraubter Innenschraube 109 in das erste Lagerteil 106 eingelegt. Hierauf wird nacheinander das zweite Lagerteil 107 und der zweite Ring 105 zwischen Seitenwand des Aufnahmeteils 102 und das erste und zweite Lagerteil 106, 107 eingebracht. Schließlich wird der erste Ring 104 in das Aufnahmeteil 102 gerade soweit eingeschraubt, dass ein Herausfallen der in das Aufnahmeteil 102 eingebrachten Elemente verhindert wird. Hiermit ist die Vormontage des Verankerungselementes 100 abgeschlossen.

[0037] Alternativ dazu können aber auch die Stabfassung 108, das erste und das zweite Lagerteil 106, 107, der erste und der zweite Ring 104, 105 und die Innenschraube 109 auch zuerst außerhalb des Aufnahmeteils zusammengesetzt und erst dann in das Aufnahmeteil eingeführt werden. Weitere Arten des Zusammenbaus sind möglich.

[0038] Im Betrieb bei der Operation wird mit einem Inbusschlüssel durch die Bohrungen 134, 132, 135 und 110 hindurch das Schraubenelement 2 zuerst in den Wirbel bzw. Knochen eingeschraubt. Danach wird von der Seite des Aufnahmeteils 102 her der Stab zwischen den beiden freien Schenkeln 114 und 115 des Aufnahmeteils 102 durch die Öffnungen 133 in der Stabfassung 108 und durch die Öffnungen in dem ersten und zweiten Lagerteil 106 und 107, sowie durch die Ausnehmungen in dem ersten Ring 105 eingeschoben. Anschließend wird durch Festziehen des ersten Rings 104 auf das Druckelement 103 eine Kraft ausgeübt und so das Aufnahmeteil 102 relativ zu dem Schraubenelement 2 fixiert. Dann wird durch Einsetzen und Festziehen der Innenschraube 109 der Stab 21 in der Stabfassung 108 fixiert.

[0039] So entsteht eine Verbindung zwischen dem stabförmigen Element 21 und dem Knochen bzw. Wirbel, bei der sich die Stabfassung 108 mit dem fixierten stabförmigen Element 21 um die Hauptachse des Aufnahmeteils 102 in einem vorbestimmten Winkelbereich drehen kann. Der Winkelbereich ist dabei durch die Abmessung des Stabes 21 und die Breite der Ausnehmung 140 in dem Aufnahmeteil 102, die Breite der rechteckigen Ausnehmungen 149, 150 in dem ersten bzw. dem zweiten Lagerteil 106, 107 der Öffnungen 149 und die Breite der Ausnehmungen 143 in dem zweiten Ring 105 festgelegt. Die Stabfassung 108 dreht sich mit dem Stab 21 mit, während das Lagerteil 106, 107 durch Presspassung fest in dem ersten und zweiten Ring 104, 105 sitzt. Die Winkelstellung der Schraubenachse relativ zu dem Aufnahmeteil 102 bleibt erhalten.

[0040] In den Figuren 7a und 7b sind zwei verschiedene Grenzwinkelstellungen α, β des stabförmigen Elementes 21 gegenüber dem Aufnahmeteil 102 dargestellt.

[0041] Im Gegensatz zum Verankerungselement 1 nach der ersten Ausführungsform, das drei Rotationsfreiheitsgrade des Stabes relativ zum Schraubenelement aufweist, weist die Verbindung mit einem Verankerungselement 100 nach der zweiten Ausführungsform nur einen Rotationsfreiheitsgrad auf.

Dritte Ausführungsform

[0042] Nach einer dritten Ausführungsform der Erfindung wird eine drehbare Verbindung zwischen einem Stab und einem Knochen bzw. Wirbel dadurch hergestellt, indem wie in Fig. 8a dargestellt in einer Polyaxialschraube, bei der der Winkel zwischen Stab 407 und Aufnahmeteil 408, sowie zwischen Schraubenelement und Aufnahmeteil fixiert ist, ein zweiteiliges Schraubenelement 400 verwendet wird, bei dem der Kopf 401 des Schraubenelementes drehbar mit dem Gewindeschaft 412 verbunden ist. Die Polyaxialschraube beinhaltet wie in Fig. 8a dargestellt ein Aufnahmeteil 408, ein Druckelement 409, eine Innenschraube 410 und eine Außenschraube 411.

[0043] Wie aus Fig. 8b ersichtlich ist besteht der Kopf 401 des Schraubenelementes 400 aus einem kugelsegmentförmigen Kopfabschnitt 402 mit einem zylindrischen Hals 403. An der Seitenfläche des Halses 403 ist weiter ein Stift 404 vorgesehen, der entlang seiner Längsachse gegen eine Federkraft in den Hals 403 eindrückbar ist.

[0044] Der Gewindeschaft 412 weist an seiner dem Kopf 401 des Schraubenelementes 400 zugewandten Seite eine koaxiale Ausnehmung 405 auf, in welche der Hals 403 eingreift. In der Seitenwand dieser Ausnehmung 405 ist ein Langloch 406 vorgesehen, in welches der Stift 404 eingreift.

[0045] Im Betrieb wird der Stift in den Hals soweit eingedrückt, dass der Hals 403 in die Ausnehmung 405 des Gewindeschaftes 412 eingeschoben werden kann. Der Hals 403 wird dann derart in die Ausnehmung 405 eingeschoben, dass der Stift 404 von der Federkraft nach außen gedrückt in das Langloch 406 in der Wand der Ausnehmung 405 eingreift. Dadurch wird eine Verbindung zwischen dem Kopf 401 und dem Gewindeschaft

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 650 of 2152

412 des Schraubenelementes 400 gebildet, bei der der Kopf 401 gegen den Gewindeschaft 412 des Schraubenelementes innerhalb eines durch die Länge des Langlochs 406 vorbestimmten Winkelbereichs koaxial gegeneinander gedreht werden können.

[0046] Das Schraubenelement 400 wird dann in ein Aufnahmeteil 408 eingeführt und in den Knochen eingeschraubt. Anschließend wird in bekannter Weise die Stellung des Schraubenelements zum Aufnahmeteil fixiert, sowie der Stab 407 eingelegt und fixiert.

[0047] Die Verbindung mit einem Verankerungselement nach der dritten Ausführungsform weist wie bei der zweiten Ausführungsform einen Rotationsfreiheitsgrad auf.

[0048] In einer in Fig. 8c dargestellten Abwandlung der dritten Ausführungsform ist das Knochenverankerungselement 420 als Monoaxialschraube ausgebildet, bei der das Aufnahmeteil 421 fest mit dem Kopf des zweiteiligen Schraubenelementes verbunden ist bzw. ein integraler Bestandteil desselben ist. Im übrigen ist das Knochenverankerungselement 420 wie die zuvor beschriebene dritte Ausführungsform ausgebildet.

[0049] Abwandlungen der zuvor beschriebenen Ausführungsformen sind möglich.

[0050] Die Öffnung 19 des Verankerungselementes nach der ersten Ausführungsform wurde so beschrieben, dass ihr Durchmesser kleiner als der des Kopfes 6, aber größer als der Durchmesser des Gewindeabschnittes 7 ist. Der Durchmesser der Öffnung 19 kann aber auch kleiner als der Durchmesser des Gewindeschaftes 7 sein, wenn das Schraubenelement 2 zweiteilig ausgebildet ist, sodass der Gewindeschaft beim Zusammenbau nicht durch die Öffnung 19 hindurchgeführt werden muss. Weiter ist es möglich, dass die Öffnung so ausgebildet ist, dass das Schraubenelement durch diese hindurchgeschraubt werden kann.

[0051] Bei dem Verankerungselement nach der ersten Ausführungsform kann eine nicht-sphärische aber bezüglich der Schraubenachse rotationssymmetrische Form des Kopfes eine Einschränkung der Drehbewegung des Schraubenelementes relativ zu dem Aufnahmeteil auf einen Freiheitsgrad bewirken. Das Lagerteil 5 nach der ersten Ausführungsform muss nicht zwingend wenigstens einen oder mehrere Schlitze 20 aufweisen, wenn die Elastizität des verwendeten Materials ein Einbringen des Kopfes 6 des Schraubenelementes 2 auch ohne Schlitze 20 erlaubt.

[0052] Der Durchmesser der Bohrung 120 in dem zweiten Abschnitt des Aufnahmeteils 102 nach der zweiten Ausführungsform ist so beschrieben worden, dass er angrenzend an das zweite Ende 113 größer als der Durchmesser des Gewindeschaftes 7 des Schraubenelementes 2 ist. Der Durchmesser der Bohrung 120 kann aber angrenzend an das zweite Ende auch so bemessen sein, dass das Schraubenelement durch die Bohrung hindurchgeschraubt wird oder aber, bei einem mehrteiligen Schraubenelement, geringer ist als der Durchmesser des Gewindeschafts 7, der in diesem Fall nicht durch die Bohrung 120 hindurchgeführt werden muss, sondern von außen mit dem in dem Aufnahmeteil befindlichen Kopf verbunden wird.

[0053] Weiter kann das erste Lagerteil 106 auch ohne den Vorsprung 148 ausgebildet sein.

[0054] Das Verankerungselement 100 nach der zweiten Ausführungsform kann als Monoaxialschraube ausgebildet sein, bei der das Aufnahmeteil 102 fest mit dem Schraubenelement 2 verbunden ist bzw. ein integraler Bestandteil desselben ist.

[0055] Bei allen beschriebenen Verankerungselementen kann anstelle der Verankerung mit einem Schraubenelement eine andere Art der Verankerung in dem Knochen bzw. Wirbel vorgesehen sein, wie z.B. die Verankerung durch Haken.

[0056] Die Knochenverankerungselemente nach der ersten und der zweiten Ausführungsform der Erfindung wurden für stabförmige Elemente mit quadratischen Querschnitt beschrieben. Durch entsprechende Abwandlung der Ausnehmungen und Bohrungen zur Aufnahme des Stabes können dies Knochenverankerungselementes auch für die Verwendung von stabförmigen Elementen mit einem kreisförmigen oder einem anderen Querschnitt angepasst werden. Ebenso kann auch das Knochenverankerungselement nach der dritten Ausführungsform für die Verwendung mit einem stabförmigen Element mit einem rechteckigen oder mit einem anderen Querschnitt abgewandelt werden.

[0057] Bei der dritten Ausführungsform wurde beschrieben, dass der Stift 404 gegen eine Federkraft in den Hals 403 eingedrückt werden kann. Der Stift 404 kann jedoch auch mit Presspassung in einem Loch in dem Hals 403 bzw. 422 eingebracht und so fest mit dem Hals 403 bzw. 422 verbunden sein. In diesem Fall ist im Betrieb der Hals zuerst ohne Stift in die Ausnehmung 405 einzuführen und dann der Stift durch das Langloch 406 hindurch in das Loch in dem Hals einzubringen. Es ist auch möglich, den Stift und den Hals so auszubilden, dass der Stift mit einem Außengewinde in ein in dem Loch des Halses vorgesehenes Innengewinde eingeschraubt werden kann. Eine Vielzahl weiterer Drehverbindungen zwischen Schraubenkopf 401 und dem Gewindeabschnitt 402 ist möglich.

[0058] Eine erfindungsgemäße Stabilisierungseinrichtung zur dynamischen Stabilisierung von Knochen bzw. Wirbeln besteht wie die in Fig. 9 dargestellte bekannte Stabilisierungseinrichtung aus wenigstens zwei mit einem stabförmigen Element verbundenen Knochenverankerungselementen von denen wenigstens eines ein Knochenverankerungselement nach der ersten bis dritten Ausführungsform ist.

Patentansprüche

1. Verankerungselement (1, 1', 100, 415, 420) zum Verankern eines stabförmigen Elements (21, 407) in einem Knochen oder Wirbel

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 651 of 2152

mit einem in dem Knochen oder Wirbel zu verankernden Schaft (7, 412),

einem mit dem Schaft (7, 412) verbundenen Aufnahmeteil (3, 102, 408, 421) zur Aufnahme des stabförmigen Elements (21, 407), und

einer Fixationsvorrichtung (4, 109, 410) zum Fixieren des stabförmigen Elements (21, 407) in dem Aufnahmeteil (3, 102, 408, 421),

dadurch gekennzeichnet, daß in fixiertem Zustand des stabförmigen Elements (21, 407) der Schaft (7, 412) über das Aufnahmeteil (3, 102, 408, 421) mit dem stabförmigen Element (21, 407) derart beweglich verbunden ist, daß der Schaft (7, 412) relativ zu dem stabförmigen Element (21, 407) eine Bewegung mit wenigstens einem Rotationsfreiheitsgrad, aber keinem Translationsfreiheitsgrad ausführen kann.

2. Verankerungselement (100) nach Anspruch 1, wobei der Schaft (7) mit dem Aufnahmeteil (102) fest verbunden ist und das stabförmige Element (21) in einer Fassung (108) in dem Aufnahmeteil (102) drehbar gehalten ist.

3. Verankerungselement (100) nach Anspruch 2,

wobei die Fassung (108) in einem Lagerelement (106, 107) drehbar gelagert ist.

4. Verankerungselement (100) nach Anspruch 3, das als Polyaxialschraube mit einem aus dem Schaft (7) und einem kugelsegmentförmigen Kopf (6) bestehenden Knochenverankerungselement (2) ausgebildet ist, wobei

an das eine Ende des Aufnahmeteils (102) angrenzend ein sphärischer Sitz (121) zur Aufnahme des kugelsegmentförmigen Kopfes (6) des Knochenverankerungselementes (2) vorgesehen ist,

an das andere Ende des Aufnahmeteils (102) angrenzend zwei sich gegenüberliegende Ausnehmungen (140) vorgesehen sind, durch die zwei freie Schenkel (114, 115) gebildet werden,

an den Innenseiten der freien Schenkel (114, 115) ein Gewinde (122) vorgesehen ist, in welches ein ringförmiges Element (104) einschraubbar ist, mit dem direkt oder indirekt Druck auf ein Druckelement (103) ausgeübt wird, welches diesen Druck wiederum an den Kopf (6) des Knochenverankerungselementes (2) weitergibt, sodass das Knochenverankerungselement (2) in einer vorbestimmten Winkelstellung relativ zu dem Aufnahmeteil (102) fixiert wird, wobei

das Lagerelement (106, 107) innerhalb des ringförmigen Elementes (104) sitzt.

5. Verankerungselement (100) nach Anspruch 4, wobei das Lagerelement (106, 107) durch Presspassung fest mit dem ringförmigen Element (104) verbunden ist.

6. Verankerungselement (1, 1') nach Anspruch 1 , wobei angrenzend an den Schaft (7) ein Kopf (6) vorgesehen ist, der in dem Aufnahmeteil (3) in einem Lagerelement (5, 5') relativ zum dem stabförmigen Element drehbar gehalten ist.

7. Verankerungselement (1, 100) nach einem der Ansprüche 3 bis 6, wobei das Lagerelement (5, 106, 107) aus körperverträglichem Kunststoff, bevorzugt aus Polyethylen ausgeführt ist.

8. Verankerungselement (415) nach Anspruch 1, wobei angrenzend an den Schaft (412) ein Kopf (401) vorgesehen ist, der in dem Aufnahmeteil (408) so fixierbar ist, daß der Schaft (412) eine vorgegebene Winkelstellung relativ zu dem Aufnahmeteil (408) aufweist und wobei der Kopf (401) und der Schaft (412) separate Teile sind, die drehbar miteinander verbunden sind.

9. Verankerungselement (420) nach Anspruch 1, wobei angrenzend an den Schaft (412) ein Kopf vorgesehen ist, der mit dem Aufnahmeteil (421) fest verbunden ist bzw. ein integraler Bestandteil desselben ist und wobei der Kopf und der Schaft (412) separate Teile sind, die drehbar miteinander verbunden sind.

10. Verankerungselement (1, 1', 100, 415, 420) nach einem der Ansprüche 1 bis 9, wobei ein Anschlag (149, 150, 406) zum Begrenzen der Drehbewegung vorgesehen ist.

11. Verankerungselement nach einem der Ansprüche 1 bis 10, wobei der in dem Knochen oder Wirbel zu verankernde Schaft (7, 412) ein Knochengewinde aufweist.

12. Stabilisierungseinrichtung (200) mit wenigstens zwei Verankerungselementen (202, 202') und einem diese verbindenden stabförmigen Element (201), wobei

wenigstens ein Verankerungselement nach einem der Ansprüche 1 bis 11 ausgebildet ist.

13. Verankerungselement (1, 1', 100, 415, 420) zum Verankern eines stabförmigen Elements (21, 407) in einem Knochen oder Wirbel

mit einem in dem Knochen oder Wirbel zu verankernden Schaft (7, 412),

einem mit dem Schaft (7, 412) verbundenen Aufnahmeteil (3, 102, 408, 421) zur Aufnahme des stabförmigen Elements (21, 407), und

einer Fixationsvorrichtung (4, 109, 410) zum Fixieren des stabförmigen Elements (21, 407) in dem Aufnahmeteil (3, 102, 408, 421),

dadurch gekennzeichnet, daß in fixiertem Zustand des stabförmigen Elements (21, 407) der

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 652 of 2152

Schaft (7, 412) über das Aufnahmeteil (3, 102, 408, 421) mit dem stabförmigen Element (21, 407) drehbar verbunden ist, und

eine Führungsfläche vorgesehen ist, welche die relative Bewegung zwischen dem Schaft (7, 412) und dem stabförmigen Element (21, 407) auf einen Rotationsfreiheitsgrad einschränkt.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 653 of 2152

Fig. 1a

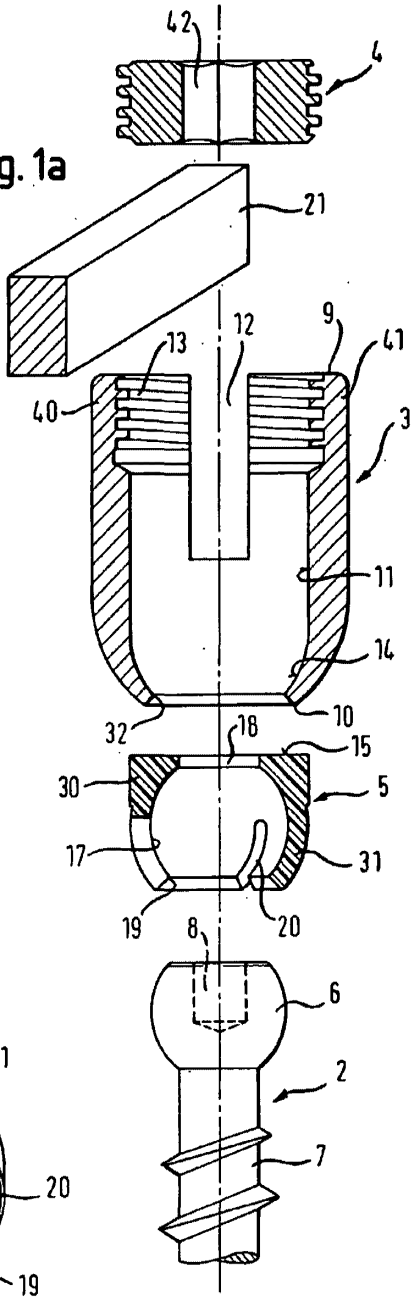


Fig. 1b

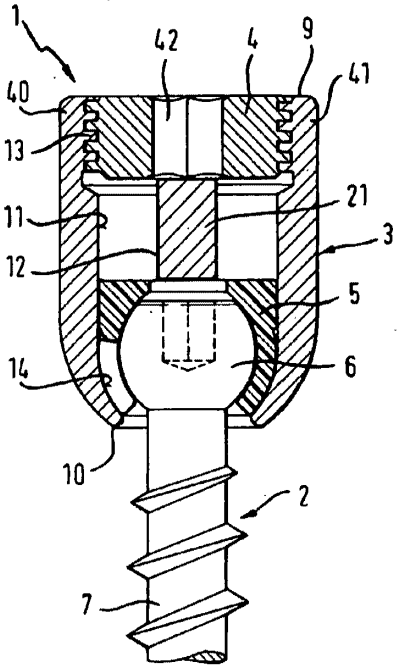
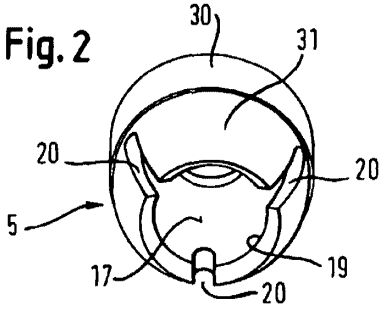
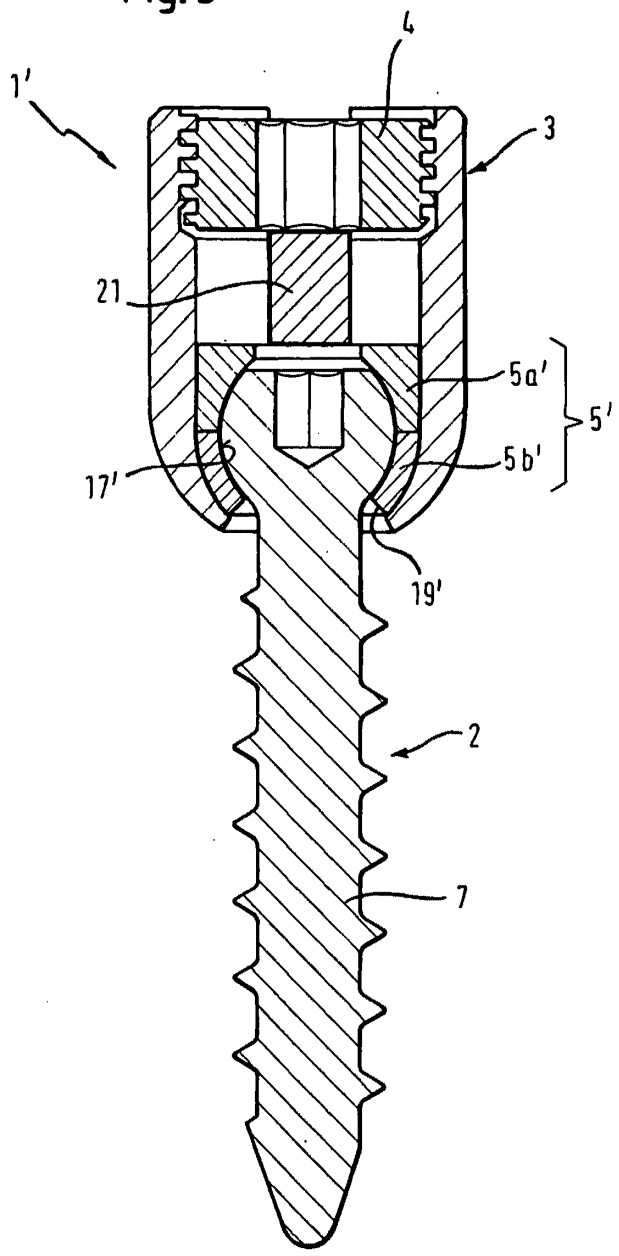


Fig. 2



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 654 of 2152

Fig. 3



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 655 of 2152

Fig. 4

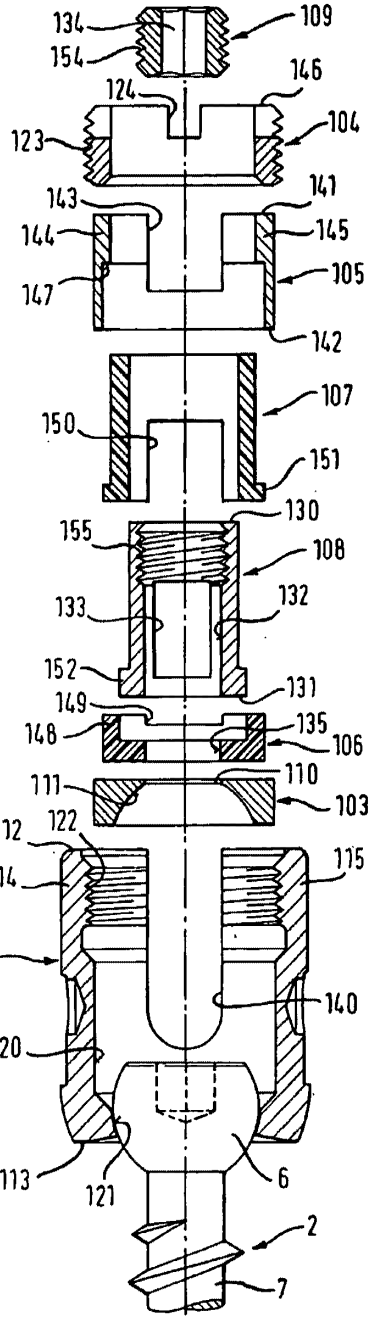
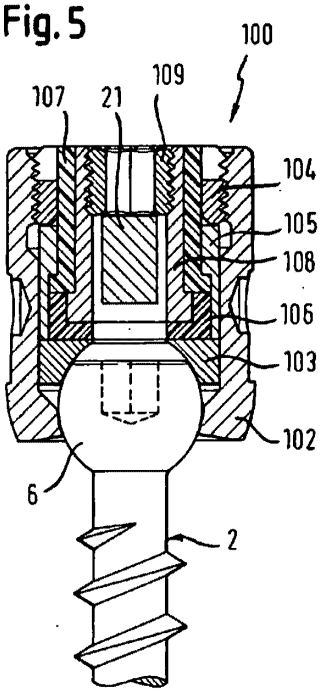


Fig. 5



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 656 of 2152

Fig. 6a

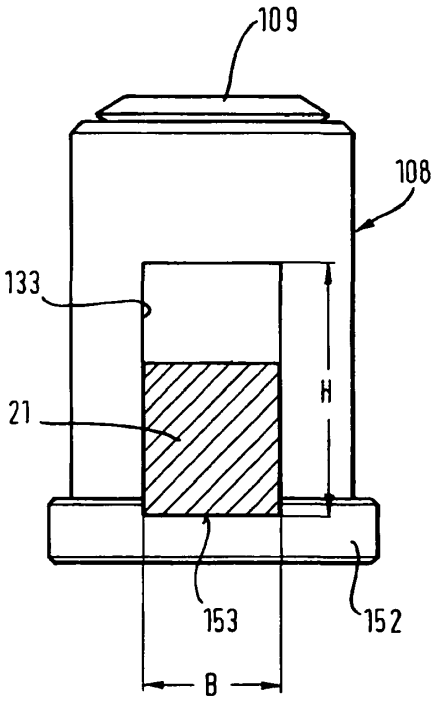
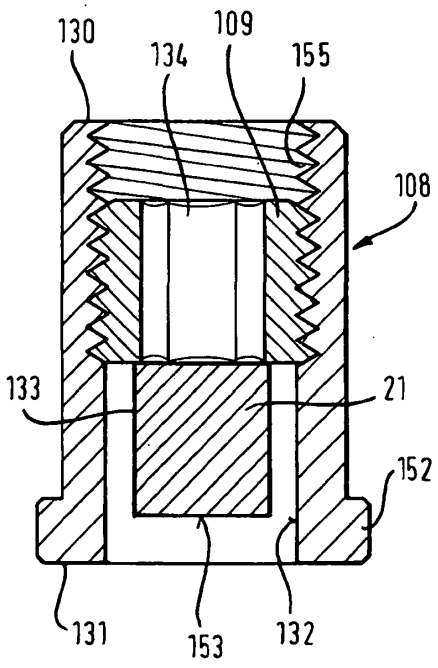


Fig. 6b



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 657 of 2152

Fig. 7a

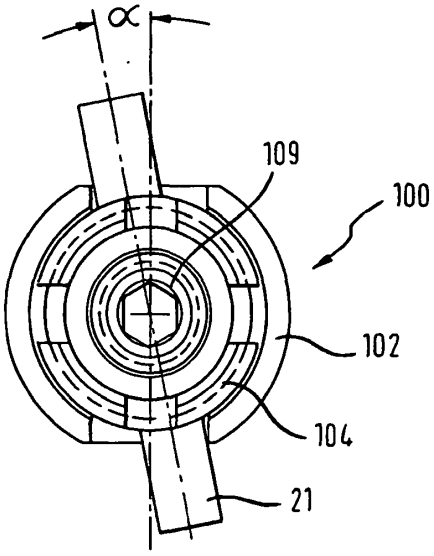
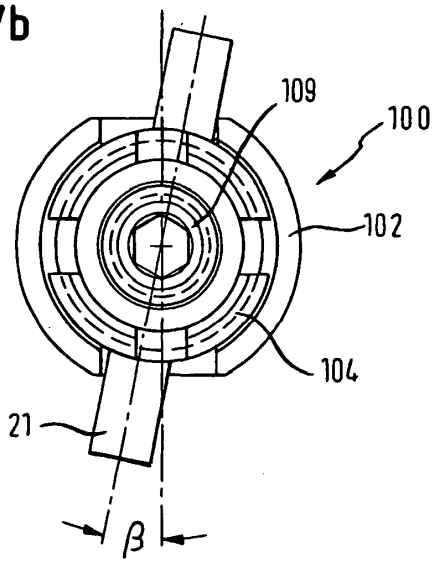


Fig. 7b



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 658 of 2152

Fig. 8a

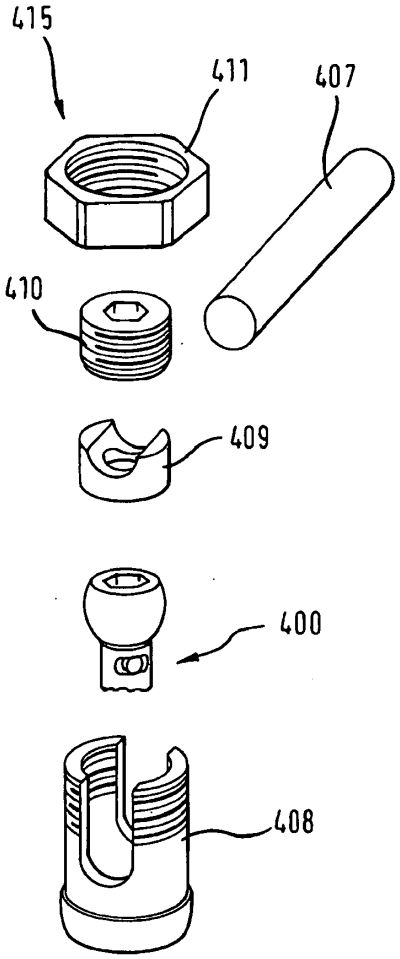
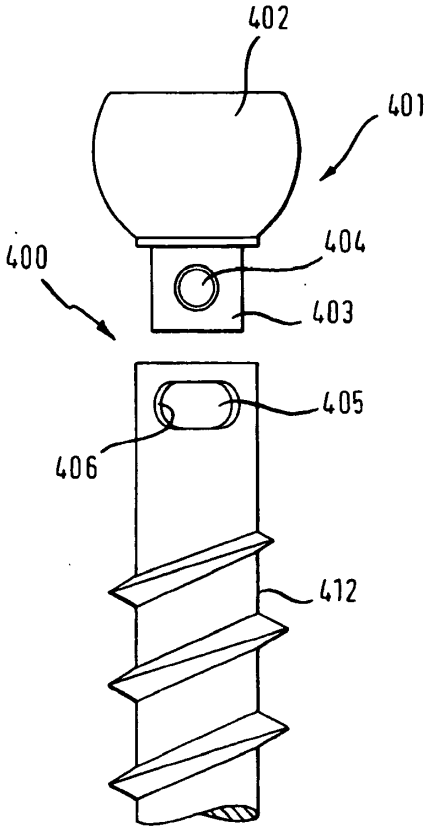
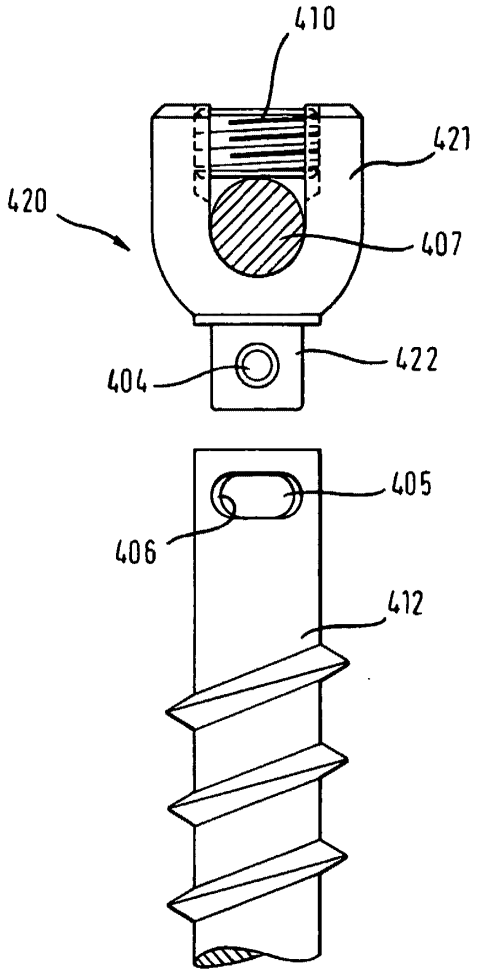


Fig. 8b



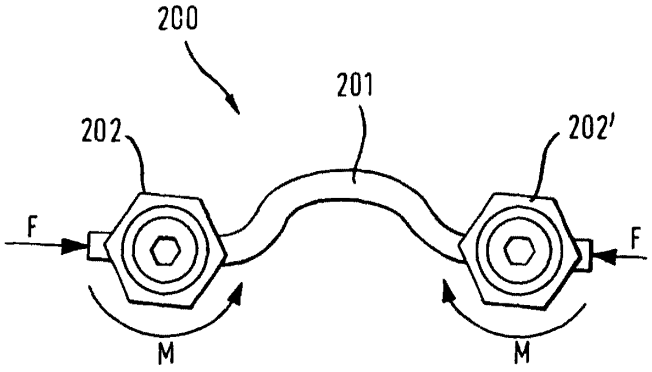
Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 659 of 2152

Fig. 8c



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 660 of 2152

Fig. 9



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 661 of 2152

Europäisches Patentamt

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Nummer der Anmeldung
EP 05 00 3913

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Zimvie_Zimmer Biomet v. Jackson
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Page 662 of 2152

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Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 663 of 2152

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Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 664 of 2152

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Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 665 of 2152

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Zimvie_Zimmer Biomet v. Jackson
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Page 666 of 2152

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(11) EP 1 570 795 A1

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(71) Anmelder: **BIEDERMANN MOTECH GmbH**
78054 VS-Schwenningen (DE)

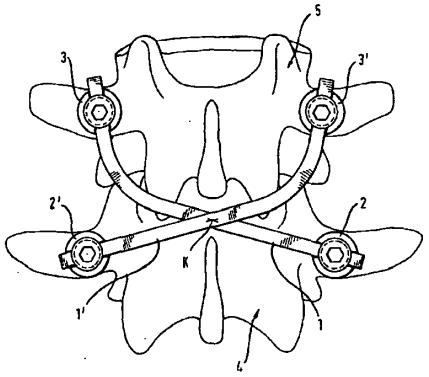
(72) Erfinder:
- **Harms, Jürgen**
  76227 Karlsruhe (DE)
- **Biedermann, Lutz**
  78084 VS-Villingen (DE)
- **Matthis, Wilfried**
  79367 Weisweil (DE)

(74) Vertreter: **Hofer, Dorothea et al**
Prüfer & Partner GbR
Patentanwälte
Harthauser Strasse 25 d
81545 München (DE)

(54) Einrichtung zur dynamischen Stabilisierung von Wirbeln oder Knochen und stabförmiges Element dafür

(57) Es wird eine Stabilisierungseinrichtung zur dynamischen Stabilisierung von Knochen oder Wirbeln bereitgestellt
mit einem ersten Knochenverankerungselement (2) zum Verankern in einem ersten Knochenteil oder einem ersten Wirbel (4),
einem zweiten Knochenverankerungselement (3) zum Verankern in einem zweiten Knochenteil oder einem zweiten Wirbel (5),
einem stabförmigen Element (1; 101) zum Verbinden des ersten und des zweiten Knochenverankerungselements,
wobei das stabförmige Element (1; 101) einen gekrümmten Abschnitt (7) aufweist, der sich unter Einwirkung einer über ein Verankerungselement auf das stabförmige Element ausgeübten Kraft elastisch verformt,
und wobei das stabförmige Element und die Verankerungselemente im Betriebszustand so angeordnet sind, daß die Deformation unter Einwirkung einer Kraft in einer Hauptbewegungsrichtung der Knochenteile oder Wirbel relativ zueinander erfolgt, während eine Deformation unter Krafteinwirkung in einer Richtung im wesentlichen senkrecht zu der Hauptbewegungsrichtung unterdrückt ist.

Fig.1



EP 1 570 795 A1

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Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 667 of 2152

Beschreibung

[0001] Die Erfindung betrifft eine Stabilisierungseinrichtung zur dynamischen Stabilisierung von Wirbeln oder Knochen und ein stabförmiges Element für eine derartige Stabilisierungseinrichtung.

[0002] Aus der EP 1 188 416 A1 ist eine dynamische Stabilisierungseinrichtung zum Stabilisieren benachbarter Rückenwirbel bekannt, die zwei Pedikelschrauben und ein kabelartiges Band umfasst, welches in den Aufnahmeteilen der Pedikelschrauben jeweils über eine Klemmschraube befestigt ist und welche ein auf das Band aufgezogenes Stützelement in Form eines druckfesten Körpers beinhaltet.

[0003] Aus der US 2003/0109880 A1 ist eine dynamische Stabilisierungseinrichtung für Wirbel bekannt, die eine erste und eine zweite in einem Wirbel zu verankernde Schraube jeweils mit einem Aufnahmeteil zum Einlegen einer die Schrauben verbindenden Feder und eine solche Feder umfasst.

[0004] Aus der US 5,415,661 und der US 2003/0191470 A1 ist jeweils eine Stabilisierungseinrichtung für die Wirbelsäule bekannt, die einen gekrümmten elastischen Stab aufweist, der an seinen Enden über Verankerungselemente mit einem Schaft in den Fortsätzen benachbarter Wirbeln auf derselben Seite so verankert wird, daß der gekrümmte Stab und die Schäfte im wesentlichen in zueinander parallelen Ebenen liegen. Dadurch liegt die Krümmung in der anterioren/posterioren Richtung. Die Krümmung erfüllt die Funktion eines Federstabs.

[0005] Bei den bekannten Stabilisierungseinrichtungen werden jeweils zwei dieser Stabilisierungseinrichtungen zum Stabilisieren von zwei benachbarten Wirbeln verwendet, die jeweils rechts bzw. links von der Mittellängsachse der Wirbelsäule verankert sind.

[0006] Aus der US 6,440,169 B1 ist eine Stabilisierungseinrichtung für die Wirbelsäule bekannt, die einen sich zwischen Verankerungspunkten in benachbarten Wirbeln erstreckenden elastischen Körper aus einer Blattfeder aufweist, die so geformt ist, daß sie die Wand einer Öffnung bildet, wobei sich die Öffnung in der anterioren/posterioren Richtung unter Bezug auf den Körper des Patienten erstreckt und in der medialen/lateralen Richtung geschlossen ist.

[0007] Insbesondere beim Vorhandensein einer geschädigten oder einer künstlichen Bandscheibe ist es wünschenswert, diese durch eine posteriore dynamische Stabilisierungseinrichtung hinsichtlich der zu übertragenden Kräfte in definierter Weise zu unterstützen und die Bewegung zu kontrollieren. Dabei sollen eine Flexion und eine Extension der Wirbelsäule bzw. des die betreffende Bandscheibe enthaltenden Segments, wie in Fig. 8a ersichtlich ist, möglich sein, während eine seitliche Translationsbewegung, sowie eine Torsion um die die Mittellängsachse der Wirbelsäule, wie in Fig. 8b gezeigt ist, unerwünscht sind.

[0008] Es ist Aufgabe der Erfindung eine dynamische Stabilisierungseinrichtung zur Stabilisierung und zur Bewegungsbegrenzung von benachbarten Wirbeln oder Knochen bereitzustellen, welche einfach gebaut ist und mit der eine Bewegungsbegrenzung dahingehend erzielbar ist, daß eine Flexion und Extension in begrenztem Maße erlaubt ist, eine seitliche Translationsbewegung bzw. eine Rotationsbewegung der Wirbel oder Knochen zueinander jedoch weitgehend verhindert wird.

[0009] Die Aufgabe wird durch eine Stabilisierungseinrichtung nach dem Patentanspruch 1 gelöst.

[0010] Weiterbildungen der Erfindung sind in den Unteransprüchen angegeben.

[0011] Die Erfindung weist den Vorteil auf, daß eine gewünschte Bewegungsbegrenzung auf einfache Weise durch Auswahl geeignet dimensionierter stabförmiger Elemente erzielt werden kann. Die stabförmigen Elemente der Stabilisierungseinrichtung sind ferner leicht herstellbar. Die Stabilisierungseinrichtung ist vorteilhaft anwendbar zur Stabilisierung der Wirbel bei der Verwendung von künstlichen Bandscheiben.

[0012] Weitere Merkmale und Zweckmäßigkeiten der Erfindung ergeben sich aus der Beschreibung von Ausführungsbeispielen anhand der Figuren.

[0013] Von den Figuren zeigen:

- Fig. 1 eine Draufsicht auf die erfindungsgemäße Stabilisierungseinrichtung nach einer ersten Ausführungsform von der posterioren Seite der Wirbelsäule gesehen;
- Fig. 2a eine perspektivische Ansicht eines stabförmigen Elements der Stabilisierungseinrichtung nach Fig. 1;
- Fig. 2b eine perspektivische Ansicht der Stabilisierungseinrichtung von Fig. 1 von oben mit bevorzugter Ausbildung der stabförmigen Elemente ohne Darstellung der oberen zwei Verankerungselemente;
- FIG. 3 eine teilgeschnittene Ansicht eines Verankerungselements zum Verankern des stabförmigen Elements von Fig. 2 nach einer ersten Ausführungsform;
- Fig. 4 eine teilgeschnittene Explosionsdarstellung eines Verankerungselements zum Verankern des stabförmigen Elements von Fig. 2 nach einer zweiten Ausführungsform;
- Fig 5 eine teilgeschnittene Ansicht des Verankerungselements von Fig. 4 in Verbindung mit dem stabförmigen Element;
- Fig. 6a eine schematische Darstellung der Bewegungsmöglichkeit eines stabförmigen Elements der Stabilisierungseinrichtung von Fig.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 668 of 2152

1;

Fig. 6b eine schematische Darstellung der Funktionsweise der Stabilisierungseinrichtung nach der ersten Ausführungsform;

Fig. 7 eine Abwandlung der Stabilisierungseinrichtung der ersten Ausführungsform;

Fig. 8a eine Darstellung eines Abschnitts der Wirbelsäule von der Seite; und

Fig. 8b eine Darstellung eines Abschnitts der Wirbelsäule von hinten.

[0014] Wie aus Fig. 1 ersichtlich ist, umfaßt die Stabilisierungseinrichtung in einer ersten Ausführungsform ein erstes und ein zweites stabförmiges Element 1, 1'. Diese sind jeweils mit zwei Verankerungselementen, im gezeigten Anwendungsbeispiel mit Pedikelschrauben 2, 3 bzw. 2', 3' verbunden, welche in den Pedikeln zweier benachbarter Wirbel 4, 5 verankert sind. Die erste Pedikelschraube 2 des stabförmigen Elements 1 ist dabei im rechten Pedikel des unteren Wirbels 4 verankert, während die zweite Pedikelschraube 3 des stabförmigen Elements 1 im linken Pedikel des oberen Wirbels 5 verankert ist. Symmetrisch dazu ist die erste Pedikelschraube 2' des stabförmigen Elements 1' im linken Pedikel des unteren Wirbels 4 verankert, während die zweite Pedikelschraube 3' des stabförmigen Elements 1' im rechten Pedikel des oberen Wirbels 5 verankert ist. Somit kreuzen sich die stabförmigen Elemente 1, 1' an einem Punkt K in der Symmetrieebene.

[0015] Wie aus Fig. 2a ersichtlich ist, ist das erste stabförmige Element 1 als ein gekrümmter Stab mit einem rechteckigen Querschnitt ausgebildet. Das stabförmige Element 1 weist einen ersten geraden Abschnitt 6 mit einer Länge L1, daran angrenzend einen gekrümmten Abschnitt 7 mit einer Länge L2 und daran angrenzend wieder einen geraden Abschnitt 8 mit einer Länge L3 auf. Die Mittellängsachsen M1 und M2 der geraden Abschnitte schließen in dem gezeigten Ausführungsbeispiel einen stumpfen Winkel α miteinander ein. Die Länge L1 des ersten geraden Abschnitts beträgt in dem gezeigten Ausführungsbeispiel etwa das Dreifache der Länge L3 des zweiten geraden Abschnitts 8. Die Krümmung verläuft über die breite Seite B des stabförmigen Elements. Die Biegesteifigkeit gegenüber einer Kraftkomponente, die senkrecht auf seine breite Seite B wirkt, ist kleiner als gegenüber einer Kraftkomponente, die senkrecht auf seine schmale Seite S wirkt. Ferner ist die Biegesteifigkeit des stabförmigen Elements aufgrund der Hebelwirkung durch die unterschiedlichen Längen L1 und L3 der geraden Abschnitte 6, 8 gegenüber einer Kraftkomponente, die am Ende des langen Abschnitts 6 senkrecht zum Stab angreift, geringer, als gegenüber einer Kraftkomponente, die am Ende des kurzen Abschnitts 8 senkrecht angreift.

[0016] Das stabförmige Element besitzt somit eine orientierte Biegesteifigkeit, die durch Wahl des Querschnitts, der Krümmung und der Länge in gewünschter Weise bei der Herstellung einstellbar ist. Das stabförmige Element 1 ist ferner einstückig aus einem körperfreundlichen Material, wie z.B. aus Titan ausgebildet und bevorzugt aus dem Vollen gefräßt.

[0017] Das zweite stabförmige Element 1' ist in der einfachsten Ausführungsform spiegelsymmetrisch zu dem ersten stabförmigen Element 1 befestigt, so daß die gekrümmten Abschnitte in entgegengesetzte Richtungen zeigen.

[0018] Fig. 2b zeigt die Stabilisierungseinrichtung von Fig. 1 von oben mit einer bevorzugten Ausbildung der stabförmigen Elemente 1, 1', wobei jeweils die oberen Verankerungselemente nicht dargestellt sind. Die stabförmigen Elemente 1, 1' sind in einem Bereich 1a, 1a' angrenzend an den Abschnitt mit dem sie im Verankerungselement befestigt sind, derart aus der Ebene, die durch die Verbindungsstellen definiert ist, nach außen gebogen, daß sie im Betriebszustand der Stabilisierungseinrichtung aneinander vorbeigeführt sind, ohne sich zu behindern. Dies ermöglicht, daß die Verbindungsstellen der Verankerungselemente zu den stabförmigen Elementen alle in einer Ebene senkrecht zu der in Fig. 8a angedeuteten Medianebene liegen.

[0019] Wie in Fig. 3 gezeigt ist, ist in einer ersten Ausführungsform das stabförmige Element 1, 1' in einer monoaxialen Pedikelschraube fixiert. Diese weist einen Gewindeschaft 10 mit einem Knochengewinde und ein damit starr verbundenes Aufnahmeteil 11 auf. Das Aufnahemteil 11 ist im wesentlichen zylindrisch ausgebildet und weist eine sich von seinem dem Gewindeschaft 10 abgewandten freien Ende zum Gewindeschaft hin erstreckende Ausnehmung 12 mit rechteckigem Querschnitt auf, die so bemessen ist, daß darin das stabförmige Element 1, 1' einlegbar und noch in Richtung seiner Längsachse verschiebbar ist. Die Ausnehmung 12 ist so gebildet, daß die schmale Seite S des stabförmigen Elements 1 im Grund der Ausnehmung ruht. Ausgehend von seinem freien Ende weist das Aufnahmeteil ein Außengewinde 13 auf, das sich über eine vorbestimmte Länge erstreckt, die so bemessen ist, daß das Außengewinde bei eingelegtem stabförmigen Element bis unterhalb dessen Oberseite reicht. Zum Fixieren des stabförmigen Elements in dem Aufnahmeteil ist eine auf das Außengewinde aufschraubbare Mutter 14 vorgesehen.

[0020] In einer weiteren Ausführungsform ist eine in den Figuren 4 und 5 gezeigte Polyaxialschraube zum Verbinden mit dem stabförmigen Element 1, 1' vorgesehen. Diese weist ein Schraubenelement 15 mit einem Gewindeschaft 16 mit einem Knochengewinde und einen kugelsegmentförmigen Kopf 17 mit einer nichtdargestellten Ausnehmung zum Einschrauben auf. Ferner ist ein mit dem Schraubenelement 15 verbindbares Aufnahmeteil 18 vorgesehen. Das Aufnahmeteil 18 ist im wesentlichen zylindrisch ausgebildet und hat an seinem

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 669 of 2152

einen Ende eine axialsymmetrisch ausgerichtete erste Bohrung 19, deren Durchmesser kleiner als der des Kopfes 17 ist. Ferner weist das Aufnahmeteil 18 eine koaxiale zweite Bohrung 20 auf, die auf dem der ersten Bohrung 19 gegenüberliegenden Ende offen ist und deren Durchmesser so groß ist, daß das Schraubenelement 15 durch das offene Ende mit seinem Gewindeschaft durch die erste Bohrung 19 hindurch und mit dem Kopf 17 bis zum Grund der zweiten Bohrung 20 führbar ist. Zwischen der ersten und der zweiten Bohrung ist ein sphärischer Abschnitt 21 zum Anliegen des Kopfs 17 vorgesehen.

[0021] Das Aufnahmeteil 18 weist ferner eine zur Mitte des Teiles symmetrisch angeordnete Ausnehmung 22 mit einem rechteckigen Querschnitt zur Aufnahme des stabförmigen Elements 1, 1' auf, durch die zwei freie Schenkel 23, 24 gebildet sind. In einem Bereich angrenzend an ihr freies Ende weisen die Schenkel 23, 24 in diesem Ausführungsbeispiel ein Außengewinde 25 und ein Innengewinde 26 auf.

[0022] Es ist ferner ein in der Bohrung 20 zu dem Kopf hin verschiebbares Druckelement 27 vorgesehen. Das Druckelement 27 weist eine koaxiale Bohrung 28 zum Hindurchführen eines Schraubendrehers, sowie an seiner dem Kopf 17 zugewandten Seite eine sphärische Ausnehmung 29 für den Kopf 17 auf. An seiner dem Kopf abgewandten Seite weist das Druckelement 27 eine Ausnehmung 30 mit rechteckigem Querschnitt zur Aufnahme des stabförmigen Elements 1, 1' auf. Die Breite der Ausnehmung 30 ist gerade ein wenig größer als die schmale Seite S des stabförmigen Elements 1, 1', so daß dieses mit seiner schmalen Seite S zum Grund der Ausnehmung hin einführbar ist und in der Ausnehmung in Längsrichtung verschiebbar ist. Die Tiefe der Ausnehmung 30 ist etwas kleiner als die Höhe B des stabförmigen Elements.

[0023] Zum Fixieren des stabförmigen Elements 1, 1' in dem Aufnahmeteil und zum Fixieren der Winkelstellung des Schraubenelements 15 relativ zu dem Aufnahmeteil sind ferner eine zwischen die Schenkel einschraubbare Innenschraube 31 und zur Sicherung eine auf die Schenkel aufschraubbare Mutter 32 vorgesehen.

[0024] Im Betrieb werden zunächst die Pedikelschrauben 2, 3, 2', 3' in die mit der Stabilisierungseinrichtung zu verbindenden Wirbel 4, 5 eingeschraubt. Im Fall der Monoaxialschrauben nach Fig. 4 werden die Gewindeschäfte 10 soweit eingeschraubt, bis die Aufnahmeteile 11 der mit jeweils einem stabförmigen Element 1, 1' zu verbindenden Pedikelschrauben 2, 3 bzw. 2', 3' zueinander so ausgerichtet sind, daß das stabförmige Element ohne zu verkanten einführbar ist. Dann wird das stabförmige Element durch Aufschrauben der Mutter 14 fixiert.

[0025] Im Fall der Polyaxialschrauben nach den Figuren 4 und 5 wird erst das Schraubenelement 15 in das Aufnahmeteil 18 eingeführt, dann das Druckelement 27 eingesetzt und anschließend das Schraubenelement in den Pedikel eingeschraubt. Anschließend wird das stabförmige Element 1 bzw. 1' in die Aufnahmeteile eingesetzt. Die Aufnahmeteile 18 zweier mit dem stabförmigen Element 1 bzw. 1' zu verbindender Pedikelschrauben 2, 3 bzw. 2', 3' richten sich dabei auf Grund der gelenkigen Verbindung zwischen dem Kopf 17 und dem Aufnahmeteil 18 selbst richtig zum Stab hin aus, was bei der überkreuzten Anordnung der stabförmigen Elemente von Vorteil ist. Anschließend werden die Aufnahmeteile relativ zum Kopf und zum Stab durch die Innenschraube und die Mutter fixiert.

[0026] Die Figuren 6a und 6b zeigen schematisch die Funktionsweise der Stabilisierungseinrichtung. Wie in Fig. 6a gezeigt ist kann das stabförmige Element 1 in unbelastetem Zustand in idealisierter Weise als ein Winkelhebel mit einem langen Hebelarm 6 und einem kurzen Hebelarm 8 angesehen werden. Bei Belastung durch Flexion oder Extension des Wirbelsäulensegments führt eine kleine an den Verankerungspunkten senkrecht zum langen Hebelarm 6 angreifende Kraftkomponente zur elastischen Deformation des stabförmigen Elements 1, indem der lange Hebelarm ausgelenkt wird und sich der Krümmungsradius relativ zu der Ruhestellung bei der Flexion vergrößert und bei der Extension verkleinert.

[0027] In Fig. 6b zeigen die durchgezogenen Linien die stabförmigen Elemente 1, 1' in einem ersten Zustand und die gestrichelten Linien in einem zweiten Zustand, der in diesem Fall eine Flexion des Wirbelsäulensegments ist. In dem ersten Zustand haben die Pedikelschrauben 2', 3 mit denen das stabförmige Element 1 verbunden ist, in Richtung der Mittellängsachse M der Wirbelsäule einen Abstand H voneinander. Bei der Flexion des Wirbelsäulensegments kommt es zu einer Biegung des stabförmigen Elements 1, wobei der Krümmungsradius dabei größer wird und somit in dem gezeigten zweiten Zustand der Abstand der Pedikelschrauben in Richtung der Mittellängsachse auf H' vergrößert wird. Umgekehrt wird bei einer Extension des Wirbelsäulensegments der Krümmungsradius der stabförmigen Elemente verkleinert. Damit verringert sich der Abstand der Pedikelschrauben.

[0028] Bei Einwirkung einer Kraftkomponente senkrecht zu dem kurzen Hebelarm, ist eine Änderung der Krümmung der stabförmigen Elemente aufgrund der erforderlichen größeren Kraft erschwert oder gar nicht möglich. Somit wird eine seitliche Translationsbewegung verhindert. Aufgrund der länglichen Ausbildung der stabförmigen Elemente besteht ferner weitgehend Rotationsstabilität gegenüber einer Rotationsbewegung der Wirbel zueinander.

[0029] Fig. 7 zeigt eine zweite Ausführungsform. Die Stabilisierungseinrichtung erstreckt sich auf zwei Bewegungssegmente, bestehend jeweils aus den Wirbeln 4, 5 bzw. 5, 5'. Es sind stabförmige Elemente 101, 101' vorgesehen, die eine Form haben, die durch Spiegelung eines stabförmigen Elements 1, 1' der ersten Ausführungsform an einer auf dem freien Ende des kurzen Ab-

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 670 of 2152

schnitts senkrecht stehenden Ebene entsteht. Die stabförmigen Elemente 101, 101' sind jeweils durch Pedikelschrauben 2, 2" bzw. 2', 3" an ihren Enden in den Pedikeln auf derselben Seite der jeweils übernächsten Wirbel 4, 5' verankert und mit ihrem mittleren Abschnitt über Pedikelschrauben 3 bzw. 3' in den Pedikeln der gegenüberliegenden Seite des dazwischenliegenden Wirbels 5 verankert.

[0030] Eine mehrsegmentale Ausbildung ist ebenso möglich.

[0031] Abwandlungen der zuvor beschriebenen Ausführungsformen sind möglich. So werden die Längen der einzelnen Abschnitte der stabförmigen Elemente entsprechend den Dimensionen der zu verbindenden Wirbel gewählt. Die Erfindung ist nicht darauf beschränkt, daß die stabförmigen Elemente der Stabilisierungseinrichtung der ersten Ausführungsform einen langen und einen kurzen geraden Abschnitt aufweisen. Es können auch nur ein langer und ein gekrümmter Abschnitt vorhanden sein. Bei der Stabilisierungseinrichtung der zweiten Ausführungsform können die geraden Abschnitte auch unterschiedlich lang sein, entscheidend ist, daß das stabförmige Element zwischen dem einen Befestigungspunkt und dem anderen Befestigungspunkt eine Krümmung aufweist, damit das stabförmige Element unter Einwirkung von Biegemomenten eine Abstandsänderung der Befestigungspunkte bewirkt.

[0032] Ferner sind die Merkmale der beschriebenen Ausführungsformen miteinander kombinierbar. Die Stabilisierungseinrichtung der ersten Ausführungsform kann auch stabförmige Elemente mit kreisförmigem Querschnitt aufweisen. Auch ein quadratischer Stabquerschnitt ist möglich, wobei dann aber ein Freiheitsgrad bei der Wahl der biegeelastischen Eigenschaften des stabförmigen Elements wegfällt.

[0033] Anstelle der beschriebenen Monoaxialschrauben und Polyaxialschrauben können auch Monoaxialschrauben und Polyaxialschrauben verwendet werden, bei denen die Kopf- oder die Stabfixierung auf andere Weise erfolgt.

[0034] Die Erfindung ist ferner nicht auf eine Stabilisierungseinrichtung für die Wirbelsäule beschränkt, sondern kann auch zum Stabilisieren von Knochen eingesetzt werden.

Patentansprüche

1. Stabilisierungseinrichtung zur dynamischen Stabilisierung von Wirbeln oder Knochen, mit

   einem ersten Knochenverankerungselement (2) und einem zweiten Knochenverankerungselement (2') zur Verankerung in einem ersten Knochenteil (4) oder einem Wirbel und mit

   einem dritten Knochenverankerungselement (3) und einem vierten Knochenverankerungselement (3') zur Verankerung in einem zweiten Knochenteil (5) oder Wirbel,

   einem ersten stabförmigen Element (1; 101), das mit dem ersten oder mit dem zweiten Knochenverankerungselement (2) und mit dem dritten oder dem vierten Knochenverankerungselement verbunden ist;

   einem zweiten stabförmigen Element (1'; 101'), das mit dem zweiten oder mit dem ersten Knochenverankerungselement und mit dem vierten oder dem dritten Knochenverankerungselement verbunden ist;

   wobei die Verbindungsstellen der Verankerungselemente mit den stabförmigen Elementen eine Ebene aufspannen;

   wobei die stabförmigen Elemente (1, 1'; 101; 101') zwischen den Verbindungsstellen jeweils einen gekrümmten Abschnitt (7) aufweisen, der sich unter Einwirkung einer über ein Verankerungselement auf das stabförmige Element ausgeübten Kraft elastisch verformt; und

   wobei die stabförmigen Elemente so angeordnet sind, daß der gekrümmte Abschnitt im wesentlichen in der durch die Verbindungsstellen aufgespannten Ebene oder parallel zu dieser liegt.

2. Stabilisierungseinrichtung nach Anspruch 1, **dadurch gekennzeichnet, daß** die stabförmigen Elemente (1, 1'; 101, 101') so angeordnet sind, daß sie sich wenigstens einmal überkreuzen.

3. Stabilisierungseinrichtung nach Anspruch 1 oder 2 wobei die stabförmigen Elemente und die Verankerungselemente im Betriebszustand so angeordnet sind, daß die Deformation unter Einwirkung einer Kraft in einer Hauptbewegungsrichtung der Knochenteile oder Wirbel relativ zueinander erfolgt, während eine Deformation unter Krafteinwirkung in einer Richtung im wesentlichen senkrecht zu der Hauptbewegungsrichtung unterdrückt ist.

4. Stabilisierungseinrichtung nach einem der Ansprüche 1 bis 3, **dadurch gekennzeichnet, daß** das erste (2) und das dritte Knochenverankerungselement (3) relativ zur Hauptbewegungsrichtung diagonal gegenüberliegend angeordnet sind.

5. Stabilisierungseinrichtung nach einem der Ansprüche 1 bis 4, **dadurch gekennzeichnet, daß** die Stabilisierungseinrichtung zum Stabilisieren wenigstens zweier benachbarter Wirbel (4, 5) vorgesehen ist und so ausgebildet ist, daß die mit einem stabförmigen Element verbundenen Knochenverankerungselemente je in diagonal gegenüberliegenden Pedikeln der Wirbel verankerbar sind.

6. Stabilisierungseinrichtung nach einem der Ansprüche 1 bis 5, **dadurch gekennzeichnet, daß** das zweite (2') und das vierte (3') Knochenveranke-

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 671 of 2152

rungselement und das diese verbindende zweite stabförmige Element (1'; 101') symmetrisch zu dem ersten (2) und dem dritten (3) Knochenverankerungselement mit dem ersten stabförmigen Element (1; 101) angeordnet sind.

7. Stabilisierungseinrichtung nach einem der Ansprüche 1 bis 6, **dadurch gekennzeichnet, daß** die stabförmigen Elemente im wesentlichen L-förmig gekrümmt sind.

8. Stabilisierungseinrichtung nach einem der Ansprüche 1 bis 7, **dadurch gekennzeichnet**, die stabförmigen Elemente einen rechteckigen oder quadratischen Querschnitt aufweisen.

9. Stabilisierungseinrichtung nach einem der Ansprüche 1 bis 7, **dadurch gekennzeichnet, daß** die stabförmigen Elemente einen kreisförmigen Querschnitt aufweisen.

10. Stabilisierungseinrichtung nach einem der Ansprüche 1 bis 9, **dadurch gekennzeichnet, daß** das Verankerungselement je einen Verankerungsabschnitt (10; 15) zum Verankern in einem Knochen und ein mit diesem verbundenes Aufnahmeteil (11; 18) aufweist, welches eine dem Querschnitt des jeweiligen stabförmigen Elements angepaßte Ausnehmung (12; 22) zur Aufnahme des stabförmigen Elements hat.

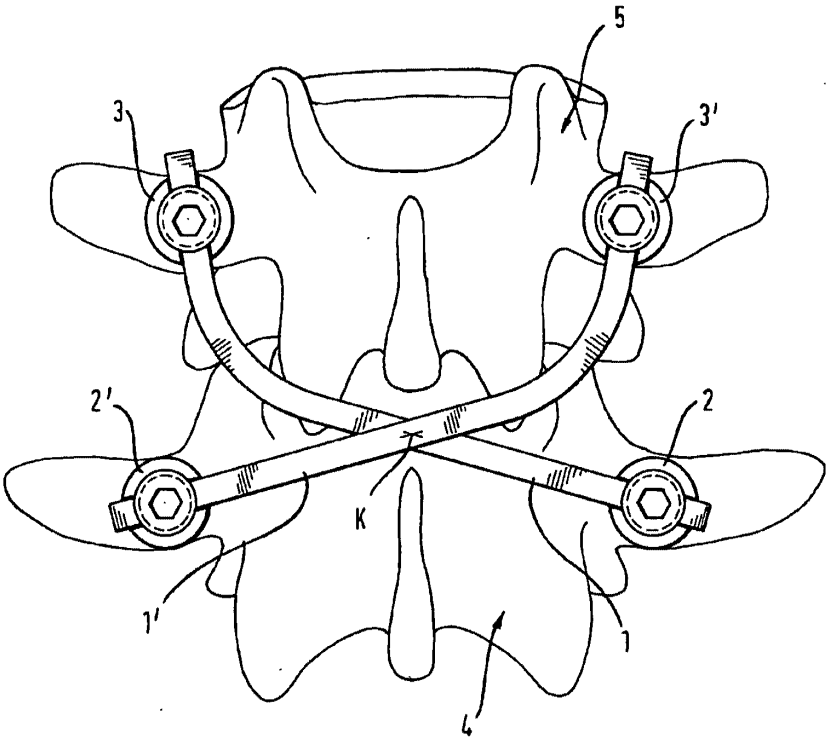
11. Stabilisierungseinrichtung nach Anspruch 10, **dadurch gekennzeichnet, daß** der Verankerungsabschnitt (10) monoaxial mit dem Aufnahmeteil (11) verbunden ist.

12. Stabilisierungseinrichtung nach Anspruch 10, **dadurch gekennzeichnet, daß** der Verankerungsabschnitt (15) polyaxial mit dem Aufnahmeteil (18) verbunden ist.

13. Stabilisierungseinrichtung nach einem der Ansprüche 1 bis 12, **dadurch gekennzeichnet, daß** die Anzahl der Verankerungselemente ein Vielfaches von zwei beträgt und die stabförmigen Elemente (101, 101') jeweils mehr als zwei Verankerungselemente verbinden.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 672 of 2152

Fig. 1



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 673 of 2152

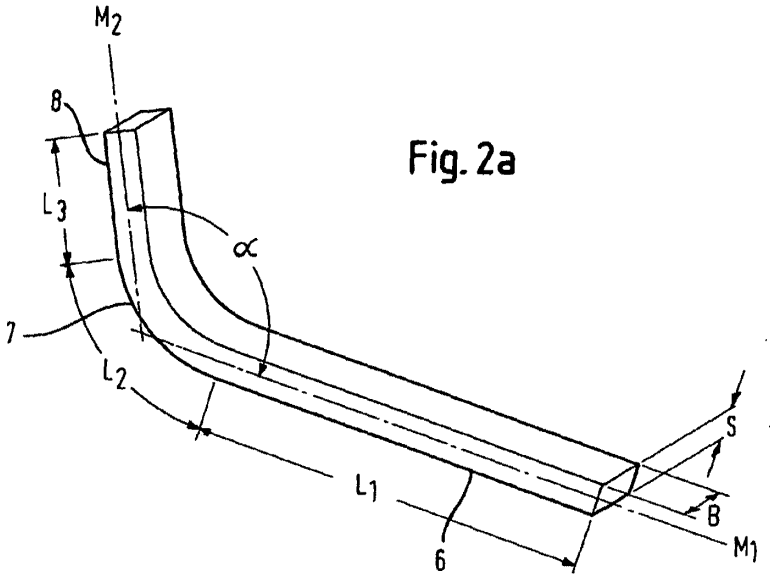
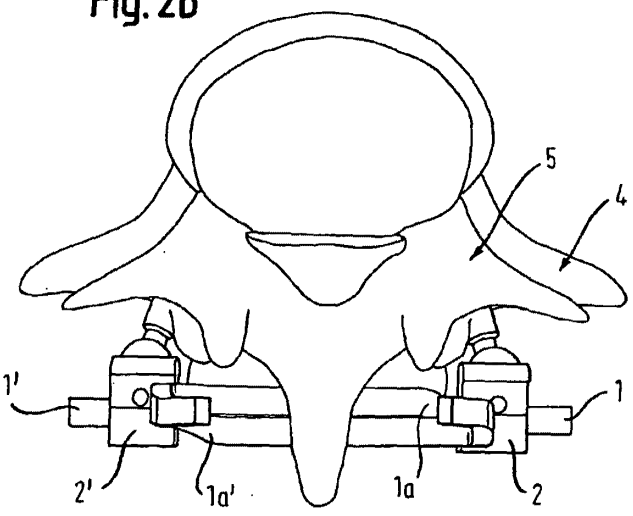


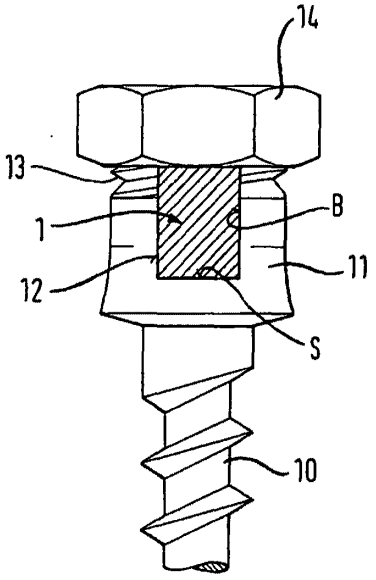
Fig. 2a

Fig. 2b



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 674 of 2152

Fig. 3



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 675 of 2152

Fig. 4

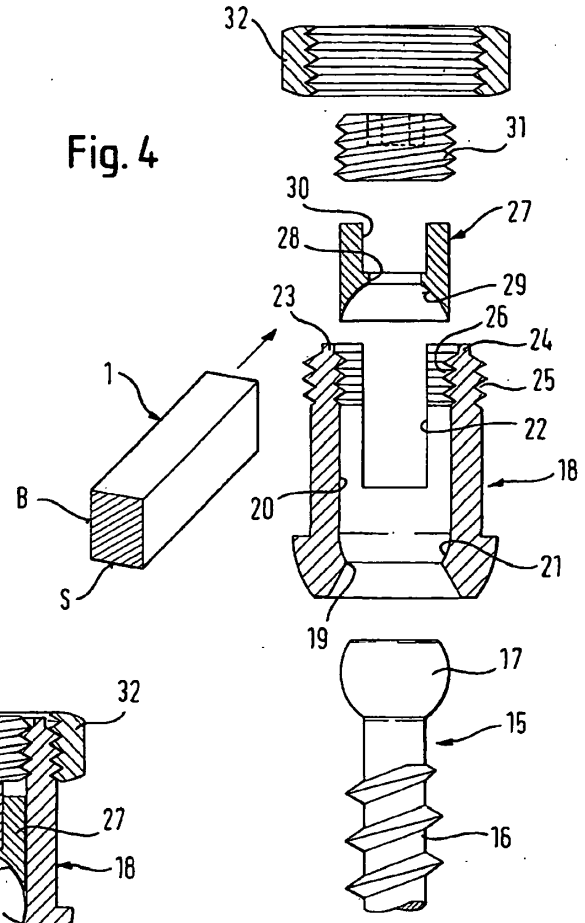
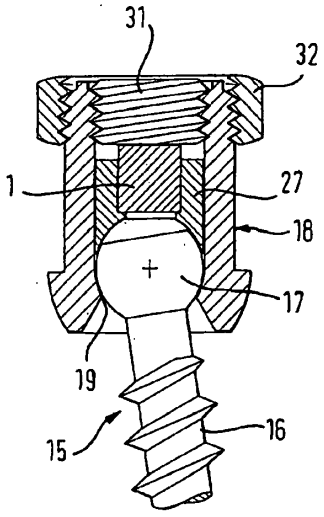


Fig. 5



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 676 of 2152

Fig. 6a

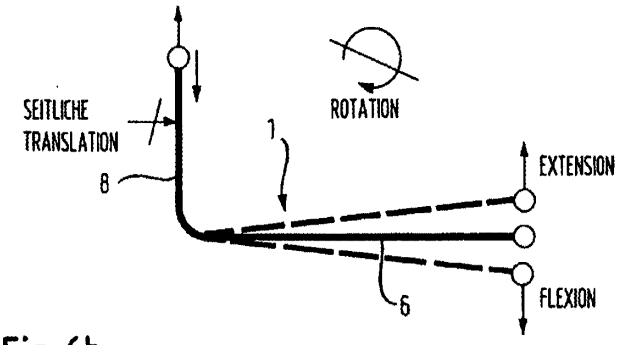
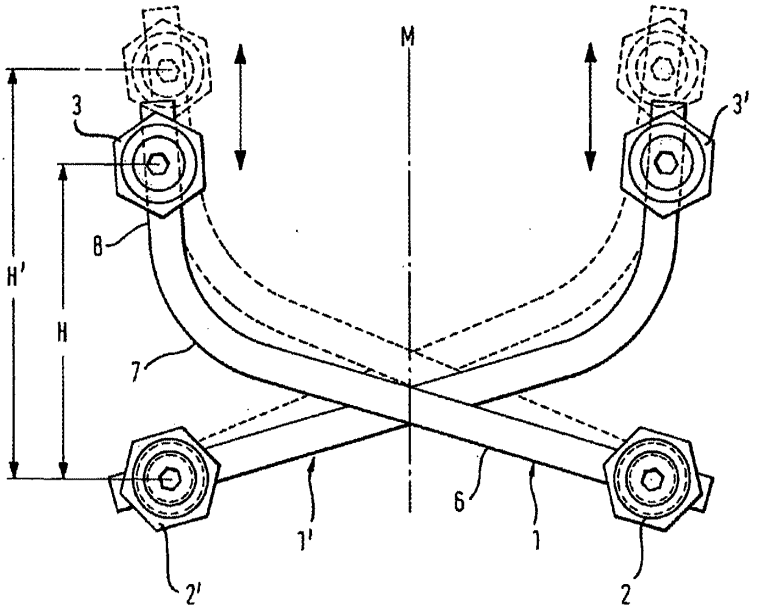
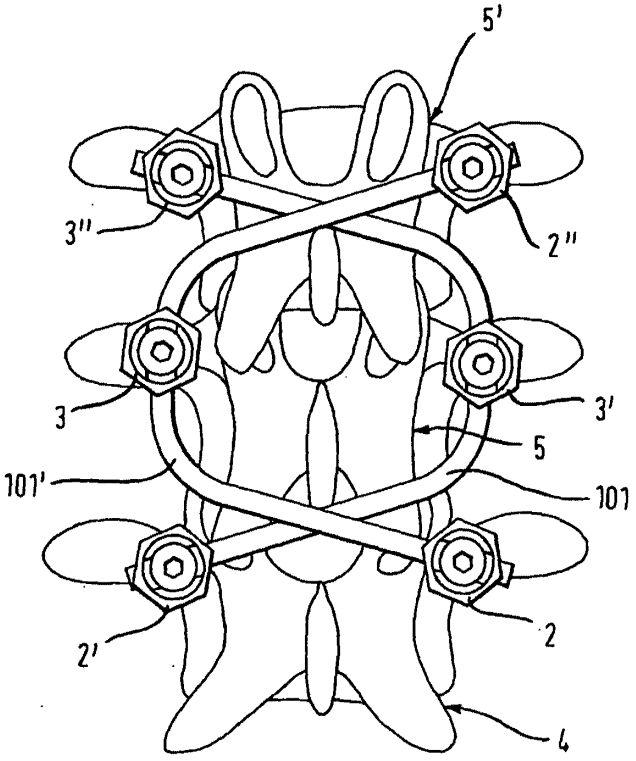


Fig. 6b



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 677 of 2152

Fig. 7

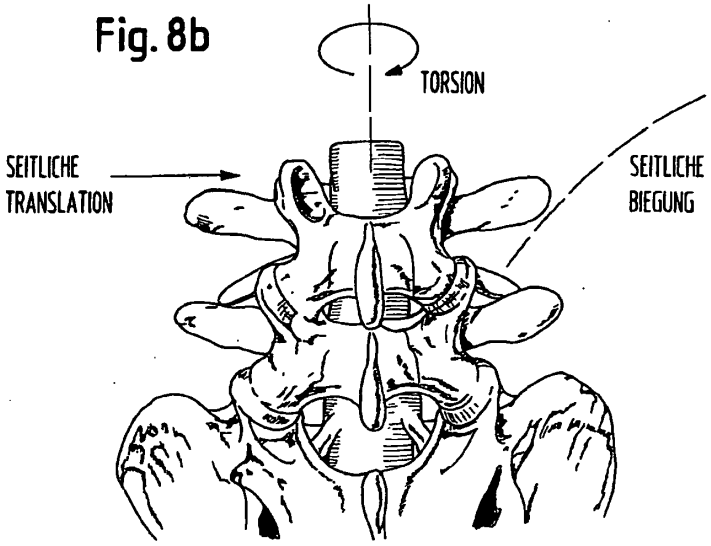


Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 678 of 2152

Fig. 8a



Fig. 8b



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 679 of 2152

Europäisches Patentamt

EUROPÄISCHER RECHERCHENBERICHT

Nummer der Anmeldung
EP 05 00 3401

EINSCHLÄGIGE DOKUMENTE

Kategorie	Kennzeichnung des Dokuments mit Angabe, soweit erforderlich, der maßgeblichen Teile	Betrifft Anspruch	KLASSIFIKATION DER ANMELDUNG (Int.Cl.7)
X Y	WO 02/102259 A (SENGUPTA D.K. & MULHOLLAND R.C.) 27. Dezember 2002 (2002-12-27) * Zusammenfassung; Abbildungen * * Seite 3, Zeile 9 - Seite 4, Zeile 22 * * Seite 8, Zeile 11 - Seite 9, Zeile 10 * * Seite 10, Zeile 5 - Zeile 11 *	1,3-6, 9-11 12	A61B17/70 A61B17/64
X	EP 0 667 127 A (ACROMED) 16. August 1995 (1995-08-16) * Anspruch 1; Abbildungen 1,6,8 *	1,3-6,8, 10,11	
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X,D	US 2003/191470 A1 (RITLAND S.) 9. Oktober 2003 (2003-10-09) * Zusammenfassung; Abbildungen 3,4,9 * * Absätze [0044], [0045], [0053] *	1,3-6, 9-11	
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KATEGORIE DER GENANNTEN DOKUMENTE

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Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 680 of 2152

ANHANG ZUM EUROPÄISCHEN RECHERCHENBERICHT ÜBER DIE EUROPÄISCHE PATENTANMELDUNG NR. EP 05 00 3401

In diesem Anhang sind die Mitglieder der Patentfamilien der im obengenannten europäischen Recherchenbericht angeführten Patentdokumente angegeben.
Die Angaben über die Familienmitglieder entsprechen dem Stand der Datei des Europäischen Patentamts am
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Für nähere Einzelheiten zu diesem Anhang : siehe Amtsblatt des Europäischen Patentamts, Nr.12/82

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 681 of 2152

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(71) Applicant *(for all designated States except US)*: **SPINE WAVE, INC.** [US/US]; 2 Enterprise Drive, Shelton, CT 06484 (US).

(72) Inventors: **PAFFORD, John**; 11022 Raleigh LaGrange Road, Eads, TN 38028 (US). **WILSON, Thomas**; 24 Overlook Lane, Guilford, CT 06437 (US). **BOYD, Lawrence, M.**; 25 Birnham Lane, Durham, NC 27707 (US). **LOGUIDICE, Mark, D.**; 621 Warner Hill Road, Southport, CT 06890-3040 (US).

(74) Agent: **BECK, Michael, D.**; Bank One Center Tower, 111 Monument Circle, Suite 3000, Indianapolis, IN 46204-5115 (US).

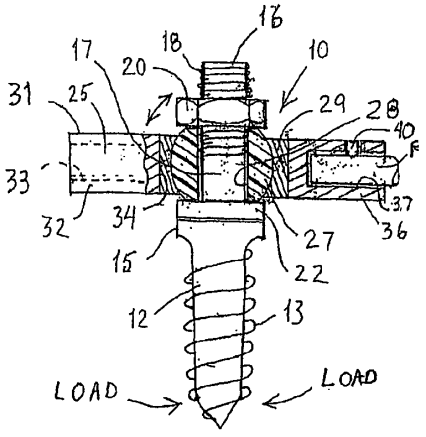
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(54) Title: DYNAMIC SPINAL STABILIZATION SYSTEM

(57) Abstract: A dynamic stabilization system includes a stabilization element, such as a spinal rod, a plurality of bone anchors, such as bone bolts, and a like plurality of connectors for connecting the bolts to the spinal rod. At least some of the connectors include a flexible element between the bone anchor and the rod and an adjustment element for adjusting the flexibility of the flexible element, to thereby adjust the dynamic flexibility between the rod and the bone anchor. In one embodiment, the flexible element is a flexible bearing element of a rod end bearing.



WO 2005/065375 A2

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 682 of 2152

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DYNAMIC SPINAL STABILIZATION SYSTEM

The present invention relates to spinal implant systems, and particularly to systems for stabilization of the spine. The invention provides a dynamic stabilization system that permits limited relative movement between the instrumented vertebrae and the stabilization system.

In the past, the principal protocol for the treatment of the spine has been rigid fixation combined with fusion of the affected vertebral body or intervertebral disc. Arthrodesis, as this approach is known, has been achieved with a variety of rigid fixation elements, such as spinal rods or plates that are rigidly fixed to a vertebra using bone screws, bone bolts and spinal hooks. However, spinal fusion has been recognized to have limitations in the treatment of disc degeneration, especially in the earlier stages of the degeneration where it may be unnecessary to eliminate motion of the spinal motion segments.

Clinical studies suggest that cells of the intervertebral disc respond favorably to reduced (but not eliminated) mechanical loading through deposition of extracellular matrix proteins (collagen, proteoglycan, fibronectin, etc.) into the disc space. In some cases, a degenerated disc may simply involve a mechanically overloaded and hypermobile segment that can be repaired by reversing the mechanically damaging load environment. For instance, clinical experiences with dynamic stabilization systems suggest that the disc becomes increasingly hydrated over time, as judged by MRI scanning.

Spinal instability is a recognized effect of degenerative disc disease. In contrast to arthrodesis, arthroplasty is a protocol that contemplates restoring segmental spinal motion while treating the degenerative condition. Arthroplasty has been successfully used in the treatment of degenerative conditions of the hip and knee. In recent years, efforts have been made to implement arthroplasty in the spine, and most particularly in the intervertebral space. Intradiscal arthroplasty is now clinically available in the form of articulating prosthetic discs and polymeric disc nucleus replacements. With the availability of viable

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 684 of 2152

intradiscal arthroplasty devices, interest has grown in providing some means for dynamic spinal stabilization – i.e., stabilization that still permits some degree of mobility between spinal segments.

Drawing from the approaches developed for intradiscal arthroplasty, efforts have made to develop an extradiscal arthroplasty. These systems offer the advantage of "soft stabilization" that limit, rather than eliminate, spinal segment motion. Current theories suggest that preventing movement of the spinal segments may not be a significant factor in clinical success of spinal stabilization systems. Instead, these theories focus on creating a normal loading pattern for the spine as a primary vehicle for successful spinal instrumentation. Thus, the goals for dynamic stabilization has been to restrict movement of the spine to a zone or range where normal or near normal loading of the spinal segments can occur. At the same time, dynamic stabilization techniques have sought to prevent the spine from adopting a position or orientation where abnormal loading of the spine can occur.

One approach to achieve these goals for dynamic stabilization utilizes the spinous process. Thus, in one system, flexible "ligaments' are engaged around the spinous process of adjacent vertebrae. Another form of flexible "ligament" is attached to the spinous process by way of small screws. In yet another approach, a polymeric spacer is held in place between the adjacent spinous processes. One system utilizes a coil spring that spans several vertebrae and that is anchored to the lamina of the end vertebrae. In one version, a rod extends through part of the coil spring to control rotation.

Some dynamic stabilization systems have relied upon fixation to the pedicle of the vertebrae. In these types of systems, a pedicle screw is threaded into the pedicle of adjacent vertebrae. A member spans between the heads of the pedicle screws to limit the movement of the spinal segments. In one device, known as the Graf Ligament, a non-elastic band is wrapped around pedicle screw anchors. The non-elastic bands lock the spinal segment into lordosis, while permitting minimal rotation movements of the spine.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 685 of 2152

Another system utilizing pedicle screws, provided by Sulzer Spine-Tech as the Dynesys System, incorporates a polymeric cylinder between the bone anchors. The Dynesys System permits, but limits, relative motion between adjacent vertebrae. The FASS System essentially integrates features from the Graf and Dynesys systems.

The DSS System employs still another approach by including a spring element connected to pedicle screws. The spring element is contained within a polyurethane tube to prevent tissue ingrowth. Finally, some systems utilize a rigid member, such as a spinal plate, spanning between vertebrae. The flexible stabilization feature is incorporated into the interface between the pedicle screw and the rigid member, such as through a flexible washer or a spherical screw-plate interface.

These prior extradiscal arthroplasty approaches all involve the introduction of flexible elements between spinal motion segments. Consequently, many of these systems are susceptible to over-loading the disc annulus or are, by necessity, unduly restrictive with respect to motion of the spinal segment.

Moreover, these prior systems are not capable of altering the stiffness of a segment in various loading modes (e.g., flexion/extension, compression, lateral bending and axial rotation). Furthermore, these early approaches to arthrodesis do not allow selection of where, or at which motion segment, dynamic movement is permitted. Finally, no system exists that can readily convert to and from a soft stabilization to a more rigid or completely rigid system.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 686 of 2152

Summary of the Invention

In response to these limitations of the prior art, the present invention contemplates a dynamic stabilization system that relies upon flexible elements interposed between a bone anchor, such as a bone screw or spinal hook. and a stabilization member, such as a rod or a plate. Furthermore, the present invention incorporates features that allow "fine tuning" of the dynamic flexibility of the total construct during the initial spinal instrumentation surgery, and even later during a revision procedure.

In one embodiment of the invention, a dynamic stabilization system for stabilization of the spine comprises a stabilization element configured to span between at least two vertebrae of the spine, at least two bone anchors, each having a bone engagement portion, and at least two connectors for connecting a corresponding one of the bone anchors to the stabilization element. At least one of the connectors includes a flexible element between the bone anchor and the stabilization element to permit relative pivoting therebetween. In another embodiment, the connector also includes an adjustment element for adjusting the flexibility of the flexible element.

In certain embodiments, the connector includes a bearing member attached to the stabilization element, in which the bearing member includes the flexible element. Where the stabilization element includes an elongated spinal rod, the bearing member is a rod end bearing including a rod engagement portion, and the flexible element is a bearing element of the rod end bearing. Where an adjustment element is provided, the bearing element is received within a bearing race of the rod end bearing and the adjustment element is arranged to compress the bearing element within the bearing race. The rod engagement portion includes a bore for receiving a portion of the spinal rod therein and a set screw for clamping the spinal rod within the bore.

In another embodiment of the invention, at least one of the bone anchors of the stabilization system includes a stem having a threaded portion and the flexible element includes a bore for receiving the stem therethrough. In certain

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 687 of 2152

embodiments, the adjustment element includes a nut engaging the threaded portion and arranged to compress the flexible element as the nut is threaded onto the threaded portion.

The dynamic stabilization system of the present invention can include come connectors that are configured to substantially rigidly connect one of the bone anchors to the stabilization element. Thus, the stabilization system can include a mix of rigid and flexible connectors that integrate the bone anchors to the stabilization element spanning the spine.

In embodiments of the dynamic stabilization system in which the stabilization element is an elongated spinal rod, at least one of the bone anchors includes a stem having a threaded portion and defining slot sized to receive the spinal rod therethrough. The flexible element includes a sleeve disposed around the stem with at least a portion disposed between the bone engagement portion of the bone anchor and the spinal rod when the rod extends through the opening. Where an adjustment element is provided, it includes a nut engaging the threaded portion that is arranged to compress the sleeve as the nut is threaded onto the threaded portion. In certain embodiments, the flexible element includes a first sleeve disposed between the bone engagement portion and the spinal rod and a second sleeve disposed between the spinal rod and the nut. In other embodiments, the sleeve is disposed between the bone engagement portion and the nut and includes an opening for receiving rod therethrough when the rod extends through the slot in the stem.

In embodiments of the dynamic stabilization system in which the stabilization element is an elongated spinal plate defining at least one opening therethrough, at least one of the bone anchors includes a stem having a threaded portion and the flexible element is a bushing engaged within the opening. The bushing defines a bore for receiving the stem therethrough and includes an upper head portion disposed between spinal plate and the nut. An adjustment element includes a nut engaging the threaded portion, whereby the nut compresses the head portion when the nut is threaded onto the threaded

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 688 of 2152

portion. In certain embodiments, the flexible element includes a lower head portion disposed between the spinal plate and the bone engaging portion of the bone anchor. The bone anchor further includes an intermediate portion between the bone engagement portion and the lower head portion of the bushing.

The present invention contemplates a method for dynamic stabilization of motion segments of the spine comprising the steps of positioning a stabilization element adjacent the spine, the stabilization element configured to span a length of the spine between at least two motion segments, engaging bone anchors to at least two motion segments, and coupling the bone anchors to the stabilization element with a flexible element between at least one bone anchor and the stabilization element. The method further contemplates the step of adjusting the flexibility of the flexible element. This step of adjusting the flexibility includes compressing the flexible element. This method can be coupled with the step of repairing or replacing all or part of the intervertebral disc between at least two motion segments. In a more specific embodiment, the method is coupled with the replacement or augmentation of all or part of the nucleus pulposus with a polymeric prosthesis adapted to emulate the physical properties of the natural nucleus.

In another aspect of the invention, a method for dynamic stabilization of a motion segment of the spine comprises the steps of introducing a device into an intervertebral space to at least partially maintain or restore the natural motion of the disc at the motion segment and then coupling a dynamic stabilization system across the motion segment that permits natural motion of the disc. The device can include a device for replacing or augmenting the nucleus pulposus of the intervertebral disc. In certain embodiments, the device includes a polymeric prosthesis configured to replace or augment the nucleus pulposus in which the polymeric prosthesis exhibits physical properties similar to the natural nucleus pulposus.

It is one object to provide a system for the dynamic stabilization of the spine in which at least some of the natural motion of a spinal motion segment is

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 689 of 2152

retained. It is another object to provide a dynamic stabilization system that permits adjustment in the flexibility at different locations along the dynamic construct.

One benefit of the present invention is that it can be readily adapted to existing stabilization constructs and can be integrated with known constructs that are fixed or that permit limited micro-motion. Another benefit is that the invention provides the orthopaedic surgeon with a great deal of flexibility in the initial surgical procedure or in a subsequent revision procedure.

Other objects and benefits of the invention can be discerned from the following written description taken along with the accompanying figures.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 690 of 2152

Description of the Drawings

FIG. 1 is an anterior view of a human spine instrumented with a stabilization construct.

FIG. 2 is a side view of a connector capable of providing dynamic fixation within the stabilization construct shown in **FIG. 1**.

FIG. 3 is a top view of a flexible bearing component of the connector illustrated in **FIG. 2**.

FIG. 4 is a perspective view of an alternative bearing element for use in a flexible bearing component of the type depicted in **FIG. 3**.

FIG. 5 is a side view of a connector according to a further embodiment of the invention for providing dynamic fixation within the stabilization construct shown in **FIG. 1**.

FIG. 6 is a side partial view of the connector shown in **FIG. 5**.

FIG. 7 is a perspective view of an elastomeric sleeve for use with the connector **50** shown in **FIG. 5**.

FIG. 8 is a perspective view of a stabilization plate for use in a dynamic spinal stabilization construct.

FIG. 9 is a cross-sectional view of the stabilization plate shown in **FIG. 7**, taken along line **9-9** as viewed in the direction of the arrows.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 691 of 2152

Description of the Preferred Embodiments

For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the embodiments illustrated in the drawings and described in the following written specification. It is understood that no limitation to the scope of the invention is thereby intended. It is further understood that the present invention includes any alterations and modifications to the illustrated embodiments and includes further applications of the principles of the invention as would normally occur to one skilled in the art to which this invention pertains.

An exemplary spinal construct is depicted in **FIG. 1**. In this construct, a scaffolding is affixed to opposite sides of the spine. In the illustrated configuration, a pair of stabilization elements, in the form of spinal rods **R**, span from the **L3** vertebra, across the **L4** and **L5** vertebrae and ending at the sacrum **S**. A series of connectors **C1-C4** fasten the rod **R** to the vertebrae. The connectors in a typical stabilization construct include some form of anchor element, such as a bone screw or a spinal hook. In recent years, the pedicle screw has become a bone anchor of choice.

In prior stabilization constructs, the connectors and associated bone anchors have been common at each instrumented vertebral level. In the typical case, the stabilization element, such as rod **R**, was rigidly fixed to the bone anchor, or at best was permitted some "micro-motion". In accordance with one feature of the present invention, the connectors **C1-C4** can be different – e.g., they can provide different levels of flexibility or rigidity depending upon the physiological requirements for the particular patient and the nature of the injury or damage to the spine that is being addressed by the stabilization construct.

Connectors and bone anchors for a generally rigid fixation are well known. Connectors providing dynamic stabilization may be constructed in accordance with the embodiments disclosed herein. For instance, in one embodiment, a connector **10**, depicted in **FIG. 2**, includes a bone anchor **12** that is in the form of a bone screw with bone engaging threads **13**. The bone anchor **12** includes an

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 692 of 2152

intermediate platform **15** from which projects a post **16**. The post **16** includes a non-threaded portion **17** and terminate in a threaded portion **18**. The threaded portion **18** preferably carries machine threads for engaging a threaded nut **20**. As thus far described, the bone anchor is constructed similar to the bone screw described and illustrated in U.S. Patent No. 4,836,196 to Park et al., the disclosure of which is incorporated herein by reference. It is understood that the post **16** can include an internal or an external driving feature (not shown) for engagement by a tool to thread the bone threads **13** into a vertebra. It is also contemplated that a locking nut is provided that can lock the position of nut **20** on the bone anchor **12**.

The bone anchor **12** is engaged to the stabilization element R by way of a bearing member **25**. The bearing member is similar to a rod-end bearing used in industrial machinery applications. For example, the bearing member **25** can be similar to the HME self-lubricating rod end manufactured by Heim Bearings of Fairfield, CT. The bearing member **25** includes a bearing element **27** that defines a passageway **28** to receive the stem **16** of the bone anchor **12**, as shown in **FIG. 2**. The bearing element is slidably disposed within a bearing race **29** so that the bearing element **27** articulates within the race in its permitted degrees of freedom.

The race **29** is mounted within a bore **34** defined in a bearing housing **31**. The race is fixed within the housing in a conventional manner, such as by a press-fit engagement. As shown in **FIGS. 2-3**, the housing **31** generally conforms to the shape of the bearing element **27** – in this case the bearing element is spherical so the housing is circular. The housing defines at least one rod engagement element **32**. When the connector **10** is situated at the end of a construct, such as the connector **C1** in **FIG. 1**, only one engagement element is necessary. However, if the connector **10** is situated within the length of the construct, such as the connectors **C2** or **C3**, then a second rod engagement element **36** can be provided on the housing **31**.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 693 of 2152

The rod engagement element **32** is configured for attachment or connection to the stabilization rod **R**. Thus, in its simplest form, the element **32** is welded to the rod end. Preferably, the engagement element **32** defines a bore **33** for snugly receiving the rod end. Alternatively, the element **32** can define a press-fit engagement with the rod end. The bore **33** and the rod end can define complementary non-circular features to prevent rotation of the rod about its axis within the rod engagement element **32**.

Most preferably, some additional fixation is provided to positively and solidly engage the bearing housing to the rod **R**. Thus, as shown with respect to the rod engagement element **36**, the rod bore **37** is intersected by a set screw **40**, which is configured as is typical for spinal implants. The set screw can be threaded into the engagement element **37** to bear against the rod end to clamp the bearing housing **31** to the rod **R**. Several set screws **40** are provided to ensure a solid fixation between the two parts.

As shown in **FIG. 2**, the stem **16** of the bone anchor **12** extends through the bore **28** in the bearing element **27**. The bearing element is sandwiched between the intermediate portion **15** of the bone anchor and the nut **20**. Alternatively, a spacer **22** may be interposed between the intermediate portion **15** and the bearing element **27**. The spacer **22** can be utilized where necessary to accommodate height differences between the rod and the vertebrae along the length of the rod **R**.

In accordance with the present invention, the bearing member **25** allows articulation of the rod **R** and bone anchor **12** relative to each other in certain degrees of freedom. For instance, the stem **16** of the bone anchor can move in the direction of the arrows in **FIG. 2** when subjected to the loads applied to the threaded portion **13** of the anchor that is engaged within a vertebra. The present invention contemplates a connector **10** that allows adjustment of the relative flexibility of this articulating bearing joint. Thus, in one specific embodiment, at least one set screw **42** is threaded into the housing **31** to engage the bearing element **29**, as shown in **FIG. 3**. In this specific embodiment, the bearing

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 694 of 2152

element **29** is fixed to the housing **31**, thereby producing an essentially rigid connection between the bone anchor **12** and the stabilization rod **R**.

In another embodiment, the degree of flexibility is adjusted by the amount of compression of the bearing element **27**. In this embodiment, the bearing element is formed of an elastomeric material that is compressed between the intermediate portion **15** and the nut **20**. As the nut is tightened onto the threaded end **18** of the stem **16**, it presses the bearing element **27** which causes it to bulge transverse to the compressive force. As the bearing element bulges, it presses outward into the race **29**, thereby increasing the frictional resistance between the two components. Thus, the nut **20** operates as an adjustment element to adjust the dynamic flexibility of the bearing element.

It can be appreciated that this flexibility adjustment can occur at any time during the life of the stabilization construct. In other words, the construct can be initially implanted with a particular degree of flexibility in the connector **10** at any instrumented vertebral level. Moreover, if it is later determined that this degree of flexibility requires adjustment, minimally invasive procedures can be used to access the nut **20** and either tighten or loosen the nut depending upon whether the connector **10** needs less or more flexibility.

It is understood that the elements of the connector must be formed of medical grade materials, and especially of materials that can withstand the extreme loads experienced by the spinal construct. Thus, the bone anchor **12**, nut **20** and bearing housing **31** may be formed of a biocompatible metal, such as stainless steel or titanium. The bearing race **29** can also be formed of a biocompatible metal, provided that its surface is polished to provide a sufficient articulating surface for the bearing element. Preferably, the bearing race **29** is formed of a biocompatible polymer, including UHMWPE, PTFE, nylon, polyurethane, or thermoplastic elastomers, such as HYTRL™. The bearing element **27** may be formed of the same material as the bearing race. Alternatively, the bearing element may be formed of a material that is more elastic than the material of the bearing race.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 695 of 2152

In the embodiment illustrated in **FIG. 2**, the bearing element **27** is spherical and the race **29** defines a articulating surface. Thus, with this embodiment, the connector nominally permits relative movement between the rod **R** and the bone anchor **12** (and consequently the instrumented vertebra) in several degrees of freedom and in several planes that intersect the plane of the rod and bone anchor. Thus, while the pivot arrows in **FIG. 2** reside in the rod/bone anchor plane, the bone anchor can also pivot along transverse planes projecting out of the paper. In many stabilization constructs, the dynamic stabilization is limited to specific planes or degrees of freedom, and most particularly to the rod/bone anchor plane (i.e., the plane of the paper in **FIG. 2**).

In order to control the degree of freedom of the connector **10**, the set screws **42** can be replaced with pivot pins that fit within corresponding bores (not shown) formed in the bearing element **27**. Alternatively, the bearing element can assume different configurations, such as the oblong element **45** shown in **FIG. 4**. The element **45** defines a central bore **48** for receiving the stem **16** of the bone anchor **12**. This oblong bearing element includes generally linear sides **46** bounded by generally spherically shaped ends **47**. The bearing race can be configured accordingly to receive the oblong bearing element **45**. The generally linear sides **46** prevent pivoting relative to those surfaces, while the spherical ends **47** permit pivoting in that corresponding plane. The bearing element **45** exhibits the same compressive properties as the element **27** discussed above to permit adjustment of the flexibility of the bearing joint.

In one feature of the invention, the interface between the bone anchor and the stabilization element is adjustable, either during or subsequent to the initial surgery in which the stabilization scaffolding is implanted. This feature is accomplished by the use of elastomeric elements that can be compressed to adjust their dynamic flexibility. This feature is implemented in an additional embodiment of the present invention depicted in **FIGS. 5** and **6**. In this embodiment, a connector **50** includes a bone anchor **52** that includes bone engaging threads **53**, an intermediate portion **55** and a stem **56** having a non-

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 696 of 2152

threaded portion **57** and a threaded end **59**. A nut **60** is also provided for engaging the threaded end of the stem. The bone anchor **52** is thus far similar to the anchor **12** described above.

However, with this embodiment, the non-threaded portion **57** of the stem **56** defines a vertical slot **58** configured to receive the stabilization rod **R** therethrough. Preferably, the width of the slot is close to the outer diameter of the rod, while the vertical height of the slot is greater than the diameter. As can be seen in the figures, the rod **R** passes through the vertical slot **58** and is sandwiched between opposite sleeves 65_U and 65_L. Both sleeves are preferably formed of an elastomeric material that is resiliently compressed as the bone anchor **52** pivots in the direction indicated by the arrows in **FIG. 5**. The sleeves **65** define a bore **66** through which the stem **56** of the bone anchor **52** extends.

As with the previous embodiment, the nut **60** is used to change the dynamic flexibility of the connector **50** by adjusting the amount that the resilient sleeves **65** are compressed. A washer (not shown) is provided between the nut **60** and the uppermost sleeve 65_U so that tightening the nut does not compromise the integrity of the sleeve. The dynamic flexibility of the connector **50** may also be adjusted by using sleeves having different thicknesses or different elastomeric material properties. The elongated slot **58** may be sized to accommodate an expected range of thicknesses of the lowermost sleeve 65_L.

In the embodiment shown in **FIGS. 5** and **6**, upper and lower sleeves 65_U, 65_L are provided. In an alternative embodiment, a single sleeve **70** may be utilized, as shown in **FIG. 7**. The sleeve defines a bore **72** that is sized to receive the stem **56** of the bone anchor **52**. The sleeve **70** further defines a transverse bore **74** that is sized to receive the stabilization rod **R**. The sleeve **70** can be compressed by the nut **60** to adjust the dynamic flexibility of the connector, in the manner described above.

Adjustability of dynamic flexibility of a stabilization construct may also be implemented in a system that relies upon an elongated stabilization plate. In particular, a stabilization plate **80**, as shown in **FIGS. 8-9**, is provided with a

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 697 of 2152

plurality of openings **83** for engagement with a plurality of bone anchors, such as the anchor **52** depicted in phantom lines in **FIG. 9**. The stabilization plate is sized to span several vertebral levels, with the openings **83** spaced accordingly. The openings in the plate **80** may be individual bores or may be in the form of elongated slots, similar to the slotted spinal plate disclosed in U.S. Patent No. 4,836,196, the disclosure of which has been incorporated by reference.

In order to provide the dynamic flexibility feature of the present invention, the plate **80** includes a plurality of elastomeric bushings **85** that are pressed into a corresponding one of the openings **83**. As shown in **FIG. 9**, the bushings **85** include a central collar **84** that is sized to fit within an opening **83**, preferably snugly. The collar defines a bore **91** for receiving the stem **56** of the anchor **52** therethrough. The collar terminates at its ends in upper and lower head portions $\mathbf{87_U}$, $\mathbf{87_L}$ that are larger than the openings **83** in the plate **80** to trap the bushing **85** within the opening.

The lower head portion $\mathbf{87_L}$ is supported on the intermediate portion **55** of the anchor, which the nut **60** bears against the upper head portion $\mathbf{87_U}$. The two head portions **87** are compressed by tightening the nut **60** onto the stem **56** of the bone anchor **52**, to thereby increase the rigidity (or decrease the dynamic flexibility) of the plate-to-bone anchor interface.

The dynamic stabilization system of the present invention is well suited as an adjunct to a disc repair procedure. For instance, an intervertebral disc may require augmentation or replacement, depending upon the severity of the damage or disease to the disc. Where the disc is intact, it is important to maintain the loading pattern as normal as possible since this loading pattern helps hydrate the disc and flush toxins from the disc. The dynamic stabilization systems disclosed herein provide stabilization for the affected disc while allowing a meaningful amount of motion at that vertebral level.

Devices have been developed for replacement of the intervertebral disc. In some cases, the device is a mechanical device that is configured to mimic the mechanics of the disc motion. In more recent years, the nucleus pulposus of the

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 698 of 2152

intervertebral disc has been replaced with a polymer prosthesis that emulates the physical and chemical properties of the disc. In particular, these types of prostheses are intended to preserve or restore the movement and load response of the affected disc as close to the natural disc as possible. One such material is a hydrogel that has similar elastic properties to the natural nucleus pulposus and that shares a similar fluid transport mechanism to the natural disc. This material can be used to replace the entire nucleus pulposus, or to augment the existing nucleus where voids or other defects in the nucleus exist.

Even where the intervertebral disc has been replaced with a mechanical device, or where all or part of the nucleus pulposus has been replaced or augmented by a polymer prosthesis, restoration and maintenance of normal spinal segment motion is important. Consequently, it is contemplated that the dynamic stabilization system of the present invention, including connectors **10**, **50** or the plate **80**, may be used in connection with disc/nucleus repair or replacement procedures.

Thus, in one aspect of the invention, a method for dynamic stabilization of a motion segment includes the step of introducing a device into an intervertebral space that at least partially restore or maintain the natural motion of the intervertebral disc. The motion segment is instrumented with a dynamic stabilization system that includes one or more of the connectors **10**, **50** or the plate **80**, which permits the natural motion of the disc.

While the invention has been illustrated and described in detail in the drawings and foregoing description, the same should be considered as illustrative and not restrictive in character. It is understood that only the preferred embodiments have been presented and that all changes, modifications and further applications that come within the spirit of the invention are desired to be protected.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 699 of 2152

What is claimed is:

1. A dynamic stabilization system for stabilization of the spine, comprising:

a stabilization element configured to span between at least two vertebrae of the spine:

at least two bone anchors, each having a bone engagement portion; and

at least two connectors for connecting a corresponding one of said bone anchors to said stabilization element, at least one connector including;

a flexible element between the bone anchor and the stabilization element to permit relative pivoting therebetween; and

an adjustment element for adjusting the flexibility of said flexible element.

2. The dynamic stabilization system according to claim 1, wherein said at least one connector includes a bearing member attached to said stabilization element, said bearing member including said flexible element.

3. The dynamic stabilization system according to claim 2, wherein:

said stabilization element includes an elongated spinal rod;

said bearing member is a rod end bearing including a rod engagement portion;

and said flexible element is a bearing element of said rod end bearing.

4. The dynamic stabilization system according to claim 3, wherein:

said bearing element is received within a bearing race of said rod end bearing; and

said adjustment element is arranged to compress said bearing element within said bearing race.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 700 of 2152

5. The dynamic stabilization system according to claim 3, wherein said rod engagement portion includes a bore for receiving a portion of said spinal rod therein and a set screw for clamping said spinal rod within said bore.

6. The dynamic stabilization system according to claim 1, wherein:

at least one of said bone anchors includes a stem having a threaded portion;

said flexible element includes a bore for receiving said stem therethrough; and

said adjustment element includes a nut engaging said threaded portion and arranged to compress said flexible element as said nut is threaded onto said threaded portion.

7. The dynamic stabilization system according to claim 6, wherein said at least one of said bone anchors includes an intermediate portion between said stem and said bone engagement portion, said intermediate portion configured to support said flexible element so that said flexible element is compressed between said intermediate portion and said nut when said nut is threaded onto said threaded portion.

8. The dynamic stabilization system according to claim 1, wherein another of said connectors is configured to substantially rigidly connect one of said bone anchors to said stabilization element.

9. The dynamic stabilization system according to claim 1, wherein:

said stabilization element includes an elongated spinal rod;

at least one of said bone anchors includes a stem having a threaded portion and defining slot sized to receive said spinal rod therethrough;

said flexible element includes a sleeve disposed around said stem with at least a portion disposed between the bone engagement portion of the bone anchor and the spinal rod when the rod extends through said opening; and

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 701 of 2152

said adjustment element includes a nut engaging said threaded portion and arranged to compress said sleeve as said nut is threaded onto said threaded portion.

10. The dynamic stabilization system according to claim 9, wherein said flexible element includes a first sleeve disposed between said bone engagement portion and the spinal rod and a second sleeve disposed between said spinal rod and said nut.

11. The dynamic stabilization system according to claim 9, wherein said sleeve is disposed between said bone engagement portion and said nut and includes an opening for receiving rod therethrough when said rod extends through said slot in said stem.

12. The dynamic stabilization system according to claim 1, wherein:

said stabilization element is an elongated spinal plate defining at least one opening therethrough;

at least one of said bone anchors includes a stem having a threaded portion;

said adjustment element includes a nut engaging said threaded portion; and

said flexible element is a bushing engaged within said at least one opening, said bushing defining a bore for receiving said stem therethrough and including an upper head portion disposed between spinal plate and said nut, whereby said nut compresses said head portion when said nut is threaded onto said threaded portion.

13. The dynamic stabilization system according to claim 12, wherein said flexible element includes a lower head portion disposed between said spinal plate and said bone engaging portion of said bone anchor.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 702 of 2152

14. The dynamic stabilization system according to claim 13, wherein said bone anchor includes an intermediate portion between said bone engagement portion and said lower head portion of said bushing.

15. A dynamic stabilization system for stabilization of the spine, comprising:

a stabilization element configured to span between at least two vertebrae of the spine:

at least two bone anchors, each having a bone engagement portion and a stem portion; and

at least two connectors for connecting a corresponding one of said bone anchors to said stabilization element, at least one connector including a bearing member associated with said stabilization element and including bearing race and a flexible bearing element mounted within said bearing race, said flexible bearing element configured to receive said stem portion of said bone anchor therethrough.

16. The dynamic stabilization system according to claim 15 wherein said at least one connector includes an adjustment element for adjusting the flexibility of said flexible bearing element.

17. The dynamic stabilization system according to claim 16, wherein said adjustment element is arranged to compress said bearing element within said bearing race.

18. The dynamic stabilization system according to claim 17, wherein:

said stem of least one of said bone anchors includes a threaded portion; and

said adjustment element includes a nut engaging said threaded portion and arranged to compress said flexible bearing element as said nut is threaded onto said threaded portion.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 703 of 2152

19. The dynamic stabilization system according to claim 15, wherein:

said stabilization element includes an elongated spinal rod;

said bearing member is a rod end bearing including a rod engagement portion configured for engagement to said spinal rod.

20. The dynamic stabilization system according to claim 19, wherein said rod engagement portion includes a bore for receiving a portion of said spinal rod therein and a set screw for clamping said spinal rod within said bore.

21. A dynamic stabilization system for stabilization of the spine, comprising:

an elongated spinal stabilization rod configured to span between at least two vertebrae of the spine:

at least two bone anchors, each having a bone engagement portion and at least one of said bone anchors including a stem defining slot sized to receive said spinal rod therethrough; and

a flexible sleeve disposed around said stem with at least a portion disposed between the bone engagement portion of the bone anchor and the spinal rod when the rod extends through said opening.

22. The dynamic stabilization system according to claim 21, wherein:

said stem includes a threaded portion, and

said system further comprises a nut engaging said threaded portion and arranged to compress said sleeve as said nut is threaded onto said threaded portion.

23. The dynamic stabilization system according to claim 22, wherein said flexible sleeve includes a first sleeve disposed between said bone engagement portion and the spinal rod and a second sleeve disposed between said spinal rod and said nut.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 704 of 2152

24. The dynamic stabilization system according to claim 23, wherein said flexible sleeve is disposed between said bone engagement portion and said nut and includes an opening for receiving rod therethrough when said rod extends through said slot in said stem.

25. A method for dynamic stabilization of motion segments of the spine comprising the steps of:

positioning a stabilization element adjacent the spine, the stabilization element configured to span a length of the spine between at least two motion segments;

engaging bone anchors to at least two motion segments;

coupling the bone anchors to the stabilization element with a flexible element between at least one bone anchor and the stabilization element; and

adjusting the flexibility of said flexible element.

26. The method for dynamic stabilization according to claim 25, wherein the step of adjusting the flexibility includes compressing said flexible element.

27. The method for dynamic stabilization according to claim 25, further comprising the step of repairing or replacing all or part of the intervertebral disc between at least two motion segments.

28. A method for dynamic stabilization of a motion segment of the spine comprising the steps of:

introducing a device into an intervertebral space to at least partially maintain or restore the natural motion of the disc at the motion segment; and

coupling a dynamic stabilization system across the motion segment that permits natural motion of the disc.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 705 of 2152

29. The method for dynamic stabilization according to claim 28, wherein the device includes a device for replacing or augmenting the nucleus pulposus of the intervertebral disc.

30. The method for dynamic stabilization according to claim 29, wherein the step of introducing a device includes introducing a polymeric prosthesis to replace or augment the nucleus pulposus in which the polymeric prosthesis exhibits physical properties similar to the natural nucleus pulposus

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 706 of 2152

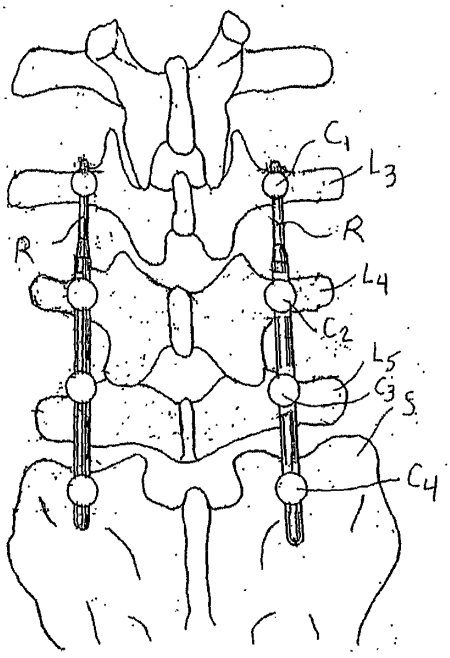


FIG. 1

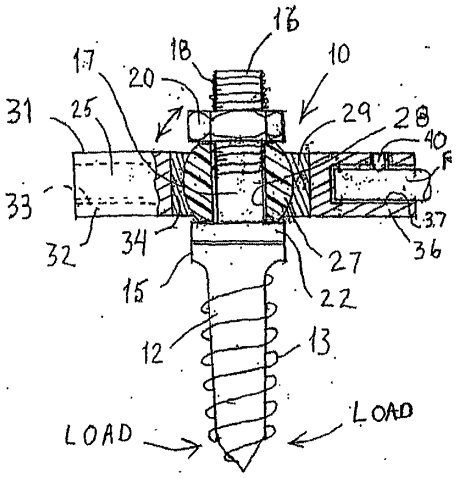


FIG. 2

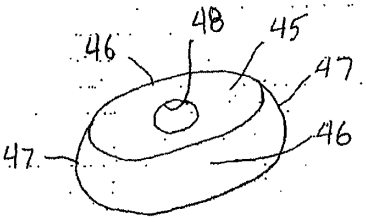


FIG. 4

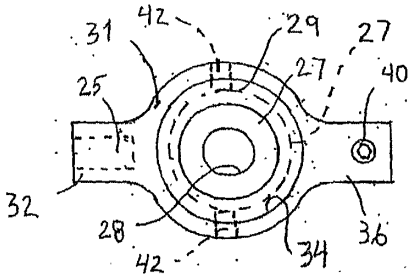


FIG. 3

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 707 of 2152

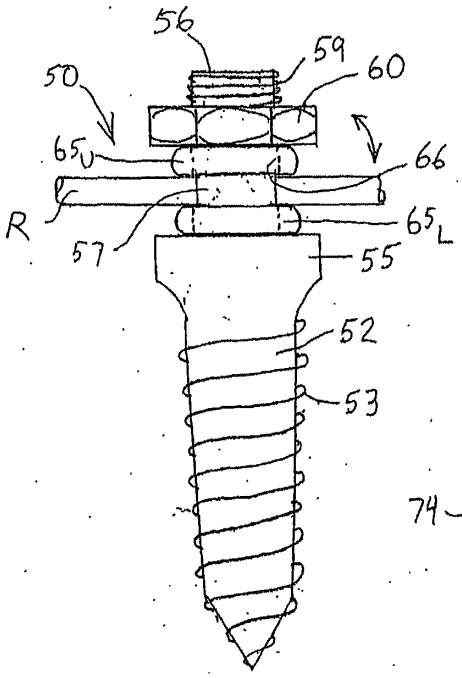


FIG. 5

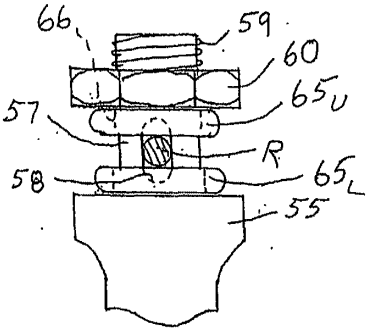


FIG. 6

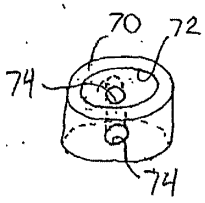


FIG. 7

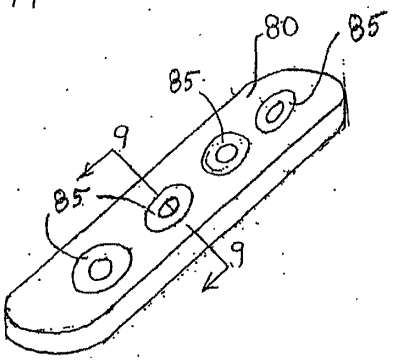


FIG. 8

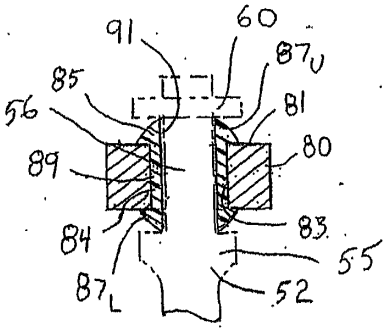


FIG. 9

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 708 of 2152

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(71) Applicant *(for all designated States except US)*: **SPINE WAVE, INC.** [US/US]; 2 Enterprise Drive, Shelton, CT 06484 (US).

(72) Inventors: **BOYD, Lawrence, M.**; 25 Birnham Lane, Durham, NC 27707 (US). **LIPSCHULTZ, Typer, P.**; 6112 Avalon Drive East, New Canaan, CT 06840 (US). **LOGUIDICE, Mark, D.**; 621 Warner Hill Road, Southport, CT 06890-3040 (US). **CARTER, Andrew**; 9R Conant Street, Acton, MA 017220 (US).

(74) Agent: **BECK, Michael, D.**; Bank One Center Tower, 111 Monument Circle, Suite 3000, Indianapolis, IN 46204-5115 (US).

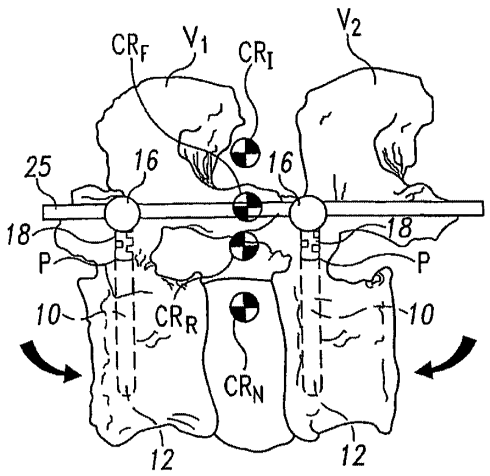
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[Continued on next page]

(54) Title: DYNAMIC SPINAL STABILIZATION SYSTEM



(57) Abstract: A dynamic stabilization construct for implantation within the spine comprises bone anchors that include a flexible portion between the bone engaging and head portions of the anchor. The head portion is configured to mate with different types of stabilization elements adapted to span between spinai motion segments. The engagement portion can also be configured for different types of fixation to a motion segment, such as within the pedicle of a vertebra. The flexible portion permits limited bending of the bone anchor beneath the level of the stabilizafiion element. In one embodiment, the flexible portion is integrated finto the body of the bone anchor in the form of hinge elements. In another embodiment, a separate flexible element, such as a spacer or spring, is interposed between the head and engagement portions. In a further embodiment, the bone anchor includes a portion having a reduced cross-section. The flexible bone anchors may be used to tailor the dynamic flexibility of spinai stabilization instrumentation at each level of the construct.

WO 2005/065374 A2

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 709 of 2152

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.

DYNAMIC SPINAL STABILIZATION SYSTEM

The present invention relates to spinal implant systems, and particularly systems for stabilization of the spine. The invention provides a dynamic stabilization system that permits limited relative movement between the instrumented vertebrae and the stabilization system.

In the past, the principal protocol for the treatment of the spine has been rigid fixation combined with fusion of the affected vertebral body or intervertebral disc. Arthrodesis, as this approach is known, has been achieved with a variety of rigid fixation elements, such as spinal rods or plates that are rigidly fixed to a vertebra using bone screws, bone bolts and spinal hooks. However, spinal fusion has been recognized to have limitations in the treatment of disc degeneration, especially in the earlier stages of the degeneration where it may be unnecessary to eliminate motion of the spinal motion segments.

Clinical studies suggest that cells of the intervertebral disc respond favorably to reduced (but not eliminated) mechanical loading through deposition of extracellular matrix proteins (collagen, proteoglycan, fibronectin, etc.) into the disc space. In some cases, a degenerated disc may simply involve a mechanically overloaded and hypermobile segment that can be repaired by reversing the mechanically damaging load environment. For instance, clinical experiences with dynamic stabilization systems suggest that the disc becomes increasingly hydrated over time, as judged by MRI scanning.

Spinal instability is a recognized effect of degenerative disc disease. In contrast to arthrodesis, arthroplasty is a protocol that contemplates restoring segmental spinal motion while treating the degenerative condition. Arthroplasty has been successfully used in the treatment of degenerative conditions of the hip and knee. In recent years, efforts have been made to implement arthroplasty in the spine, and most particularly in the intervertebral space. Intradiscal arthroplasty is now clinically available in the form of articulating prosthetic discs and polymeric disc nucleus replacements. With the availability of viable

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 711 of 2152

intradiscal arthroplasty devices, interest has grown in providing some means for dynamic spinal stabilization – i.e., stabilization that still permits some degree of mobility between spinal segments.

Drawing from the approaches developed for intradiscal arthroplasty, efforts have made to develop an extradiscal arthroplasty. These systems offer the advantage of "soft stabilization" that limit, rather than eliminate, spinal segment motion. Current theories suggest that preventing movement of the spinal segments may not be a significant factor in clinical success of spinal stabilization systems. Instead, these theories focus on creating a normal loading pattern for the spine as a primary vehicle for successful spinal instrumentation. Thus, the goals for dynamic stabilization has been to restrict movement of the spine to a zone or range where normal or near normal loading of the spinal segments can occur. At the same time, dynamic stabilization techniques have sought to prevent the spine from adopting a position or orientation where abnormal loading of the spine can occur.

One approach to achieve these goals for dynamic stabilization utilizes the spinous process. Thus, in one system, flexible "ligaments' are engaged around the spinous process of adjacent vertebrae. Another form of flexible "ligament" is attached to the spinous process by way of small screws. In yet another approach, a polymeric spacer is held in place between the adjacent spinous processes. One system utilizes a coil spring that spans several vertebrae and that is anchored to the lamina of the end vertebrae. In one version, a rod extends through part of the coil spring to control rotation.

Some dynamic stabilization systems have relied upon fixation to the pedicle of the vertebrae. In these types of systems, a pedicle screw is threaded into the pedicle of adjacent vertebrae. A member spans between the heads of the pedicle screws to limit the movement of the spinal segments. In one device, known as the Graf Ligament, a non-elastic band is wrapped around pedicle screw anchors. The non-elastic bands lock the spinal segment into lordosis, while permitting minimal rotation movements of the spine.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 712 of 2152

Another system utilizing pedicle screws, known as the Dynesys System, incorporates a polymeric cylinder between the bone anchors. The Dynesys System permits, but limits, relative motion between adjacent vertebrae. The FASS System essentially integrates features from the Graf and Dynesis systems.

The DSS System employs still another approach by including a spring element connected to pedicle screws. The spring element is contained within a polyurethane tube to prevent tissue ingrowth. Finally, some systems utilize a rigid member, such as a spinal plate, spanning between vertebrae. The flexible stabilization feature is incorporated into the interface between the pedicle screw and the rigid member, such as through a flexible washer or a spherical screw-plate interface.

These prior extradiscal arthroplasty approaches all involve the introduction of flexible elements between spinal motion segments. Consequently, many of these systems are susceptible to over-loading the disc annulus or are, by necessity, unduly restrictive with respect to motion of the spinal segment.

Moreover, these prior systems are not capable of altering the stiffness of a segment in various loading modes (e.g., flexion/extension, compression, lateral bending and axial rotation). Furthermore, these early approaches to arthrodesis do not allow selection of where, or at which motion segment, dynamic movement is permitted. Finally, no system exists that can readily convert to and from a soft stabilization to a more rigid or completely rigid system.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 713 of 2152

SUMMARY OF THE INVENTION

In order to address some of the difficulties associated with prior dynamic stabilization systems, the present invention contemplates a novel bone anchor for use in the stabilization of motion segments of the spine. In a preferred embodiment, the bone anchor comprises an engagement portion configured for engagement within a spinal motion segment and a head portion configured for engagement to a stabilization element outside the vertebral body. The engagement portion can be of many known forms, such as bone screw, bone bolt or spinal hook. The head portion can also assume a variety of known configurations depending upon the type of stabilization element being utilized for the construct. For instance, the stabilization element can be a spinal rod or an elongated plate. The head portion can be configured to engage either type of stabilization element.

In an important feature of this embodiment of the invention, the bone anchor further comprises a flexible portion between the shank and the head portion. The flexible portion permits movement of the head portion relative to the engagement portion when both portions are fixed to the stabilization element and the vertebral body, respectively. In certain embodiments, the flexible portion is arranged to reside substantially extra-pedicular when the bone anchor is engaged within the pedicle of a vertebra. The flexible portion is configured to limit the relative movement between the head portion and the engagement portion to a single plane, most typically a plane parallel to the sagittal plane through the spine.

In one embodiment, the flexible portion includes an elongated body spanning between the engagement portion and the head portion. The elongated body defines at least one hinge element, and preferably several such hinge elements. The hinge element includes a slot defined in the elongated body having an axis substantially transverse to the longitudinal axis of the body. Several hinge elements can be arranged in alternating opposing relation along

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 714 of 2152

the length of the body. To reduce stress risers, each slot terminates within the elongated body with a bore substantially perpendicular to the axis of the slot.

In an alternative embodiment, the flexible portion includes a helical spring disposed between the engagement portion and the head portion. The spring can be constrained to deflect in a predetermined plane or planes.

In a further embodiment, the flexible portion includes an elongated flexible element disposed between the engagement portion and the head portion. The flexible element is a flexible sleeve or a similar tube-like structure spanning between the head and engagement portions. In one configuration, the engagement portion includes an elongated shank, and the elongated shank and the flexible sleeve have substantially equal outer diameters. Moreover, the elongated shank and the flexible sleeve can be configured for interlocking engagement.

The flexible sleeve may be affixed to the head and engagement portions. Alternatively, a tension element may be provided that is anchored at one end to the engagement portion and at an opposite end to the head portion. The tension element extends through the flexible sleeve to clamp the sleeve between the head portion and the engagement portion.

In one embodiment, the tension element is a cable. With this embodiment, the engagement portion includes an elongated shank that defines a longitudinal bore, opening at a proximal and an opposite distal end of the shank. The flexible element and the head portion also define a respective bore therethrough aligned with the longitudinal bore. The cable is then anchored to the shank at the distal end and extends through the longitudinal bore and the bores in the flexible element and the head portion. The cable anchor can be accomplished by the cable including an enlarged head relative to the diameter of the longitudinal bore at the distal end of the shank.

In yet another embodiment of the invention, the bone anchor includes an engagement portion having an elongated shank, in which at least the shank and

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 715 of 2152

the flexible portion are integral. The flexible portion defines a cross-sectional area along the longitudinal axis of the shank that is substantially less than the cross-sectional area of the shank along the longitudinal axis. Thus, the flexible portion will exhibit bending tendencies in the region of the reduced cross section. This bone anchor comprises means surrounding the flexible portion for preventing bone overgrowth at the flexible portion.

To achieve the reduced cross sectional area, the flexible portion has a first dimension in a first plane passing through the bone anchor that is less than a dimension of the engagement portion in the first plane. In certain embodiments, the flexible portion has a second dimension in a second plane substantially transverse to the first plane that is greater than the first dimension. With this configuration, the bone anchor exhibits greater flexibility in the first plane than in the second plane. In still other embodiments, the second dimension of the flexible portion is also greater than a dimension of the engagement portion in the second plane.

An alternative embodiment of the inventive bone anchor utilizes a flexible portion that includes an elongated body spanning between the engagement portion and the head portion, in which the elongated body defines an elongated slot therethrough. The slot extends generally parallel to the longitudinal axis of the elongated body in a sort of "clothes pin" configuration. Preferably, the elongated slot originates in the head portion and extends toward the engagement portion.

The present invention further contemplates a dynamic spinal stabilization system comprising a stabilization element configured to span a length of the spine adjacent the vertebrae and at least one bone anchor having a flexible intermediate portion and at least one other anchor selected from the group including a bone anchor having a flexible intermediate portion, a spinal hook having a hook portion configured to engage a portion of a vertebra and a head portion configured to engage the stabilization element, and a substantially rigid

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 716 of 2152

bone screw having a threaded portion configured to engage a portion of a vertebra and a head portion configured to engage the stabilization element.

The stabilization element can be an elongated plate defining at least two openings therethrough for receiving a corresponding one of the bone anchors. In this case, the head portion of the bone anchors can include a substantially spherical surface, while the elongated plate can define a substantially spherical recess at each of the openings.

The present invention further contemplates a method for dynamic stabilization of motion segments of the spine comprising the steps of:

1) positioning a stabilization element adjacent the spine, the stabilization element configured to span a length of the spine between at least two motion segments;

2) engaging bone anchors to at least two motion segments; and

3) coupling the bone anchors to the stabilization element, with at least one of the bone anchors coupled to permit deflection of the bone anchor between the stabilization element and the motion segment.

This method may be performed in conjunction with repairing or replacing all or part of the intervertebral disc between at least two motion segments.

Another inventive method dynamic stabilization of motion segments of the spine comprises the steps of:

1) positioning a stabilization element adjacent the spine, the stabilization element configured to span a length of the spine between at least two motion segments;

2) engaging bone anchors to at least two motion segments; and

3) coupling the bone anchors to the stabilization element, with at least one of the bone anchors configured to produce a center of rotation for the motion segment between the stabilization element and the normal anatomic center of rotation for the motion segment.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 717 of 2152

The present invention contemplates improvements to a method for correction of scoliosis in which a contoured rod is engaged to at least a portion of the deformed spine and is rotated to de-rotate the spine in the transverse plane. In particular, the improvement comprises engaging at least one vertebrae at either or both the superior and inferior ends of the rod to the rod to provide a center of rotation for the at least one vertebra that is between the rod and the normal anatomic center of rotation for the vertebra.

The invention also provides improvements to a method for correction of spondylolisthesis in which a slipped vertebra is pulled posteriorly to a stabilization element engaged to spinal elements adjacent the slipped vertebra. This improvement comprises engaging a bone anchor to the slipped vertebra that is configured to be pulled toward the stabilization element and that is configured to provide a center of rotation for the slipped vertebra that is between the stabilization element and the normal anatomic center of rotation for the vertebra.

It is one object of the invention to provide devices and methods that permit improved dynamic stabilization of the spine. A further object resides in features of the invention that allow tailoring of the flexibility at each instrumented spinal motion segment. Other objects and certain benefits of the invention will be appreciated from the following written description of the preferred embodiments, taken together with the accompanying figures.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 718 of 2152

DESCRIPTION OF THE FIGURES

FIG. 1 is an elevational view of a bone anchor in accordance with one embodiment of the present invention.

FIGS. 2a-2b are enlarged views of alternative embodiments for the flexible portion for the bone anchor shown in **FIG. 1**.

FIG. 3 is a side view of a dynamic stabilization system for implantation into a portion of the spine utilizing the bone anchor shown in **FIG. 1**.

FIGS. 4a-4c are alternative configurations for the head portion of the bone anchor shown in **FIG. 1**.

FIG. 5 is a perspective view of a known spinal plate for use with the bone anchor shown in **FIG. 1**.

FIGS. 6a-6b are enlarged partial cross-sectional views of alternative head portions for use with the bone anchor shown in **FIG. 1**, engaged to the spinal plate shown in **FIG. 5**.

FIG. 7 is an elevational view of a bone anchor in accordance with another embodiment of the present invention.

FIGS. 8a-8b are enlarged views of flexible portions for use with the bone anchor shown in **FIG. 7**.

FIG. 9 is a view of a vertebra instrumented with bone anchors as shown in **FIG. 8** and a spinal plate as shown in **FIG. 5**.

FIG. 10 is an elevational view of a bone anchor in accordance with a further embodiment of the invention.

FIG. 11 is an enlarged view of an alternative flexible portion for the bone anchor shown in **FIG. 10**.

FIG. 12 is a cross-sectional view of the bone anchor shown in **FIG. 10**, taken along line A-A as viewed in the direction of the arrows.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 719 of 2152

FIG. 13 is a front view of a bone anchor according to a further embodiment of the invention.

FIG. 14 is a side view of the bone anchor shown in **FIG. 13**.

FIG. 15 is a front cross-sectional view of a clamp for engaging the head portion of the bone anchor shown in **FIGS. 13** and **14**.

FIGS. 16a-16b are schematic representations of a scoliotic spine before correction using a rod de-rotation technique, showing the rod from an A/P and a lateral view.

FIGS. 17a-17b are schematic representations of the spine after de-rotation.

FIG. 18 is a lateral schematic representation of a correction for spondylolisthesis.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 720 of 2152

DESCRIPTION OF THE PREFERRED EMBODIMENTS

While the invention has been illustrated and described in detail in the drawings and foregoing description, the same should be considered as illustrative and not restrictive in character. It is understood that only the preferred embodiments have been presented and that all changes, modifications and further applications that come within the spirit of the invention are desired to be protected.

The present invention contemplates a bone fastener or anchor that is configured to engage a portion of a vertebra and to connect to a stabilization element adapted to span across a spinal motion segment. The bone anchor includes a flexible portion between the vertebra and the stabilization element that permits limited movement of the instrumented vertebrae without commensurate movement of the stabilization element.

In accordance with one embodiment of the invention shown in **FIG. 1**, a bone anchor **10** is provided that has an engagement portion **12** which may be an elongated shank with external threads **14** configured for engagement within a vertebra. The shank **12** and threads **14** are sized and configured for engagement within any portion of the vertebra, such as the pedicle or vertebral body. Preferably, the threads are configured for anchoring within the cancellous bone of the vertebra.

For the purposes of illustrating the present invention, the bone engagement portion of the anchor has been described as a bone screw or bolt configuration. However, it is understood that other devices for engaging a spinal motion segment or vertebra are contemplated, such as a spinal hook. Moreover, it is understood that the configuration of the elongated shank can be modified, for instance to promote bone ingrowth, or to permit implantation within the intradiscal space.

The anchor **10** includes a head portion **16** that is configured to engage a stabilization member spanning between adjacent vertebrae. As explained in

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 721 of 2152

detail herein, the head portion **16** can assume a variety of configurations depending upon the configuration of the stabilization member.

In one feature of the invention, the anchor **10** includes a flexible portion **18** interposed between the head portion **16** and the engagement portion **12**. In the embodiment depicted in **FIG. 1**, this flexible portion **18** includes one or more hinge elements **20**. More particularly, in the specific embodiment the hinge elements include elements **20a** oriented in one direction relative to the longitudinal axis **L** of the anchor, and elements **20b** in an opposing orientation. These hinge elements **20** represent a region of reduced bending stiffness that permits localized bending about the hinge element. It is thus contemplated that this localized bending will act to open or close the hinge elements, depending upon the direction of movement of the head portion **16** relative to the engagement portion **12**, as represented by the curved arrows in **FIG. 1**.

The number, size and arrangement of the hinge elements **20** may be modified depending upon the amount of bending flexibility that is desired for the particular spinal stabilization. For instance, fewer hinges result in a stiffer bone anchor than a greater number of hinges. In addition, the width of the mouth of the slots will determine the range of bending movement of the flexible portion **18**. In other words, a wider hinge element will be capable of a greater angular range of movement than a narrower hinge element.

Two exemplary hinge configurations are shown in **FIGS. 2a** and **2b**. In one specific embodiment shown in **FIG. 2a**, the hinge elements **20a** and **20b** are defined by slots **21** cut into the bone anchor perpendicular to its longitudinal axis. Each slot **21** terminates in a bore **22** that is most preferably formed along a circumference of the bone anchor. The bores **22** help limit the occurrence of stress risers at the interior of the slots, and may also improve the bending characteristics of the hinge element **20a, 20b**.

In the specific embodiment shown in **FIG. 2b**, the hinge elements **20'** of the flexible portion **18'** are in the form of curved slots. Moreover, the elements **20'** are aligned at a non-perpendicular angle relative to the longitudinal axis of

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 722 of 2152

the anchor. As shown in **FIG. 2b**, each hinge element **20'** is shown with one slot **23a** extending past the center of the flexible portion **18'** and an adjacent shorter slot **23b**. The configuration of **FIG. 2b** allows the slots **23a, 23b** to be thinner in width than the slots **21** of the embodiment in **FIG. 2a**, while achieving substantially the same degree of bending movement.

Referring to **FIG. 3**, one form of dynamic stabilization system is shown using the bone anchor **10** shown in **FIG. 1**. In particular, the engagement portion **12** of two anchors are engaged within adjacent vertebrae V_1 and V_2. Preferably, the anchors are threaded into the pedicle P of each vertebra. In accordance with the preferred embodiment, the anchors **10** are threaded into the pedicle to a depth where the flexible portions **18** are outside the pedicle so that the anchor can deflect through its full range of angular motion. However, the anchor may be embedded within the vertebra to a depth that encompasses part of the flexible portion **18**. It is contemplated in this circumstance that the amount of bending flexibility of the bone anchor **10** may be calibrated by embedding one or more hinge elements, thereby preventing bending of the anchor about that hinge element.

In an alternative embodiment, the bone anchor **10** can include a bore **24**, as shown in dashed lines in **FIG. 1**, which extends along the axis **L** of the anchor. The bore **24** is configured to receive a stiffening rod (not shown) that can be placed within the bore to essentially convert the anchor into a substantially rigid fastener. The rod can have a length sufficient to fill substantially the entire bore **24**, or can have a shorter length. Where the rod has a shorter length, it will traverse less than all of the hinge elements **20**. Thus, the rod can prevent deflection of the anchor at the lowermost hinge elements, such as elements **20a, 20b** in **FIG. 1**, while the upper most hinge elements are unencumbered.

As with any spinal implant, fatigue resistance is an important property of the bone anchors of the present invention, such as anchor **10**. Thus, the implant can be formed of accepted medical grade materials, such as stainless steel, or other materials, such as polymers, composites or super-elastic alloys, that exhibit

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 723 of 2152

sufficient fatigue resistance under normal spinal loading conditions and load cycles. Preferably, the hinge elements **20** are configured to minimize stress concentrations, such as through the use of radiused corners. Furthermore, the material can be strengthened during the manufacturing process, such as by minimizing surface roughness, pre-treating the surface (e.g., Ti nitriding, chroming), or pre-stressing the surface (e.g., by shot-peening).

As indicated above, each bone anchor includes a head portion **16** that is configured to engage a stabilization element, such as the element **25** shown in **FIG. 3**. The stabilization element can be an elongated rod or a spinal plate. The head portion **16** is configured appropriately for the specific type of stabilization element **25**. When the dynamic stabilization construct is complete, load applied to the vertebrae, as indicated by the large arrows in **FIG. 3**, causes each vertebra V_1, V_2 to rotate relative to the stabilization element **25**, as accommodated by the flexible portions **18**. Nominally, movement of one vertebra under external load is isolated from the other vertebra as the flexible portion **18** of the bone anchor **10** bends.

The representation in **FIG. 3** illustrates one significant benefit of the present dynamic stabilization system over prior systems. In particular, the center of rotation (CR) for a normal motion segment is represented by the marking CR_N. It is believed that an optimum dynamic stabilization system will emulate the normal movement of the motion segment as accurately as possible, given the limited ways in which the system can be fastened to the spine. Consequently, where the dynamic stabilization system permits rotation in the A/P plane, as represented by the center of rotation marking CR_N, the more optimum system will exhibit a center of rotation as close to the normal center CR_N as possible. Systems that rely upon providing inter-spinous flexibility, - i.e., those anchored to the transverse process that are connected between adjacent spinous processes via wires or lamina, cables - produce a center of rotation CR_I that is well remote from the normal center of rotation. Systems that rely upon flexibility at the point

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 724 of 2152

of fixation to the elongated spinal rod or plate have a center of rotation CR_F that is essentially along the axis of the elongated rod/plate.

However, the present invention offers a center of rotation CR_R that can be is at the surface of the pedicle, and therefor as close as possible to the normal center of rotation as is physically and anatomically possible. The posteriorly positioned centers of rotation CR_I, CR_F tend to generate abnormal loading patterns and greater loads on the anterior annulus during normal movements of the spine. The present invention beneficially moves the center of rotation CR_R of the instrumented motion segment anteriorly toward the normal center so that the disc experiences more normal loading patterns during flexion and extension of the spine.

In one embodiment of the invention, the dynamic stabilization system relies upon an elongated rod sized to span a length of the spine between two or more vertebrae. The elongated rod can be configured like a variety of known spinal implants and can include a number of surface finishes, such as smooth polish, knurling or threading. Likewise, a number of engagement mechanisms can be provided for connecting the bone anchor **10** to the stabilization element **25**. Thus, the head portion **16** of the anchor may assume a number of configurations, including the configurations shown in **FIGS. 4a-4c**. The head portion may include an open top connector **30** within which a spinal rod **26** is seated as shown in **FIG. 4a**. A compression member **31** clamps the rod within the connector **30**. Exemplary connectors of this type are described in U.S. Patent No. 5,545,165 to Biedermann et al. The head portion in **FIG. 4b** includes a top tightening connector **32** that uses a set screw **33** to clamp the rod **26** within the connector. U.S. Patent No. 5,282,801 to Sherman is directed to an exemplary top tightening mechanism.

Finally, an eyebolt-type connector **34** may be used as shown in **FIG. 4c**. Connectors of this type are described in U.S. Patent No. 5,246,442 to Ashman et al. The specification and figures of each of these patents are incorporated herein by reference. The details of each of these exemplary constructs are known to

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 725 of 2152

the person of skill in the field of spinal implants. It should be understood that the connectors shown in **FIGS. 4a-4c** can be readily used with the anchor **10**, as well as other connector configurations adapted to engage an elongated spinal rod.

The dynamic stabilization system of the present invention also contemplates implementation using a spinal plate, such as the slotted plate **28** shown in **FIG. 5**. This plate can be of many known configurations, such as the design described in U.S. Patent No. **5,209,751** to Farris et al., the disclosure of which is incorporated herein by reference. As shown in **FIGS. 6a-6b**, the head portion **16** of the bone anchor can assume a number of configurations for engagement with the spinal plate **28**. For instance, as shown in **FIG. 6a**, the head portion may assume a bone screw configuration in which the head **36** of the screw engages the top of the spinal plate **28**. In an alternative embodiment, shown in **FIG. 6b**, the anchor may be in the form of a bone bolt in which an intermediate portion **38** engages the underside of the plate **28**. A threaded stem **39** extends through an opening in the plate for engagement with a nut **40**. The nut thus sandwiches the plate **28** against the intermediate portion **38**. The bone anchor configuration of **FIG. 6a** and the bone bolt configuration of **FIG. 6b** are described further in the '751 Patent to Farris et al.

Again, it should be understood that these configurations for the head portion **16** for engagement to a spinal plate **26** are merely exemplary. The principles of the present invention do not depend upon the type of head portion **16** or the type of stabilization element (rod **26** or plate **28**) used. Any connection configuration can suffice provided that the function of the flexible portion **18** of the bone anchor **10** is not significantly impeded.

Where the bone engaging portion **12** includes bone threads **14**, the bone anchor **10** and/or the head portion **16** must incorporate some feature to allow threading of the anchor into the bone. In the bone anchor configuration **36** of **FIG. 6a** or the bone bolt configuration **38** of **FIG. 6b**, the head portion itself includes features for accepting a driving tool, such as a wrench. The feature may include external flats or an internal hex, for instance. External driving flats can be

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 726 of 2152

provided on the connectors shown in **FIGS. 4a-4c**. Alternatively, an internal driving bore may extend through the head portion **16** and into the engagement portion **12**, with an appropriately sized Allen wrench used to thread the anchor into the bone.

An alternative embodiment of a bone anchor **50** is depicted in **FIG. 7**. This bone anchor includes a bone engaging portion **52** that can include bone engaging threads **54**. Again, as with the anchor **10** discussed above, the bone engaging portion can assume a variety of know configurations adapted for engagement within a spinal motion segment or vertebra. The anchor **50** also includes a head portion **56** that can adopt a number of configurations depending upon the type of stabilization element used for the dynamic stabilization system. For example, the head portion may be configured like the connectors **30**, **32**, **34**, **36** or **38** shown in **FIGS. 4a-4c** and **6a-6b**. For the purposes of illustration, the head portion **56** shown in **FIG. 7** is generally in the form of a bone screw, as depicted in **FIG. 6a**.

In one aspect of this embodiment of the invention, the bone anchor **50** includes a flexible portion **58** interposed between the bone engagement portion **52** and the head portion **56**. Unlike the embodiment of **FIG. 1**, the flexible portion **58** is separate from one or the other, or both, of the engagement portion and the head portion. In other words, in the specific illustrated embodiment the flexible portion **58** is a separate component from the other two portions of the anchor **50**. Alternatively, the flexible portion may be integrated into either the engagement portion or the head portion.

However, in one embodiment, the flexible portion **58** is in the form of a generally cylindrical insert body **68** as shown in **FIG. 8a**. This insert body **68** is sized and shaped to generally conform to the outer configuration of the engagement portion **52** and/or the head portion **56** to present a substantially smooth transition between these portions. In this embodiment, the insert body **68** is formed of a bio-compatible polymeric or elastomeric material. For instance, the material can be PEEK (polyetheretherketone), polyurethane or similar

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 727 of 2152

resilient and flexible materials. Certain bio-compatible "soft" metals, such as Nitinol™ may also be used, taking into account the potential for adverse interaction with the metal of the other portions. The insert body can be formed using conventional techniques for the particular material, such as injection molding.

The choice of material dictates the amount of flexibility for the portion **58**. Moreover, the length of the insert body **68** is also a factor in defining the degree of relative motion permitted by the flexible portion **58**. It is contemplated that a range of pre-determined insert bodies **68** may be made available to the orthopaedic surgeon, with the bodies calibrated by anticipated range of angular motion. One benefit of the embodiment shown in **FIG. 7** is that the bone anchor **50** can be converted into a substantially rigid anchor by replacement of the flexible portion **58** with a substantially rigid spacer having the same size and configuration. Thus, unlike prior arthrodesis systems, the flexibility of each bone anchor used in a dynamic stabilization system can be varied from substantially rigid to very flexible depending upon the patient's pathology and indications. The flexibility of the construct can be established during the implantation surgery by choosing among the range insert bodies. That range of bodies may also include components having varying heights to accommodate differences in vertebral geometry depending upon instrumented vertebral level and patient anatomy.

In one embodiment, the insert body **68** includes interlocking segments **70** that are seated within interlocking notches **72** defined in the engagement portion **52** and head portion **56**. The interlocking segments **70** and notches **72** nominally prevent relative rotation between the three components. In addition, the interlocking elements permit torque transmission through the flexible portion **58** when the engagement portion **52** includes bone engaging threads **54**. More importantly, the interlocking elements **70, 72** facilitate transmission of bending forces across the flexible portion **58**. The interlocking segments **70** also help keep the construct together under bending loads and act as a fulcrum when load is applied to the engagement portion **52**. It is understood that the engagement

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 728 of 2152

portion 52 can be engaged to the vertebral bone prior to introduction of the insert body 68.

In an alternative embodiment, shown in **FIG. 8b**, the flexible portion **58** is in the form of a spring element **74**. In the illustrated embodiment, the spring element **74** is a coil spring that is interposed between the lower engagement portion **52** and the upper head portion **56**. Preferably, the spring element **74** is affixed to these lower and upper portions in a suitable manner, such as by welding or mechanical fastening. As with the insert body **68**, the flexibility of the spring element **74** can be determined by spring material and dimensions. Preferably, the spring element **74** is formed of a bio-compatible and fatigue-resistant metal, such as stainless steel. The wire diameter and coil dimensions may be adjusted to modify the anticipated flexibility of the flexible portion **58**. Preferably, the outer dimension of the spring element **74** is sized to provide a uniform transition from the adjoining portions **52** and **56** to the flexible portion **58**. Most preferably, the spring element **74** is surrounded by a sheath to prevent bone ingrowth into the spring element.

Both embodiments of the flexible portion **58** shown in **FIGS. 8a-8b** permit relative movement between the engagement portion **52** and head portion **56** in radial-longitudinal planes transverse to the longitudinal axis **L** of the anchor **50**. Unlike the anchor **10** of the previous embodiment in which the relative movement is limited to a single transverse plane, the movement permitted by the flexible portion **58** in the embodiment of **FIG. 7** permits movement in all radial-longitudinal planes about the longitudinal axis **L**.

This range of flexible motion can be modified on the embodiment of **FIG. 8a** by introducing stiffening elements **73** to the insert body. These stiffening elements may be integrally formed with the body itself, such as an injection molded feature in a polymer body. Alternatively, the stiffening elements may be a separate component, such as a metal strip, that is attached to or formed within the insert body **73**. Adding stiffening elements **73** within certain radial-longitudinal planes can limit or prevent bending in that plane, relative to other

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 729 of 2152

radial-longitudinal planes without the stiffening elements. In lieu of stiffening elements, it is contemplated that the insert body **68** can present a non-cylindrical form and even a non-uniform cross-section to adjust bending properties in different radial-longitudinal planes.

Returning to **FIG. 7**, a further aspect of the present embodiment is depicted in which a tensioning element **60** is associated with the bone anchor **50**. In the specific embodiment, the tensioning element **60** is a cable that extends through a cable bore **64** defined through each of the portions of the bone anchor. The cable **60** terminates at its distal end in a retention member **62** that is configured to prevent its passage through the bore **64**. In a specific embodiment, the retention member is in the form of an enlarged head or a ball that bears against the distal tip of the engagement portion **52**. Alternatively, the retention member and engagement portion can be configured so that the retention member is buried within the bone anchor **50**.

As shown in **FIG. 7**, the tensioning cable **60** extends through each of the engagement portion **52**, flexible portion **58** and head portion **56**, exiting the anchor at the proximal end of the head portion. The cable **60** is used to pull the three components together and hold them in compression. Consequently, a cable fixation feature **66** is provided that maintains the cable in tension and the bone anchor components in compression. In a preferred embodiment, the cable fixation feature is a crimp that is crimped around the cable and that bears against the proximal face of the head portion **56**. One type of crimp suitable for the present invention, known as a top-hat crimp, is shown and described in U.S. Patent No. 5,312,410 to Miller et al. The '410, the disclosure of which is incorporated herein by reference, also describes a tensioning apparatus that can be used to draw the cable **60** into tension.

Other forms of cable fixation feature other than the crimp **66** are contemplated by the present invention. The selection of fixation feature is generally contingent on the type of stabilization member **25** to which the bone anchor **50** is engaged. The bone anchor configuration shown in **FIG. 7** is

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 730 of 2152

particularly suited for use with a spinal plate, such as the plate **28** shown in **FIG. 5**. A bone bolt configuration, such as the anchor **78** shown in **FIG. 9** can also implement the flexible portion **58** and tensioning cable **60** just described. The anchor **78** is similar to the bone bolt configuration **38** shown in **FIG. 6b**.

A stabilization system is shown in **FIG. 9** that utilizes two spinal plates **28** adjacent each pedicle of the vertebra **V**. A bone anchor **50** is anchored in each pedicle and is engaged to a corresponding spinal plate **28**. A crimp, such as the crimp fixation feature **66** shown in **FIG. 7**, is used to complete the compression assembly of each bone anchor **50**. Alternatively, as depicted in **FIG. 9**, the two cables **60** from the two anchors **50** can be fastened together, such as by a cable twist **76**. Alternatively, an interlocking configuration using a cable loop and top-hat crimp can be utilized, in a manner similar to that depicted in the '410 Patent discussed above.

Other cable arrangements may be used with the present invention. For instance, the cable **60** can be wrapped and fastened around a spinal rod, such as the rod **26** described above. For instance, the tensioning element **60** may include two cable portions extending upward through the cable bore **64**. The ends of the cable portions can be twisted or crimped together around a spinal, in the manner shown in U.S. Patent No. 5,242,446 to Steffee et al., the disclosure of which is incorporated herein by reference. With this type of cable arrangement, the head portion **56** may be modified to engage a spinal rod while also accommodating the twisted cable portions. Another exemplary cable arrangement for use with a spinal rod is shown in U.S. Patent No. 6,514,255 to Ferree, the disclosure of which is incorporated by reference.

In one aspect of the invention, the amount of flexibility accommodated by the flexible portion **58** may be modified by the amount of tension in the tensioning element **60**, or more particularly, the amount of compression between the components of the anchor **50**. In order to maintain the proper compression over the life of the stabilization implant, it is desirable that the cable be formed of a material that is not susceptible to stretching or loosening over time. Thus, in a

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 731 of 2152

preferred embodiment, the cable is formed of wound filament strands that are pre-stretched. The filaments can be formed from a variety of biocompatible materials, such as stainless steel or some form of polyester.

When the engagement portion **52** of the bone anchor **50** includes threads **54**, the bone anchor must provide some means for driving the anchor into bone. As explained above in connection with the bone anchor **10**, the head portion **56** can be configured for engagement with a known driving tool. However, the interposition of the flexible portion **58** can limit the ability to transmit torque between the head portion **56** and the bone engaging portion **52**. Where the flexible portion includes the insert body **68** and interlocking elements **70**, **72**, torque can be transmitted across the insert body.

In an alternative embodiment, the engagement portion **52** is provided with an internal driving feature at its proximal face **53**. Thus, the proximal face defines a hex recess to receive a hex driving tool. The tool can be used to drive the engagement portion **52** into the bone so that the proximal face **53** is generally flush with the bone surface. Some modification to a standard hex driving tool may be necessary to accept the tensioning cable **60** that extends upward through the cable bore **64**. Once the engagement portion **52** is within the vertebra, the flexible portion **58** and head portion **56** can be successively threaded onto the cable **60** and the cable tensioned and fixed to complete the assembly.

The tension element **60** can also take on the form of a flexible rod having a threaded proximal end that projects outside the head portion **56** when the construct is assembled. A nut is threaded down onto the threaded end of the flexible rod to draw the retention member **62** upward and to compress the portions of the bone anchor **50**. The proximal end of the flexible rod can be enlarged to increase the diameter of the threaded end for greater holding power.

A further embodiment of the invention resides in a bone anchor **80** shown in **FIG. 10**. This anchor includes an engagement portion **82** which, like the anchors **10** and **50** above, includes threads **82** or any other configuration suitable for engagement to the spine or a spinal motion segment. The anchor **80** also

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 732 of 2152

includes a head portion **86**, which includes a threaded post **88** as part of a bone bolt configuration similar to that shown in **FIG. 6b**. Again, like the prior embodiments the head portion **86** can take on a number of configurations depending upon the nature of the stabilization element.

In accordance with one feature of this embodiment, the anchor **80** is provided with a flexible portion **90** that has a reduced cross-section relative to at least the bone engagement portion **82**. Where the bone anchor is a cylindrical anchor, such as a bone bolt, the flexible portion **90** can have a diameter less than the diameter of the engagement portion. The reduced diameter of the flexible portion determines the amount of flexibility of the portion **90**. In addition, the overall dimension of the flexible portion affects the flexibility. For instance, in the specific embodiment shown in **FIG. 10**, the flexible portion **90** is elongated. In an alternative embodiment, the flexible portion can have a much more limited axial dimension, such as the circumferential groove configuration **94** shown in **FIG. 11**.

As with the bone anchor **50**, the flexible portion **90** can permit bending movement in all radial-longitudinal planes transverse to the longitudinal axis **L**. Alternatively, the flexible portion **90** has a modified cross-section – i.e., a cross-section that does not necessarily parallel the shape of the cross-section of the engagement portion **82**. The cross-section of the flexible portion may be altered to control the degree of stiffness in different radial-longitudinal planes. For instance, the flexible portion can be generally elliptical so that the width or thickness in one direction is equal to the width or diameter of the engagement portion in that direction, but the width perpendicular to that direction is less than the engagement portion diameter.

In this preferred embodiment, a sleeve **92** surrounds the flexible portion **90**. The sleeve is intended to prevent bone ingrowth into the reduced cross-section of the flexible portion. In specific embodiment, the sleeve **92** is formed by a polymer molded into the space surrounding the reduced cross-section portion. The surface of the molded sleeve may be tailored to conform to the outer profile of the anchor **80**. Alternatively, the sleeve may be a flexible washer that is

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 733 of 2152

pushed over the exposed head portion and flexible portion of the anchor when it is initially engaged to the motion segment. The sleeve **92** must be flexible enough so that its presence is generally transparent to the bending capabilities of the flexible portion **90**. As a further alternative, the sleeve **92** can be configured to add stiffness to the flexible portion **90** of the bone anchor. With this alternative, a common bone anchor design can be used for most dynamic stabilization constructs, with only the sleeve being changed depending upon the desired flexibility.

As mentioned above, fatigue resistance is an important characteristic for the bone anchor **80**. The strength of the anchor can be enhanced by the material, design and manufacturing approaches noted above. With the bone anchor **80** the flexion point falls within the reduced diameter portion **90**. The reduced diameter in this region can be expected to be more susceptible to fatigue than the remainder of the anchor. As discussed above, material selection for the anchor may impart sufficient fatigue resistance to the reduced diameter portion **90**.

Alternatively, the geometry of the reduced diameter portion may be altered to increase the fatigue limit of that portion of the anchor. In one alternative embodiment, the bone anchor **80** shown in **FIG. 10** can be modified in its transverse cross-section (i.e., the cross-section taken along line A-A of **FIG. 10** as viewed in the direction of the arrows). In particular, a modified bone anchor **80'** includes a shank **82'**, head portion **86'** and threaded post **88'** similar to the like components of the anchor **80**. Furthermore, the intermediate flexible portion **90'** has the same reduced profile as the portion **90** as viewed in **FIG. 10.** However, in this alternative embodiment, the portion **90'** has an increased dimension transverse to the reduced dimension. The portion **90'** is thinner in the plane that defines the flexion point CR_R for the anchor (i.e., the plane depicted in **FIG. 10**) and thicker in the transverse plane (i.e., the plane depicted in **FIG. 12**). The width or thickness of the portion **90'** in the transverse plane can be increased in proportion to the decrease in thickness in the flexion plane, so that the portion

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 734 of 2152

exhibits a width that extends outside the diameter of the shank **82'** or of the head portion **86'**. Since the flexible portion **90'** is situated outside the pedicle of the vertebra, it is not driven into the bone so the portion can assume a larger non-cylindrical dimension. This provides a secondary benefit of preventing inadvertent countersinking of the flexible portion within the pedicle during insertion.

Another embodiment of the invention resides in a bone anchor as shown in **FIGS. 13-15**. The bone anchor **100** includes a bone engaging portion **102**, a head portion **104** and an intermediate flexible portion **106**. The head portion can be configured as shown in U.S. Patent No. 5,261,912 to Frigg, the disclosure of which is incorporated herein by reference. In particular, the head portion **104** defines a rod receiving channel **108** for top loading of a spinal rod, such as the rod **26**. The base of the channel can include includes features **110** for holding the rod against translation. The channel **108** includes internal threads **112** that are configured to engage a clamping member **120** shown in **FIG. 15**. The clamping member **120** includes an externally threaded boss **122** that engages the internal threads **112** of the channel **108**. The boss **122** defines a surface **123** that bears against the rod within the channel **108** to clamp the rod against the holding features **110**. The clamping member **120** also includes an outer cap **124** that fits around the outside of the head portion **104** to close the clamp and to prevent outward flaring of the head portion when the clamping member is tightened onto the head portion. The clamping member **120** can include an internal feature **126** to engage a driving tool.

Returning to **FIGS. 13** and **14**, the bone anchor **110** includes an intermediate flexible portion **106** that serves the same function as the flexible portions described above. In this embodiment, the flexible portion includes a slot **106** that originates at the head portion **104** and extends longitudinally along the axis **L** of the anchor toward the engagement portion **102** of the anchor. The slot **107** is oriented perpendicular to the channel **108** so that the anchor provides flexibility in the plane that includes the rod **26** and the bone anchor **100**. As with

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 735 of 2152

the above described bone anchors of the present invention, the bone anchor **100** is engaged within a vertebra, and particularly the pedicle of the vertebra, with the flexible portion **106** outside the bone.

It is understood that the bone anchor **100** can include a head portion **104** configured to engage a spinal rod in a different manner, or to engage an elongated plate spanning a portion of the spine. For instance, any of the alternative configurations shown in **FIGS. 4a-4c** can be adapted to the bone anchor **100**. Moreover, the slot **107** may be modified to define a closed slot within the intermediate flexible portion **106** only. In other words, rather than originating at the top of the head portion, as shown in **FIG. 14**, the slot **107** can originate near, and preferably below, the base of the rod channel as represented by the dashed line **109** in **FIG. 14**.

With each of the embodiments of the present invention it is contemplated that each motion segment can be instrumented with a bone anchor having a flexibility tailored to that particular level. For instance, where the dynamic stabilization construct spans several vertebrae, only some of the motion segments may be amenable to use of the dynamic or soft stabilization. Some motion segments may require rigid stabilization, in which case a known rigid bone anchor can be employed if appropriate. Different flexibilities may be incorporated into bone anchors along the length of the spine, and even on opposite sides of the sagittal plane, bearing in mind that a principal goal of the construct is to restore normal loading patterns for the spine.

Certain embodiments of the invention are also well-suited to revision surgeries, where changes to the construct may be necessary months and even years after the initial implantation. Since the preferred construct maintains the flexible portion outside the vertebral bone, it can be accessible in a revision surgery to replace the flexible portion **58** of the bone anchor **50**, for instance.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 736 of 2152

The dynamic stabilization system of the present invention is well suited as an adjunct to a disc repair procedure. For instance, the intervertebral disc **D** (see **FIG. 3**) may require augmentation or replacement, depending upon the severity of the damage or disease to the disc. Where the disc is intact, it is important to maintain the loading pattern as normal as possible since this loading pattern helps hydrate the disc **D** and flush toxins from the disc.

Devices have been developed for replacement of the intervertebral disc. In some cases, the device is a mechanical device that is configured to mimic the mechanics of the disc motion. In more recent years, the nucleus pulposus of the intervertebral disc has been replaced with a polymer prosthesis that emulates the physical and chemical properties of the disc. In particular, these types of prostheses are intended to preserve or restore the movement and load response of the affected disc as close to the natural disc as possible. One such material is a hydrogel that has similar elastic properties to the natural nucleus pulposus and that shares a similar fluid transport mechanism to the natural disc. This material can be used to replace the entire nucleus pulposus, or to augment the existing nucleus where voids or other defects in the nucleus exist.

Even where the intervertebral disc has been replaced with a mechanical device, or where all or part of the nucleus pulposus has been replaced with a polymer prosthesis, restoration and maintenance of normal spinal segment motion is important. Consequently, it is contemplated that the dynamic stabilization system of the present invention, including bone anchors such as the anchors **10, 50, 80** and **100**, can be used in connection with disc/nucleus repair or replacement procedures.

Prior dynamic stabilization systems rely upon flexible elements spanning between transverse processes or laminae. One significant drawback of these types of systems is that they cannot be used for all types of spinal surgical procedures. For instance, in one procedure for the correction of scoliosis, a spinal rod, such as the rod **26** shown in **FIGS. 16a-b**, is bent to a contour **C** and engaged to each vertebra of the deformed spinal column. The rod **26** is then

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 737 of 2152

rotated about its axis in the direction **R** shown in **FIG. 16a** to de-rotate the spine. The resulting spine assumes the more normal configuration and curvature shown in **FIG. 17a-b** in which the lateral curvature has been corrected (**FIG. 17a**) and the normal lordosis and kyphosis has been restored to the spine in the A/P plane (**FIG. 17b**). In many cases, a second rod **26** can be added to the contra-lateral side of the spine to stabilize the construct.

The above mentioned prior dynamic stabilization systems cannot accomplish correction of scoliosis through rod de-rotation because they lack the force-transmission interface with the rotated rod. These prior systems are also unable to maintain a fixed relationship between adjacent vertebrae because the flexible segments span the vertebrae. On the other hand, the bone anchors **10**, **50**, **80** and **100** of the present invention are well-suited to this type of procedure because the anchors can be engaged to a spinal rod for the necessary force transmission. Moreover, the bone anchors of the present invention allow for different degrees of flexibility at each instrumented vertebral level. For instance, as depicted in **FIG. 16a**, the two vertebrae at the superior and inferior ends of the construct may incorporate the flexible bone anchors of the present invention, while the intermediate vertebrae can be instrumented with known rigid fasteners (and in some cases can be fused). Adding dynamic flexibility at the distal ends of long constructs, such as the construct depicted for correction of scoliosis, is believed to reduce the occurrence of "transition syndrome", a condition manifested by accelerated degeneration of the distal vertebrae. due to abnormal loading at distal segments in a rigid construct. The stress concentration present at the interface between the rigid fusion and the flexible natural segments is believed to accelerate the degeneration process. By adding flexible segments, with the ability to vary the stiffness of the segments as described above, the distribution of stress along the spine can be made more uniform.

The present invention offers a similar benefit to a reduction procedure, such as for correction of spondylolisthesis, as depicted in **FIG. 18**. Where a severe slip has occurred, such the slip of the L_5 vertebra shown in **FIG. 18**, one

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 738 of 2152

approach has been to pull the slipped vertebra up to a rigid stabilization member, such as the rod **26**. In this case, a bone anchor **130** is engaged to the flanking spinal elements, such as the L_4 vertebra and the sacrum **S**. Preferably, the anchor engaging the sacrum is a rigid fastener, while the anchors engaging one or both of the vertebrae can be one the bone anchors of the present invention. Since the bone anchors **10**, **50**, **80** and **100** allow force transmission through the anchor, the anchor engaged to the L_5 vertebra is pulled toward the rod **26** to reduce the slip at that vertebra. Again, the prior dynamic stabilization systems cannot accomplish this type of reduction.

For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the embodiments illustrated in the drawings and described in the following written specification. It is understood that no limitation to the scope of the invention is thereby intended. It is further understood that the present invention includes any alterations and modifications to the illustrated embodiments and includes further applications of the principles of the invention as would normally occur to one skilled in the art to which this invention pertains.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 739 of 2152

What is claimed is:

1. A bone anchor for use in the stabilization of motion segments of the spine, comprising:

an engagement portion configured for engagement within a spinal motion segment;

a head portion configured for engagement to a stabilization element outside the vertebral body; and

a flexible portion between said engagement portion and said head portion.

2. The bone anchor according to claim 1, wherein said engagement portion includes an elongated shank having bone engaging threads.

3. The bone anchor according to claim 2, wherein:

said elongated shank is sized for engagement within the pedicle of a vertebra; and

said flexible portion is arranged to reside substantially extra-pedicular when said bone anchor is engaged within the pedicle of a vertebra.

4. The bone anchor according to claim 1, wherein said head portion includes a threaded stem configured for threaded engagement with a nut.

5. The bone anchor according to claim 1, wherein said flexible portion includes an elongated body spanning between said engagement portion and said head portion, said elongated body defining at least one hinge element.

6. The bone anchor according to claim 5, wherein said at least one hinge element includes a slot defined in said elongated body having an axis substantially transverse to the longitudinal axis of said body.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 740 of 2152

7. The bone anchor according to claim 6, wherein said slot terminates within said elongated body with a bore substantially perpendicular to said axis of said slot.

8. The bone anchor according to claim 5, wherein said flexible portion includes at least two hinge elements arranged to permit flexing of said bone screw in a common plane.

9. The bone anchor according to claim 8, wherein said at least two hinge elements each include a slot defined in said elongated body having an axis substantially transverse to the longitudinal axis of said body.

10. The bone anchor according to claim 9, wherein said at least two hinge elements includes opposing pairs of hinges.

11. The bone anchor according to claim 1, wherein said flexible portion includes a helical spring disposed between said engagement portion and said head portion.

12. The bone anchor according to claim 1, wherein said flexible portion includes an elongated flexible element disposed between said engagement portion and said head portion.

13. The bone anchor according to claim 12, wherein said flexible element is a flexible sleeve.

14. The bone anchor according to claim 13, wherein said engagement portion includes an elongated shank, said elongated shank and said flexible sleeve have substantially equal outer diameters.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 741 of 2152

15. The bone anchor according to claim 13, wherein said elongated shank and said flexible sleeve are configured for interlocking engagement.

16. The bone anchor according to claim 12, further comprising a tension element anchored at one end to said engagement portion and at an opposite end to said head portion and extending through said flexible sleeve to clamp said sleeve between said head portion and said engagement portion.

17. The bone anchor according to claim 16, wherein said tension element is a cable.

18. The bone anchor according to claim 17, wherein:

said engagement portion includes an elongated shank that defines a longitudinal bore, opening at a proximal and an opposite distal end of said shank;

said flexible element defines a bore therethrough aligned with said longitudinal bore;

said head portion defines a bore therethrough aligned with said longitudinal bore; and

said cable is anchored to said shank at said distal end and extends through said longitudinal bore and said bores in said flexible element and said head portion.

19. The bone anchor according to claim 18, wherein said cable includes an enlarged head relative to the diameter of said longitudinal bore at said distal end of said shank.

20. The bone anchor according to claim 1, wherein:

said engagement portion includes an elongated shank;

at least said shank and said flexible portion are integral; and

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 742 of 2152

said flexible portion defines a cross-sectional area along the longitudinal axis of said shank that is substantially less than the cross-sectional area of said shank along the longitudinal axis.

21. The bone anchor according to claim 20, wherein said head portion is integral with said flexible portion.

22. The bone anchor according to claim 21, wherein said head portion defines a cross sectional area along the longitudinal axis of the shank and adjacent said flexible portion that is greater than the cross sectional area of said flexible portion.

23. The bone anchor according to claim 20, further comprising means surrounding said flexible portion for preventing bone overgrowth at said flexible portion.

24. The bone anchor according to claim 23, wherein said means surrounding said flexible portion includes a sleeve configured to conform to said flexible portion.

25. The bone anchor according to claim 1, wherein said flexible portion has a first dimension in a first plane passing through said bone anchor that is less than a dimension of said engagement portion in said first plane.

26. The bone anchor according to claim 25, wherein said flexible portion has a second dimension in a second plane substantially transverse to said first plane that is greater than said first dimension.

27. The bone anchor according to claim 26, wherein said second dimension of said flexible portion is greater than a dimension of said engagement portion in said second plane.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 743 of 2152

28. The bone anchor according to claim 1, wherein said flexible portion includes an elongated body spanning between said engagement portion and said head portion, said elongated body defining an elongated slot therethrough, said slot extending generally parallel to the longitudinal axis of said elongated body.

29. The bone anchor according to claim 28, wherein said elongated slot originates in said head portion and extends toward said engagement portion.

30. The bone anchor according to claim 28, wherein said head portion defines a channel for receiving an elongated spinal rod therethrough, said channel extending transverse to said elongated slot.

31. The bone anchor according to claim 30, wherein said head portion includes a clamping member configured to engage said head portion to clamp the spinal rod within said channel.

32. A dynamic spinal stabilization system comprising:

a stabilization element configured to span a length of the spine adjacent the vertebrae; and

at least two bone anchors including one bone anchor in accordance with claim 1 and at least one other anchor selected from the group including;

a bone anchor in accordance with claim 1;

a spinal hook having a hook portion configured to engage a portion of a vertebra and a head portion configured to engage the stabilization element; and

a substantially rigid bone screw having a threaded portion configured to engage a portion of a vertebra and a head portion configured to engage the stabilization element.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 744 of 2152

33. The dynamic stabilization system according to claim 32, wherein said stabilization element is an elongated plate defining at least two openings therethrough for receiving a corresponding one of said at least two bone anchors.

34. The dynamic stabilization system according to claim 33, wherein:

said head portion of said at least two bone anchors includes a substantially spherical surface; and

said elongated plate defines a substantially spherical recess at each of said at least two openings.

35. A dynamic stabilization apparatus for stabilization of motion segments of the spine comprising:

a stabilization element configured to span a length of the spine between at least two motion segments; and

at least two anchors, each of said anchors including a head portion configured for contacting said stabilization element and an engagement portion configured for engaging a motion segment, and at least one of said anchors including a flexible portion between said head portion and said engagement portion configured to permit relative movement between said head portion and said engagement portion.

36. A method for dynamic stabilization of motion segments of the spine comprising the steps of:

positioning a stabilization element adjacent the spine, the stabilization element configured to span a length of the spine between at least two motion segments;

engaging bone anchors to at least two motion segments; and

coupling the bone anchors to the stabilization element, with at least one of the bone anchor coupled to permit deflection of the bone anchor between the stabilization element and the motion segment.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 745 of 2152

37. The method for dynamic stabilization according to claim 36, further comprising the step of repairing or replacing all or part of the intervertebral disc between at least two motion segments.

38. The method for dynamic stabilization according to claim 37, wherein the step of repairing or replacing includes replacing all or part of the nucleus pulposus with a polymeric prosthesis having physical properties substantially similar to the physical properties of a natural nucleus pulposus.

38. A method for dynamic stabilization of motion segments of the spine comprising the steps of:

positioning a stabilization element adjacent the spine, the stabilization element configured to span a length of the spine between at least two motion segments;

engaging bone engaging anchors to at least two motion segments; and

coupling the bone engaging anchors to the stabilization element, with at least one of the bone engaging anchors configured to produce a center of rotation for the motion segment between the stabilization element and the normal anatomic center of rotation for the motion segment.

39. In a method for correction of scoliosis in which a contoured rod is engaged to at least a portion of the deformed spine and is rotated to de-rotate the spine in the transverse plane, the improvement of engaging at least one vertebrae at either or both the superior and inferior ends of the rod to the rod to provide a center of rotation for the at least one vertebra that is between the rod and the normal anatomic center of rotation for the vertebra.

40. In a method for correction of spondylolisthesis in which a slipped vertebra is pulled posteriorly to a stabilization element engaged to spinal elements adjacent the slipped vertebra, the improvement comprising engaging a bone anchor to the slipped vertebra that is configured to be pulled toward the

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 746 of 2152

stabilization element and that is configured to provide a center of rotation for the slipped vertebra that is between the stabilization element and the normal anatomic center of rotation for the vertebra.

41. A method for dynamic stabilization of a motion segment of the spine comprising the steps of:

introducing a device into an intervertebral space to at least partially maintain or restore the natural motion of the disc at the motion segment; and

coupling a dynamic stabilization system across the motion segment, the system including at least one bone anchor that permits natural motion of the disc by deforming a portion of the bone anchor.

42. The method for dynamic stabilization according to claim 41, wherein the device includes a device for replacing or augmenting the nucleus pulposus of the intervertebral disc.

43. The method for dynamic stabilization according to claim 42, wherein the step of introducing a device includes introducing a polymeric prosthesis to replace or augment the nucleus pulposus in which the polymeric prosthesis exhibits physical properties similar to the natural nucleus pulposus

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 747 of 2152

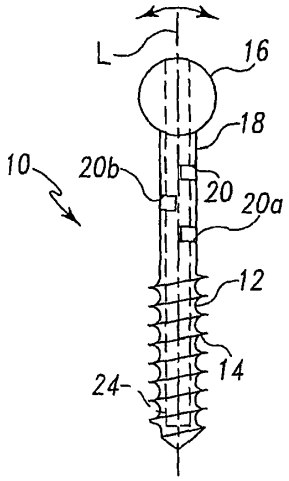


Fig. 1

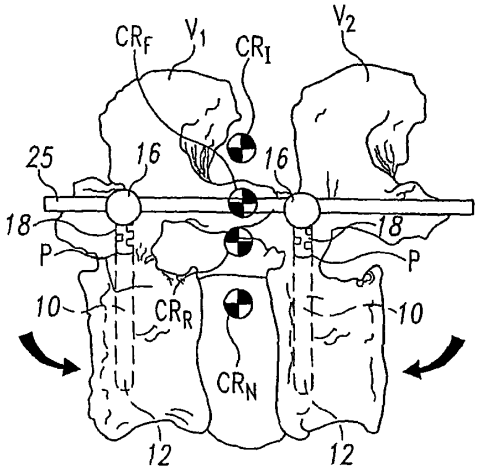


Fig. 3

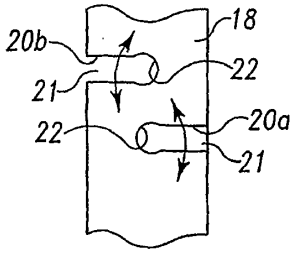


Fig. 2A

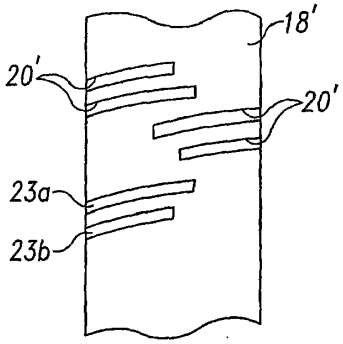


Fig. 2B

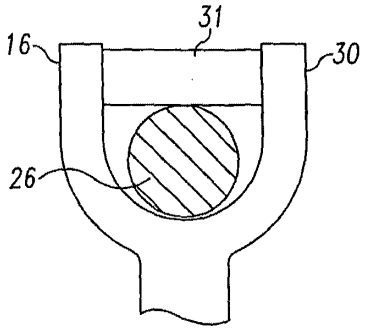


Fig. 4A

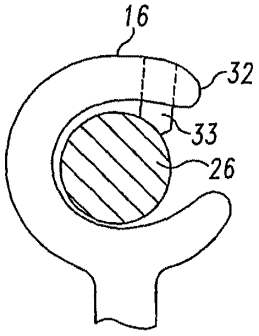


Fig. 4B

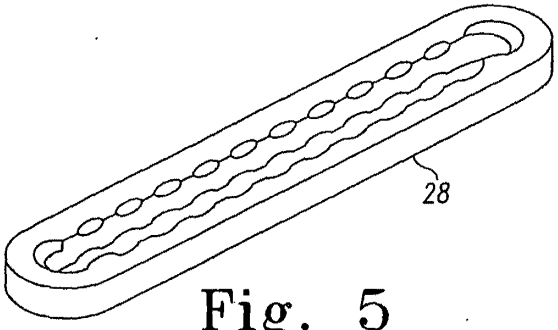


Fig. 5
(Prior Art)

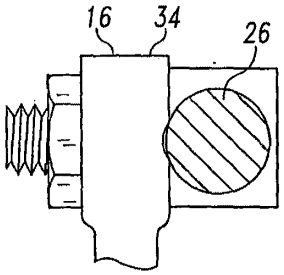


Fig. 4C

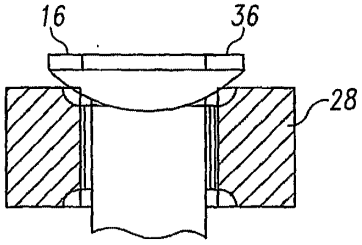


Fig. 6A

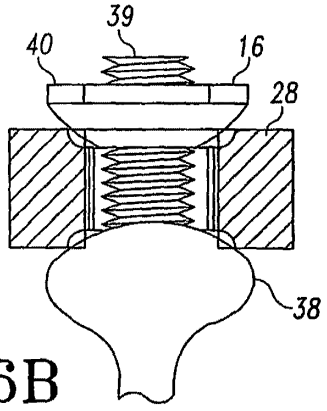


Fig. 6B

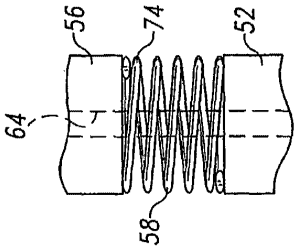


Fig. 8B

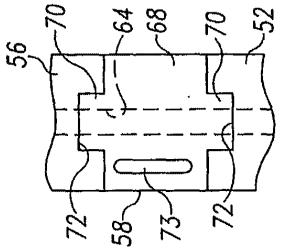


Fig. 8A

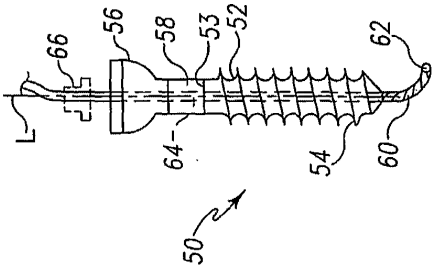


Fig. 7

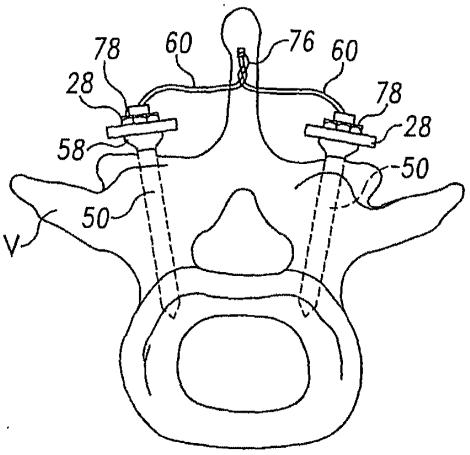


Fig. 9

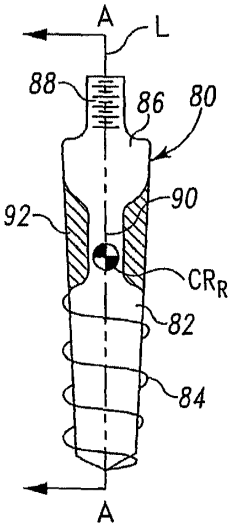


Fig. 10

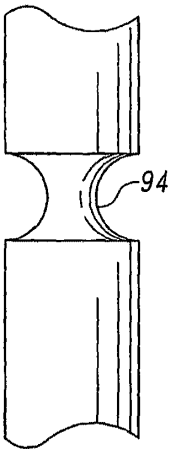


Fig. 11

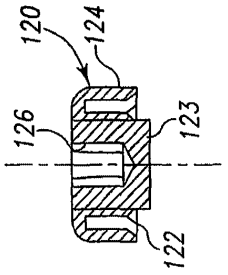


Fig. 15

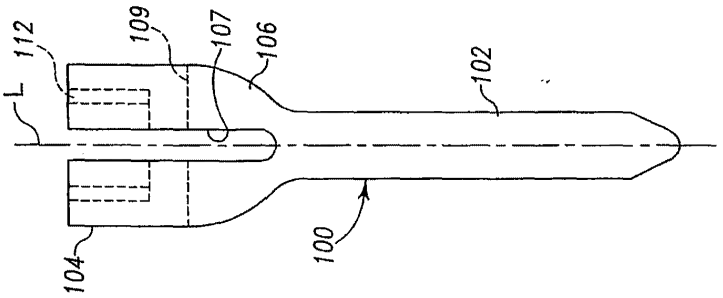


Fig. 14

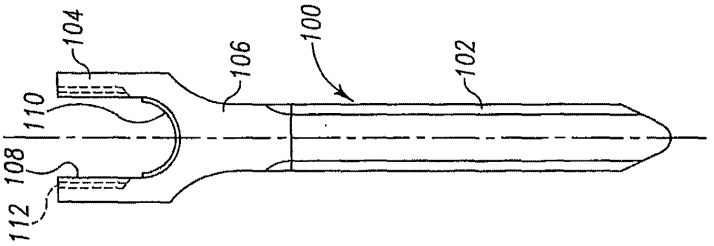


Fig. 13

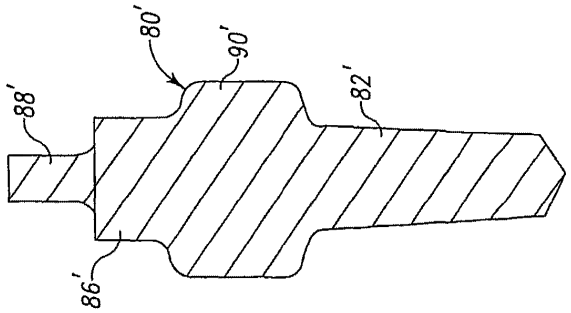


Fig. 12

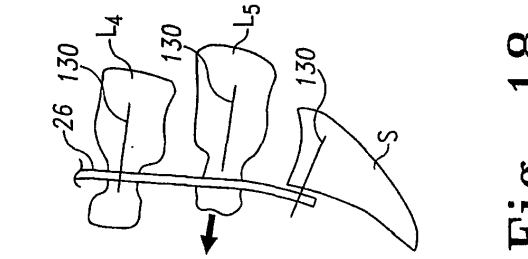


Fig. 18

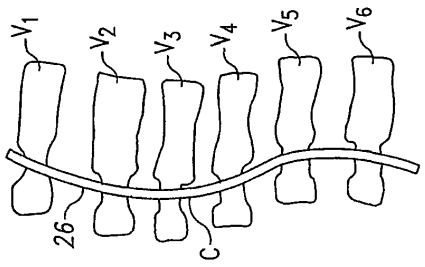


Fig. 17B

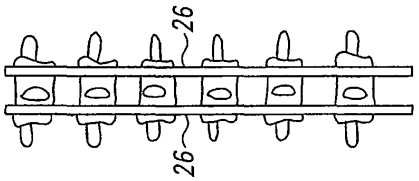


Fig. 17A

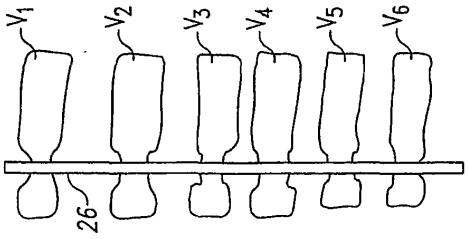


Fig. 16B

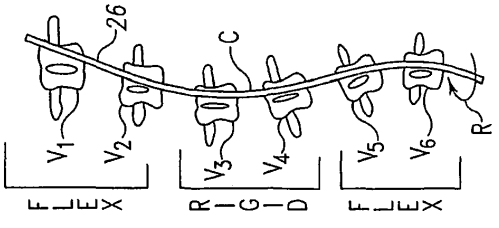


Fig. 16A

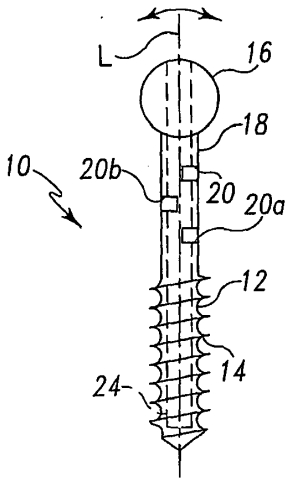


Fig. 1

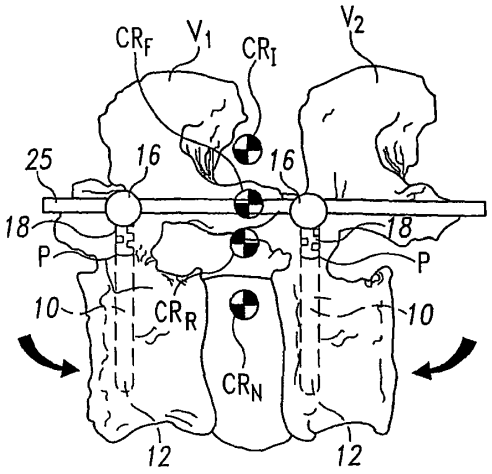


Fig. 3

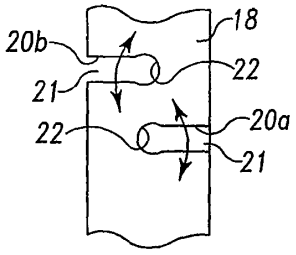


Fig. 2A

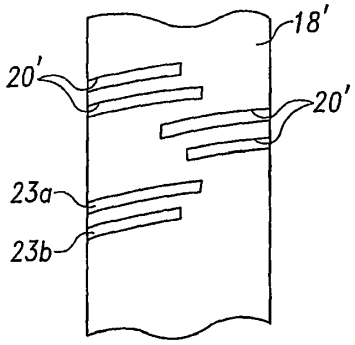


Fig. 2B

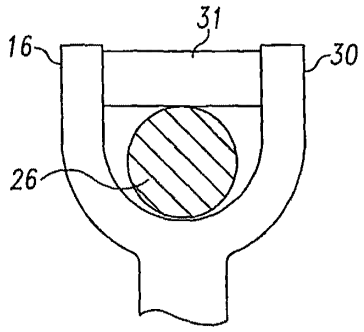


Fig. 4A

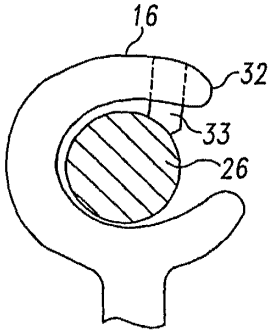


Fig. 4B

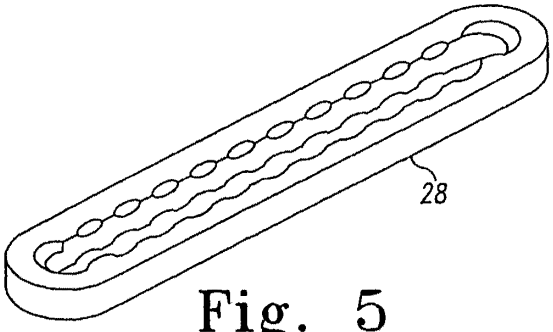


Fig. 5
(Prior Art)

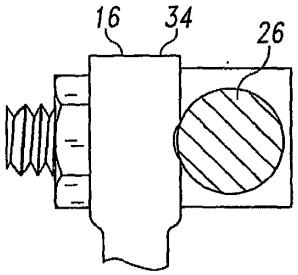


Fig. 4C

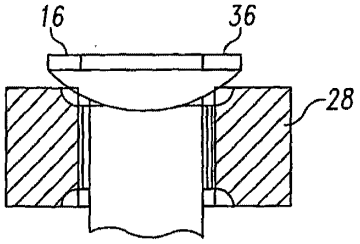


Fig. 6A

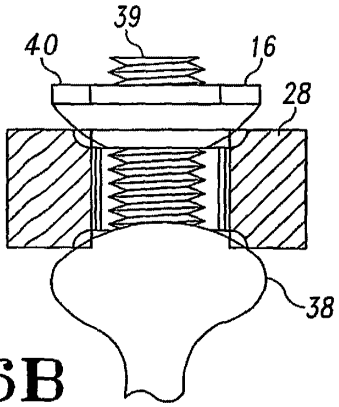


Fig. 6B

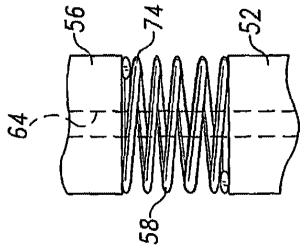


Fig. 8B

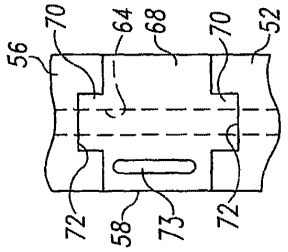


Fig. 8A

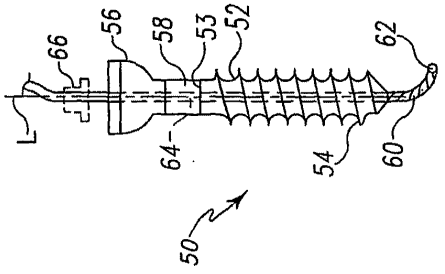


Fig. 7

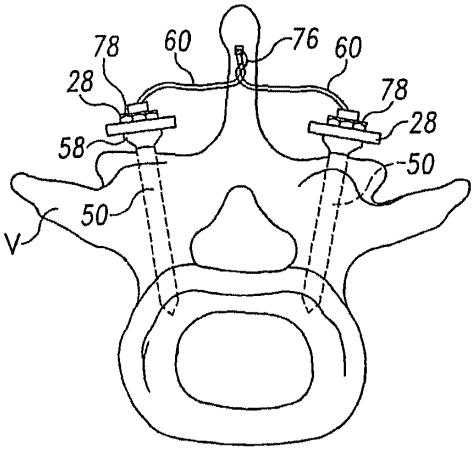


Fig. 9

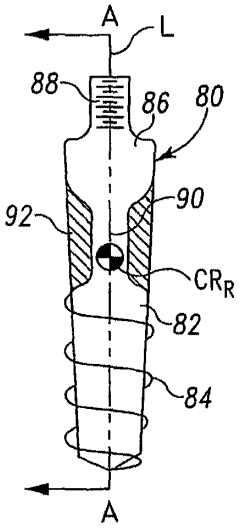


Fig. 10

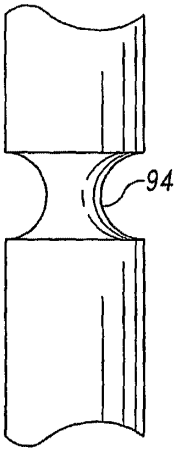


Fig. 11

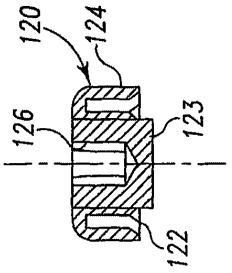


Fig. 15

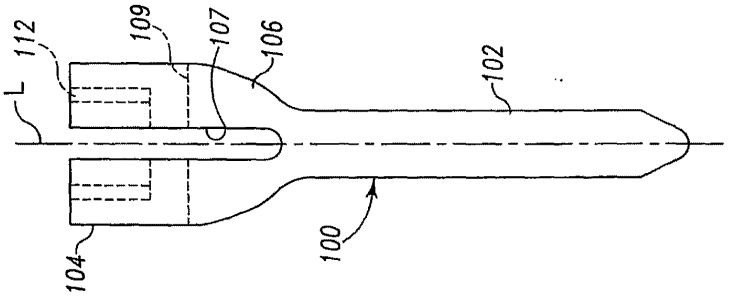


Fig. 14

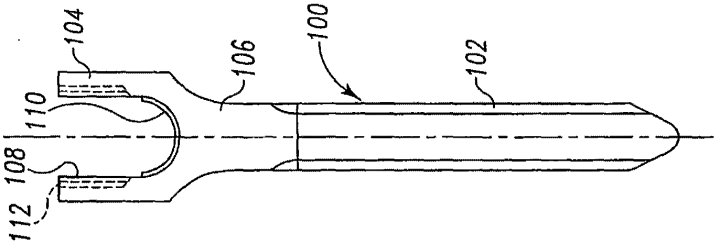


Fig. 13

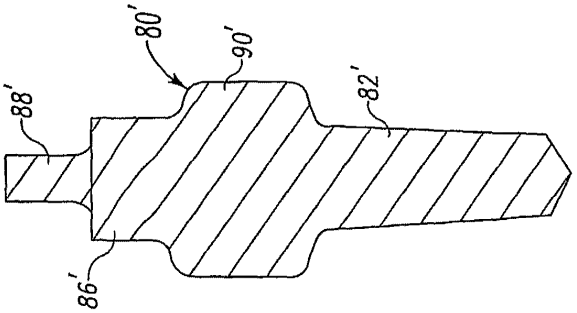


Fig. 12

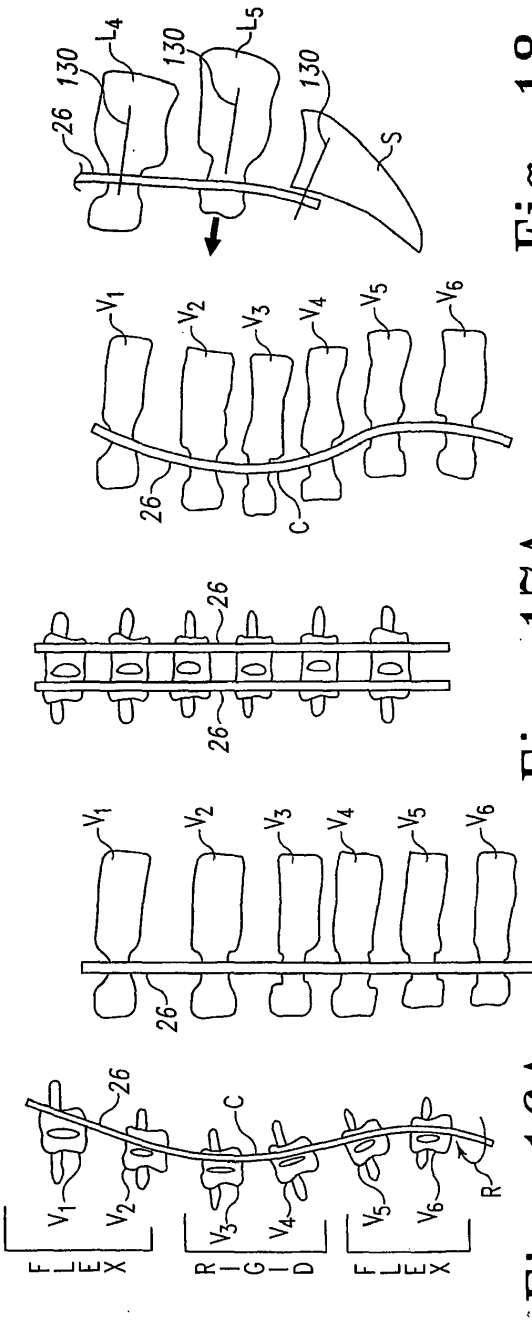


Fig. 18

Fig. 17B

Fig. 17A

Fig. 16B

Fig. 16A

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(71) Applicant *(for all designated States except US)*: **LDR MEDICAL** [FR/FR]; 2, rue Gustave Eiffel, F-10430 Rosieres Pres Troyes (FR).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **RENAUD, Christian** [FR/FR]; Chemin Lucien Calmels, F-81160 Arthes (FR). **CASTERA, Gérard** [FR/FR]; Route de la Césarde, F-13480 Cabries (FR).

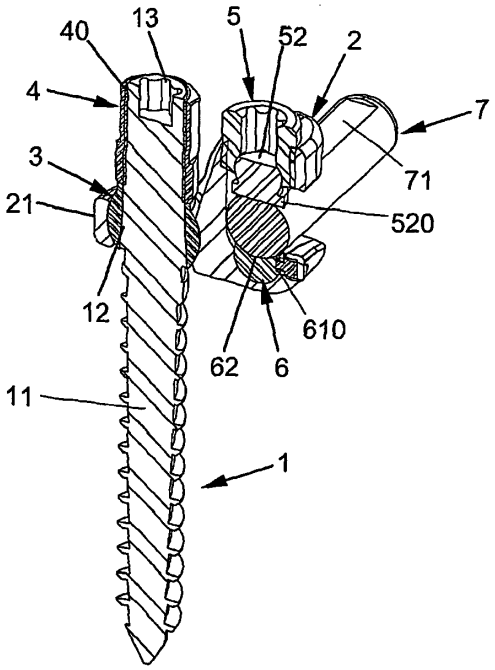
(74) Agent: **DEBAY, Yves**; Cabinet Debay, 126, Elysée 2, F-78170 La Celle St Cloud (FR).

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

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[Continued on next page]

(54) Title: OSSEOUS ANCHORING IMPLANT WITH A POLYAXIAL HEAD AND METHOD FOR INSTALLING THE IMPLANT



(57) Abstract: The present invention relates to an osseous anchoring implant comprising osseous anchoring means (11) and a head (2) bearing fixation means capable of receiving and fixing at least one bar, the head (2) of the implant being traversed by at least one duct (20), which receives the bar through a lateral aperture (23), and by a threaded channel (22), whose axis is not parallel to the axis of the duct (20), which receives a fixation screw (5) of the bar, the implant being characterised in that it comprises fixation means of the head (2) on the part (10) of the implant which extends from the osseous anchoring means (11), these fixation means allowing, prior to blocking and fixing, at least a determined mobility of the head (2) around at least one axis not parallel to the axis of symmetry (Al) of the osseous anchoring means (11) . The fixation screw (5) of the bar comprises a ball and socket (52) at its base, allowing a determined mobility of the bar.

WO 2005/020829 A1

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 760 of 2152

ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report*

— *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.

Osseous anchoring implant with a polyaxial head and method for installing the implant

The present invention relates to an implant providing osseous anchorage in a vertebra, for example to anchor an osteosynthesis device. This implant has a polyaxial head allowing to receive, in a plurality of angular positions, a bar linking several implants. The present invention also relates to a method for installing the implant, in particular to perform a reduction of a spondylolistesis (i.e., a jutting out of a vertebra with respect to the adjacent vertebrae).

It is known, in the prior art, to fix a plurality of implants, each to a vertebra, and to connect them together with a bar or a plate, fixed to each implant, along the vertebral column, so as to maintain or correct the rachis. These implants are generally fixed to the vertebrae, either via screwing of a threaded part of the implant in a vertebra, or by fixing of a hook of the implant onto a vertebra. The implants known to the prior art are equipped with a fixation channel, at the head, allowing to fix the bar or plate into a duct. Sometimes, a lateral aperture allows introducing the bar via the side of the duct.

The international patent application WO 03/049629 shows an implant with polyaxial head allowing to orient the bar in different positions before fixing it, these positions being restricted by a determined clearance of the bar around the axis of the implant and/or around the axis of the duct, thanks to a ball and socket connection. This polyaxial system allows to simplify the positioning of the bar and to reduce the constraints exercised by the implant on the bar, but offers a limited number of levels of movement (i.e., a limited freedom of motion of the various elements of the implant with respect to each other).

On the other hand, the implants known in the prior art generally allow to completely reduce a spondylolistesis of the rachis but do not allow to partially reduce it, a spondylolistesis reduction consisting in a repositioning of

the vertebra in the axis of the adjacent vertebrae in the vertebral column. Yet, in some cases, it is necessary to only partially reduce a spondylolistesis or to control, during implantation, the reduction level of the spondylolistesis.

The international patent application WO 00/15125 mentions that an implant with polyaxial head allowing to orient the bar in different positions before fixing it. However, the different embodiments of this implant in the prior art have the inconveniences, when the bar is inserted into its duct, of either not offering all the possible levels of movement, or of not allowing to continue to screw the implant into the vertebrae.

The object of the present invention is to overcome these inconveniences in the prior art by proposing an implant for osseous anchoring allowing to restrict the constraints exercised on the rachis during a correcting of the latter and to control the reduction level of a spondylolistesis.

This object is reached through an implant of osseous anchoring comprising a body equipped with osseous anchoring means and a head bearing fixation means capable of receiving and fixing at least one bar, in particular of osteosynthesis, the head of the implant being traversed by at least one duct receiving the bar through a lateral aperture and by a threaded channel having an axis not parallel to the axis of the duct and receiving a fixation screw of the bar, the implant being characterised in that it comprises fixation means of the head on a part of the body of the implant extending along the osseous anchoring means, these fixation means of the head consisting in a portion of the head which forms a ring into which is inserted a fixation olive threaded onto the part of the body of the implant extending along the osseous anchoring means and allowing, prior to blocking and fixing, at least a determined clearance of the head around at least one axis not parallel to the axis of symmetry of the osseous anchoring means, and in that the fixation screw of the bar comprises a ball and socket at its base allowing at least a determined clearance of the bar around at least one axis parallel to the duct axis, the fixation means of the head and the ball and socket of the fixation screw of the bar allowing a determined clearance of the

head around the axis of symmetry of the osseous anchoring means, even when the bar is inserted into the duct.

According to another feature, the inside diameter of the ends of the duct of the head is greater than the inside diameter of the centre of the duct, which confers a widened out profile to the duct allowing, in association with the ball and socket at the base of the fixation screw, a determined clearance of the bar around the axis of the duct.

According to another feature, the head is equipped with a ring, which is placed on the other side of the head in relation to the duct, and in that the part of the implant extending along the osseous anchoring means, which is threaded through a fixation olive, itself threaded through a ring, is cylindrical and threaded and extends, widening out from the cylindrical part towards the anchoring means, by a tapered part, complementary of a tapered internal surface of the fixation olive which is sectioned at a point along its entire height.

According to another feature, the external surface of the fixation olive is convex and complementary of a concave internal surface of the ring, the external diameter of the olive being slightly less than the internal diameter of the ring, so that the olive, compression inserted into the ring thanks to the section of the olive along its entire height, allows a retaining of the head on the olive, whilst allowing the orientation and the determined clearance of the head around at least one axis parallel to the axis of symmetry of the osseous anchoring means.

According to another feature, a nut has, along its entire height, a threaded drilling intended to be screwed to the cylindrical part of the implant which is threaded so as to initially provoke, either the rise of the body of the implant up to the bar, or the descending of the olive and the head onto the body of the implant, according to the relative positions of the head, the olive and the body in relation to the bar, then secondly, the leaning of the olive on the tapered part of the implant, which engenders the expansion of the fixation olive, and thus the blocking of the head in the desired position.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 764 of 2152

According to another feature, the nut is equipped with flats capable of co-operating with a tool adapted to the screwing of the nut to the threaded cylindrical part of the implant.

According to another feature, the osseous anchoring means are a hook.

According to another feature, the osseous anchoring means are a threaded part.

According to another feature, the cylindrical part of the body of the implant is equipped, at its end opposite the osseous anchoring means, with a blind hole with six faces capable of co-operating with a tool adapted to the screwing of the implant.

According to another feature, the ball and socket of the fixation screw of the bar comprises a flat at its base.

According to another feature, the flat at the base of the ball and socket of the fixation screw of the bar consists in a disc prominent at the periphery of the ball and can be used as a stop limiting the movement of the ball in relation to the fixation screw of the bar.

According to another feature, the ball and socket at the base of the fixation screw of the bar is associated with a mobile base located between the bar and the duct in a housing in the duct, this base facilitating, prior to blocking and fixing of the bar, the determined clearance of the bar around at least one axis parallel to the axis of the duct.

According to another feature, the mobile base has formal irregularities co-operating with formal irregularities of the duct, so as to restrict the movement of the base in its housing and therefore restrict the clearance of the bar around the axis parallel to the axis of the duct.

Another object of the invention is to propose a method for installing the implant according to the invention.

This object is reached via a method for preparing out with the body prior to the implanting of an osseous anchoring implant comprising a threaded part extended by a smooth tapered part itself extended by a threaded cylindrical part, said cylindrical part being threaded through a

fixation olive itself threaded in a head equipped with a duct receiving an osteosynthesis bar by a lateral aperture and with a channel receiving a fixation screw provided with a ball and socket at its base, the fixation olive and the head being retained by a nut screwed to the cylindrical part, the ball and socket being provided, at its base, with a flat consisting in a disc which is prominent at the periphery of the base of the ball and can thus be used as a stop limiting the rotation of the ball in relation to the fixation screw, the method being characterised in that it comprises at least the following successive steps:

- the insertion of the bar, via the lateral aperture, into the duct in which it is at least retained via a partial screwing of a fixation screw;

- the positioning of the flat at the base of the ball as a stop in the duct, on its internal surface opposite to the lateral aperture, in order to prevent a rotation of the bar in the duct, thanks to the contact of this flat of the ball with a flat on the bar and, consequently prevent, the descending of the head in relation to the bar;

- the partial screwing of the nut on the cylindrical part of the implant, so that the nut comes into contact with the fixation olive, so as to prevent a disengagement of the fixation olive and the head from the cylindrical part of the implant, whilst allowing the movement of the head of the implant around at least the axis of symmetry of the osseous anchoring means, in the expectation of the screwing of the osseous anchoring means which will provoke the rise of the body and the vertebra, followed by the screwing of the nut, which will end the rise of the body and the vertebra and will then block the head and the body in the desired position.

According to another feature, the method comprises at least the following successive steps:

- the insertion of the bar, via the lateral aperture, into the duct in which it is at least retained via a partial screwing of a fixation screw;

- the positioning of the flat at the base of the ball as a stop in the duct, on its internal surface opposite to the lateral aperture, in order to prevent a

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 766 of 2152

rotation of the bar in the duct, thanks to the contact of this flat of the ball with a flat on the bar and, consequently prevent, the descending of the head in relation to the bar;

- the partial screwing of the nut on the cylindrical part of the implant, so that the nut comes into contact with the fixation olive, so as to retain the vertical position of the cylindrical part of the implant, in relation to the head, whilst allowing the movement of the head of the implant around at least the axis of symmetry of the osseous anchoring means, in the expectation of the complete screwing of the nut which will provoke the rise of the body and the vertebra and will then block the head and the body in the desired position.

According to another feature, the steps of the partial screwing of the fixation screw and the positioning of the flat at the base of the ball as a stop in the duct, on its internal surface opposite to the lateral aperture, can be replaced by a step of a complete screwing of the fixation screw, so as to prevent any movement of the ball and the bar and, consequently, prevent the descending of the head in relation to the bar.

Other features and advantages of the present invention will be clearer upon reading the description thereafter with reference to the annexed drawings, wherein:

- figure 1 represents a blown-up perspective view of the osseous anchoring implant according to a first embodiment of the invention;

- figure 2 represents a side view of the osseous anchoring implant according to the embodiment of figure 1;

- figure 3 represents a blown-up perspective view of the osseous anchoring implant according to another embodiment of the invention;

- figure 4 represents a side view of the osseous anchoring implant according to the embodiment of figure 3;

- figure 5a represents a perspective view of an embodiment of the head of the osseous anchoring implant with the section planes B-B and C-C of figures 5a and 5b, respectively, figure 5c also representing the fixation bar and the fixation screw equipped with a ball and socket connection at its base;

- figures 6a and 6b represent sectional views, respectively, according to the axis of the duct and according to an axis perpendicular to the axis of the duct, of the head of the osseous anchoring implant equipped with the fixation bar and the fixation screw equipped with a ball and socket connection at its base and associated with a mobile base.

The osseous anchoring implant according to the invention comprises four elements: a body (1), a head (2), a fixation olive (3) and a nut (4). The body (1) of the implant comprises, at its upper end, a cylindrical part (10) and, at its lower end, osseous anchoring means (11) for anchoring in a vertebra. The cylindrical part (10) is threaded on its external wall. The cylindrical part (10) and the anchoring means (11) are linked via a smooth tapered part (12), whose transversal section increases between the cylindrical part (10) and the anchoring means (11). The weakest section of the tapered part (12) is substantially equal to the transversal section of the cylindrical part (10). The cylindrical part (10), the tapered part (12) and the anchoring means (11) constituting the body (1) of the implant are placed according to a first axis (A_1).

The head (2) of the implant comprises a duct (20) allowing to receive a bar (7), which links several implants together within the context of an osteosynthesis device so as to retain, support or correct the rachis when the implants are screwed in vertebrae. The head (2) of the implant is called polyaxial as it has several levels of free movement, thanks to the fact that it is fixed to the body (1) by a ring (21) clamping a fixation olive (3) constituted of a ring with a tapered and smooth internal wall, complementary of the smooth tapered part (12) of the body (1) of the implant. The external wall of the olive (3) is convex and complementary of the internal surface of the fixation ring (21) of the head (2). This freedom of movement of the head (2), in relation to the body (1) of the implant, consists in a rotation or a combination of several rotations according to three axes substantially perpendicular to one another, particularly visible in figure 2 and passing through the geometric centre of the olive (3). The polyaxial head (2) thus has a determined clearance around at least one axis not parallel to the axis (A_1) of symmetry of the osseous

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 768 of 2152

anchoring means (11). This clearance is due to the fact that the head (2) is free in rotation around the axis (A_1) of the body (1), in rotation around the axis (A_2) of the head (2), substantially perpendicular to the axis (A_1) of the body (1) of the implant, and in rotation around the axis (A_5), substantially perpendicular to the axes (A_1) of the body (1) and (A_2) of the head and parallel to the axis (A_4) of the duct. This freedom of rotation of the head (2) around these axes (A_1, A_2 and A_5) allows a determined clearance of the head (2), in whatsoever direction, around osseous anchoring means notably constituted of the body (1) of the implant. This clearance allows the head (2), in the absence of the fixation bar (7), to follow a circular ring centred on the olive (3) and bearing a shape substantially identical to the external surface of the olive (3) and therefore take whatsoever position in this ring, in relation to the olive (3). The head (2) is equipped with a lateral aperture (23) allowing to introduce the bar via the side of the duct (20). The head (2) also comprises a channel (22) of axis (A_3), not parallel (for example substantially perpendicular) to the axis of the duct (20). This channel (22) is threaded so as to receive a fixation screw (5) of the bar (7). The head (2) is also equipped, on the other side of the latter in relation to the duct (20), of a ring (21) whose internal surface is concave, smooth and complementary of the convex and smooth external wall of the fixation olive (3). In relation to the bar (7), the internal surface of the duct (20) is sufficiently large to allow some clearance of the bar (7) in the duct (20).

According to an embodiment of the invention, the fixation screw (5) of the bar bears, at its end located on the side of the bar (7), a mobile and articulated element, called ball and socket (52), as that described in the international patent application WO 03/049629 filed by the applicant. The ball and socket (52) consists in a sphere portion (the ball) inserted into a housing (the socket) in the lower end of the fixation screw (5) whose shape is complementary of the sphere portion of the ball and socket (52). This complementary nature of the shape ensures a ball and socket connection between the fixation screw (5) and the bar (7). The ball (52) can have a flat (520) at its base. The bar (7) can also have a flat (71), complementary of the

flat (520) at the base of the ball (52), so as to allow a better fixing of the bar (7) when screwing the fixation screw (5) of the bar. This mobile link authorises some clearance of the ball (52) in relation to the fixation screw (5), in rotation around the centre of this ball and socket (52). This ball and socket connection also allows the flat (71) of the bar (7) to remain in contact with the flat (520) of the ball and socket (52) without slippage, which avoids deteriorating the surfaces in contact, renders the blocking more reliable, and reduces the risks of residual stress. In addition, the flat (520) of the ball (52) can consist, as represented on figures 5b, 6a and 6b, in a disc (520) prominent at the periphery of the base of the ball (52). The fact that this disc (520) is prominent at the periphery of the base of the ball (52) and thus protruding in the duct (20) makes it possible to use it as a stop limiting the rotation of the ball (52) in its socket (thus limiting the rotation of the ball in relation to the fixation screw). For instance, the disc (520) can be placed as a stop in the internal surface of the duct (20), on the side opposite to the one where the lateral aperture (23) is. This placement of the disc (520) as a stop prevents the rotation of the bar (7) around the axis (A_4) of the duct (20), thanks to the contact between the disc (520) of the flat at the base of the ball (52) and the flat (71) of the bar (7). The corresponding rotation of the head (2) around the axis (A_5) is thus also prevented and it prevents the descending of the head (2) in relation to the bar (7).The ball and socket connection (52) can be associated with a widening of the duct (20) whose ends have a diameter greater than that at the centre of the duct (20), as particularly visible in figure 5c. The bar (7) is thus fixed between the ball and socket (52) and the central part of the duct (20), but has a freedom of movement around its longitudinal axis (A_4). This freedom of movement can naturally consist in a rotation of the bar (7) around the axis (A_3) of the duct (22) and/or a rotation of the bar (7) around the axis (A_4) of the duct (20) and/or a rotation of the bar (7) around an axis parallel to the axis (A_2) and passing through the point of intersection between the axes (A_3) and (A_4). The ball and socket connection (52) at the base of the fixation screw (5) therefore allows a determined clearance of the bar (7) around at least one axis (A_4) parallel to the axis of

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 770 of 2152

the duct. This clearance allows the bar to follow a conical course with, for its summit, the point of intersection between the axes (A_3) and (A_4) (that meaning, for example, the centre of the duct) and bearing an acute angle at its summit.

In an alternative of the embodiment, the ball and socket (52) can be associated with a mobile base (6) placed between the bar (7) and the duct (20). The base (6) is mobile compared to the fixation head (2) and has on its upper face, called support face (62), in contact with the bar (7), a shape complementary of the external surface of this bar (7), for example in the form of a cylinder portion, which provides a good contact surface when tightening the fixation screw (5) of the bar. This mobile base (6) has a part (61) in the shape of a sphere portion, leaning via a complementary contact in a housing formed in the wall of the duct (20). By virtue of this spherical contact, the mobile base (6) has some freedom of rotation around the centre of its spherical part (61). On its part (61) in form of a sphere portion the mobile base (6) can have one or a plurality of irregularities (610) in its shape co-operating with one or a plurality of irregularities in the shape of its housing in the duct (20) of the fixation head (2), so as to form a stop limiting the clearance in rotation of the mobile base. These irregularities (610) can be, for example, a pin protruding from the mobile base and co-operating with a larger dimensioned cavity formed on the complementary contact surface. On the contrary, the pin can be in the head (2), at the housing in the duct (20), and protruding into this housing so as to co-operate with a larger dimensioned cavity in the base (6), as for example the pin formed by the screw shown in figure 6b, fixed in the head (2), at the housing in the duct (20). This stop, for example, allows avoiding excessive turning of the mobile base (6) and assuring that it properly presents its support facing the bar (7). Just as when the ball and socket (52) is associated with a widening of the duct (20), the bar (7), clamped between the ball and socket (52) and the mobile base (6), has a freedom of movement around its longitudinal axis (A_4), in any direction, for example by a combination of rotations around the axes described for the above alternative of the embodiment. The embodiment

alternative including the mobile base (6) additionally allows that this freedom of movement is restricted thanks to the irregularities (610) co-operating with the irregularity (or irregularities) of the housing in the duct (20) of the head (2).

Thus, it can be understood that the bar (7) can be inserted and blocked in different angular positions inside the duct (20), while providing a flat contact surface both with the fixation screw, possibly including the ball and socket (52) and with a part of the wall of the widened out duct (20) or with the support face (62) of the mobile base (6). It can also be understood that the invention has the advantage of providing different elements of the implant with a complete freedom of movement in relation to one another. Indeed, the head (2) has, as previously indicated, a freedom of movement around the centre of the olive (3) and the bar (7) has a freedom of movement around, for example, the centre of the duct (20), thanks to angular clearances by rotation around the axes represented in figure 2. Thus, all the possible levels of freedom are reached for the position of the head (2) in relation to the body (1) of the implant and for the bar (7) in relation to the duct (20) of the head (2). The combination of these levels of freedom of the head and of the bar provide the implant of the present invention with the advantage of allowing a clearance, in every direction, of the bar (7) in relation to the body (1) of the implant. In particular, even when the bar (7) is inserted into the duct (20) of the head (2), the position of the bar (7) can be adjusted, for example, thanks to a rotation of the head around the axis (A_1) of the body of the implant and a rotation of the bar substantially around the axis (A_3) of the channel (22) of the fixation screw. These possible rotations are particularly interesting for the reduction of a spondylolistesis, because the natural movement of a vertebra during this reduction is substantially circular. It is thus of particular interest to provide the implant with a freedom of movement during the reduction. Only an implant as the present invention, combining a polyaxial head (2) with a ball and socket (52), allows this freedom of movement facilitating the reduction of the spondylolistesis. Even when the bar (7) is inserted into the duct (20), the invention allows for a determined

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 772 of 2152

clearance of the head (2) around the axis of symmetry (A_1) of the osseous anchoring means. This clearance allows the head (2) to follow a conical course, if the bar (7) inserted into the duct (20) is not fixed, a cone whose base has a perimeter in the shape of a disc or ellipse, whose summit is located at the centre of the olive (3) and which has an acute angle at its summit. The different angular clearances allow to insert the bar (7) into the head (2) with greater ease and to obtain a tightening of the bar in its most natural position in relation to the implants, which reduces or cancels out the stresses that could remain in the device after tightening. Moreover, the tightening efforts converge in this way directly to the blocking without having to conflict with the rigidity of the bar, and the reliability of the blocking is therefore improved. The bar is fixed to the head (2) via screwing of the fixation screw (5) in the channel (22) once the bar is in the desired position. The fixation olive (3) is constituted of a ring with a tapered and smooth internal wall, complementary of the smooth tapered part (12) of the body (1) of the implant. The external wall of the olive (3) is convex and complementary of the internal surface of the fixation ring (21) of the head (2). The olive (3) is sectioned at a point (30) of the ring, along the entire height of the latter. The minimum diameter of the tapered internal wall of the ring is slightly greater than the external diameter of the cylindrical part (10) of the body of the implant, so that the cylindrical part (10) of the body (1) of the implant can be threaded into the olive. The olive (3) is inserted into the fixation ring (21) of the head (2) by applying pressure to the olive (3) which compresses thanks to the section made along its height, to allow its insertion into the ring (21), then by releasing the pressure on the olive (3) so as to allow it to dilate in the ring (21). The positioning and the retaining of the olive (3) in the ring (21) is thus done automatically thanks to the complementary nature between its convex external wall of the olive (3) and the concave internal surface of the ring (21) and thanks to the fact that the olive has an external diameter slightly smaller than the internal diameter of the ring.

The nut (4) comprises at its centre, and along its height, a threaded cylindrical drilling (40), of internal diameter substantially equal to the external

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 773 of 2152

diameter of the cylindrical part (10) of the body (1) of the implant. The nut (4) comprises on its external wall a plurality of flats (41) allowing to screw the nut (4) to the cylindrical part (10) of the body of the implant using an adapted tool, for example a monkey wrench.

In a first embodiment represented in figures 1 and 2, the anchoring means (11) of the body (1) of the implant are an extended part comprising a thread, which is intended to be screwed into the osseous matter, for example at the pedicle or the body of a vertebra, or in the sacrum. To facilitate the installing of the body (1) of the implant, the upper part of the cylindrical part (10) of the body (1) of the implant is fitted with a blind hole (13) with six faces, which is of a complementary nature of a known screwing tool of the implant. It is to be noted that thanks to the drilling (40) performed along the entire height of the nut (4), this blind hole (13) remains accessible for screwing of the osseous anchoring means (11), even when the nut (4) is inserted on the cylindrical part (10) of the body (1) of the implant.

In a second embodiment represented in figures 3 and 4, the anchoring means (11) of the body (1) of the implant are a hook, intended to be hooked onto a formal irregularity of the osseous element, such as a pedicle, a blade or a vertebrae transversal apophysis.

As aforementioned, the fixation olive (3) is inserted into the ring (21) of the head (2) and stays automatically retained there thanks to the complementary nature between the shape of the convex external surface of the olive (3) and the concave internal surface of the ring (21). The fixation olive (3) and the head (2) are threaded to the cylindrical part (10) of the body (1) of the implant, as far as the tapered part (12) of the body, complementary of the tapered internal surface of the olive (3). The nut (4) is partially screwed onto the cylindrical part (10) of the body (1) of the implant, so as to retain the head (2) and the fixation olive (3) on the cylindrical part (10) of the body (1) of the implant, whilst maintaining their freedom of movement. Thus, the head (2) can be orientated in any given direction, thanks to its rotation around the aforementioned axes (A_1, A_2 et A_5). At this stage, the different elements of the implant do not need to be integrally retained between themselves as the

olive (3) automatically holds in the ring (21) and on the tapered part (12) of the body (1). The head (2) will therefore be spontaneously vertically stable compared to the body (1) of the implant, only its orientation, according to the different possible angular clearances, requires a screwing of the nut (4) in order to be stabilised. As aforementioned, the blind hole (13) with six faces, allowing the screwing of the body (1) of the implant, remains accessible even when the nut (4) is threaded onto the threaded part (10) of the body (1), the relative vertical stability of the unit made of the head and the olive on the body of the implant will allow to screw the body (1) of the implant driving the head and the olive. When the bar (7) is fixed, the screwing of the nut (4) on the threaded part (10) of the body (1) of the implant will allow, thanks to this relative stability of the head and the olive in relation to the body, either the rise (the ascension) of the body of the implant if the latter was too low compared to the bar (7), or the lowering of the olive and the head on the body if the first elements were too high compared to the latter and the bar (7). Then the screwing of the nut provokes the contact of the olive on the tapered part (12) of the body engendering the dilating of the olive and the blocking of the head according to the desired orientation.

The implant according to the invention is particularly useful for reducing the jutting out of a vertebra of the rachis compared to a first vertebra.

In a first embodiment of the method for installing the implant such as represented in figures 1 and 2, the body (1) of the implant, fitted with the fixation olive (3) the head (2) and the nut (4), is screwed into the jutting out vertebrae until the duct (20) arrives substantially at the same level as a bar (7) already fixed in another implant previously fixed to the first vertebrae. The bar (7) is then inserted into the duct (20) of the head (2) via the lateral aperture (23) and is retained in the duct (20) via a partial screwing of the fixation screw (5) in the channel (22) of the head (2). The disc (520) of the flat at the base of the ball (52) is placed at the contact of the flat (71) of the bar (7) and as a stop in internal surface of the duct (20) of the head (2), on the opposite side lateral aperture (23), so as to prevent the lowering (i.e.,

descending) of the head (2) in relation to the bar (7). Another possibility for preventing the descending of the head (2), via a rotation of the bar (7) around the axis (A_4) and an associated rotation of the head (2) around the axis (A_5), consists in a complete screwing of the fixation screw (5) which will then prevent any possible rotation of the ball (52) in its socket. Nevertheless, as aforementioned, the natural movement of a vertebra during the reduction of a spondylolistesis necessitate a freedom pf movement of the implant, particularly a freedom of rotation of the head (2) around the axis (A_1) of the body (1) and a freedom of rotation of the bar (7) around the axis (A_3) of the channel (22). It is thus better to prevent the lowering of the head (2) by placing the ball (52) as a stop in the duct (20), so as to allow the rotations of the head (2) and the bar (7) around their two other possible axis. The method continues with the partial screwing of the nut (4) on the cylindrical part (10) of the body (1) of the implant, so that it comes into contact with the fixation olive (3). In this manner, the vertical position of the head (2) is retained in relation to the body (1) of the implant whilst allowing the movement of the head (2) in relation to the body (1) of the implant, around the axes (A_1), (A_2) and (A_5). The head (2) and the fixation olive (3) can not be disengaged from the cylindrical part (10) of the body (1), even if a downward force is applied to the body (1). The method continues with the screwing of the body (1) of the implant in the jutting out vertebra, thanks to the blind hole (13) with six faces. The head (2) of the implant being substantially motionless in the vertical position compared to the bar (7), thanks to the disc (520) of the ball placed as a stop, the traction due to the screwing of the osseous anchoring means (11) of the body (1) engenders the correcting of the jutting out vertebra, thanks to the rise of the body (1) along its axis (A_1), whilst the olive (3) and the head (2) stay vertically stable in relation to the bar (7). The vertebra can now be returned to a level chosen by the person implementing the method, which is no more than the same as the first vertebra. The reduction of a spondylolistesis is generally more difficult at the end of its course than at the beginning. The screwing of the osseous anchoring means (11) coming with a reduction of the jutting out of a vertebra may thus become more and more

difficult while the jutting out is reduced. The reduction thus includes a risk of a tearing out of the osseous anchoring means (11) from the vertebra. Thus, at the end of the reduction, it is better to screw the nut (4) than the osseous anchoring means (11), in order to end the rise of the body (1) and the vertebra. Then, when the vertebra has been brought back to an appropriate level, the head (2) is fixed to the body (1) of the implant via complete screwing of the nut (4) on the cylindrical part (10) of the body of the implant, which engenders the pushing of the fixation olive (3) towards the tapered part (12) of the body (1) of the implant. Under this pressure, the fixation olive (3) undergoes an expansion when its tapered and smooth internal wall starts to come into contact with the tapered part (12) of the body (1) of the implant. The head (2), whose ring (21) clasps the fixation olive (3), is then blocked in the desired position, the internal diameter of the ring (21) being slightly greater than that of the fixation olive (3). If it has not already been, the bar is then fixed to the head (2) of the implant via complete screwing of the fixation screw (5) in the channel (22) of the head (2).

In a second embodiment of the method for installing the implant such as represented in figures 1 and 2, the body (1) of the implant fitted with the fixation olive (3), the head (2) and the nut (4), is screwed into the jutting out vertebrae until the duct (20) arrives substantially at the same level as a bar (7) already fixed in another implant previously fixed to the first vertebrae. The bar (7) is then inserted into the duct (20) of the head (2) via the lateral aperture (23) and is at least retained via screwing of the fixation screw (5) in the channel (22) of the head (2). As aforementioned, the disc (520) of the flat at the base of the ball (52) can be placed at the contact of the flat (71) of the bar (7) and as a stop in internal surface of the duct (20) of the head (2), on the opposite side lateral aperture (23), so as to prevent the lowering (i.e., the descending) of the head (2) in relation to the bar (7). This lowering can also be prevented by a complete screwing of the fixation screw (5), so as to block the ball and socket (52) and thus prevent the rotation of the bar (7) in the duct, because of the contact between the flat (71) of the bar (7) and the flat (520) of the ball (52). We then continue to screw the body (1) of the implant

into the jutting out vertebrae to lower it by a distance chosen by the person implementing the method, and which corresponds to no more than the gap of the jutting out vertebrae compared to the first vertebrae. The nut (4) is then completely screwed down, which results in rising the implant, and therefore the jutting out vertebrae, by the distance travelled by the implant once the bar (7) was introduced in the duct (20) of the head, therefore moving it said distance. This embodiment of the method can be chosen when the initial jutting out of the vertebra is not very big and the length of the cylindrical and threaded part (10) of the body is sufficient for reducing the spondylolistesis. This embodiment has the advantage to limit the risks of tearing out the osseous anchoring means (11) from the vertebra since their screwing in the osseous matter is performed in the absence of the constraints due to the vertical stability of the head (2). As long as the nut (4) is simply in contact with the fixation olive (3), this correcting of the vertebrae is performed by the traction produced by the bar (7) on the head (2) under the effect of the screwing of the nut (4), thanks to the stability of the olive (3) and therefore of the head (2), in relation to the body (1), thanks to the contact between the flat (71) of the bar (7) with the stop formed by the disc (520) of the ball, as aforementioned. The screwing of the nut (4) thus corrects the position of the vertebra and the body (), via rising of the body (1) along its axis (A_1), whilst the olive (3) and the head (2) stay vertically stable in relation to the bar (7) and then engenders the fixing of the head (2) onto the body (1) of the implant via expansion of the fixation olive (3) which produces the blocking of the head (2) in the desired position. If it has not already been, the bar (7) is then fixed to the head (2) of the implant via complete screwing of the fixation screw (5) in the channel (22) of the head (2).

In a third embodiment of the method for installing the implant such as represented in figures 3 and 4, the body (1) of the implant, fitted with the fixation olive (3), the head (2) and the nut (4), is hooked to a formal irregularity of the jutting out vertebrae, thanks to the hook of the body (1) visible in figures 3 and 4. The bar is then inserted into the duct (20) of the head (2) via the lateral aperture (23) and is at least retained, even fixed, via

screwing of the fixation screw (5) in the channel (22). The method continues with the screwing of the nut (4), which results in rising the body (1) of the implant, and thus the jutting out vertebrae, by moving it to a level chosen by the person implementing the method, which is no more than the first vertebrae, and as long as the nut (4) is simply in contact with the fixation olive (3), then engenders the fixing of the head onto the body (1) of the implant via expansion of the fixation olive (3) which produces the blocking of the head (2) in the desired position. If it has not already been, the bar is then fixed to the head (2) of the implant via complete screwing of the fixation screw in the channel (22) of the head (2).

In these three embodiments of the method, the raising of the jutting out vertebrae to a level chosen by the person implementing the method, performed according to a curve, the polyaxiality of the connection between the body (1) of the implant and the head (2), via the possibility of rotation around the axes (A_1), (A_2) and (A_5), is then entirely suitable. If the fixation screw (5) does not comprise a flat at its base but instead a ball and socket (52), possibly associated to a mobile base (6) placed between the bar (7) and the duct (20), the implant is provided with a double polyaxiality allowing to further reduce the stresses on both the rachis and the bar, thanks to the possibilities for rotating the head (2) around the axes (A_1), (A_2) and (A_5), even when the bar (7) is inserted in the duct (20) of the head (2).

It should be clear to the specialist in the art that the present invention enables embodiments in many specific forms without moving it away from the field of application of the invention as claimed. Consequently, the present embodiments must be considered as illustrative, but can be modified in the field defined by the import of the attached claims and the invention should not be limited to the details provided above.

CLAIMS

1. Osseous anchoring implant comprising a body equipped with osseous anchoring means (11) and a head (2) bearing fixation means capable of receiving and fixing at least one bar (7), in particular of osteosynthesis, the head (2) of the implant being traversed by at least one duct (20) receiving the bar (7) through a lateral aperture (23) and by a threaded channel (22) having an axis not parallel to the axis of the duct (20) and receiving a fixation screw (5) of the bar, the implant being characterised in that it comprises fixation means of the head (2) on a part (10) of the body (1) of the implant extending along the osseous anchoring means (11), these fixation means of the head (2) consisting in a portion of the head (2) which forms a ring (21) into which is inserted a fixation olive (3) threaded onto the part (10) of the body (1) of the implant extending along the osseous anchoring means (11) and allowing, prior to blocking and fixing, at least a determined clearance of the head (2) around at least one axis (A_2, A_5) not parallel to the axis (A_1) of symmetry of the osseous anchoring means (11), and in that the fixation screw (5) of the bar comprises a ball and socket (52) at its base allowing at least a determined clearance of the bar around at least one axis (A_4) parallel to the axis of the duct (20), the fixation means of the head (2) and the ball and socket (52) of the fixation screw (5) of the bar allowing a determined clearance of the head (2) around the axis (A_1) of symmetry of the osseous anchoring means, even when the bar (7) is inserted into the duct (20).

2. Osseous anchoring implant set forth in claim 1, wherein the inside diameter of the ends of the duct (20) of the head (2) is greater than the inside diameter of the centre of the duct (20), which confers a widened out profile to the duct allowing, in association with the ball and socket (52) at the base of the fixation screw (5), a determined clearance of the bar around the axis of the duct.

3. Osseous anchoring implant set forth in claims 1 and 2, wherein the head (2) is equipped with a ring (21), which is placed on the other side of the head (2) in relation to the duct (20), and in that the part (10) of the implant extending along the osseous anchoring means (11), which is threaded through a fixation olive (3), itself threaded through a ring (21), is cylindrical and threaded and extends, widening out from the cylindrical part towards the anchoring means (11), by a tapered part (12), complementary of a tapered internal surface of the fixation olive (3) which is sectioned at a point (30) along its entire height.

4. Osseous anchoring implant set forth in claim 3, wherein the external surface of the fixation olive (3) is convex and complementary of a concave internal surface of the ring (21), the external diameter of the olive (3) being slightly less than the internal diameter of the ring (21), so that the olive (3), compression inserted into the ring (21) thanks to the section (30) of the olive (3) along its entire height, allows a retaining of the head (2) on the olive (3), whilst allowing the orientation and the determined clearance of the head (2) around at least one axis parallel to the axis (A_1) of symmetry of the osseous anchoring means (11).

5. Osseous anchoring implant set forth in claim 4, wherein a nut (4) has, along its entire height, a threaded drilling (40) intended to be screwed to the cylindrical part (10) of the implant which is threaded so as to initially provoke, either the rise of the body (1) of the implant up to the bar (7), or the descending of the olive (3) and the head (2) onto the body (1) of the implant, according to the relative positions of the head (2), the olive (3) and the body (1) in relation to the bar (7), then secondly, the leaning of the olive (3) on the tapered part (12) of the implant, which engenders the expansion of the fixation olive (3), and thus the blocking of the head (2) in the desired position.

6. Osseous anchoring implant set forth in claim 5, wherein the nut (4) is equipped with flats capable of co-operating with a tool adapted to the screwing of the nut to the threaded cylindrical part (10) of the implant.

7. Osseous anchoring implant set forth in any of claims 1 to 6, wherein the osseous anchoring means (11) are a hook.

8. Osseous anchoring implant set forth in any of claims 1 to 6, wherein the osseous anchoring means (11) are a threaded part.

9. Osseous anchoring implant set forth in any of claims 1 to 8, wherein the cylindrical part (10) of the body (1) of the implant is equipped, at its end opposite the osseous anchoring means (11), with a blind hole with six faces capable of co-operating with a tool adapted to the screwing of the implant.

10. Osseous anchoring implant set forth in any of claims 3 to 9, wherein the ball and socket (52) of the fixation screw (5) of the bar comprises a flat (520) at its base.

11. Osseous anchoring implant set forth in any of claims 1 to 10, wherein the flat at the base of the ball and socket (52) of the fixation screw (5) of the bar consists in a disc (520) prominent at the periphery of the ball (52) and can be used as a stop limiting the movement of the ball (52) in relation to the fixation screw (5) of the bar.

12. Osseous anchoring implant set forth in any of claims 1 to 11, wherein the ball and socket (52) at the base of the fixation screw (5) of the bar is associated with a mobile base (6) located between the bar (7) and the duct (20) in a housing in the duct, this base facilitating, prior to blocking and fixing of the bar (7), the determined clearance of the bar (7) around at least one axis (A_4) parallel to the axis of the duct (20).

13. Osseous anchoring implant set forth in claim 12, wherein the mobile base (6) has irregularities (610) in its shape, co-operating with irregularities in the shape of the duct (20), so as to restrict the movement of the base (6) in its housing.

14. Method for preparing out with the body prior to the implanting of an osseous anchoring implant comprising a threaded part (11) extended by a smooth tapered part itself extended by a threaded cylindrical part (10), said cylindrical part being threaded through a fixation olive (3) itself threaded in a

head (2) equipped with a duct (20) receiving a bar (7) by a lateral aperture (23) and with a channel (22) receiving a fixation screw (5) provided with a ball and socket (52) at its base, the fixation olive (3) and the head (2) being retained by a nut (4) screwed to the cylindrical part (10), the ball and socket (52) being provided, at its base, with a flat (520) consisting in a disc which is prominent at the periphery of the base of the ball and can thus be used as a stop limiting the rotation of the ball (52) in relation to the fixation screw (5), the method being characterised in that it comprises at least the following successive steps:

- the insertion of the bar (7), via the lateral aperture (23), into the duct (20) in which it is at least retained via a partial screwing of a fixation screw (5);

- the positioning of the flat (520) at the base of the ball (52) as a stop in the duct (20), on its internal surface opposite to the lateral aperture (23), in order to prevent a rotation of the bar (7) in the duct (20), thanks to the contact of this flat (520) of the ball (52) with a flat (71) on the bar (7) and, consequently prevent, the descending of the head (2) in relation to the bar (7);

- the partial screwing of the nut (4) on the cylindrical part (10) of the implant, so that the nut (4) comes into contact with the fixation olive (3), so as to prevent a disengagement of the fixation olive (3) and the head (2) from the cylindrical part (10) of the implant, whilst allowing the movement of the head (2) of the implant around at least the axis (A_1) of symmetry of the osseous anchoring means (11), in the expectation of the screwing of the osseous anchoring means (11) which will provoke the rise of the body (1) and the vertebra, followed by the screwing of the nut (4) which will end the rise of the body (1) and the vertebra and will then block the head (2) and the body (1) in the desired position.

15. Method for preparing out with the body prior to the implanting of an osseous anchoring implant comprising a threaded part (11) extended by a smooth tapered part itself extended by a threaded cylindrical part (10), said

cylindrical part being threaded through a fixation olive (3) itself threaded in a head (2) equipped with a duct (20) receiving an bar (7) by a lateral aperture (23) and with a channel (22) receiving a fixation screw (5) provided with a ball and socket (52) at its base, the fixation olive (3) and the head (2) being retained by a nut (4) screwed to the cylindrical part (10), the ball and socket (52) being provided, at its base, with a flat (520) consisting in a disc which is prominent at the periphery of the base of the ball and can thus be used as a stop limiting the rotation of the ball (52) in relation to the fixation screw (5), the method being characterised in that it comprises at least the following successive steps:

- the insertion of the bar (7), via the lateral aperture (23), into the duct (20) in which it is at least retained via a partial screwing of a fixation screw (5);

- the positioning of the flat (520) at the base of the ball (52) as a stop in the duct (20), on its internal surface opposite to the lateral aperture (23), in order to prevent a rotation of the bar (7) in the duct (20), thanks to the contact of this flat (520) of the ball (52) with a flat (71) on the bar (7) and, consequently prevent, the descending of the head (2) in relation to the bar (7);

- the partial screwing of the nut (4) on the cylindrical part (10) of the implant, so that the nut (4) comes into contact with the fixation olive (3), so as to retain the vertical position of the cylindrical part (10) of the implant, in relation to the head (2), whilst allowing the movement of the head (2) of the implant around at least the axis (A_1) of symmetry of the osseous anchoring means (11), in the expectation of the complete screwing of the nut (4) which will provoke the rise of the body (1) and the vertebra and will then block the head (2) and the body (1) in the desired position.

16. Method set forth in any of claims 14 and 15, wherein the steps of the partial screwing of the fixation screw (5) and the positioning of the flat (520) at the base of the ball (52) as a stop in the duct (20), on its internal surface opposite to the lateral aperture (23), can be replaced by a step of a

complete screwing of the fixation screw (5), so as to prevent any movement of the ball (52) and the bar (7) and, consequently, prevent the descending of the head (2) in relation to the bar (7).

Figure 1

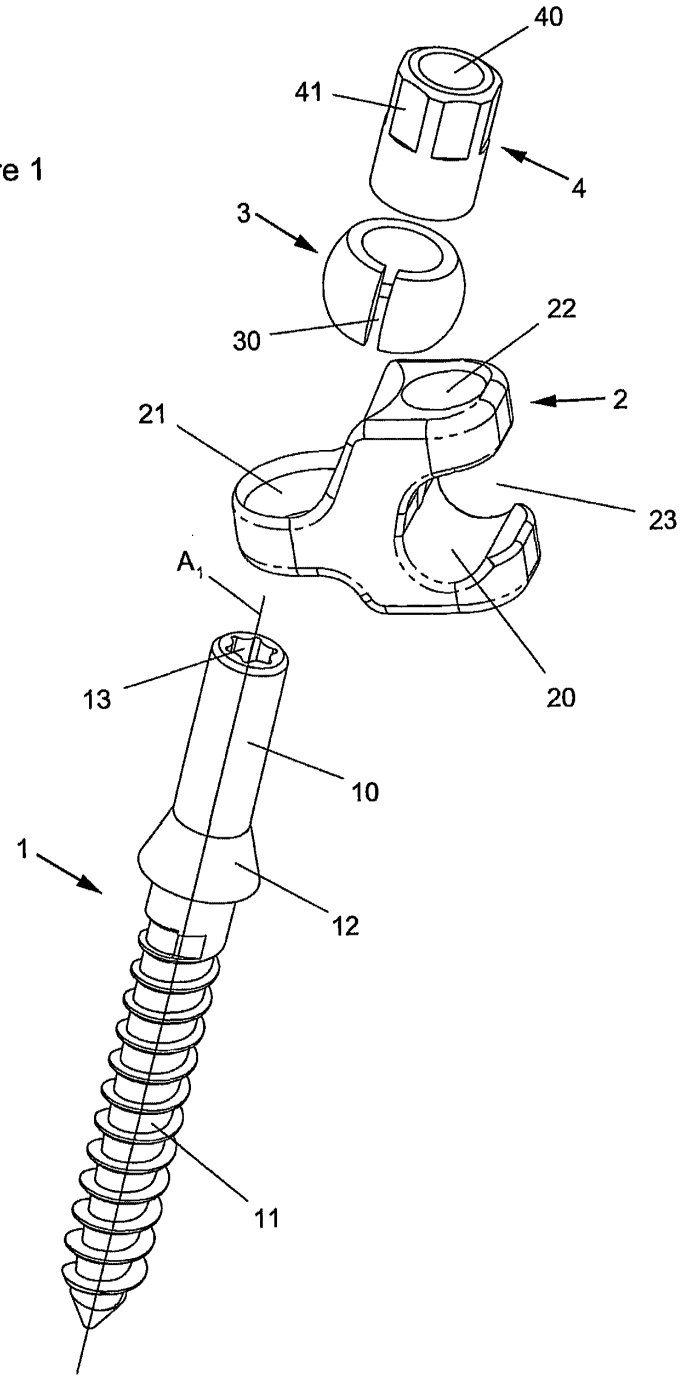


Figure 2

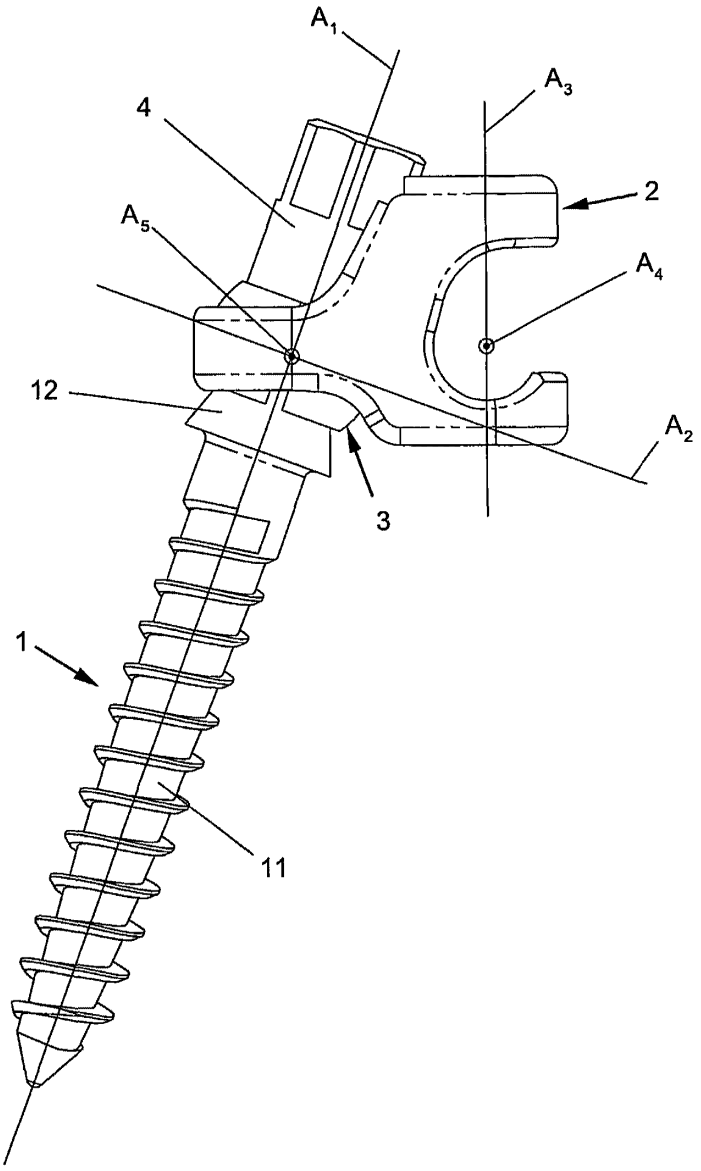


Figure 3

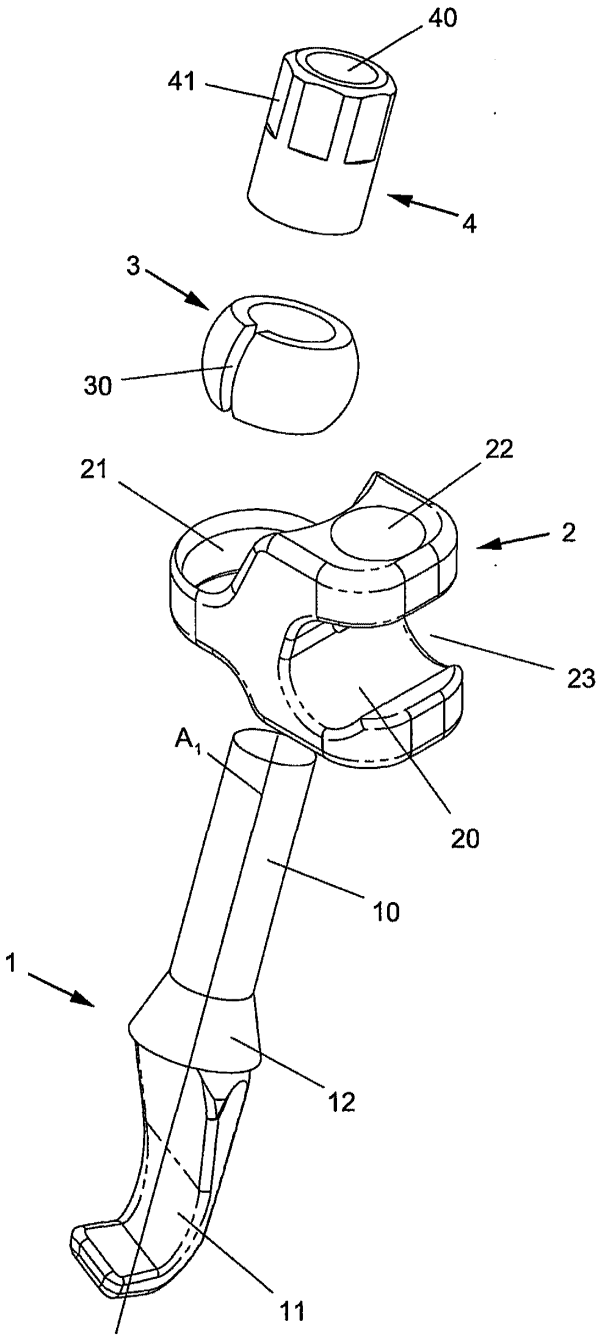


Figure 4

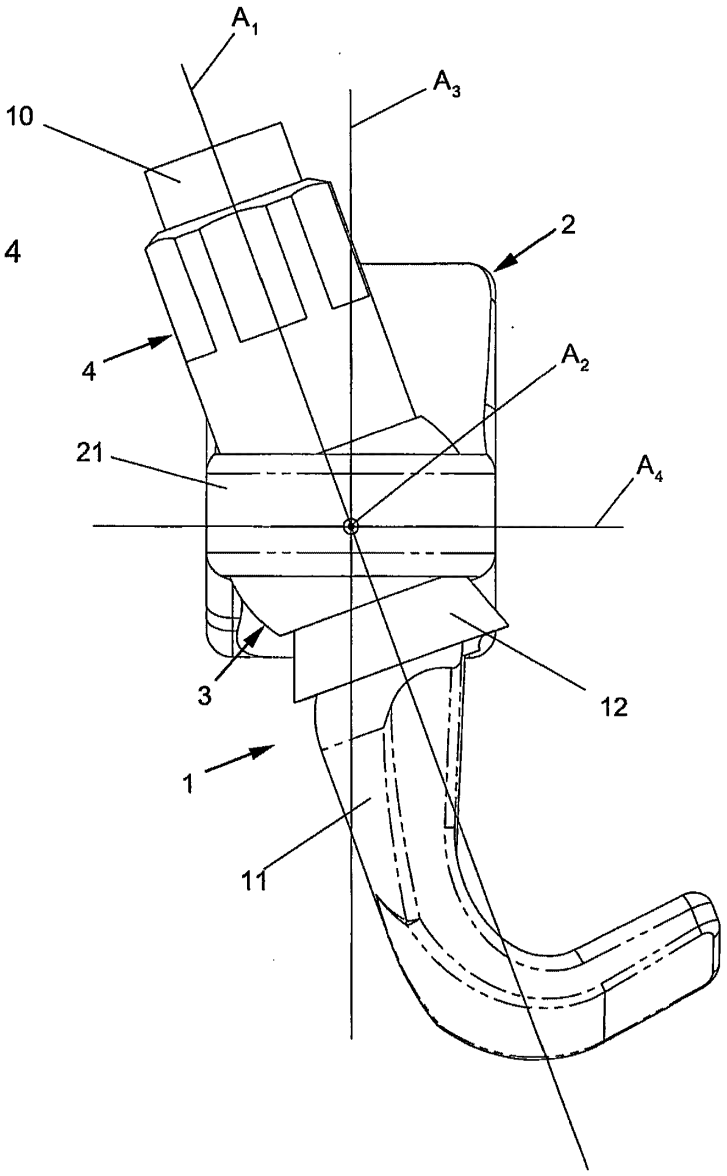


Figure 5a

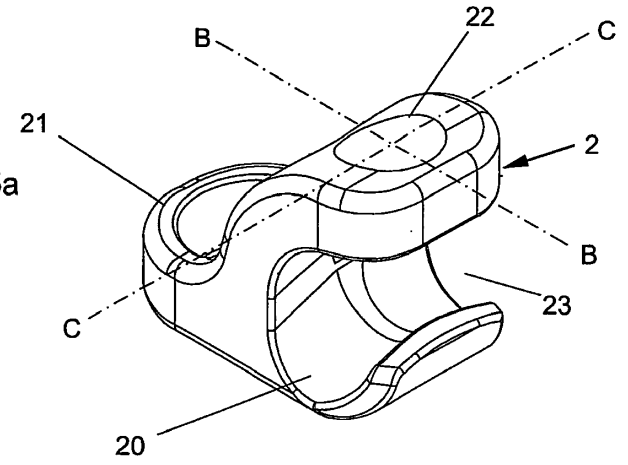


Figure 5b

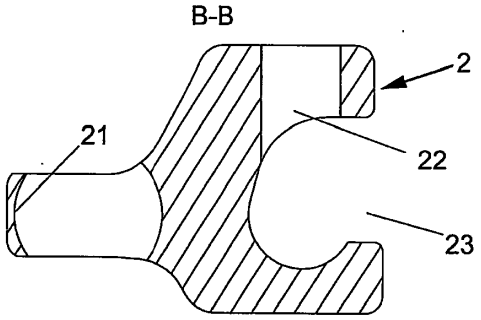
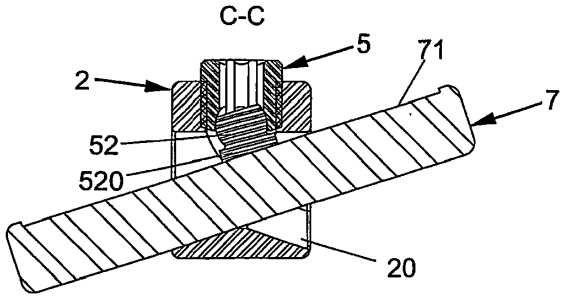


Figure 5c



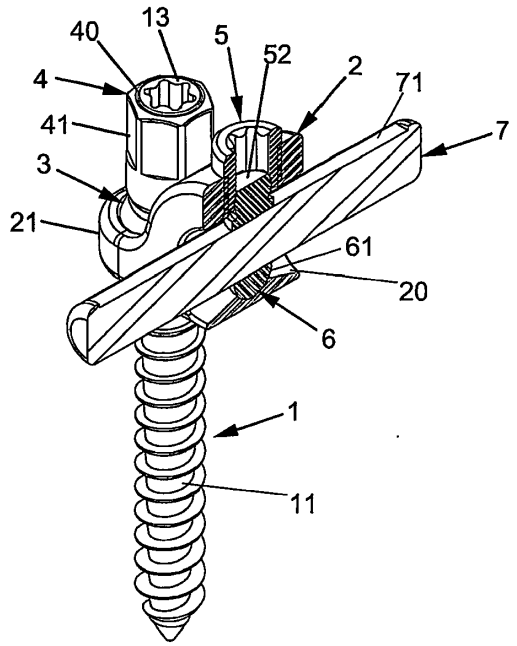


Figure 6a

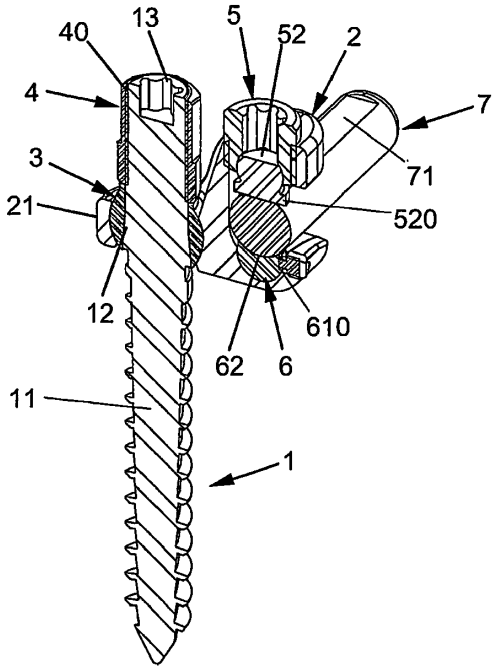


Figure 6b

INTERNATIONAL SEARCH REPORT

International Application No
PCT/IB2004/002825

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.
Y	WO 00/15125 A (SYNTHES AG CHUR) 23 March 2000 (2000-03-23) cited in the application page 7, line 10 - line 22; figures 9,11	1-16
Y	WO 03/049629 A (LDR MEDICAL) 19 June 2003 (2003-06-19) cited in the application page 1, line 8 - line 14 page 2, line 20 - line 23 page 6, line 11 - line 18 page 7, line 23 - line 25 page 8, line 5 - line 15 page 9, line 25 - page 10, line 2 figures 1,2,5-7	1-16

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

[X] Patent family members are listed in annex.

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

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Date of the actual completion of the international search	Date of mailing of the international search report
28 December 2004	07/01/2005

Name and mailing address of the ISA	Authorized officer
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INTERNATIONAL SEARCH REPORT

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 501 684 A (SCHLAPFER J.F. & HESS M.) 26 March 1996 (1996-03-26) figures 1,2	1-16
A	EP 1 254 640 A (BIOMET MERCK) 6 November 2002 (2002-11-06) column 3, line 21 - column 4, line 57; figure 2	1,3,4,7

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/IB2004/002825

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
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			EP	1254640 A2	06-11-2002

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 794 of 2152

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(71) Anmelder: **BIEDERMANN MOTECH GmbH**
78054 VS-Schwenningen (DE)

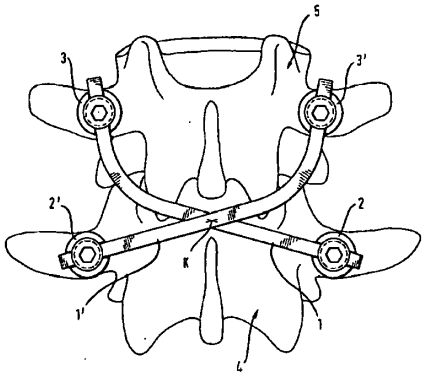
(72) Erfinder:
- **Harms, Jürgen**
  76227 Karlsruhe (DE)
- **Biedermann, Lutz**
  78084 VS-Villingen (DE)
- **Matthis, Wilfried**
  79367 Weisweil (DE)

(74) Vertreter: **Hofer, Dorothea et al**
Prüfer & Partner GbR
Patentanwälte
Harthauser Strasse 25 d
81545 München (DE)

(54) Einrichtung zur dynamischen Stabilisierung von Wirbeln oder Knochen und stabförmiges Element dafür

(57) Es wird eine Stabilisierungseinrichtung zur dynamischen Stabilisierung von Knochen oder Wirbeln bereitgestellt
mit einem ersten Knochenverankerungselement (2) zum Verankern in einem ersten Knochenteil oder einem ersten Wirbel (4),
einem zweiten Knochenverankerungselement (3) zum Verankern in einem zweiten Knochenteil oder einem zweiten Wirbel (5),
einem stabförmigen Element (1; 101) zum Verbinden des ersten und des zweiten Knochenverankerungselements,
wobei das stabförmige Element (1; 101) einen gekrümmten Abschnitt (7) aufweist, der sich unter Einwirkung einer über ein Verankerungselement auf das stabförmige Element ausgeübten Kraft elastisch verformt,
und wobei das stabförmige Element und die Verankerungselemente im Betriebszustand so angeordnet sind, daß die Deformation unter Einwirkung einer Kraft in einer Hauptbewegungsrichtung der Knochenteile oder Wirbel relativ zueinander erfolgt, während eine Deformation unter Krafteinwirkung in einer Richtung im wesentlichen senkrecht zu der Hauptbewegungsrichtung unterdrückt ist.

Fig. 1



EP 1 570 795 A1

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Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 795 of 2152

Beschreibung

[0001] Die Erfindung betrifft eine Stabilisierungseinrichtung zur dynamischen Stabilisierung von Wirbeln oder Knochen und ein stabförmiges Element für eine derartige Stabilisierungseinrichtung.

[0002] Aus der EP 1 188 416 A1 ist eine dynamische Stabilisierungseinrichtung zum Stabilisieren benachbarter Rückenwirbel bekannt, die zwei Pedikelschrauben und ein kabelartiges Band umfasst, welches in den Aufnahmeteilen der Pedikelschrauben jeweils über eine Klemmschraube befestigt ist und welche ein auf das Band aufgezogenes Stützelement in Form eines druckfesten Körpers beinhaltet.

[0003] Aus der US 2003/0109880 A1 ist eine dynamische Stabilisierungseinrichtung für Wirbel bekannt, die eine erste und eine zweite in einem Wirbel zu verankernde Schraube jeweils mit einem Aufnahmeteil zum Einlegen einer die Schrauben verbindenden Feder und eine solche Feder umfasst.

[0004] Aus der US 5,415,661 und der US 2003/0191470 A1 ist jeweils eine Stabilisierungseinrichtung für die Wirbelsäule bekannt, die einen gekrümmten elastischen Stab aufweist, der an seinen Enden über Verankerungselemente mit einem Schaft in den Fortsätzen benachbarter Wirbeln auf derselben Seite so verankert wird, daß der gekrümmte Stab und die Schäfte im wesentlichen in zueinander parallelen Ebenen liegen. Dadurch liegt die Krümmung in der anterioren/posterioren Richtung. Die Krümmung erfüllt die Funktion eines Federstabs.

[0005] Bei den bekannten Stabilisierungseinrichtungen werden jeweils zwei dieser Stabilisierungseinrichtungen zum Stabilisieren von zwei benachbarten Wirbeln verwendet, die jeweils rechts bzw. links von der Mittellängsachse der Wirbelsäule verankert sind.

[0006] Aus der US 6,440,169 B1 ist eine Stabilisierungseinrichtung für die Wirbelsäule bekannt, die einen sich zwischen Verankerungspunkten in benachbarten Wirbeln erstreckenden elastischen Körper aus einer Blattfeder aufweist, die so geformt ist, daß sie die Wand einer Öffnung bildet, wobei sich die Öffnung in der anterioren/posterioren Richtung unter Bezug auf den Körper des Patienten erstreckt und in der medialen/lateralen Richtung geschlossen ist.

[0007] Insbesondere beim Vorhandensein einer geschädigten oder einer künstlichen Bandscheibe ist es wünschenswert, diese durch eine posteriore dynamische Stabilisierungseinrichtung hinsichtlich der zu übertragenden Kräfte in definierter Weise zu unterstützen und die Bewegung zu kontrollieren. Dabei sollen eine Flexion und eine Extension der Wirbelsäule bzw. des die betreffende Bandscheibe enthaltenden Segments, wie in Fig. 8a ersichtlich ist, möglich sein, während eine seitliche Translationsbewegung, sowie eine Torsion um die die Mittellängsachse der Wirbelsäule, wie in Fig. 8b gezeigt ist, unerwünscht sind.

[0008] Es ist Aufgabe der Erfindung eine dynamische Stabilisierungseinrichtung zur Stabilisierung und zur Bewegungsbegrenzung von benachbarten Wirbeln oder Knochen bereitzustellen, welche einfach gebaut ist und mit der eine Bewegungsbegrenzung dahingehend erzielbar ist, daß eine Flexion und Extension in begrenztem Maße erlaubt ist, eine seitliche Translationsbewegung bzw. eine Rotationsbewegung der Wirbel oder Knochen zueinander jedoch weitgehend verhindert wird.

[0009] Die Aufgabe wird durch eine Stabilisierungseinrichtung nach dem Patentanspruch 1 gelöst.

[0010] Weiterbildungen der Erfindung sind in den Unteransprüchen angegeben.

[0011] Die Erfindung weist den Vorteil auf, daß eine gewünschte Bewegungsbegrenzung auf einfache Weise durch Auswahl geeignet dimensionierter stabförmiger Elemente erzielt werden kann. Die stabförmigen Elemente der Stabilisierungseinrichtung sind ferner leicht herstellbar. Die Stabilisierungseinrichtung ist vorteilhaft anwendbar zur Stabilisierung der Wirbel bei der Verwendung von künstlichen Bandscheiben.

[0012] Weitere Merkmale und Zweckmäßigkeiten der Erfindung ergeben sich aus der Beschreibung von Ausführungsbeispielen anhand der Figuren.

[0013] Von den Figuren zeigen:

- Fig. 1 eine Draufsicht auf die erfindungsgemäße Stabilisierungseinrichtung nach einer ersten Ausführungsform von der posterioren Seite der Wirbelsäule gesehen;
- Fig. 2a eine perspektivische Ansicht eines stabförmigen Elements der Stabilisierungseinrichtung nach Fig. 1;
- Fig. 2b eine perspektivische Ansicht der Stabilisierungseinrichtung von Fig. 1 von oben mit bevorzugter Ausbildung der stabförmigen Elemente ohne Darstellung der oberen zwei Verankerungselemente;
- FIG. 3 eine teilgeschnittene Ansicht eines Verankerungselements zum Verankern des stabförmigen Elements von Fig. 2 nach einer ersten Ausführungsform;
- Fig. 4 eine teilgeschnittene Explosionsdarstellung eines Verankerungselements zum Verankern des stabförmigen Elements von Fig. 2 nach einer zweiten Ausführungsform;
- Fig 5 eine teilgeschnittene Ansicht des Verankerungselements von Fig. 4 in Verbindung mit dem stabförmigen Element;
- Fig. 6a eine schematische Darstellung der Bewegungsmöglichkeit eines stabförmigen Elements der Stabilisierungseinrichtung von Fig.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 796 of 2152

1;

Fig. 6b eine schematische Darstellung der Funktionsweise der Stabilisierungseinrichtung nach der ersten Ausführungsform;

Fig. 7 eine Abwandlung der Stabilisierungseinrichtung der ersten Ausführungsform;

Fig. 8a eine Darstellung eines Abschnitts der Wirbelsäule von der Seite; und

Fig. 8b eine Darstellung eines Abschnitts der Wirbelsäule von hinten.

[0014] Wie aus Fig. 1 ersichtlich ist, umfaßt die Stabilisierungseinrichtung in einer ersten Ausführungsform ein erstes und ein zweites stabförmiges Element 1, 1'. Diese sind jeweils mit zwei Verankerungselementen, im gezeigten Anwendungsbeispiel mit Pedikelschrauben 2, 3 bzw. 2', 3' verbunden, welche in den Pedikeln zweier benachbarter Wirbel 4, 5 verankert sind. Die erste Pedikelschraube 2 des stabförmigen Elements 1 ist dabei im rechten Pedikel des unteren Wirbels 4 verankert, während die zweite Pedikelschraube 3 des stabförmigen Elements 1 im linken Pedikel des oberen Wirbels 5 verankert ist. Symmetrisch dazu ist die erste Pedikelschraube 2' des stabförmigen Elements 1' im linken Pedikel des unteren Wirbels 4 verankert, während die zweite Pedikelschraube 3' des stabförmigen Elements 1' im rechten Pedikel des oberen Wirbels 5 verankert ist. Somit kreuzen sich die stabförmigen Elemente 1, 1' an einem Punkt K in der Symmetrieebene.

[0015] Wie aus Fig. 2a ersichtlich ist, ist das erste stabförmige Element 1 als ein gekrümmter Stab mit einem rechteckigen Querschnitt ausgebildet. Das stabförmige Element 1 weist einen ersten geraden Abschnitt 6 mit einer Länge L1, daran angrenzend einen gekrümmten Abschnitt 7 mit einer Länge L2 und daran angrenzend wieder einen geraden Abschnitt 8 mit einer Länge L3 auf. Die Mittellängsachsen M1 und M2 der geraden Abschnitte schließen in dem gezeigten Ausführungsbeispiel einen stumpfen Winkel α miteinander ein. Die Länge L1 des ersten geraden Abschnitts beträgt in dem gezeigten Ausführungsbeispiel etwa das Dreifache der Länge L3 des zweiten geraden Abschnitts 8. Die Krümmung verläuft über die breite Seite B des stabförmigen Elements. Die Biegesteifigkeit gegenüber einer Kraftkomponente, die senkrecht auf seine breite Seite B wirkt, ist kleiner als gegenüber einer Kraftkomponente, die senkrecht auf seine schmale Seite S wirkt. Ferner ist die Biegesteifigkeit des stabförmigen Elements aufgrund der Hebelwirkung durch die unterschiedlichen Längen L1 und L3 der geraden Abschnitte 6, 8 gegenüber einer Kraftkomponente, die am Ende des langen Abschnitts 6 senkrecht zum Stab angreift, geringer, als gegenüber einer Kraftkomponente, die am Ende des kurzen Abschnitts 8 senkrecht angreift.

[0016] Das stabförmige Element besitzt somit eine orientierte Biegesteifigkeit, die durch Wahl des Querschnitts, der Krümmung und der Länge in gewünschter Weise bei der Herstellung einstellbar ist. Das stabförmige Element 1 ist ferner einstückig aus einem körperfreundlichen Material, wie z.B. aus Titan ausgebildet und bevorzugt aus dem Vollen gefräßt.

[0017] Das zweite stabförmige Element 1' ist in der einfachsten Ausführungsform spiegelsymmetrisch zu dem ersten stabförmigen Element 1 befestigt, so daß die gekrümmten Abschnitte in entgegengesetzte Richtungen zeigen.

[0018] Fig. 2b zeigt die Stabilisierungseinrichtung von Fig. 1 von oben mit einer bevorzugten Ausbildung der stabförmigen Elemente 1, 1', wobei jeweils die oberen Verankerungselemente nicht dargestellt sind. Die stabförmigen Elemente 1, 1' sind in einem Bereich 1a, 1a' angrenzend an den Abschnitt mit dem sie im Verankerungselement befestigt sind, derart aus der Ebene, die durch die Verbindungsstellen definiert ist, nach außen gebogen, daß sie im Betriebszustand der Stabilisierungseinrichtung aneinander vorbeigeführt sind, ohne sich zu behindern. Dies ermöglicht, daß die Verbindungsstellen der Verankerungselemente zu den stabförmigen Elementen alle in einer Ebene senkrecht zu der in Fig. 8a angedeuteten Medianebene liegen.

[0019] Wie in Fig. 3 gezeigt ist, ist in einer ersten Ausführungsform das stabförmige Element 1, 1' in einer monoaxialen Pedikelschraube fixiert. Diese weist einen Gewindeschaft 10 mit einem Knochengewinde und ein damit starr verbundenes Aufnahmeteil 11 auf. Das Aufnahemteil 11 ist im wesentlichen zylindrisch ausgebildet und weist eine sich von seinem dem Gewindeschaft 10 abgewandten freien Ende zum Gewindeschaft hin erstreckende Ausnehmung 12 mit rechteckigem Querschnitt auf, die so bemessen ist, daß darin das stabförmige Element 1, 1' einlegbar und noch in Richtung seiner Längsachse verschiebbar ist. Die Ausnehmung 12 ist so gebildet, daß die schmale Seite S des stabförmigen Elements 1 im Grund der Ausnehmung ruht. Ausgehend von seinem freien Ende weist das Aufnahmeteil ein Außengewinde 13 auf, das sich über eine vorbestimmte Länge erstreckt, die so bemessen ist, daß das Außengewinde bei eingelegtem stabförmigen Element bis unterhalb dessen Oberseite reicht. Zum Fixieren des stabförmigen Elements in dem Aufnahmeteil ist eine auf das Außengewinde aufschraubbare Mutter 14 vorgesehen.

[0020] In einer weiteren Ausführungsform ist eine in den Figuren 4 und 5 gezeigte Polyaxialschraube zum Verbinden mit dem stabförmigen Element 1, 1' vorgesehen. Diese weist ein Schraubenelement 15 mit einem Gewindeschaft 16 mit einem Knochengewinde und einen kugelsegmentförmigen Kopf 17 mit einer nichtdargestellten Ausnehmung zum Einschrauben auf. Ferner ist ein mit dem Schraubenelement 15 verbindbares Aufnahmeteil 18 vorgesehen. Das Aufnahmeteil 18 ist im wesentlichen zylindrisch ausgebildet und hat an seinem

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 797 of 2152

einen Ende eine axialsymmetrisch ausgerichtete erste Bohrung 19, deren Durchmesser kleiner als der des Kopfes 17 ist. Ferner weist das Aufnahmeteil 18 eine koaxiale zweite Bohrung 20 auf, die auf dem der ersten Bohrung 19 gegenüberliegenden Ende offen ist und deren Durchmesser so groß ist, daß das Schraubenelement 15 durch das offene Ende mit seinem Gewindeschaft durch die erste Bohrung 19 hindurch und mit dem Kopf 17 bis zum Grund der zweiten Bohrung 20 führbar ist. Zwischen der ersten und der zweiten Bohrung ist ein sphärischer Abschnitt 21 zum Anliegen des Kopfs 17 vorgesehen.

[0021] Das Aufnahmeteil 18 weist ferner eine zur Mitte des Teiles symmetrisch angeordnete Ausnehmung 22 mit einem rechteckigen Querschnitt zur Aufnahme des stabförmigen Elements 1, 1' auf, durch die zwei freie Schenkel 23, 24 gebildet sind. In einem Bereich angrenzend an ihr freies Ende weisen die Schenkel 23, 24 in diesem Ausführungsbeispiel ein Außengewinde 25 und ein Innengewinde 26 auf.

[0022] Es ist ferner ein in der Bohrung 20 zu dem Kopf hin verschiebbares Druckelement 27 vorgesehen. Das Druckelement 27 weist eine koaxiale Bohrung 28 zum Hindurchführen eines Schraubendrehers, sowie an seiner dem Kopf 17 zugewandten Seite eine sphärische Ausnehmung 29 für den Kopf 17 auf. An seiner dem Kopf abgewandten Seite weist das Druckelement 27 eine Ausnehmung 30 mit rechteckigem Querschnitt zur Aufnahme des stabförmigen Elements 1, 1' auf. Die Breite der Ausnehmung 30 ist gerade ein wenig größer als die schmale Seite S des stabförmigen Elements 1, 1', so daß dieses mit seiner schmalen Seite S zum Grund der Ausnehmung hin einführbar ist und in der Ausnehmung in Längsrichtung verschiebbar ist. Die Tiefe der Ausnehmung 30 ist etwas kleiner als die Höhe B des stabförmigen Elements.

[0023] Zum Fixieren des stabförmigen Elements 1, 1' in dem Aufnahmeteil und zum Fixieren der Winkelstellung des Schraubenelements 15 relativ zu dem Aufnahmeteil sind ferner eine zwischen die Schenkel einschraubbare Innenschraube 31 und zur Sicherung eine auf die Schenkel aufschraubbare Mutter 32 vorgesehen.

[0024] Im Betrieb werden zunächst die Pedikelschrauben 2, 3, 2', 3' in die mit der Stabilisierungseinrichtung zu verbindenden Wirbel 4, 5 eingeschraubt. Im Fall der Monoaxialschrauben nach Fig. 4 werden die Gewindeschäfte 10 soweit eingeschraubt, bis die Aufnahmeteile 11 der mit jeweils einem stabförmigen Element 1, 1' zu verbindenden Pedikelschrauben 2, 3 bzw. 2', 3' zueinander so ausgerichtet sind, daß das stabförmige Element ohne zu verkanten einführbar ist. Dann wird das stabförmige Element durch Aufschrauben der Mutter 14 fixiert.

[0025] Im Fall der Polyaxialschrauben nach den Figuren 4 und 5 wird erst das Schraubenelement 15 in das Aufnahmeteil 18 eingeführt, dann das Druckelement 27 eingesetzt und anschließend das Schraubenelement in den Pedikel eingeschraubt. Anschließend wird das stabförmige Element 1 bzw. 1' in die Aufnahmeteile eingesetzt. Die Aufnahmeteile 18 zweier mit dem stabförmigen Element 1 bzw. 1' zu verbindender Pedikelschrauben 2, 3 bzw. 2', 3' richten sich dabei auf Grund der gelenkigen Verbindung zwischen dem Kopf 17 und dem Aufnahmeteil 18 selbst richtig zum Stab hin aus, was bei der überkreuzten Anordnung der stabförmigen Elemente von Vorteil ist. Anschließend werden die Aufnahmeteile relativ zum Kopf und zum Stab durch die Innenschraube und die Mutter fixiert.

[0026] Die Figuren 6a und 6b zeigen schematisch die Funktionsweise der Stabilisierungseinrichtung. Wie in Fig. 6a gezeigt ist kann das stabförmige Element 1 in unbelastetem Zustand in idealisierter Weise als ein Winkelhebel mit einem langen Hebelarm 6 und einem kurzen Hebelarm 8 angesehen werden. Bei Belastung durch Flexion oder Extension des Wirbelsäulensegments führt eine kleine an den Verankerungspunkten senkrecht zum langen Hebelarm 6 angreifende Kraftkomponente zur elastischen Deformation des stabförmigen Elements 1, indem der lange Hebelarm ausgelenkt wird und sich der Krümmungsradius relativ zu der Ruhestellung bei der Flexion vergrößert und bei der Extension verkleinert.

[0027] In Fig. 6b zeigen die durchgezogenen Linien die stabförmigen Elemente 1, 1' in einem ersten Zustand und die gestrichelten Linien in einem zweiten Zustand, der in diesem Fall eine Flexion des Wirbelsäulensegments ist. In dem ersten Zustand haben die Pedikelschrauben 2', 3 mit denen das stabförmige Element 1 verbunden ist, in Richtung der Mittellängsachse M der Wirbelsäule einen Abstand H voneinander. Bei der Flexion des Wirbelsäulensegments kommt es zu einer Biegung des stabförmigen Elements 1, wobei der Krümmungsradius dabei größer wird und somit in dem gezeigten zweiten Zustand der Abstand der Pedikelschrauben in Richtung der Mittellängsachse auf H' vergrößert wird. Umgekehrt wird bei einer Extension des Wirbelsäulensegments der Krümmungsradius der stabförmigen Elemente verkleinert. Damit verringert sich der Abstand der Pedikelschrauben.

[0028] Bei Einwirkung einer Kraftkomponente senkrecht zu dem kurzen Hebelarm, ist eine Änderung der Krümmung der stabförmigen Elemente aufgrund der erforderlichen größeren Kraft erschwert oder gar nicht möglich. Somit wird eine seitliche Translationsbewegung verhindert. Aufgrund der länglichen Ausbildung der stabförmigen Elemente besteht ferner weitgehend Rotationsstabilität gegenüber einer Rotationsbewegung der Wirbel zueinander.

[0029] Fig. 7 zeigt eine zweite Ausführungsform. Die Stabilisierungseinrichtung erstreckt sich auf zwei Bewegungssegmente, bestehend jeweils aus den Wirbeln 4, 5 bzw. 5, 5'. Es sind stabförmige Elemente 101, 101' vorgesehen, die eine Form haben, die durch Spiegelung eines stabförmigen Elements 1, 1' der ersten Ausführungsform an einer auf dem freien Ende des kurzen Ab-

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 798 of 2152

schnitts senkrecht stehenden Ebene entsteht. Die stabförmigen Elemente 101, 101' sind jeweils durch Pedikelschrauben 2, 2" bzw. 2', 3" an ihren Enden in den Pedikeln auf derselben Seite der jeweils übernächsten Wirbel 4, 5' verankert und mit ihrem mittleren Abschnitt über Pedikelschrauben 3 bzw. 3' in den Pedikeln der gegenüberliegenden Seite des dazwischenliegenden Wirbels 5 verankert.

[0030] Eine mehrsegmentale Ausbildung ist ebenso möglich.

[0031] Abwandlungen der zuvor beschriebenen Ausführungsformen sind möglich. So werden die Längen der einzelnen Abschnitte der stabförmigen Elemente entsprechend den Dimensionen der zu verbindenden Wirbel gewählt. Die Erfindung ist nicht darauf beschränkt, daß die stabförmigen Elemente der Stabilisierungseinrichtung der ersten Ausführungsform einen langen und einen kurzen geraden Abschnitt aufweisen. Es können auch nur ein langer und ein gekrümmter Abschnitt vorhanden sein. Bei der Stabilisierungseinrichtung der zweiten Ausführungsform können die geraden Abschnitte auch unterschiedlich lang sein, entscheidend ist, daß das stabförmige Element zwischen dem einen Befestigungspunkt und dem anderen Befestigungspunkt eine Krümmung aufweist, damit das stabförmige Element unter Einwirkung von Biegemomenten eine Abstandsänderung der Befestigungspunkte bewirkt.

[0032] Ferner sind die Merkmale der beschriebenen Ausführungsformen miteinander kombinierbar. Die Stabilisierungseinrichtung der ersten Ausführungsform kann auch stabförmige Elemente mit kreisförmigem Querschnitt aufweisen. Auch ein quadratischer Stabquerschnitt ist möglich, wobei dann aber ein Freiheitsgrad bei der Wahl der biegeelastischen Eigenschaften des stabförmigen Elements wegfällt.

[0033] Anstelle der beschriebenen Monoaxialschrauben und Polyaxialschrauben können auch Monoaxialschrauben und Polyaxialschrauben verwendet werden, bei denen die Kopf- oder die Stabfixierung auf andere Weise erfolgt.

[0034] Die Erfindung ist ferner nicht auf eine Stabilisierungseinrichtung für die Wirbelsäule beschränkt, sondern kann auch zum Stabilisieren von Knochen eingesetzt werden.

Patentansprüche

1. Stabilisierungseinrichtung zur dynamischen Stabilisierung von Wirbeln oder Knochen, mit

   einem ersten Knochenverankerungselement (2) und einem zweiten Knochenverankerungselement (2') zur Verankerung in einem ersten Knochenteil (4) oder einem Wirbel und mit

   einem dritten Knochenverankerungselement (3) und einem vierten Knochenverankerungselement (3') zur Verankerung in einem zweiten Knochenteil (5) oder Wirbel,

   einem ersten stabförmigen Element (1; 101), das mit dem ersten oder mit dem zweiten Knochenverankerungselement (2) und mit dem dritten oder dem vierten Knochenverankerungselement verbunden ist;

   einem zweiten stabförmigen Element (1'; 101'), das mit dem zweiten oder mit dem ersten Knochenverankerungselement und mit dem vierten oder dem dritten Knochenverankerungselement verbunden ist;

   wobei die Verbindungsstellen der Verankerungselemente mit den stabförmigen Elementen eine Ebene aufspannen;

   wobei die stabförmigen Elemente (1, 1'; 101; 101') zwischen den Verbindungsstellen jeweils einen gekrümmten Abschnitt (7) aufweisen, der sich unter Einwirkung einer über ein Verankerungselement auf das stabförmige Element ausgeübten Kraft elastisch verformt; und

   wobei die stabförmigen Elemente so angeordnet sind, daß der gekrümmte Abschnitt im wesentlichen in der durch die Verbindungsstellen aufgespannten Ebene oder parallel zu dieser liegt.

2. Stabilisierungseinrichtung nach Anspruch 1, **dadurch gekennzeichnet, daß** die stabförmigen Elemente (1, 1'; 101, 101') so angeordnet sind, daß sie sich wenigstens einmal überkreuzen.

3. Stabilisierungseinrichtung nach Anspruch 1 oder 2 wobei die stabförmigen Elemente und die Verankerungselemente im Betriebszustand so angeordnet sind, daß die Deformation unter Einwirkung einer Kraft in einer Hauptbewegungsrichtung der Knochenteile oder Wirbel relativ zueinander erfolgt, während eine Deformation unter Krafteinwirkung in einer Richtung im wesentlichen senkrecht zu der Hauptbewegungsrichtung unterdrückt ist.

4. Stabilisierungseinrichtung nach einem der Ansprüche 1 bis 3, **dadurch gekennzeichnet, daß** das erste (2) und das dritte Knochenverankerungselement (3) relativ zur Hauptbewegungsrichtung diagonal gegenüberliegend angeordnet sind.

5. Stabilisierungseinrichtung nach einem der Ansprüche 1 bis 4, **dadurch gekennzeichnet, daß** die Stabilisierungseinrichtung zum Stabilisieren wenigstens zweier benachbarter Wirbel (4, 5) vorgesehen ist und so ausgebildet ist, daß die mit einem stabförmigen Element verbundenen Knochenverankerungselemente je in diagonal gegenüberliegenden Pedikeln der Wirbel verankerbar sind.

6. Stabilisierungseinrichtung nach einem der Ansprüche 1 bis 5, **dadurch gekennzeichnet, daß** das zweite (2') und das vierte (3') Knochenveranke-

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 799 of 2152

rungselement und das diese verbindende zweite stabförmige Element (1'; 101') symmetrisch zu dem ersten (2) und dem dritten (3) Knochenverankerungselement mit dem ersten stabförmigen Element (1; 101) angeordnet sind.

7. Stabilisierungseinrichtung nach einem der Ansprüche 1 bis 6, **dadurch gekennzeichnet, daß** die stabförmigen Elemente im wesentlichen L-förmig gekrümmt sind.

8. Stabilisierungseinrichtung nach einem der Ansprüche 1 bis 7, **dadurch gekennzeichnet**, die stabförmigen Elemente einen rechteckigen oder quadratischen Querschnitt aufweisen.

9. Stabilisierungseinrichtung nach einem der Ansprüche 1 bis 7, **dadurch gekennzeichnet, daß** die stabförmigen Elemente einen kreisförmigen Querschnitt aufweisen.

10. Stabilisierungseinrichtung nach einem der Ansprüche 1 bis 9, **dadurch gekennzeichnet, daß** das Verankerungselement je einen Verankerungsabschnitt (10; 15) zum Verankern in einem Knochen und ein mit diesem verbundenes Aufnahmeteil (11; 18) aufweist, welches eine dem Querschnitt des jeweiligen stabförmigen Elements angepaßte Ausnehmung (12; 22) zur Aufnahme des stabförmigen Elements hat.

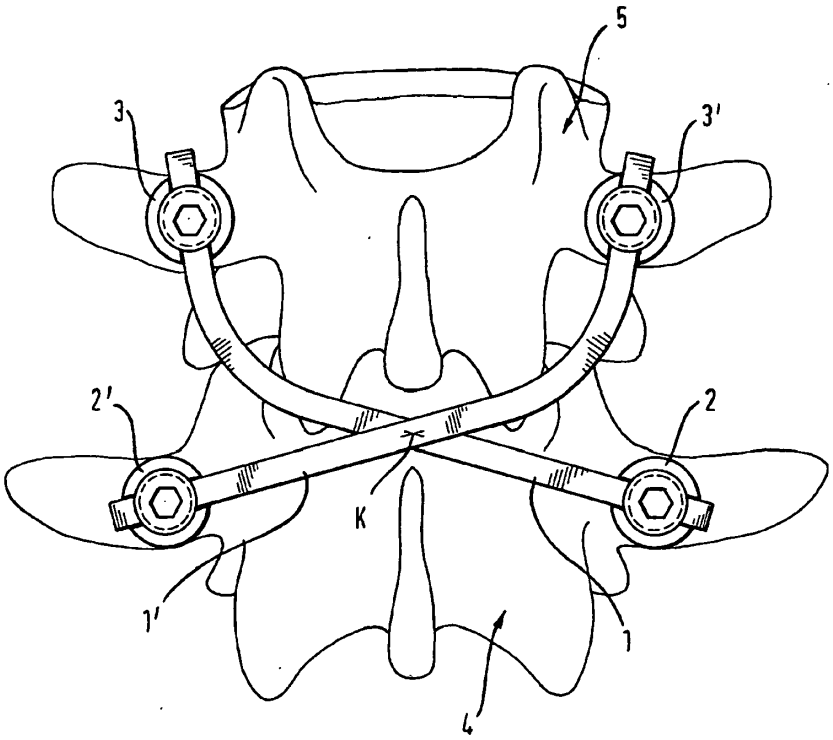
11. Stabilisierungseinrichtung nach Anspruch 10, **dadurch gekennzeichnet, daß** der Verankerungsabschnitt (10) monoaxial mit dem Aufnahmeteil (11) verbunden ist.

12. Stabilisierungseinrichtung nach Anspruch 10, **dadurch gekennzeichnet, daß** der Verankerungsabschnitt (15) polyaxial mit dem Aufnahmeteil (18) verbunden ist.

13. Stabilisierungseinrichtung nach einem der Ansprüche 1 bis 12, **dadurch gekennzeichnet, daß** die Anzahl der Verankerungselemente ein Vielfaches von zwei beträgt und die stabförmigen Elemente (101, 101') jeweils mehr als zwei Verankerungselemente verbinden.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 800 of 2152

Fig. 1



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 801 of 2152

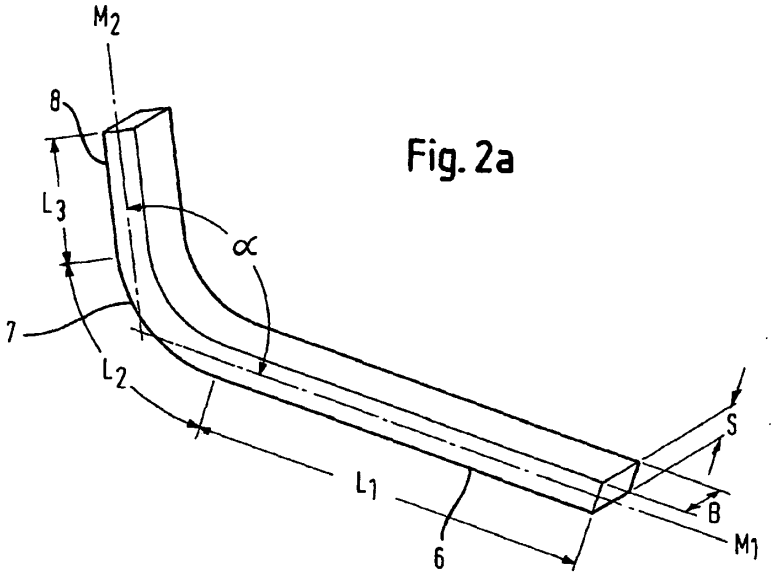
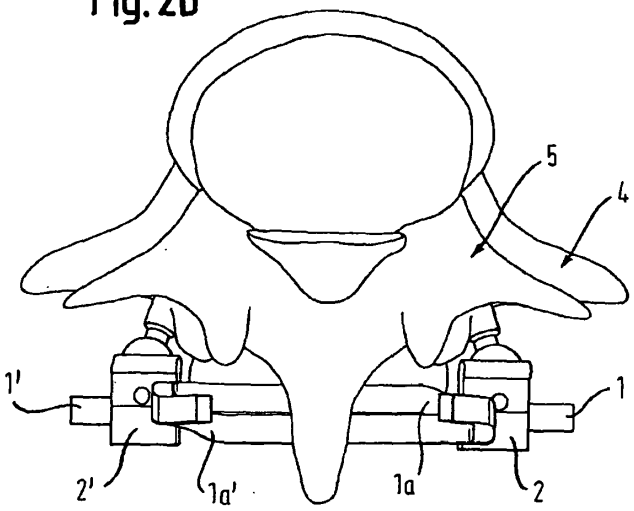


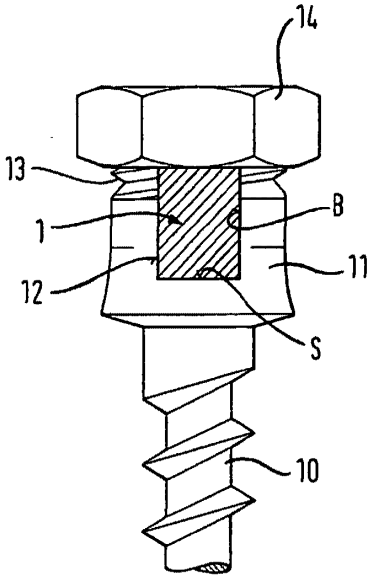
Fig. 2a

Fig. 2b



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 802 of 2152

Fig. 3



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 803 of 2152

Fig. 4

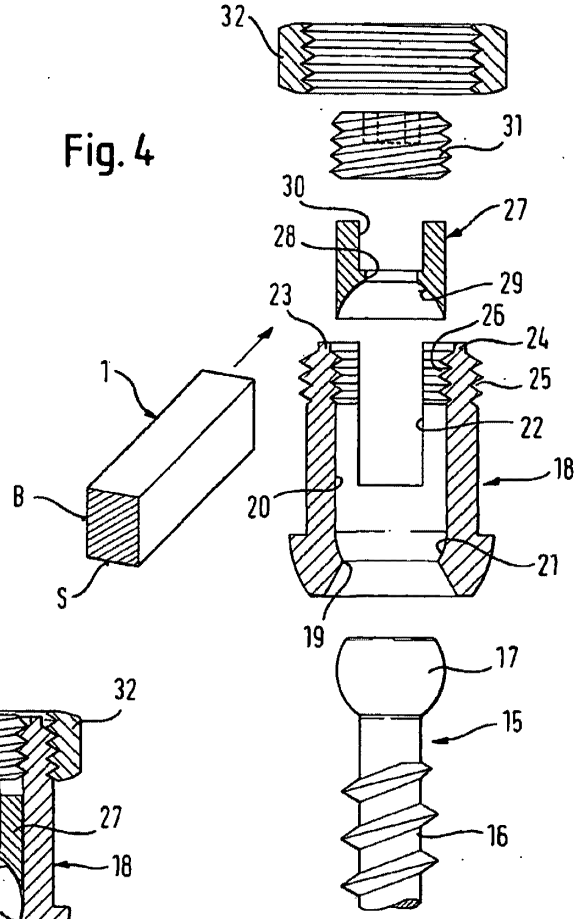
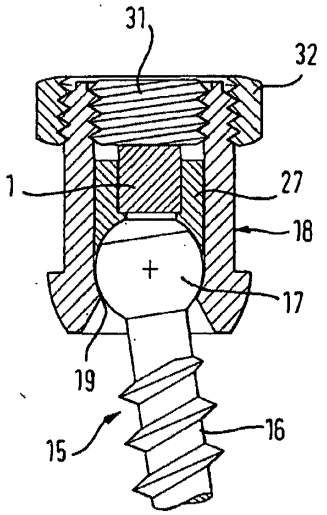


Fig. 5



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 804 of 2152

Fig. 6a

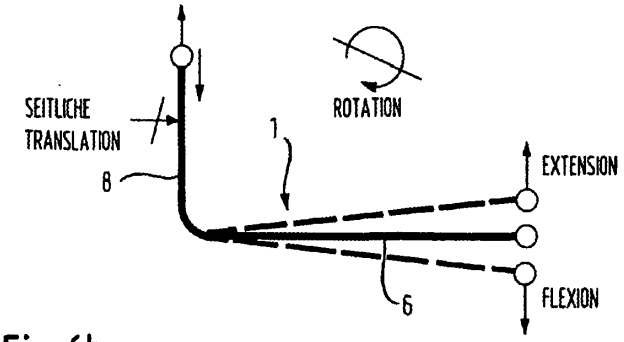
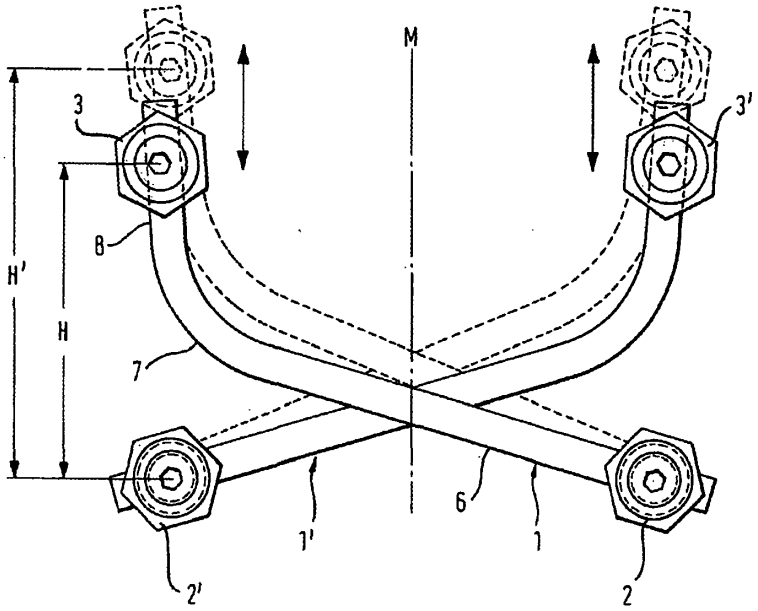
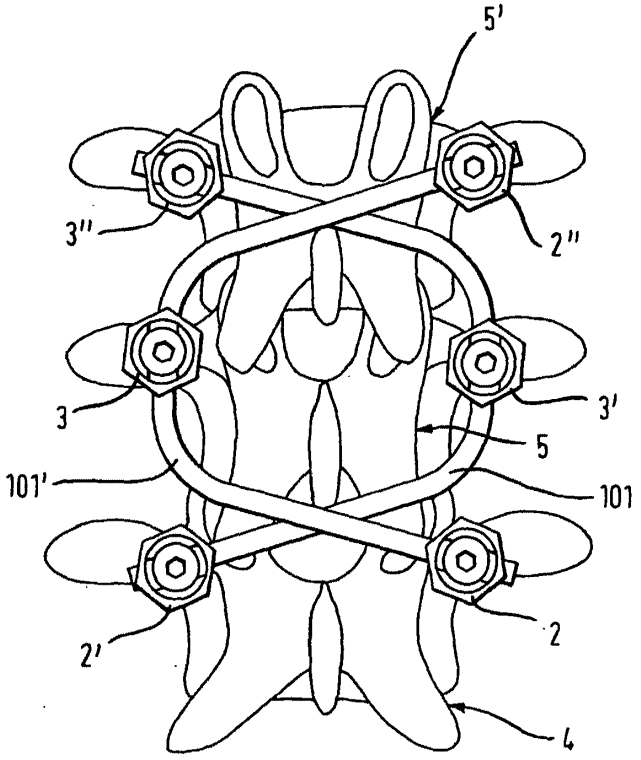


Fig. 6b



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 805 of 2152

Fig. 7



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 806 of 2152

Fig. 8a

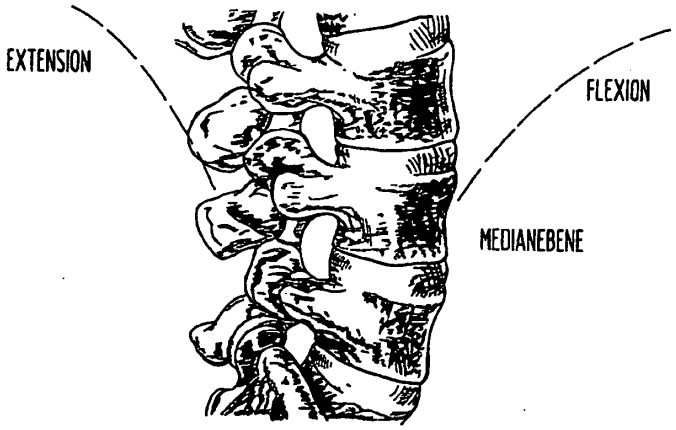
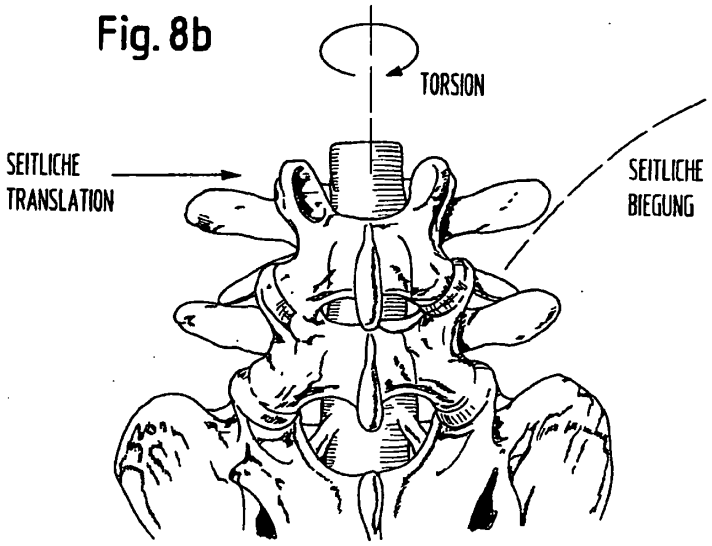


Fig. 8b



Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 807 of 2152

Europäisches Patentamt

EUROPÄISCHER RECHERCHENBERICHT

Nummer der Anmeldung
EP 05 00 3401

EINSCHLÄGIGE DOKUMENTE

Kategorie	Kennzeichnung des Dokuments mit Angabe, soweit erforderlich, der maßgeblichen Teile	Betrifft Anspruch	KLASSIFIKATION DER ANMELDUNG (Int.Cl.7)
X Y	WO 02/102259 A (SENGUPTA D.K. & MULHOLLAND R.C.) 27. Dezember 2002 (2002-12-27) * Zusammenfassung; Abbildungen * * Seite 3, Zeile 9 - Seite 4, Zeile 22 * * Seite 8, Zeile 11 - Seite 9, Zeile 10 * * Seite 10, Zeile 5 - Zeile 11 *	1,3-6, 9-11 12	A61B17/70 A61B17/64
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Recherchenort	Abschlußdatum der Recherche	Prüfer
Den Haag	23. Mai 2005	Nice, P

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X : von besonderer Bedeutung allein betrachtet
Y : von besonderer Bedeutung in Verbindung mit einer anderen Veröffentlichung derselben Kategorie
A : technologischer Hintergrund
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D : in der Anmeldung angeführtes Dokument
L : aus anderen Gründen angeführtes Dokument

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Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 808 of 2152

ANHANG ZUM EUROPÄISCHEN RECHERCHENBERICHT ÜBER DIE EUROPÄISCHE PATENTANMELDUNG NR. EP 05 00 3401

In diesem Anhang sind die Mitglieder der Patentfamilien der im obengenannten europäischen Recherchenbericht angeführten Patentdokumente angegeben.
Die Angaben über die Familienmitglieder entsprechen dem Stand der Datei des Europäischen Patentamts am
Diese Angaben dienen nur zur Unterrichtung und erfolgen ohne Gewähr.

23-05-2005

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Für nähere Einzelheiten zu diesem Anhang : siehe Amtsblatt des Europäischen Patentamts, Nr.12/82

Zimvie_Zimmer Biomet v. Jackson
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(71) Applicant *(for all designated States except US)*: **MEDICREA TECHNOLOGIES** [FR/FR]; ZI Chef de Baie, F-17000 La Rochelle (FR).

(72) Inventors; and

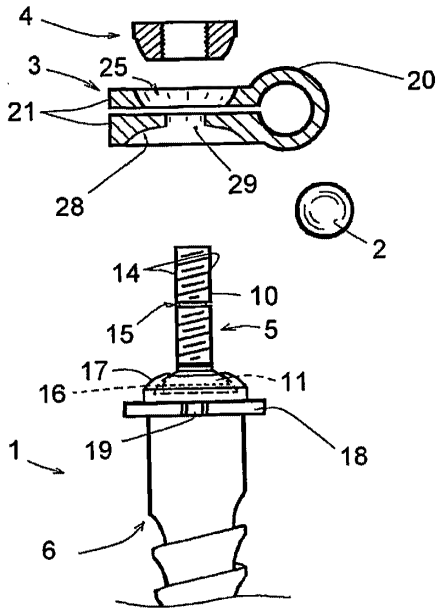
(75) Inventors/Applicants *(for US only)*: **CLEMENT, Jean-Luc** [FR/FR]; 230 Chemin de Montfort, F-06480 La Colle Sur Loup (FR). **FIERE, Vincent** [FR/FR]; 50 Boulevard des Belges, F-69006 Lyon (FR). **TAYLOR, Jean** [FR/FR]; Villa Poralto, 25 Avenue de Poralto, F-06400 Cannes (FR). **ADAM, Yves** [FR/FR]; 4 route de Saint Louet, F-14280 Authie (FR). **VILLARET, Bernard** [FR/FR]; 20 rue de Salles, F-17220 Croix-Chapeau (FR).

(74) Common Representative: **MEDICREA TECHNOLOGIES**; ZI Chef de Baie, F-17000 La Rochelle (FR).

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[Continued on next page]

(54) Title: VERTEBRAL OSTEOSYNTHESIS EQUIPMENT



(57) Abstract: This equipment includes bony anchoring members, one or two linking rods (2), intended to be connected to these anchoring members and to be attached to the vertebrae by dint thereof, parts (3) for connecting this (these) linking rod(s) (2) to these anchoring members, and clamping means, such as nuts (4), for locking the linking rod(s) (2) in said connecting parts (3) ; at least one anchoring member is of the "polyaxial" type, i.e. comprises one proximal stud (5) articulated with respect to a body (6) intended for gripping a vertebra. According to the invention, - the proximal stud (5) of said polyaxial anchoring member exhibits an articulation head (11) in the form of a spherical cap ; and said body (6) of this anchoring member comprises a cavity (16) intended for accommodating this articulation head (11) and a wall (17) surrounding this cavity (16), this wall (17) being crimped around said articulation head (11).

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VERTEBRAL OSTEOSYNTHESIS EQUIPMENT

This patent application claims the priorities to :

- FR 03 07777, filed on June 27, 2003 ;
- US Provisional application N° 60/490,520, filed on July 29, 2003.

The present invention relates to vertebral osteosynthesis equipment and a manufacturing process of a bony anchoring member included in such equipment.

A vertebral osteosynthesis equipment generally includes bony anchoring members, such as pedicular screws or lamar hooks, one or two linking rods, intended to be connected to these anchoring members and to be attached to the vertebrae by dint thereof, and parts for connecting this(these) linking rod(s) to these anchoring members. The equipment may also comprise length-adjustable crossbeams, which link transversally two parallel linking rods in order to hold said rods with respect to one another.

In an existing type of equipment, each anchoring member comprises a proximal threaded stud whereon a nut may be screwed, and each connecting part comprises a rounded section intended for surrounding a linking rod and two parallel drilled wings. These wings are intended for engaging onto said proximal threaded stud and for being clamped, by means of that nut, against a bearing surface provided on the anchoring member, said operation enabling to clamp said rounded section around the linking rod and thereby ensuring longitudinal immobilisation of this rod with respect to the anchoring member. The anchoring members may be of "monoaxial" type, i.e. comprise a proximal threaded stud integral with of the portion of the anchoring member intended for gripping the bone, or may be of "polyaxial" type, i.e. comprise a proximal threaded stud articulated with respect to that portion intended for gripping the bone.

A polyaxial anchoring member known comprises, for the purpose of articulation of said proximal stud, a spherical head integral with this stud, received in a corresponding spherical cavity. In several types of existing anchoring members, this cavity is formed by providing a spherical semi-cavity in the proximal zone of the anchoring member and a portion of spherical cavity in the internal zone of a shouldered nut which is screwed on this proximal

zone, this nut and this proximal zone locking said spherical head therebetween.

The shortcoming of the anchoring members known is that, after implantation, they protrude high above the bony zone whereon they are placed. These significant heights, if they are admissible for treating certain locations of a vertebral spine, in particular the lumbar vertebrae or the lumbar sacral articulation, may prove disturbing, let alone unacceptable, for treating other segments of a vertebral spine, in particular dorsal vertebrae, or for implanting particular equipment such as equipment placed laterally on the vertebrae to be treated.

A polyaxial anchoring member known comprises moreover a proximal gripping portion enabling of hold said member when clamping the nut. This proximal gripping portion, notably in the form of a hexagonal zone intended for co-operating with a corresponding holding key on known equipment, contributes to confer significant height to the anchoring member.

The purpose of the present invention is to remedy the shortcomings resulting from the height of a polyaxial anchoring member above the bony zone whereon this anchoring member is placed.

The vertebral osteosynthesis equipment affected comprises bony anchoring members, such as pedicular screws and/or lamar hooks, one or two linking rods, intended to be connected to these anchoring members and to be attached to the vertebrae by dint thereof, parts for connecting this(these) linking rod(s) to these anchoring members, and clamping means, such as nuts, for locking the linking rod(s) in said connecting parts ; at least one of said bony anchoring members is of the "polyaxial" type, i.e. comprises one proximal stud articulated with respect to a body intended for gripping a vertebra.

According to the invention,

- the proximal stud of said polyaxial anchoring member exhibits an articulation head in the form of a spherical cap ; and

- said body of this anchoring member comprises a cavity intended for accommodating this articulation head and a wall surrounding this cavity, this wall being crimped around said articulation head and shaped in order to provide a proximal form, at least partially hemispherical.

The anchoring member according to the invention does not comprise therefore any spherical head no shouldered nut for capturing this spherical head but an articulation head in the form of a spherical cap retained in an articulation cavity by a wall crimped around said cavity.

The height of the portion of the anchoring member according to the invention which protrudes from a vertebra after implantation is, consequently, quite notably reduced with respect to the height of the anchoring members according to prior techniques.

The method according to the invention comprises the steps consisting in :

- providing, on the part intended for the proximal stud of said polyaxial anchoring member, an articulation head in the form of a spherical cap ;

- providing a cavity in the proximal zone of the part intended for said body of said anchoring member polyaxial, and, around this cavity, a wall which may be crimped ;

- engaging said articulation head into said cavity, and

- crimping said wall around said articulation head so that this wall exhibits a proximal form at least partially hemispherical.

Said body comprises advantageously a proximal gripping portion enabling to hold said body when tightening said clamping means, this proximal gripping portion being formed of a collar exhibiting several radial notches, notably four notches at 90° to one another.

This proximal gripping portion exhibits a height which is noticeably smaller than that of a hexagonal zone according to the prior technique, and thus contributes to limiting the height of the anchoring member.

Preferably, the equipment according to the invention comprises at least one connecting part exhibiting a rounded section intended for surrounding a linking rod and two parallel drilled wings, these wings being intended for engaging onto said proximal stud and for being clamped, using said clamping means, against a bearing surface contained in said polyaxial anchoring member ; the distal wing of this connecting part exhibits moreover a distal cavity in the form of a spherical cap, of greater diameter than that of said

crimped wall, the connecting part being intended for resting against this crimped wall at of this cavity.

This cavity, its diameter being greater than that of said crimped wall, enables to lock said proximal stud in an angular position with respect to the body of the anchoring member.

Advantageously, said clamping means is a nut and the proximal branch of this connecting part comprises a proximal cavity wherein a corresponding zone exhibited by this nut is intended for engaging.

After assembly, the nut is thus partially effaced in this cavity, which contributes further to reducing the height of the equipment above a vertebra, after implantation.

Preferably, this cavity, and said corresponding zone of the nut, are conical in shape, in order to increase the bearing surface of the nut against the connecting part.

The proximal stud and said connecting part may comprise means enabling to immobilise the proximal stud in rotation when the connecting part is engaged on this proximal stud. These means may in particular be at least one flat surface provided on the proximal stud and at least one flat surface provided on the connecting part, whereas these flats surfaces are immediately close to one another when the connecting part is engaged on the proximal stud.

The invention will be better understood, and other characteristics and advantages thereof will appear, with reference to the appended schematic drawing, representing, for non-limiting exemplification purposes, a preferred embodiment of parts included in the equipment affected.

Figure 1 is a partial view, before assembly, of a polyaxial pedicular screw, of a linking rod, represented as seen from its end, and, as a cross sectional view, of a connecting part and of a nut enabling to assemble a linking rod to this screw ; and

Figure 2 is a view of these parts similar to Figure 1, after assembly.

Figure 1 represents a polyaxial pedicular screw 1, a linking rod 2 for connecting several of these screws 1, a part 3 for connecting this rod 2 to one

of these screws 1 and a nut 4 enabling to assemble the linking rod 2 to this screw 1.

The screw 1 comprises a proximal threaded stud 5 and a threaded distal screw body 6. The stud 5 is intended for receiving the part 3 engaged thereon and the nut 4 screwed thereon while the body 6 is intended for insertion into the pedicula of a vertebra.

The stud 5 exhibits a threaded cylindrical portion 10 and an enlarged distal head 11.

The portion 10 exhibits a zone 15 of reduced diameter, enabling to break its proximal portion after placing and clamping the nut 4, as appears by comparison of Figures 1 and 2.

This portion 10 also comprises two lateral flat surfaces 14.

The head 11 exhibits a diameter of the order of double the diameter of the portion 10 and looks like a spherical cap. This head 11 is intended for engaging in a proximal cavity 16 delineated by the proximal zone of the body 6 and for retention in this cavity 16 by crimping a proximal wall 17 exhibited by this body 6 around the cavity 16. After crimping, the wall 17 is shaped in order to have a proximal hemispherical form. As shown on Figure 1, the dimensions of the cavity 16 and of the aperture delineated by the wall 17 after crimping to let through the stud 5 are such that a multidirectional backlash of this stud 5 with respect to the body 6 is possible.

The body 6 also comprises a proximal collar 18, intended for abutting against the pedicula of the vertebra treated. This collar 18 exhibits several radial notches 19, notably four notches at 90° to one another, for holding the body 6 in rotation when clamping the nut 4.

The linking rod 2 is cylindrical and exhibits such rigidity as to hold several vertebrae with respect to one another. This rod 2 is however deformable in order to be shaped relative to the correction of the rachis to be performed.

The connecting part 3 comprises a rounded section 20 intended for surrounding the linking rod 2 and two parallel lateral wings 21 drilled with holes for engaging the part 3 on the stud 5. These wings 21 are distant mutually so that, in a distant position, the rod 2 may be inserted and may slide in the portion 20, and that, in a close position provided by the clamping of the nut 4,

they clamp the portion 20 around the rod 2, immobilising the latter with respect to the part 3.

As shown on Figures, the proximal wing 21 exhibits a proximal pan 25 whereof the shape is suitable for the nut 4 to rest on, the latter exhibiting a corresponding conical zone. The distal wing 21 exhibits, for its own part, a distal cavity 28 in the form of a spherical cap, whereof the diameter is greater than that of the wall 17, and a hole 29. This hole 29 comprises two flat surfaces whereof the distance is slightly greater than that between both flat surfaces 14, so that when the stud 5 is engaged in this hole, the stud 5 is immobilised in rotation with respect to the part 3.

In practice, the number of screws 1 necessary to the treatment to be performed is placed in the pediculae of the vertebrae affected, then the connecting parts 3, with the rod 2 engaged in the portions 20, are placed on the studs 5. The nuts 4 are then clamped to immobilise the rod 2 with respect to the parts 3 and the proximal portions of the studs 5 are cut off.

As shown by the foregoing, the invention provides a vertebral osteosynthesis equipment whereof the anchoring members only protrude marginally beyond the vertebrae wherein they are implanted and are, consequently, only little sensitive under the skin, or even not sensitive at all. Such equipment may thus be used for treating not only lumbar vertebrae or the lumbar sacral articulation, but also dorsal vertebrae or for implanting equipment placed laterally on the vertebrae to be treated.

It is obvious that the invention is not limited to the embodiment described above for exemplification purposes but that it extends to all the embodiments covered by the claims appended therein.

CLAIMS

1 – Vertebral osteosynthesis equipment, including bony anchoring members, such as pedicular screws (1) and/or lamar hooks, one or two linking rods (2), intended to be connected to these anchoring members and to be attached to the vertebrae by dint thereof, parts (3) for connecting this(these) linking rod(s) (2) to these anchoring members, and clamping means, such as nuts (4), for locking the linking rod(s) (2) in said connecting parts (3) ; at least one anchoring member is of the "polyaxial" type, i.e. comprises one proximal stud (5) articulated with respect to a body (6) intended for gripping a vertebra ;

equipment characterized in that :

- the proximal stud (5) of said polyaxial anchoring member exhibits an articulation head (11) in the form of a spherical cap ; and

- said body (6) of this anchoring member comprises a cavity (16) intended for accommodating this articulation head (11) and a wall (17) surrounding this cavity (16), this wall (17) being crimped around said articulation head (11) and shaped in order to provide a proximal form, at least partially hemispherical.

2 – Vertebral osteosynthesis equipment according to claim 1, characterized in that said body (6) comprises a proximal gripping portion enabling to hold said body (6) when tightening said clamping means, this proximal gripping portion being formed of a collar (18) exhibiting several radial notches (19).

3 – Vertebral osteosynthesis equipment according to claim 2, characterized in that said collar (18) exhibits four notches (19) at 90° to one another.

4 – Vertebral osteosynthesis equipment according to anyone of claims 1 to 3, characterized in that comprises at least one connecting part (3) exhibiting a rounded section (20) intended for surrounding a linking rod (2) and two parallel drilled wings (21), these wings (21) being intended for engaging onto said proximal stud (5) and for being clamped, using said clamping means (4), against a bearing surface (17) contained in said polyaxial anchoring member ; the distal wing (21) of this connecting part (3) exhibits a distal cavity (28) in the form of a spherical cap, of greater diameter than that of said crimped wall (17),

the connecting part (3) being intended for resting against this crimped wall (17) at of this cavity (28).

5 – Vertebral osteosynthesis equipment according to claim 4, characterized in that said clamping means is a nut (4) and the proximal branch (21) of this connecting part (3) comprises a proximal cavity (25) wherein a corresponding zone exhibited by this nut (4) is intended for engaging.

6 – Vertebral osteosynthesis equipment according to claim 5, characterized in that said cavity (25) and said corresponding zone of the nut (4) are conical in shape.

7 – Vertebral osteosynthesis equipment according to anyone of claims 1 to 6, characterized in that the stud (5) exhibits a zone (15) of reduced diameter, enabling to break its proximal portion after placing and clamping the nut (4).

8 – Vertebral osteosynthesis equipment according to anyone of claims 1 to 6, characterized in that the proximal stud (5) and said connecting part (3) comprise means (14, 29) enabling to immobilise the proximal stud (5) in rotation when the connecting part (3) is engaged on this proximal stud (5)

9 – Vertebral osteosynthesis equipment according to claim 8, characterized in that said means comprise at least one flat surface (14) provided on the proximal stud (5) and at least one flat surface provided on the connecting part (3), whereas these flats surfaces are immediately close to one another when the connecting part (3) is engaged on the proximal stud (5).

10 – Method for manufacturing the polyaxial anchoring member according to anyone of claims 1 to 9, characterized in that it comprises the steps consisting in :

- providing, on the part intended for the proximal stud (5) of said polyaxial anchoring member, an articulation head (11) in the form of a spherical cap ;
- providing a cavity (16) in the proximal zone of the part intended for said body (6) of said anchoring member polyaxial, and, around this cavity (16), a wall (17) which may be crimped ;
- engaging said articulation head (11) into said cavity (16), and
- crimping said wall (17) around said articulation head (11) so that this wall (17) exhibits a proximal form at least partially hemispherical.

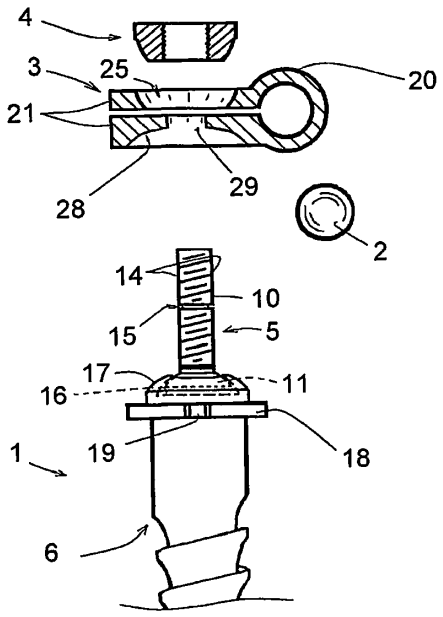


FIG. 1

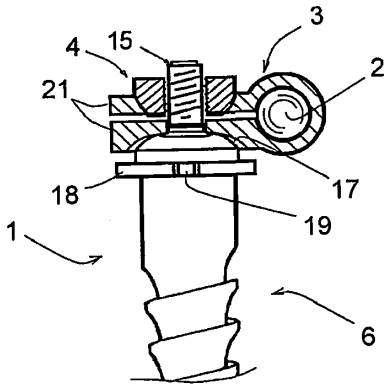


FIG. 2

INTERNATIONAL SEARCH REPORT

Inter nal Application No
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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)
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C. DOCUMENTS CONSIDERED TO BE RELEVANT

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☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
17 November 2004	29/11/2004

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Nistor, L

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(71) Applicant *(for all designated States except US)*: **MEDICREA TECHNOLOGIES** [FR/FR]; ZI Chef de Baie, F-17000 La Rochelle (FR).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **CLEMENT, Jean-Luc** [FR/FR]; 230 Chemin de Montfort, F-06480 La Colle Sur Loup (FR). **FIERE, Vincent** [FR/FR]; 50 Boulevard des Belges, F-69006 Lyon (FR). **TAYLOR, Jean** [FR/FR]; Villa Poralto, 25 Avenue de Poralto, F-06400 Cannes (FR). **ADAM, Yves** [FR/FR]; 4 route de Saint Louet, F-14280 Authie (FR). **VILLARET, Bernard** [FR/FR]; 20 rue de Salles, F-17220 Croix-Chapeau (FR).

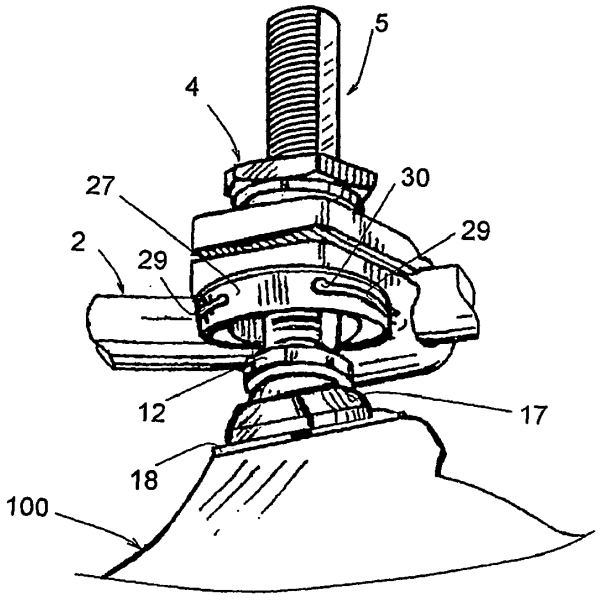
(74) Common Representative: **MEDICREA TECHNOLOGIES**; ZI Chef de Baie, F-17000 La Rochelle (FR).

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[Continued on next page]

(54) Title: VERTEBRAL OSTEOSYNTHESIS EQUIPMENT



(57) Abstract: This equipment includes bony anchoring members, one or two linking rods (2) and parts (3) for connecting this(these) rod(s) (2) to these anchoring members ; at least one of the anchoring members is of the "polyaxial" type, i.e. it comprises a proximal stud (5) articulated with respect to a base portion (6) ; clamping means (4) enable assembly of the connecting part (3) on the anchoring member. According to the invention, the proximal stud (5) comprises a surface (12, 32) forming an axial stop, against which the connecting part (3) to be installed on the polyaxial anchoring member is intended for resting, and said clamping means (4) enable to clamp this connecting part (3) against this surface (12, 32), said surface (12, 32) being positioned so that the connecting part (3), when it is clamped against this surface (12, 32), is not clamped against the base portion (6) so that there remains, after clamping, a possibility of articulated backlash of the proximal stud (5) with respect to said base portion (6).

WO 2005/000137 A1

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 823 of 2152

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

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VERTEBRAL OSTEOSYNTHESIS EQUIPMENT

This patent application claims the priorities to :

- FR 03 07776, filed on June 27, 2003 ;
- US Provisional application N° 60/490,519, filed on July 29, 2003 ;
- FR 04 00747, filed on January 27, 2004 ;
- FR 04 03413, filed on April 1st, 2004.

The present invention relates to a vertebral osteosynthesis equipment.

A vertebral osteosynthesis equipment generally includes bony anchoring members, such as pedicular screws and/or hooks, one or two linking rods, intended to be connected to these anchoring members and to be attached to the vertebrae by dint thereof, and parts for connecting this(these) linking rod(s) to these anchoring members. The equipment may also comprise length-adjustable crossbeams, which link transversally two parallel linking rods in order to hold said rods with respect to one another.

In an existing type of equipment, at least one anchoring member is "polyaxial", i.e. comprises a base portion enabling bony anchoring thereof and a proximal threaded stud, articulated with respect to that base portion, whereon a nut may be screwed. Each connecting part may comprise a rounded section intended for surrounding a linking rod and two parallel drilled wings, these wings being intended for engaging onto said proximal threaded stud and for being clamped, by means of that nut, against a bearing surface provided on the base portion, said operation enabling to clamp said rounded section around the linking rod and thereby ensuring longitudinal immobilisation of this rod with respect to the anchoring member.

The existing vertebral osteosynthesis equipment is designed for immobilising two vertebrae with respect to one another, for eliminating any relative movement of these vertebrae, liable to be painful, or to restore the adequate position of a vertebra with respect to the other. To provide such immobilisation, such equipment is designed for ensuring perfectly rigid assembly of the linking rods with the anchoring members.

Such rigid assembly may however not prove desirable in all cases. It leads in particular to significant loads being exerted at anchoring bony zones of said anchoring members, as well as to increased loads at the vertebral

articulations situated on both sides of the vertebral segment(s) treated, which may lead to precocious degenerescences of these articulations.

It is known by the document US 5,735,851 to provide a polyaxial anchoring member whereof the proximal threaded stud may accommodate one or several concave spacers screwed thereon, these spacers being intended for resting against the convex head of the base portion of the anchoring member. The function of these spacers, besides adjusting the height of the connecting part, is to generate an additional clamping load on the head of the base portion in order to enhance the immobilisation of the stud with respect to that base portion after clamping.

The anchoring member according to this prior document realises consequently a rigid assembly of the stud with respect to the base portion, which does not enable to remedy the shortcomings aforementioned.

The document FR 2 697 742 describes a monoaxial anchoring member including a washer made of shock-absorbing material placed between a bearing surface formed by the base portion and the connecting part. The clamping nut immobilises however this connecting part with respect to the proximal threaded stud of the anchoring member, and said washer only enables very limited movements of the connecting part with respect to the anchoring member.

The equipment according to this prior document also realises consequently a rigid or quasi-rigid assembly which does not enable to remedy the shortcomings aforementioned.

The purpose of the present invention is precisely to remedy these shortcomings.

The equipment affected comprises, in itself, bony anchoring members, such as pedicular screws and/or hooks, one or two linking rods, intended to be connected to these anchoring members, and parts for connecting this(these) rod(s) to these anchoring members ; at least one of the anchoring members is of the "polyaxial" type, i.e. it comprises a proximal stud articulated with respect to a base portion enabling bony anchoring ; clamping means enable assembly of the connecting part on the anchoring member.

According to the invention, the proximal stud comprises a surface forming an axial stop, against which the connecting part to be installed on the polyaxial anchoring member is intended for resting, and said clamping means enable to clamp this connecting part against this surface, said surface being positioned so that the connecting part, when it is clamped against this surface, is not clamped against the base portion so that there remains, after clamping, a possibility of articulated backlash of the proximal stud with respect to said base portion.

Thus, in the equipment according to the invention, said connecting part is not immobilised with respect to the anchoring member but may move slightly, relative thereto, in order to allow limited movements of the vertebrae. The stresses exerted on the anchoring bony zones of the anchoring member are thus notably reduced, as well as the risks of over-stresses at the vertebral articulations situated on both sides of the vertebral segment treated.

Preferably, at least one polyaxial anchoring member comprises at least one part or portion of a part with elastically deformable structure, interposed, after assembly, between said connecting part and a bearing surface.

This part or portion of a part with elastically deformable structure enables to dampen the movement of the connecting part, and hence of the linking rod, with respect to said base portion. Thanks to the axial stop surface shown by the stud, the clamping of the connecting part is carried out independent of any clamping of said part or portion of a part, which is elastically deformable, and hence does not interfere therewith.

Said part or portion of a part with elastically deformable structure may be formed in order to dampen the movement of the proximal stud over the whole backlash of this stud, notably if it is composed of a compressible material, or may be formed to provide this dampening effect only in the extreme positions of such backlash.

According to a possible embodiment of the invention in the latter case, said part or portion of a part with elastically deformable structure is composed of a circular wall attached to the connecting part, this wall including at least one transversal slot running therethrough, provided on one side of this wall according to a direction substantially perpendicular to that occupied by a

linking rod when this rod is engaged in the connecting part, this slot enabling to reduce the thickness of this circular wall when a load is exerted on this wall in the axial direction, on the side where the slot is.

The proximal stud and said surface forming an axial stop may be formed in order to enable the adjustment of the axial position of this surface with respect to the proximal stud, and this surface may be formed to clamp said part or portion of a part with elastically deformable structure between said surface and said bearing surface against which this part or portion of a part rests.

Said surface forming an axial stop enables then, according to the clamping performed, to adjust the dampening effect produced by said part or portion of a part with elastically deformable structure.

According to an embodiment of the invention in such a case, the proximal stud is threaded and said surface forming an axial stop is in the form of a part with a tapered hole which may be screwed on this stud.

Said bearing surface against which the part or portion of a part with elastically deformable structure rests, may be a surface provided on said base portion or the vertebral bone itself.

The walls of the proximal stud and of the anchoring member which slip against one another during the backlash of this stud may include a smooth and resistant coating layer, capable of resisting a very large number of slipping movements of these walls against one another, such as a ceramic or titanium nitride coating layer.

When the articulation of this proximal stud consists of faces in the form of a sphere or of portions of a sphere slipping against one another, advantageously, these faces exhibit a diameter which is significantly greater than that of the proximal stud, notably at least double the diameter of this stud, in order to increase the contact surface of its faces with one another.

The frictions are thus exerted on enlarged surfaces, thereby reducing the risk of wear of said faces.

Besides, at least one linking rod of the equipment may comprise :

- a portion of rod including a part with elastically deformable structure and an articulated stud,

- another portion of rod including a bearing zone against this part with elastically deformable structure, and

- clamping means to clamp this bearing zone against this part with elastically deformable structure.

The connecting part comprises preferably a rounded section intended for surrounding a linking rod and two parallel drilled wings, intended for engaging onto said proximal stud and for being clamped towards one another in order to provide the clamping of said rounded section around a linking rod.

The invention will be better understood, and other characteristics and advantages thereof will appear, with reference to the appended schematic drawing, representing, for non-limiting exemplification purposes, two embodiments of parts included in the equipment affected.

Figure 1 is one of these parts, before assembly, according to an embodiment ;

Figure 2 is a view of these parts similar to Figure 1, after assembly ;

Figure 3 is a view of these parts similar to Figure 2, according to a direction perpendicular to that according to this figure 2, in a first position ;

Figure 4 is a view of these parts similar to Figure 3, in a second position ;

Figure 5 is a view of these parts similar to Figure 3, in a third position ;

Figure 6 is a perspective view of the same parts, after placing the screw in a vertebra and before final clamping ;

Figure 7 is a view of these parts similar to Figure 6, after final clamping ;

Figure 8 is a view of said parts, before assembly, according to the second embodiment ;

Figure 9 is a view of said parts similar to Figure 8, after assembly ;

Figure 10 is a partial sectional view of a linking rod, before assembly, and

Figure 11 is a view similar to Figure 10, after assembly.

Figure 1 represents a polyaxial pedicular screw 1, a rod 2 linking several of these screws 1, a part 3 connecting this rod 2 to one of these screws 1 and a nut 4 enabling to assemble the linking rod 2 to this screw 1.

The screw 1 comprises a proximal threaded stud 5 and a threaded base portion 6. The stud 5 is intended for receiving the part 3 engaged thereon and

the nut 4 screwed thereon while the body 6 is intended for insertion in the pedicula 100 of a vertebra, as shown on Figures 6 and 7.

The stud 5 exhibits a threaded cylindrical portion 10, an enlarged distal head 11 and a collar 12 forming a stopping surface.

The portion 10 exhibits a zone 15 of reduced diameter, enabling to break its proximal portion after placing and clamping the nut 4, as appears by comparison of Figures 2 and 3.

The head 11 exhibits a diameter double the diameter of the portion 10 and looks like a spherical cap. This head 11 is intended for engaging in a proximal cavity 16 delineated by the proximal zone of the body 6 and for retention in this cavity 16 by crimping a proximal wall 17 exhibited by this body 6. After crimping, the wall 17 is shaped in order to show a hemispherical proximal form. As shown on Figure 1, the dimensions of the cavity 16 and of the aperture delineated by the wall 17 after crimping to let through the stud 5 are such that a multidirectional backlash of this stud 5 with respect to the body 6 is possible.

The body 6 also comprises a proximal collar 18, intended for abutting against the pedicula 100. This collar 18 exhibits several radial notches 19, notably four notches at 90° to one another, for holding the body 6 in rotation when clamping the nut 4.

The linking rod 2 is cylindrical and exhibits such rigidity as to hold several vertebrae with respect to one another. This rod 2 is however deformable in order to be shaped relative to the correction of the rachis to be performed.

The connecting part 3 comprises a rounded section 20 intended for surrounding the linking rod 2 and two parallel lateral wings 21 drilled with holes for engaging the part 3 on the stud 5. These wings 21 are distant mutually so that, in a distant position, the rod 2 may be inserted and may slide in the portion 20, and that, in a close position provided by the clamping of the nut 4, they clamp the portion 20 around the rod 2, immobilising the latter with respect to the part 3.

As shown on Figures 1 and 2, the proximal wing 21 exhibits a proximal pan 25 whereof the shape is suitable for the nut 4 to rest on, while the distal

wing 21 comprises a circular cavity 26 enabling the engagement of this wing on the collar 12.

This distal wing 21 comprises moreover a circular wall 27 integral therewith. The height of this wall 27 is smaller than that of the wall 17, and delineates an internal concave spherical face 28 of greater diameter than that of this wall 17.

Moreover, two transversal slots 29 are provided in this wall 27, on two opposite sides of the wall 27, and according to a direction substantially perpendicular to that occupied by the linking rod 2 when this rod is engaged in the rounded section 20. Each slot 29 extends angularly over approximately 120° of the wall 27 and terminated by a widened zone 30 in the form of a circle.

As can be understood with reference to Figure 5, the distal portions of the wall 27 delineated by the slots 29 have, at these rounded zones 30, reduced height, so that these portions may flex at these zones 30, enabling thereby reduction in height of the wall 27.

In practice, the number of screws 1 necessary to the treatment to be performed is placed in the pediculae 100 of the vertebrae affected, then the connecting parts 3, with the rod 2 engaged in the portions 20, are placed on the studs 5, until engagement of the collars 12 in the cavities 26. The nuts 4 are then clamped to immobilise the rod 2 with respect to the parts 3 and the proximal portions of the studs 5 are cut off.

In this clamping position of each part 3 against the corresponding collar 12, the wall 27 only rests against the wall 17 by a very small surface, as shown on Figure 2. This clamping preserves the possibility of articulated backlash of the proximal stud 5 with respect to the body of screw 6, this backlash being free as long as the wall 27 has not abutted against the body 6 (cf. figure 4) then being possible with a deformation of the wall 27 beyond, thereby dampening the movement of the stud 5 in the maximal angles of backlash of this stud (cf. figure 5). The possible limit of the backlash of the latter corresponds to the contact of the edges of the wall 27 delineating the slots 29.

Thanks to the diameter of its face 28, greater than the diameter of the wall 17, the wall 27 does not oppose the backlash of the stud 5.

The slipping zones of the head 11 against the wall 17 and of the face 28 against the wall 17 may include a smooth and resistant coating layer, capable of resisting a very large number of slipping movements of these walls against one another, such as a ceramic or titanium nitride coating layer.

Figures 8 and 9 represent parts 2 to 4 identical or similar to those described with reference to Figures 1 and 2, the parts proving identical or similar being designated by the same numeric references.

In this case, the part 3 is deprived of the wall 27, and the equipment comprises, for at least one anchoring member 1, a part 31 in the form of a washer made of material with elastically deformable structure, notably silicon or PMMA, and a washer 32, notably metallic, with a tapered bore to be screwed on the stud 5 until the part 31 is clamped between said washer and the portion 6 of the screw.

The part 31 delineates a cavity as a portion of a sphere, of dimensions adjusted to the external face of the wall 17.

The washer 32 comprises an upper portion adjusted to the cavity 26 and a lower widened portion, including a peripheral rim which may be engaged on the upper portion of the washer 31, as shown on Figure 9.

This washer 32 may be screwed on the stud 5 until the part 31 is clamped relative to a given dampening effect requested for the backlash of the stud 5. Once such clamping has been provided, the part 3, with the rod 2 engaged therein, is placed on the stud 5, then the nut 4 is clamped to immobilise the rod 2 with respect to the part 3.

Figures 10 and 11 show a linking rod 2 of the equipment which comprises :

- a portion of rod 2a including a part 41 with elastically deformable structure and a articulated threaded stud 5, this articulation being identical to that described previously,

- another portion of rod 2b, including a bearing zone 42 against this part 41 and a tapered bore 43 for screwing this portion 2b on the stud 5 in order to clamp the bearing zone 42 against the part 41.

The linking rod 2 may thus also present a certain degree of elastic flexibility.

As shown by the foregoing, the invention provides a vertebral osteosynthesis equipment enabling certain clearance of the connecting part 3, and therefore of the linking rod 2, with respect to the base anchoring portion 6 to the vertebra, to allow limited movements of the vertebrae treated. The stresses exerted on the anchoring bony zones of the anchoring member are thus notably reduced, as well as the risks of over-stresses at vertebral articulations situated on both sides of the vertebral segment treated.

It is obvious that the invention is not limited to the embodiment described above for exemplification purposes but it extends to all the embodiments covered by the claims appended therein. Consequently, one would not depart from the framework of the invention by replacing the wall 27 with a washer of elastic material or with an elastic structure, for instance in the form of a spring.

CLAIMS

1 – Vertebral osteosynthesis equipment, including bony anchoring members, such as pedicular screws (1) and/or hooks, one or two linking rods (2), intended to be connected to these anchoring members, and parts (3) for connecting this(these) rod(s) (2) to these anchoring members ; at least one of the anchoring members is of the "polyaxial" type, i.e. it comprises a proximal stud (5) articulated with respect to a base portion (6) enabling bony anchoring ; clamping means (4) enable assembly of the connecting part (3) on the anchoring member ;

equipment characterized in that the proximal stud (5) comprises a surface (12, 32) forming an axial stop, against which the connecting part (3) to be installed on the polyaxial anchoring member is intended for resting, and in that said clamping means (4) enable to clamp this connecting part (3) against this surface (12, 32), said surface (12, 32) being positioned so that the connecting part (3), when it is clamped against this surface (12, 32), is not clamped against the base portion (6) so that there remains, after clamping, a possibility of articulated backlash of the proximal stud (5) with respect to said base portion (6).

2 – Vertebral osteosynthesis equipment according to claim 1, characterized in that at least one polyaxial anchoring member comprises at least one part or portion of a part (31) with elastically deformable structure, interposed, after assembly, between said connecting part (3) and a bearing surface (17, 18).

3 – Vertebral osteosynthesis equipment according to claim 2, characterized in that said part or portion of a part (31) with elastically deformable structure is formed in order to dampen the movement of the proximal stud (5) over the whole backlash of this stud, and is notably composed of a compressible material.

4 – Vertebral osteosynthesis equipment according to claim 2, characterized in that said part or portion of a part (31) with elastically deformable structure is formed in order to provide this dampening effect only in the extreme positions of the backlash of the proximal stud (5).

5 – Vertebral osteosynthesis equipment according to any of claims 1 to 4, characterized in that the proximal stud (5) and said surface (12, 32) forming an axial stop are formed in order to enable the adjustment of the axial position of this surface (12, 32) with respect to the proximal stud (5), and in that this surface (12, 32) is formed to clamp said part or portion of a part (31) with elastically deformable structure between said surface (12, 32) and said bearing surface (17, 18) against which this part or portion of a part rests.

6 – Vertebral osteosynthesis equipment according to claim 5, characterized in that the proximal stud (5) is threaded and said surface (32) forming an axial stop is in the form of a part with a tapered hole which may be screwed on this stud (5).

7 – Vertebral osteosynthesis equipment according to any of claims 2 to 6, characterized in that said bearing surface (17, 18) against which the part or portion of a part (31) with elastically deformable structure rests, may be a surface (17, 18) provided on said base portion (6) or the vertebral bone itself.

8 – Vertebral osteosynthesis equipment according to any of claims 1 to 7, characterized in that the walls (11, 17) of the proximal stud (5) and of the base portion (6) which slip against one another during the backlash of this stud (5) include a smooth and resistant coating layer, capable of resisting a very large number of slipping movements of these walls against one another, such as a ceramic or titanium nitride coating layer.

9 – Vertebral osteosynthesis equipment according to any of claims 1 to 8, characterized in that the articulation of the proximal stud (5) consists of faces (11, 17) in the form of a sphere or of portions of a sphere slipping against one another, and in that these faces (11, 17) exhibit a diameter which is significantly greater than that of the proximal stud (5), notably at least double the diameter of this stud.

10 – Vertebral osteosynthesis equipment according to any of claims 1 to 9, characterized in that at least one linking rod (2) of the equipment comprises :

- a portion (2a) of rod including a part (41) with elastically deformable structure and an articulated stud (5),

- another portion (2b) of rod including a bearing zone (42) against this part (41) with elastically deformable structure, and

- clamping means (43) to clamp this bearing zone (42) against this part (41) with elastically deformable structure.

11 – Vertebral osteosynthesis equipment according to any of claims 1 to 10, characterized in that the connecting part (3) comprises preferably a rounded section (20) intended for surrounding a linking rod (2) and two parallel drilled wings (21), intended for engaging onto said proximal stud (5) and for being clamped towards one another in order to provide the clamping of said rounded section (20) around a linking rod (2).

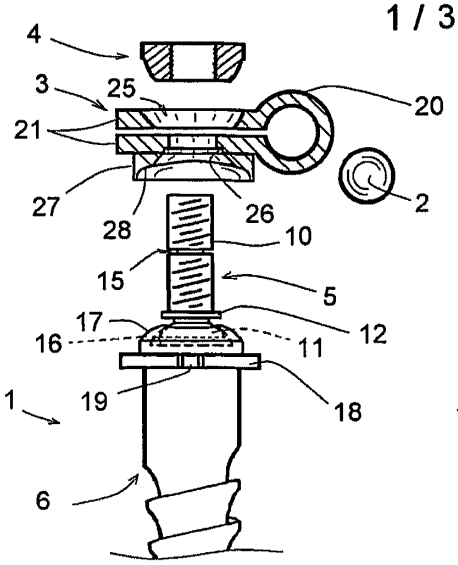


FIG. 1

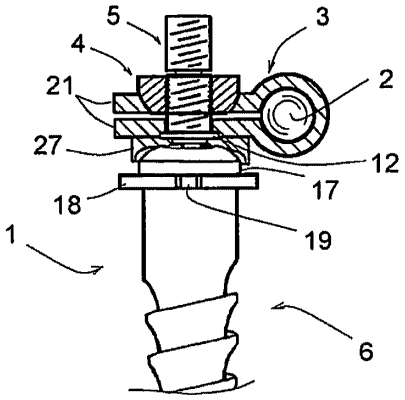


FIG. 2

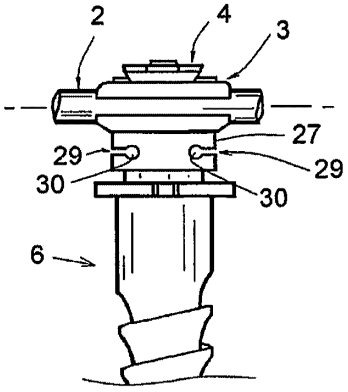


FIG. 3

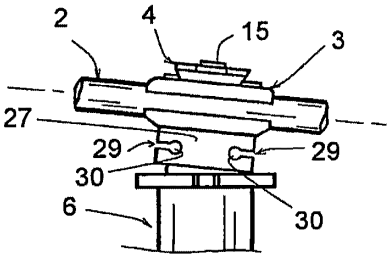


FIG. 4

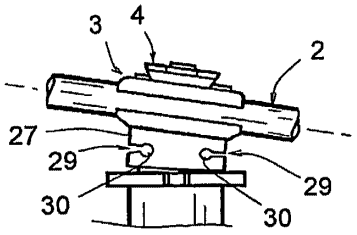


FIG. 5

FIG. 6

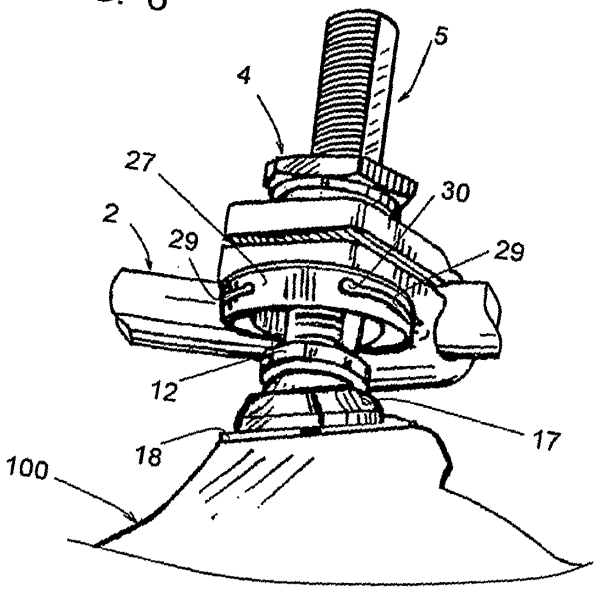
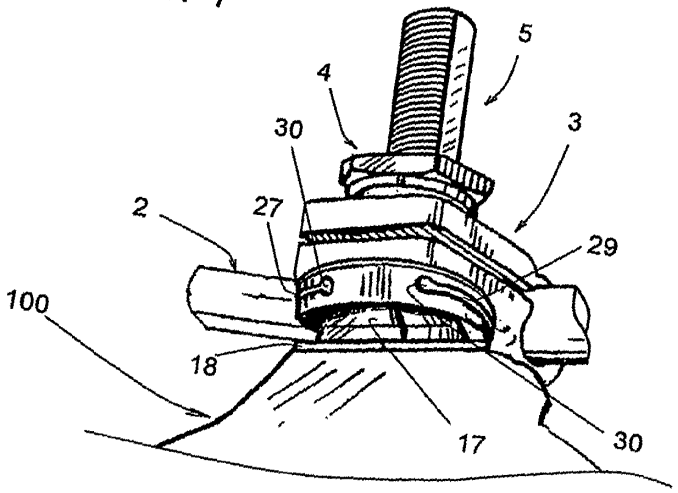
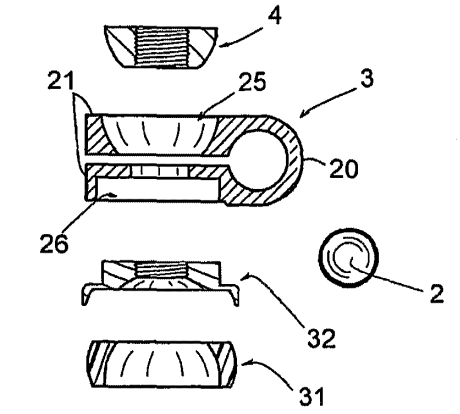


FIG. 7





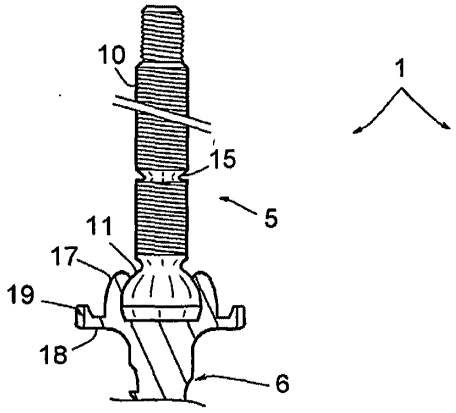


FIG. 8

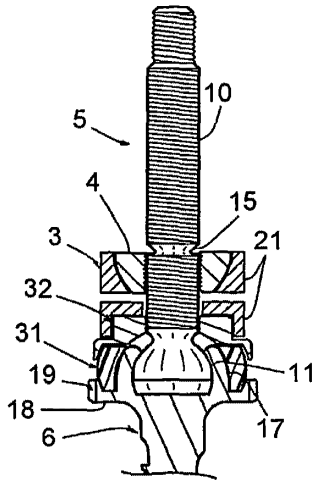


FIG. 9

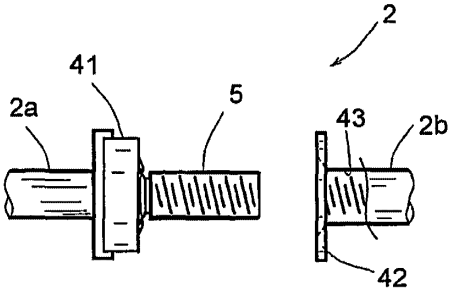


FIG. 10

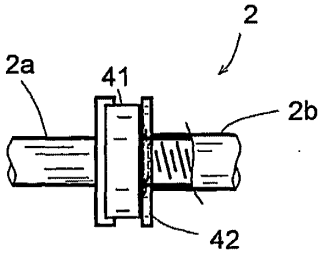


FIG. 11

INTERNATIONAL SEARCH REPORT

In tional Application No
PCT/IB2004/002463

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	WO 98/55038 A (TAYLOR J.) 10 December 1998 (1998-12-10) figures 1-3	1
A	US 5 735 851 A (ERRICO J.P.ET AL) 7 April 1998 (1998-04-07) cited in the application figure 10a	1
A	FR 2 697 742 A (BIOMAT) 13 May 1994 (1994-05-13) cited in the application page 11, line 14 - page 12, line 9; figure 1	1

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

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Date of the actual completion of the international search	Date of mailing of the international search report
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INTERNATIONAL SEARCH REPORT

Ir ional Application No
PCT/IB2004/002463

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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A	EP 0 242 708 A (HARMS J. & BIEDERMANN L.) 28 October 1987 (1987-10-28) column 3, line 6 - line 10; figures 1,3 column 3, line 55 - column 44, line 15	1
A	WO 91/06254 A (BIEDERMANN L. & HARMS J.) 16 May 1991 (1991-05-16) page 7, line 2 - line 10; figures 5-8 page 7, line 37 - page 8, line 13	1

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INTERNATIONAL SEARCH REPORT

Information on patent family members

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Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 842 of 2152

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(71) Déposant *(pour tous les États désignés sauf US)* : **SPINEVISION** [FR/FR]; 180, avenue Daumesnil, F-75012 Paris (FR).

(72) Inventeurs; et

(75) Inventeurs/Déposants *(pour US seulement)* : **BETTE, Stéphane** [FR/FR]; 2bis, impasse Morlet, F-75011 Paris (FR). **PETIT, Dominique** [FR/FR]; 2, rue des Peupliers, F-62180 Verton (FR). **THIBOUT, Didier** [FR/FR]; 13, avenue du Père Lachaise, F-75020 Paris (FR). **VANACKER, Gérard** [FR/FR]; 52, avenue François Adam, F-94100 Saint-Maur (FR).

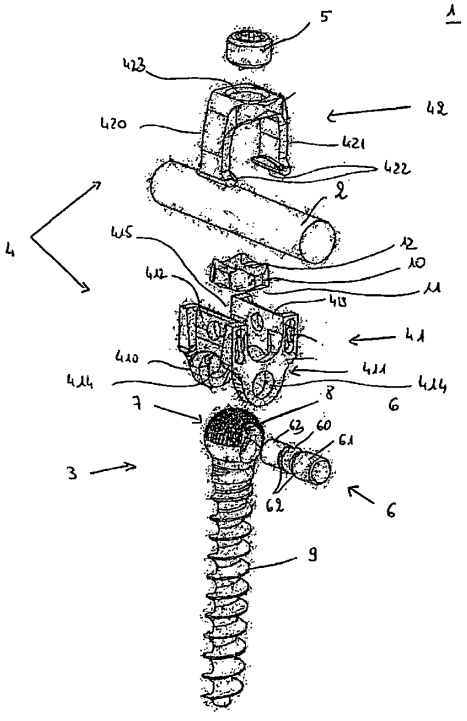
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[Suite sur la page suivante]

(54) Title: CONNECTING DEVICE FOR SPINAL OSTEOSYNTHESIS

(54) Titre : DISPOSITIF DE CONNEXION POUR OSTEOSYNTHESE RACHIDIENNE



(57) Abstract: The invention relates to a connecting device (1) for spinal osteosynthesis, comprising an osseous anchoring means (3), a connector (4) that accommodates a joining shaft (2) and is fixed to one end of the anchoring means (3), and a tightening means (5) for immobilizing the joining shaft (2). The inventive connecting device (1) is characterized in that the connector (4) is fixed to the anchoring means (3) with the aid of a pin (6) that penetrates the anchoring means (3) and embodies a pivot joint. Furthermore, said device (1) comprises a means for stabilizing the connector relative to the anchoring means when the device is implanted in the patient, said stabilizing means being located on the plane encompassing the shaft and the anchoring means.

(57) Abrégé : La présente invention se rapporte à un dispositif de connexion (1) pour l'ostéosynthèse rachidienne comprenant un moyen d'ancrage (3) osseux, un connecteur (4) destiné à recevoir une tige de liaison (2) et assemblé avec une extrémité du moyen d'ancrage (3), ainsi qu'un moyen de serrage (5) pour immobiliser la tige de liaison (2), caractérisé en ce que l'assemblage du connecteur (4) et du moyen d'ancrage (3) est assuré par un axe (6) traversant le moyen d'ancrage (3), ledit axe (6) constituant une liaison pivot, et en ce que le dispositif (1) comporte un moyen de stabilisation, dans le plan contenant la tige et le moyen d'ancrage, du connecteur par rapport au moyen d'ancrage lorsqu'il est implanté sur le patient.

WO 2004/107997 A2

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 843 of 2152

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Dispositif de connexion pour ostéosynthèse rachidienne

La présente invention se rapporte au domaine de l'ostéosynthèse rachidienne destinée à la chirurgie du rachis pour la correction et la stabilisation de la colonne vertébrale.

La présente invention se rapporte plus particulièrement à un dispositif de connexion pour l'ostéosynthèse rachidienne comprenant un moyen d'ancrage osseux, un connecteur destiné à recevoir une tige de liaison et assemblé avec une extrémité du moyen d'ancrage, ainsi qu'un moyen de serrage, pour immobiliser la tige de liaison.

Il est connu dans l'art antérieur de nombreux systèmes pour corriger ou stabiliser la colonne vertébrale

Il est proposé dans le certificat d'utilité allemand DE4107480 une vis à os destinée à la fixation d'un dispositif pour corriger et stabiliser la colonne vertébrale. Pour ce faire, ladite vis à os est constituée d'une tête présentant une zone évidée semicirculaire destinée à recevoir la tige de liaison. Ladite tige de liaison est bloquée sur la tête de la vis à os par une pièce de fermeture en forme sensiblement de U, ladite pièce de fermeture formant pince sur la tête de ladite vis.

Le problème qui se pose avec cette solution est que la tige n'est pas stabilisée dans le basculement dans le plan contenant la tige de liaison et passant par la vis à os.

Il est également proposé, dans la demande de brevet européen EP0614649 une vis à os comprenant un élément vis présentant une partie filetée et une tête qui possède une partie en forme de segment sphérique, et une pièce réceptrice cylindrique destinée à recevoir la tête de l'élément vis et une barre qui doit être assemblée à la vis

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 845 of 2152

à os. Ladite pièce réceptrice présente, à une de ses extrémités, un premier perçage destiné à laisser passer la partie filetée de l'élément vis, une partie de forme sphérique creuse destinée à l'application de la tête, un second perçage ouvert formé à l'opposé du premier perçage et destiné à l'introduction de la partie fileté munie de la tête. Ladite pièce réceptrice présente en outre une section sensiblement en forme de U possédant deux branches libres munies d'un filetage extérieur et un filetage intérieur, et dans laquelle sont prévus un élément de pression agissant sur la tête, une vis de coincement vissée sur le côté ouvert, au-dessus de la barre destinée à être placée dans la section en forme de U, et un écrou de blocage vissé sur le filetage extérieur des branches de ladite pièce réceptrice.

Les dispositifs de l'art antérieur présentent cependant des inconvénients. D'une part, les mouvements permis sur les vis à os restent relativement faibles en particulier dans le plan frontal. Il en découle alors des difficultés pour manipuler, et notamment monter ou démonter les tiges de liaison sur les vis à os. D'autre part, lors de la chirurgie de reprise, le dévissage de la vis à os peut s'avérer difficile du fait d'un non-alignement du moyen d'entraînement de la vis avec la tête réceptrice de la tige de liaison.

La présente invention entend remédier aux inconvénients de l'art antérieur en proposant un dispositif de connexion permettant d'augmenter le débattement du connecteur maintenant la tige de liaison, sur le moyen d'ancrage utilisé sur les vertèbres.

La présente invention a pour but ainsi d'offrir un dispositif permettant une manipulation aisée, et plus particulière de faciliter le montage et démontage de la tige de liaison sur le moyen d'ancrage, ainsi que de

faciliter le dévissage du moyen d'ancrage lors de l'opération de chirurgie de reprise.

Pour ce faire, la présente invention est du type décrit ci-dessus et elle est remarquable, dans son acception la plus large, en ce que l'assemblage du connecteur et du moyen d'ancrage est assuré par un axe traversant le moyen d'ancrage, ledit axe constituant une liaison pivot, et en ce que le dispositif comporte un moyen de stabilisation, dans le plan contenant la tige et le moyen d'ancrage, du connecteur par rapport au moyen d'ancrage lorsqu'il est implanté sur le patient.

De préférence, le connecteur coopère avec ledit axe avec un degré de rotation par rapport à la direction axiale, et un débattement angulaire par rapport à au moins une direction perpendiculaire.

Avantageusement, le connecteur coopère avec ledit axe avec une amplitude de rotation par rapport à la direction axiale comprise entre 90 et 180° et l'amplitude du débattement angulaire par rapport à au moins une direction perpendiculaire est comprise entre 20 et 60°.

De préférence, la partie de l'axe destinée à être disposée dans ledit moyen d'ancrage présente une convexité répartie uniformément sur la circonférence dudit axe (6) pour permettre un débattement angulaire dudit axe (6) sur ledit moyen d'ancrage par rapport à une direction perpendiculaire audit axe.

Selon un premier mode de réalisation de l'invention, ledit moyen de stabilisation est constitué par le fait que ledit axe présente une direction axiale parallèle à la direction axiale de ladite tige de liaison, autorisant un degré de rotation axial seulement, à l'exclusion d'un basculement dans le plan perpendiculaire à la tige.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 847 of 2152

Avantageusement, la partie de l'axe destinée à être disposée dans ledit moyen d'ancrage présente une convexité répartie uniformément sur la circonférence dudit axe pour permettre un débattement angulaire sagittal dudit axe sur ledit moyen d'ancrage.

Selon une première variante du premier mode de réalisation de l'invention, ledit connecteur comporte une surface d'appui sur laquelle la tige de liaison s'appuie, ladite surface d'appui étant configurée de manière à permettre un mouvement angulaire sagittal supplémentaire de ladite tige de liaison par rapport audit moyen d'ancrage.

Avantageusement, ladite surface d'appui est de forme bombée ou consiste en un élément formant berceau disposé dans le connecteur, ledit élément formant berceau présentant un logement inférieur coopérant avec le connecteur de manière à permettre le mouvement angulaire sagittal supplémentaire, et un logement supérieur destiné à recevoir la tige de liaison.

Selon une seconde variante du premier mode de réalisation de l'invention, le connecteur est traversé par un élément intermédiaire recevant ladite tige de liaison (2), ledit élément intermédiaire traversant présentant un logement inférieur coopérant avec l'extrémité dudit moyen d'ancrage de manière à permettre le verrouillage de tous les degrés de liberté de rotation dudit dispositif.

Avantageusement, ledit élément intermédiaire traversant présente une face supérieure de forme bombée permettant le mouvement angulaire sagittal de ladite tige de liaison par rapport audit connecteur ou consiste en un élément traversant formant berceau permettant le mouvement angulaire sagittal de ladite tige de liaison par rapport audit connecteur.

Avantageusement, le logement inférieur dudit élément intermédiaire traversant présente au moins une zone

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 848 of 2152

crantée ou striée. De même, l'extrémité du moyen d'ancrage est sur tout ou partie crantée ou striée.

Selon un second mode de réalisation de l'invention, ledit moyen de stabilisation est constitué par le fait que ledit axe présente une direction axiale perpendiculaire à la direction axiale de ladite tige de liaison et en ce que le dispositif comprend des moyens de blocage pour bloquer le mouvement de pivotement du connecteur sur ledit moyen d'ancrage.

De préférence, la partie de l'axe destinée à être disposée dans ledit moyen d'ancrage présente une convexité répartie uniformément sur la circonférence dudit axe pour permettre un débattement angulaire frontal dudit axe sur ledit moyen d'ancrage.

Avantageusement, les moyens de blocage consistent en une pièce traversant le connecteur, ladite pièce traversante présentant une face inférieure constituée d'un logement coopérant avec l'extrémité dudit moyen d'ancrage et une face supérieure recevant ladite tige de liaison, de manière à permettre le verrouillage de tous les degrés de liberté de rotation dudit dispositif. Dans un premier exemple de réalisation, la pièce traversante présente une face supérieure de forme bombée. Dans un autre exemple de réalisation, la pièce traversante consiste en un élément formant berceau lequel présente sur sa face supérieure un logement recevant ladite tige de liaison.

Avantageusement, le logement de la face inférieure de ladite pièce traversante est au moins en partie crantée ou striée. De même, l'extrémité dudit moyens d'ancrage en contact avec la pièce traversante est au moins en partie crantée ou striée.

Avantageusement, ledit axe présente sur tout ou partie de sa surface des stries longitudinales.

Avantageusement, ledit axe traverse l'extrémité du moyen d'ancrage et coopère avec deux trous prévus dans des branches du connecteur lesquels présentent des sections complémentaires à la section de l'axe (6), lesdites branches étant disposées de part et d'autre dudit axe.

Avantageusement, le moyen d'ancrage est une vis laquelle présente une partie filetée et une tête sphérique pourvue d'une cavité pour recevoir en partie ledit axe cylindrique.

Avantageusement, le connecteur est constitué d'une pièce réceptrice en forme sensiblement de U destinée à recevoir une extrémité dudit moyen d'ancrage pourvu de l'axe et la tige de liaison, et d'une pièce de fermeture en forme de U inversé, ladite pièce de fermeture venant s'emboîter sur la pièce réceptrice pour maintenir la tige de liaison sur la partie réceptrice dudit connecteur par l'intermédiaire dudit moyen de serrage.

La présente invention se rapporte également à un système pour ostéosynthèse sur la colonne vertébrale, en particulier pour la stabilisation des vertèbres comprenant au moins une tige de liaison et au moins deux dispositifs de connexion selon l'une quelconque des revendications précédentes, lesdits dispositifs de connexion étant susceptibles d'être chacun ancrés dans une vertèbre.

On comprendra mieux l'invention à l'aide de la description, faite ci-après à titre purement explicatif, d'un mode de réalisation de l'invention, en référence aux figures annexées :

1. la figure 1 illustre une vue éclatée en perspective d'un dispositif de connexion et d'une tige de liaison selon un premier mode de réalisation de l'invention ;

2. la figure 2 illustre une vue en perspective du dispositif de connexion et de la tige de liaison de la figure 1 assemblés ;

3. la figure 3 illustre une vue en coupe en perspective du dispositif de connexion de la figure 2 avec la tige de liaison ;

4. la figure 4 illustre une vue de côté du dispositif de connexion sans la tige de liaison, ledit dispositif de connexion présentant un débattement angulaire frontal ;

5. la figure 5 illustre une vue en coupe axiale de face du dispositif de connexion et de la tige de liaison de la figure 2 ;

6. la figure 6 illustre une vue en coupe axiale de face du dispositif de connexion de la figure 5 pourvu de la tige de liaison, présentant un premier débattement angulaire sagittal ;

7. la figure 7 illustre une vue en coupe axiale de face du dispositif de connexion de la figure 5 pourvu de la tige de liaison, ledit dispositif de connexion présentant un débattement angulaire sagittal maximum ;

8. les figures 8 et 9 illustrent une vue en perspective d'un élément formant berceau du dispositif de connexion respectivement selon deux variantes de réalisation de l'invention ;

9. la figure 10 illustre une vue en perspective d'un axe traversant du dispositif de connexion selon une variante de l'invention ;

10. les figures 11 et 12 illustrent une vue en perspective d'un moyen d'ancrage du dispositif de connexion selon deux variantes de réalisation de l'invention ;

11. la figure 13 illustre une vue en coupe en perspective du dispositif de connexion pourvu d'une tige de liaison selon un autre mode de réalisation de l'invention.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 851 of 2152

La figure 1 illustre une vue éclatée d'un dispositif (1) de connexion pour l'ostéosynthèse rachidienne selon l'invention. Ledit dispositif de connexion (1) est représenté avec une tige de liaison (2) de vertèbres.

Ledit dispositif de connexion (1) comprend un moyen d'ancrage osseux (3) et un connecteur (4) de tige de liaison (2). Ledit dispositif (1) comprend en outre un moyen de serrage (5) pour immobiliser le moyen d'ancrage (3) et le connecteur (4) maintenant la tige de liaison (2).

Avantageusement, ledit moyen d'ancrage osseux (3) consiste en une vis osseuse (3) constituée d'une partie filetée (9) et, à l'une des extrémités, d'une tête sphérique (7). La tête (7) de ladite vis (3) est pourvue d'une cavité (8) destinée à être traversée par un axe (6) cylindrique. La liaison entre la cavité (8) et l'axe (6) est réalisée de façon à permettre un mouvement de rotation dudit axe (6) dans ladite cavité (8). Pour ce faire, l'homme du métier pourra en particulier jouer sur les dimensions de la cavité (8) formée dans la tête (7) de la vis (3) et/ou dudit axe (6). Par exemple, des chanfreins d'entrée pourront être réalisés dans la cavité (8) de la tête (7) de la vis (3) afin de permettre un débattement angulaire dudit axe (6) accru.

En outre, il sera également possible d'utiliser un axe (6) présentant une surface non plane comme on le verra plus loin dans la description afin de permettre de contrôler le mouvement entre ledit axe (6) et ladite cavité (8).

Ledit axe (6) présente avantageusement sur sa circonférence une portion centrale (60) bombée. Ladite portion centrale (60) est séparée de part et d'autre des portions d'extrémité (61, 63) par une gorge (62). Ainsi, lorsque l'axe (6) est positionné au travers de la cavité

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 852 of 2152

(8) formée dans la tête (7) de la vis (3), la portion centrale (60) est disposée dans ladite cavité (8).

Le connecteur (4), destiné à connecter la tige de liaison (2) à ladite vis (3) comprend deux pièces, une pièce réceptrice (41) et une pièce de fermeture (42).

La pièce réceptrice (41) présente sensiblement une forme de U. Ladite pièce (41) est constituée en particulier de deux branches (410, 411) sensiblement en forme de chape. Lesdites branches (410, 411), disposées symétriquement l'une à l'autre, sont jointes l'une à l'autre par deux parois de raccordement (412, 413) latérales.

L'extrémité inférieure de chacune desdites branches (410, 411) est pourvue respectivement d'un trou (414), lesdits trous (414) présentant des sections complémentaires à la section de l'axe (6), pour être avantageusement monté serré sur le connecteur (4).

L'écartement entre chacune des extrémités desdites branches (410, 411) munies desdits trous (414) définit un espacement suffisant pour recevoir la tête (7) de ladite vis (3) lors de l'assemblage de la tige de liaison (2) sur la vis (3) par l'intermédiaire dudit connecteur (4) et ce, quelle que soit la position angulaire de ladite vis (3).

L'espacement supérieur défini par lesdites branches (410, 411) en forme de U et les parois de raccordement (412, 413) définit un logement (415) de réception pour la tige de liaison (2).

La pièce de fermeture (42) dudit connecteur (4) est de forme générale en U dont l'extrémité des branches (420, 421) est pourvue respectivement d'un épaulement (422) arqué vers l'intérieur desdites branches (420, 421) en U. Les dimensions et les formes des branches (420, 421) et des épaulements (422) sont déterminées de façon à permettre la mise en place et l'emboîtement de la pièce de fermeture (42) sur la pièce réceptrice (41).

La pièce de fermeture (42) présente sur le fond formé par les branches (420, 421), un logement (423). Avantageusement, ledit logement (423) comporte un taraudage (non représenté) pour recevoir ledit moyen de serrage (5), lequel permet le verrouillage définitif de ladite pièce de fermeture (42) par serrage dudit moyen de serrage (5).

Un élément intermédiaire traversant (10) formant berceauest disposé entre la pièce réceptrice (41) et la tige de liaison (2). Ledit élément berceau (10) présente sur sa face inférieure un logement (11) concave, ledit logement (11) étant dimensionné pour coopérer avec la tête de la vis (3). De la même manière, ledit élément intermédiaire traversant (10) présente sur sa face supérieure, laquelle est destinée à recevoir ladite tige de liaison (2), un second logement (12) concave, ledit logement (12) étant dimensionné pour coopérer avec ladite tige de liaison (2).

Le verrouillage du dispositif ainsi constitué est opéré par l'intermédiaire des forces exercées entre chacun des éléments. Ainsi, le moyen de serrage (5) exerce une pression sur la tige de liaison (2), qui elle-même exerce une pression sur l'élément intermédiaire traversant (10), lui-même exerçant une pression sur le moyen d'ancrage osseux (3). L'axe (6) traversant la tête (7) de ladite vis (3) exerce alors une traction sur la pièce réceptrice (41) qui elle-même exerce une traction sur la pièce de fermeture (42) par l'intermédiaire des épaulements (422) de la pièce de fermeture (42) se fixant dans des ogives formées dans la pièce réceptrice (41), la pièce de fermeture exerçant à son tour une traction sur le moyen de serrage (5) par l'intermédiaire du logement (423) fileté,

La figure 2 illustre une vue en perspective du dispositif de connexion (1) et de la tige de liaison (2) de la figure 1 assemblés.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 854 of 2152

Le connecteur (4) est assemblé avec la tête (7) de la vis (3) par l'intermédiaire de l'axe (6), lequel traverse la tête (7) de ladite vis (3) et coopère avec les deux trous (414) prévus dans les branches (410, 411) du connecteur (4), lesdites branches (410, 411) étant disposées de part et d'autre dudit axe (6).

La pièce de fermeture (42) dudit connecteur (4) est positionnée sur la pièce réceptrice (41) complémentaire de telle sorte que la face intérieure des branches (420, 421) de ladite pièce de fermeture (42) soit en contact avec les parois de raccordement (412, 413) de ladite partie réceptrice (41). La pièce de fermeture (42) refermée sur ladite pièce réceptrice (41) supportant la tige de liaison (2), ladite tige de liaison (2) est alors maintenue et associée avec la vis (3).

L'interaction entre chacun des éléments constituant le dispositif de connexion (1) selon l'invention est représenté sur la figure 3 laquelle illustre une vue en coupe dudit dispositif de connexion (1) assemblé sur la tige de liaison (2).

En particulier, il apparaît sur la figure 3 le blocage de la pièce de fermeture (42) sur la pièce réceptrice (41) dudit connecteur (4). Le blocage est réalisé par l'intermédiaire des épaulements (422) de la pièce de fermeture (42) lesquels sont insérés dans des ogives formées sur les parois de raccordement (412, 413) de ladite pièce réceptrice (41)

Le dispositif de connexion (1) ainsi assemblé permet d'obtenir du connecteur (4), lequel maintient fermement la tige de liaison (2), un mouvement de pivotement par rapport à ladite vis (3) selon deux directions, à savoir : un premier mouvement de pivotement parallèle à la direction axiale de la tige de liaison (2) (débattement frontal dudit connecteur (4) sur ladite vis

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 855 of 2152

(3)) et un mouvement de pivotement selon un axe perpendiculaire à la direction axiale de ladite tige de liaison (2) (débattement sagittal dudit connecteur (4) sur ladite vis (3)), ce dernier pouvant être augmenté d'un mouvement de pivotement latéral supplémentaire. Ces différents mouvements sont illustrés sur les figures 4 à 7.

En particulier, le débattement frontal dudit connecteur (4) sur ladite vis (3) est montré sur la figure 4, laquelle illustre une vue en coupe latérale dudit dispositif de connexion (1) où, pour une meilleure compréhension du fonctionnement, seuls la pièce réceptrice (41) dudit connecteur (4), l'élément intermédiaire traversant (10) et ladite vis (3) sont représentés.

Comme expliqué précédemment, de par les dimensions et la forme respectivement de la cavité (8) formée au niveau de la tête (7) de ladite vis (3) et dudit axe (6), il est possible de générer audit axe (6) un mouvement de rotation perpendiculaire à l'axe de la tige de liaison (2) (débattement sagittal). Et la partie réceptrice (41) dudit connecteur (4), fixée sur ledit axe (6), pivote sur la tête (7) de la vis (3). L'élément intermédiaire traversant (10), de par sa configuration, suit le pivotement de la partie réceptrice (41) par rapport à ladite vis (3) en glissant sur la tête (7) de ladite vis (3) sur laquelle ledit élément intermédiaire traversant (10) repose.

Avantageusement, le débattement frontal peut atteindre 180 degrés.

Le pivotement sagittal est représenté sur les figures 6 et 7, illustrant des vues en coupe de face du dispositif de connexion (1) selon l'invention avec une tige de liaison (2). Le pivotement sagittal peut s'effectuer, comme précisé précédemment, selon deux mouvements indépendants ou combinés.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 856 of 2152

Afin de bien comprendre les deux mouvements sagittaux qui peuvent être effectués, il a été représenté sur la figure 5 une vue en coupe de face dudit dispositif de connexion (1) en position plane. Dans cette position, il apparaît que l'axe (6) traversant la tête (7) de la vis (3) présente une direction axiale parallèle à celle de la tige de liaison (2).

De cette position de repos, un premier mouvement de pivotement de ladite tige de liaison (2) peut être obtenu par le glissement de l'élément intermédiaire traversant (10) sur la tête (7) de ladite vis (3) sur lequel ledit élément intermédiaire traversant (10) repose (figure 6). Ce premier mouvement peut être complété, comme l'illustre la figure 7, par un second mouvement de pivotement lié au pivotement de la portion convexe (60) de l'axe (6) dans la cavité (8) de la tête (7) de la vis (3). De même que la direction axiale de la tige de liaison (2) avait été modifiée lors du premier mouvement de pivotement, il s'ensuit également un changement de la direction axiale dudit axe (6).

Il est bien entendu évident que, bien que non représenté, le mouvement de pivotement de l'axe (6) peut être réalisé indépendamment d'un mouvement de pivotement dudit élément intermédiaire traversant (10) et s'additionner à ce mouvement pour atteindre préférentiellement un débattement angulaire de 60 degrés.

Afin de contrôler les mouvements de pivotement, qu'il s'agisse du pivotement frontal ou des pivotements sagittaux, il sera avantageux de proposer des surfaces de liaison, non pas nécessairement lisses, mais présentant avantageusement des reliefs.

En particulier, il sera avantageux, en ce qui concerne le mouvement de pivotement frontal, d'utiliser un axe (6) pourvu de stries longitudinales (13). Celles-ci

seront réparties, sinon sur toute sa surface, sur au moins la partie destinée à être disposée dans la cavité (7) de ladite vis (figure 10).

Il sera également avantageux que ladite vis (3) présente une tête (7) striée ou crantée comme illustré sur les figures 11 et 12.

De même, l'élément intermédiaire traversant (10) pourra présenter sur la surface en contact avec la tête (7) de ladite vis (3) une zone crantée ou striée (figures 8 et 9).

La figure 13 illustre une vue en coupe en perspective du dispositif de connexion (1) pourvue d'une tige de liaison (2) selon un autre mode de réalisation de l'invention.

Dans ce mode de réalisation, ledit dispositif de connexion (1) est constitué d'un moyen d'ancrage consistant en une vis (3), d'un connecteur (4) et d'un moyen de serrage (5).

Avantageusement, ladite pièce réceptrice (41) comprend une surface d'appui (14) bombée sur laquelle la tige de liaison (2) est disposée. Le mouvement de pivotement obtenu au moyen de l'élément intermédiaire traversant (10) dans le mode de réalisation précédent sera alors obtenu par le basculement de la tige de liaison (2) sur ladite surface d'appui (14). Dans ce mode de réalisation, la vis (3) reste donc libre en rotation frontale après serrage, et le cheminement des forces entre les éléments constitutifs du dispositif de connexion (1) est opéré comme suit : le moyen de serrage (5) exerce une pression sur la tige de liaison (2), laquelle exerce une pression sur la surface d'appui (14) de la surface réceptrice (41), laquelle exerce une traction sur la pièce de fermeture (42), elle-même exerçant une traction sur le bouchon de serrage (5).

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 858 of 2152

L'invention est décrite dans ce qui précède à titre d'exemple. Il est entendu que l'homme du métier est à même de réaliser différentes variantes de l'invention sans pour autant sortir du cadre du brevet.

REVENDICATIONS

1. Dispositif de connexion (1) pour l'ostéosynthèse rachidienne comprenant un moyen d'ancrage (3) osseux, un connecteur (4) destiné à recevoir une tige de liaison (2) et assemblé avec une extrémité du moyen d'ancrage (3), ainsi qu'un moyen de serrage (5) pour immobiliser la tige de liaison (2), caractérisé en ce que l'assemblage du connecteur (4) et du moyen d'ancrage (3) est assuré par un axe (6) traversant le moyen d'ancrage (3), ledit axe (6) constituant une liaison pivot, et en ce que le dispositif (1) comporte un moyen de stabilisation, dans le plan contenant la tige et le moyen d'ancrage, du connecteur par rapport au moyen d'ancrage lorsqu'il est implanté sur le patient.

2 . Dispositif de connexion (1) selon la revendication 1, caractérisé en ce que ledit moyen de stabilisation est constitué par le fait que ledit axe (6) présente une direction axiale parallèle à la direction axiale de ladite tige de liaison (2), autorisant un degré de rotation axial seulement, à l'exclusion d'un basculement dans le plan perpendiculaire à la tige.

3 . Dispositif de connexion (1) selon la revendication 1, caractérisé en ce que ledit moyen de stabilisation est constitué par le fait que ledit axe (6) présente une direction axiale perpendiculaire à la direction axiale de ladite tige de liaison (2) et en ce que le dispositif comprend des moyens de blocage pour bloquer le mouvement de pivotement du connecteur (4) sur ledit moyen d'ancrage (3).

4 . Dispositif de connexion (1) selon la revendication 1, caractérisé en ce que le connecteur (4)

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 860 of 2152

coopère avec ledit axe (6) avec un degré de rotation par rapport à la direction axiale, et un débattement angulaire par rapport à au moins une direction perpendiculaire.

5. Dispositif de connexion (1) pour l'ostéosynthèse rachidienne selon la revendication 4, caractérisé en ce que le connecteur (4) coopère avec ledit axe (6) avec une amplitude de rotation par rapport à la direction axiale comprise entre 90 et 180°.

6. Dispositif de connexion (1) pour l'ostéosynthèse rachidienne selon la revendication 4, caractérisé en ce que l'amplitude du débattement angulaire par rapport à au moins une direction perpendiculaire est comprise entre 20 et 60° .

7 . Dispositif de connexion (1) selon la revendication 1, caractérisé en ce que la partie de l'axe (6) destinée à être disposée dans ledit moyen d'ancrage (3) présente une convexité répartie uniformément sur la circonférence dudit axe (6) pour permettre un débattement angulaire dudit axe (6) sur ledit moyen d'ancrage (3) par rapport à une direction perpendiculaire audit axe (6).

8 . Dispositif de connexion (1) selon la revendication 2, caractérisé en ce que la partie de l'axe (6) destinée à être disposée dans ledit moyen d'ancrage (3) présente une convexité répartie uniformément sur la circonférence dudit axe (6) pour permettre un débattement angulaire sagittal dudit axe (6) sur ledit moyen d'ancrage (3).

9 . Dispositif de connexion (1) selon la revendication 3, caractérisé en ce que la partie de l'axe (6) destinée à être disposée dans ledit moyen d'ancrage (3)

présente une convexité répartie uniformément sur la circonférence dudit axe (6) pour permettre un débattement angulaire frontal dudit axe (6) sur ledit moyen d'ancrage (3).

10.Dispositif de connexion (1) selon la revendication 2 ou 8, caractérisé en ce que ledit connecteur (4) comporte une surface d'appui (14) sur laquelle la tige de liaison (2) s'appuie, ladite surface d'appui (2) étant configurée de manière à permettre un mouvement angulaire sagittal supplémentaire de ladite tige de liaison (2) par rapport audit moyen d'ancrage (3).

11.Dispositif de connexion (1) selon la revendication précédente, caractérisé en ce que ladite surface d'appui (14) est de forme bombée.

12.Dispositif de connexion (1) selon la revendication 10, caractérisé en ce que ladite surface d'appui (14) consiste en un élément formant berceau disposé dans le connecteur (4), ledit élément formant berceau présentant un logement inférieur (11) coopérant avec le connecteur (4) de manière à permettre le mouvement angulaire sagittal supplémentaire, et un logement supérieur (12) destiné à recevoir la tige de liaison (2).

13.Dispositif de connexion (1) selon la revendication 2 ou 8, caractérisé en ce que le connecteur (4) est traversé par un élément intermédiaire (10) recevant ladite tige de liaison (2), ledit élément intermédiaire (10) traversant présentant un logement inférieur (11) coopérant avec l'extrémité dudit moyen d'ancrage (3) de manière à permettre le verrouillage de tous les degrés de liberté de rotation dudit dispositif (1).

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 862 of 2152

14.Dispositif de connexion (1) selon la revendication précédente, caractérisé en ce que ledit élément intermédiaire (10) traversant présente une face supérieure de forme bombée permettant le mouvement angulaire sagittal de ladite tige de liaison (2) par rapport audit connecteur (4).

15.Dispositif de connexion (1) selon la revendication 11, caractérisé en ce que ledit élément traversant consiste en un élément traversant formant berceau (10) permettant le mouvement angulaire sagittal de ladite tige de liaison (2) par rapport audit connecteur (4).

16.Dispositif de connexion (1) selon l'une quelconque des revendications 13 à 15, caractérisé en ce que le logement inférieur dudit élément intermédiaire traversant (10) présente au moins une zone crantée ou striée.

17.Dispositif de connexion (1) selon l'une quelconque des revendications 13 à 16, caractérisé en ce que l'extrémité du moyen d'ancrage (3) est sur tout ou partie crantée ou striée.

18.Dispositif de connexion (1) selon la revendication 3 ou 9, caractérisé en ce que les moyens de blocage consistent en une pièce traversant le connecteur (4), ladite pièce traversante présentant une face inférieure constituée d'un logement coopérant avec l'extrémité dudit moyen d'ancrage (3) et une face supérieure recevant ladite tige de liaison (2), de manière à permettre le verrouillage de tous les degrés de liberté de rotation dudit dispositif (1).

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 863 of 2152

19.Dispositif de connexion (1) selon la revendication précédente, caractérisé en ce que la face supérieure est de forme bombée.

20.Dispositif de connexion (1) selon la revendication 18, caractérisé en ce que la pièce traversante consiste en un élément formant berceau lequel présente sur sa face supérieure un logement recevant ladite tige de liaison (2).

21.Dispositif de connexion (1) selon l'une quelconque des revendications 18 à 20, caractérisé en ce que le logement de la face inférieure de ladite pièce traversante est au moins en partie crantée ou striée.

22.Dispositif de connexion (1) selon l'une quelconque des revendications 18 à 21, caractérisé en ce que l'extrémité dudit moyens d'ancrage (3) en contact avec la pièce traversante est au moins en partie crantée ou striée.

23.Dispositif de connexion (1) selon l'une quelconque des revendications précédentes, caractérisé en ce que ledit axe (6) présente sur tout ou partie de sa surface des stries longitudinales (13).

24.Dispositif de connexion (1) selon l'une quelconque des revendications précédentes, caractérisé en ce que ledit axe (6) traverse l'extrémité du moyen d'ancrage (3) et coopère avec deux trous (414) prévus dans des branches (410, 411) du connecteur (4) lesquels présentent des sections complémentaires à la section de l'axe (6), lesdites branches (410, 411) étant disposées de part et d'autre dudit axe (6).

25.Dispositif de connexion (1) selon l'une quelconque des revendications précédentes, caractérisé en ce que le moyen d'ancrage (3) est une vis (3) laquelle présente une partie filetée (9) et une tête sphérique (7) pourvue d'une cavité (8) pour recevoir en partie ledit axe (6) cylindrique.

26.Dispositif de connexion (1) selon l'une quelconque des revendications précédentes, caractérisé en ce que le connecteur (4) est constitué d'une pièce réceptrice (41) en forme sensiblement de U destinée à recevoir une extrémité dudit moyen d'ancrage (3) pourvu de l'axe (6) et la tige de liaison (2), et d'une pièce de fermeture (42) en forme de U inversé, ladite pièce de fermeture (42) venant s'emboîter sur la pièce réceptrice (41) pour maintenir la tige de liaison (2) sur la partie réceptrice (41) dudit connecteur (4) par l'intermédiaire dudit moyen de serrage (5).

27.Système pour ostéosynthèse sur la colonne vertébrale, en particulier pour la stabilisation des vertèbres comprenant au moins une tige de liaison (2) et au moins deux dispositifs de connexion (1) selon l'une quelconque des revendications précédentes, lesdits dispositifs de connexion (1) étant susceptibles d'être chacun ancrés dans une vertèbre.

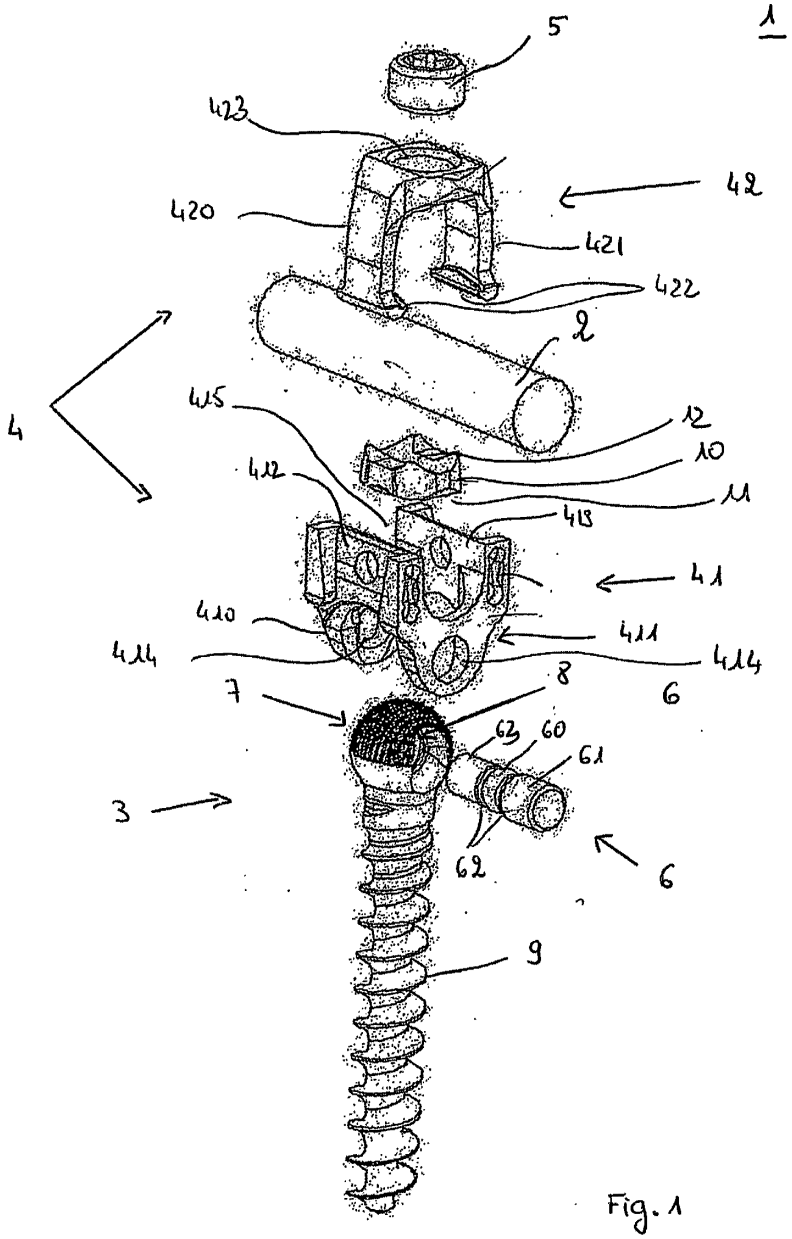

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Fig. 1

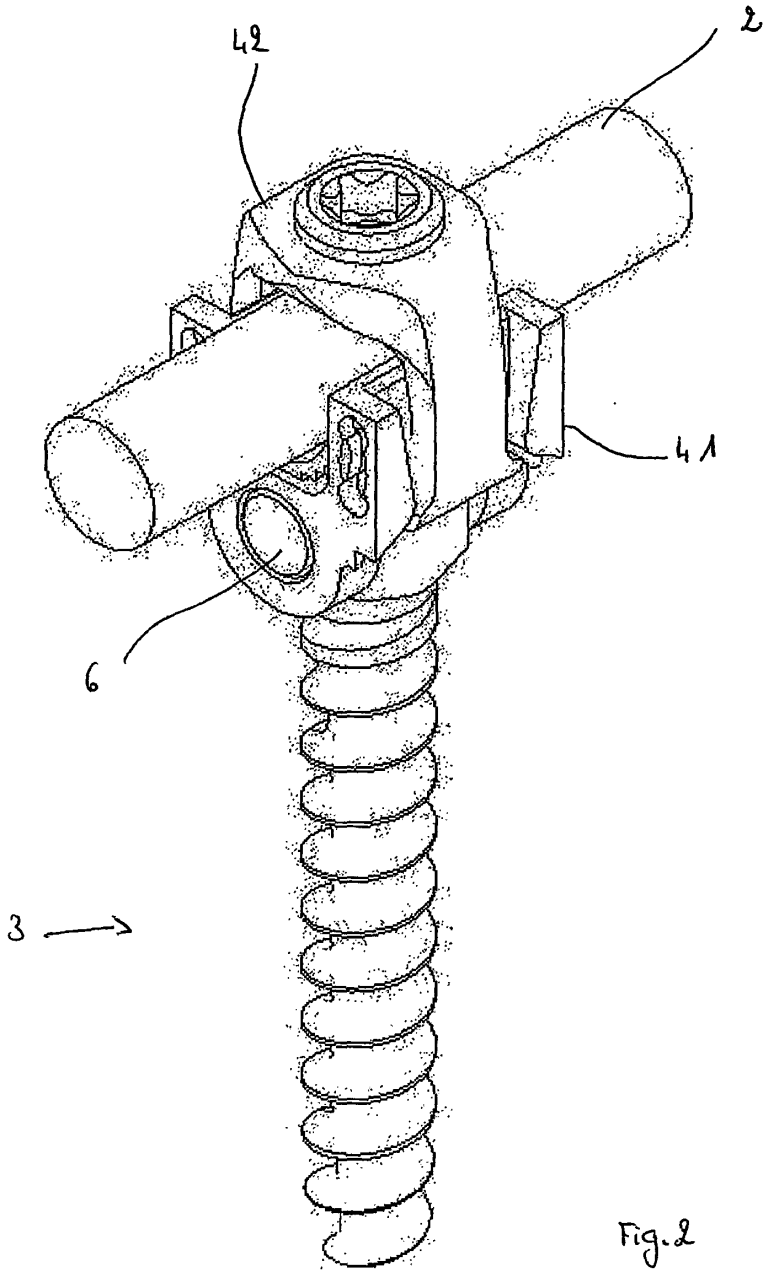


Fig. 2

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 867 of 2152

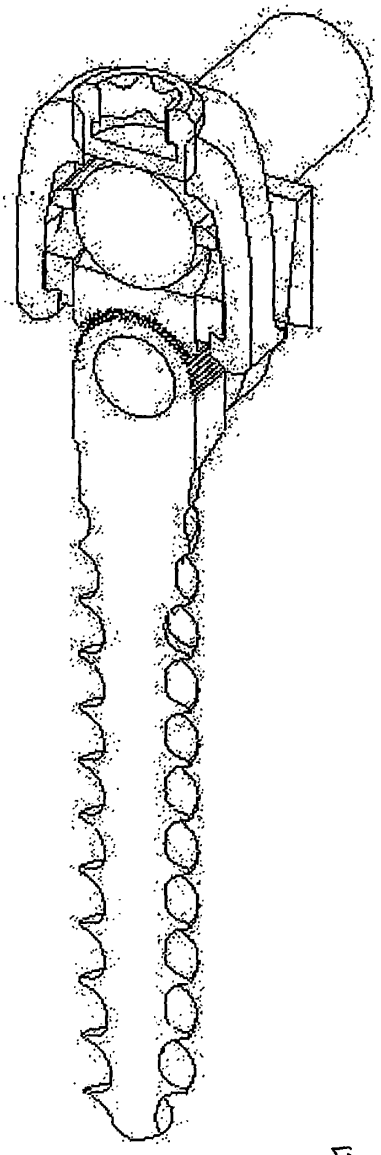


Fig. 3

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 868 of 2152

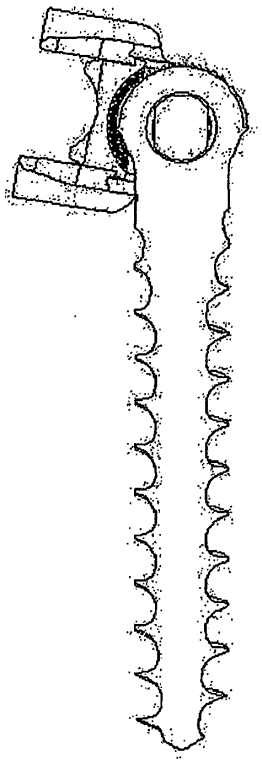


Fig. 4

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 869 of 2152

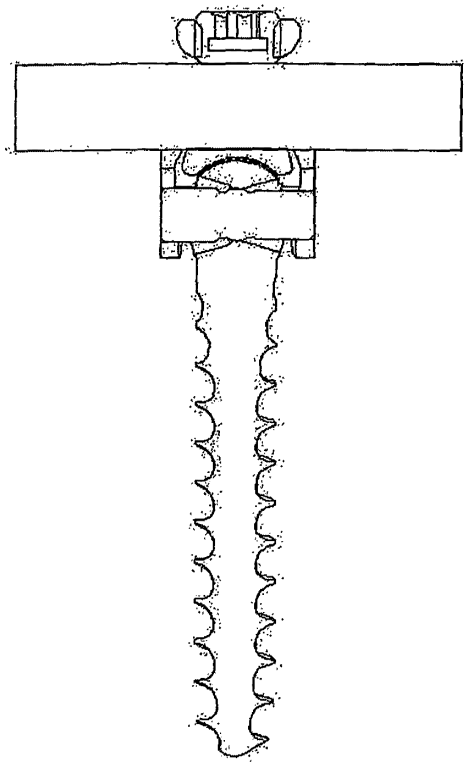


Fig.5

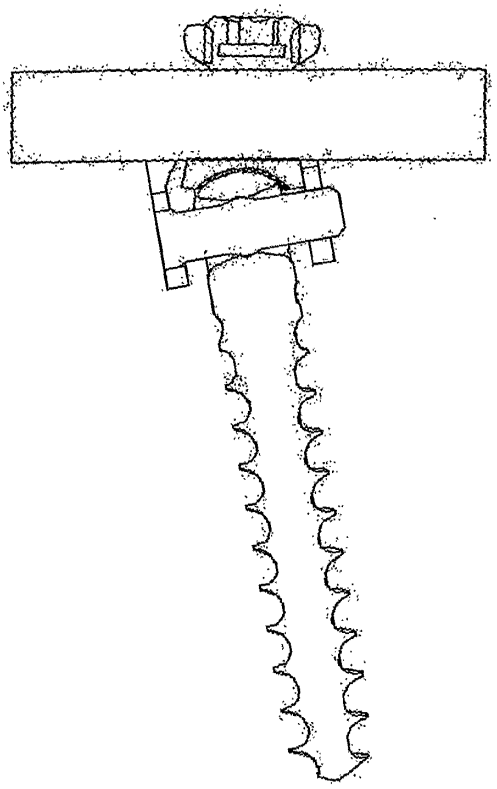


Fig. 6

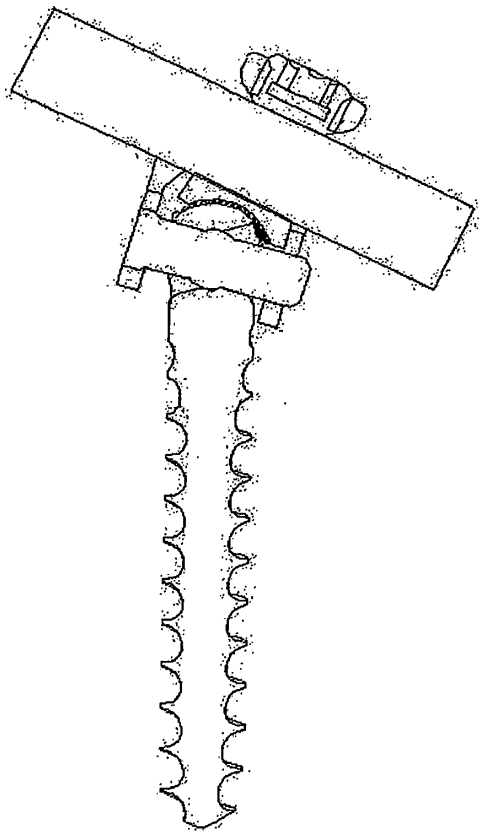


Fig. 7

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 872 of 2152

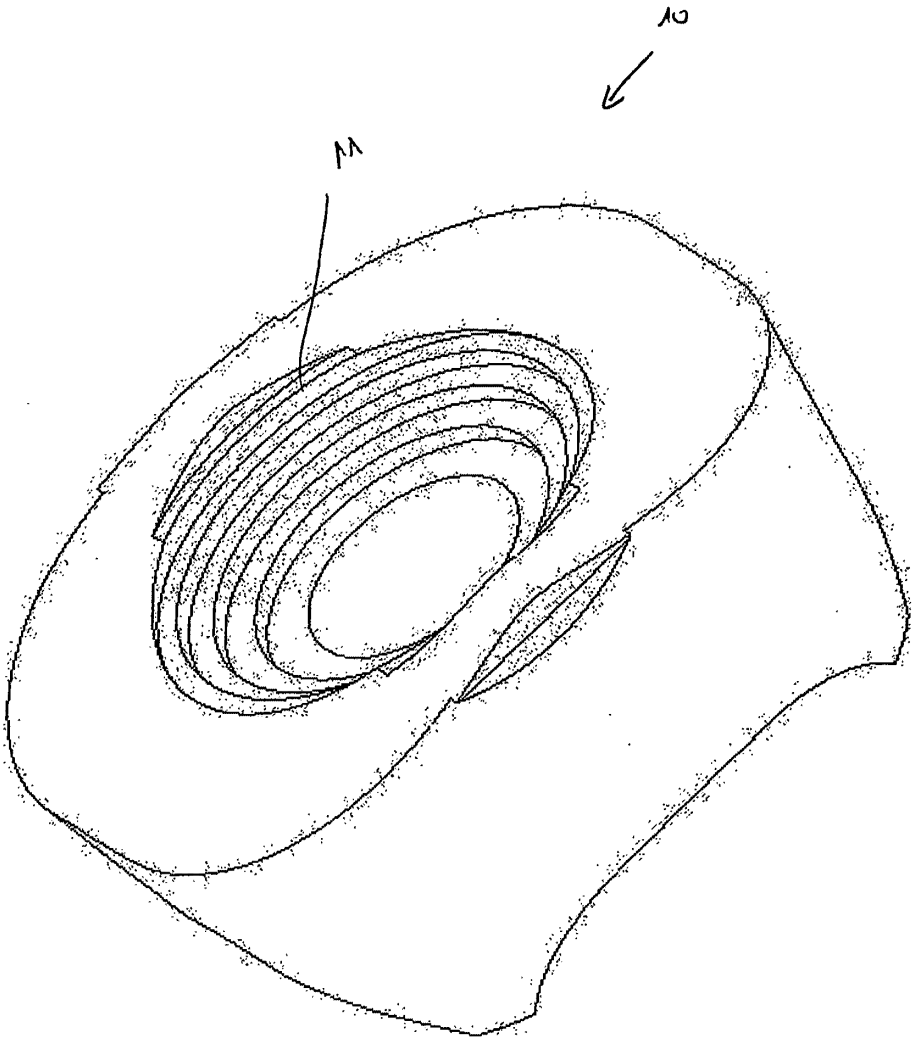


Fig. 8

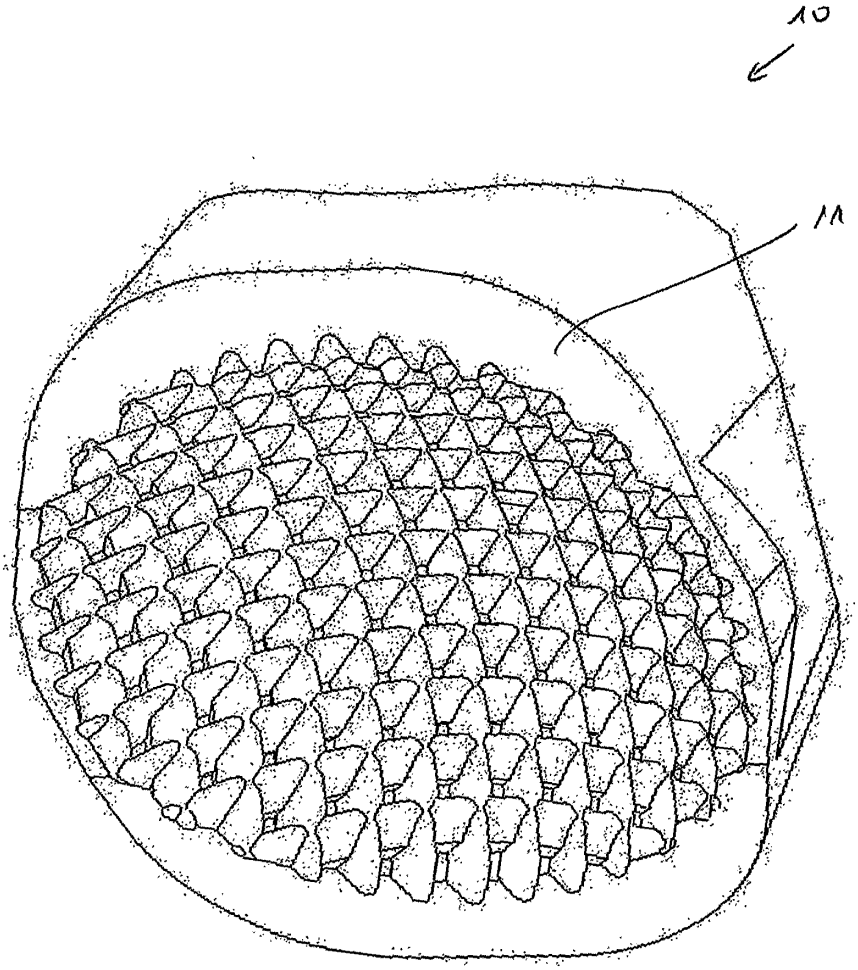


Fig. 9

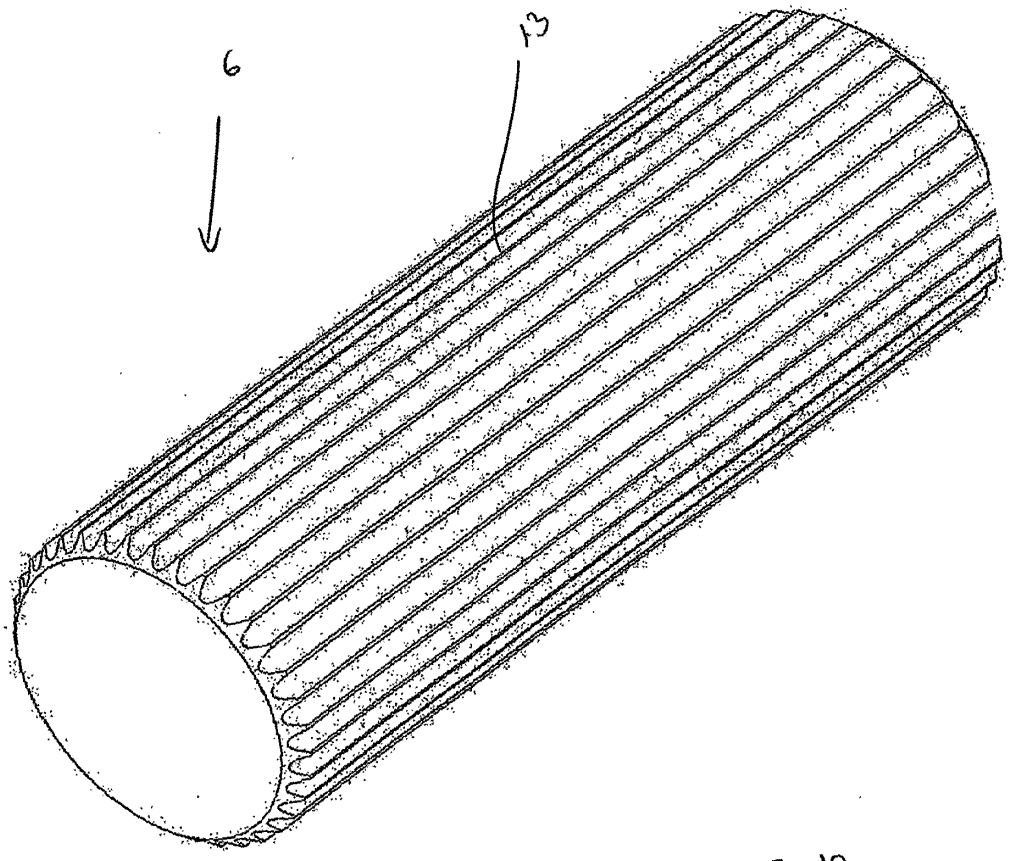


Fig. 10

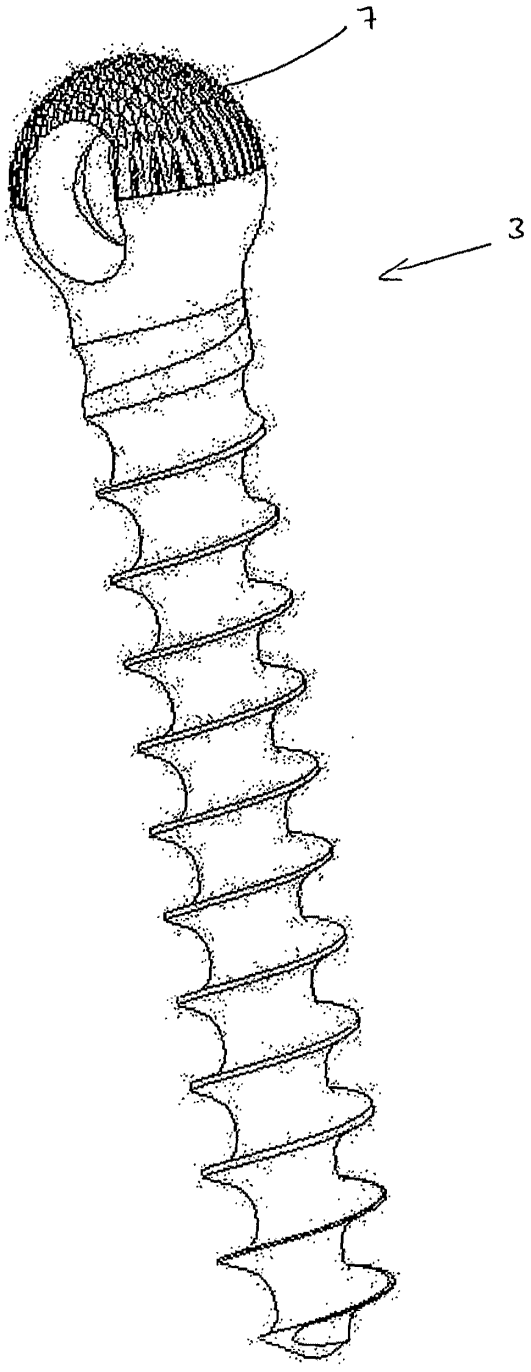


Fig.11

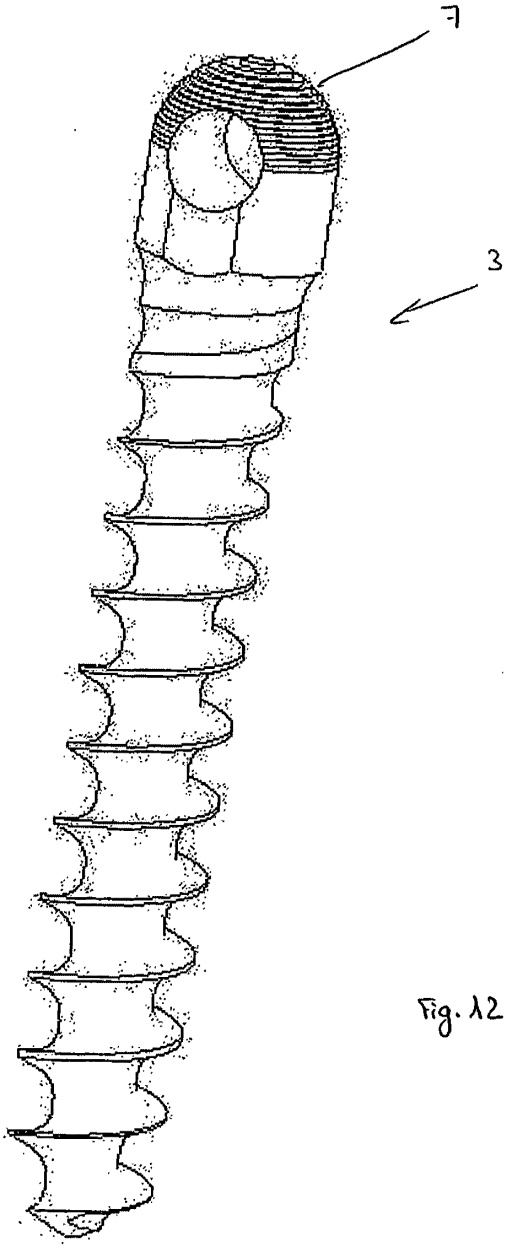


Fig. 12

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 877 of 2152

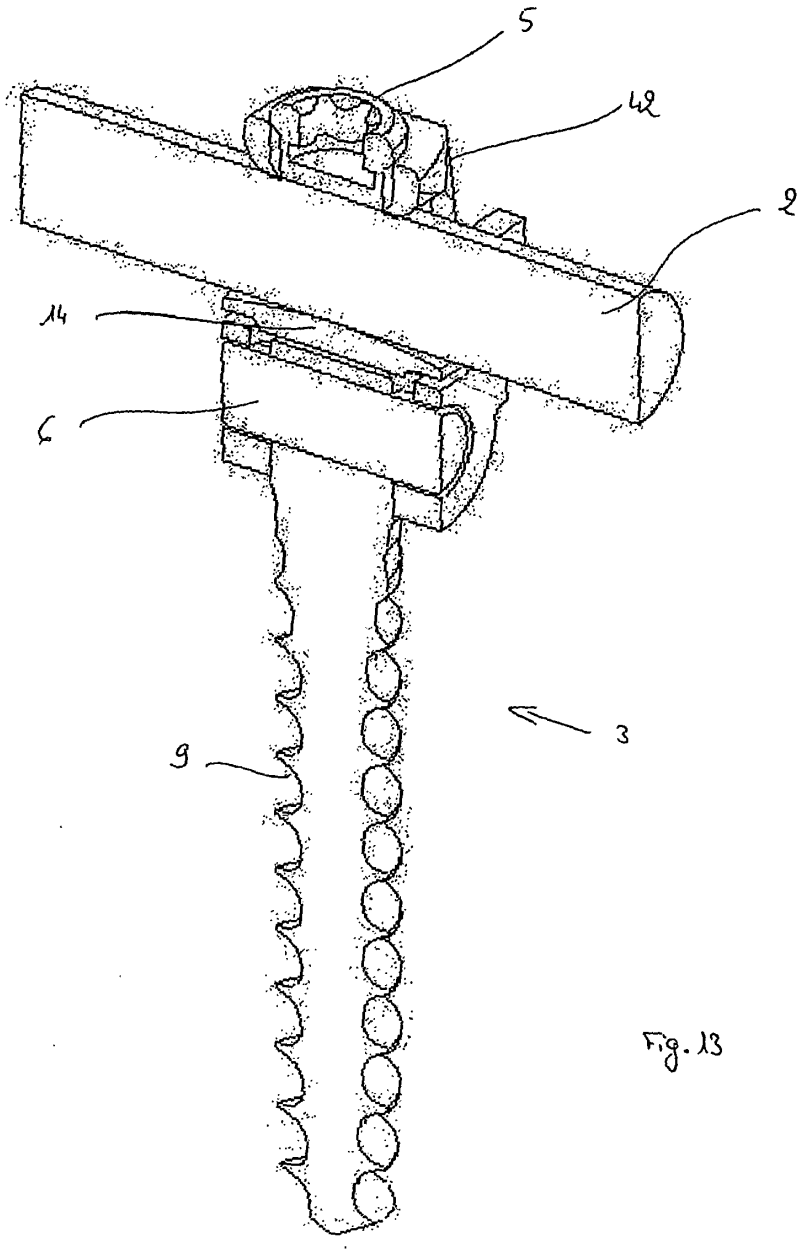


Fig. 13

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(71) Applicant *(for all designated States except US)*: **THEKEN SURGICAL, LLC** [US/US]; 283 East Waterloo Road, Akron, OH 44319 (US).

(72) Inventor; and

(75) Inventor/Applicant *(for US only)*: **MUELLER, Richard** [US/US]; 887 Elmwood Drive, Macedonia, OH 44056 (US).

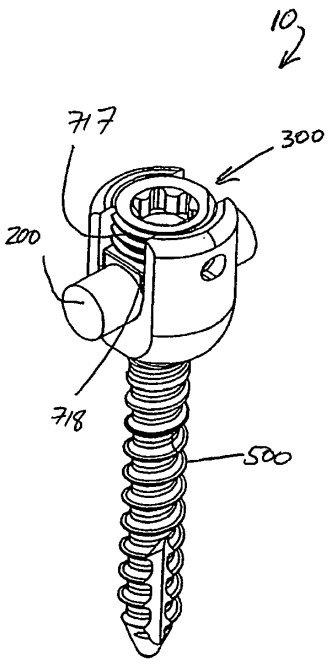
(74) Agent: **EICHENBERGER, Robert**; Frost Brown Todd LLC, 120 West Spring Street, Suite 400, New Albany, IN 47150 (US).

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(54) Title: BONE ANCHOR



(57) Abstract: A spinal rod and bone for anchoring a spinal rod to a bone anchor is provided for use in polyaxial constructs as well as non-polyaxial constructs. In general, a bone anchor is provided having a proximal end for engaging a rod and securing the rod with a coming or threaded locking assembly, and a distal end for engaging the bone. A partially cylindrical body is provided at the proximal end of the apparatus having opposed flanges and a rod-receiving channel therebetween. The locking device comprises an upper wave cap and a lower cap joined by a post with preset timing grooves therein, and having camming surfaces therebetween. The upper cap has an opening for engaging a drive mechanism and the lower cap has a surface for engaging the rod. Alternatively, the locking device comprises external camming configurations or threaded configurations.

WO 2004/089245 A2

Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii)) for the following designations AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW, ARIPO patent (BW, 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, PL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)*

— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii)) for the following designations AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW, ARIPO patent (BW, 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, PL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)*

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Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 880 of 2152

BONE ANCHOR

BACKGROUND OF THE INVENTION

1. Field of the Invention

[0001] The present invention generally relates to the correction of spinal deformities. Specifically, the present invention provides an improved apparatus and method for maintaining vertebrae in a desired spatial relationship.

2. Background

[0002] The human spinal column is composed of many vertebral bones stacked one upon the other, with an intervertebral disc between each pair of adjacent vertebral bones. The discs act as cartilaginous cushions and shock absorbers. The spinal cord runs in a bony canal formed by successive openings in these bones. Spinal nerves exit the spinal cord between pairs of vertebrae and supply nerve signals to and from other body structures.

[0003] Various problems with the human spine have been encountered that adversely affect its health. These problems include spinal column disorders such as scoliosis, kyphosis, spondylolisthesis, as well as traumatic events such as ruptured or slipped discs, broken or fractured spinal columns, and the like. Various forms of instrumentation and procedures are known for the surgical treatment of spinal disorders, for example, Harrington Spinal Instrumentation, Bobechko Hooks, Edwards Hooks and Rod Sleeves, Luque Segmental Spinal Instrumentation and Luque Rectangles, the Dunn Anterior Spinal System, and the Kostuik-Harrington Instrumentation.

[0004] The use of longitudinally extending surgical rods in the treatment of diseases or instability of the spine is well-known in the medical arts. Such rods achieve rigid spinal fixation when mechanically coupled to bone anchors, such as hooks or screws. These surgical rods are used, generally, in pairs placed on the posterior surface of the left and right sides of the lamina of the human spine.

[0005] Some of the above systems utilize hook-type members which are merely hooked over the laminae or on selected transverse processes of the spine. Other systems, such as the Luque Segmental Spinal Rectangles, used to stabilize spinal fractures and low back fusions, use Luque wires to secure the rectangle to the spine. In some of the prior art systems, screws are used to hold a single rod in place. In other systems, screws are used to hold a slotted plate in place, the location of the screws and slots being such that the plate is

moved in order to align the plate apertures or slots with the end of the screw, a nut being used to hold the plate to the screw. With this latter arrangement there is little purchase between the plate and the screw and nut since only a small portion of the plate is engaged adjacent to the slots. Also, the plate cannot be configured to a fixed and stable curvature to follow the curvature desired by the surgeon.

[0006] Another known corrective device includes a plurality of plates. Each of the plates is secured over one end of a vertebra. Fasteners are connected to the vertebrae through the plates. A cable is then crimped in the head of the fastener to attach the cable to one vertebra. Tension is put on the cable while it is crimped to an adjacent vertebra until the desired correction is accomplished. This device can only put compressive forces on the spine so that the cables are always in tension. Once the cable is crimped in place, no further adjustment between the crimped fastener and cable is possible.

[0007] In devices utilizing rods, the corrective forces are generated by (usually) two rods that are wired around the spine. The rods may be bent to a desired curvature. The rods are not directly attached to all the vertebrae that the rods span; rather, they span numerous vertebrae and are connected to only a few vertebrae using anchors, generally hooks or screws.

[0008] One widely used anchor for rod systems is the conventional orthopedic hook having a block-shaped head portion, with a central, cylindrical bore therethrough, and a hook portion. The bore of the conventional orthopedic hook is adapted to receive the surgical rod, and the head is slidably positioned over the surface of the surgical rod to the selected vertebra for attachment. The hook may have a variety of different shapes, lengths and openings to accommodate the specific vertebra to which it is to be anchored. With the hook portion properly anchored, the conventional orthopedic hook is locked to the surgical rod either by ratchet or by one or more set screws located within the block-shaped head. However, these systems do not provide polyaxial alignments of the anchors. Rather, the anchors are fixed in a given orientation with respect to the bone and allow no movement in vivo or in response to applied loads.

[0009] Another type of anchor is a special orthopedic screw having a block-shaped head with cylindrical bore therethrough. The screw, when its threaded end is attached to the selected anatomical site, is adapted for receiving and passing the elongated surgical rod through its cylindrical bore. Since the shank and threaded end of the screw extends perpendicularly with respect to the axis of the bore, once the screw has been anchored, the

position of the head, with its cylindrical bore, is fixed with respect to the spine of the patient.

[0010] If the nature of the disease of the spine should require the attachment of a number of orthopedic screws at spaced-apart anatomical sites, it will be appreciated that manual insertion of an elongated surgical rod through the bores of the several spaced-apart orthopedic screws is surgically difficult. The alignment of the axis of the bore in the head of each screw must, of necessity, bear some relationship to a common axis related to the axis of the surgical rod, which rod must be inserted through the several bores. Since the nature of the surgical operation places the surgical rod under stress, as by resisting deforming forces of the spine, it will be appreciated that proper positioning of the heads and alignment of the bores of the several anchor attachment members is of paramount concern.

[0011] Some systems have attempted to provide bone screw/rod anchor devices that include polyaxial screws, with varying degrees of success. Most systems that attempt to provide for polyaxial capabilities employ a spherical head or ball-shaped head for the screw. While this allows angulation, it also provides an undesirable structure as the spherical head takes up too much space in the construct. Moreover, such systems rely on a locking screw to apply a compressive force between the lower surface of the rod and the upper surface of the ball to "lock" the angle of entry of the screw. Several disadvantages have been noted with these systems. The threaded locking screw is cumbersome and can become cross threaded, thus ruining the anchor that has already been inserted into the bone. The caps have internal threads that engage external threads on the anchor seat. This arrangement is cumbersome and inefficient from space-savings standpoint. Threaded connections provide no indication when tightening is completed; thus, overthreading is likely, which results in a connection that is not secure. By using a set screw without the "saddle" type of contact on the rod created by the present invention, two separate detrimental effects occur. First, just having single point contact, as a flat bottom set-screw meets at only one point with a circular rod, provides little to no holding force. The "saddle" contact area of the present invention, which is nearly half the circumference of the rod, provides a great deal of holding force. Second, as a result of the single point contact, rod "notching" can occur because all the axial force of driving the set screw is transferred into a single point on the rod. This notch created in the rod to hold the two together creates an instant stress riser, which is a failure point for systems using that type of design.

[0012] Recognizing that the surgical rods, with their anchor attachments, are installed during open-back surgery, while the patient is under anesthesia, it is important that the orthopedic surgeon have available for immediate use anchor attachments that are easily positioned and aligned between the vertebrae and the surgical rods to which they are to be secured. A device is needed that accommodates both angularly adjustable anchor attachment members as well as non-angularly adjustable anchor attachment members for mechanical intercoupling between selected vertebrae of the spine and a surgical rod. In addition, a device is needed that provides the surgeon with a simple, effective, lock that optionally can provide the surgeon with feedback as to the status of the lock situation. All of these features are needed in a low profile device that is space-efficient.

BRIEF SUMMARY OF THE INVENTION

[0013] The present invention is directed to an anchor assembly for the internal fixation of the spine. The anchor assembly in several embodiments provides a quick-connect head and quick-disconnect cam locking cap to allow surgeons the ability to quickly and simply lock the anchor assembly to spinal rods or other stabilization means. In other embodiments the anchor assembly provides the surgeon with a simple threaded head that can be timed with the saddle to prevent cross-threading of the

[0014] In a first embodiment of the anchor assembly, the apparatus comprises a non-polyaxial bone anchor having a distal end for engaging a bone and a proximal end for engaging a surgical rod. The proximal end further comprises first and second opposed flanges defining a channel therebetween. The channel has a circular bottom surface for receiving a surgical rod. A radially-extending undercut having a leading surface and a trailing surface is disposed in the first and second opposed flanges for receiving a camming surface of a quick-connect cam device. The trailing surface further comprises a protruding portion to serve as a stop for engaging timing stops of the cam device.

[0015] The cam device comprises an upper portion and a lower portion. The upper portion comprises a substantially cylindrical body with an upper surface and a lower surface and an outer surface and a drive opening in said upper surface for receiving a drive mechanism (such as a hex drive, a Torx drive, and so forth). The drive opening has a bottom surface. A longitudinal opening extends through the bottom surface of the drive opening to receive a post wave cap. The outer surface of the upper portion further comprises radially extending flanges oriented approximately 180 degrees from each other

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 884 of 2152

for engaging the undercut within the first and second opposed flanges. Preferably the outer surface also comprises two timing stops, also oriented 180 degrees from each other but preferably offset from the radially extending flanges. The timing stops allow the upper portion to be turned 90 degrees (but no farther) inside the undercut. The anchor is inserted into the bone using an engaging device. A rod is placed in the channel in the appropriate orientation and a cam device is placed in the channel atop the rod. A drive instrument is inserted into the cam and a torque is applied to turn the cam 90 degrees to lock it into place.

[0016] In a second embodiment of the anchor assembly, the apparatus comprises a polyaxial anchor having a distal end for engaging a bone and a proximal end for engaging a rod. The proximal end comprises a head having a lower curvate surface and an upper low profile nonspherical surface. A top cap is provided having an upper portion for receiving the cam device and a lower portion for receiving the head of the polyaxial anchor. In addition, a bottom ring is provided that surrounds the lower portion of the top cap. The lower portion has fingers thereon that provide a radial force to help lock the angle of the anchor when the bottom ring is moved from its unlocked position to its locked position.

[0017] An alternative embodiment of the cam device is provided wherein the flanges have an upwardly extending ridge thereon that mates with an upwardly extending opening in the undercut. Once the ridges engage the upwardly extending opening, splaying of the flanges is prevented.

[0018] Another embodiment provides a two-piece threaded cap assembly in place of the cam cap assembly. The thread is preferably of buttress design and can have single or double start threads. The lower cap is similar to the lower cap of the cam embodiments. The threads can be timed with the lower surface of the lower cap so that when the lower surface of the lower cap is in position to receive a rod, the start threads are line up for automatic threading to prevent cross threading.

BRIEF DESCRIPTION OF THE DRAWINGS

[0019] The teachings of the present invention can be readily understood by considering the following detailed description in conjunction with the accompanying drawings, in which:

[0020] Figure 1 is a perspective view of the apparatus according to a first non-polyaxial embodiment;

[0021] Figure 2 is a perspective view of the apparatus of Fig. 1 having removed the rod and the cam assembly, showing a first non-polyaxial bone anchor embodiment;

[0022] Figure 3 is a top view of the bone anchor of Fig. 2;

[0023] Figure 4 is a side view in a first radial direction of the bone anchor of Fig. 2;

[0024] Figure 5 is a side view in a second radial direction of the bone anchor of Fig. 2, wherein the second radial direction is rotated 90 degrees from the first radial direction;

[0025] Figure 6 is a perspective view of the partially cylindrical body of a first non-polyaxial embodiment of the invention;

[0026] Figure 7 is a section view of the partially cylindrical body of Fig. 6 in a first radial direction;

[0027] Figure 8 is a section view of the partially cylindrical body shown in Fig. 7 in a second radial direction;

[0028] Figure 9 is a perspective view of the cam assembly showing upper wave cap and lower cap in mating contact;

[0029] Figure 10 is a side elevation view of the cam assembly of Fig. 9 taken from a first radial direction;

[0030] Fig. 11 is a side elevation view of the cam assembly of Fig. 9 taken from a second radial direction;

[0031] Fig. 12 is a top view of the cam assembly;

[0032] Fig. 13 is a bottom view of the cam assembly;

[0033] Fig. 14 is a perspective view of the cam assembly of Fig. 9, shown with the upper wave cap having been rotated 90 degrees;

[0034] Fig. 15 is a perspective view of the upper wave cap;

[0035] Fig. 16 is a perspective view of the lower cap;

[0036] Fig. 17 is a top view of the apparatus showing the cam assembly in the unlocked position;

[0037] Fig. 18 is a top view of the apparatus showing the cam assembly in the locked position;

[0038] Fig. 19 is a perspective view of the apparatus according to a first polyaxial embodiment;

[0039] Fig. 20 is a top view of an embodiment of a polyaxial bone anchor, shown as a screw, for use in the apparatus;

[0040] Fig. 21 is a side elevation view of the bone anchor of Fig. 20;

[0041] Fig. 22 is a section view of the bone anchor of Fig. 21;

[0042] Fig. 23 is a perspective view of a first embodiment of the top cap for a polyaxial bone anchor;

[0043] Fig. 24 is a top view of the top cap of Fig. 23;

[0044] Fig. 25 is a side elevation view taken in a first radial direction of the top cap of Fig. 23;

[0045] Fig. 25A is a section view of the cam housing;

[0046] Fig. 25B is a section view of the bone anchor fitted within the cam housing;

[0047] Fig. 26 is a side elevation view taken in a second radial direction of the top cap of Fig. 23;

[0048] Fig. 27 is a side elevation view of the apparatus of Fig. 19 showing the bone anchor angulated within the apparatus and the bottom ring in an unlocked position;

[0049] Fig. 28 is a side elevation view of the apparatus of Fig. 19 showing the bone anchor angulated within the apparatus and the bottom ring in a locked position;

[0050] Fig. 29 is a perspective view of an embodiment of a polyaxial apparatus showing the bone anchor angulated and the bottom ring in the unlocked position and the upper wave cap in the unlocked position; and

[0051] Fig. 30 is a perspective view of an embodiment of a polyaxial apparatus showing the bone anchor angulated and the bottom ring in the locked position and the upper wave cap in the locked position.

[0052] Fig. 31 is a perspective view of an alternative embodiment showing a cam assembly external to the flanges shown in the locked position;

[0053] Fig. 32 is a side elevation view of the embodiment of Fig. 31;

[0054] Fig. 33 is a perspective view of the upper cap of the embodiment shown in Fig. 31;

[0055] Fig. 34 is a side elevation view of the upper cap shown in Fig. 33;

[0056] Fig. 35 is a perspective view of the embodiment shown in Fig. 31 shown in an unlocked position;

[0057] Fig. 36 is a side elevation view of the embodiment shown in Fig. 35;

[0058] Fig. 37 is a perspective view of a second alternative embodiment showing a cam assembly external to the flanges shown in the locked position;

[0059] Fig. 39 is a side elevation view of the embodiment of Fig. 37;

[0060] Fig. 39 is a perspective view of the upper cap of the embodiment shown in Fig. 37;

[0061] Fig. 40 is a side elevation view of the upper cap shown in Fig. 39;

[0062] Fig. 41 is a perspective view of the embodiment shown in Fig. 37 shown in an unlocked position;

[0063] Fig. 42 is a side elevation view of the embodiment shown in Fig. 41;

[0064] Fig. 43 is a perspective view of another embodiment of the invention showing a non-polyaxial anchor utilizing a threaded locking assembly to secure a rod;

[0065] Fig. 44 is a side view in a first radial direction of the embodiment shown in Fig. 43;

[0066] Fig. 45 is a perspective view of the apparatus of the embodiment shown in Fig. 43;

[0067] Fig. 46 is a side view in a first radial direction of the apparatus shown in Fig. 45;

[0068] Fig. 47 is a side view in a second radial direction of the apparatus shown in Fig. 45;

[0069] Fig. 48 is a top view of the apparatus shown in Fig. 45;

[0070] Fig. 49 is a perspective view of a polyaxial bone anchor for use with another embodiment of the invention;

[0071] Fig. 50 is a side view of the polyaxial bone anchor shown in Fig. 49;

[0072] Fig. 51 is a section view of the polyaxial bone anchor shown in Fig. 49;

[0073] Fig. 52 is a top view of the polyaxial bone anchor shown in Fig. 49;

[0074] Fig. 53 is a perspective view of a housing for use with the polyaxial bone anchor shown in Fig. 49;

[0075] Fig. 54 is a side view of the housing shown in Fig. 53;

[0076] Fig. 55 is a section view of the housing shown in Fig. 53;

[0077] Fig. 56 is a top view of the housing shown in Fig. 53;

[0078] Fig. 57 is a perspective view of a threaded locking assembly for use with several threaded embodiments of the invention;

[0079] Fig. 58 is a side view of the threaded locking assembly shown in Fig. 57; and

[0080] Fig. 59 is a top view of the threaded locking assembly shown in Fig. 57.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

[0081] While the present invention will be described more fully hereinafter with reference to the accompanying drawings, in which particular embodiments and methods are shown, it is to be understood from the outset that persons of ordinary skill in the art may modify the invention herein described while achieving the functions and results of this invention. Accordingly, the description which follows is to be understood as illustrative and exemplary of specific embodiments within the broad scope of the present invention and not as limiting the scope of the invention. In the following descriptions, like numbers refer to similar features or like elements throughout.

[0082] Ideally, an anchor apparatus for a spinal rod system will provide the surgeon with a device that rapidly and securely couples the spinal rod to the bone anchor. Figures 1-8 show an apparatus 10 according to a first non-polyaxial embodiment of the present invention. In general, the apparatus 10 generally comprises a bone anchor 100, a surgical rod 200, and a locking assembly 300. The bone anchor 100 can be any form of anchor suitable for the surgical technique employed, including, for example, a hook or a screw. In the figures, the bone anchor 100 is depicted as a screw for the sake of consistency. The bone anchor 100 comprises a proximal end 102 and a distal end 104. The distal end 104 engages a bone at a bone interface. The proximal end 102 engages the surgical rod 200 in a manner that will be described below.

[0083] Because the invention is directed to an anchor system, the following directional references will be employed herein. When discussing the bone anchor 100 or any component thereof, the word "longitudinal" shall refer to the direction of the longitudinal axis of the bone anchor 100. For embodiments where the bone anchor 100 is a screw, the longitudinal direction will therefore be in the direction of the length of the screw. In these cases, "proximal" or "proximally" shall mean in the direction of or toward the proximal end 102; and "distal" or "distally" shall mean in the direction of or toward the distal end 104. Similarly, the term "radially" shall refer to a direction that is perpendicular to the longitudinal axis of the bone anchor 100. When referring to the spine, however, the term "longitudinal" shall refer to a direction along the length of the spine.

[0084] Referring to Figures 2-5, the proximal end 102 of the bone anchor 100 comprises preferably a partially cylindrical body 103 having a first flange 110 and a second flange 120 opposed to and spaced-apart from said first flange 110. The first flange 110 and the second flange 120 extend longitudinally in the proximal direction, and are separated by a channel

105 therebetween. A head 109 for engaging a driving instrument is preferably disposed within the partially cylindrical body 103.

[0085] First flange 110 has a convex outer surface 111 and a concave inner surface 112. Similarly, second flange 120 has a convex outer surface 121 and a concave inner surface 122. As referenced above, preferably the outer surfaces 111, 121 circumscribe a portion of a circle, with a gap coinciding with the channel 105, when viewed in the longitudinal direction, as best seen in Figures 3 and 4. In a similar fashion, preferably the inner surfaces 112, 122 circumscribe a portion of a smaller circle, with a gap coinciding with the channel 105. Other shapes, however, are possible, including polygonal shapes, ovoidal shapes, and so forth. The channel 105 is preferably a U-shaped channel disposed about the outer surfaces 111, 121, such that it creates a rod-receiving groove in a first radial direction. The channel 105 further comprises a bottom surface 106 that is dimensioned to receive a surgical rod. Preferably, the bottom surface 106 is semi-circular to receive the outer surface of a cylindrical rod 200.

[0086] Referring now to Figures 6 and 7, first flange 110 further comprises an undercut 107 in the inner surface 112. The undercut 107 receives a portion of the locking assembly 300 (described below) and serves only to prevent the locking assembly 300 from exiting the head 109. Because most threads used in surgical procedures are standard, right-hand threads, the figures are drawn accordingly, and terminology such as "leading" and "trailing" are used accordingly. Obviously, if left-hand threads are used, the terminology can remain the same, but the reference numerals in the attached figures would need to be switched: leading structures would become trailing structures, and vice versa. For simplicity, standard threads are assumed.

[0087] First flange 110 further comprises a leading surface 113 and a trailing surface 114. Undercut 107 is preferably a partial cylindrical surface defining a groove. However, many other shapes are possible, including partially spherical, partially ovoidal, and so forth, it being more important that a radial groove be provided thereby. Undercut 107 further comprises an outer surface 115 having a leading edge 116 and a trailing edge 117. Outer surface 115 is preferably, though not necessarily, a partially cylindrical surface. In addition, undercut 107 further comprises a bottom surface 118 and a top surface 119.

[0088] Preferably, second flange 120 is identical to first flange 110, and so the following structures are comparable to those for the first flange 110, but are not shown in Figure 6. As a result, second flange 120 further comprises a leading surface 123 and a trailing surface

124. Undercut 107 is essentially a partial cylindrical surface defining a groove. Undercut 107 further comprises an outer surface 125 having a leading edge 126 and a trailing edge 127. As state above, outer surface 125 is preferably, though not necessarily, a partially cylindrical surface. In addition, undercut 107 further comprises a bottom surface 128 and a top surface 129.

[0089] Because the undercut 107 extends radially through inner surfaces 112, 122 toward outer surfaces 111, 121, undercut 107 defines a diameter larger than the diameter of the inner surfaces 112, 122, but smaller than the diameter of the outer surfaces 111, 121.

[0090] Referring now to Figures 9-18, a locking assembly 300 according to a first embodiment is depicted. The locking assembly 300 preferably comprises two parts: an upper cap 310 and a lower cap 330. The lower cap 330 according to this embodiment (Figure 16) is a substantially cylindrical disk-like member having an upper surface 331 and a lower surface 332 and an outer surface 333 having a diameter 333A. A post 334 extends longitudinally away from the upper surface 331. The post 334 is substantially cylindrical and has a diameter 334A smaller than the diameter of the lower cap 330. Preferably three timing grooves 335A, 335B, and 335C (collectively, 335) are provided longitudinally along the post 334, as is shown in Figure 9. Timing grooves 335 are preferably spaced 45 degrees apart.

[0091] Upper surface 331 further comprises opposed helical segments 336, 337. Helical segment 336 further comprises upper camming surface 338 having a leading edge 339 and a trailing edge 340. Upper camming surface 338 resides above the upper surface 331 a first height H1 at the leading edge and a second height H2 at the trailing edge, where H2 is greater than H1. Lower surface 332 is concave in a first radial direction so as to create a channel or saddle to engage an outer surface of a rod 200.

[0092] The upper cap 310 (Figure 15) according to this embodiment is a generally cylindrical member having an outer surface 311 and a height 311A and a diameter 311B, and preferably having an inner cavity 312 therein for receiving a driving instrument (such as, a square driver, a pentagonal driver, a star driver, a hex driver, a Torx driver, a modified Torx driver, or any other geometric driving device that utilizes mating male/female members utilized to apply a torque). Inner cavity 312 therefore comprises sidewalls 313 (the number and shape of which are determined by the desired type of driving instrument) and a floor 314. The diameter 311B of the outer surface 311 is preferably the same as the diameter 333A of the outer surface 333 of lower cap 330.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 891 of 2152

[0093] Preferably, an opening 315 is disposed longitudinally in the floor 314 to receive the post 334. The opening 315 can take many shapes, depending on the shape of the desired post 334 and its resulting functions. However, most preferably the opening 315 is cylindrical with a projection 316 therein for mating with the timing grooves 335 in the post 334.

[0094] Referring again to the upper cap 310, it can be seen that the upper cap 310 further comprises flanges or wings protruding radially outwardly from the outer surface 311. In particular, first wing 317 and second wing 318 extend outwardly from the outer surface 311 in order to engage undercut 107, as will be described below. First wing 317 and second wing 318 are disposed about the outer surface 311 preferably 180 degrees apart. Additionally, upper cap 310 further comprises lower camming surfaces 328, preferably spaced ninety degrees out of phase with the first wing 317 and second wing 318, to engage the upper camming surfaces 338 of the lower cap 330 (as will be described below). Preferably, first wing 317 and second wing 318 are identical. Therefore, the following structural description will preferably apply to both first wing 317 and second wing 318.

[0095] First wing 317 comprises an upper surface 319 and a lower surface 320 having a leading edge 321 and a trailing edge 322. The upper surface 319 is inclined in the direction of the trailing edge 322.

[0096] In the preferred form of this embodiment (both polyaxial and non-polyaxial) depicted in Figures 9-18, the upper cap 310 further comprises structure to prevent splaying of the flanges 110, 120 or 410, 420. Because the locking assembly 300 uses camming surfaces 328, 338 to apply compression to the rod 200, forces can be created radially outwardly that tend to splay the flanges 110, 120 away from one another. Therefore, as best seen in Figure 15, some modifications exist to prevent splaying.

[0097] First wing 317 and second wing 318 further comprise a ridge 326, 327 respectively located outwardly thereof and away from outer surfaces 311, 321, respectively. Ridge 326 comprises an upper surface 351, an outer surface 352, and an inner surface 353. Similarly (though not visible in the figures), ridge 327 comprises an upper surface 361, an outer surface 362, and an inner surface 363. Additionally, as best seen in Figures 7 and 8, undercut 107 further comprises a slot 140 adjacent the outer surfaces 115, 125, respectively. Slot 140 further comprises an upper surface 141, an inner surface 142 and an outer surface 143. Upon insertion of the upper cap 310 into the cylindrical body 103, 403, rotation of the upper cap 310 causes ridges 326, 327 to enter slots 140. Inner surface 353 of the ridge 326

engages inner surface 142 of slot 140 as the upper cap 310 is rotated, thus preventing splaying.

[0098] Additionally, upper cap 310 preferably comprises one or more stops 323. In the preferred embodiment, stops 323 comprise protuberances extending radially from the outer surface 311 of the upper cap 310, having a leading surface 324 and a trailing surface 325. A depression 108 is located near the trailing surface 114 of the first flange 110 or the trailing surface 124 of the second flange 120, or both. The depressions 108 are situated in such an orientation such that no more than 90 degrees of rotation is allowed once the upper cap 310 is inserted therein. In the preferred form of this embodiment, the stops 323 are inserted into the depression 108 at approximately fifty-five degrees from the first radial along the axis of the channel 105.

[0099] It should be noted that the upper cap 310 may have many arrangements and orientations of stops 323. For instance, a stop 323 may be alternatively fitted at the leading or trailing edge 321, 322 of the first wing 317 or second wing 318 such that, upon rotation of 90 degrees inside the undercut 107, the stop 323 contacts a mating surface within the undercut 107. Alternatively, the stop 323 may be provided by a combination of the timing grooves 335 of the lower cap 330 and the projection 316 of the upper cap 310, such that upon rotation of 90 degrees, the projection 316 contacts a terminal edge of one of the timing grooves 335. Additionally, depression 108 could be located substantially on one flange 110, 120 such that all or a majority of the rotation of 90 degrees occurs atop the flange. This would result in a fairly large depression 108. Many other variations are possible.

[00100] Upper cap 310 and lower cap 330 are preferably joined by inserting the post 334 into the opening 315, aligning the timing grooves 335 with the projection 316 in such a manner that the upper cap 310 is timed for three positions: 0, 45, and 90 degrees (first timing groove 335A, second timing groove 335B, and third timing groove 335C, respectively). Initial assembly of the upper cap 310 and lower cap 330, and indeed the manner in which the surgeon will receive the assembly, results in the projection 316 residing in first timing groove 335A. Preferably the top of the post 334 is then compressed, either mechanically or hydraulically, in order to "mushroom" the top. This prevents the post 334 from thereafter passing through the opening 315, which would separate the upper cap 310 from the lower cap 330.

[00101] The apparatus 10 is used typically with a surgical rod 200 having an outer surface 201 and a length 202. Any type of surgical rod is allowable for use. Typically, the rod will

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 893 of 2152

be a surgical grade stainless steel, titanium, titanium alloy, carbon fiber, memory metal, or other material suitable for implantation. The rod 200 is preferably cylindrical and may have texture or form on its outer diameter as well as a means for rotating the spine such as a hex on one or either end, flats along the rod, and so forth.

[00102] Now that the structure for a first non-polyaxial anchor embodiment has been described, attention is turned to the operation and use of the system according to this embodiment. The surgical site is prepared by the surgeon by first exposing the appropriate spinal area. The surgeon then drills or probes the bone for initial provision of anchor holes. Next, the surgeon obtains the bone anchor 100 and engages the driving instrument with the head 109. The bone anchor 100 is inserted into the prepared opening in the bone, and a torque is applied to the driving instrument, driving the bone anchor 100 into the bone until the bone anchor 100 is seated on the bone at the bone interface and the channel 105 is oriented in the desired direction. Numerous anchor assemblies can be inserted in this manner, and a rod 200, with proper contours, is then inserted into the respective channels 105.

[00103] Next, the surgeon inserts a locking assembly 300 within each channel 105 atop the rod 200 such that the lower surface 332 of the lower cap 330 engages the outer surface 201 of the rod 200. This proper orientation results in the first wing 317 and second wing 318 aligned substantially in the same radial direction as the axis of the channel 105, and causes the stop 323 to reside in the depression 108, and causes projection 316 to reside in the first timing groove 335A (Figure 17). The surgeon then engages a driving instrument with the inner cavity 312 of the upper cap 310 and applies a torque to begin rotating the upper cap 310 to quickly and positively lock the locking assembly 300 inside the cylindrical body 103 and the first flange 110 and second flange 120.

[00104] As torque is applied to the upper cap 310, this causes the upper camming surface 338 of the lower cap 330 and the lower camming surface 328 of the upper cap 310 to engage. This in turn causes leading edge 321 of the upper surface 319 and lower surface 320 of the first wing 317 and second wing 318 to enter the leading edges 116, 126 of the undercut 107, respectively. The application of additional torque causes lower camming surface 328 of the upper cap 310 to rotatingly traverse upon the upper camming surface 338 of the lower cap 330. Since the upper camming surface 338 and the lower camming surface 328 are inclined planes wrapped about a centroidal axis of rotation (thus, helixes), additional torque causes the upper cap 310 to continue to rotate about its axis and thus forces the lower

cap 330 to translate longitudinally in the distal direction of the bone anchor 100. This translational movement compresses the lower surface 332 of the lower cap 330 onto the outer surface 201 of the rod 200. This compression is translated through the rod 200 and forces the outer surface 201 of the rod into compressive contact with the bottom surface 106 of the channel 105. Once the upper cap 310 has been turned 45 degrees, the projection 316 of the opening 315 of the upper cap 310 moves into the second timing groove 335B of the post 334. This provides the surgeon with tactile feedback that the upper cap 310 has been inserted halfway, and allows the surgeon to make any final minor adjustments of the rod/anchor interface.

[00105] Application of additional torque continues to rotate the upper cap 310 about the longitudinal axis and continues to cause lower camming surface 328 to traverse along upper camming surface 338, which in turn continues to translate the lower cap 330 longitudinally in the distal direction toward the bone. This continues to apply compressive force on the rod 200 as it seats within the channel 105 with increasing force. The surgeon continues to apply torque until the upper cap 310 has been turned 90 degrees. This then allows the projection 316 of the opening 315 of the upper cap 310 to seat into the third timing groove 335C of the post 334 (Figure 18). At this point, the leading surface 324 of the stop 323 contacts the leading surfaces 113, 123 of the first flange 110 and second flange 120, respectively. This provides a positive mechanical stop and prevents any overtorque from being applied, thus preventing movement past 90 degrees. The seating of the projection 316 into the third timing groove 335C also provides a positive locking force tending to prevent rotation in the opposite, unlocking, direction.

[00106] Now that the apparatus 10 has been described for use with a first non-polyaxial embodiment, the apparatus 10 will be described for use with polyaxial bone anchors 500 according to a second embodiment, depicted in Figures 19-30. Several modifications are present in this second polyaxial embodiment. As with the non-polyaxial bone anchor 100, the figures and descriptions depict a screw for the sake of simplicity.

[00107] Referring to Figures 19-22, the polyaxial bone anchor 500 omits the partially cylindrical body 103 of the nonpolyaxial embodiment. Instead, the polyaxial bone anchor 500 comprises a proximal end 502 and a distal end 504. At the proximal end is a head 501 having a lower surface 503 and an upper surface 505. At the distal end 504 are threads 509. A shank portion 510 is typically present between proximal end 502 and distal end 504. In the preferred polyaxial embodiment, the lower surface 503 is a spherical section. The

spherical surface allows the anchor 500 to angulate at varying angles in a ball-and-socket manner, as will be described below. The lower surface 503 has a diameter 503A adjacent the shank 510 of the anchor 500 and a diameter 505A at the union of the upper surface 505 and the lower surface 503, wherein the diameter 505A is greater than the diameter 503A. Similarly, in the preferred polyaxial embodiment, the upper surface 505 is a conic section. The conic section is used to reduce the height of the head 501 compared to that of a known spherical or ball-shaped heads, while still allowing for the same amount of anchor/rod interface that would be possible with a ball-shaped head.

[00108] The upper surface 505 of the head 501 may also have an internal cavity 506 therein for engagement with a driving mechanism. Many forms of engagement geometries are possible. In the figures a modified Torx system is shown, having a center hub 507 having an upper surface 508 and a diameter 507A. The upper surface 508 maintains the conic section of the upper surface 505, and contacts the rod 200. The diameter of the center hub 507 is dependent upon the amount of angulation of the anchor 500 desired, as will be described below.

[00109] Referring to Figures 23-26, a housing 400 is provided to accept the rod 200 and join it with the polyaxial anchor 500. Housing 400 is akin to the partially cylindrical body 103 of the non-polyaxial anchor described above, with a few modifications. Indeed, housing 400 further comprises a partially cylindrical body 403 having a first flange 410 and a second flange 420 opposed to and spaced-apart from said first flange 410. The first flange 410 and the second flange 420 extend longitudinally in the proximal direction, and are separated by a channel 405 therebetween.

[00110] Referring to Figures 27-30, one modification present in the preferred form of this polyaxial embodiment resides in the structure of the outer surfaces of the flanges 410, 420. First flange 410 has an upper portion 411 and a lower portion 412, wherein an outer diameter 411A of the upper portion 411 first flange 410 and second flange 420 is greater than an outer diameter 412A of the lower portion 412, thus creating a step 431 at the junction of upper portion 411 and lower portion 412 (Figure 28). Preferably upper portion 411 further comprises one or more slots 432 therein to receive and properly orient a bottom ring 450 (described below). Upper portion 411 has a convex outer surface 413 and a concave inner surface 414, in a manner similar to that of surfaces 111, 112 of first flange 110 in the preferred non-polyaxial embodiment.

[00111] Similarly, second flange 420 has an upper portion 421 and a lower portion 422 akin to the upper portion 411 and lower portion 412 of the first flange 410. Upper portion 421 has a convex outer surface 423 and a concave inner surface 424, in a manner similar to that of surfaces 121, 122 of second flange 120 in the preferred non-polyaxial embodiment. Upper portions 411, 421 also preferably have a depression 408 akin to depression 108 in the non-polyaxial embodiment.

[00112] As referenced previously with respect to a non-polyaxial embodiment, preferably the outer surfaces 413, 423 circumscribe a portion of a circle, with a gap coinciding with the channel 405, when viewed in the longitudinal direction, as best seen in Figure 25. In a similar fashion, preferably the inner surfaces 414, 424 circumscribe a portion of a smaller circle, with a gap coinciding with the channel 405, when viewed in an axial or longitudinal direction.

[00113] The lower portion 440 further comprises a generalized cylinder having a height 445 and having multiple resiliently opposed fingers 441 depending longitudinally in the distal direction. Lower portion 440 further comprises a convex outer surface 415 and a concave inner surface 416 (Figure 24). Fingers 441 define an inner diameter 442 and an outer diameter 443. The inner diameter 442 is preferably the same as the diameter 503A of the lower surface 503 of the head 501 of the polyaxial bone anchor 500 (Figures 25, 25A, and 25B). Because there is a chamfer on the bottom of the head fingers, this allows the screw head 503 to be installed into the head as the fingers are forced outwards creating a large diameter due to the radial spring effect. This also means the outer ring must be up to allow this to occur. Fingers 441 also have a lip 444 on the outer surface thereof such that the diameter of the lip 444 is greater than the outer diameter 443. As an added feature of versatility, fingers 441 are dimensioned such that, upon application of a minimal amount of force in the longitudinal direction (which results in a spreading of the fingers 441), the lower portion 440 can be placed on the head 501 of the anchor 500 after the anchor 500 has been placed in the bone. In other words, two methods of insertion are possible. First, the anchor 500 can be inserted into the bone and then the housing 400 can be placed thereon. Second, the housing 400 can be placed on the anchor 500 and then the anchor/top cap assembly can be inserted into the bone.

[00114] The channel 405 is preferably a U-shaped channel disposed about the junction of outer surfaces 413, 415 and 423,425, such that it creates a rod-receiving groove in a first radial direction. The channel 405 further comprises a bottom surface 406 that is

dimensioned to receive a surgical rod 200. Preferably, the bottom surface 406 is semi-circular to receive the outer surface of a cylindrical rod 200.

[00115] Referring again to Figures 27-30, when the anchor 500 is inserted into the partially cylindrical body 403 of the housing 400, the lower surface 503 seats on the inner diameter 442 of the fingers 441. Since the lower surface 503 is curvate, angulation of the anchor 100 is possible. This creates a sort of ball and socket arrangement. In the preferred embodiment, angulation of approximately 0 to 60 degrees included angle is possible.

[00116] Referring again to Figures 24-30, a further modification for the preferred form of this polyaxial embodiment is the addition of a bottom ring 450. Bottom ring 450 comprises a generalized open cylindrical body 451 having an inner diameter 452 (not visible in the figures), an outer diameter 453, a height 454, an outer surface 455, an inner surface 456, a proximal end 457, and a distal end 458. When assembled, the bottom ring 450 surrounds the lower portion 440 such that the inner surface 456 lies on the outside of the outer diameter 443 of the lower portion 440. Inner surface 456 is dimensioned such that bottom ring 450 can translate longitudinally about outer diameter 443 of the lower portion. Similarly, bottom ring 450 is dimensioned such that height 454 is less than height 445 of the lower portion 440.

[00117] Referring again to Figures 23 and 25, the outer surface 455 further comprises a U-shaped slot 463 having a bottom surface 464. In the locked position, the bottom surface 464 is adjacent the bottom surface 406 of the lower portion 440 so as to lockingly facilitate the rod 200.

[0100] The proximal end 457 preferably can have one or more tabs 459 (not shown) dimensioned and positioned for mating with slots 432 in the upper portion 430. Thus, when assembled, bottom ring 450 can translate longitudinally in a path defined by the combination of tabs 459 and slots 432. Two terminal positions are possible for the bottom ring 450, and bottom ring 450 can slide between these two positions. In an unlocked position (shown in Figures 17, 23, 25, 26, 27, and 29), the bottom ring 450 resides toward the proximal end of the lower portion 440, and tabs 459 reside within slots 432. In a locked position (shown in Figures 18, 19, 25B, 28, and 30), the bottom ring 450 resides at the distal end of the lower portion 440 such that the distal end 458 is in contact with lip 444. The distal end 458 terminates in a bottom surface 460 having an inner diameter 461 and an outer diameter 462. The inner diameter 461 is slightly less than the outer diameter 443 of the fingers 441. Thus, when the bottom ring 450 is translated longitudinally toward the bone,

the inner diameter 461 applies a radial force directed inwardly on the fingers 441. As this occurs upon further translation of the bottom ring 450, the fingers 441 compress upon the lower surface 503 of the head 501 of the anchor.

[0101] The internal characteristics of the upper portion 430 are largely similar to those of the cylindrical body 403 of the non-polyaxial embodiment described above. For this reason, many reference numerals are duplicated for this embodiment. Thus, as shown in Figures 23-28, first flange 410 further comprises an undercut 107 in the inner surface 414. The undercut 107 receives a camming surface of the locking assembly 300 (described above). First flange 410 further comprises a leading surface 113 and a trailing surface 114. Undercut 107 is preferably a partial cylindrical surface defining a groove. Undercut 107 further comprises an outer surface 115 having a leading edge 116 and a trailing edge 117. Outer surface 115 is preferably, though not necessarily, a partially cylindrical surface. In addition, undercut 107 further comprises a bottom surface 118 and a top surface 119.

[0102] Preferably, second flange 420 is identical to first flange 410. As a result, second flange 420 further comprises a leading surface 123 and a trailing surface 124. Undercut 107 is essentially a partial cylindrical surface defining a groove. Undercut 107 further comprises an outer surface 125 having a leading edge 126 and a trailing edge 127. Outer surface 125 is preferably, though not necessarily, a partially cylindrical surface. In addition, undercut 107 further comprises a bottom surface 128 and a top surface 129.

[0103] Because the undercut 107 extends radially within inner surface 414, 424, undercut 107 defines a partial cylindrical section having a diameter larger than the diameter of the inner surfaces 414, 424, but smaller than a diameter of the outer surfaces 413, 423.

[0104] The operation and use of the this embodiment of the polyaxial anchor assembly is very similar to that of the non-polyaxial embodiment described above, except that angulation of the anchor 500 is allowed with the polyaxial embodiment. The surgical site is prepared by the surgeon in the same manner. The housing 400 and bottom ring 450 are pre-connected prior to being provided to the surgeon, and the bottom ring 450 is in its unlocked position. Next, the surgeon obtains the bone anchor 500 and, preferably, inserts it into the partially cylindrical body 403 of the housing 400 until the lower surface 503 of the head 501 contacts the inner diameter 442 of the fingers 441. As noted above, the anchor 500 can be installed with or without the housing 400 pre-installed. The surgeon engages the driving instrument with the internal cavity 506 of the head 501. The bone anchor 500 is inserted into the prepared opening in the bone, and a torque is applied to the driving instrument,

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 899 of 2152

driving the bone anchor 500 into the bone until the bone anchor 500 is seated on the bone at the bone interface at the desired angulation. The housing 400 is then freely turned until the channel 405 is oriented in the desired direction. Numerous anchor assemblies can be inserted in this manner, and a rod 200, with proper contours, is then inserted into the respective channels 405. Once the top caps 400 have been properly positioned, the surgeon then pushes longitudinally on the bottom ring 450 until the inner diameter 461 forces the fingers 441 to move radially inward and the bottom surface 460 of the bottom ring 450 rests on lip 444 of the lower portion 440. This aligns bottom surface 464 with bottom surface 406 and locks the bone anchor 500 in the desired angulation.

[0105] Next, the surgeon inserts a locking assembly 300 within each channel 405 atop the rod 200 such that the lower surface 332 of the lower cap 330 engages the outer surface 201 of the rod 200. This proper orientation results in the first wing 317 and second wing 318 aligned substantially in the same first radial direction as the longitudinal axis of the channel 405, and causes the stop 323 to reside in the depression 408. The surgeon then engages a driving instrument with the inner cavity 312 of the upper cap 310 and applies a torque to rotate the upper cap 310 to easily and positively lock the locking assembly 300 inside the cylindrical body 403 and the first flange 410 and second flange 420.

[0106] As torque is applied to the upper cap 310, this causes the upper camming surface 338 of the lower cap 330 and the lower camming surface of the upper cap 310 to engage. This in turn causes leading edge 321 of the upper surface 319 and lower surface 320 of the first wing 317 and second wing 318 to enter the leading edges 116, 126 of the undercut 107, respectively. The application of additional torque causes lower camming surface 328 of the upper cap 310 to rotatingly traverse upon the upper camming surface 338 of the lower cap 330. Since the upper camming surface 338 and the lower camming surface 328 are inclined planes wrapped about a centroidal axis of rotation (helixes), additional torque causes the upper cap 310 to continue to rotate about its axis and thus force the lower cap 330 to translate longitudinally in the distal direction of the longitudinal axis of the bone anchor 500. This translational movement compresses the lower surface 332 of the lower cap 330 onto the outer surface 201 of the rod 200. This compression is translated through the rod 200 and forces the outer surface 201 of the rod into compressive contact with the bottom surface 464 of the channel 405 and in contact with the upper surface 505 of the head 501. Once the upper cap 310 has been turned 45 degrees, the projection 316 of the opening 315 of the upper cap 310 seats into the second timing groove 335B of the post 334. This

provides the surgeon with tactile feedback that the upper cap 310 has been inserted halfway, and allows the surgeon to make any final minor adjustments of the rod/anchor interface.

[0107] Application of additional torque continues to rotate the upper cap 310 about the longitudinal axis and continues to cause lower camming surface 328 to traverse along upper camming surface 338, which in turn continues to translate the lower cap 330 longitudinally in the distal direction toward the bone. This continues to apply compressive force on the rod 200 as it seats within the channel 405 with increasing force. The surgeon continues to apply torque until the upper cap 310 has been turned 90 degrees. This then allows the projection 316 of the opening 315 of the upper cap 310 to seat into the third timing groove 335C of the post 334. At this point, the leading surface 324 of the stop 323 contacts the leading surfaces 113, 123 of the first flange 410 and second flange 420, respectively. This provides a positive mechanical stop and prevents any overtorque from being applied, thus preventing movement past 90 degrees. The seating of the projection 316 into the third timing groove 335C provides a positive locking force tending to prevent rotation in the opposite, unlocking, direction.

[0108] Referring now to Figures 31-42, another embodiment of the invention is shown. The locking assembly 300 can be external to the first flange 110 and second flange 120. In this embodiment, the flanges 110, 120 preferably contain a circumferential groove 607 in the convex outer surfaces 111, 121 thereof. A first wing 617 and a second wing 618 of the upper cap 310 enter the circumferential groove 607 upon activation of the locking assembly 300. Alternatively, the outer surfaces 111, 121 can contain a protrusion 608 for engaging a circumferential groove in the portion of the upper cap 310 that resides external to the outer surfaces 111, 121. In both cases, due to the external cam configuration, splaying of the flanges 110, 120 is easily remedied. In the external cam configurations, the camming action can be provided by an upper wave cap and lower cap as described above in reference to the internal configurations. However, the camming action can also be provided by the interaction of the first wing 617 and the second wing 618 and the circumferential groove 607. For instance, the circumferential groove itself can comprise an arcuate engagement slot for engaging opposed arcuate engagement surfaces (for example, a helical surface) on the first wing 617 and second wing 618. These and other methods of camming the wings to the head 501 are contemplated.

[0109] Referring now to Figures 43-59 another embodiment of both the polyaxial apparatus 10 and the non-polyaxial apparatus 10 is shown having a locking assembly 300

that utilizes a threaded upper cap 310. Figures 45-48 depict a non-polyaxial apparatus 10. Figures 43, 44, and 49-59 depict a polyaxial embodiment.

[0110] Referring now to Figures 45-48, the apparatus 10 is seen to be quite similar to that described above with regard to Figures 2-5. However, this embodiment utilizes a threaded locking assembly 300. The first flange 110 and second flange 120 have similar structure as that described above, but instead of comprising an undercut 107 in inner surface 112, the flanges 110, 120 comprise female threads 707. These threads 707 are for engagement by corresponding threads 717 on upper cap 310.

[00118] As stated, the locking assembly 300 of this embodiment comprises an upper cap 310 that is threaded, and a lower cap 330 that is similar to the lower cap 330 described previously. The upper cap 310 in this embodiment comprises threads 707 on its outer surface. Preferably the threads 707 are of the buttress type, but many forms of thread are possible. The upper cap 310 further comprises an inner cavity 312 therein that can have sidewalls 313 and floor 314 as described previously. The floor 314 can likewise contain an opening 315 to receive post 334. Projection 316 and timing grooves 335 in post 334 are optional.

[00119] The lower cap 330 comprises upper surface 331 and lower surface 332 wherein upper surface 331 is generally flat and wherein lower surface 332 is generally cylindrical (e.g., forming a saddle) to engage an outer surface of a rod 200. In the preferred form of this embodiment, the lower cap 330 preferably comprises an extension 718 of the lower surface 332. This extension 718 is dimensioned to fit within the channel 105 and to properly orient the locking assembly 300 during implantation. Ideally, the threads 717 can include single or double starts that can be timed with the lower surface 332 of the lower cap 330, and also with the extension 718. In this manner, once a rod is placed into the channel 105, the locking assembly 300 is inserted into the channel 105 atop the rod 200. Because the threads 717 are timed in conjunction with the extension 718 and threads 707 of the anchor 100, this prevents cross threading that is common in many devices.

[0111] Referring now to Figures 43, 44, and 49-59, another embodiment of a polyaxial anchor 10 is shown, this embodiment likewise includes a threaded locking assembly 300 akin to that just described. With particular reference to Figures 49-52, in this polyaxial embodiment slight modifications are included in the anchor 500. In particular, the head 501 comprises one or more depression 501A about its circumference. The upper surface 505

optionally is conically shaped and is convex on its top and tapers to a slight concavity at its outer circumference.

[0112] Referring now to Figures 53-56, a housing 400 of this embodiment is shown. The housing 400 is similar in many respects to the housing 400 previously described, with several notable exceptions. The first flange 410 and second flange 420 do not contain the undercut 107. Rather, as explained, the flanges 410, 420 comprise female threads 707 to receive the threads 717 of the upper cap 310. Due to the presence of the threads 707, this embodiment does not comprise the structural details related to the lower portion 440, fingers 441, and so forth. This embodiment instead comprises a single part housing 400 for receiving the anchor 500. The housing 400 does include a convex outer surface 413 and a concave inner surface 414, in similar fashion to previously described embodiments. In this embodiment, however, the inner surface 413 further comprises one or more appurtenance 713 protruding radially inwardly. This appurtenance 713 serves to engage the depression 501A in the head 501 of the anchor 500, thus forcing the anchor 500 to be inserted therein in a particular orientation. Once the depression 501A passes by the appurtenance 713, the anchor 500 is free to rotate. Upon any rotation thereafter, the depression 501A will not line up with the appurtenance 713, and therefore the anchor will not readily be removed from the housing 400.

[0113] While there has been described and illustrated particular embodiments of a novel spinal rod anchor assembly, and in particular, one that provides a quick-connect release, it will be apparent to those skilled in the art that variations and modifications may be possible without deviating from the broad spirit and principle of the present invention, which shall be limited solely by the scope of the claims appended hereto.

What is claimed:

1. A bone fixation apparatus for a rod system comprising:

a bone anchor having a proximal end for engaging a driving device and a distal end for engaging a bone;

a housing coupled to said proximal end of said bone anchor having opposed spaced-apart flanges extending longitudinally defining a channel therebetween for receiving a rod, said flanges having an outer surface and an inner surface having female threads therein;

a locking assembly for locking said surgical rod to said housing in contact with said proximal end of said bone anchor;

wherein said locking assembly further comprises an upper cap and a lower cap joined by a post and rotatable relative one to the other, wherein said upper cap is a generally cylindrical member having an outer surface containing threads thereon and an inner cavity and an upper surface and a lower surface and wherein said inner cavity further comprises an opening to receive said post; and wherein said lower cap comprises an upper surface and a lower semi-cylindrical surface for engaging said rod; and

wherein said rod is insertable into said channel of said housing and said locking assembly is thereafter insertable into said channel of said housing, and wherein a driving instrument is insertable into said inner cavity of said upper cap and rotates said upper cap relative to said lower cap about said post, thereby engaging said threads, thus causing said locking assembly to translate longitudinally toward said distal end of said anchor into a forcing relationship with said rod, thus forcing said rod into a locking relationship with said proximal end of said anchor.

2. The bone fixation system of claim 1 wherein said bone anchor is a screw.

3. The bone fixation apparatus of claim 2 wherein said housing is fixed to said proximal end of said bone anchor so as to prevent angulation of said bone anchor.

4. The bone fixation system of claim 3 wherein said lower cap further comprises an extension of said lower semi-cylindrical surface dimensioned to reside within said channel.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 904 of 2152

5. The bone fixation system of claim 4 wherein said threads on said upper cap and said threads in said flanges further comprise at least one start thread timed to properly engage each other when said extension is located within said channel.

6. The bone fixation system of claim 1 wherein said bone anchor is a hook.

7. The bone fixation apparatus of claim 6 wherein said housing is fixed to said proximal end of said hook so as to prevent angulation thereof.

8. The bone fixation system of claim 7 wherein said lower cap further comprises an extension of said lower semi-cylindrical surface dimensioned to reside within said channel.

9. The bone fixation system of claim 8 wherein said threads on said upper cap and said threads in said flanges further comprise at least one start thread timed to properly engage each other when said extension is located within said channel.

10. The bone fixation system of claim 1 wherein said bone anchor is a polyaxial screw further comprising a head disposed at said distal end having a conic or aspheric upper surface and a partially spherical lower surface and defining a periphery at a junction of said upper and lower surfaces.

11. The bone fixation system of claim 10 wherein said lower cap further comprises an extension of said lower semi-cylindrical surface dimensioned to reside within said channel.

12. The bone fixation system of claim 11 wherein said threads on said upper cap and said threads in said flanges further comprise at least one start thread timed to properly engage each other when said extension is located within said channel.

13. The bone fixation system of claim 12 wherein said proximal end of said polyaxial screw further comprises a depression disposed about said periphery.

14. The bone fixation system of claim 13 wherein said inner surface of said flanges further comprise an appurtenance projecting substantially radially inwardly.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 905 of 2152

15. The bone fixation system of claim 14 wherein said polyaxial screw is removable from said housing when said depression aligns with said appurtenance, but is not removable when said depression is not aligned with said appurtenance.

16. A bone fixation apparatus for a rod system comprising:

a bone anchor having a proximal end for engagement with a driving device and a distal end for engagement with a bone;

a housing coupled to said proximal end of said bone anchor having opposed spaced-apart flanges extending longitudinally and having a channel therebetween to receive a surgical rod therein, each flange having an outer surface and an inner surface and an undercut within said inner surface;

a locking assembly for locking said surgical rod to said housing in contact with said proximal end of said bone anchor, further comprising an upper cap and a lower cap joined by a post and rotatable relative one to the other, wherein said upper cap is a generally cylindrical member having an outer surface and an inner cavity and an upper surface and a lower surface having camming surfaces thereon and wherein said inner cavity further comprises an opening to receive said post; wherein said outer surface has a first wing and a second wing projecting radially outwardly therefrom for insertion into said undercut to prevent removal of said locking assembly; and wherein said lower cap further comprises an upper surface having camming surfaces thereon for engagement with said camming surfaces of said upper cap and a lower semi-cylindrical surface for engaging said rod;

wherein said rod is insertable into said channel of said housing and said locking assembly is thereafter insertable into said channel of said housing, and wherein a driving instrument is insertable into said inner cavity of said upper cap and rotates said upper cap relative to said lower cap about said post, thereby moving said camming surfaces of said upper cap relative to said camming surfaces of said lower cap, thus causing said lower cap to translate longitudinally toward said distal end of said anchor into a forcing relationship with said rod, thus forcing said rod into a locking relationship with said proximal end of said anchor.

17. The bone fixation apparatus of claim 16 wherein said bone anchor is a screw.

18. The bone fixation apparatus of claim 17 wherein said housing is fixed to said proximal end of said bone anchor so as to prevent angulation of said bone anchor.

19. The bone fixation apparatus of claim 18 wherein said undercut further comprises a slot adjacent thereto disposed radially outwardly of said undercut having an inner surface and an outer surface and longitudinal dimension greater than that of said undercut.

20. The bone fixation apparatus of claim 19 wherein said first wing and said second wing further comprise ridges located outwardly thereof.

21. The bone fixation apparatus of claim 20 wherein said ridges engage said inner surfaces of said slots in said flanges to prevent splaying.

22. The bone fixation apparatus of claim 21 wherein said post further comprises a first timing groove and a second timing groove disposed longitudinally thereon.

23. The bone fixation apparatus of claim 22 wherein said upper cap further comprises a projection in said opening.

24. The bone fixation apparatus of claim 23 wherein said upper cap and said first and second timing grooves are timed such that said projection mates with said first timing groove when said locking assembly is in an unlocked position and mates with said second timing groove when said locking assembly is rotated to a locked position.

25. The bone fixation apparatus of claim 24 wherein said upper cap further comprises a stop disposed adjacent said upper surface thereof and projecting radially outwardly from said outer surface of said upper cap, said stop being located out of phase with said wings.

26. The bone fixation apparatus of claim 25 wherein said housing further comprises a depression disposed about said inner surface of said flanges.

27. The bone fixation apparatus of claim 26 wherein said stop engages said depression when said upper cap is rotated into a locked position.

28. The bone fixation apparatus of claim 16 wherein said bone anchor is a hook.

29. The bone fixation apparatus of claim 28 wherein said housing is fixed to said proximal end of said bone anchor so as to prevent angulation of said bone anchor.

30. The bone fixation apparatus of claim 29 wherein said undercut further comprises a slot adjacent thereto disposed radially outwardly of said undercut having an inner surface and an outer surface and longitudinal dimension greater than that of said undercut.

31. The bone fixation apparatus of claim 30 wherein said first wing and said second wing further comprise ridges located outwardly thereof.

32. The bone fixation apparatus of claim 31 wherein said ridges engage said inner surfaces of said slots in said flanges to prevent splaying.

33. The bone fixation apparatus of claim 32 wherein said post further comprises a first timing groove and a second timing groove disposed longitudinally thereon.

34. The bone fixation apparatus of claim 33 wherein said upper cap further comprises a projection in said opening.

35. The bone fixation apparatus of claim 34 wherein said upper cap and said first and second timing grooves are timed such that said projection mates with said first timing groove when said locking assembly is in an unlocked position and mates with said second timing groove when said locking assembly is rotated to a locked position.

36. The bone fixation apparatus of claim 35 wherein said upper cap further comprises a stop disposed adjacent said upper surface thereof and projecting radially outwardly from said outer surface of said upper cap, said stop being located out of phase with said wings.

37. The bone fixation apparatus of claim 36 wherein said housing further comprises a depression disposed about said inner surface of said flanges.

38. The bone fixation apparatus of claim 37 wherein said stop engages said depression when said upper cap is rotated into a locked position.

39. The bone fixation apparatus of claim 17 wherein said housing further comprises a separable body for lockable attachment to said proximal end of said screw.

40. The bone fixation apparatus of claim 39 wherein said separable body further comprises an upper portion having an outer diameter and an inner diameter and a lower portion having an outer diameter and an inner diameter and wherein said outer diameter of said lower portion is less than said outer diameter of said upper portion.

41. The bone fixation apparatus of claim 40 wherein said lower portion further comprises fingers oriented longitudinally and extending from said upper portion terminating at a distal end, wherein said fingers receive said proximal end of said screw in varying orientations.

42. The bone fixation apparatus of claim 41 wherein said distal end of said fingers define an inner diameter and an outer diameter.

43. The bone fixation apparatus of claim 42 wherein said lower portion further comprises a ring disposed externally on said fingers and slideable from an unlocked position to a locked position.

44. The bone fixation apparatus of claim 43 wherein said inner diameter of said ring at a bottom end thereof is slightly less than said outer diameter of said fingers such that as said ring is slid from said unlocked position to said locked position, said ring imparts a radial force on said fingers, thus locking said proximal end of said screw in a given orientation.

45. The bone fixation apparatus of claim 44 wherein said undercut further comprises a slot adjacent thereto disposed radially outwardly of said undercut having an inner surface and an outer surface and longitudinal dimension greater than that of said undercut.

46. The bone fixation apparatus of claim 45 wherein said first wing and said second wing further comprise ridges located outwardly thereof.

47. The bone fixation apparatus of claim 46 wherein said ridges engage said inner surfaces of said slots in said flanges to prevent splaying.

48. The bone fixation apparatus of claim 47 wherein said post further comprises a first timing groove and a second timing groove disposed longitudinally thereon.

49. The bone fixation apparatus of claim 48 wherein said upper cap further comprises a projection in said opening.

50. The bone fixation apparatus of claim 49 wherein said upper cap and said first and second timing grooves are timed such that said projection mates with said first timing groove when said locking assembly is in an unlocked position and mates with said second timing groove when said locking assembly is rotated to a locked position.

51. The bone fixation apparatus of claim 50 wherein said upper cap further comprises a stop disposed adjacent said upper surface thereof and projecting radially outwardly from said outer surface of said upper cap, said stop being located out of phase with said wings.

52. The bone fixation apparatus of claim 51 wherein said housing further comprises a depression disposed about said inner surface of said flanges.

53. The bone fixation apparatus of claim 52 wherein said stop engages said depression when said upper cap is rotated into a locked position.

54. A bone fixation apparatus for a rod system comprising:

a bone anchor having a proximal end for engagement with a driving device and a distal end for engagement with a bone;

a housing coupled to said proximal end of said bone anchor having opposed spaced-apart flanges extending longitudinally and having a channel therebetween to receive a surgical rod therein, each flange having an outer surface and an inner surface, said outer surface having a circumferential groove therein;

a locking assembly for locking said surgical rod to said housing in contact with said proximal end of said bone anchor, further comprising an upper cap and a lower cap joined by a post and rotatable relative one to the other, wherein said upper cap is a generally cylindrical member having an outer surface and an inner cavity and an upper surface and a lower surface having camming surfaces thereon and wherein said inner cavity further comprises an opening to receive said post; wherein said outer surface has a first wing and a second wing projecting radially outwardly therefrom for insertion into said circumferential groove in said outer surface of said housing to prevent removal of said locking assembly; and wherein said lower cap further comprises an upper surface having camming surfaces thereon for engagement with said camming surfaces of said upper cap and a lower semi-cylindrical surface for engaging said rod;

wherein said rod is insertable into said channel of said housing and said locking assembly is thereafter insertable into said channel of said housing, and wherein a driving instrument is insertable into said inner cavity of said upper cap and rotates said upper cap relative to said lower cap about said post, thereby moving said camming surfaces of said upper cap relative to said camming surfaces of said lower cap, thus causing said lower cap to translate longitudinally toward said distal end of said anchor into a forcing relationship with said rod, thus forcing said rod into a locking relationship with said proximal end of said anchor.

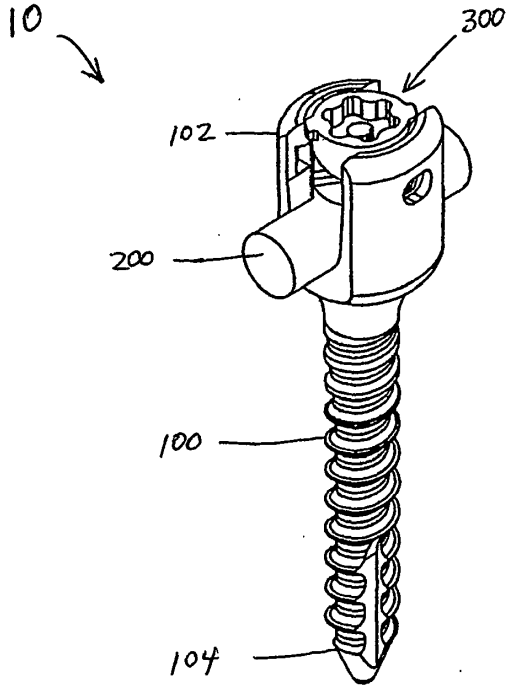


Fig 1

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 913 of 2152

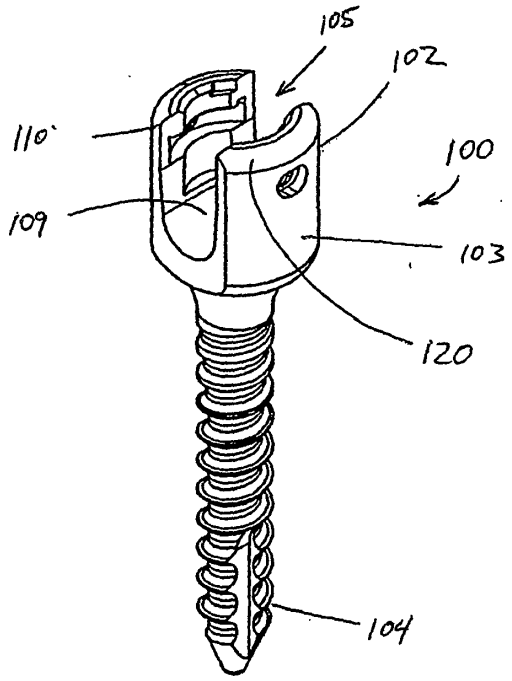
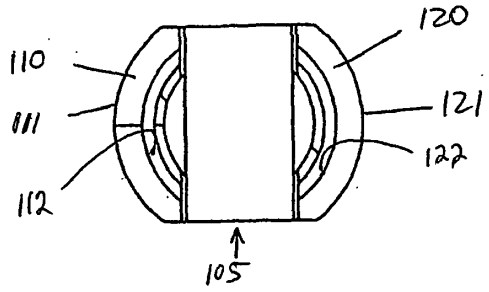


Fig. 2

Fig. 3



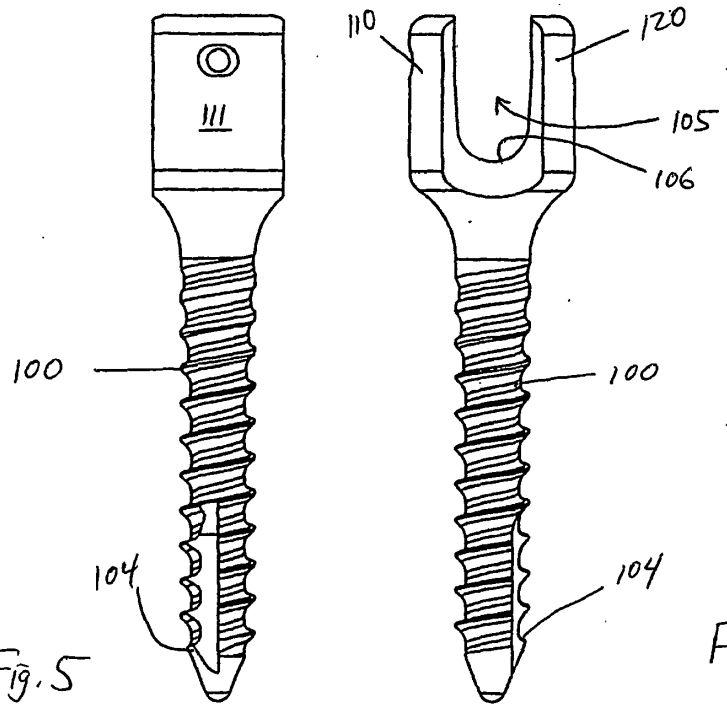


Fig. 5

Fig. 4

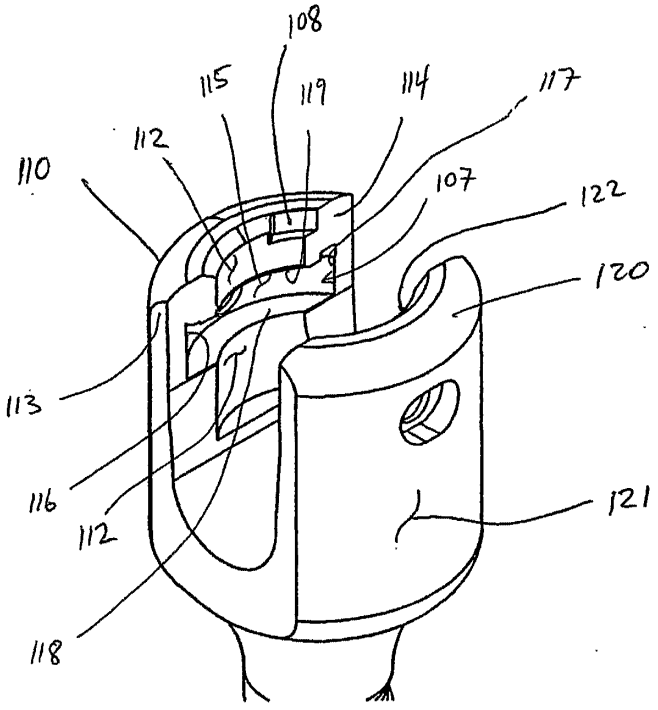


Fig. 6

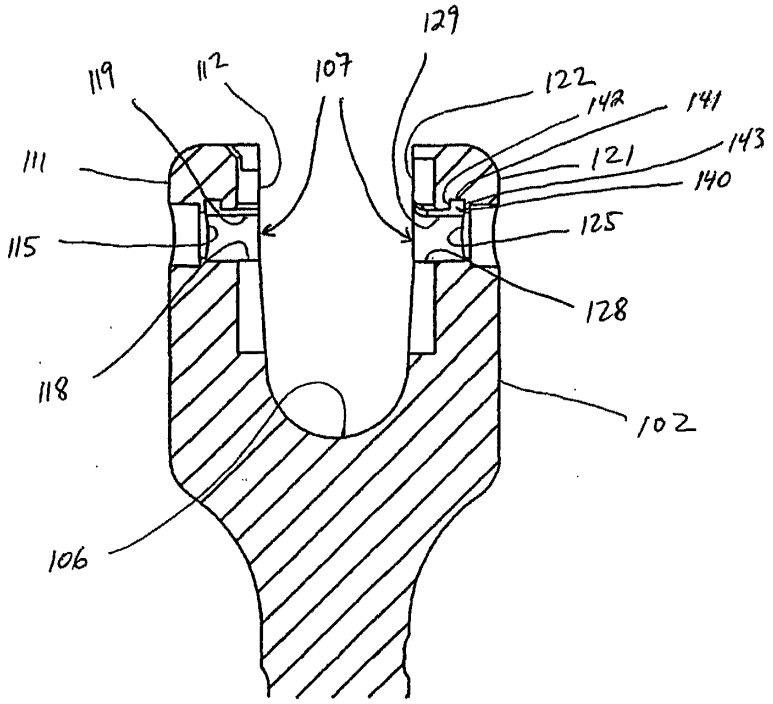

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Fig. 7

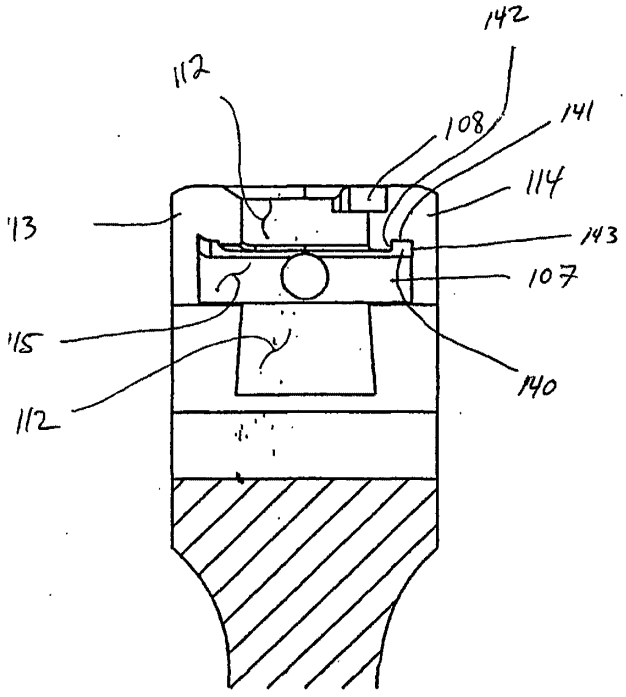
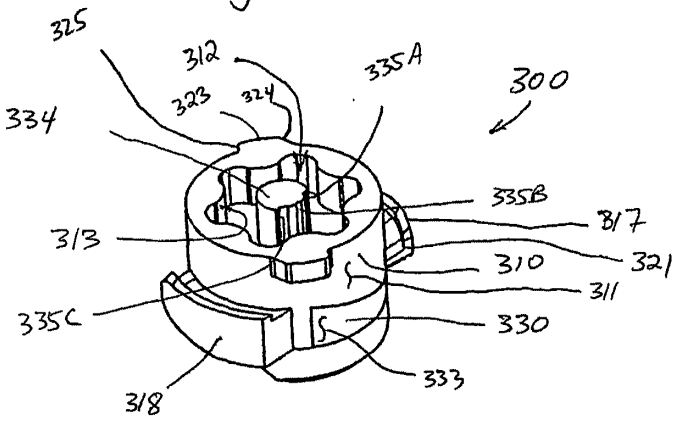


Fig. 8

Fig. 9



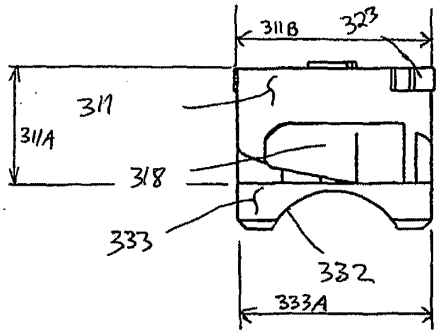


Fig. 10

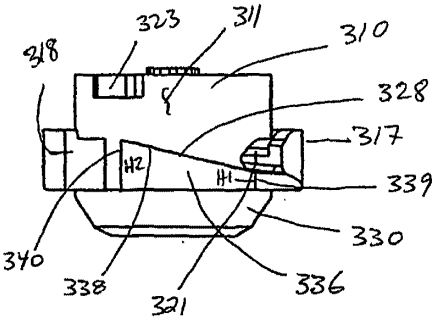
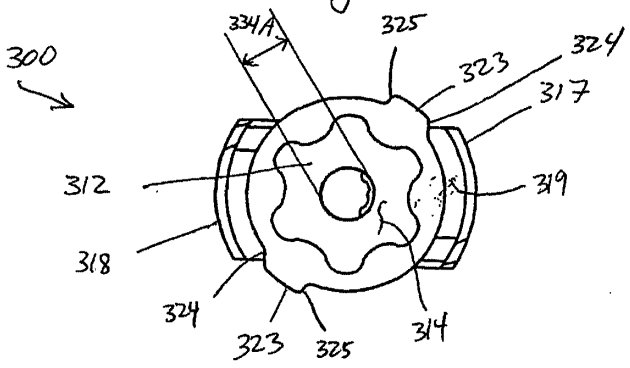


Fig. 11

Fig. 12



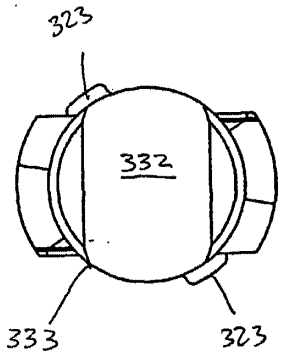


Fig. 13

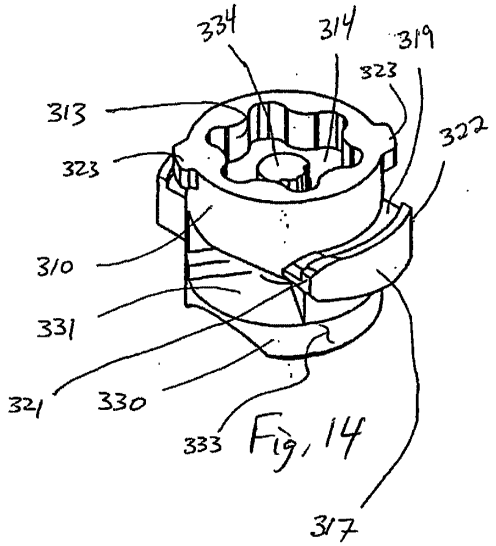


Fig. 14

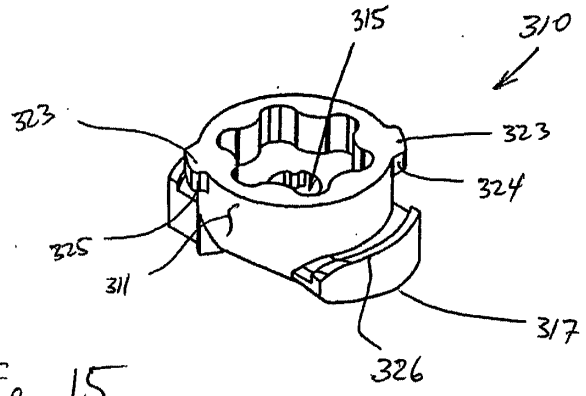

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Fig. 15

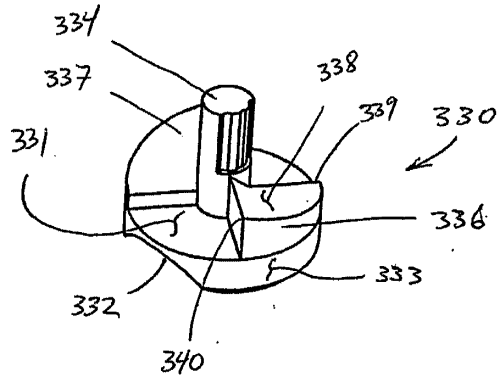

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Fig. 16

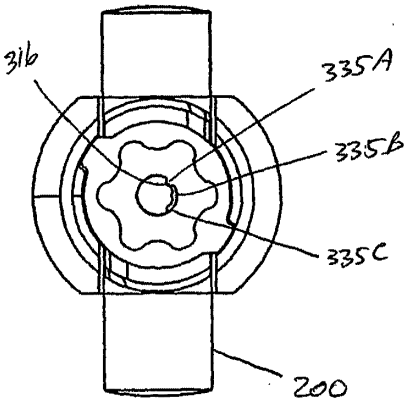


Fig. 17

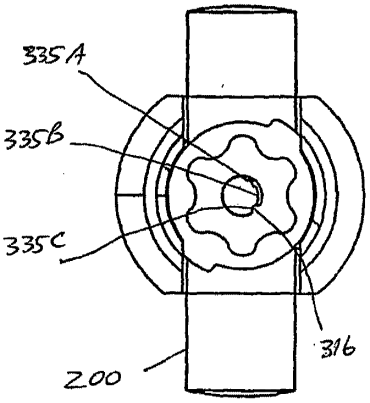


Fig. 18

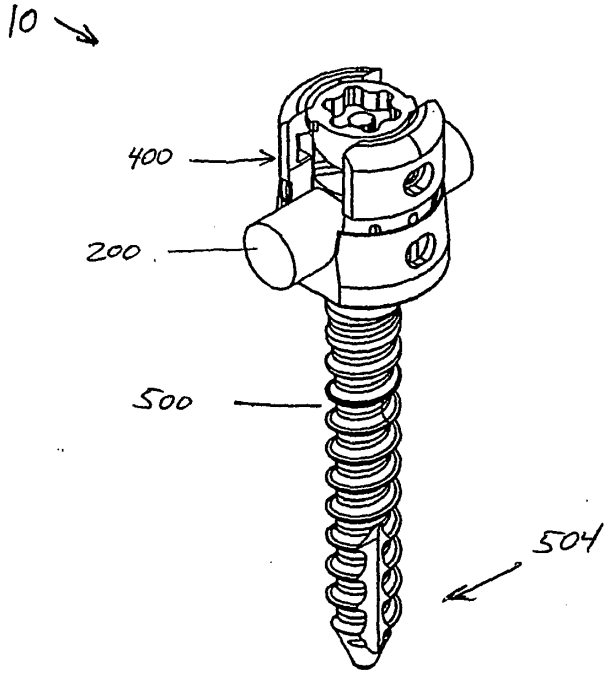


Fig. 19

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 923 of 2152

Fig. 20

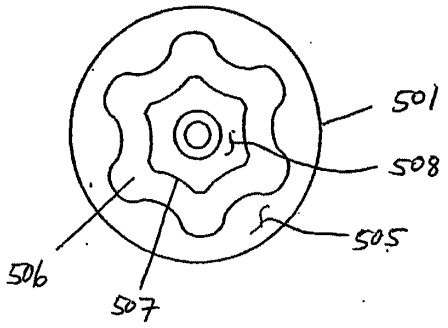


Fig. 21

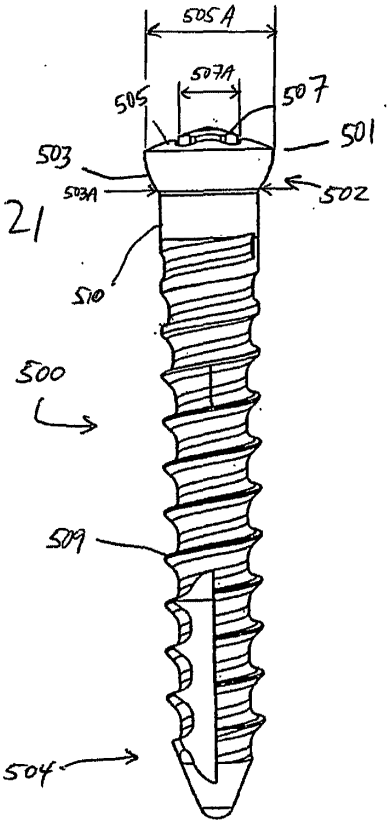
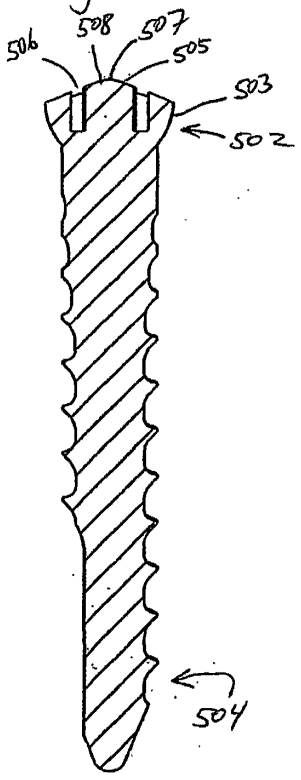


Fig. 22



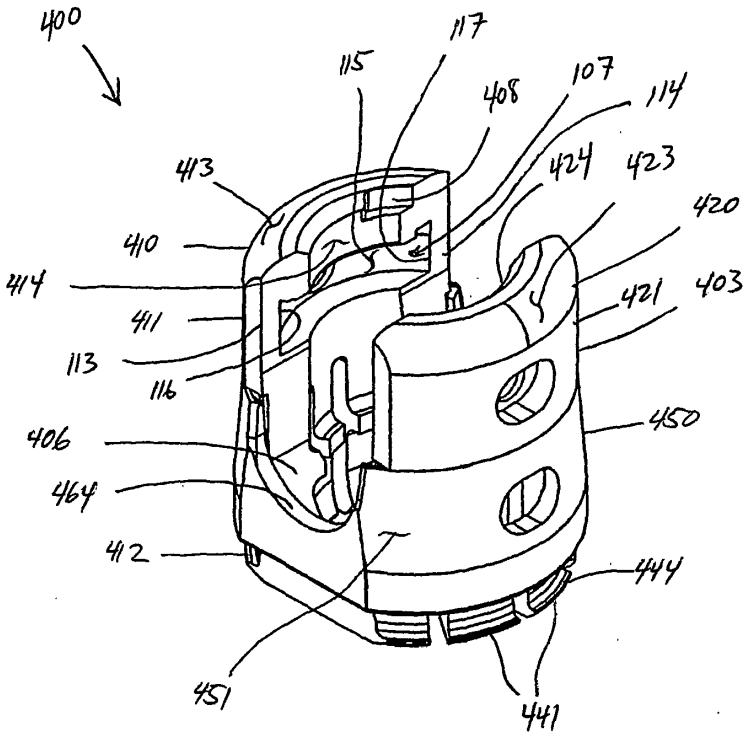
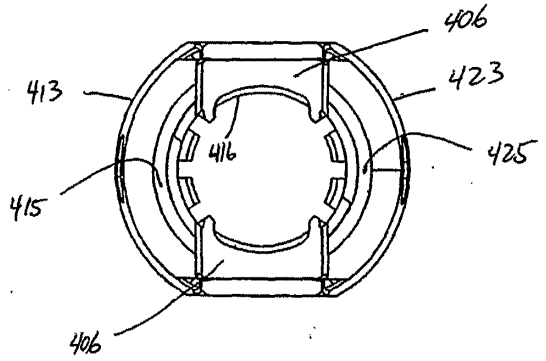

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Fig. 23

Fig. 24



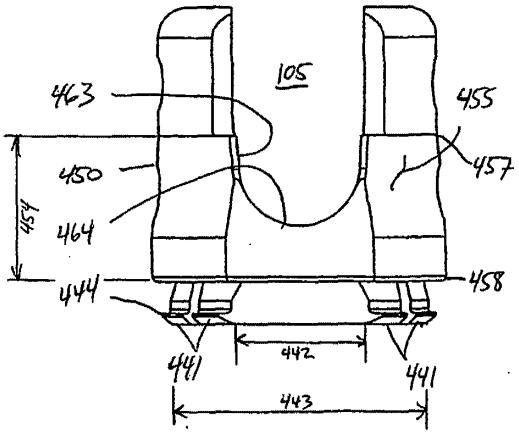


Fig. 25

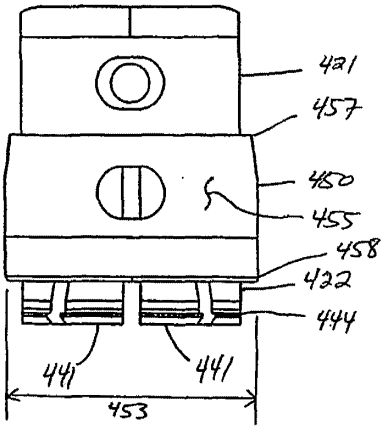


Fig. 26

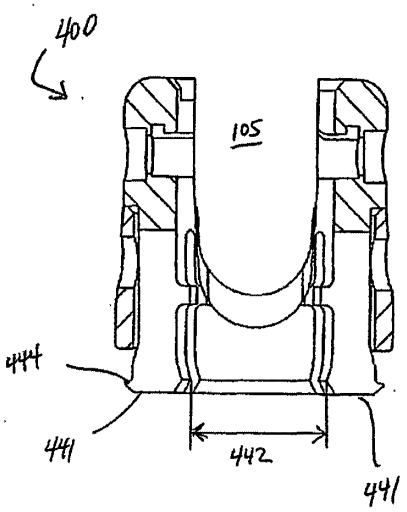


FIG. 25A

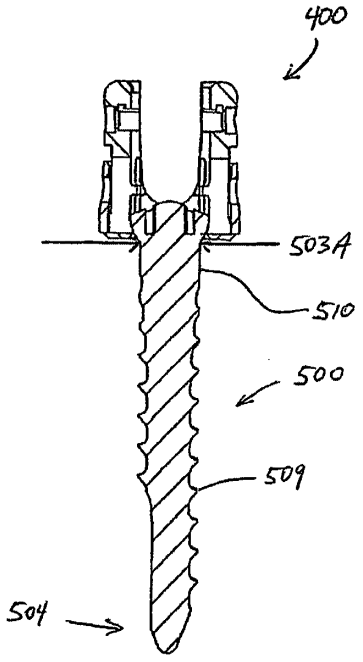


FIG. 25B

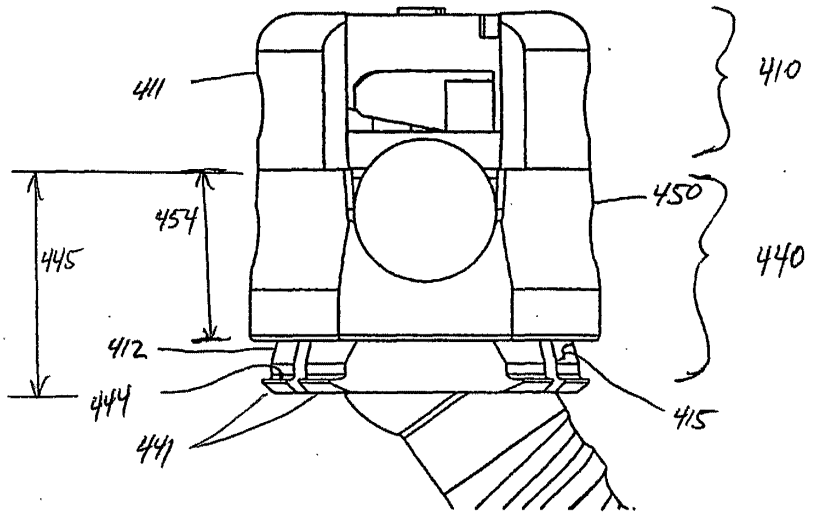


Fig. 27

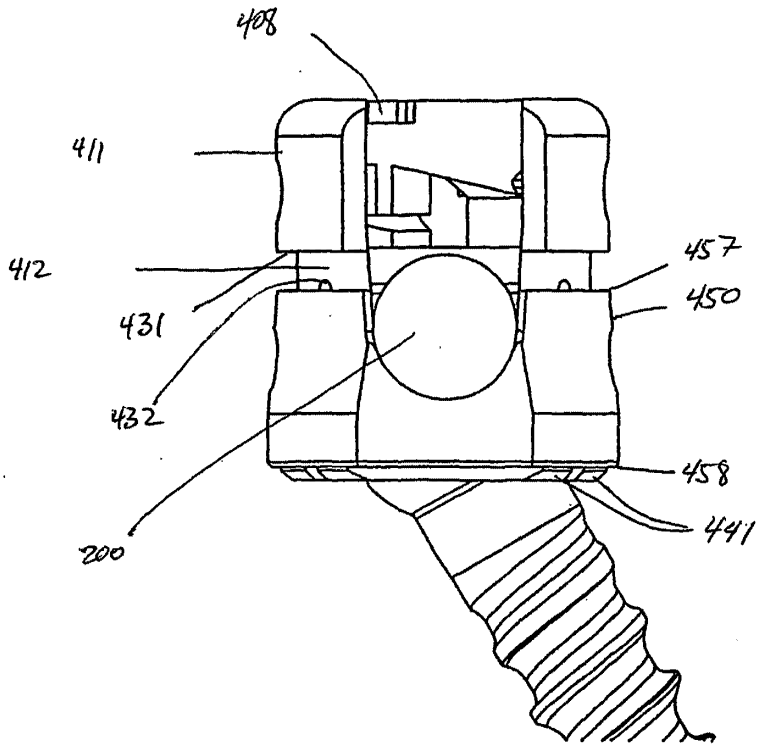


Fig. 28

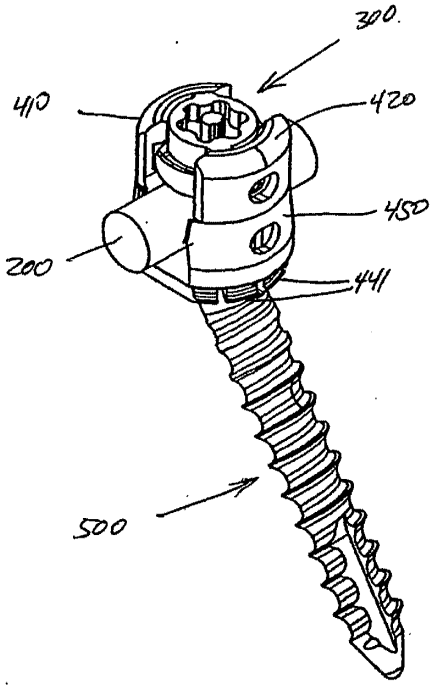


Fig. 29

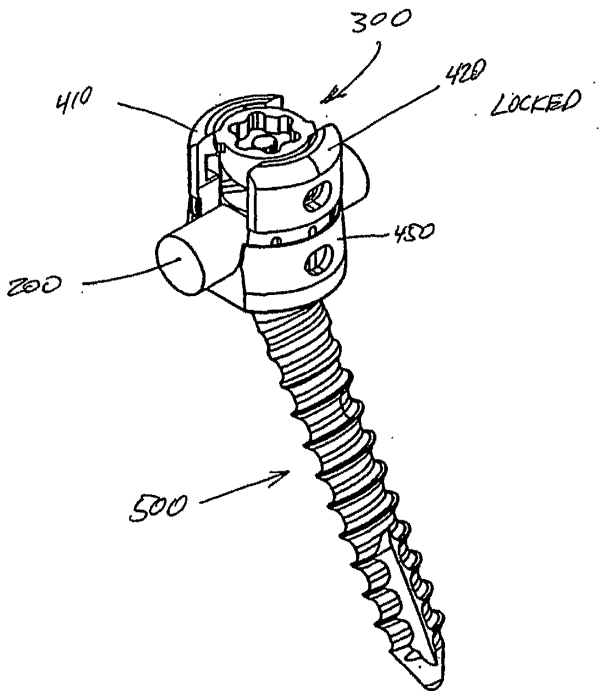


Fig. 30

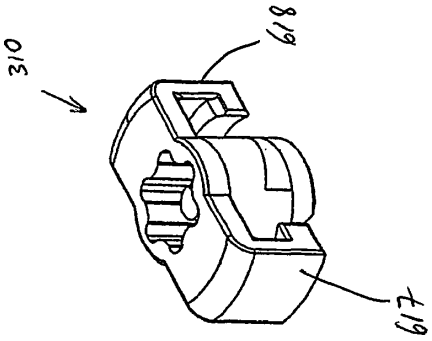


FIG. 33

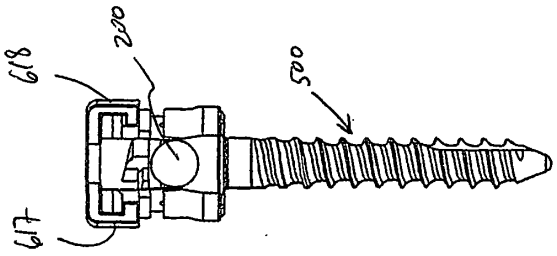


FIG. 32

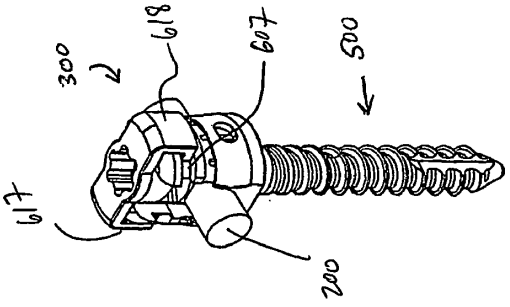


FIG. 31

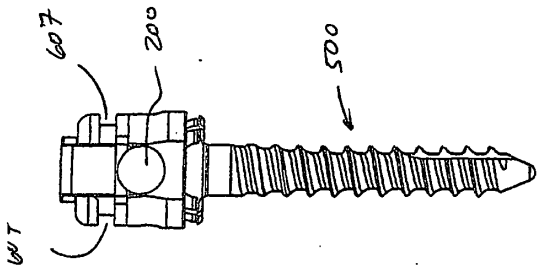


FIG. 36

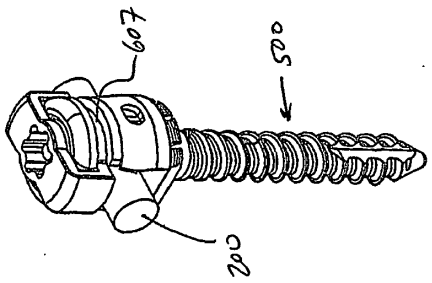


FIG. 35

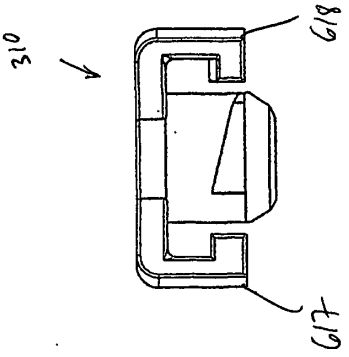


FIG. 34

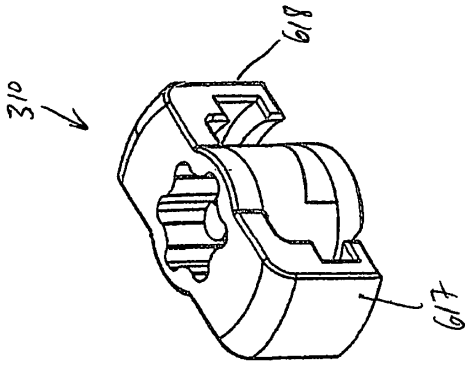


FIG. 39

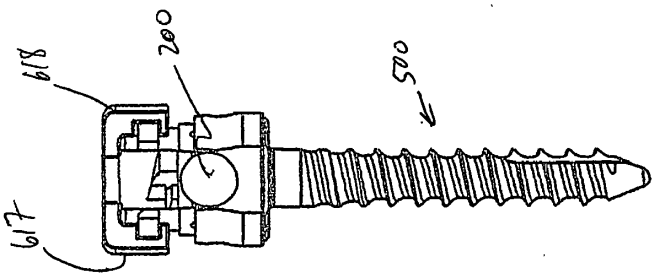


FIG. 38

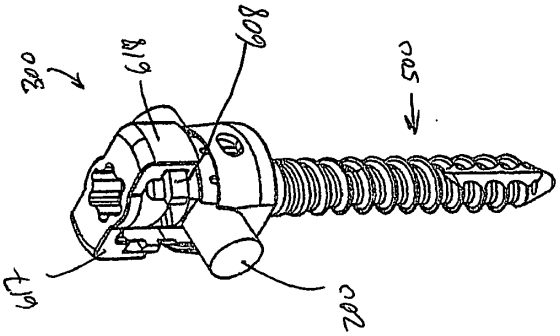


FIG. 37

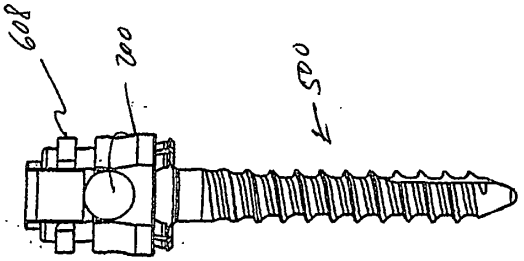


FIG. 42

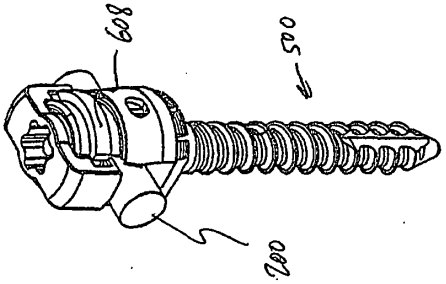


FIG. 41

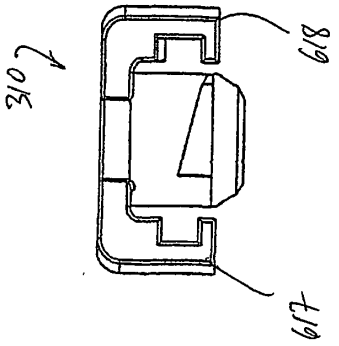


FIG. 40

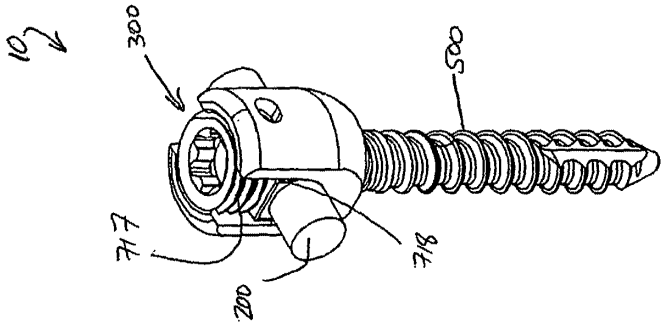


FIG. 43

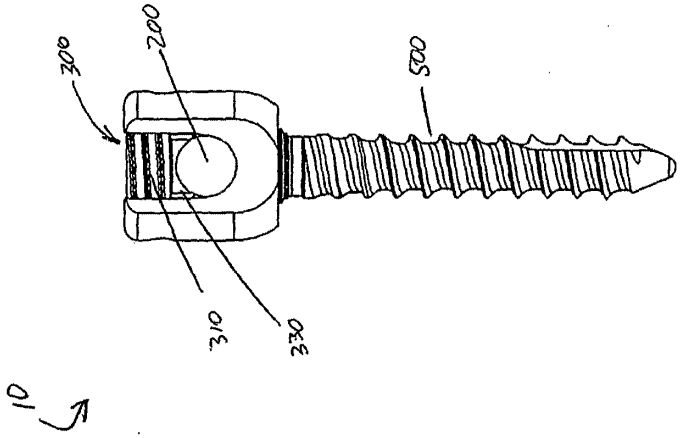


FIG. 44

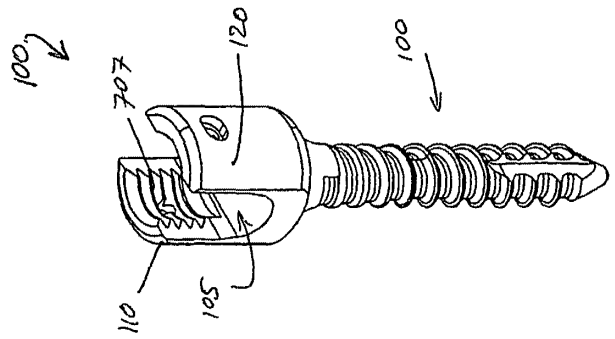


FIG. 45

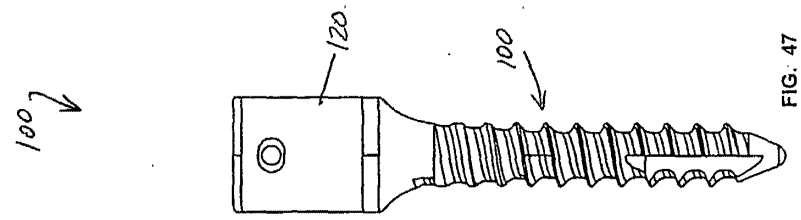


FIG. 47

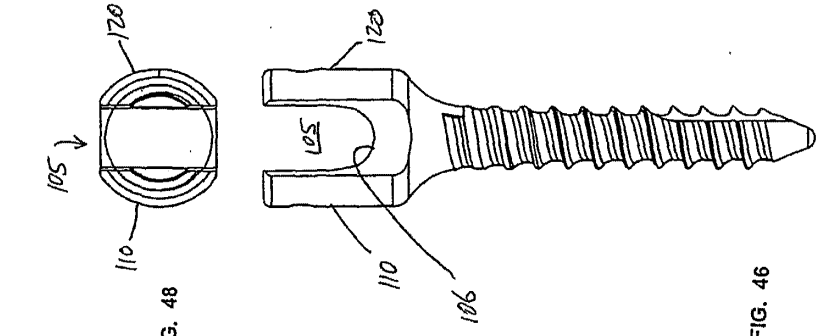


FIG. 48

FIG. 46

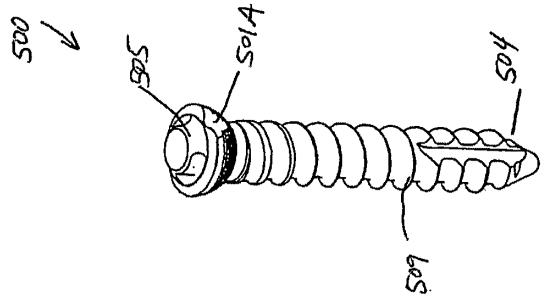


FIG. 49

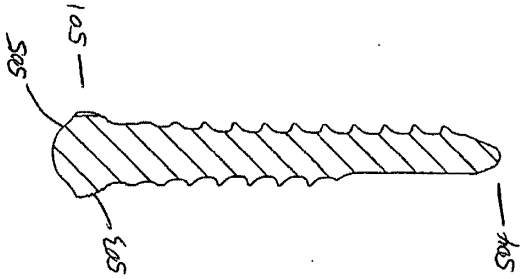


FIG. 51

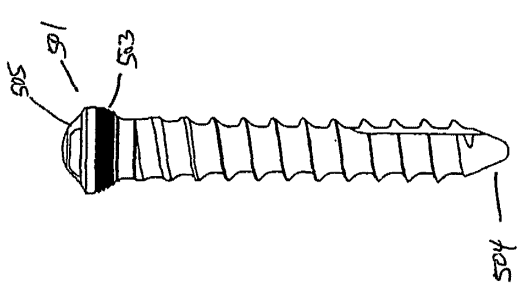


FIG. 50

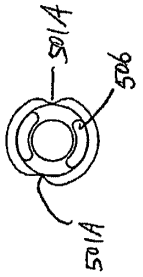


FIG. 52

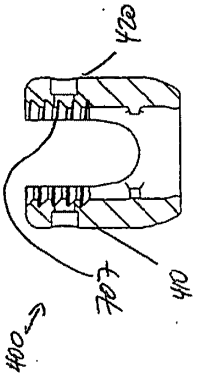


FIG. 55

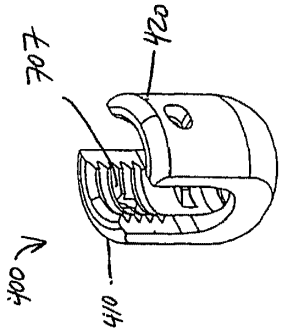


FIG. 53

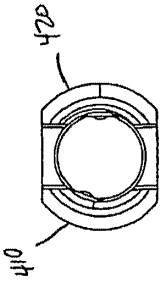


FIG. 56

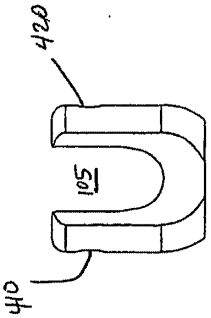
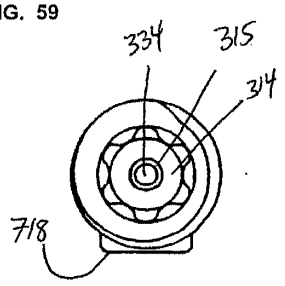


FIG. 54

FIG. 59



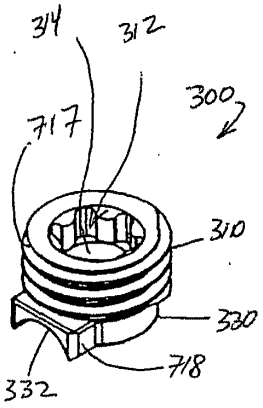


FIG. 57

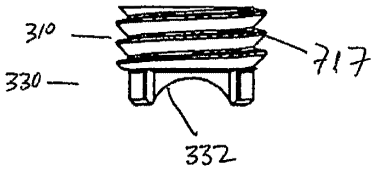


FIG. 58

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

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

(71) **Demandeur(s) :** *MEDICREA INTERNATIONAL Société anonyme* — FR.

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

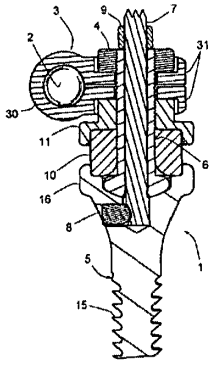
(73) **Titulaire(s) :**

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

(54) MATERIEL D'OSTEOSYNTHESE VERTEBRAL.

(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 2 865 378 - A1

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 941 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.

Dans un autre type de matériel existant, chaque organe d'ancrage peut être "en tulipe", c'est-à-dire comporter une tête dans laquelle est aménagé un passage transversal de réception d'une tige de liaison.

Les organes d'ancrage peuvent être de type "polyaxial", c'est-à-dire permettre, avant serrage, une articulation de la pièce de connexion (pion proximal fileté ou tête "en tulipe") 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 les organes d'ancrages "polyaxiaux" existants, l'articulation est réalisée sous forme d'une rotule à parties sphériques, soit en aménageant une sphère à l'extrémité distale d'un 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, soit en aménageant une sphère à l'extrémité proximale de la partie de base et une cavité correspondante dans le fond de la tête "en tulipe". Les documents US 5,882,350 ou WO 00/15125 illustrent des matériels de ce genre.

Ce type d'articulation a pour inconvénient de ne permettre qu'un débattement limité de la pièce de connexion, compte tenu de la venue en butée de cette pièce contre la partie de base au niveau du bord refermant 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 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 ledit bord, 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.

Un objectif supplémentaire de l'invention est de fournir un matériel d'ostéosynthèse vertébrale permettant un tel assemblage non rigide, voire souple, ayant une partie mobile dont la localisation se rapproche des conditions de mouvement anatomiques.

Un objectif supplémentaire de l'invention est de fournir un matériel d'ostéosynthèse vertébrale ayant un faible encombrement afin de permettre de minimiser les interventions nécessaires pour réaliser l'implantation.

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 un ensemble de connexion articulé par rapport à une partie de base destinée à être fixée à l'os.

Selon l'invention, ledit organe d'ancrage "polyaxial" comprend une partie de jonction reliant une pièce dudit ensemble de connexion et ladite partie de base, cette partie de jonction ayant une structure flexible permettant l'articulation recherchée de cet ensemble de connexion par rapport à la partie de base.

L'articulation de l'ensemble de connexion est ainsi réalisée non pas par une rotule à parties sphériques mais par la seule flexion de ladite partie de jonction. Le débattement de l'ensemble de connexion peut être très nettement supérieur à celui d'un ensemble de connexion d'un organe d'ancrage existant. De plus, la tension axiale exercée entre l'ensemble de connexion et la partie de base une fois le montage réalisé s'applique sur la partie de jonction globalement et non sur une surface restreinte d'une partie d'articulation, comme selon la technique antérieure.

L'absence de contact de parties d'articulation sur des surfaces restreintes permet de réduire très notablement, voire d'éliminer, le risque de

diffusion de particules de métal dans l'organisme, et d'usure du matériel. Il en résulte la possibilité de laisser jouer la flexibilité de ladite partie de jonction après implantation, permettant ainsi un assemblage non rigide, voire souple, des tiges de liaison avec les organes d'ancrage.

La partie de jonction permet plusieurs degrés de mouvements multidirectionnels dudit ensemble de connexion par rapport à la partie de base, tant en translation qu'en pivotement.

En outre, l'articulation selon l'invention est nettement mois encombrante qu'une articulation selon la technique antérieure, ce qui permet non seulement de minimiser les interventions à réaliser pour l'implantation mais aussi de localiser cette articulation de manière à se rapprocher autant que possible des conditions de mouvement anatomiques.

Selon une possibilité, la partie de jonction est constituée par une pièce distincte de la pièce dudit ensemble de connexion et de la partie de base. La partie de jonction peut alors notamment être constituée par une tige de matériau flexible.

Selon une autre possibilité, la partie de jonction est constituée par un prolongement de la partie de base ou de ladite pièce de l'ensemble de connexion, rendu flexible par une forme appropriée et/ou par des fentes ou évidements. Ce prolongement peut par exemple avoir une structure tubulaire et présenter une fente hélicoïdale, ou peut présenter des évidements radiaux étagés, de préférence décalés angulairement.

La partie de jonction et les liaisons de ladite pièce dudit ensemble de connexion et de ladite partie de base peuvent être conçues de telle sorte que ladite pièce dudit ensemble de connexion et ladite partie de base ne sont jamais en contact l'une de l'autre.

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

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

Ces surfaces de ladite pièce et de la partie de base peuvent être conformées pour réaliser un guidage du mouvement d'articulation de cette pièce 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 à ladite partie 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 dudit ensemble de connexion par rapport à la partie de base afin d'éviter de soumettre la partie de jonction à des contraintes transversales trop importantes.

Dans le même but, ces mêmes surfaces de la pièce dudit ensemble de connexion et de la partie de base peuvent être bordées par des surfaces latérales d'appui, permettant un calage latéral de ladite pièce 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 une pièce de l'ensemble de connexion et ladite partie de base, cette pièce ou partie de pièce à structure élastiquement déformable permettant une mobilité de l'ensemble 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, l'ensemble de connexion n'est pas immobilisé 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.

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 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, selon une première forme de réalisation ;

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 ;

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

les figures 5 à 7 sont des vues de l'organe d'ancrage, de l'ensemble de connexion et de la tige de liaison selon une deuxième forme de réalisation, respectivement en perspective éclatée, de coté et en coupe selon la ligne VII - VII de la figure 6 ;

les figures 8 à 10 sont des vues similaires de l'organe d'ancrage, de l'ensemble de connexion et de la tige de liaison selon une troisième forme de réalisation, et

les figures 11 et 12 sont des vues de l'organe d'ancrage, de l'ensemble de connexion et de la tige de liaison selon une quatrième forme de réalisation, respectivement en perspective avant montage et en coupe selon l'axe de l'organe d'ancrage.

Par simplification, les parties ou éléments décrits pour la première forme de réalisation, qui se retrouvent de manière identique ou similaire dans les autres formes de réalisation, seront désignés par les mêmes références numériques et ne seront pas à nouveau décrits.

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.

Le pion 6, l'étrier 3, l'écrou 4, la pièce 10 et la bague 11 forment un ensemble de connexion d'une tige de liaison 2 à une partie de base 5.

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 concave 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.

Les figures 5 à 7 représentent une autre forme de réalisation du matériel d'ostéosynthèse selon l'invention, comprenant également une pièce de base 5, un pion proximal fileté 6, un étrier 3 et un écrou 4.

Dans ce cas, la pièce de base 5 comprend un prolongement tubulaire proximal 40 dans lequel est aménagée une fente hélicoïdale 41.

Ce prolongement 40 est également percé de deux trous coaxiaux transversaux 42 et le pion 6 comprend un trou transversal 43 venant, lors de l'assemblage du pion 6 et de la partie de base 5, en regard de ces trous 42, les trous 42, 43 pouvant alors recevoir une goupille 44 chassée en force au travers d'eux.

La fente 41 permet de conférer au prolongement 40 la flexibilité requise pour permettre un débattement du pion 6 par rapport à la partie de base 5 et pour permettre un assemblage non rigide d'une tige de liaison 2 à une partie de base 5.

L'étrier 3 et l'écrou 4 peuvent être identique à ceux décrits précédemment ou, comme cela est représenté, l'écrou 4 peut présenter une face périphérique extérieure en portion de sphère et l'étrier 3 peut présenter une cavité supérieure 33 de forme correspondante, dans laquelle l'écrou 4 est totalement engagé après complet vissage, comme le montre la figure 7.

Les figures 8 à 10 représentent une autre forme de réalisation du matériel d'ostéosynthèse selon l'invention, comprenant également une partie de base 5 à prolongement tubulaire proximal 40, un pion proximal fileté 6, un étrier 3 et un écrou 4.

Dans ce cas, le prolongement tubulaire proximal 40 comprend des évidements radiaux étagés 45, dont chacun est aménagé sur légèrement moins d'une moitié de la circonférence du prolongement 40 et est aménagé avec un décalage angulaire par rapport aux évidements 45 des étages adjacents. Ces évidements 45 permettent de délimiter des espaces autorisant la déformation transversale du prolongement 40 à la manière d'un "accordéon", donnant à ce prolongement 40 la flexibilité requise.

L'assemblage du pion 6 au prolongement 40 peut être réalisé au moyen d'une goupille comme précédemment décrit, ou, ainsi que cela est représenté, par vissage et collage d'une base filetée du pion 6 dans l'alésage du prolongement 40, lui-même taraudé.

Le pion proximal fileté 6 peut comprendre un pion supérieur 46 pour le vissage d'un prolongateur (non représenté) permettant de faciliter la descente de l'ensemble étrier 3 - tige de liaison 2 sur le pion 6 lors de l'implantation du matériel.

Les figures 11 et 12 représentent une vis 1 de type "tulipe", c'est-à-dire dont la tête 50 est élargie et présente un logement transversal 51 de réception d'une tige de liaison 2. Cette tête 50 présente un alésage taraudé axial 52 aménagé dans les parois en regard délimitées par le logement transversal 51 et reçoit un écrou 4 de verrouillage de la tige de liaison 2 dans le logement 51.

Dans ce cas, la base de la tête 50 comprend également des évidements radiaux étagés 45, dont chacun est aménagé sur légèrement moins d'une moitié de la circonférence de la tête 50 et est aménagé avec un décalage angulaire par rapport aux évidements 45 des étages adjacents. Ces évidements 45 permettent, de la même manière que décrit précédemment, de délimiter des espaces autorisant la déformation transversale de la tête 50 à la manière d'un "accordéon", donnant à cette tête 50 la flexibilité requise.

Comme cela apparaît de ce qui précède, l'invention fournit un matériel d'ostéosynthèse vertébrale dans lequel une pièce 6, 50 de l'ensemble de

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 951 of 2152

connexion a un débattement important par rapport à la partie de base 5 de l'organe d'ancrage 1 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 de plus un assemblage non rigide, voire souple, des tiges de liaison 2 avec les organes d'ancrage 1, avec un éventuel amortissement du mouvement des pièces mobiles.

En outre, ce matériel a une partie mobile dont la localisation se rapproche des conditions de mouvement anatomiques, et a un faible encombrement afin de permettre de minimiser les interventions nécessaires pour réaliser l'implantation.

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, 4, 10, 11 ; 40, 50, 4) 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 un ensemble de connexion (6, 3, 4, 10, 11 ; 40, 50, 4) articulé par rapport à une 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 une partie de jonction (7, 40) reliant une pièce (6, 50) dudit ensemble de connexion (6, 3, 4, 10, 11 ; 40, 50, 4) et ladite partie de base (5), cette partie de jonction ayant une structure flexible permettant l'articulation recherchée de cet ensemble de connexion (6, 3, 4, 10, 11 ; 40, 50, 4) par rapport à la partie de base (5).

2 – Matériel selon la revendication 1, caractérisé en ce que la partie de jonction est constituée par une pièce (7) distincte de la pièce (6, 50) dudit ensemble de connexion (6, 3, 4, 10, 11 ; 40, 50, 4) et de la partie de base (5).

3 - Matériel selon la revendication 2, caractérisé en ce que la partie de jonction est constituée par une tige (7) de matériau flexible.

4 – Matériel selon la revendication 1, caractérisé en ce que la partie de jonction est constituée par un prolongement (40) de la partie de base (5) ou de ladite pièce (50) de l'ensemble de connexion, rendu flexible par une forme appropriée et/ou par des fentes (41) ou évidements (45).

5 – Matériel selon la revendication 4, caractérisé en ce que le prolongement (40) a une structure tubulaire et présente une fente hélicoïdale (41), ou présente des évidements radiaux étagés (45), de préférence décalés angulairement.

6 - Matériel selon l'une des revendications 1 à 5, caractérisé en ce que la partie de jonction et les liaisons de ladite pièce dudit ensemble de connexion et de ladite partie de base sont conçues de telle sorte que ladite pièce dudit

ensemble de connexion et ladite partie de base ne sont jamais en contact l'une de l'autre.

7 - Matériel selon l'une des revendications 1 à 5, caractérisé en ce que la partie de jonction (7) est légèrement étirable longitudinalement, et en ce que des moyens (6, 9, 3, 4, 10, 11) sont prévus pour réaliser un léger étirement longitudinal de cette partie de jonction (7), cet étirement permettant un écartement des surfaces par lesquelles ladite pièce (6) dudit ensemble de connexion et ladite partie de base (5) viennent en contact l'une de l'autre.

8 – Matériel selon l'une des revendications 1 à 7, caractérisé en ce que les surfaces par lesquelles ladite pièce (6) dudit ensemble de connexion 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).

9 – Matériel selon la revendication 8, caractérisé en ce que lesdites surfaces de la pièce (6) dudit ensemble de connexion et de la partie de base (5) sont bordées par des surfaces latérales d'appui, permettant un calage latéral de ladite pièce (6) par rapport à la partie de base (5).

10 – Matériel selon l'une des revendications 1 à 9, 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 une pièce (11) de l'ensemble de connexion et ladite partie de base (5), cette pièce ou partie de pièce (10) à structure élastiquement déformable permettant une mobilité de l'ensemble de connexion, et donc de la tige de liaison (2), par rapport à la partie de base (5), avec amortissement.

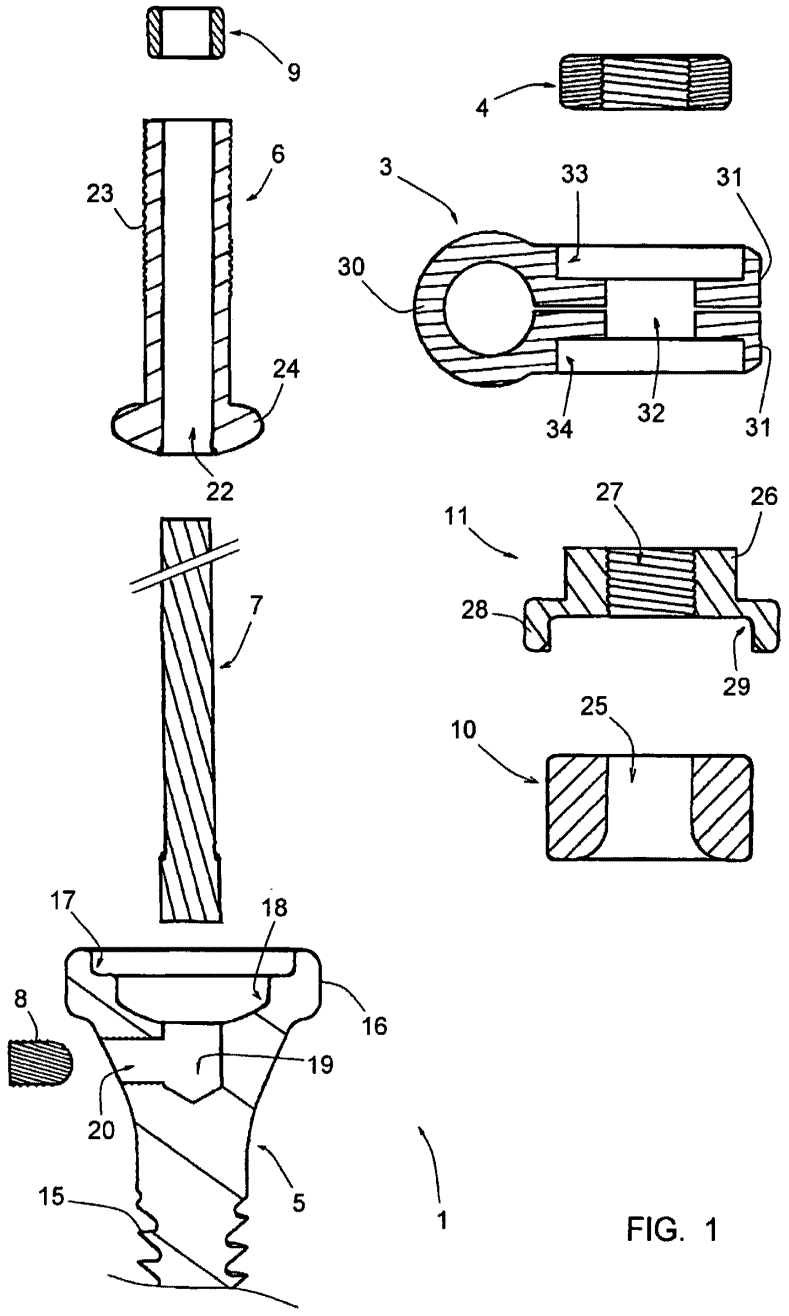
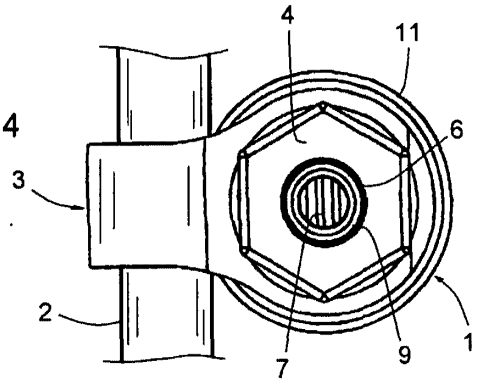

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FIG. 1

FIG. 4



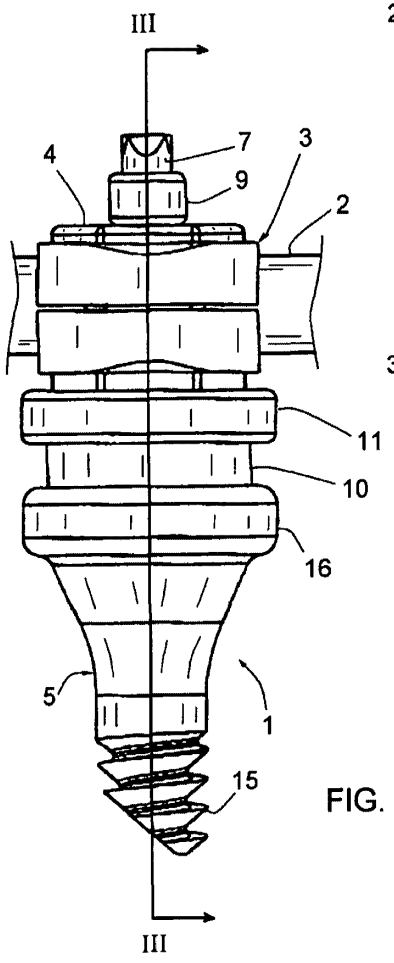


FIG. 2

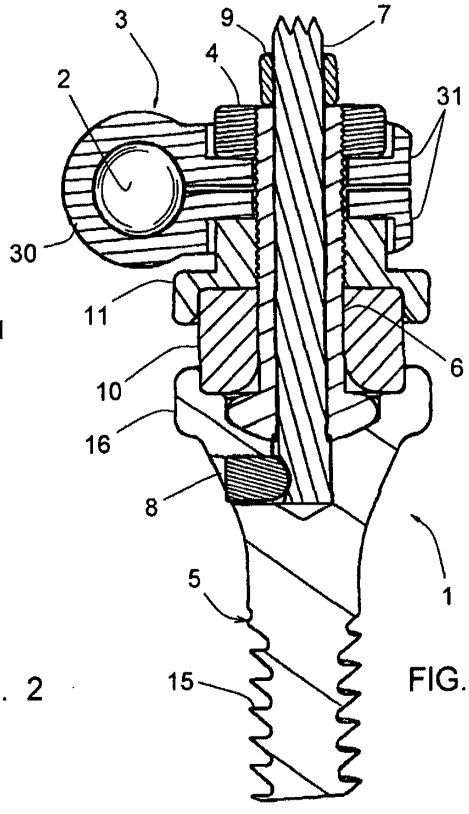


FIG. 3

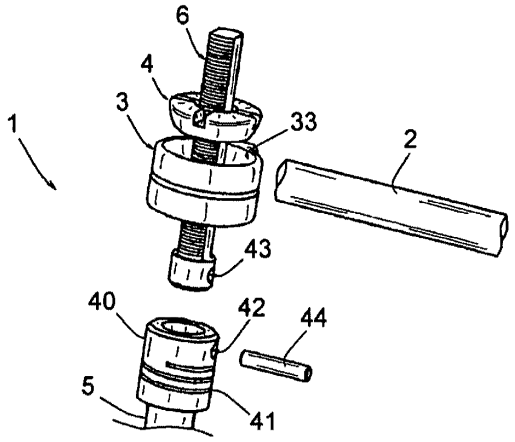


FIG. 5

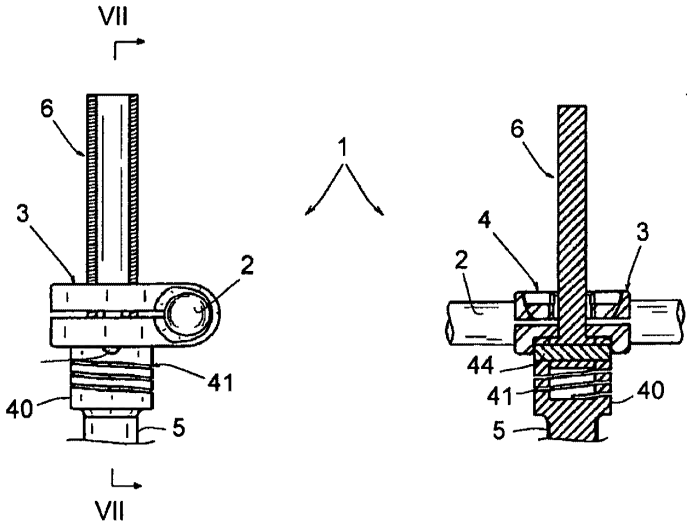


FIG. 6

FIG. 7

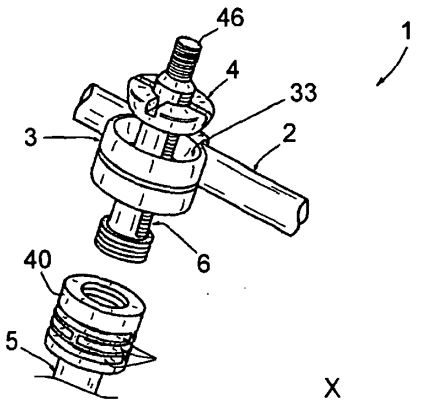


FIG. 8

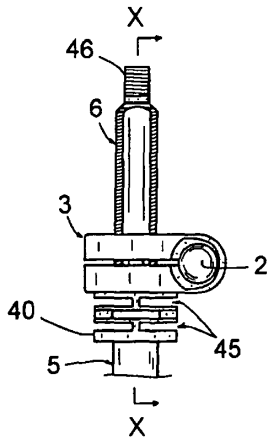


FIG. 9

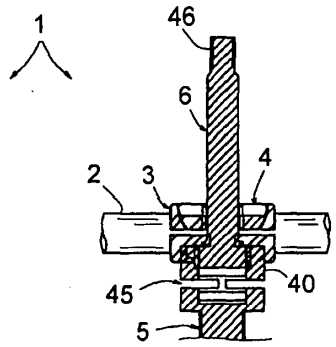


FIG. 10

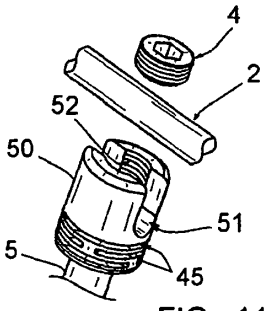


FIG. 11

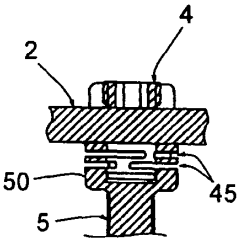


FIG. 12

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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 655951
FR 0411266

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 4 946 458 A (HARMS ET AL) 7 août 1990 (1990-08-07) * colonne 3, ligne 4 - ligne 27; figures 1,2 *	1,2,6,10	A61B17/70
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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	

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A	FR 2 697 742 A1 (BIOMAT) 13 mai 1994 (1994-05-13) * page 11, ligne 14 - page 12, ligne 9; figure 1 *	1	

DOMAINES TECHNIQUES RECHERCHÉS (Int.Cl.7)

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Date d'achèvement de la recherche	Examinateur
3 février 2005	Ducreau, F

CATÉGORIE DES DOCUMENTS CITÉS

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

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

& : membre de la même famille, document correspondant

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ANNEXE AU RAPPORT DE RECHERCHE PRÉLIMINAIRE
RELATIF A LA DEMANDE DE BREVET FRANÇAIS NO. FR 0411266 FA 655951

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 03-02-2005
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

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 960 of 2152

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Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 961 of 2152

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(71) Applicant: SPINAL CONCEPTS, INC. [US/US]; 5301 Riata Park Court, Building F, Austin, TX 78727 (US).

(72) Inventors: LANDRY, Michael, E.; 12602 Brightside, Austin, TX 78729 (US). KHOO, Larry, T.; 12144 Laurel Terrace Drive, Studio City, CA 91604 (US). WAGNER, Erik, J.; 16920 Squaw Valley Lane, Austin, TX 78717 (US). FORTON, Charles, R.. JONES, Robert, J.; 13125 Troops Trail, Austin, TX 78727 (US).

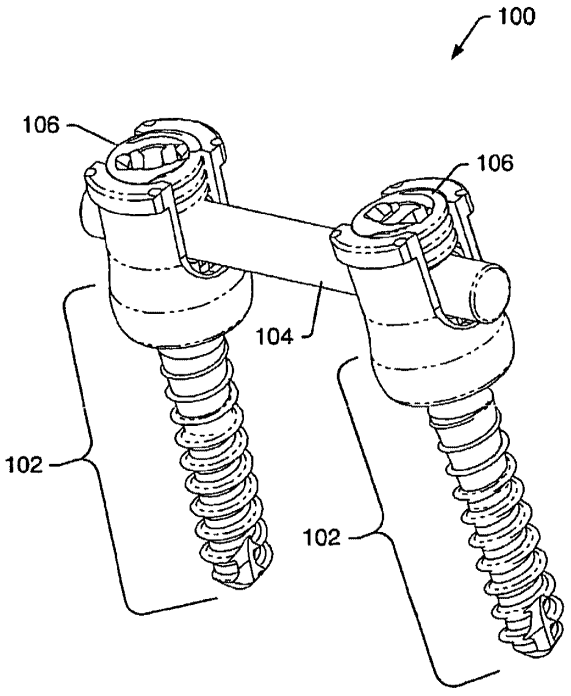
(74) Agent: MEYERTONS, Eric, B.; Meyertons, Hood, Kivlin, Kowert & Goetzel, P.C., P.O. Box 398, Austin, TX 78767-0398 (US).

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(54) Title: SPINAL STABILIZATION SYSTEM INSERTION AND METHODS



(57) Abstract: A spinal stabilization system (100) may be formed in a patient. In some embodiments, a minimally invasive procedure may be used to form a spinal stabilization system (100) in a patient. Bone fastener assemblies (102) may be coupled to vertebrae. Each bone fastener assembly (102) may include a bone fastener (108) and a collar (112). The collar (112) may be rotated and/or angulated relative to the bone fastener (108). Detachable members may be coupled to the collar (112) to allow for formation of the spinal stabilization system (100) through a small skin incision. The detachable members may allow for alignment of the collars (112) to facilitate insertion of an elongated member (104) in the collars (112). An elongated member (104) may be positioned in the collars (112) and a closure member (106) may be used to secure the elongated member (106) to the collars (112).

WO 2004/041100 A1

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 962 of 2152

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TITLE: SPINAL STABILIZATION SYSTEM INSERTION AND METHODS

BACKGROUND

1. Field of the Invention

The present invention generally relates to spinal stabilization systems that include at least one polyaxial fastener. Embodiments of the invention relate to spinal stabilization systems that may be inserted into a patient during a minimally invasive surgical procedure. Embodiments of the invention relate to tools used during a minimally invasive surgical procedure. Embodiments of the invention relate to methods of forming implant system components, methods of forming stabilization systems and components, and methods for performing minimally invasive spinal stabilization procedures.

2. Description of Related Art

Bone may be subject to degeneration caused by trauma, disease, and/or aging. Degeneration may destabilize bone and affect surrounding structures. For example, destabilization of a spine may result in alteration of a natural spacing between adjacent vertebrae. Alteration of a natural spacing between adjacent vertebrae may subject nerves that pass between vertebral bodies to pressure. Pressure applied to the nerves may cause pain and/or nerve damage. Maintaining the natural spacing between vertebrae may reduce pressure applied to nerves that pass between vertebral bodies. A spinal stabilization procedure may be used to maintain the natural spacing between vertebrae and promote spinal stability.

Spinal stabilization may involve accessing a portion of the spine through soft tissue. Conventional stabilization systems may require a large incision and/or multiple incisions in the soft tissue to provide access to a portion of the spine to be stabilized. Conventional procedures may result in trauma to the soft tissue, for example, due to muscle stripping.

Spinal stabilization systems for a lumbar region of the spine may be inserted during a spinal stabilization procedure using a posterior spinal approach. Conventional systems and methods for posterolateral spinal fusion may involve dissecting and retracting soft tissue proximate the surgical site. Dissection and retraction of soft tissue may cause trauma to the soft tissue, and extend recovery time. Minimally invasive procedures and systems may reduce recovery time as well as trauma to the soft tissue surrounding a stabilization site.

U.S. Patent No. 6,530,929 to Justis et al. (hereinafter "Justis") describes minimally invasive techniques and instruments for stabilizing a bony structure in an animal subject. Justis provides a method for using an instrument to connect at least two bone anchors with a connecting element. The instrument is secured to the anchors and manipulated to place the connecting element in a position more proximate the anchors.

SUMMARY

A spinal stabilization system may be installed in a patient to stabilize a portion of a spine. A spinal stabilization system may be installed using a minimally invasive procedure. An instrumentation kit may provide instruments and spinal stabilization system components necessary for forming a spinal stabilization system in a patient.

A spinal stabilization system may be used to achieve rigid pedicle fixation while minimizing the amount of damage to surrounding tissue. In some embodiments, a spinal stabilization system may be used to provide stability

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 964 of 2152

to two or more vertebrae. A spinal stabilization system may include an elongated member, two or more bone fastener assemblies, and/or a closure member. The bone fastener assembly may include, but is not limited to, a bone fastener and a collar. A first portion of the bone fastener may couple to a portion of the spine during use. A first portion of a collar may couple to a second portion of the bone fastener. A second portion of the collar may couple to an elongated member during use. In some embodiments, an orientation of the bone fastener may be independent of the orientation of the collar for a bone fastener assembly. After the bone fastener is placed in a vertebral body, the collar coupled to the bone fastener may be positioned so that the elongated member can be positioned in the collar and in at least one other collar that is coupled to another vertebral body by a bone fastener.

In an embodiment, a bone fastener assembly may include a bone fastener, a ring, and a collar. The ring may be positioned in the collar. Removal of the ring from the collar may be inhibited. A bone fastener may be positioned in the ring through a lower opening in the ring and in the collar. Splines of the bone fastener may be aligned with seats in the ring. The splines may be forced into the seats to couple the ring to the bone fastener. Separation of the ring from the bone fastener may be inhibited after the bone fastener is forced into the seats. The ring may angulate within the collar (i.e., the bone fastener may move relative to the collar within a defined range of motion).

In an embodiment, a collar may include, but is not limited to, arms and a body. Arms and body of a collar may form a slot to receive an elongated member. When the elongated member is positioned in the collar, a portion of the elongated member may be coupled to a head of a bone fastener of the bone fastener assembly.

Inner surfaces of the arms of a bone fastener assembly collar may include a modified thread. The modified thread may engage a complementary modified thread of a closure member. A closure member may secure an elongated member to a bone fastener assembly. In some embodiments, a range of motion of a collar relative to a bone fastener may be skewed from a conical range of motion relative to a longitudinal center axis of the collar. The skew may be used to accommodate lordotic alignment and/or pedicle angle shift in adjacent vertebrae.

Different instruments may be used to form a spinal stabilization system in a patient using a minimally invasive procedure. The instruments may include, but are not limited to, positioning needles, guide wires, sleeves, bone fastener driver, mallets, tissue wedges, tissue retractors, tissue dilators, bone awls, taps, and an elongated member length estimator. An instrumentation kit may include, but is not limited to, two or more detachable members (e.g., sleeves), a tissue wedge, an elongated member positioner, a counter torque wrench, an estimating tool, a seater, closure member driver, and/or combinations thereof.

Detachable members may be used during installation of one vertebral level stabilization systems at each of the two vertebrae to be stabilized. In an embodiment, a detachable member may be coupled to a collar of a bone fastener assembly. A detachable member may include channels to allow movable members to advance and/or retract relative to the detachable member. In certain embodiments, movable members may be positioned through other portions of a detachable member. Movable members may couple to a bone fastener assembly collar. The movable members may inhibit translational and/or rotational movement of the collar relative to the detachable member.

An estimating tool may be used prior to insertion of an elongated member into bone fastener assemblies to estimate a desired length of the elongated member. The estimating tool may include arms. The arms may be positioned down detachable members to rest on top of collars or bone fasteners of bone fastener assemblies that are coupled to vertebral bodies. The arms of the estimating tool may be expanded to contact inner surfaces of the detachable members. When the ends of the arms contact the inner surfaces of the detachable members at the bone

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 965 of 2152

fastener assemblies, the estimating tool may be withdrawn from the detachable members. The arms may compress during removal, but will spring back to the measured distance between the detachable members adjacent the collar. The distance between the arms may be measured using a scale to provide an estimate of the appropriate elongated member length. Some additional length may be added to the estimated value to account for contouring of the elongated member and/or to allow the elongated member to extend beyond an end of at least two collars.

A tissue wedge may be used to form a plane between a first vertebra and a second vertebra during a minimally invasive procedure. The plane may accept an elongated member. In an embodiment, a tissue wedge may include a handle portion and a blunted blade. In some embodiments, the blade may be a double-wedged blade. One edge of the blade may include a hooked portion. The hooked portion may include a cutting edge for severing fascia. The hooked portion may cut fascia positioned in the hooked portion when the tissue wedge is drawn upwards.

In some embodiments, an elongated member positioner may be used to guide an elongated member through detachable members and position the elongated member in collars proximate pedicles of vertebrae. In an embodiment, an elongated member positioner may include a body and a plunger. The body may include a passageway, a handle portion, and an engaging portion. The plunger may contact the elongated member in the engaging portion. In some cases, pressure supplied to an elongated member with an elongated member positioner may not be sufficient to seat the elongated member in collars of bone fastener assemblies. When the elongated member positioner cannot place the elongated member in the collars, a seater may be used to place the elongated member in the collars. The seater may include a handle portion. A grooved portion of the seater may be used to push the elongated member downwards into the collars.

In an embodiment, a closure member driver may position a closure member in a collar coupled to a bone fastener. The closure member driver may include a handle, an elongated portion, and a coupling portion.

In certain embodiments, a detachable member may be held with a counter torque wrench to inhibit injury to the patient as the tool portion of a secured closure member is sheared off. In some embodiments, a counter torque wrench may include a handle portion and a sleeve portion. A distal end of the sleeve portion may engage an elongated member.

In an embodiment, a method for inserting a stabilization system in a spine may involve determining one or more vertebrae of the spine to be targeted for stabilization, making an incision in the skin, inserting a spinal stabilization system, and closing the incision in the skin.

During some surgical procedures, images of a patient may be taken to assist in determining target locations for insertion of bone fastener assemblies in vertebrae to be stabilized. A marking or markings may be made on the patient to indicate the target locations. An incision may be made in the patient's skin between the target locations. In some embodiments, the incision may be enlarged after insertion of a first bone fastener assembly. The targeting needle may be inserted into a first pedicle. Imaging may be used to monitor orientation and depth of the targeting needle during insertion.

After insertion of the targeting needle, a guide wire may be inserted through a hollow shaft of the targeting needle into the first pedicle. The targeting needle may be removed from the patient. A first bone fastener assembly coupled to a first detachable member may be inserted into the first pedicle.

A plane may be created in soft tissue between the first bone fastener assembly and a second pedicle. The plane may be formed without severing muscle tissue. If needed, fascia may be cut to facilitate formation of the plane. After the plane is formed, the targeting needle may be inserted in the first detachable member. A distal end

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 966 of 2152

of the targeting needle may be wanded through the plane and placed at an entry point of the second pedicle. The targeting needle may be inserted into the second pedicle in a desired orientation and to a desired depth. A guide wire may be inserted through a hollow shaft of the targeting needle into the second pedicle. The targeting needle may be removed, and a second bone fastener assembly coupled to a second detachable member may be inserted into the second pedicle.

An elongated member may be guided down the detachable members. The elongated member may be seated in the collars. A position of the elongated member in the collars may be confirmed using fluoroscopic imaging. After confirming the position of the elongated member, a first closure member coupled to a driver may be advanced down the first detachable members. The first closure member may be coupled to the first collar. A counter torque wrench may be coupled to the detachable member. A head of the first closure member may be sheared. When the head is sheared, enough force is applied to the elongated member by the closure member to inhibit movement of the elongated member relative to the bone fastener assembly. The driver may be removed from the first closure member after coupling the first closure member to the first collar. The sheared off head may be removed from the driver.

The driver may be coupled to a second closure member. A second closure member coupled to the driver and a counter torque wrench may be used while the head of the closure member is sheared off to form the spinal stabilization system. The detachable members may be removed from the collars. The incision in the skin may be closed.

BRIEF DESCRIPTION OF THE DRAWINGS

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

FIG. 1 depicts a perspective view of an embodiment of a spinal stabilization system.

FIG. 2 depicts a perspective view of an embodiment of a bone fastener assembly.

FIG. 3 depicts a perspective view of an embodiment of a bone fastener.

FIGS. 4A and 4B depict perspective views of embodiments of bone fastener assembly rings.

FIG. 5 depicts a perspective view of an embodiment of a bone fastener assembly collar.

FIG. 6 depicts a cross-sectional view of an embodiment of a bone fastener assembly.

FIG. 7 depicts a perspective view of an embodiment of a bone fastener assembly.

FIGS. 8A-8C depict schematic views of a method of positioning a ring in a collar of a bone fastener assembly.

FIGS. 9A-9C depict schematic views of a method of positioning a ring in a collar of a bone fastener assembly.

FIGS. 10A and 10B depict schematic views of positioning a bone fastener in a ring and collar to form a bone fastener assembly.

FIG. 11 depicts a front view of an embodiment of a bone fastener assembly with a collar that allows for angulation of a bone fastener relative to the collar in a conical range of motion that is symmetrical relative to an axis that passes through a central axis of the collar and a central axis of a bone fastener.

FIG. 12A depicts a front view of an embodiment of a bone fastener assembly with a collar that allows for angulation of a bone fastener relative to the collar in a conical range of motion that is not symmetrical relative to an

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 967 of 2152

axis that passes through a central axis of the collar and a central axis of a bone fastener. The collar allows additional lateral bias relative to a non-biased collar.

FIG. 12B depicts a side view of an embodiment of a bone fastener assembly with a collar that allows for angulation of a bone fastener relative to the collar in a conical range of motion that is not symmetrical relative to an axis that passes through a central axis of the collar and a central axis of a bone fastener. The collar allows additional caudal or cephalid bias relative to a non-biased collar.

FIG. 13A depicts a schematic side view representation of embodiments of bone fastener assemblies positioned in vertebrae.

FIG. 13B depicts a schematic top view representation of an embodiment of a single-level spinal stabilization system.

FIG. 14 depicts a perspective view of an embodiment of a closure member.

FIG. 15 depicts a cross-sectional representation of the closure member taken substantially along plane 15-15 indicated in FIG. 14.

FIG. 16 depicts a perspective view of an embodiment of a portion of a spinal stabilization system.

FIG. 17A depicts a cross-sectional representation of an embodiment of a spinal stabilization system.

FIG. 17B depicts a detailed view of a portion of FIG. 17A.

FIGS. 18A depicts a cross-sectional representation of an embodiment of a spinal stabilization system.

FIG. 18B depicts a detailed view of a portion of FIG. 18A.

FIG. 19 depicts a perspective view of an embodiment of a targeting needle.

FIG. 20 depicts a perspective view of an outer housing of a targeting needle.

FIG. 21 depicts a perspective view of an embodiment of a member of a targeting needle.

FIG. 22 depicts a perspective view of an embodiment of a guide wire.

FIG. 23 depicts a perspective view of an embodiment of a guide wire.

FIG. 24 depicts a perspective view of an embodiment of a bone awl.

FIG. 25 depicts a perspective view of an embodiment of a bone tap.

FIG. 26 depicts a perspective view of an embodiment of a multi-channel sleeve.

FIG. 27 depicts a top view of an embodiment of a multi-channel sleeve with a bone fastener assembly coupled to the sleeve.

FIG. 28 depicts a cross-sectional representation of a portion of the sleeve with the bone fastener assembly taken substantially along line 28-28 of FIG. 27.

FIG. 29 depicts a cross-sectional representation of a portion of the sleeve with the bone fastener assembly taken substantially along line 29-29 of FIG. 27.

FIG. 30 depicts a perspective view of an embodiment of a single-channel sleeve.

FIG. 31 depicts a perspective view of an embodiment of a sleeve during connection of the sleeve to a collar of a bone fastener assembly.

FIG. 31A depicts a detailed view of a portion of FIG. 31.

FIG. 32 depicts a partial cross-sectional representation of an embodiment of a sleeve coupled to a collar of a bone fastener assembly.

FIG. 33 depicts a partial cross-sectional representation of an embodiment of a sleeve coupled to a collar of a bone fastener assembly.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 968 of 2152

FIG. 34 depicts a partial cross-sectional representation of an embodiment of a sleeve coupled to a collar of a bone fastener assembly.

FIG. 35 depicts a partial cross-sectional representation of an embodiment of a sleeve coupled to a collar of a bone fastener assembly.

FIG. 36 depicts top view representation of an embodiment of a collar.

FIG. 37 depicts a partial cross-sectional representation of an embodiment of a sleeve coupled to an embodiment of a collar of a bone fastener assembly, such as the collar depicted in FIG. 36.

FIG. 38 depicts a top view representation of an embodiment of a collar.

FIG. 39 depicts a partial cross-sectional representation of an embodiment of a sleeve coupled to an embodiment of a collar of a bone fastener assembly, such as the collar depicted in FIG. 38.

FIG. 40 depicts a partial cross-sectional view of an embodiment of a sleeve with an inner sleeve.

FIG. 41 depicts a partial cross-sectional representation of an embodiment of a sleeve coupled to a collar of a bone fastener assembly.

FIG. 42 depicts a partial cross-sectional representation of an embodiment of a sleeve coupled to a collar of a bone fastener assembly.

FIG. 43 depicts a partial cross-sectional representation of an embodiment of a sleeve coupled to a collar of a bone fastener assembly.

FIG. 44 depicts a cross-sectional representation of an embodiment of a hinged sleeve coupled to a collar of a bone fastener assembly.

FIG. 45 depicts a cross-sectional representation of an embodiment of a hinged sleeve coupled to a collar of a bone fastener assembly.

FIG. 46 depicts a schematic representation of sleeve embodiments coupled to collars of a spinal stabilization system.

FIG. 47 depicts a schematic representation of sleeve embodiments with connections that allow relative movement of portions of a sleeve.

FIG. 48 depicts a perspective view of an embodiment of sleeves coupled to bone fastener assemblies.

FIG. 49 depicts a perspective view of an embodiment of sleeves that are coupled to bone fastener assemblies.

FIG. 50 depicts a schematic view of sleeve embodiments that are coupled to an embodiment of a frame.

FIG. 51 depicts a perspective view of an embodiment of a driver coupled to a bone fastener and a sleeve.

FIG. 52 depicts a partial cross-sectional view of an embodiment of a bone fastener and collar coupled to a driver positioned in a dilator.

FIG. 53 depicts a perspective view of an embodiment of a tissue wedge.

FIG. 54 depicts a perspective view of an embodiment of an estimating tool.

FIG. 55 depicts a perspective view of an embodiment of an estimating tool.

FIG. 56 depicts a perspective view of an embodiment of an estimating tool.

FIG. 57 depicts a perspective view of a tool designed to position an elongated member proximate vertebrae.

FIG. 58 depicts a perspective view of a seater for placing an elongated member proximate vertebrae.

FIGS. 59A and 59B depict perspective views of a tool designed to position a closure member in a collar coupled to a bone fastener.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 969 of 2152

FIGS. 60A and 60B depict perspective views of a tool designed to position a closure member in a collar coupled to a bone fastener.

FIG. 61 depicts an embodiment of a counter torque wrench coupled to a sleeve.

FIG. 62 depicts an embodiment of a counter torque wrench.

FIG. 63 depicts a schematic view of the counter torque wrench shown in FIG. 62 coupled to an elongated member.

FIGS. 64A-64E depict schematic views of guide wire placement during a minimally invasive spinal stabilization procedure.

FIGS. 65A-65D depict schematic views of tissue dilation during a minimally invasive spinal stabilization procedure.

FIGS. 66A-66F depict schematic views of vertebra preparation for receiving a bone fastener assembly during a minimally invasive spinal stabilization procedure.

FIGS. 67A-67D depict schematic views of insertion of a sleeve and bone fastener assembly during a minimally invasive spinal stabilization procedure.

FIGS. 68A-68D depict schematic views of tissue plane creation during a minimally invasive spinal stabilization procedure.

FIG. 69 depicts an embodiment of a tissue wedge.

FIGS. 70A-70D depict schematic views of placement of a sleeve and a bone fastener assembly in second vertebra during a minimally invasive spinal stabilization procedure.

FIG. 71 depicts a tissue plane between adjacent vertebrae with anchored sleeves crossing at the surface of the skin.

FIG. 72 depicts an embodiment of an elongated member.

FIG. 73 depicts an embodiment of an elongated member.

FIG. 74 depicts an embodiment of an elongated member.

FIG. 75 depicts an embodiment of an elongated member.

FIGS. 76A-76D depict schematic views of elongated member placement during a minimally invasive spinal stabilization.

FIG. 77 depicts a perspective view of a distal portion of a two-pronged driver.

FIGS. 78A-78D depict schematic views of a sleeve removal during a minimally invasive spinal stabilization procedure.

FIGS. 79A-79E depict schematic views of elongated member placement in sleeves for a multi-level spinal stabilization system.

FIGS. 80A-80C depict schematic views of bone fastener assemblies coupled to sleeves.

FIG. 81 depicts a perspective view of a bone fastener used in an invasive procedure.

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 970 of 2152

DETAILED DESCRIPTION

A spinal stabilization system may be installed in a patient to stabilize a portion of a spine. Spinal stabilization may be used, but is not limited to use, in patients having degenerative disc disease, spinal stenosis, spondylolisthesis, pseudoarthrosis, and/or spinal deformities; in patients having fracture or other vertebral trauma; and in patients after tumor resection. A spinal stabilization system may be installed using a minimally invasive procedure. An instrumentation set may include instruments and spinal stabilization system components for forming a spinal stabilization system in a patient.

A minimally invasive procedure may be used to limit an amount of trauma to soft tissue surrounding vertebrae that are to be stabilized. In some embodiments, the natural flexibility of skin and soft tissue may be used to limit the length and/or depth of an incision or incisions needed during the stabilization procedure. Minimally invasive procedures may provide limited direct visibility in vivo. Forming a spinal stabilization system using a minimally invasive procedure may include using tools to position system components in the body.

A minimally invasive procedure may be performed after installation of one or more spinal implants in a patient. The spinal implant or spinal implants may be inserted using an anterior procedure and/or a lateral procedure. The patient may be turned and a minimally invasive procedure may be used to install a posterior spinal stabilization system. A minimally invasive procedure for stabilizing the spine may be performed without prior insertion of one or more spinal implants in some patients. In some patients, a minimally invasive procedure may be used to install a spinal stabilization system after one or more spinal implants are inserted using a posterior spinal approach.

A spinal stabilization system may be used to achieve rigid pedicle fixation while minimizing the amount of damage to surrounding tissue. In some embodiments, a spinal stabilization system may be used to provide stability to two adjacent vertebrae (i.e., one vertebral level). A spinal stabilization system may include two bone fastener assemblies. One bone fastener assembly may be positioned in each of the vertebrae to be stabilized. An elongated member may be coupled and secured to the bone fastener assemblies. As used herein, "coupled" components may directly contact each other or may be separated by one or more intervening members. In some embodiments, a single spinal stabilization system may be installed in a patient. Such a system may be referred to as a unilateral, single-level stabilization system or a single-level, two-point stabilization system. In some embodiments, two spinal stabilization systems may be installed in a patient on opposite sides of a spine. Such a system may be referred to as a bilateral, single-level stabilization system or a single-level, four-point stabilization system.

In some embodiments, a spinal stabilization system may provide stability to three or more vertebrae (i.e., two or more vertebral levels). In a two vertebral level spinal stabilization system, the spinal stabilization system may include three bone fastener assemblies. One bone fastener assembly may be positioned in each of the vertebrae to be stabilized. An elongated member may be coupled and secured to the three bone fastener assemblies. In some embodiments, a single two-level spinal stabilization system may be installed in a patient. Such a system may be referred to as a unilateral, two-level stabilization system or a two-level, three-point stabilization system. In some embodiments, two three-point spinal stabilization systems may be installed in a patient on opposite sides of a spine. Such a system may be referred to as a bilateral, two-level stabilization system or a two-level, six-point stabilization system.

In some embodiments, combination systems may be installed. For example, a two-point stabilization system may be installed on one side of a spine, and a three-point stabilization system may be installed on the opposite side of the spine. The composite system may be referred to a five-point stabilization system.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 971 of 2152

Minimally invasive procedures may reduce trauma to soft tissue surrounding vertebrae that are to be stabilized. Only a small opening may need to be made in a patient. For example, for a single-level stabilization procedure on one side of the spine, the surgical procedure may be performed through a 2 cm to 4 cm incision formed in the skin of the patient. In some embodiments, the incision may be above and substantially between the vertebrae to be stabilized. In some embodiments, the incision may be above and between the vertebrae to be stabilized. In some embodiments, the incision may be above and substantially halfway between the vertebrae to be stabilized. Dilators, a targeting needle, and/or a tissue wedge may be used to provide access to the vertebrae to be stabilized without the need to form an incision with a scalpel through muscle and other tissue between the vertebrae to be stabilized. A minimally invasive procedure may reduce an amount of post-operative pain felt by a patient as compared to invasive spinal stabilization procedures. A minimally invasive procedure may reduce recovery time for the patient as compared to invasive spinal procedures.

Components of spinal stabilization systems may be made of materials including, but not limited to, titanium, titanium alloys, stainless steel, ceramics, and/or polymers. Some components of a spinal stabilization system may be autoclaved and/or chemically sterilized. Components that may not be autoclaved and/or chemically sterilized may be made of sterile materials. Components made of sterile materials may be placed in working relation to other sterile components during assembly of a spinal stabilization system.

Spinal stabilization systems may be used to correct problems in lumbar, thoracic, and/or cervical portions of a spine. Various embodiments of a spinal stabilization system may be used from the C1 vertebra to the sacrum. For example, a spinal stabilization system may be implanted posterior to the spine to maintain distraction between adjacent vertebral bodies in a lumbar portion of the spine.

FIG. 1 depicts an embodiment of spinal stabilization system 100 that may be implanted using a minimally invasive surgical procedure. Spinal stabilization system 100 may include bone fastener assemblies 102, elongated member 104, and/or closure members 106. Other spinal stabilization system embodiments may include, but are not limited to, plates, dumbbell-shaped members, and/or transverse connectors. FIG. 1 depicts a spinal stabilization system for one vertebral level. In some embodiments, the spinal stabilization system of FIG. 1 may be used as a multi-level spinal stabilization system if one or more vertebrae are located between the vertebrae in which bone fastener assemblies 102 are placed. In other embodiments, multi-level spinal stabilization systems may include additional bone fastener assemblies to couple to one or more other vertebrae.

FIG. 2 depicts a perspective view of bone fastener assembly 102. FIG. 3, FIGS. 4A and 4B, and FIG. 5 depict embodiments of bone fastener assembly components. Components of bone fastener assembly 102 may include, but are not limited to, bone fastener 108 (shown in FIG. 3), ring 110 (shown in FIGS. 4A and 4B), and collar 112 (shown in FIG. 5). Bone fastener 108 may couple bone fastener assembly 102 to a vertebra. Ring 110 may be positioned between a head of bone fastener 108 and collar 112.

FIG. 6 depicts a cross-sectional representation of bone fastener 108, ring 110, and collar 112 of bone fastener assembly 102. Bone fastener 108 of bone fastener assembly 102 may include passage 114. Bone fastener 108 may be cannulated (i.e., passage 114 may run through the full length of the bone fastener). A guide wire may be placed through passage 114 so that bone fastener 108 may be inserted into a vertebra at a desired location and in a desired angular orientation relative to the vertebra with limited or no visibility of the vertebra

In some embodiments, a bone fastener assembly may be a fixed angle fastener. FIG. 7 depicts an embodiment of a fixed angle bone fastener. Collar and bone fastener may be formed as a unitary piece of metal. A fixed angle fastener may be positioned as the first bone fastener assembly inserted into a vertebra.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 972 of 2152

A bone fastener may be, but is not limited to, a bone screw, a ring shank fastener, a barb, a nail, a brad, or a trocar. Bone fasteners and/or bone fastener assemblies may be provided in various lengths in an instrumentation set to accommodate variability in vertebral bodies. For example, an instrumentation set for stabilizing vertebrae in a lumbar region of the spine may include bone fastener assemblies with lengths ranging from about 30 mm to about 75 mm in 5 mm increments. A bone fastener assembly may be stamped with indicia (i.e., printing on a side of the collar). In some embodiments, a bone fastener assembly or a bone fastener may be color-coded to indicate a length of the bone fastener. In certain embodiments, a bone fastener with a 30 mm thread length may have a magenta color, a bone fastener with a 35 mm thread length may have an orange color, and a bone fastener with a 55 mm thread length may have a blue color. Other colors may be used as desired.

Each bone fastener provided in an instrumentation set may have substantially the same thread profile and thread pitch. In an embodiment, the thread may have about a 4 mm major diameter and about a 2.5 mm minor diameter with a cancellous thread profile. In certain embodiments, the minor diameter of the thread may be in a range from about 1.5 mm to about 4 mm or larger. In certain embodiments, the major diameter of the thread may be in a range from about 3.5 mm to about 6.5 mm or larger. Bone fasteners with other thread dimensions and/or thread profiles may also be used. A thread profile of the bone fasteners may allow bone purchase to be maximized when the bone fastener is positioned in vertebral bone.

FIG. 3 depicts an embodiment of bone fastener 108. Bone fastener 108 may include shank 116, head 118, and neck 120. Shank 116 may include threading 122. In some embodiments, threading 122 may include self-tapping start 124. Self-tapping start 124 may facilitate insertion of bone fastener 108 into vertebral bone.

Head 118 of bone fastener 108 may include various configurations to engage a driver that inserts the bone fastener into a vertebra. In some embodiments, the driver may also be used to remove an installed bone fastener from a vertebra. In some embodiments, head 118 may include one or more tool portions 126. Tool portions 126 may be recesses and/or protrusions designed to engage a portion of the driver. In some embodiments, bone fastener 108 may be cannulated for use in a minimally invasive procedure.

Head 118 of bone fastener 108 may include one or more splines 128, as depicted in FIG. 3. In some head embodiments, head 118 may include three splines. Splines 128 may be equally spaced circumferentially around head 118 of bone fastener 108. In some head embodiments, splines 128 may be spaced at unequal distances circumferentially around head 118. Splines 128 may include various surface configurations and/or texturing to enhance coupling of bone fastener 108 with a ring of a bone fastener assembly. In some embodiments, sides of the splines may be tapered so that the splines form a dovetail connection with a ring. In some embodiments, spline width may be tapered so that a good interference connection is established when the bone screw is coupled to a ring. Splines 128 may include one or more projections 130 to facilitate coupling bone fastener 108 with an inner surface of a ring. In some embodiments, projections 130 may be positioned on a lower portion of splines 128. In some embodiments, the splines may include recessed surfaces that accept projections extending from surfaces of the ring.

Neck 120 of bone fastener 108 may have a smaller diameter than adjacent portions of head 118 and shank 116. The diameter of neck 120 may fix the maximum angle that the collar of the bone fastener assembly can be rotated relative to bone fastener 108. In some embodiments, neck 120 may be sized to allow up to about 40° or more of angulation of the collar relative to the bone fastener. In some embodiments, the neck may be sized to allow up to about 30° of angulation of the collar relative to the bone fastener. In some embodiments, the neck may be sized to allow up to about 20° of angulation of the collar relative to the bone fastener.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 973 of 2152

FIGS. 4A and 4B depict perspective views of embodiments of ring 110. Outer surface 132 of ring 110 may have a contour that substantially complements a contour of an inner surface of a collar in which the ring resides. A contour of the outer surface of the ring may be a spherical portion. When the ring is positioned in the collar, the complementary shape of the ring outer surface and the inner surface of the collar that contacts the ring allows angulation of the collar relative to a bone fastener coupled to the ring. The contour of the outer surface of the ring and the inner surface of the collar may inhibit removal of the ring from the collar after insertion of the ring into the collar.

Outer surface 132 of ring 110 may have a smooth finish. In some embodiments, outer surface 132 may be surface treated or include coatings and/or coverings. Surface treatments, coatings, and/or coverings may be used to adjust frictional and/or wear properties of the outer surface of the ring. In some embodiments, a portion of the outer surface of the ring may be shaped and/or textured to limit a range of motion of the collar relative to a bone fastener of a bone fastener assembly.

An inner surface of ring 110 may include one or more grooves 134 and/or one or more seats 136. Seats 136 may be circumferentially offset from grooves 134. Grooves 134 may be sized to allow passage of splines of a bone fastener (e.g., splines 128 shown in FIG. 3) through the ring. When the splines are inserted through grooves 134, the bone fastener may be rotated until the splines align with seats 136. The bone fastener may be pulled or driven so that the splines are positioned in seats 136. In some embodiments, projections (e.g., projections 130 in FIG. 3) may pass over ridges 138 of ring 110. Passage of the projections over ridges 138 may securely couple the bone fastener to the ring and inhibit separation of the ring from the bone fastener.

In a ring embodiment, a number of grooves 134 and a number of seats 136 may equal a number of splines 128 on a head of a bone fastener. Seats 136 and grooves 134 may be equally spaced circumferentially around the inner surface of ring 110. In some embodiments, seats 136 may be circumferentially offset about 60° from grooves 134.

In some embodiments, as shown in FIG. 4A, a ring may be a complete ring without a split or slots. In some embodiments, a ring may include a split or slots to facilitate insertion of the ring into a collar. FIG. 4B depicts a ring with a split. In some embodiments, a ring with a split and/or slots may be compressed to ease insertion into a collar. Once positioned in the collar, the ring may expand to its original uncompressed dimensions, thus inhibiting removal from the collar.

As used herein, the term "collar" includes any element that wholly or partially encloses or receives one or more other elements. A collar may enclose or receive elements including, but not limited to, a bone fastener, a closure member, a ring, and/or an elongated member. In some embodiments, a collar may couple two or more other elements together (e.g., an elongated member and a bone fastener). A collar may have any of various physical forms. In some embodiments, a collar may have a "U" shape, however it is to be understood that a collar may also have other shapes.

A collar may be open or closed. A collar having a slot and an open top, such as collar 112 shown in FIG. 2 and in FIG. 5, may be referred to as an "open collar." A bone fastener assembly that includes an open collar may be referred to as an "open fastener." In some embodiments, an elongated member may be top loaded into the open fastener. A closure member may be coupled to the collar to secure the elongated member to the open fastener.

A collar that does not include a slot and an open top may be referred to as a "closed collar." A spinal implant that includes a closed collar may be referred to as a "closed implant." A closed collar may include an

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 974 of 2152

aperture, bore, or other feature in side surfaces for accommodating other components of a stabilization system (e.g., an elongated member). A setscrew may be used to securely couple an elongated member to a closed implant.

Collar 112 may include body 140 and arms 142. Arms 142 may extend from body 140. Body 140 of collar 112 may be greater in width than a width across arms 142 of collar 112 (i.e., body 140 may have a maximum effective outer diameter greater than a maximum effective outer diameter of arms 142). A reduced width across arms 142 may allow a detachable member to be coupled to the arms without substantially increasing a maximum effective outer diameter along a length of collar 112. Thus, a reduced width across arms 142 may reduce bulk at a surgical site.

A height of body 140 may range from about 3 millimeters (mm) to about 7 mm. In an embodiment, a height of body 140 is about 5 mm. Body 140 may include opening 144 in a lower surface of the body. To inhibit passage of a ring from collar 112, opening 144 may be smaller than an outer diameter of the ring. Inner surface 146 may be machined to complement a portion of an outer surface of a ring that is to be positioned in collar 112. Machining of inner surface 146 may enhance retention of a ring in collar 112. Inner surface 146 of body 140 may be complementary in shape to a portion of outer surface 132 of ring 110 (see FIG. 4) so that the ring is able to swivel in the collar. Inner surfaces and/or outer surfaces of collar 112 may be surface treated or include coatings and/or coverings to modify frictional properties or other properties of the collar.

Inner surfaces of arms 142 may include modified thread 148. Modified threads 148 may engage complementary modified threads of a closure member to secure an elongated member to a bone fastener assembly. Modified threads 148 may have a constant pitch or a variable pitch.

A height and a width of arms 142 may vary. Arms 142 may range in height from about 8 mm to about 15 mm. In an embodiment, a height of arms 142 is about 11 mm. A width (i.e., effective diameter) of arms 142 may range from about 5 mm to 14 mm. Arms 142 and body 140 may form slot 150. Slot 150 may be sized to receive an elongated member. Slot 150 may include, but is not limited to, an elongated opening of constant width, an elongated opening of variable width, a rectangular opening, a trapezoidal opening, a circular opening, a square opening, an ovoid opening, an egg-shaped opening, a tapered opening, and combinations and/or portions thereof. In some embodiments, a first portion of slot 150 may have different dimensions than a second portion of slot 150. In certain embodiments, a portion of slot 150 in first arm 142 may have different dimensions than a portion of slot 150 in second arm 142. When an elongated member is positioned in slot 150, a portion of the elongated member may contact a head of a bone fastener positioned in the collar.

In an embodiment of a collar, arms 142 of collar 112 may include one or more openings and/or indentions 152. Indentions 152 may vary in size and shape (e.g., circular, triangular, rectangular). Indentions 152 may be position markers and/or force application regions for instruments that perform reduction, compression, or distraction of adjacent vertebrae. In some embodiments, openings and/or indentions may be positioned in the body of the collar.

Arms 142 may include ridges or flanges 154. Flange 154 may allow collar 112 to be coupled to a detachable member so that translational motion of the collar relative to the detachable member is inhibited. Flanges 154 may also include notches 156. A movable member of a detachable member may extend into notch 156. When the movable member is positioned in notch 156, a channel in the detachable member may align with a slot in collar 112. With the movable member positioned in notch 156, rotational movement of collar 112 relative to the detachable member may be inhibited.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 975 of 2152

FIGS. 8A-8C show views of collar 112 and ring 110 during top loading insertion of the ring into the collar. Ring 110 may be positioned as shown in FIG. 8A and inserted past arms 142 into body 140. FIG. 8B depicts a cross-sectional view of ring 110 and collar 112 after insertion of the ring into the collar through slot 150. After insertion of ring 110 into collar 112, the ring may be rotated so that a bone fastener may be positioned through the ring. FIG. 8C depicts a cross-sectional view of ring 110 and collar 112 after rotation of the ring in the collar.

FIGS. 9A-9C show views of collar 112 and ring 110 during bottom loading insertion of the ring into the collar. Ring 110 may be positioned as shown in FIG. 9A and inserted into body 140 through an opening in the bottom of collar 112. In some embodiments, ring 110 may be inserted into body 140 through a groove or a slot in the bottom of collar 112. In certain embodiments, collar 112 designed for bottom insertion of ring 110 may have narrower slot 150 than a collar designed for top insertion of a ring. Collar 112 with narrower slot 150 may allow an elongated member with a reduced diameter to be used in a spinal stabilization system. Collar 112 with narrower slot 150 may be used to reduce bulk at a surgical site.

FIG. 9B depicts a cross-sectional view of ring 110 and collar 112 after insertion of the ring into the collar through the opening in the bottom of the collar. After insertion of ring 110 into collar 112, the ring may be rotated so that a bone fastener may be positioned through the ring. Tolerance between an outer surface of ring 110 and an inner surface of body 140 shown in FIGS. 8A-8C and 9A-9C may require force to be applied to the ring to drive the ring into the body. Once ring 110 is positioned in body 140, the ring may expand slightly. In certain embodiments, significant force may be required to remove ring 110 from body 140 (i.e., the ring may be substantially unreleasable from the body). The required force may inhibit unintentional removal of ring 110 from body 140. FIG. 9C depicts a cross-sectional view of ring 110 and collar 112 after rotation of the ring in the collar.

FIG. 10A depicts bone fastener 108 before insertion of the bone fastener into ring 110 positioned in collar 112. Splines 128 may be aligned with grooves 134 to allow passage of head 118 through ring 110 and into collar 112. FIG. 10B depicts bone fastener 108, ring 110, and collar 112 after the bone fastener has been rotated and head 118 has been coupled to seats in the ring to form bone fastener assembly 102. Inserting bone fastener 108 through opening 144 in collar 112 (depicted in FIG. 10A) may allow use of bone fasteners that have shanks and/or heads with larger diameters than can pass through slot 150. Bone fasteners with large diameter shanks may form a bone fastener assembly (threaded or otherwise) that securely fastens to vertebral bone during use.

A bone fastener may be rotatably positioned in a collar such that the bone fastener is able to move radially and/or rotationally relative to the collar (or the collar relative to the bone fastener) within a defined range of motion. The range of motion may be provided within a plane, such as by a hinged connection, or within a three-dimensional region, such as by a ball and socket connection. Motion of the bone fastener relative to the collar (or the collar relative to the bone fastener) may be referred to as "angulation" and/or "polyaxial movement". FIG. 11 depicts bone fastener assembly 102 with central axis 158 of collar 112 aligned with central axis 160 of bone fastener 108. Bone fastener 108 may be angulated in a symmetrical conical range of motion characterized by angle α about the aligned axes. Bone fastener 108 may be constrained from motion outside of limit axis 162 by contact between neck 120 of bone fastener 108 and collar 112. Alignment of axis 160 of bone fastener 108 with central axis 158 of collar 112 may be considered a neutral position relative to the range of motion. The alignment is a neutral position because bone fastener 108 may be angulated an equal amount in any direction from central axis 158. When a driver is inserted into bone fastener 108, axis 160 of bone fastener 108 may be substantially aligned with axis 158 of collar 112 to facilitate insertion of the bone fastener into a vertebral body.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 976 of 2152

In certain embodiments, a range of motion of a collar may be skewed from a full conical range of motion relative to aligned central axes of the collar and a bone fastener coupled to the collar. In some embodiments, a distal end of a collar may be shaped to skew, or bias, the range of motion from the range of motion depicted in FIG. 11. FIGS. 12A and 12B depict bone fastener assemblies 102 with biased collars 112. Body 140 of biased collar 112 may be shaped to restrict relative movement of bone fastener 108 (and/or the collar) to a skewed conical range of motion defined by limit axes 162. As depicted by limit axes 162 in FIG. 12A, a first arm 142 of collar 112 may approach bone fastener 108 more closely than a second arm of the collar. As suggested by limit axes 162 in FIG. 12B, a first opening of the slot between arms 142 of collar 112 may approach bone fastener 108 more closely than a second opening of the slot.

Other biased collars may be designed to selectively restrict relative movement of collars and/or bone fasteners. In some embodiments, a biased collar may be attached to a detachable member such that a surgeon performing a minimally invasive procedure may selectively align the portion of the collar with the greater range of motion as needed. For example, the collar depicted in FIG. 12B may be coupled to a single-level (e.g., C-shaped) sleeve so that the side of the collar (i.e., the side of the slot) with a larger range of motion is positioned next to a channel opening of the sleeve.

When a biased collar of a bone fastener assembly is coupled to a detachable member and a drive mechanism is coupled to a bone fastener of the bone fastener assembly, central axis 158 of collar 112 may align with central axis 160 of bone fastener 108 to facilitate insertion of the bone fastener into bone. In some embodiments, the bias of the collar may be so large that a flexible drive member is needed to drive the bone fastener into bone.

In some embodiments, one or more biased collars may be used in a spinal stabilization system. The spinal stabilization systems may be single-level systems or multi-level systems. Biased collars may be used to accommodate the increasing angle of the pedicle corridor for each lumbar vertebra. The angle may increase by about 5 degrees for each successive lumbar vertebra. FIGS. 13A and13B depict a single-level spinal stabilization system including bone fastener assembly 102A coupled to pedicle 164A and vertebra 166A and bone fastener assembly 102B coupled to pedicle 164B and vertebra 166B.

A bone fastener of bone fastener assembly 102A may engage pedicle 164A at pedicle angle ϕA relative to sagittal plane 168. Pedicle angle ϕA may range between about 13° and about 17°. Collar 112A of bone fastener assembly 102A may be unbiased. Pedicle angle ϕB may range between about 18° and about 22°. Collar 112B may have a bias angle β of about 5°. Bone fastener assembly 102B may engage pedicle 164B at pedicle angle ϕB. Because the bias of collar 112B is approximately equal to the difference between the pedicle angles of the two vertebrae, slots 150A and 150B in bone fastener assemblies 102A and 102B, respectively, may be generally aligned when both bone fasteners are in neutral positions.

Angulation of either or both collars of the bone fastener assemblies may allow fine adjustment of engagement angles of the bone fasteners. In addition, collar angulation may allow adjustment in the orientation of bone fasteners in a sagittal plane (i.e., to conform to lordosis of a spine) while still allowing the collars to be easily coupled with elongated member 104. Elongated member 104 may be disposed in slots 150A and 150B and secured by closure members. In some embodiments, a flexible driver or a polyaxial driver (e.g., a driver with a universal joint) may be used to drive the heads of the bone fasteners from a position that is off-axis from the bone fasteners to reduce the size of an opening of the body needed to implant the spinal stabilization system.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 977 of 2152

A closure member may be coupled to a collar of a bone fastener assembly to fix an elongated member positioned in the collar to the bone fastener assembly. In some embodiments, a closure member may be cannulated. In certain embodiments, a closure member may have a solid central core. A closure member with a solid central core may allow more contact area between the closure member and a driver used to couple the closure member to the collar. A closure member with a solid central core may provide a more secure connection to an elongated member than a cannulated closure member by providing contact against the elongated member at a central portion of the closure member as well as near an edge of the closure member.

FIG. 1 depicts closure members 106 coupled to bone fastener assemblies 102. FIG. 14 depicts closure member 106 prior to insertion of the closure member into a collar of a bone fastener assembly. Closure member 106 may include tool portion 170 and male modified thread 172. Tool portion 170 may couple to a tool that allows closure member 106 to be positioned in a collar. Tool portion 170 may include various configurations (e.g., threads, hexalobular connections, hexes) for engaging a tool (e.g., a driver). Male modified thread 172 may have a shape that complements the shape of a female modified thread in arms of a collar (e.g., modified thread 148 depicted in FIG. 5).

FIG. 15 depicts a cross-sectional representation of closure member 106 taken substantially along plane 15-15 of FIG. 14. Closure member 106 may include removal openings 174. A drive tool may be inserted into removal openings 174 to allow removal of closure member 106 after tool portion 170 has been sheared off. Removal openings 174 may include any of a variety of features including, but not limited to, sockets, holes, slots, and/or combinations thereof. In an embodiment, removal openings 174 are holes that pass through bottom surface 176 of closure member 106.

A bottom surface of a closure member may include structure and/or texturing that promotes contact between the closure member and an elongated member. A portion of the structure and/or texturing may enter and/or deform an elongated member when the closure member is coupled to the elongated member. Having a portion of the closure member enter and/or deform the elongated member may couple the elongated member to the closure member and a bone fastener assembly so that movement of the elongated member relative to the bone fastener assembly is inhibited. In a closure member embodiment, such as the embodiment depicted in FIG. 15, bottom surface 176 of closure member 106 may include point 178 and rim 180. In some embodiments, rim 180 may come to a sharp point. In some embodiments, a height of rim 180 may be less than a height of point 178. In other embodiments, a height of rim 180 may be the same or larger than a height of point 178. In some embodiments, rim 180 may not extend completely around the closure member. For example, eight or more portions of rim 180 may be equally spaced circumferentially around closure member 106. In certain embodiments, a solid central core including point 178 and rim 180 may enhance the ability of closure member 106 to secure an elongated member in a collar.

FIG. 16 depicts a portion of a spinal stabilization system with closure member 106 coupled to collar 112 before tool portion 170 is sheared off. Closure member 106 may couple to collar 112 by a variety of systems including, but not limited to, standard threads, modified threads, reverse angle threads, buttress threads, or helical flanges. A buttress thread on a closure member may include a rearward-facing surface that is substantially perpendicular to the axis of the closure member. Closure member 106 may be advanced into an opening in a collar to engage a portion of elongated member 104. In some embodiments, closure member 106 may inhibit movement of elongated member 104 relative to collar 112.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 978 of 2152

FIG. 17A depicts a cross-sectional view of closure member 106 coupled to bone fastener assembly 102. Closure member 106 may include male modified thread 172. Male modified thread 172 may include male distal surface 182 and male proximal surface 184, as shown in FIG. 17B. Collar 112 may include female modified thread 148 on an inside surface of arms 142. Female modified thread 148 may include female proximal surface 186 and female distal surface 188. Male proximal surface 184 may couple to female distal surface 188 during use. Male proximal surface 184 and female distal surface 188 may be load-bearing surfaces. A load may result from an upward load on closure member 106, such as a load resulting when elongated member 104 positioned in a slot of collar 112 is secured to bone fastener assembly 102 by closure member 106.

Raised portions 190 and recessed portions 192 may be included on male distal surface 182 and female proximal surface 186. Cooperating surfaces 194 of modified threads 172 and 148 may contact or be proximate to one another during use. As used herein, "proximate" means near to or closer to one portion of a component than another portion of a component. Engagement of cooperating surfaces 194 of modified threads 172 and 148 during use may inhibit radial expansion of collar 112. Engagement of cooperating surfaces 194 may inhibit spreading of arms 142 away from each other (i.e., inhibit separation of the arms). In some embodiments, cooperating surfaces 194 may be substantially parallel to a central axis of closure member 106. In other embodiments, cooperating surfaces 194 may be angled relative to a central axis of closure member 106.

In some embodiments, a proximal surface of a male modified thread may include raised and recessed portions. FIG. 18A depicts a cross-sectional view of bone fastener assembly 102 coupled to closure member 106 with raised and recessed portions on a proximal surface of male modified thread 172. FIG. 18B depicts a cross-sectional view of raised portions 190 at male proximal surface 184 of male modified thread 172 and female distal surface 188 of female modified thread 148. Male proximal surface 184 may include an overall positive slope S such that point A near the top of male modified thread 172 is distal from point B at the base of the male modified thread. Alternatively, male proximal surface 184 may include an overall negative slope or a slope of about zero.

In an embodiment, a bone fastener assembly and a closure member may be coupled with a running fit. A running fit (i.e., a fit in which parts are free to rotate) may result in predictable loading characteristics of a coupling of a bone fastener assembly and a closure member. Predictable loading characteristics may facilitate use of a closure member with a break-off portion designed to shear off at a predetermined torque. A running fit may also facilitate removal and replacement of closure members. In some embodiments, a closure member may include an interference fit (e.g., crest-to-root radial interference).

In an embodiment, a position (i.e., axial position and angular orientation) of a modified thread of a collar may be controlled, or "timed," relative to selected surfaces of the collar. For example, a modified thread form may be controlled relative to a top surface of a collar and an angular orientation of the slots of the collar. In some embodiments, positions of engaging structural elements of other coupling systems (e.g., thread forms) may be controlled.

Controlling a position of a modified thread form may affect a thickness of a top modified thread portion of a collar. In FIG. 5, top modified thread portion 196 is the first modified thread portion to engage a closure member. In an embodiment, a position of a modified thread form may be selected such that the thickness of the leading edge of a top modified thread portion is substantially equal to the full thickness of the rest of the modified thread.

Controlling a position of a modified thread form of a collar may increase a combined strength of engaged modified thread portions for a collar of a given size (e.g., wall height, modified thread dimensions, and thread pitch). Controlling a position of the modified thread form may reduce a probability of failure of modified thread

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 979 of 2152

portions, and thus reduce a probability of coupling failure between a collar and a closure member. Controlling the position of a modified thread form in a collar of a bone fastener assembly may increase a combined strength of engaged collar and closure member modified thread portions such that failure of the modified thread portions does not occur prior to the intended shearing off of a tool portion of the closure member. For example, a tool portion of a closure member may be designed to shear off at about 90 in-lbs of torque, while the combined modified thread portions may be designed to withstand a torque on the closure member of at least 120 in-lbs.

If a thickness of a modified thread portion of a given size and profile is reduced below a minimum thickness, the modified thread portion may not significantly contribute to the holding strength of the modified thread of a collar. In an embodiment, a position of a modified thread form of a collar may be controlled such that a thickness of a top modified thread portion is sufficient for the portion to increase a holding strength of the collar. In one embodiment, a top modified thread portion may have a leading edge thickness of about 0.2 mm.

In an embodiment, a position of a modified thread form of a collar may be selected to ensure that a closure member engages a selected minimum number of modified thread portions on each arm of the collar. In an embodiment, at least two modified thread portions having a full thickness over width w of a collar arm (shown in FIG. 5) may be engaged by a closure member at each arm. Alternatively, a closure member may engage parts of three or more modified thread portions on each arm, with the total width of the portions equal to at least two full-width portions. Allowances may be made for tolerances in the components (e.g., diameter of the elongated member) and/or anticipated misalignment between the components, such as misalignment between an elongated member and a slot. In an embodiment, a substantially equal number of modified thread portions in each arm may engage the closure member when an elongated member is coupled to a bone fastener assembly.

Various instruments may be used in a minimally invasive procedure to form a spinal stabilization system in a patient. The instruments may include, but are not limited to, positioning needles, guide wires, dilators, bone awls, bone taps, sleeves, drivers, tissue wedges, elongated member length estimating tools, mallets, tissue retractors, and tissue dilators. The instruments may be provided in an instrumentation set. The instrumentation set may also include components of the spinal stabilization system. The components of the spinal stabilization system may include, but are not limited to, bone fastener assemblies of various sizes and/or lengths, elongated members, and closure members.

Instruments used to install a spinal stabilization system may be made of materials including, but not limited to, stainless steel, titanium, titanium alloys, ceramics, and/or polymers. Some instruments may be autoclaved and/or chemically sterilized. Some instruments may include components that cannot be autoclaved or chemically sterilized. Components of instruments that cannot be autoclaved or chemically sterilized may be made of sterile materials. The sterile materials may be placed in working relation to other parts of the instrument that have been sterilized.

A targeting needle may be used to locate an entry point in a vertebral body for a bone fastener of a bone fastener assembly. In some embodiments, the targeting needle may be a Jamshidi® bone marrow biopsy needle. FIG. 19 depicts an embodiment of targeting needle 198. Targeting needle 198 may include outer housing 200 and member 202. FIG. 20 depicts an embodiment of outer housing 200. Outer housing 200 may include hollow shaft 204 and handle 206. Scale markings 208 may be printed, etched, or otherwise placed on hollow shaft 204. Scale markings 208 may be used to approximate a length of a bone fastener needed for a vertebra. Handle 206 may provide a grip that allows a user to manipulate the targeting needle. Handle 206 may include threaded portion 210.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 980 of 2152

Threaded portion 210 may couple to threading on a portion of a targeting needle member to secure the member to outer housing 200.

FIG. 21 depicts an embodiment of member 202 of a targeting needle. Member 202 may include point 212 and cap 214. Point 212 may be placed through a hollow shaft of an outer housing of the targeting needle. Cap 214 may include threading 216. Member 202 may be rotated relative to the outer housing to couple threading 216 with threading in a handle of the outer housing. In some embodiments, the member may be coupled to the outer housing by another type of connection system (e.g., by placement of a key in a keyway). With member 202 positioned in an outer housing, point 212 may extend from a distal end of a hollow shaft of the outer housing. Cap 214 may be used as an impact surface for driving the targeting needle in bone.

FIG. 22 and FIG. 23 depict embodiments of guide wire 218. Guide wire 218 may be an 18-gauge K-wire. Guide wire 218 may pass down a shaft of a targeting needle outer housing. A guide wire may be from about 15 cm to about 65 cm in length. In some embodiments, guide wires provided in an instrumentation set are about 46 cm in length. The length of guide wire 218 may allow a surgeon and/or assistants to hold at least one portion of the guide wire at all times when the guide wire is inserted into vertebral bone, even during insertion, use, and removal of instruments along a length of the guide wire. A guide wire that can be held continuously during a surgical procedure may inhibit removal or advancement of the guide wire from a desired position during a minimally invasive surgical procedure.

As depicted in FIG. 22, a distal end of guide wire 218 may include point 220. Point 220 may facilitate insertion of the distal end of guide wire 218 into vertebral bone. As depicted in FIG. 23, a distal end of guide wire 218 may not be pointed. A position of an unpointed guide wire in bone may be easier to maintain during a spinal stabilization procedure.

Dilators may be used during a minimally invasive surgical procedure to push aside tissue and create space to access vertebral bone. In some embodiments, four tissue dilators of increasing diameter may be used to establish sufficient working space to accommodate instruments and spinal stabilization system components. In some embodiments, especially for a mid-vertebra or for mid-vertebrae of a multi-level stabilization system, only three dilators may be needed to form sufficient working space. Dilators in an instrumentation set may increase in diameter incrementally by a selected amount. For example, outside diameters of dilators in an instrumentation set may increase sequentially by increments of about 0.5 mm.

A bone awl may be used to breach cortical bone of a pedicle. FIG. 24 depicts an embodiment of bone awl 222. Bone awl 222 may include handle 224, passage 226, and tip 228. Handle 224 may provide a secure grip that allows a surgeon to breach cortical bone of a pedicle with tip 228. A guide wire that is inserted in vertebral bone in a desired orientation may be inserted through passage 226 that extends through bone awl 222. Bone awl 222 may be moved down the guide wire so that tip 228 contacts the pedicle.

Bone awl 222 may have a length that allows a guide wire positioned in vertebral bone to always be held in at least one location when the guide wire is placed through passage 226 in the needle. In some embodiments, handle 224 may be removable from a shaft of bone awl 222 so that the guide wire may always be held during use of the bone awl.

During some surgical procedures downward force and some rotation of the bone awl may be sufficient to breach cortical of a vertebra. During some surgical procedures, an impact force may be needed for the bone awl to breach cortical bone. In some embodiments, a guide wire may be removed, the bone awl may be used to breach cortical bone, and the guide wire may be reinserted. In some embodiments, a small dilator may be placed over the

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 981 of 2152

portion of the guide wire extending from the bone awl so that a first end of the dilator contacts the bone awl. A mallet or other impact device may be used against a second end of the dilator so that the bone awl breaches cortical bone of the vertebra. The dilator may be removed from the bone awl and contact with the guide wire may be reestablished.

A bone tap may be used to form a threaded passage of a desired depth through a pedicle and into a vertebral body. FIG. 25 depicts an embodiment of tap 230. Tap 230 may include passage 232, shaft 234, removable handle 236, flutes 238, and indicia 240. Passage 232 may extend through a length of shaft 234 and removable handle 236. A guide wire positioned in vertebral bone may be inserted into a distal end of passage 232 so that tap 230 can be moved down the guide wire toward the bone.

In an embodiment of tap 230, a proximal portion of shaft 234 may include at least one flat portion that fits in a mating portion of removable handle 236. Proximal end of shaft 234 may also include a detent depression. The flat portion may allow for rotation of shaft 234 when removable handle 236 is rotated. An embodiment of removable handle 236 may include spring-loaded release 242. When spring-loaded release 242 is compressed (i.e., drawn upwards), a detent in removable handle 236 may be movable. When spring-loaded release 242 is not compressed, movement of the detent may be inhibited. When shaft 234 is positioned in removable handle 236, the detent of the removable handle may be positioned in the detent depression of shaft 234 to couple the shaft to the removable handle.

A tap portion of tap 230 may have a known length. As shown in FIG. 25, a tap portion of tap 230 may have a length *t*. In some embodiments, *t* may be about 20 mm, about 40 mm, about 60 mm, or greater. For example, *t* may be about 45 mm. X-ray monitoring of a depth of a tap portion of known length may allow a medical practitioner to assess a depth of a hole tapped in a bone. In some embodiments, the hole may be tapped to accommodate a bone fastener of a desired length. In certain embodiments, a bone fastener may be chosen to accommodate a hole tapped to a desired depth.

A guide wire positioned in vertebral bone may be held near a top of a dilator inserted over the guide wire at a surgical site. A proximal end of the guide wire may be positioned through a distal end of a passage in shaft 234 of tap 230 without a removable handle coupled to the shaft. A proximal portion of the guide wire may be held when the proximal portion of the guide wire extends beyond the top of shaft 234. A portion of the guide wire may always be held during use of tap 230. Shaft 234 may be moved down the guide wire until the shaft contacts the vertebral bone. The guide wire may be held near the top of shaft 234 and the guide wire may be positioned through passage 232 of removable handle 236. When the guide wire extends out of passage 232 through removable handle 236, the guide wire may be held above the removable handle. The handle may be coupled to the shaft using spring-loaded release 242.

A first reading of indicia 240 relative to a proximal end of a dilator may be taken when a first flute of flutes 238 is located at a pedicle. Tap 230 may be rotated so that flutes 238 form a threaded opening through the pedicle and into a vertebral body. Flutes 238 may have a diameter that is about 0.1 mm to about 0.7 mm less than a maximum thread flight of a bone fastener to be positioned in the threaded opening formed by the flutes. In an embodiment, tap may form a thread that is about 0.5 mm less than a maximum thread flight of a bone fastener to be positioned in the threaded opening formed by the flutes. A position of tap 230 may be monitored using a fluoroscope. When the threaded opening is formed to a desired depth, a second reading of indicia 240 relative to the dilator may be taken. A length of a bone fastener to be inserted into the vertebral body may be estimated by taking the difference between the indicia readings.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 982 of 2152

After a threaded opening is formed to a desired depth, tap 230 may be removed by rotating the tap until flutes 238 are disengaged from vertebral bone. Removable handle 236 may be separated from shaft 234, and the removable handle may be removed with the guide wire always held in at least one location. After removable handle 236 is removed from the guide wire, shaft 234 may be removed with the guide wire always held in at least one location.

A detachable member may be used as a guide to install bone fasteners of a bone fastener assembly in vertebral bone. A detachable member may be coupled to a collar of a bone fastener assembly. A distal end of a detachable member may be tapered or angled to reduce bulk at a surgical site. Instruments may be inserted into the detachable member to manipulate the bone fastener assembly. Movement of the detachable member may alter an orientation of a collar relative to a bone fastener of the bone fastener assembly. In some embodiments, a detachable member may be used as a retractor during a spinal stabilization procedure.

A detachable member for a single-level vertebral stabilization system may include one or more channels in a wall of the detachable member to allow access to an adjacent vertebra. For some single-level vertebral stabilization procedures, only single-channel detachable members (i.e., detachable members with a single channel in a wall of the detachable member) may be used. For other single-level vertebral stabilization procedures, one or more multi-channel detachable members (i.e., detachable members with two or more channels in a wall of the detachable member) may be used. Channels may provide flexibility to or enhance flexibility of a multi-channel detachable member. In some embodiments, a proximal portion of a multi-channel detachable member may have a solid circumference. A region of solid circumference in a multi-channel detachable member may enhance stability of the multi-channel detachable member. In some embodiments, a multi-channel detachable member may be longer than a single-channel detachable member.

A detachable member used at a middle vertebra in a multi-level stabilization procedure may be a multi-channel detachable member. Channels in a multi-channel detachable member may allow access to adjacent vertebrae from a middle vertebra. A detachable member used at an end vertebra of a multi-level stabilization system may be a single-channel detachable member or a multi-channel detachable member. A system for coupling a bone fastener assembly to a multi-channel detachable member may include a limiter that inhibits spreading of arms of the detachable member to inhibit release of the bone fastener assembly from the detachable member.

A channel in a wall of a detachable member may allow access to a vertebra that is to be stabilized with a spinal stabilization system being formed. In some embodiments, a single-channel detachable member may be coupled to a bone fastener assembly to be inserted into vertebral bone of a first vertebra. The single-channel detachable member may allow access to a second vertebra from the first vertebra. In other embodiments, a multi-channel detachable member may be coupled to a bone fastener assembly to be inserted into vertebral bone of a first vertebra. The multi-channel detachable member may allow access from the first vertebra to adjacent vertebrae.

Instruments may access a bone fastener assembly through a passage in a detachable member. In some embodiments, a channel in a wall of a detachable member may extend a full length of the detachable member. In some embodiments, especially in embodiments of multi-channel detachable members, a channel in a wall of a detachable member may extend only a portion of the length of the detachable member. In some embodiments, a channel in a wall of a detachable member may extend 25%, 50%, 75%, 80%, 90%, 95% or more of the length of the detachable member. A channel may extend to a distal end of a detachable member such that an elongated member inserted in the channel may pass from the detachable member into a slot of a collar of a bone fastener assembly coupled to the detachable member.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 983 of 2152

A channel in a detachable member may be any of a variety of shapes. A channel may have a width that exceeds a width (e.g., a diameter) of an elongated member that is to be inserted in the channel. In some embodiments, a channel may be a linear opening parallel to a longitudinal axis of the detachable member. In some embodiments, a channel may have a non-linear shape including, but not limited to, a helical pattern, an arc, an "L" shape, or an "S" shape. A non-linear channel may allow an elongated member to travel along a predetermined path. In certain embodiments, adjacent detachable members may include channels with matching profiles, allowing ends of an elongated member to follow similar paths down the detachable member channels.

Movable members may extend through portions of a detachable member proximate a channel in the detachable member. Movable members may engage notches in a collar to establish a radial orientation of the detachable member on the collar and/or to inhibit rotation of the collar relative to the detachable member. A distal end of a movable member may be flat, curved, or angled. In some embodiments, a distal end of a movable member may be threaded. In other embodiments, a distal end of a movable member may be a projection that engages an opening in a collar. In some embodiments, an upper surface of a collar and/or a surface of a distal end of a movable member may be textured to inhibit rotation of the collar relative to the detachable member. In certain embodiments, a proximal end of a movable member may include a tool engaging portion. A tool engaging portion may include, but is not limited to, a hex section, a hexalobular section, a tapered section, a bead, a knot, a keyed opening, a coating, a threading, and/or a roughened surface for engaging a drive that rotates or otherwise displaces the movable member.

A cross section transverse to a longitudinal axis of a detachable member may have shapes including, but not limited to, circular, ovoid, square, pentagonal, hexagonal, and combinations thereof. In some embodiments, a detachable member may be hollow. In certain embodiments, a thickness of a hollow detachable member may be uniform. In certain embodiments, a thickness of a hollow detachable member may vary along the length of the detachable member. A detachable member with a passage extending longitudinally from a first end of the detachable member to a second end of the detachable member may be referred to as a "sleeve".

FIG. 26 depicts an embodiment of sleeve 244. Sleeve 244 may be a multi-channel sleeve. Sleeve 244 may include wall 246, channels 248, passage 250, movable members 252, and flange 254. Channels 248 may extend from a distal end of sleeve 244 through a portion of wall 246. Channels 248 may allow instruments to be positioned and used to form a plane through soft tissue to one or more adjacent vertebrae. An elongated member may be inserted in the tissue plane and positioned in collars of bone fastener assemblies anchored in vertebrae and coupled to sleeves. Passage 250 may allow instruments to be positioned and used to manipulate a bone fastener assembly that is coupled to a distal end of sleeve 244. Movable members 252 may be part of a system that couples a bone fastener assembly to sleeve 244. In some embodiments, movable members 252 may include tool engaging portion 256. A driver may be positioned in tool portion 256. The driver (e.g., a hex wrench) may be used to extend or retract a distal end of movable member 252. A distal end of sleeve 244 may include flange 254 that mates with a complementary flange on a collar of a bone fastener assembly. A distal end of sleeve 244 may be tapered to reduce bulk (e.g., reduce spin diameter) at a surgical site.

FIG. 27 depicts a top view of an embodiment of sleeve 244 coupled to a bone fastener assembly. Tool portion 126 of bone fastener 108 is a hexalobular connection.

FIG. 28 depicts a cross-sectional representation of a portion of sleeve 244 with bone fastener assembly 102 taken substantially along line 28-28 of FIG. 27. Flange 254 of sleeve 244 may mate with flange 154 of collar 112

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 984 of 2152

to inhibit translation of the sleeve relative to the collar. Sleeve 244 may also include stop 258. Stop 258 may engage a portion of collar 112 to inhibit separation of walls 246. During use, stop 258 may inhibit undesired separation of bone fastener assembly 102 from sleeve 244.

FIG. 29 depicts a cross-sectional representation of a portion of sleeve 244 with bone fastener assembly 102 and elongated member 104 taken substantially along line 29-29 of FIG. 27. Distal ends of movable members 252 may extend into notches (e.g., notches 156 depicted in FIG. 5) in collar 112. Portions of walls 246 of sleeve 244 may include threading. Portions of movable members 252 may include threading complementary to threaded portions of walls 246. Threading of movable members 252 may engage threading in walls 246 such that rotation of the movable members advances or retracts the movable members relative to the walls.

As shown in FIG. 29, collar 112 may be designed such that elongated member 104 lies below a distal end of sleeve 244. Coupling sleeve 244 to collar 112 above elongated member 104 may reduce bulk at a surgical site. With elongated member 104 coupled to collar 112 below a distal end of sleeve 244, the sleeve may be removed without interference from the elongated member of a spinal stabilization system.

FIG. 30 depicts an embodiment of sleeve 244. Sleeve 244 may be a single-channel sleeve for use in single-level or multi-level spinal stabilization procedures. Sleeve 244 may be used at the outermost vertebrae to be stabilized during installation of a multi-level vertebral stabilization system. Sleeve 244 may be coupled to a collar of a bone fastener assembly with movable members 252 and/or flange 254. Instruments may be inserted through passage 250 of sleeve 244 to access an anchored bone fastener assembly coupled to the sleeve. An instrument may be moved through channel 248 toward an adjacent vertebra to form a tissue plane in soft tissue between sleeve 244 and the adjacent vertebra.

A sleeve may be coupled to a bone fastener assembly in various ways to inhibit movement of the sleeve relative to a collar of the bone fastener assembly. A system used to couple the sleeve to the bone fastener assembly may inhibit rotation and translation of the sleeve relative to the collar.

FIG. 31 depicts a perspective view of a sleeve embodiment during connection of the sleeve to collar 112 of a bone fastener assembly. Sleeve 244 may include movable members 252. Movable members 252 may include threaded distal end portions. FIG. 31A depicts a detailed view of a portion of sleeve 244 and collar 112. Collar 112 may include openings 260. Openings 260 may be threaded. Openings 260 of collar 112 may be aligned with movable members 252. A drive end of driver 262 may be positioned in tool engaging portion 256 of movable member 252. Driver 262 may be rotated to couple a threaded end of movable member 252 with threads in opening 260. The driver may be positioned in a tool opening of second movable member 252. The driver may be used to couple a threaded end of second movable member 252 with threads in second opening 260. Threaded connections between movable members 252 and collar 112 may inhibit movement of the collar relative to sleeve 244.

A detachable member may be coupled to a collar of a bone fastener assembly in various ways. When a detachable member is coupled to a collar, rotation and translation of the detachable member relative to the collar may be inhibited. A system used to couple a detachable member and collar should be simple, inexpensive to implement, and should not significantly weaken the mechanical strength of the collar and/or the detachable member. Detachable members may be coupled to collars using various coupling systems including, but not limited to, flanges, threaded connections, interlocking connections (e.g., ratcheting connection systems), and/or interference fits.

In an embodiment of an interlocking connection system, a detachable member may include an opposing pair of deflectable arms. Each deflectable arm may include a tooth. The deflectable arms may be forced outwards

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 985 of 2152

during coupling of a collar to the detachable member. When the collar is coupled to the detachable member, the deflectable arms may be positioned in channels in the collar, with the teeth positioned in indentions in the collar. The presence of the deflectable arms in the channels of the collar may inhibit rotation and translation of the detachable member relative to the collar. Separation of the detachable member from the collar may be achieved by insertion of an expander in the detachable member. The expander may be used to force the deflectable arms outwards and expel the teeth from the indentions.

FIGS. 32-45 depict embodiments of sleeves coupled to bone fastener assemblies. In each bone fastener assembly/sleeve embodiment depicted in FIGS. 32-43 and FIG. 45, an elongated member seated in the collar of the bone fastener assembly would lie below a distal end of sleeve 244. Having the elongated member below the distal end of sleeve 244 reduces bulk at the surgical site. With sleeve 244 positioned above the elongated member, interference of the secured elongated member with the sleeve is avoided during removal of the sleeve.

FIG. 32 depicts a cross-sectional representation of sleeve 244 including sleeve flange 254. Sleeve 244 may be rotated onto collar 112 until slot 150 aligns with channel 248. Sleeve flange 254 may engage flange 154 of collar 112 to inhibit translation of sleeve 244 relative to collar 112 of bone fastener assembly 102.

In some detachable member and collar coupling embodiments, the detachable member and the collar may include members that work together to inhibit radial expansion of walls of the detachable member. FIG. 33 depicts an embodiment of sleeve 244 coupled to an embodiment of bone fastener assembly 102. Sleeve 244 may include sleeve flange 254 and stop 258. Sleeve flange 254 may engage flange 154 of collar 112 to inhibit translation of sleeve 244 relative to the collar. Stop 258 may contact ledge 264 of collar 112. Contact of stop 258 against ledge 264 may inhibit release of collar 112 from sleeve 244 caused by radial expansion of walls of the sleeve. A stop in a sleeve and a ledge in a collar may be needed in a multi-channel sleeve embodiment. A stop in a sleeve and/or a ledge in a collar may not be needed in a single-channel sleeve embodiment or in a collar for a single-level stabilization.

In some detachable member and collar coupling embodiments, a detachable member may include a protrusion that mates with a complementary groove in a collar. Alternatively, a detachable member may include a groove that mates with a complementary protrusion of a collar. FIG. 34 depicts a cross-sectional view of sleeve 244 with ridge 266. Ridge 266 may couple with groove 268 in collar 112. Ridge 266 and groove 268 may form a dovetail joint. The dovetail joint may inhibit radial expansion of sleeve walls 246. In some embodiments, such as the embodiment depicted in FIG. 35, ridge 266 and groove 268 may not form a dovetail joint.

In some embodiments, a detachable member and/or a collar may include a locking system to inhibit rotation of the detachable member relative to the collar. The locking system may be, but is not limited to, threading, interference fits, frictional engagement, or a press-fit connection. In some embodiments, a locking system may inhibit translation and/or rotation of a detachable member relative to a collar.

FIG. 36 depicts a top view representation of an embodiment of collar 112 of a bone fastener assembly. Collar 112 includes openings 260. In some embodiments, openings 260 may be threaded. In some embodiments, openings 260 may not include threading. The body of collar 112 adjacent to openings 260 may include extra material to provide strength to the collar.

FIG. 37 depicts a partial cross-sectional representation of an embodiment of sleeve 244 coupled to an embodiment of collar 112, such as the collar depicted in FIG. 36. Distal end portions of movable members 252 may extend into openings 260. When distal end portions of movable members 252 are positioned in openings 260, rotational movement of sleeve 244 relative to collar 112 may be inhibited. Sleeve 244 may include flange 254.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 986 of 2152

Flange 254 may engage flange 154 of collar 112 to inhibit translation of sleeve 244 relative to the collar. In an embodiment in which distal end portions of movable members in a sleeve are threaded and openings in the collar are threaded, rotation and translation of the collar relative to the sleeve may be inhibited when distal end portions of the movable members are positioned in the openings.

As depicted in FIG. 37, portion 270 of movable member 252 may include threading. Threading of portion 270 may engage threading in wall 246 of sleeve 244. Engagement of threading of portion 270 with threading in wall 246 may allow distal end portion of movable member 252 to advance towards, or retract from, a distal end of sleeve 244 when the movable member is rotated.

FIG. 38 depicts a top view representation of an embodiment of collar 112 of a bone fastener assembly. Collar 112 may include notches 156. FIG. 39 depicts a partial cross-sectional representation of an embodiment of sleeve 244 coupled to an embodiment of collar 112, such as the collar depicted in FIG. 38. Distal end portions of movable members 252 of sleeve 244 may be extended and positioned in notches 156 of collar 112. An interference fit between the distal end portions of movable members 252 and the body of collar 112 that defines the notches may inhibit rotation of sleeve 244 relative to the collar.

Portion 270 of movable member 252 may include threading. Threading of portion 270 may engage threading in wall 246 of sleeve 244. Engagement of threading of portion 270 with threading in wall 246 may allow a distal end portion of movable member 252 to advance towards, or retract from, a distal end of sleeve 244 when the movable member is rotated.

In an embodiment, an inner sleeve may be positioned in a sleeve to inhibit translation and/or rotation of the sleeve relative to a collar of a bone fastener assembly. FIG. 40 depicts a cross-sectional view of sleeve 244 with inner sleeve 272. A distal end of inner sleeve 272 may contact an upper end of collar 112. A proximal portion of inner sleeve 272 may engage a proximal portion of sleeve 244. The engagement may allow inner sleeve 272 to apply a force against collar 112 that presses flange 154 against flange 254 of sleeve 244 to inhibit translation of the sleeve relative to the collar. The engagement may be, but is not limited to, a threaded connection, an interference fit, a frictional fit, or a keyway type of connection.

In some embodiments, a distal end of an inner sleeve may be roughened or textured to frictionally engage a proximal surface of the collar. The frictional engagement may inhibit rotation of the sleeve relative to the collar. In some embodiments, inner sleeve 272 may include passage 274. A pin may pass through passage 274 into an opening in collar 112. When a pin is positioned through passage 274 into the opening, rotation of sleeve 244 relative to collar 112 may be inhibited.

In some embodiments, threading may be used to couple a detachable member to a collar. FIG. 41 and FIG. 42 depict partial cross-sectional representations of sleeves 244 that couple to collars 112 by threaded connections. Sleeves 244 may include female threading that is complementary to male threading of collar 112. In some embodiments, threading of the sleeve and threading of the collar may be modified threads.

FIG. 43 depicts a partial cross-sectional representation of sleeve 244 that couples to collar 112 by a threaded connection. Sleeve 244 may include male threading, and collar 112 may include complementary female threading. In some embodiments, portion 276 of collar 112 that includes threading which mates with threading of sleeve 244 may be a break-off section. Collar 112 may be held in a fixed position. Torque may be applied to sleeve 244 to shear off portion 276.

In some embodiments, a detachable member may include a pair of hinged arms configured to couple to a collar. FIG. 44 and FIG. 45 depict embodiments of sleeves that include hinged portions. Sleeve 244 may include

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 987 of 2152

arms 278. Arms 278 may be pivotally coupled together by hinge 280. Hinge 280 may be located near a proximal end of sleeve 244. In some sleeve embodiments, sleeve 244 may include a locking element or a biasing element (e.g., a spring) near or at hinge 280. A locking element or biasing element may cause a clamping force to be exerted on collar 112 to maintain the collar in the sleeve and/or to inhibit rotation of collar 112 in sleeve 244. In some embodiments, such as in the embodiment depicted in FIG. 44, flange 254 of sleeve 244 may contact a bottom portion of collar 112. In some embodiments, such as in the embodiment depicted in FIG. 45, flange 254 of sleeve 244 may contact flange 154 of collar 112.

In some detachable member embodiments, proximal portions of detachable members may be chamfered to allow ends of the detachable members to more closely approach each other than detachable members with a uniform cross section. FIG. 46 depicts sleeves 244 coupled to collars 112 engaged in adjacent pedicles 164. Sleeves 244 may include chamfered surfaces 282. Chamfered surfaces 282 may reduce space between proximal ends of sleeves 244. During some surgical procedures, only one of the sleeves may be chamfered. During some surgical procedures, the use of a sleeve with a chamfered surface may allow for a smaller incision than required when using non-chamfered sleeves. In some embodiments, other types of detachable members may be used to reduce space between proximal ends of detachable members. Other types of detachable members may include, but are not limited to, detachable members of different lengths, detachable members of different diameters, and detachable members with flexible end portions.

Detachable members may be of various lengths. Detachable members of different lengths may be used in the same surgical procedure. A detachable member length used in a spinal stabilization procedure may be determined by a patient's anatomy. Detachable members may be just short enough to allow manipulation by a medical practitioner above an incision in a patient. In some embodiments, detachable members may be about 3.5 to about 11.5 cm long. For example, a single-channel detachable member may be about 10 cm long. In some embodiments, detachable members may be about 11.5 cm to about 14 cm long. For example, a single-channel or a multi-channel detachable member may be about 12.5 cm long. A multi-channel detachable member may be longer than a single-channel detachable member. In some embodiments, a multi-channel detachable member may be at least about 15 cm long. For example, a multi-channel detachable member may be about 16 cm long. Detachable members that are too long may require a longer incision and/or a larger tissue plane for insertion of a spinal stabilization system. Insertion of an elongated member may be more difficult with detachable members that are longer than necessary. Detachable members with excess length may be bulky and hard to manipulate during a surgical procedure.

A detachable member may be flexible over its entire length or include a flexible portion near a proximal end of the detachable member. A flexible portion may allow positioning of a proximal portion of a detachable member in a desired location. A flexible portion may be produced from any of various materials including, but not limited to, a surgical grade plastic, rubber, or metal. A flexible portion may be formed of various elements, including, but not limited to, a tube, a channel, or a plurality of linked segments.

FIG. 47 depicts an embodiment of sleeve 244 with a connection that allows movement of first portion 284 relative to second portion 286. First portion 284 may be coupled to collar 112 of a bone fastener assembly. Second portion 286 may connect to first portion 284 at linkage 288. Linkage 288 may include, but is not limited to, a locking element, a pivot point, a hinge, or a pin. In some embodiments, the linkage may be a ball and socket type of connection that allows rotational motion of second portion 286 relative to first portion 284. During some spinal stabilization procedures, a detachable member without a second portion that is able to move relative to a first

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 988 of 2152

portion may be used at one vertebra, and a detachable member with a second portion that is able to move relative to a first portion may be used at one or more vertebrae that are to be stabilized.

When bone fasteners of polyaxial bone fastener assemblies are positioned in vertebral bone, detachable members coupled to collars of the bone fastener assemblies may be moved in desired positions. During surgery, a detachable member in a patient may be oriented towards an adjacent vertebra that is to be stabilized to reduce the required incision size. In some embodiments, channels of the detachable members may be aligned so that an elongated member may be positioned in collars of the bone fastener assemblies. FIG. 48 depicts an orientation of three sleeves. Sleeves 244, 244' may couple to collars 112, 112'. Bone fasteners 108, 108' may be inserted into vertebrae. Single-channel sleeves 244 may be coupled to collars 112 before insertion of bone fasteners 108 into two outer pedicles to be stabilized. Multi-channel sleeve 244' may be coupled to collar 112' before insertion of bone fastener 108' into a central pedicle of the three adjacent pedicles. Single-channel sleeves 244 may be angled towards multi-channel sleeve 244'. In certain embodiments, multi-channel detachable members may be coupled to all three pedicles. In other embodiments, differently shaped detachable members (e.g., circular, oval) may be used in one or more of the pedicles. Channels of the detachable members may be aligned so that an elongated member may be moved down the detachable members and into collars of the bone fastener assemblies.

In some embodiments, channels of detachable members may face a direction other than toward each other. FIG. 49 depicts sleeves 244 coupled to collars 112 oriented at an angle so that channels 248 of sleeves 244 face in different directions. An elongated member may be curved in an appropriate shape to engage slots 150 in collars 112 when channels 248 of sleeves 244 are angled. In some embodiments, channels in the detachable member may not be longitudinal channels down the length of the detachable member. In embodiments of detachable members with non-longitudinal channels, the channels of two adjacent detachable members may not face towards each other when the openings of collars coupled to the detachable members are aligned.

In an embodiment, a frame may couple to two or more detachable members. FIG. 50 depicts a perspective view of sleeves 244 coupled to frame 290. As used herein, a "frame" includes any of a variety of structural elements including, but not limited, rods, bars, cages, or machined blocks. In some embodiments, frame 290 may provide a rigid coupling between sleeves 244. In other embodiments, frame 290 may allow for angular or translational movement between sleeves. For example, frame 290 may include slidable elements that allow sleeves to be translated toward each other or away from each other to facilitate compression or distraction of vertebrae. Alternatively, frame 290 may enable sleeves 244 to pivot toward each other or away from each other. In some embodiments, frame 290 may allow for movement of sleeves 244 to facilitate spinal reduction.

After a bone fastener assembly is coupled to a detachable member, a driver may be coupled to a bone fastener of the bone fastener assembly. The driver may be used to insert the bone fastener into vertebral bone.

FIG. 51 depicts an embodiment of driver 292 positioned in sleeve 244. Sleeve 244 is coupled to bone fastener assembly 102. Driver 292 may be coupled to collar 112 and to bone fastener 108 of bone fastener assembly 102. Coupling driver 292 to collar 112 and to bone fastener 108 may ensure proper alignment of the driver relative to the bone fastener. Coupling driver 292 to collar 112 and to bone fastener 108 may also inhibit movement of the collar relative to the bone fastener during insertion of the bone fastener.

Driver 292 may include outer shaft 294, inner shaft 296, and removable handle 236. Outer shaft 294 may include threading 298 and textured portion 300. A portion of outer shaft 294 may be positioned in a passage through sleeve 244 (passage 250 shown in FIG. 30). Threading 298 may couple to a modified thread of collar 112. Textured portion 300 may facilitate rotation of outer shaft 294 so that threading 298 engages the modified thread of

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 989 of 2152

collar 112. When threading 298 engages the modified thread of collar 112, driver 292 may be securely coupled to bone fastener assembly 102, which is securely fastened to sleeve 244.

A distal end of inner shaft 296 may be coupled to bone fastener 108 during use. Inner shaft 296 may be coupled at a proximal end to removable handle 236 during use. Inner shaft 296 may be rotatable relative to outer shaft 294 so that bone fastener 108 can be inserted into vertebral bone. A proximal portion of inner shaft 296 may include at least one flat portion that fits in a mating portion of removable handle 236. Removable handle 236 may be the same removable handle that is used with a bone tap that forms a threaded opening in vertebral bone for a bone fastener. Removable handle 236 may be removed from driver 292 during insertion of a guide wire through the driver so that the guide wire may be held in at least one place at all times. In some embodiments, a removable handle for the driver may be unnecessary given the length of the guide wire and/or the length of the driver (e.g., a long guide wire and/or a short driver).

FIG. 52 depicts a cross-sectional representation of a portion of an embodiment of a driver that is coupled to bone fastener 108 and collar 112 of a bone fastener assembly. Collar 112 is coupled to sleeve 244. Sleeve 244 is positioned in dilator 302. In some embodiments, clearance between outer shaft 294 and sleeve 244 may be relatively small. In some embodiments, the clearance between outer shaft 294 and sleeve 244 may range from about 0.1 mm to about 0.75 mm. For example, the clearance between outer shaft 294 and sleeve 244 may be about 0.25 mm (i.e., an inner diameter of the sleeve may be about 0.5 mm greater than an outer diameter of the outer shaft). Also, clearance between sleeve 244 and dilator 302 may be relatively small. The small clearances may inhibit undesired movement of the instruments relative to each other and/or reduce bulkiness at the surgical site.

Thread 298 of outer shaft 294 of the driver may couple to modified thread 148 of collar 112. Head 304 of inner shaft 296 of the driver may couple to tool portion 126 of bone fastener 108. Head 304 may have a complementary shape to tool portion 126 of bone fastener 108. A guide wire may be inserted into a distal end of passage 114 of bone fastener 108 and through passage 306 of the driver. When the guide wire is inserted into passage 114 and passage 306, a removable handle may not be coupled to inner shaft 296.

During a minimally invasive surgical procedure, a plane may be created in tissue from a first vertebra to a second vertebra. An elongated member may be positioned in the plane during the surgical procedure. In some embodiments, a tissue plane may be formed using a targeting needle. The targeting needle may be positioned at the first vertebra. The distal end of the needle may be moved toward the second vertebra to form the plane while maintaining a position of the needle at a surface of the skin. The needle may be moved back and forth a number of times to clearly establish the plane. Care may need to be taken to avoid bending the targeting needle during establishment of the plane.

In some embodiments, a tissue wedge may be used to form a plane in tissue between a first vertebra and a second vertebra. FIG. 53 depicts an embodiment of tissue wedge 308. Tissue wedge 308 may include handle 310 and blade 312. Handle 310 may allow blade 312 to be easily positioned at a desired location.

Blade 312 may be a double-wedged blade. Blade 312 may have a diamond-like shape. Edges of blade 312 may be blunt to avoid severing tissue during use of tissue wedge 308. Distal end 314 of blade 312 may be rounded. A shape of distal end 314 may inhibit damage to tissue and may facilitate movement of blade 312 towards a target location during formation of a plane in tissue between vertebrae. In some tissue wedge embodiments, tissue wedge 308 may include hook 316. Cutting edge 318 in hook 316 may be used to sever portions of tissue (e.g., fascia) through which blade 312 cannot form a plane. Cutting edge 318 may be oriented in blade 312 so that severing of tissue results when tissue wedge 308 is pulled away from the spine.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 990 of 2152

An estimating tool may be used to estimate a distance between bone fastener assemblies anchored in vertebrae. The bone fastener assemblies may be part of a single-level or multi-level spinal stabilization system. The distance estimated by an estimating tool may be used to determine a desired length of an elongated member to be positioned in collars of the anchored bone fastener assemblies. FIG. 54 depicts an embodiment of estimating tool 320 with handle 322 and shaft 324. Arms 326 may be pivotably coupled to coupling portion 325 of shaft 324. Distal ends of arms 326 may be rounded. In some embodiments, distal ends of arms 326 may include members 330. Members 330 may be rounded (e.g., spherical) or elongated (e.g., tubular). Members 330 may also have other shapes to meet specific needs or requirements. In embodiments, a shape and/or a size of members 330 may be designed to fit snugly into detachable members coupled to a spinal stabilization system.

Activator 328 may be located at a proximal end of handle 322. With activator 328 unengaged, a biasing element (e.g., a spring, springs, and/or elastic member) in coupling portion 325 may allow arms 326 to assume a fully extended position. With arms 326 in a fully extended position, members 330 may achieve a maximum separation distance. Estimating tool 320 may be designed such that a maximum separation distance of members 330 exceeds an expected distance between anchored bone fastener assemblies. Fully extended arms 326 may be manually compressed and inserted into passages of sleeves coupled to anchored bone fastener assemblies. For a multi-level system, arms 326 may be inserted in detachable members coupled to the outermost bone fastener assemblies while one or more detachable members coupled to one or more inner vertebrae are held out of the way. With activator 328 unengaged, the biasing element in coupling portion 325 may force members 330 against inner walls of the detachable members.

Estimating tool 320 may be advanced toward the anchored bone fastener assemblies. In some embodiments, estimating tool 320 may be advanced toward the anchored bone fastener assemblies until members 330 contact collars and/or bone fasteners of the bone fastener assemblies. With members 330 contacting collars and/or bone fasteners, activator 328 of estimating tool 320 may be engaged. Engaging activator 328 of estimating tool 320 may limit the biasing element such that the distance between outer surfaces of members 330 does not exceed the distance between the anchored bone fastener assemblies. With activator 328 engaged and the distance between outer surfaces of members 330 fixed to indicate the distance between the anchored bone fastener assemblies, estimating tool 320 may be moved upwards to remove the estimating tool from the patient. When estimating tool 320 is moved upwards, arms 326 may compress to facilitate removal of the estimating tool from the detachable members.

Once removed from the detachable members, the biasing element may restore the distance between outer surfaces of members 330 to indicate the separation between anchored bone fastener assemblies. The distance between members 330 (e.g., the distance between outer surfaces of the members) may be used to estimate a length of an elongated member needed to couple the anchored bone fastener assemblies. The distance between members 330 may be read using a scale provided in the instrumentation kit. In some embodiments, the scale may be indicia or etching on a surface of the instrumentation kit. In an embodiment, a length of an elongated member may be chosen to be greater than a distance between members 330 to allow for bending of the elongated member and/or to allow the elongated member to extend beyond the collars of the anchored bone fastener assemblies. For example, 15 mm may be added to the distance between members 330. In some embodiments, a length of an elongated member may be chosen such that the elongated member extends 2 mm or more beyond the collars. In certain embodiments, a length of an elongated member may be chosen such that ends of the elongated member do not extend from the collars.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 991 of 2152

In the embodiment shown in FIG. 55, arms 326 of engaging tool 320 may be substantially parallel to each other and/or touching each other with activator 328 unengaged. Engaging activator 328 may cause separation of arms 326 at an angle, such that a distance between distal ends of the arms is greater than a distance between proximal portions of the arms. Estimating tool 320 may be inserted (e.g., with arms 326 together) in detachable members coupled to bone fastener assemblies anchored in vertebral bone. Activator 328 may be engaged and activated until arms 326 extend through channels of the detachable members and contact inner surfaces of the detachable members. Arms 326 may contact bone fasteners in the bone fastener assemblies. With arms 326 extended to meet resistance in the detachable members, estimating tool 320 may be withdrawn from the detachable members. During withdrawal of estimating tool 320 from the detachable members, arms 326 may be compressed toward each other as the estimating tool is moved up the detachable members and out of the body. After withdrawal of estimating tool 320 from the detachable members, arms 326 may extend back to the separation achieved when the arms were touching the bone fasteners. The distance between extended arms 326 may be used to estimate a length of an elongated member needed to couple the anchored bone fastener assemblies.

In some embodiments, an estimating tool may include a gage. FIG. 56 depicts an embodiment of estimating tool 320 with gage 332. With arms 326 of estimating tool 320 positioned together, gage 332 may have or may be set to a zero reading. With arms 326 extended to meet resistance in sleeves 244, gage 332 may provide an estimate of the distance between the sleeves. The distance between the sleeves may be used to estimate a length of an elongated member needed to couple the anchored bone fastener assemblies. In an embodiment, a length of an elongated member may be chosen to be greater than the distance measured by a gage to allow the elongated member to extend beyond slots of collars of anchored bone fastener assemblies.

In some embodiments, an elongated member positioner may be used to guide an elongated member through detachable members and to position the elongated member in collars proximate pedicles of vertebrae. FIG. 57 depicts an embodiment of elongated member positioner 334. Elongated member positioner 334 may include outer shaft 336, handle 338, inner shaft 340, and grasping member 342. In some embodiments, grasping member 342 may be a hook. A first end (i.e., proximal end) of outer shaft 336 may be connected to handle 338. A second end (i.e., distal end) of outer shaft 336 may be coupled to grasping member 342. Inner shaft 340 may pass through handle 338 and outer shaft 336. A second end (i.e., distal end 344) of inner shaft 340 may contact an elongated member positioned in grasping member 342. A first end (proximal end 346) of inner shaft 340 may extend from handle 338. Proximal end 346 of inner shaft 340 may be a knob or a thumb plate. An amount of force applied to an elongated member positioned between grasping member 342 and distal end 344 of inner shaft 340 may be controlled by the amount of pressure applied to proximal end 346 of inner shaft 340. Pressure may be applied to proximal end 346 of inner shaft 340 manually or mechanically. Mechanical means of applying pressure to proximal end 346 of inner shaft 340 include, but are not limited to, forceps handles and an adjustable rotor.

Distal end 344 of inner shaft 340 may be positioned proximate grasping member 342. An elongated member may be positioned between grasping member 342 and distal end 344 of inner shaft 340 of positioning tool 334 before or after initial insertion of the elongated member into a sleeve. The elongated member may be held between grasping member 342 and distal end 344 of inner shaft 340 with pressure applied to proximal end 346 of the inner shaft. Distal end 344 of inner shaft 340 may be contoured (e.g., curved) to allow some motion (e.g., rocking motion) of the elongated member while the elongated member is coaxed into position with positioning tool 334. During some installation procedures, positioning tool 334 may remain coupled to an elongated member until the elongated member is secured in collars of anchored bone fastener assemblies with closure members.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 992 of 2152

In some cases, pressure supplied to an elongated member with an elongated member positioner may not be sufficient to seat the elongated member in a collar. A seater may be used in conjunction with an elongated member positioner to maneuver an elongated member into one or more collars. During some procedures, an elongated member positioner may be removed from the elongated member before using the seater. During some procedures, the elongated member positioner may remain attached to the elongated member until closure members are secured to bone fastener assemblies to form a spinal stabilization system.

Seater 348, shown in FIG. 58, may include handle 350 and groove or grooves 352. A portion of an elongated member to be positioned in collars may fit in grooves 352. In an embodiment, an elongated member positioner may be used to align an elongated member proximate slots in one or more collars coupled to pedicles of vertebrae. Groove 352 of seater 348 may be positioned at a desired position along a length of the elongated member. A user may apply downward force with handle 350 to seat the elongated member in a collar as the elongated member positioner is used to guide the elongated member into position.

After an elongated member has been positioned and seated in collars as desired, closure members may be used to secure the elongated member to the collars. FIGS. 59A and 59B depict perspective views of driver 354. Driver 354 may be used to position a closure member in a collar of a bone fastener assembly. As shown in FIG. 59A, driver 354 may include handle 356, elongated portion 358, and coupling portion 360. Coupling portion 360 may be used to engage closure member 106. Coupling portion 360 may engage tool portion 170 of closure member 106, shown in FIG. 59B. In some embodiments, driver 354 may include an inner shaft. The inner shaft may couple the closure member to driver 354. The inner shaft may couple to the tool portion of the closure member so that the tool portion is securely held after the tool portion is sheared from the closure member. In some embodiments, an end of inner shaft may be press fit into the tool portion. In some embodiments, the inner shaft may include a threaded end portion that engages a mating thread in the tool portion. Rotation of the inner shaft may allow closure member 106 to be locked in coupling portion 360 of driver 354. Knob 362 may be used to rotate the inner shaft.

FIG. 60A depicts driver 354 with coupled closure member 106 positioned for insertion in sleeve 244. After insertion of driver 354 in sleeve 244, closure member 106 may be positioned proximate collar 112. With driver 354 positioned in sleeve 244, as shown in FIG. 60B, the driver may be rotated to advance closure member 106 in collar 112 and secure elongated member 104 to the collar. When closure member 106 is snug and elongated member 104 is secured, driver 354 may be disengaged from the closure member and removed from sleeve 244. In an embodiment, driver 354 may be used to shear off the tool portion of secured closure member 106. In some embodiments, the coupling portion of the driver may capture the sheared tool portion of the closure member. In certain embodiments, driver 354 may include a mechanism to dislodge a closure member and/or a tool portion of a closure member from the distal end of the driver.

In some embodiments, a detachable member may be held with a counter torque wrench as the tool portion of a closure member is sheared off. In an embodiment, about 90 in-lbs of torque may be required to shear off the tool portion of a closure member. A counter torque wrench may inhibit transfer of force to the patient when a closure member is being secured to a collar. Figure 61 depicts an embodiment of counter torque wrench 364 used to inhibit application of torque to a patient's spine during shearing of a tool portion of a secured closure member. Sleeve 244 may fit in opening 366 of counter torque wrench 364. Counter torque wrench 364 may be positioned near a proximal end of sleeve 244 during use. Force may be applied to counter torque wrench 364 in a direction opposite to rotational force applied to driver 354 to shear off the tool portion of a secured closure member. Opening

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 993 of 2152

366 in torque wrench 364 may be of any shape to accommodate a cross-sectional shape of sleeve 244 and inhibit rotation of the sleeve during use.

FIG. 62 depicts an embodiment of counter torque wrench 368 designed to accommodate sleeves. Counter torque wrench 368 may include hollow shaft 370 and handle 372. Groove 374 may be located at a distal end of hollow shaft 370. FIG. 63 depicts counter torque wrench 368 fitted over multi-channel sleeve 244. In an embodiment, hollow shaft 370 may be inserted through an opening in the body over sleeve 244 and advanced toward the spine until elongated member 104 is seated in groove 374. Counter torque wrench 368 may engage the spinal stabilization system. Force may be applied to counter torque wrench 368 in a direction opposite to rotational force applied to a driver used to shear off a tool portion of a secured closure member. During a minimally invasive spinal stabilization procedure, counter torque wrench 368 may be used with various types of detachable members, including single-channel sleeves and multi-channel sleeves.

Minimally invasive procedures may involve locating a surgical site and a position for a single skin incision to access the surgical site. The incision may be located above and between (e.g., centrally between) vertebrae to be stabilized. An opening under the skin may be enlarged to exceed the size of the skin incision. Movement and/or stretching of the incision, bending of an elongated member, and angulation of collars of bone fastener assemblies may allow the length of the incision and/or the area of a tissue plane to be minimized. In some embodiments, minimally invasive insertion of a spinal stabilization system may not be visualized. In certain embodiments, insertion of a spinal stabilization system may be a top-loading, mini-opening, muscle-splitting, screw fixation technique.

Insertion of a spinal stabilization system may include gradually increasing the diameter of an opening formed in a pedicle and/or vertebral body to accept a bone fastener assembly. For example, a targeting needle may have outer diameter of about D. A bone awl inserted after the targeting needle may have an outer diameter incrementally larger than the outer diameter of the targeting needle. As used herein, an incrementally larger diameter may be large enough to allow a snug but adjustable fit. For example, the bone awl may have outer diameter of about $(D + x)$. A tap portion of a bone tap inserted after the bone awl may have a minor diameter of about $(D + 2x)$. A bone fastener may have a minor diameter of about $(D + 3x)$. In some embodiments, x may be between about 0.1 mm and about 1.0 mm. For example, x may be about 0.5 mm. Incremental sizing of the targeting needle, bone awl, tap, and bone fastener may promote a proper fit of the bone fastener in the vertebra to be stabilized.

In an embodiment of a spinal stabilization system insertion method, the patient may be placed in a prone position on a radiolucent table with clearance available for a C-arm of a fluoroscope. For example, a Jackson table with a radiolucent Wilson frame attachment may be used. The ability to obtain high quality images is very important. Bolsters, frames, and pads may be inspected for radiolucency prior to the operation. Placing the patient in a knee-chest position (e.g., using an Andrews table) should be avoided. Care should be taken to avoid placing the patient's spine in kyphosis during positioning of the patient.

The C-arm of the fluoroscope should be able to freely rotate between the anteroposterior, lateral, and oblique positions for optimal visualization of pedicle anatomy during the procedure. The arm should be rotated through a full range of motion prior to beginning the procedure to ensure that there is no obstruction or radio-opaque object in the way. The fluoroscope may be positioned so that Ferguson views and "bullseye" views are obtainable. Once the patient is positioned and the ability to obtain fluoroscopic images of the target levels for instrumentation has been confirmed, the patient may be prepared and draped sterilely.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 994 of 2152

For most of the lumbar region, the vertebral pedicle is an obliquely oriented cylindrical corridor. The angulation varies by approximately 5 degrees per level (e.g., L1: 5 degrees; L5: 25 degrees). A pre-operative fine-cut computed tomography image may be examined to determine any unique anatomy of the patient. Acquiring the pedicle in the most lateral and superior quadrant of the pedicle may be desirable to avoid the overriding facet during a minimally invasive procedure. A lateral entry point may allow for better screw convergence as well as less interference with the superior adjacent level facet joint. A targeting needle may be passed in a medial and inferior trajectory, thus following the natural pathway of the pedicle. Frequent fluoroscopic inspection in both an anteroposterior and lateral plane may ensure proper passage of the needle as the needle is inserted into vertebral bone.

Various techniques may be used to plan the skin incisions and entry points. In one embodiment, the planning sequence for a single-level stabilization may include the following four steps. First, an anteroposterior image may be obtained with the spinous processes centered at the target vertebral bodies. Vertical lines passing through midpoints of pedicles that are to receive bone fasteners may be marked on the patient. The lines do not represent skin entry points. The lines are markers of pedicle entry points used to estimate angles at which targeting needles to be inserted to contact the pedicles. In some embodiments, sets of vertical lines may be drawn corresponding to the lateral edges of the pedicles instead of lines corresponding to the midpoints of the pedicles.

Second, horizontal lines may be marked approximately through the centers of the pedicles (mid-pedicle lines) on the patient. In some embodiments, the lines may be drawn on the superior side of the center axes (superior to the mid-pedicle).

Third, an oblique or "bullseye" view (i.e., down a longitudinal axis of a pedicle) may be obtained on each side of the patient for each pedicle that is to be stabilized. Vertical oblique view lines may be marked on the skin at the midpoints of each of the pedicles that are to receive a bone fastener. The oblique view lines may be drawn in a different color than the vertical lines drawn during the first step. In some embodiments, vertical lines may be drawn corresponding to the lateral edges of the pedicles instead of lines corresponding to the midpoints of the pedicles.

The oblique view lines may be about 2 cm to about 3 cm away from the lateral pedicle border lines marked in the first step. For larger patients, the oblique view line may be greater than about 3 cm away from the midline marked in the first step. For smaller patients, the oblique view line may be closer than about 2 cm away from the midline marked in the first step. The intersection of the oblique view lines with the horizontal lines drawn in the second step may represent skin entry points for a targeting needle as the targeting needle passes through soft tissue at an angle towards the bony pedicle entry point. A side fluoroscopic image, the horizontal lines, and the vertical lines may help the surgeon triangulate between the skin entry points and bony entry points.

Fourth, an incision may be made in the skin between mid-pedicle lines along the vertical oblique view lines. The skin incision may be from about 2 cm to about 4 cm long. In some embodiments, the incision may be from about 2.5 cm to about 3 cm long. Limiting the length of the incision may enhance patient satisfaction with the procedure. The incisions may be pre-anesthetized with, for example, 1% lidocaine with 1:200,000 epinephrine. To blunt the pain response, a long spinal needle may be used to dock on the bone entry point and inject the planned muscle path in a retrograde fashion as well. Once the incision has been made, tissue surrounding the incision may be pulled and/or stretched to allow access to a target location in a vertebra.

After sterile preparation and draping, the pedicle entry points may be fluoroscopically rechecked to ensure that the previously marked lines correspond to the intersection of the midline of the transverse process and the lateral joint and pars interarticularis. The intersection of the facet and the transverse process provides a starting

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 995 of 2152

point that may help avoid the canal and follow the natural inclination of lumbar pedicles. For the spinal stabilization system described, in which sleeves coupled to bone fastener assemblies are substantially unconstrained by insertion angles of the bone fasteners, patient anatomy may determine the most advantageous insertion angles of the bone fasteners.

A scalpel may be used to make a stab wound at the junction of an oblique view line and a mid-pedicle line. In an embodiment, the scalpel may be a #11 scalpel. A targeting needle may be passed through the incision in an oblique lateral to medial trajectory towards the bony entry point defined by a lateral pedicle border line. The C-arm of the fluoroscope may be placed in an anteroposterior position for this maneuver.

As the targeting needle encounters the bony anatomy, anteroposterior fluoroscopic images may be used to place the tip of the needle at the upper outer quadrant of the pedicle. In some embodiments, the needle may be walked medially along the transverse process to the pedicle entry point. In some embodiments, the needle tip may be docked by lightly tapping the tip into the bone with a mallet or other impact device to drive the tip into the bone. In some embodiments, the needle tip may be docked by applying downward pressure to the targeting needle to force the tip into the bone.

The fluoroscope may then be moved to a lateral position. The surgeon may correct the sagittal trajectory of the needle by moving the needle in an anterior or posterior direction to match the vector of the pedicle corridor. In some embodiments, a mallet or other impact device may be used to gently advance the targeting needle into the pedicle halfway to the pedicle-vertebral body junction. In other embodiments, force may be applied to the targeting needle to drive the targeting needle into the pedicle halfway to the pedicle-vertebral body junction. An anteroposterior image may then be obtained to confirm that the needle is approximately halfway across the pedicle in the anteroposterior view. If the tip is more than halfway across the pedicle in a lateral to medial projection, the trajectory may be too medial. Further advancement of the needle may risk passing the needle through the spinal canal. The needle may be repositioned. A new starting point or new trajectory may be obtained. If the anteroposterior image demonstrates that the needle is significantly lateral in the pedicle, then the needle may have passed along the lateral portion of the pedicle. A needle that has passed along the lateral portion of the pedicle may be withdrawn and repositioned.

Once a good trajectory has been obtained, the targeting needle may be advanced using a mallet. In some embodiments, the needle may be pushed in without a mallet. The targeting needle may be advanced to the junction of the pedicle and vertebral body under lateral fluoroscopic guidance. FIG. 64A depicts targeting needle 198 advanced to the junction of pedicle 164. At this point, confirmation of position and trajectory should be repeated under anteroposterior fluoroscopy. Targeting needle 198 may be further advanced to a desired depth within vertebral body 166 using a mallet or applied force. FIG. 64B depicts targeting needle 198 advanced to the desired depth.

A scale on targeting needle 198 may be used to approximate a length of a bone fastener to be used. A first depth of targeting needle 198 may be measured relative to body surface 376 when pedicle 164 is first encountered. A second depth of targeting needle 198 may be measured relative to body surface 376 after the targeting needle has been advanced to the desired depth in vertebral body 166. An approximate length of the pedicle screw to be used may be determined by taking a difference between the depth measurements.

After targeting needle 198 has been advanced into the bone, member 202 of the targeting needle (shown in FIG. 64B) may be removed from the targeting needle. FIG. 64C depicts outer housing 200 with the member removed. After removal of the member, a guide wire may be placed through a passage in targeting needle 198 into

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 996 of 2152

vertebral body 166. FIG. 64D depicts targeting needle 198 with guide wire 218 positioned through the passage in the targeting needle. Lateral fluoroscopic images may be obtained to indicate the position of guide wire 218. In some embodiments, guide wire 218 may be pushed into vertebral body 166. In certain embodiments, guide wire 218 may be advanced about 1 cm beyond an end of outer housing 200 to secure the guide wire in vertebral body 166. In some embodiments, a small diameter tissue dilator may be placed over the guide wire and positioned on an upper surface of the targeting needle. The tissue dilator may provide stability to the guide wire. Added stability from the dilator may allow the guide wire to be successfully tapped into the vertebral body with a small mallet. Care should be taken to avoid kinking guide wire 218. After guide wire 218 is secured in vertebral body 166, outer housing 200 may be removed from the patient. FIG. 64E depicts guide wire 218 after removal of the targeting needle.

Once the guide wire has been passed through the targeting needle and the targeting needle has been removed, the guide wire may be used as a guide to position one or more successively sized dilators around a target location in a pedicle. A dilator may be a conduit with a regular shape (e.g., cylindrical) or an irregular shape (e.g., C-shaped). A dilator may form an opening through soft tissue to the pedicle. For patients with a thick fascia, it may be advantageous to make a nick in the fascia with a scalpel blade to facilitate passage of the dilators. The dilators may be passed sequentially over the guide wire. The dilators may be rotated during insertion to facilitate dilation of surrounding tissue. The dilators may be inserted until the leading edges contact the pedicle. A distal end of a dilator may be tapered to facilitate positioning of the dilator proximate the pedicle. An instrumentation set for a spinal stabilization system may include two, three, four, or more successively sized dilators.

FIG. 65A depicts first dilator 302A positioned around guide wire 218. First dilator 302A may have an inner diameter just slightly larger than an outer diameter of guide wire 218. As used herein, "an inner diameter just slightly larger than an outer diameter" may mean that the inner diameter is between about 0.03 mm and about 1.0 mm greater than the outer diameter. For example, an inner diameter of first dilator 302A may be about 0.5 mm greater than the outer diameter of guide wire 218. FIG. 65B depicts second dilator 302B positioned around first dilator 302A. Second dilator 302B may have an inner diameter just slightly larger than an outer diameter of first dilator 302A. FIG. 65C depicts third dilator 302C and fourth dilator 302D and positioned around second dilator 302B. Third dilator 302C may have an inner diameter just slightly larger than an outer diameter of second dilator 302B. Fourth dilator 302D may have an inner diameter slightly larger than an outer diameter of third dilator 302C. Once fourth dilator 302D is in position, dilators 302A, 302B, 302C may be removed, starting with dilator 302A. Lengths of dilators in a successively sized set may decrease with increasing diameter to facilitate removal of the smaller dilators. Care should be taken to avoid dislodging guide wire 218 during insertion and removal of the dilators. FIG. 65D depicts fourth dilator 302D positioned around guide wire 218 following removal of dilators 302A, 302B, 302C.

After tissue dilation has been achieved, a large diameter dilator (e.g., third dilator 302C or fourth dilator 302D shown in FIG. 65C) may be used to guide a bone fastener assembly and/or insertion instruments toward a target location in a pedicle. FIGS. 66A-66F depict portions of a procedure for preparation of pedicle 164 and vertebral body 166 for receiving a bone fastener assembly. FIG. 66A depicts bone awl 222 positioned over guide wire 218 in dilator 302 such that a tip of the bone awl is on or near a surface of pedicle 164. Bone awl 222 may be driven downwards into pedicle 164 to breach cortical bone of the pedicle. FIG. 66B depicts a position of bone awl 222 after pedicle 164 has been breached. After pedicle 164 is breached, bone awl 222 may be removed from dilator

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 997 of 2152

302. FIG. 66C depicts guide wire 218 and dilator 302 after removal of bone awl 222. In some embodiments, an initial passage may be formed in the pedicle and the vertebral body using a drill or a drill and tap combination.

FIG. 66D depicts tap 230 positioned in dilator 302. After pedicle 164 is breached, tap 230 may be inserted over guide wire 218 into dilator 302. In an embodiment, dilator 302 may be third dilator 302C. Tap 230 may be sized to fit snugly inside third dilator 302C. In some embodiments, dilator 302 may be fourth dilator 302D. In certain embodiments, fourth dilator 302D may be inserted over third dilator 302C after bone has been tapped through the third dilator. Tapping through third dilator 302C rather than fourth dilator 302D may introduce less bulk at the target site of a pedicle during the tapping procedure. In some embodiments, an outer diameter of a sleeve coupled to a bone fastener assembly to be inserted in the pedicle may be substantially the same as an outer diameter of third dilator 302C.

Tap 230 may include removable handle 236 and indicia 240. Indicia 240 may be a scale. When tap 230 is positioned such that a first thread flight contacts pedicle 164, a first measurement of the position of the tap relative to a top of dilator 302 using indicia 240 may be noted. Tap 230 may be rotated to form a threaded passage through pedicle 164 and into vertebral body 166 to a desired depth. In some embodiments, a length of the threaded portion of tap 230 may be used to determine a depth of a threaded passage formed in a bone. For a threaded portion of a known length (e.g., 30 mm, 45 mm, 60 mm), a scaled image (e.g., X-ray image) of a depth of the threaded portion in a bone monitored during tapping may allow a medical practitioner to determine the depth of the threaded passage. In some embodiments, tap 230 may form threads of major diameter about 0.5 mm smaller than a major diameter of threads of a bone fastener to be inserted into the threaded passage.

FIG. 66E depicts a position of tap 230 after a threaded passage of a desired length has been formed in pedicle 164 and vertebral body 166. Care should be exercised to ensure that guide wire 218 is not bent or kinked during the tapping process. The position of tap 230 relative to the end of guide wire 218 may be monitored to ensure that guide wire 218 is not dislodged or removed from the vertebra. In some embodiments, a position of tap 230 may be monitored using fluoroscopic imaging.

After a threaded passage of a desired length has been formed in pedicle 164 and vertebral body 166, a second measurement of the position of tap 230 relative to a top of dilator 302 using indicia 240 may be noted. A length of a threaded member may be determined by taking a difference between the first and second measurements. In some embodiments, an estimate of length may be derived based upon fluoroscopic images and a known length of the tap that is visibly recognizable in the fluoroscopic images. Tap 230 may be removed from vertebral body 166 and pedicle 164 by rotating the tap out of the vertebral body and the pedicle. Handle 236 may be removed from a blade portion of tap 230. The blade portion of tap 230 may be removed from guide wire 218 with control of the guide wire initially maintained from above the tap and then from below the tap. Care may be taken when tap 230 is removed to maintain guide wire 218 in position and to avoid damage of the guide wire. FIG. 66F depicts dilator 302 and guide wire 218 after removal of the tap.

A bone fastener assembly with a bone fastener of an appropriate length may be selected for insertion in a patient. The size of the bone fastener may be verified with measurement indicia in an instrumentation set. In some embodiments, measurement indicia may be etched or printed on a portion of an instrumentation set. For example, the chosen bone fastener embodiment may be placed over the outline of a bone fastener embodiment printed on a tray of the instrumentation set.

The chosen bone fastener assembly may be attached to a detachable member. In an embodiment, a bone fastener assembly may be rotated on a flange of a detachable member. Movable members of the detachable

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 998 of 2152

member may be extended into indentations in a collar of the bone fastener assembly. A driver may be used to extend the movable members to couple with the collar. When the bone fastener assembly is coupled to the detachable member, a drive portion of a fastener driver may be coupled to a tool portion of the bone fastener. A shaft of the fastener driver may be positioned in the passage of the detachable member. A removable handle may be attached to the shaft of the fastener driver. The detachable member, collar, and bone fastener may be substantially co-axial when the fastener driver is positioned in the detachable member. In some embodiments, the removable handle may be attached to the shaft of the fastener driver after the bone fastener, collar, detachable member, and fastener driver combination is positioned down a guide wire through a dilator and against a pedicle.

FIGS. 67A-67D depict portions of a procedure for inserting a bone fastener assembly into a patient. Driver 292 (coupled to the bone fastener), and sleeve 244 (coupled to the collar of the bone fastener assembly) may be inserted along guide wire 218 into dilator 302. For spinal stabilization procedures using four successively sized dilators, dilator 302 may be fourth dilator 302D. Guide wire 218 represents the trajectory that a bone fastener or bone fastener assembly may follow toward pedicle 164 during insertion of a spinal stabilization system. In some embodiments, tissue surrounding the incision may be pulled and/or stretched to allow a desired angular orientation of the bone fastener assembly relative to pedicle 164. FIG. 67A depicts driver 292 and sleeve 244 positioned in dilator 302. After insertion of the bone fastener assembly, sleeve 244, and driver 292 in dilator 302, the driver may be rotated to thread the bone fastener into pedicle 164 and vertebral body 166. The bone fastener may be advanced into the pedicle under fluoroscopic guidance to inhibit breaching of the pedicle walls. When the tip of the bone fastener advances beyond the posterior margin of vertebral body 166, guide wire 218 may be removed to inhibit inadvertent bending of the guide wire or unwanted advancement of the guide wire.

The bone fastener may be advanced to bring the collar down snug to the facet joint. The bone fastener may then be backed off about a quarter of a turn. Backing the fastener off about a quarter of a turn may allow for full motion of the collar relative to the bone fastener. FIG. 67B depicts driver 292 after the bone fastener has been advanced to the desired depth. After the bone fastener has been advanced to the desired depth, driver 292 may be removed from the head of the bone fastener and from dilator 302. FIG. 67C depicts dilator 302 and sleeve 244 after removal of the driver. After removal of the driver, dilator 302 may be removed from the patient. FIG. 67D depicts collar 112 of bone fastener assembly and sleeve 244 after removal of the dilator.

After the bone fastener has been secured to the vertebra and the driver has been removed from the sleeve, the polyaxial nature of the collar may allow angulation of the sleeve relative to the bone fastener. Tissue surrounding the incision may be released such that the sleeve is angled toward a central location between vertebrae to be stabilized. The sleeve may be moved to facilitate positioning of instruments and/or to facilitate access to the adjacent vertebra that is to be stabilized. For example, the sleeve may be tilted towards the adjacent pedicle so that additional length of an opening in the patient is not needed. The channel in the sleeve may be turned toward the adjacent pedicle that is to be stabilized with the spinal stabilization system being formed.

A plane of dilated tissue may be created between a first pedicle and a second pedicle to be stabilized with a spinal stabilization system. A bone fastener assembly and a sleeve may be coupled to the first pedicle. The second pedicle may be adjacent to the first pedicle. In an embodiment, a tissue wedge may be placed in the sleeve coupled to the first pedicle such that the distal end of the tissue wedge contacts the head of the bone fastener. The proximal end of the sleeve coupled to the first pedicle may be held such that tissue around the incision is not pulled or stretched. The tissue wedge may be wanded through the channel in the sleeve and the slot in the collar toward the target location at the second pedicle, thereby creating a plane in muscle and other tissue between the head of the

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 999 of 2152

installed bone fastener and the target location of a second bone fastener. In some embodiments, a tissue wedge may be pivoted about an inside proximal edge of the sleeve such that the distal end of the tissue wedge bluntly splits the muscle and fascia along fibers and create a tissue plane between the two pedicles. The wanding action may be repeated more than once (e.g., two or three times) to create a good working plane and displace unwanted tissue from the plane. The wanding may create a tissue plane. In some embodiments, the tissue plane may be substantially trapezoidal. In certain embodiments, a tissue plane may be created before a bone fastener assembly is inserted into a vertebra.

FIGS. 68A-D depict some stages during use of a tissue wedge to form a tissue plane between a sleeve in a first pedicle and a target location at a second pedicle. FIG. 68A depicts tissue wedge 308 aligned above pedicle 164A in sleeve 244. With a portion of tissue wedge 308 held proximate to the proximal end of sleeve 244 or resting on the proximal end of the sleeve, blade 312 of tissue wedge 308 may be moved through soft tissue from pedicle 164A toward pedicle 164B. FIG. 68B depicts distal end of tissue wedge 308 positioned at pedicle 164B. After tissue wedge 308 contacts pedicle 164B, handle 310 may be moved toward pedicle 164B (i.e., away from sleeve 244) to further separate soft tissue in a plane between the pedicles. FIG. 68C depicts tissue wedge 308 after handle 310 has been angled away from sleeve 244. An initial plane may be created by wanding tissue wedge from pedicle 164A to pedicle 164B. Tissue wedge 308 may be similarly wanded back to pedicle 164A to further establish the plane. FIG. 68D depicts tissue wedge 308 realigned in sleeve 244 after the plane has been established with a back-and-forth motion. In some embodiments, handle 310 may be maintained proximate sleeve 244 to minimize the area of the tissue plane.

A tissue plane may be made in a variety of shapes including, but not limited to, substantially trapezoidal, substantially rhomboidal, and substantially triangular. A tissue plane with a substantially geometric shape may have the basic geometric shape with, for example, slightly curved edges and/or slightly rounded corners or apices. In some embodiments, a sleeve length may be chosen to reduce a size of a tissue plane that needs to be formed between pedicles. In certain embodiments, creating a trapezoidal tissue plane may reduce the invasiveness of a procedure. Limiting the area of the plane may promote a faster recovery time and/or may reduce an amount of post-operative pain experienced by the patient.

In an embodiment, a tissue wedge may be coupled to a portion of a sleeve to facilitate creation of a tissue plane. FIG. 69 depicts tissue wedge 308 with blade 312 pivotally coupled to a proximal extension of sleeve 244. Tissue wedge 308 may be initially positioned in sleeve 244 with a distal end of blade 312 proximate pedicle 164A. Handle 310 may be pivoted toward pedicle 164A to allow wanding of blade 312 towards adjacent pedicle 164B. If needed, cutting edge 318 may be used to sever fascia that inhibits passage of blade 312. Sleeve 244 may be pivoted in conjunction with rotation of collar 112. In another embodiment, sleeve 244 may be extendable (e.g., telescopic) such that a pivot point may be advanced in the direction of pedicle 164B during wanding. The extendable portion of the sleeve may be selectively lockable using a variety of locking mechanisms including, but not limited to, a setscrew, a clip, a detent, or a pin.

In an embodiment, two pedicles may be targeted and bone fastener assemblies anchored in both pedicles before creation of a tissue plane. A tissue wedge may be inserted at either of the pedicles. In some embodiments, the sleeves may be coupled to each other at proximal ends of the sleeves. The tissue wedge may be coupled to a sleeve and the sleeve may be used as an anchor during wanding. Insertion of an elongated member into collars of bone fastener assemblies, however, may require cutting of some tissue between the two sleeves.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 1000 of 2152

Other procedures may be used to create a tissue plane. For example, before targeting pedicle locations (i.e., before bone fastener insertion), a tissue wedge may be worked downward from an incision to create a tissue plane. Alternatively, a scalpel may be used to cut from the surface of the body to vertebral bone. Extensive use of a scalpel, however, may remove benefits of a minimally invasive procedure.

In an embodiment, a targeting needle may be passed through the tissue to create a tissue plane for insertion of an elongated member. As depicted in FIG. 70A, targeting needle 198 may be placed in sleeve 244A coupled to pedicle 164A. Sleeve 244A may be rotated such that channel 248 is directed toward pedicle 164B. In some embodiments, a handle portion of targeting needle 198 may be positioned over pedicle 164B, as depicted in FIG. 70B. The shaft of targeting needle 198 may be wanded from sleeve 244A (e.g., from a center of sleeve 244A) in pedicle 164A to a target location in pedicle 164B to separate the soft tissue in a plane between the pedicles. FIG. 70C depicts a distal end of targeting needle 198 positioned proximate pedicle 164B. Targeting needle 198 may be moved back and forth to establish the plane. After targeting needle 198 contacts pedicle 164B and the plane is established, a bone fastener assembly may be inserted in pedicle 164B using a procedure similar to the procedure used to place a bone fastener assembly in an adjacent pedicle. FIG. 70D depicts sleeves 244A and 244B located proximate pedicles 164A and 164B, respectively.

Once a well-defined tissue plane has been formed, a targeting needle may be passed down a first sleeve coupled to a first vertebra and then wanded along the formed plane over to a target location at a second pedicle. The target location at the second pedicle may be fluoroscopically confirmed. A bone fastener assembly coupled to a sleeve may be secured in the second pedicle using a procedure similar to the procedure used to insert a bone fastener assembly in a first pedicle. FIG. 71 depicts substantially trapezoidal tissue plane 378 between sleeves 244 coupled to adjacent vertebral bodies 166. Sleeves 244 touch at incision 375 and cross above body surface 376, such that a length of the incision and/or an area of tissue plane 378 may be advantageously small. Substantially trapezoidal tissue plane 378 may have a dimension at body surface 376 equal to a length of the incision. Sides of substantially trapezoidal tissue plane 378 may be define by surfaces of sleeves 244. Opposite the body surface 376, substantially trapezoidal tissue plane 378 may extend between collars 112. In some embodiments, the edge of substantially trapezoidal tissue plane 378 closest vertebral bodies 166 may be substantially straight. In some embodiments, the edge of substantially trapezoidal tissue plane 378 closest vertebral bodies 166 may be curved to match a contour of bone between the vertebral bodies.

With bone fastener assemblies secured in the vertebral bodies, sleeves coupled to the bone fastener assemblies may be oriented to facilitate insertion of an elongated member in the sleeves. In some embodiments, sleeves may serve as tissue retractors during a spinal stabilization procedure. Angular motion of a collar may be limited by a range of motion allowed between the collar and the bone fastener that the collar is anchored to. Angular motion of a collar may be limited by patient anatomy. Angular motion or orientation of one collar (i.e., sleeve), however, may not depend upon a position of another collar (i.e., sleeve). In some embodiments, channel openings in the sleeves may face each other. In other embodiments, channel openings in the sleeves may be angled relative to each other in various arrangements. A distance between the sleeves may be estimated using an estimating tool. The distance between the sleeves may be used to select a length of an elongated member needed to couple the collars.

In an embodiment, flexible arms of estimating tool 320 depicted in FIG. 54 may be positioned in sleeves. With the activator disengaged, the estimating tool may be advanced toward the pedicles until the arms or members rest on the collars or bone fasteners of the bone fastener assemblies. The activator may be engaged. When the arms

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 1001 of 2152

are withdrawn from the sleeves, a biasing element may allow the arms to extend to the length indicative of the distance between bone fastener assemblies. An elongated member length may be selected by measuring a distance between the members of the estimating tool. The measured distance may be increased by an amount to allow the elongated member to extend beyond the collars after curvature and/or insertion. In an embodiment, about 5 mm to about 30 mm (e.g., about 15 mm) may be added to the measured distance. In some embodiments, a desired length of an elongated member may be a length that allows the elongated member to extend from each collar by about 2 mm or about 3 mm. In certain embodiments, ends of an elongated member may be flush with the outer surface of one or more collars.

In an embodiment, an elongated member of desired length may be chosen by estimating a distance between the sleeves without the use of an estimating tool. The sleeves may be positioned as desired (e.g., substantially parallel to each other). A distance between the most distant outer edges of the sleeves may be estimated. The estimated distance may be increased by an amount to allow the elongated member to extend beyond the collars after insertion. In some embodiments, from about 1 mm to about 20 mm may be added to the estimated distance. In some embodiments, a desired length of elongated member may be a length that allows the elongated member to extend from each collar by about 2 mm.

An elongated member may be cut to length and contoured as desired. For example, a medical practitioner may use experience and judgment to determine curvature of an elongated member for a patient. A desired curvature for the elongated member may be determined using fluoroscopic imaging. In some embodiments, a curvature of the elongated member may be chosen such that, when the elongated member is secured to the collars of the bone fastener assemblies, sleeves coupled to the bone fastener assemblies cross at a surface of the skin. Crossing of the sleeves at a surface of the skin allows the medical practitioner to minimize trauma to a patient by minimizing incision length and tissue plane area. The elongated member may be bent or shaped with a tool (e.g., a rod bender) to allow insertion of the elongated member through channels of sleeves with various spatial locations and/or various angular orientations.

Elongated members may have shapes including, but not limited to, straight, bent, curved, s-shaped, and z-shaped. FIG. 72 depicts an embodiment of S-shaped elongated member 104. FIG. 73 depicts an embodiment of angled elongated member 104. FIG. 74 depicts an embodiment of bent elongated member 104. FIG. 75 depicts an embodiment of straight elongated member 104. In some embodiments, elongated members 104 may have a substantially circular longitudinal cross section. In certain embodiments, elongated members 104 may have other cross-sectional shapes including, but not limited to, regular shapes (oval, rectangular, rhomboidal, square) and irregular shapes. An instrumentation kit for a spinal stabilization system may include straight rods and/or pre-shaped rods. Straight rods and/or pre-shaped rods may be contoured to accommodate patient anatomy if needed during the surgical procedure.

Channels of the sleeves and slots of the collars may be oriented by rotating the sleeves to accommodate insertion and seating of the elongated member. In certain embodiments, a channel opening in a sleeve may be non-linear (e.g., bent, curved, or angled) to allow portions of the spine to be selectively stabilized. Sleeve orientation and/or design may be chosen to allow compression, distraction, and/or reduction of vertebrae. In some embodiments, there may be no constraints governing relative location and/or orientation of the sleeves. Sleeves may be forced apart or angled toward each other or away from each other to accommodate insertion of the elongated member.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 1002 of 2152

Prior to insertion of the elongated member, the tissue wedge or targeting needle may be used to wand between the bone fasteners to ensure a clean plane between the bone fasteners. An end of the elongated member may be inserted at an angle or substantially longitudinally in a passage and/or channel of a sleeve coupled to a bone fastener assembly. Inserting the elongated member at an angle or substantially longitudinally allows the length of the incision and/or the area of the tissue plane to remain advantageously small. In some embodiments, sleeves coupled to anchored bone fastener assemblies may remain essentially unconstrained relative to each other during insertion of the elongated member. In certain embodiments, angular orientation of the collars may determine a trajectory of the elongated member down the sleeves and into collars of the bone fastener assemblies. Inserting the elongated member down two or more sleeves and through an open path (i.e., the tissue plane) may allow a medical practitioner to avoid surgical difficulties associated with anatomical abnormalities and/or misalignment of system components (e.g., in multi-level stabilization procedures).

Insertion of the elongated member may not be visualized subcutaneously. Therefore, a positioning tool may be used to guide the elongated member down the sleeves into slots in the collars. A distal portion of the positioning tool may be contoured. The contour may allow for some rotation of the elongated member. With slight pressure, the elongated member may be rotated subcutaneously into a substantially horizontal position and seated in the collars. The positioning tool may be held firmly while still allowing a rocking movement between the elongated member and the distal end of the positioning tool. Movement of the elongated member may allow the elongated member to be maneuvered down the sleeves and into the collars.

FIG. 76A depicts insertion of a first end of elongated member 104 in an opening of channel 248A of sleeve 244A. In an embodiment, elongated member 104 may be positioned between grasping member 342 and distal end 344 of the inner shaft of positioning tool 334, as shown in FIG. 76B. The elongated member may be held between grasping member 342 and distal end 344 of the inner shaft of positioning tool 334 with pressure applied to a proximal end of the inner shaft. As the first end of elongated member 104 is moved along the length of sleeve 244A toward collar 112A, a second end of the elongated member may be inserted in channel 248B of sleeve 244B. Channels in sleeves 244A and 244B may include grooves opposite channel openings to engage ends of elongated member 104 and/or to guide the elongated member along the lengths of the sleeves. Positioning tool 334 may be used to guide the elongated member along the length of the sleeves through the plane in the soft tissue.

Slots in collars 112A, 112B may be aligned with channels 248A, 248B of sleeves 244A, 244B, respectively, to allow elongated member 104 to be positioned in the collars. Positioning tool 334 may be used to angle the elongated member through slot 150A such that an end of the elongated member protrudes through collar 112A away from collar 112B. With one end of elongated member 104 extending through slot 150A in collar 112A, positioning tool 334 may be used to guide the other end of the elongated member the remaining distance down second sleeve 244B. Positioning tool 334 may then be used to seat the second end of elongated member 104 in collar 112B and translate the elongated member to a desired location relative to the collars. The distal end of the positioning tool inner shaft may be contoured (e.g., curved and/or grooved) to allow some motion (e.g., rocking) of elongated member 104 while the elongated member is coaxed into position and/or rotated subcutaneously with the positioning tool. Pressure may be applied to inner shaft 340 to seat elongated member 104 in the slots of the collars. FIG. 76C depicts elongated member 104 seated in collars 112A, 112B.

In some embodiments, a seater may be used to seat the elongated member in the collars. FIG. 76D depicts seater 348 positioned in sleeve 244B. In certain embodiments, seater 348 may be used to push elongated member 104 into slots in collar 112A and/or 112B while the positioning tool is used to maneuver the elongated member into

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 1003 of 2152

place. Once the elongated member is positioned in the collars, fluoroscopic confirmation may ensure that the elongated member is inserted fully into each collar. Prior to securing the elongated member to bone fastener assemblies with closure members, the elongated member may be gripped firmly with the positioning tool and persuaded cephalad or caudad as needed. With the elongated member seated in the collars, orientation of the sleeves may be constrained relative to each other.

After the elongated member is seated in the collars, additional fluoroscopic confirmation of elongated member positioning may be obtained. With the elongated member satisfactorily positioned, the elongated member may be secured in place with closure members. FIG. 60A depicts closure member 106 coupled to driver 354. Driver 354 is positioned for insertion into sleeve 244. A counter torque wrench may be coupled to the sleeve or to the elongated member. After insertion of driver 354 in sleeve 244, closure member 106 may be positioned proximate collar 112. With driver 354 positioned in sleeve 244, as shown in FIG. 60B, the driver may be rotated to advance the closure member in collar 112. To ensure alignment of thread of closure member with thread of collar, the driver may initially be rotated in a direction that would result in removal of the closure member from the collar. When the user of the driver feels engagement of threading of the closure member with threading of the collar, the user may reverse the direction of rotation of the driver to secure the closure member to the driver. The closure member may secure the elongated member to the collar. Sleeve 244A may serve as a coaxial guide to inhibit cross-threading during insertion of closure members 106. When the closure members are snug and elongated member 104 is secured, collars 112 are angled such that slots in the collars are substantially perpendicular to the elongated member. Driver 354 may be disengaged from the closure member and removed from sleeve 244. In some embodiments, driver 354 may be used to shear off a tool portion of a secured closure member. In certain embodiments, a coupling portion of driver 354 may capture a sheared tool portion from a closure member.

Torque required to shear off the tool portion of a closure member may be a source of pain and/or injury to a patient. In some embodiments, sleeve 244 may be held with a counter torque wrench as the tool portion of a secured closure member is sheared off. In an embodiment, about 90 in-lbs of torque may be required to shear off the tool portion of a closure member. A counter torque wrench may inhibit or reduce transfer of torque to the patient's spine. Figure 61 depicts an embodiment of counter torque wrench 364 used above the skin to inhibit application of torque to a patient's spine during shearing of a tool portion of a secured closure member. Sleeve 244 may fit in opening 366 of counter torque wrench 364. Counter torque wrench 364 may be positioned near a proximal end of sleeve 244 during use.

Force may be applied to counter torque wrench 364 in a direction opposite to rotational force applied to driver 354 to shear off a tool portion of closure member 106. Thus, the tool portion of closure member 106 may be sheared off with force exerted above the incision of a patient. In some embodiments, a collar of a bone fastener assembly may be designed such that a proximal portion of the collar may be sheared off with force exerted above the incision of a patient. In some embodiments, closure member 106 may be designed (e.g., with a solid central core) such that the torque required to shear off the tool portion does not adversely affect the body of the closure member or the coupling between the closure member and the collar. Opening 366 in torque wrench 364 may be of any shape to accommodate a cross-sectional shape of sleeve 244.

In some embodiments, counter torque wrench 368 shown in FIG. 63 may be used to inhibit application of torque to a patient's spine. Counter torque wrench sleeve 370 may be inserted through the opening in the body over sleeve 244. Counter torque wrench sleeve 370 may be advanced toward the spine until elongated member 104 is seated in groove 374 of the counter torque wrench sleeve. Force may be applied to counter torque wrench 368 in a

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 1004 of 2152

direction opposite to rotational force applied to a driver used to shear off a tool portion of a secured closure member.

Coupling failure between a collar and a closure member of a bone fastener assembly may be a concern during surgery. If failure occurs while locking down an elongated member to a bone fastener assembly in a single- or multi-level system, the failure may require removal of one or more locked closure members and the elongated member to extract a failed bone fastener assembly. Coupling failure may occur during application of other loads, such as loads used to achieve reduction with a spinal stabilization system.

FIG. 77 depicts a distal portion of driver 380 that may be used to remove closure member 106 depicted in FIGS. 14 and 15. A distal end of driver 380 may include two prongs designed to fit in removal openings 174 of closure member 106. Driver 380 may be inserted in a sleeve to engage a closure member. A handle of driver 380 may allow a medical practitioner to apply force in a rotational direction necessary to remove the closure member. In some embodiments, a counter torque wrench may be used to inhibit application of torque to the patient's spine during removal of a closure member. The closure member may be removed and replaced as necessary.

After a closure member is successfully secured to a collar and a tool portion of the closure member has been sheared off, the driver may be removed from the sleeve coupled to the anchored bone fastener assembly. FIG. 78A depicts an assembled spinal stabilization system following removal of driver 354. Key 262, shown in FIG. 78B, may be used to rotate movable members in sleeves 244A, 244B. Rotation of movable members in sleeves 244A, 244B may release the movable members from the collars. Thus, sleeves 244A, 244B may be uncoupled from the collars above the incision. FIG. 78C depicts assembled spinal stabilization system 100 following removal of sleeve 244A. FIG. 78D depicts assembled spinal stabilization system 100 coupled to adjacent pedicles following removal of sleeve 244B.

A spinal stabilization system may be used to stabilize two or more vertebral levels (i.e., at least three adjacent vertebrae). In an embodiment, an incision may be made in the skin between the outermost vertebrae to be stabilized. A first bone fastener assembly may be coupled to a first sleeve. The first bone fastener may be threaded into a first pedicle at a target location such that the first sleeve extends above the body surface. The first sleeve may rotate about the head of the first bone fastener. A tissue plane may be created between a channel opening in the first sleeve and a target location at a second pedicle. In an embodiment, the second pedicle may be adjacent to the first pedicle. A second bone fastener assembly may be coupled to a second sleeve and threaded into the second pedicle through the incision. Another tissue plane may be created between the first sleeve or the second sleeve and a target location in a third pedicle. The third pedicle may be adjacent to the first pedicle and/or the second pedicle. A third bone fastener assembly may be coupled to a third sleeve and threaded into the third pedicle through the incision.

In an embodiment of a method for a two-level spinal stabilization procedure, an incision may be made above a target location in a middle pedicle. A first bone fastener may be anchored to the middle pedicle. After the first bone fastener is secured, second and third bone fasteners may be coupled to outer pedicles as desired by pulling and/or stretching tissue surrounding the incision to allow access to the outer pedicles.

Channel openings in sleeves coupled to three bone fastener assemblies may be oriented to allow insertion of an elongated member to achieve two-level spinal stabilization. FIGS. 79A-79E depict insertion and seating of an elongated member in a two-level spinal stabilization system. Use of a rod positioner and/or seater is implied but not shown in FIGS. 79A-79E. FIG. 79A depicts insertion of a first portion of elongated member 104 through channel 248' of multi-channel sleeve 244 and into channel 248 of sleeve 244B. As the first portion of elongated member 104 is moved down the length of channels 248, 248' toward collars 112, 112', a second portion of the elongated

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 1005 of 2152

member may be inserted in channel 248 of sleeve 244A. In some embodiments, elongated member 104 may be moved down channels 248, 248' using a positioning tool. As elongated member 104 is advanced toward collars 112, 112', the elongated member may pass through an opening in the skin and into the tissue plane. FIG. 79B depicts elongated member 104 in channels 248, 248'. Channels 248 in sleeves 244A, 244B may include grooves to engage ends of elongated member 104 and/or to guide the elongated member down the lengths of the sleeves. In certain embodiments, channel openings may be curved or angled to accommodate various elongated member configurations.

FIG. 79C depicts elongated member 104 engaged in channels 248, 248'. As elongated member 104 is advanced toward collars 112, 112', a first end of the elongated member may emerge through slot 150 in collar 112 coupled to sleeve 244B. FIG. 79D depicts elongated member 104 after the elongated member has emerged through slot 150 in collar 112 coupled to sleeve 244B. In some embodiments, a seater may be used to position elongated member 104 in collars 112, 112'. FIG. 79E depicts elongated member 104 seated in collars 112, 112'.

FIGS. 80A-80C depict perspective views of various orientations sleeves 244 may assume relative to bone fasteners 108, 108'. In two-level and multi-level spinal stabilization systems, an orientation of a sleeve coupled to an anchored bone fastener assembly is not constrained by an orientation of one or more other collars coupled to adjacent bone fastener assemblies. FIGS. 80A-80C also depict various orientations that bone fasteners 108, 108' may assume relative to each other. Bone fasteners 108, 108' may be offset from each other (i.e., non-planar) and/or be inserted in pedicles at opposing angles. The range of possible orientations of bone fasteners in pedicles may allow a spinal stabilization system to securely conform to a patient's spine.

After an elongated member has been positioned and seated in collars as desired, closure members may be used to secure the elongated member to the collars. One or more counter torque wrenches may be used during shearing of the tool portions of the closure members. In an embodiment, counter torque wrench 364, depicted in FIG. 61, may be used with sleeves 244A, 244B. Counter torque wrench 368, depicted in FIG. 62, may be used with multi-channel sleeves and/or single-channel sleeves.

In certain embodiments, an external frame may be used to impose a desired constraint on one or more sleeves. For example, an external frame may hold one or more sleeves in a particular location and/or orientation such that a desired relative positioning of vertebrae may be achieved. An external frame may be used to impose a distance and/or angle between sleeves to achieve distraction or compression of vertebrae. Reduction of vertebrae may be achieved when an external frame is used to adjust a relative height of the sleeves.

In some embodiments, a spinal stabilization system may be inserted using an invasive procedure. Since insertion of a spinal stabilization system in an invasive procedure may be visualized, cannulated components (e.g., bone fasteners) and/or instruments (e.g., detachable members) may not be needed for the invasive (i.e., open) procedure. Thus, a bone fastener used in an invasive procedure may differ from a bone fastener used in a minimally invasive procedure. FIG. 81 depicts a perspective view of an embodiment of bone fastener 108 that may be used in an invasive procedure.

Bone fastener 108 may include shank 116, head 118, and neck 120. Shank 116 may include threading 122. In some embodiments, threading 122 may include self-tapping start 124. Self-tapping start 124 may facilitate insertion of bone fastener 108 into vertebral bone. Head 118 of bone fastener 108 may include various configurations to engage a driver that inserts the bone fastener into a vertebra. In certain embodiments, the driver may also be used to remove an installed bone fastener from a vertebra.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 1006 of 2152

In some embodiments, head 118 may include one or more tool portions 126. Tool portions 126 may be recesses and/or protrusions designed to engage a portion of the driver. Driver 380 depicted in FIG. 77 may be used to engage bone fastener 108 with tool portions 126 as depicted in FIG. 81. Head 118 of bone fastener 108 may include one or more splines. In some embodiments, bone fastener 108 may be used with a collar, a ring, and/or a closure member described for use with a cannulated bone fastener. In certain embodiments, bone fasteners with closed collars may be used in an invasive spinal stabilization procedure. In certain embodiments, fixed bone fasteners (e.g., open fixed bone fasteners) may be used in an invasive spinal stabilization procedure.

In some embodiments, tools used in an invasive procedure may be similar to tools used in a minimally invasive procedure. In certain embodiments, methods of installing a spinal stabilization system in an invasive procedure may be similar to methods of installing a spinal stabilization system in a minimally invasive procedure.

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 1007 of 2152

WHAT IS CLAIMED IS:

1. A bone fastener assembly, comprising:

a collar;

a ring coupled to the collar, wherein the ring comprises two or more seats;

a bone fastener comprising a shank, a head, and two or more splines on the head of the bone fastener, wherein at least one of the splines is configured to couple to at least one of the seats to inhibit separation of the bone fastener from the collar; and

wherein the ring is configured to allow polyaxial movement of the collar relative to the shank.

2. The bone fastener assembly of claim 1, wherein the two or more splines are distributed circumferentially about the head of the bone fastener.

3. The bone fastener assembly of claim 1, wherein the head of the bone fastener comprises three splines.

4. The bone fastener assembly of claim 1, wherein the collar is configured so that the ring can be inserted into the collar between two arms of the collar, and wherein removal of the ring from the collar is inhibited after the ring is coupled to the collar.

5. The bone fastener assembly of claim 1, wherein the collar is configured so that the ring can be inserted into the collar through a bottom of the collar, and wherein removal of the ring from the collar is inhibited after the ring is coupled to the collar.

6. The bone fastener assembly of claim 1, wherein the ring is configured to compress during insertion of the ring in a body of the collar, and wherein the compressed ring is configured to expand in the body of the collar after insertion to inhibit removal of the ring from the collar.

7. The bone fastener assembly of claim 1, wherein at least one of the splines is configured to couple with an inner surface of the ring to inhibit removal of the head from the ring.

8. A bone fastener assembly, comprising:

a collar;

a ring coupled to the collar, wherein the ring comprises two or more grooves and two or more seats;

a bone fastener comprising a shank, a head, and two or more splines on the head of the bone fastener, wherein the splines are configured to pass at least partially through the grooves in the ring, and wherein at least one of the splines is configured to couple to at least one of the seats to inhibit separation of the bone fastener from the collar; and

wherein the ring is configured to allow polyaxial movement of the collar relative to the shank.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 1008 of 2152

9. The bone fastener assembly of claim 8, wherein the two or more splines are distributed circumferentially about the head of the bone fastener.

10. The bone fastener assembly of claim 8, wherein the head of the bone fastener is configured to pass through a bottom of the collar, wherein the two or more splines are configured to pass through the two or more grooves, and wherein the bone fastener is configured to be rotated and positioned in the two or more seats of the ring.

11. The bone fastener assembly of claim 8, wherein the head of the bone fastener comprises three splines.

12. The bone fastener assembly of claim 8, wherein at least one of the splines is configured to couple with an inner surface of the ring to inhibit removal of the head from the ring.

13. A bone fastener, comprising:

a head and a shank;

two or more splines on the head of the bone fastener, wherein at least one of the splines is configured to couple the bone fastener to a ring in a collar; and

wherein the bone fastener is configured to be inserted head first through an opening in the ring, rotated relative to the ring, and seated in the ring.

14. The bone fastener of claim 13, wherein the two or more splines are distributed circumferentially about the head of the bone fastener.

15. The bone fastener of claim 13, wherein the bone fastener is cannulated.

16. The bone fastener of claim 13, wherein the head of the bone fastener comprises three splines.

17. The bone fastener of claim 13, wherein at least one of the splines is configured to couple with an inner surface of the ring to inhibit removal of the head from the ring.

18. The bone fastener of claim 13, wherein at least one of the splines comprises a projection configured to couple with the ring to inhibit removal of the head from the ring.

19. The bone fastener of claim 13, wherein at least one of the splines is tapered.

20. The bone fastener of claim 13, wherein an inner surface of the ring comprises two or more grooves, and wherein the grooves are configured to allow passage of the two or more splines.

21. A collar, comprising:

a body;

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 1009 of 2152

arms extending from the body, each arm comprising internal threading, wherein each arm has an end distal from the body, and wherein the end of each arm comprises an outer flange configured to couple to a detachable member; and

a slot between the arms, wherein the slot is configured to receive an elongated member.

22. The collar of claim 21, wherein the detachable member comprises a sleeve.

23. The collar of claim 21, wherein the body of the collar is configured to couple to a bone fastener such that the bone fastener can angulate with respect to the collar.

24. The collar of claim 21, wherein the body of the collar is configured to couple to a ring.

25. The collar of claim 21, wherein the detachable member is configured to couple to the flanges above the elongated member.

26. The collar of claim 21, wherein an effective diameter of the body exceeds an effective diameter of the arms.

27. The collar of claim 21, wherein at least one of the flanges comprises an indentation, and wherein the indentation is configured to allow radial orientation of a detachable member relative to the collar.

28. The collar of claim 21, wherein at least one of the flanges comprises an indentation, and wherein the indentation is configured to allow the detachable member to be secured in position relative to the collar.

29. The collar of claim 21, wherein at least one of the flanges comprises an indentation, and wherein the indention allows a channel in the detachable member to be aligned with the slot in the collar.

30. The collar of claim 21, wherein the internal threading in the arms is configured to engage external threading of a closure member, and wherein the closure member is configured to secure the elongated member to the collar.

31. The collar of claim 21, wherein the collar comprises one or more threaded openings proximate at least one of the flanges, wherein one or more of the threaded openings is configured to engage movable members coupled to the detachable member.

32. The collar of claim 21, wherein the internal threading comprises a female modified thread, and wherein the female modified thread comprises a female proximal surface and a female distal surface, and further comprising a closure member comprising a male modified thread, wherein the male modified thread comprises a male proximal surface and a male distal surface, and wherein the male proximal surface of the closure member is configured to couple with the female distal surface of the collar, and wherein the female proximal surface and the male distal

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 1010 of 2152

surface each comprise at least one raised portion, and wherein one or more surfaces of such raised portions are configured to couple during use to inhibit radial expansion of the collar.

33. The collar of claim 21, wherein the internal threading comprises a female modified thread, wherein the female modified thread comprises a female distal surface, and further comprising a closure member comprising a male modified thread, wherein the male modified thread comprises a male proximal surface, wherein the male proximal surface is configured to slope at a forward angle, wherein the male proximal surface is configured to couple with the female distal surface during use, and wherein the male proximal surface and the female distal surface each comprises a raised portion, wherein the raised portions are configured to contact each other during use to inhibit separation of the arms.

34. The collar of claim 21, wherein the flanges are located such that the detachable member can couple to the collar above the elongated member.

35. A system, comprising:

a collar, comprising:

a body configured to couple to a bone fastener such that the body, once coupled, can at least partially rotate relative to the bone fastener;

arms extending from the body, each arm comprising internal threading; and

a slot between the arms, wherein the slot is configured to receive an elongated member;

a sleeve; and

wherein the collar is configured to couple to the sleeve above the elongated member.

36. The system of claim 35, wherein the body of the collar, once coupled to the bone fastener, can at least partially angulate relative to the bone fastener.

37. The system of claim 35, wherein the internal threading of the collar is configured to couple to a closure member.

38. The system of claim 35, wherein each arm of the collar comprises a flange, wherein the flanges are configured to couple to the sleeve such that the sleeve can be coupled in a selected orientation relative to the flange.

39. The system of claim 35, wherein each arm of the collar comprises a flange, wherein the sleeve comprises one or more channels, and wherein the flanges are configured to couple to the sleeve such that the sleeve can be coupled such that at least one of the channels is substantially aligned with the slot of the collar.

40. A collar, comprising:

a body configured to couple to a bone fastener such that the body, once coupled, can at least partially rotate relative to the bone fastener;

arms extending from the body;

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 1011 of 2152

a slot between the arms, wherein the slot is configured to receive an elongated member;

wherein the collar is configured to couple to a sleeve above the elongated member; and

wherein the arms of the collar have a smaller effective diameter than a bottom of the collar.

41. The collar of claim 40, wherein each arm comprises a flange, and wherein the flanges are configured to couple to the sleeve.

42. The collar of claim 40, wherein each arm comprises internal threading configured to couple to a closure member.

43. The collar of claim 40, wherein the body is configured to couple to a ring such that the ring, once coupled, can rotate relative to the collar.

44. The collar of claim 40, wherein the collar is configured to rotate and angulate with respect to the bone fastener.

45. A method for inserting a spinal stabilization system in a human spine, comprising:

making an incision in skin near human vertebrae to be stabilized;

pulling the incision toward a first one of the human vertebrae to be stabilized;

inserting a first bone fastener assembly in the incision and securing the first bone fastener assembly to the first human vertebra;

pulling the incision toward a second one of the human vertebrae to be stabilized; and

inserting a second bone fastener assembly in the incision and securing the second bone fastener assembly to the second human vertebra.

46. The method of claim 45, wherein the incision is made in skin above and substantially between the human vertebrae to be stabilized.

47. The method of claim 45, wherein insertion angles of the bone fastener assemblies are determined by patient anatomy.

48. The method of claim 45, further comprising creating a tissue plane between the first bone fastener assembly and the second human vertebra to be stabilized.

49. The method of claim 48, wherein the tissue plane is substantially trapezoidal.

50. The method of claim 48, further comprising releasing the incision before creating the tissue plane.

51. The method of claim 45, further comprising using an estimating tool to estimate a length of an elongated member needed to couple the bone fastener assemblies.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 1012 of 2152

52. The method of claim 45, wherein the first bone fastener assembly is coupled to a first sleeve, and wherein the second bone fastener assembly is coupled to a second sleeve.

53. The method of claim 52, wherein an angle of at least one of the sleeves relative to a surface of the skin may be adjusted to maintain a size of the incision.

54. The method of claim 52, further comprising guiding an elongated member down channels in the sleeves, through the incision, and through a tissue plane toward the bone fastener assemblies.

55. The method of claim 54, further comprising bending the elongated member before inserting the elongated member in the sleeves, wherein the elongated member is bent to inhibit increasing a length of the incision.

56. The method of claim 52, wherein relative movement of the sleeves is substantially unconstrained prior to insertion of an elongated member.

57. The method of claim 52, wherein the sleeves cross substantially at or near the incision following insertion of the bone fastener assemblies.

58. The method of claim 52, further comprising initially inserting an elongated member substantially longitudinally down one of the sleeves.

59. The method of claim 52, wherein an adjustable positioner is used to guide an elongated member down the sleeves, through a tissue plane, and into the bone fastener assemblies.

60. The method of claim 59, further comprising rotating the elongated member subcutaneously to position the elongated member in the bone fastener assemblies.

61. The method of claim 60, wherein the elongated member is rotated subcutaneously without visualization.

62. The method of claim 52, further comprising securing an elongated member to the bone fastener assemblies.

63. The method of claim 52, further comprising securing an elongated member to each bone fastener assembly with a closure member and counter torquing at least one of the sleeves above the incision while a tool portion of a closure member is sheared off.

64. The method of claim 52, further comprising removing the sleeves from the bone fastener assemblies from above the incision.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 1013 of 2152

65. The method of claim 45, further comprising inserting an elongated member in the bone fastener assemblies and securing the elongated member to the bone fastener assemblies with closure members.

66. A method for inserting a spinal stabilization system in a human spine, comprising:

making an incision in skin near human vertebrae to be stabilized;

inserting a first bone fastener assembly in the incision and securing the first bone fastener assembly to a first one of the human vertebrae to be stabilized;

creating a substantially trapezoidal tissue plane near the human vertebrae to be stabilized, wherein the substantially trapezoidal plane has a dimension near the human vertebrae that is larger than the opposite dimension near the incision; and

inserting a second bone fastener assembly in the incision and securing the second bone fastener assembly to a second one of the human vertebrae to be stabilized.

67. The method claim 66, wherein the incision is made above and substantially between the human vertebrae to be stabilized.

68. The method claim 66, further comprising moving the incision to create the substantially trapezoidal tissue plane.

69. The method claim 66, wherein the human vertebrae to be stabilized comprise two human vertebrae, and wherein the substantially trapezoidal plane is near the two human vertebrae.

70. The method claim 66, wherein the human vertebrae to be stabilized comprise three human vertebrae, and wherein the substantially trapezoidal plane is near the three human vertebrae.

71. The method claim 66, further comprising inserting a third bone fastener assembly into a third one of the human vertebrae to be stabilized.

72. The method claim 66, wherein the first bone fastener assembly is coupled to a first sleeve, and wherein the second bone fastener assembly is coupled to a second sleeve.

73. A method for inserting a spinal stabilization system in a human spine, comprising:

making an incision near human vertebrae to be stabilized;

inserting a first bone fastener assembly in the incision and securing the first bone fastener assembly to a first one of the human vertebrae;

creating a tissue plane between the first bone fastener assembly and another one of the human vertebrae to be stabilized;

inserting one or more other bone fastener assemblies in the incision and securing each of the other bone fastener assemblies to another one of the human vertebrae to be stabilized; and

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 1014 of 2152

bending an elongated member to allow coupling of the bone fastener assemblies with the elongated member without substantially enlarging a length of the incision.

74. The method of claim 73, wherein a shape of the tissue plane is substantially trapezoidal.

75. The method of claim 73, wherein each bone fastener assembly is coupled to a sleeve.

76. The method of claim 75, further comprising inserting at least one end of the elongated member in at least one channel in at least one of the sleeves, guiding the elongated member through the incision, and advancing the elongated member through the tissue plane toward the bone fastener assemblies.

77. The method of claim 75, further comprising securing the elongated member to the bone fastener assemblies.

78. The method of claim 75, further comprising securing an elongated member to each bone fastener assembly with a closure member and counter torquing at least one of the sleeves above the incision while a tool portion of a closure member is sheared off.

79. The method of claim 75, further comprising removing the sleeves from the bone fastener assemblies from above the incision.

80. A method of inserting a spinal stabilization system in a human spine, comprising:

making an incision in skin near human vertebrae to be stabilized;

inserting a first bone fastener assembly coupled to a first sleeve in the incision and securing the first bone fastener assembly to a first one of the human vertebrae;

allowing the incision to determine an angle of the first sleeve relative to a bone fastener of the first bone fastener assembly;

creating a tissue plane between the first sleeve and another one or more of the human vertebrae to be stabilized;

inserting one or more other bone fastener assemblies, each coupled to a sleeve, in the incision and securing each of the other bone fastener assemblies to another one of the human vertebrae to be stabilized; and

guiding an elongated member down at least one channel in at least one of the sleeves, through the incision, and through the tissue plane toward the bone fastener assemblies.

81. The method of claim 80, further comprising moving the incision toward the first one of the human vertebrae to be stabilized before inserting the first bone fastener assembly.

82. The method of claim 80, further comprising using the first sleeve to move the incision toward the first one of the human vertebrae to be stabilized before inserting the first bone fastener assembly.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 1015 of 2152

83. The method of claim 80, wherein the tissue plane has a substantially trapezoidal shape.

84. The method of claim 80, further comprising advancing the elongated member through the tissue plane without visualization.

85. The method of claim 80, further comprising rotating the elongated member subcutaneously without visualization and securing the elongated member to the bone fastener assemblies.

86. A bone fastener assembly, comprising:

a collar;

a ring coupled to the collar;

a bone fastener comprising a shank, a head, and splines, wherein at least one of the splines is configured to couple to a seat in the ring; and

wherein the ring is configured to allow polyaxial movement of the collar relative to the shank.

87. A collar, comprising:

a body;

arms extending from the body; and

a slot between the arms, wherein the slot is configured to receive an elongated member.

88. A method for inserting a spinal stabilization system in a human spine, comprising:

making an incision in skin near human vertebrae to be stabilized;

inserting a first bone fastener assembly in the incision and securing the first bone fastener assembly to the first human vertebra;

pulling the incision toward a second one of the human vertebrae to be stabilized; and

inserting a second bone fastener assembly in the incision and securing the second bone fastener assembly to the second human vertebra.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 1016 of 2152

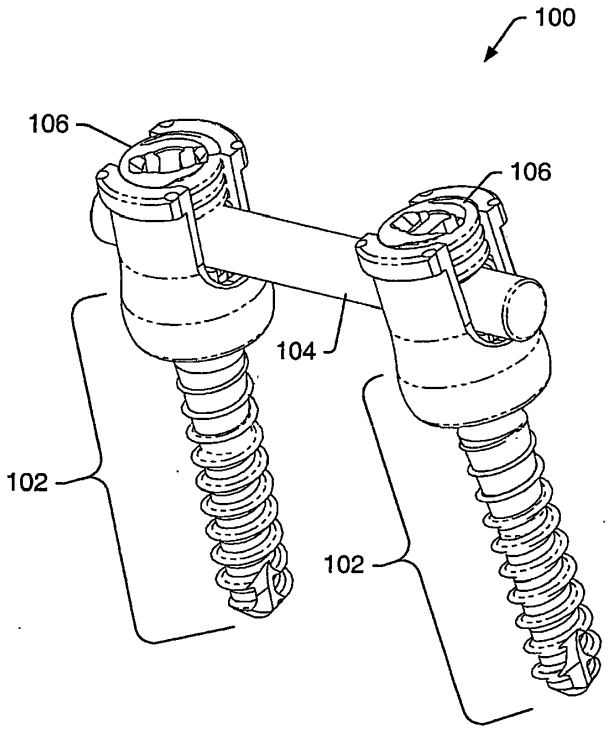


FIG. 1

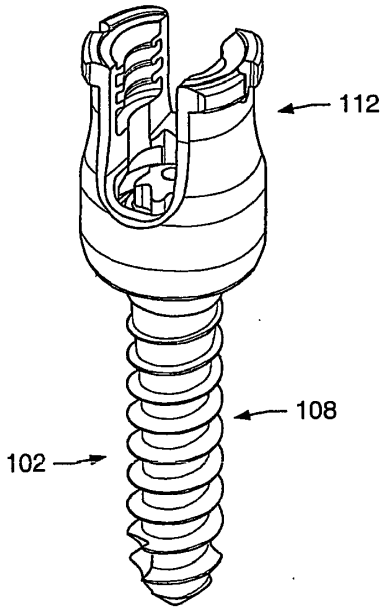


FIG. 2

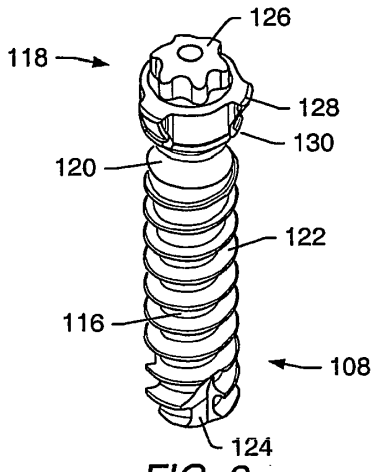


FIG. 3

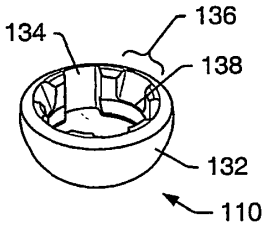


FIG. 4A

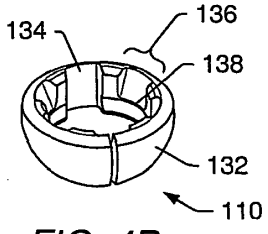


FIG. 4B

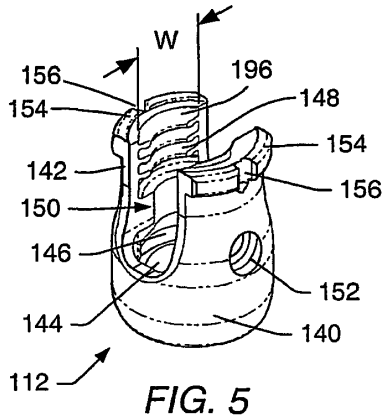


FIG. 5

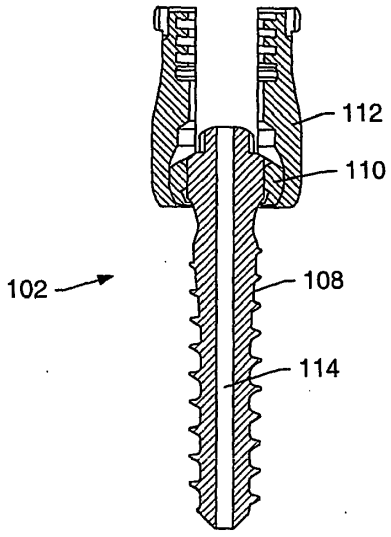


FIG. 6

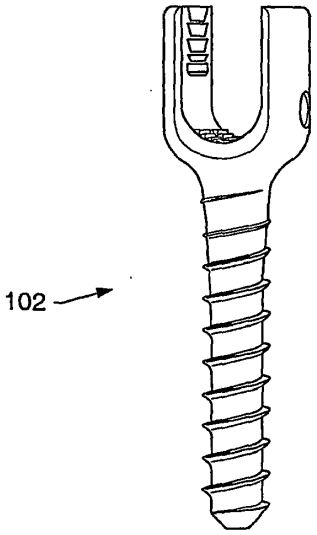


FIG. 7

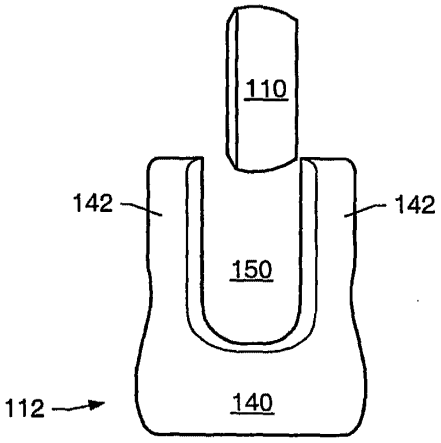


FIG. 8A

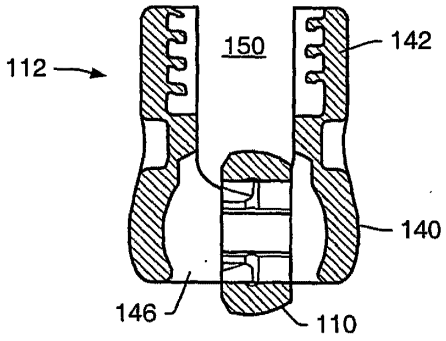


FIG. 8B

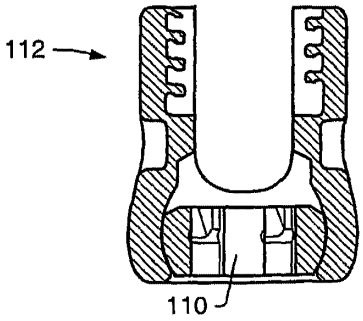


FIG. 8C

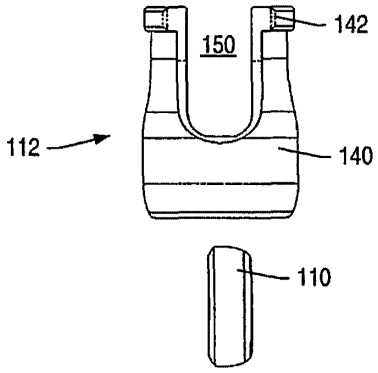


FIG. 9A

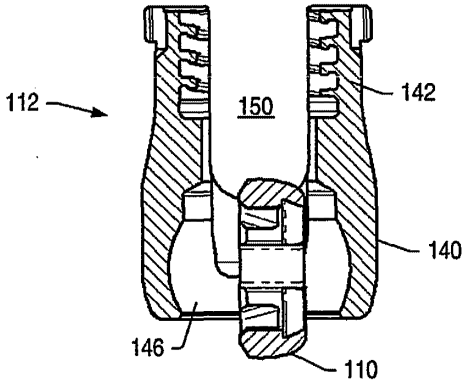


FIG. 9B

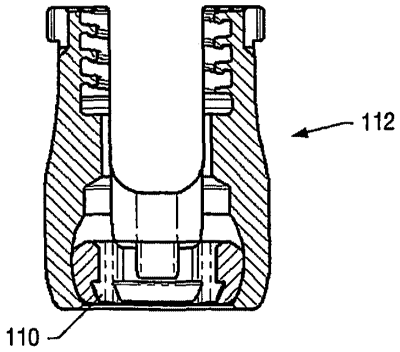


FIG. 9C

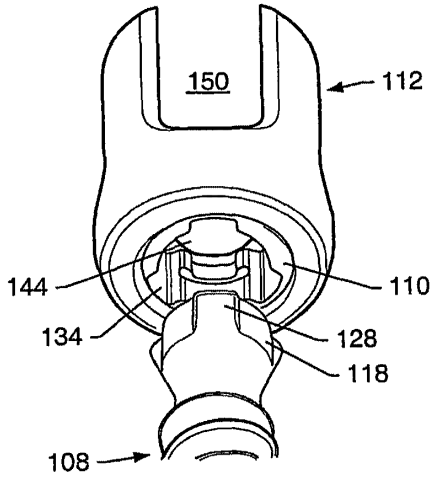


FIG. 10A

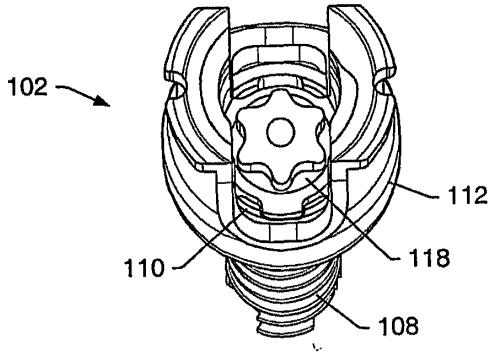


FIG. 10B

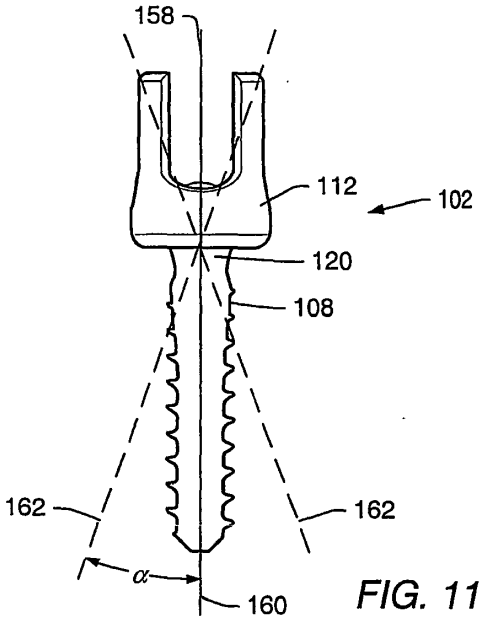


FIG. 11

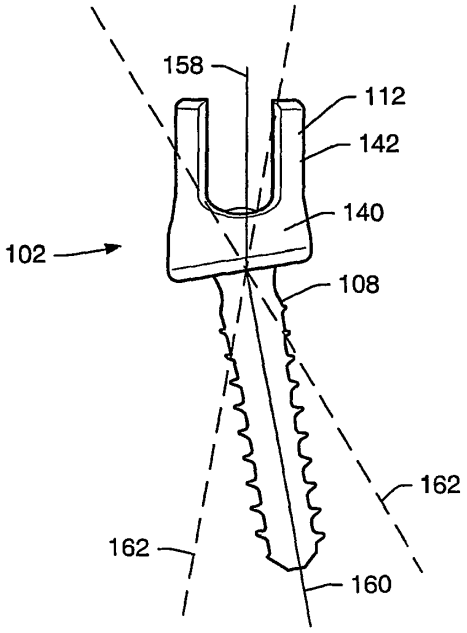


FIG. 12A

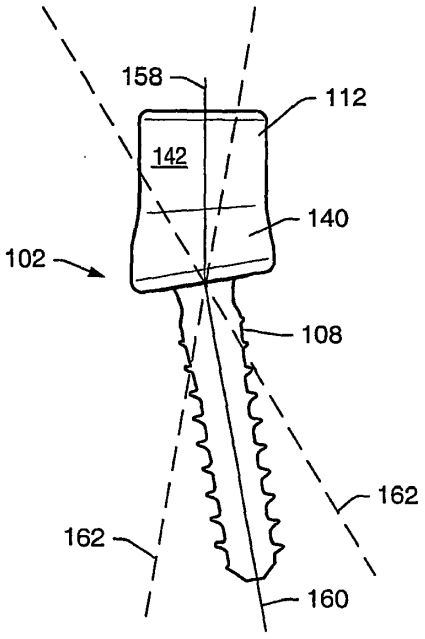


FIG. 12B

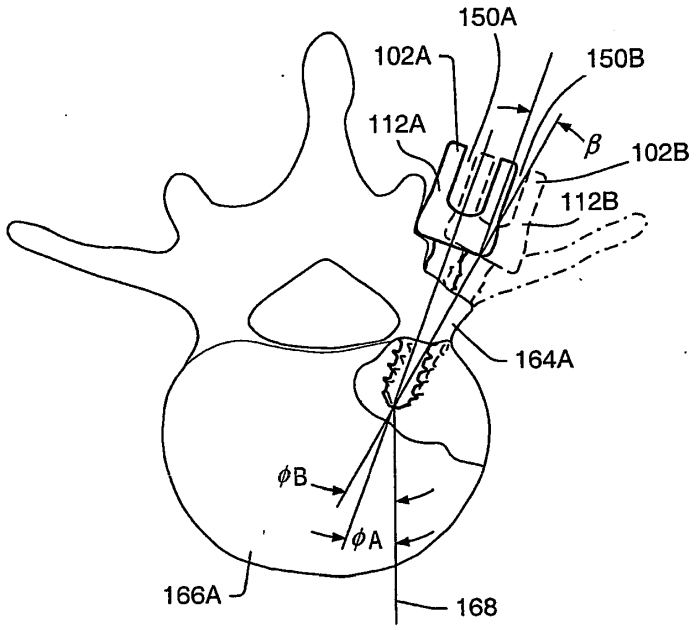


FIG. 13A

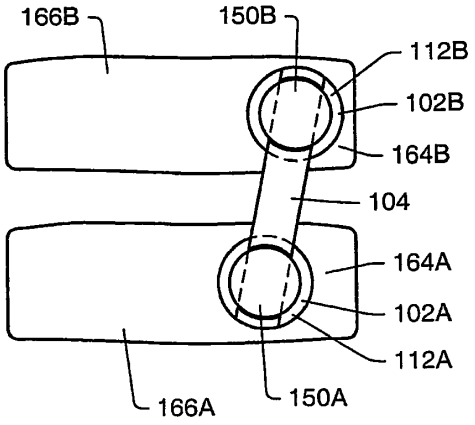


FIG. 13B

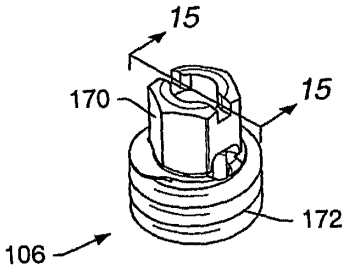


FIG. 14

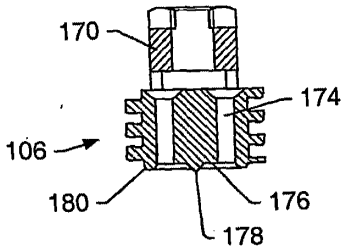


FIG. 15

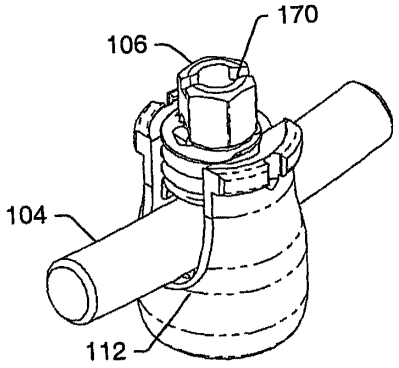


FIG. 16

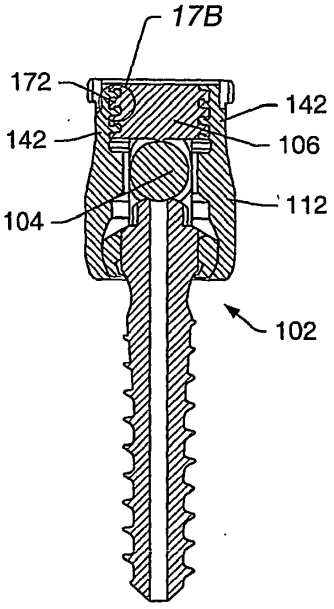


FIG. 17A

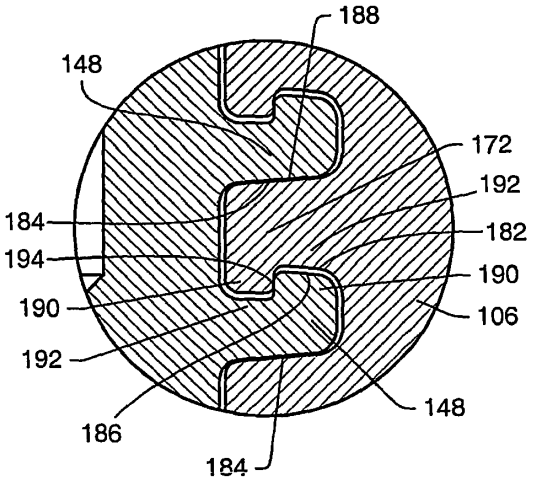


FIG. 17B

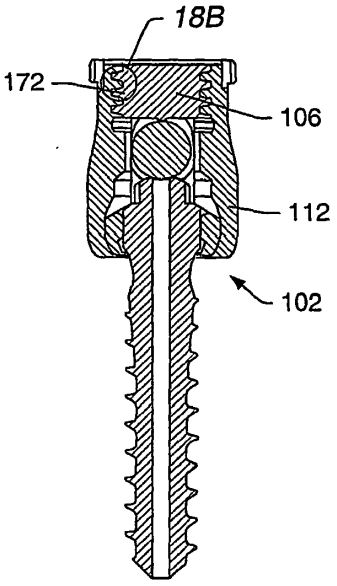


FIG. 18A

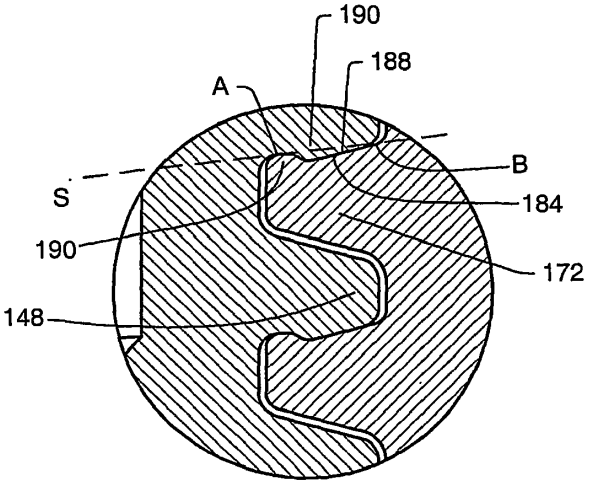


FIG. 18B

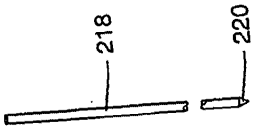


FIG. 22

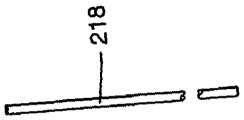


FIG. 23

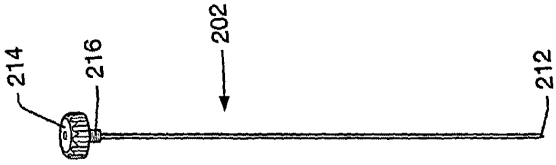


FIG. 21

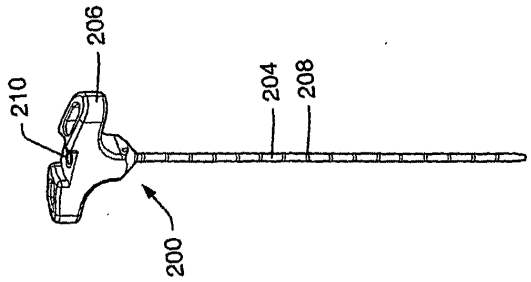


FIG. 20

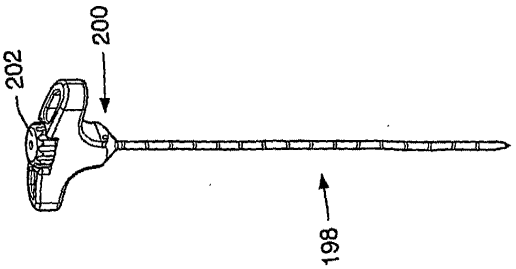


FIG. 19

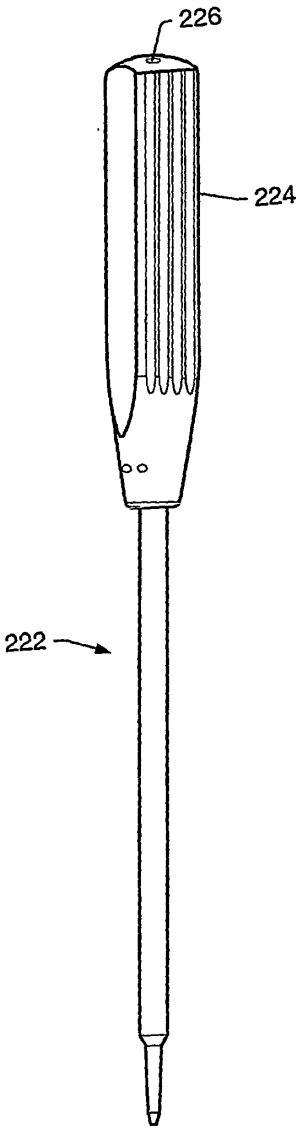


FIG. 24

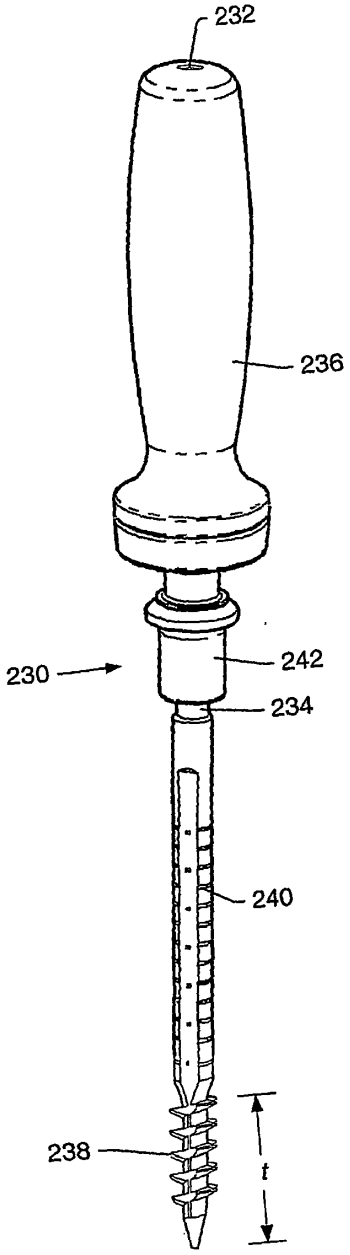


FIG. 25

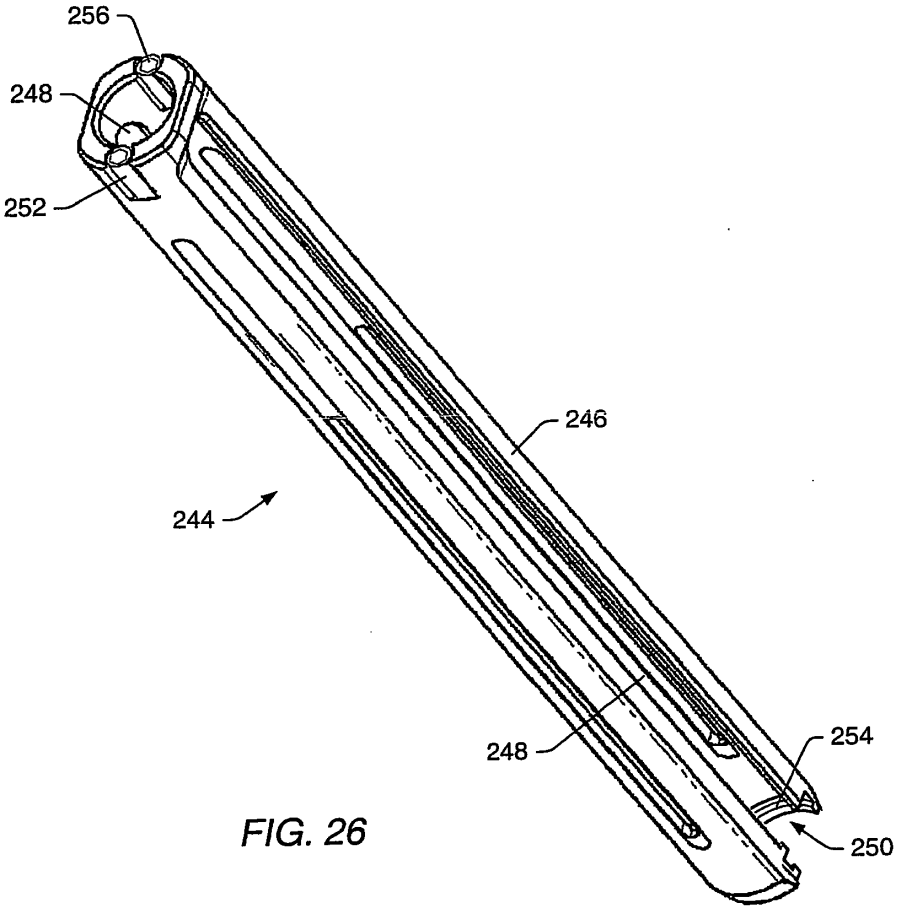


FIG. 26

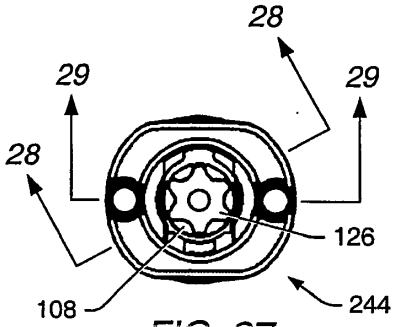


FIG. 27

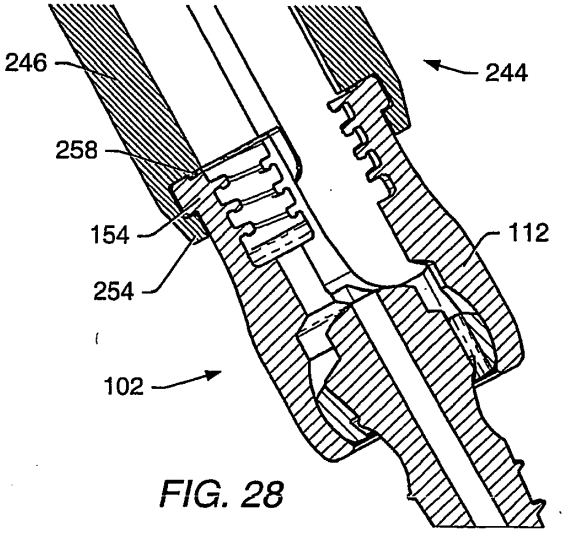


FIG. 28

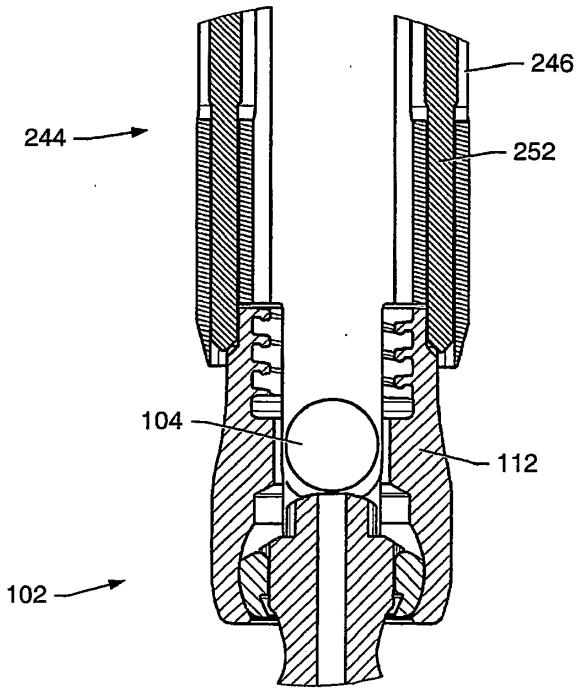


FIG. 29

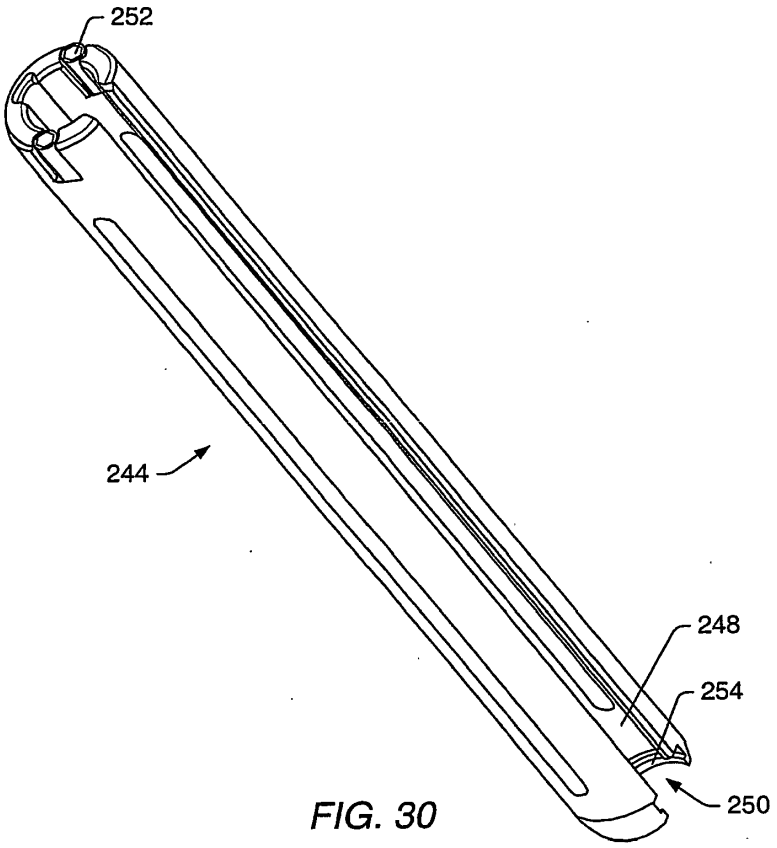


FIG. 30

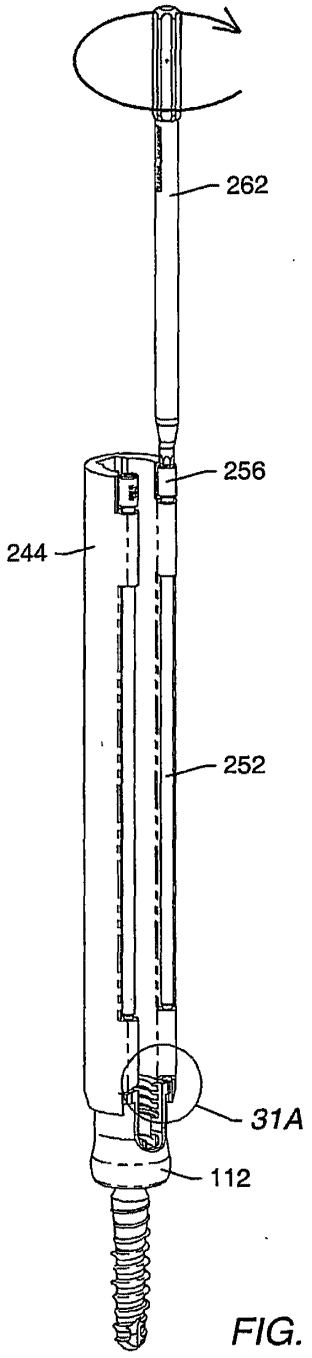


FIG. 31

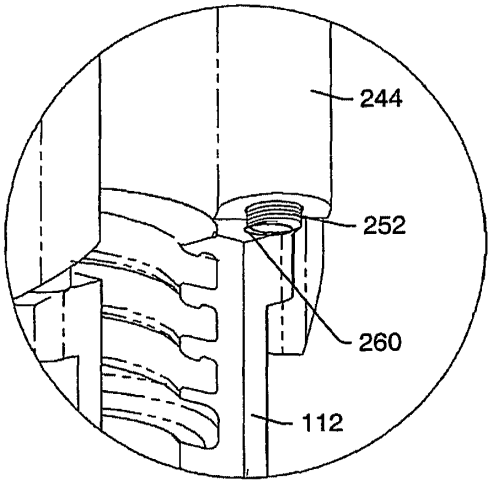


FIG. 31A

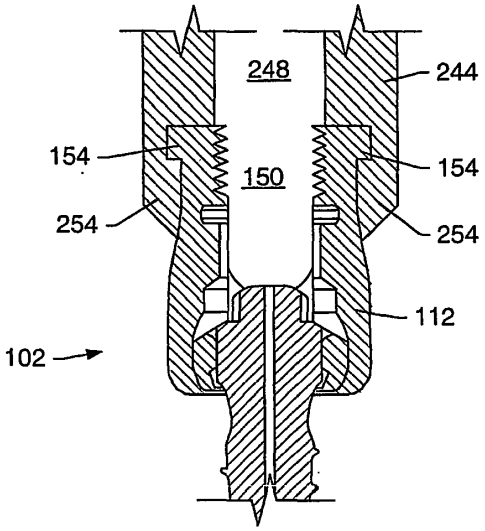


FIG. 32

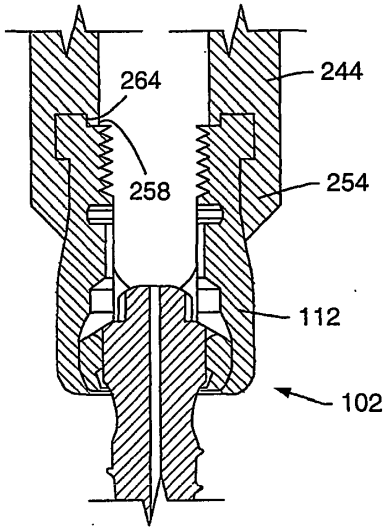


FIG. 33

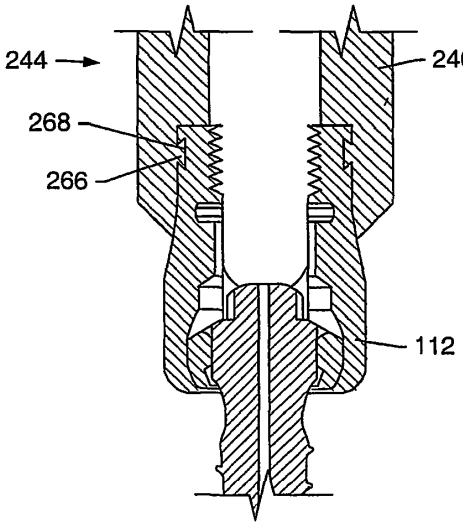


FIG. 34

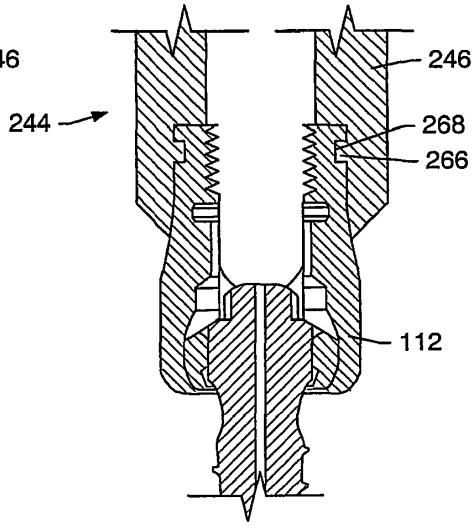


FIG. 35

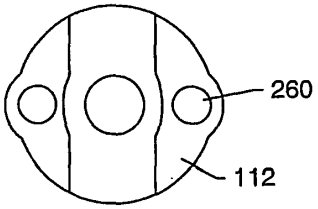


FIG. 36

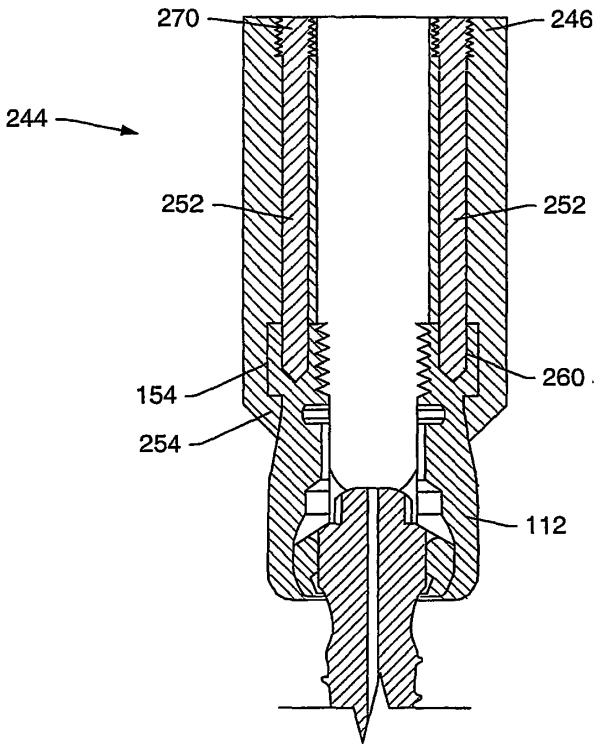


FIG. 37

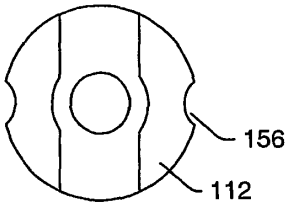


FIG. 38

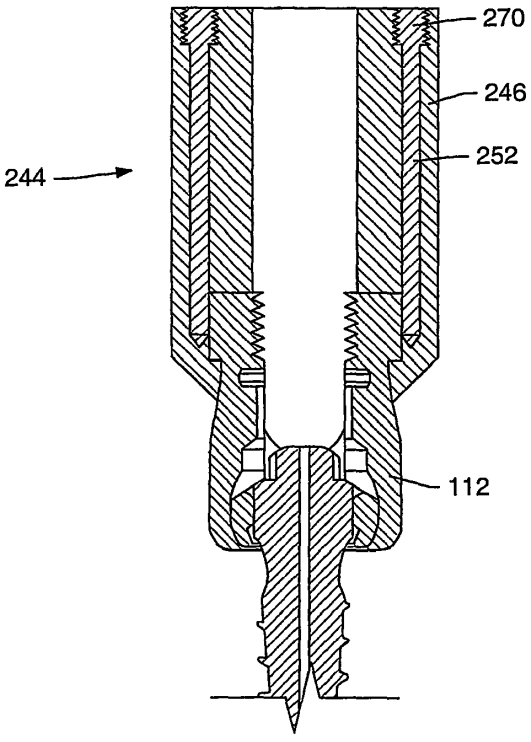


FIG. 39

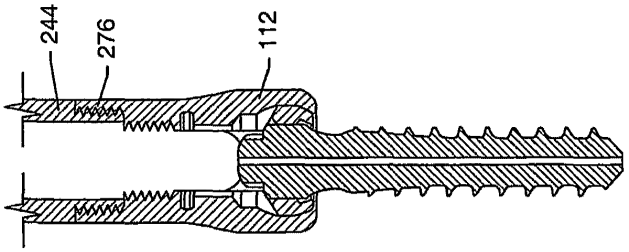


FIG. 43

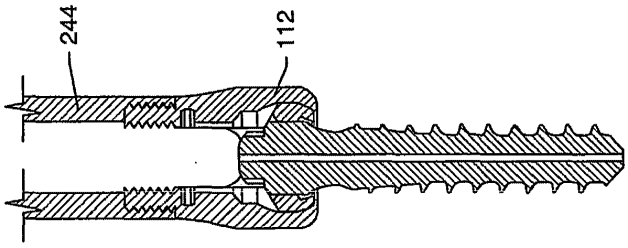


FIG. 42

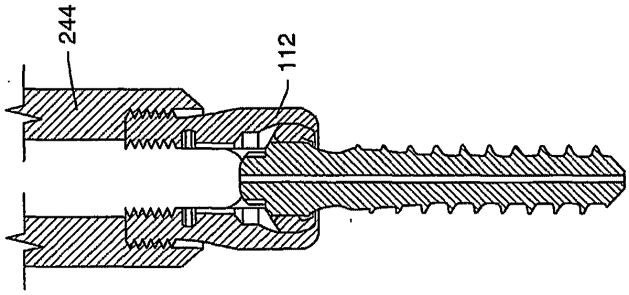


FIG. 41

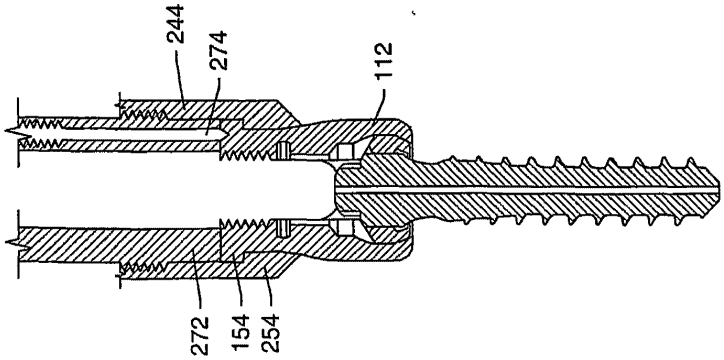


FIG. 40

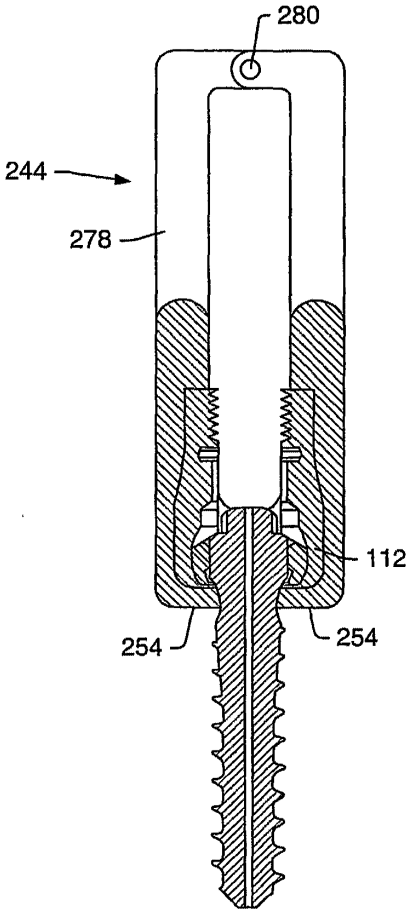


FIG. 44

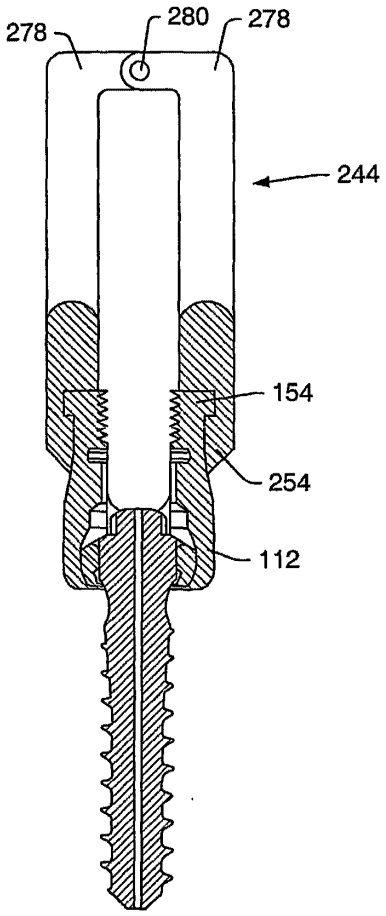


FIG. 45

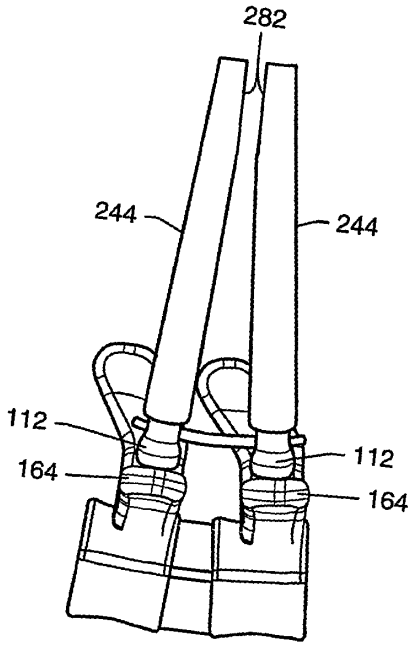


FIG. 46

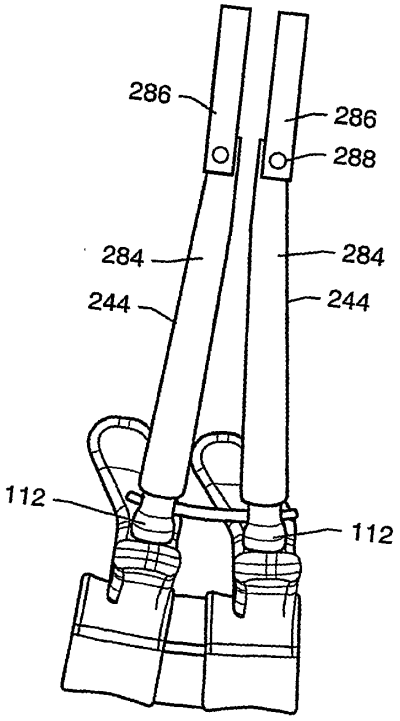


FIG. 47

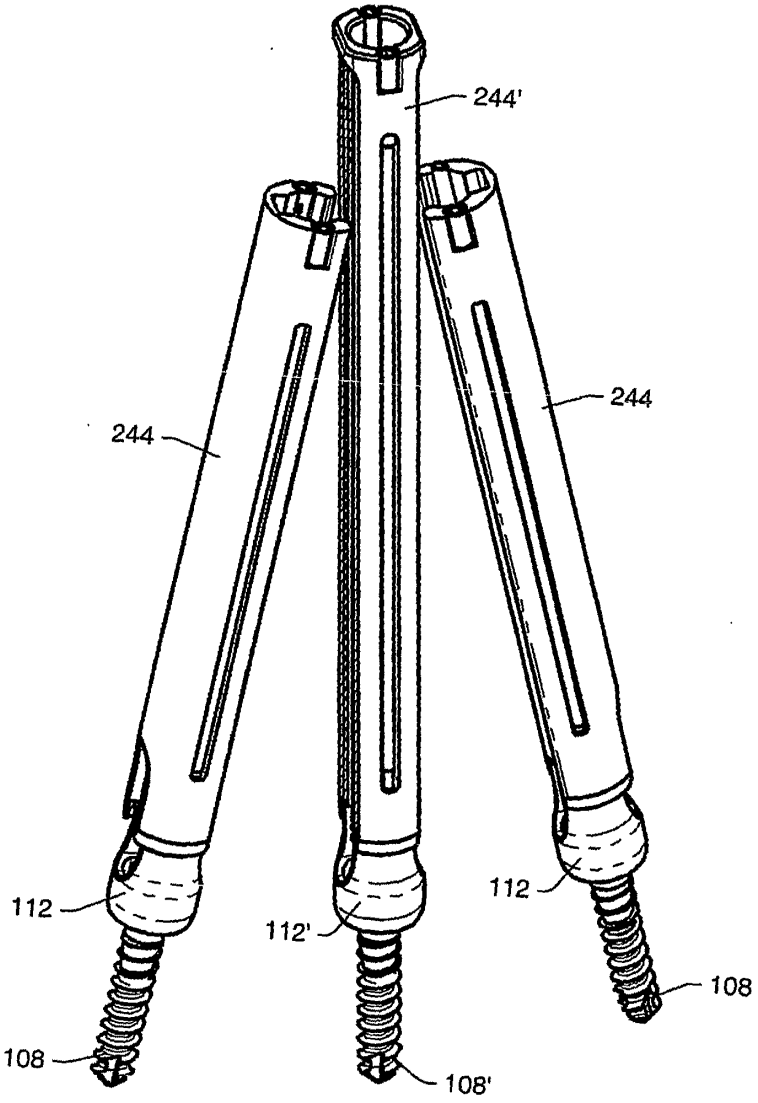


FIG. 48

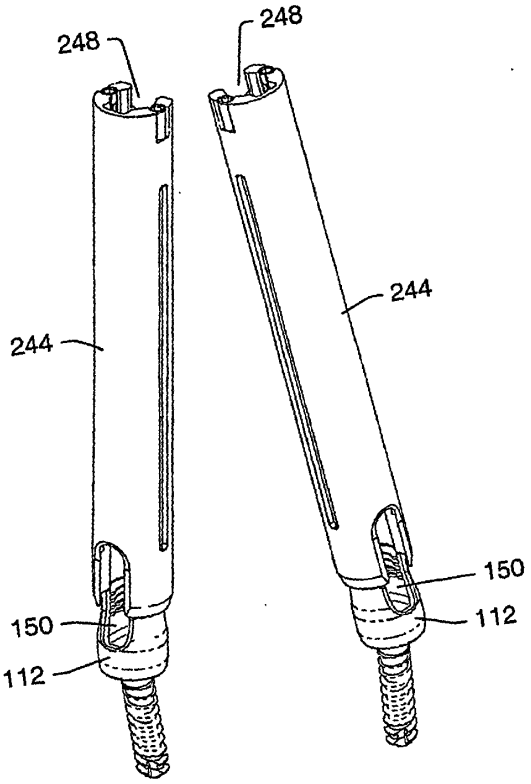


FIG. 49

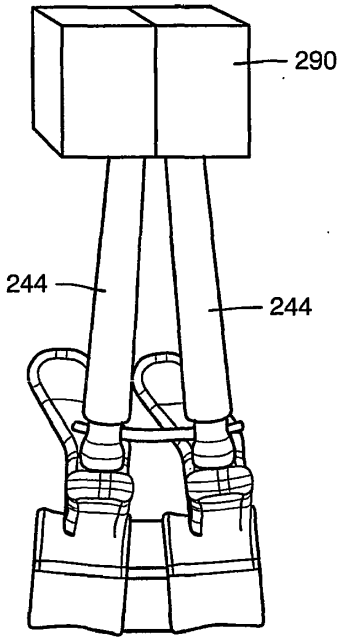


FIG. 50

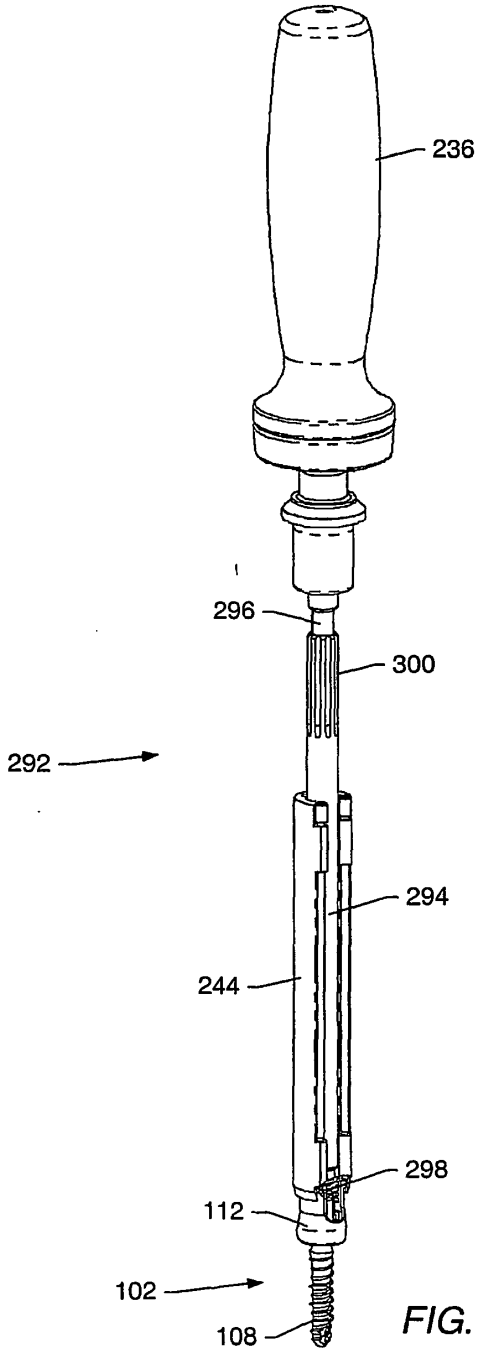


FIG. 51

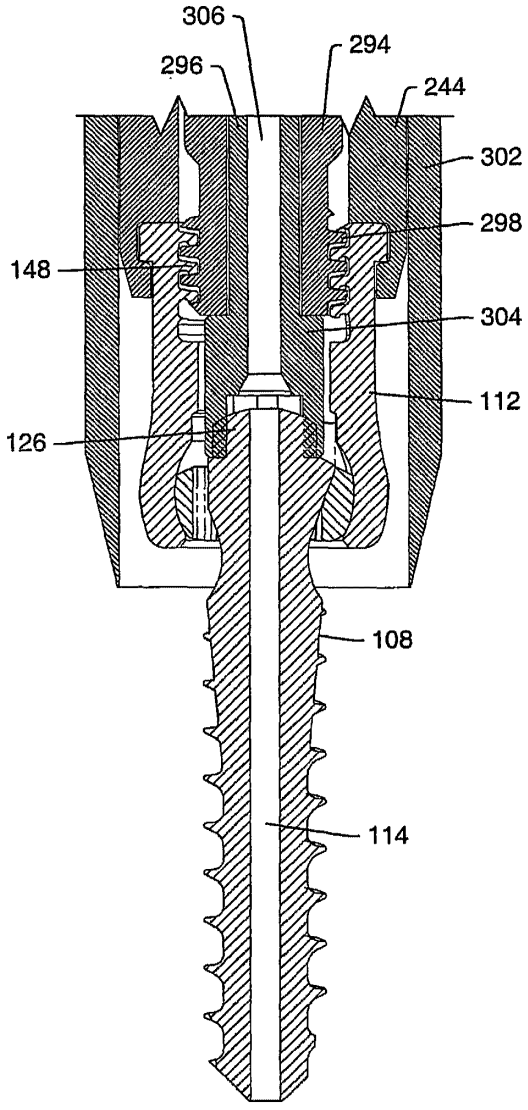


FIG. 52

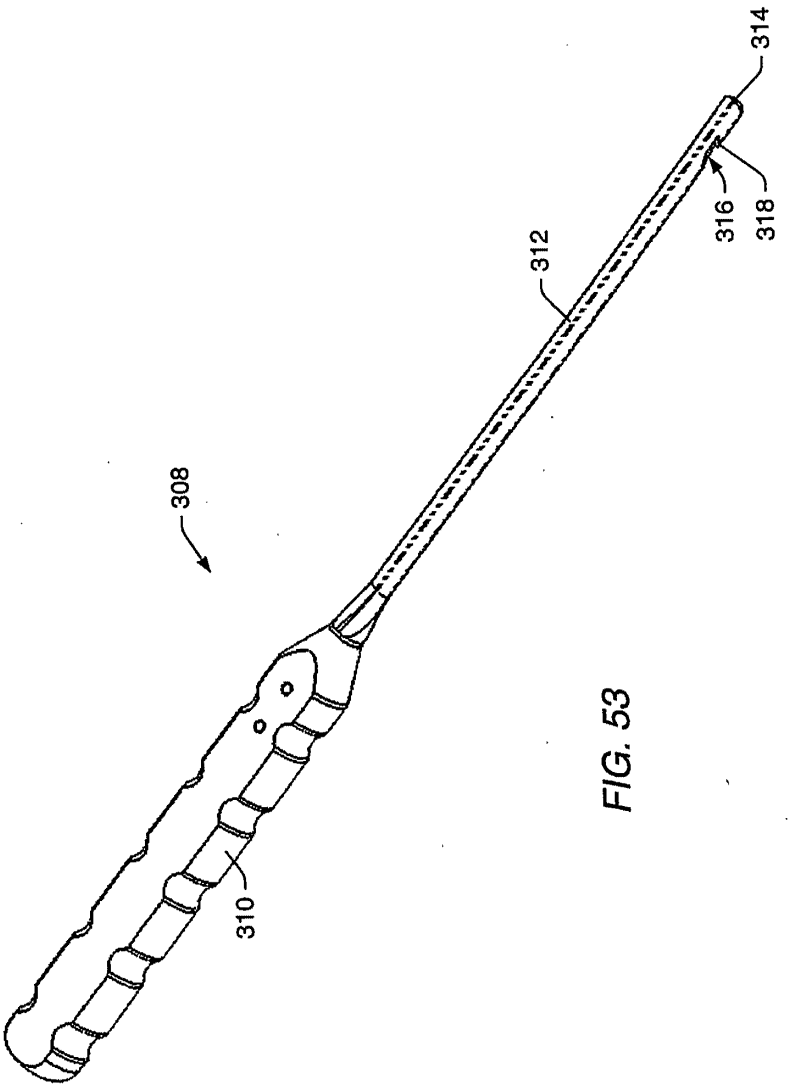


FIG. 53

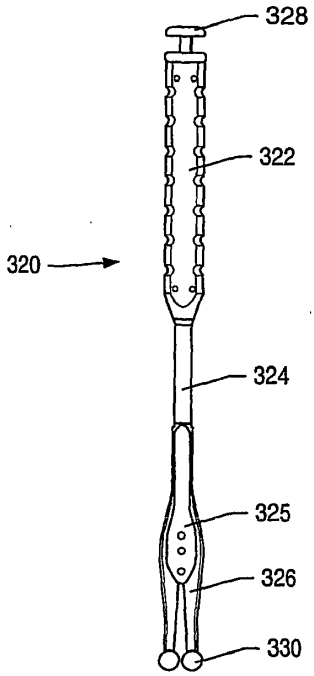


FIG. 54

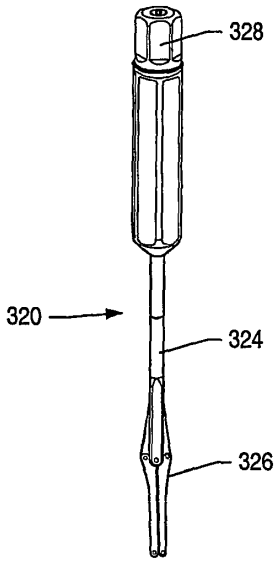


FIG. 55

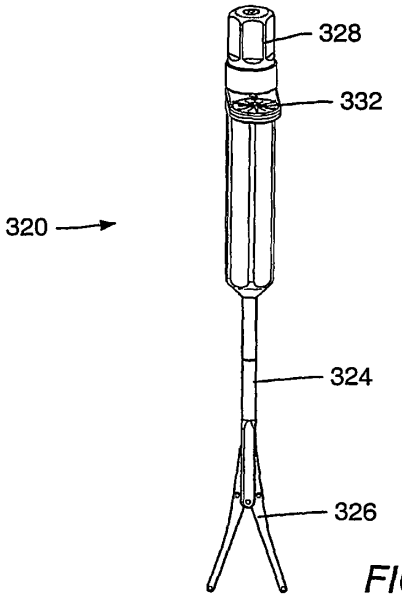


FIG. 56

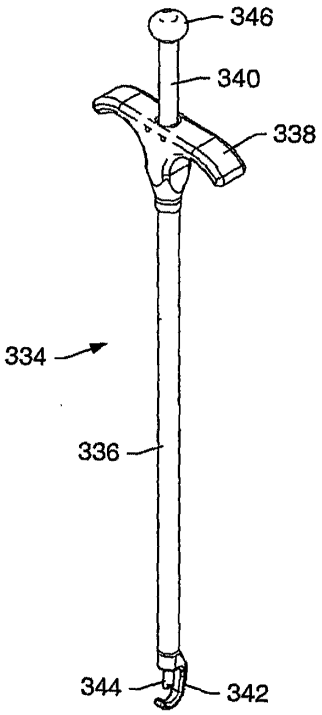


FIG. 57

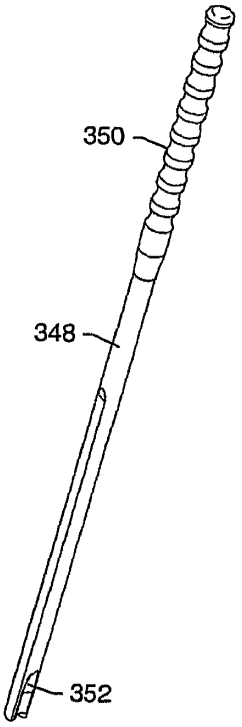


FIG. 58

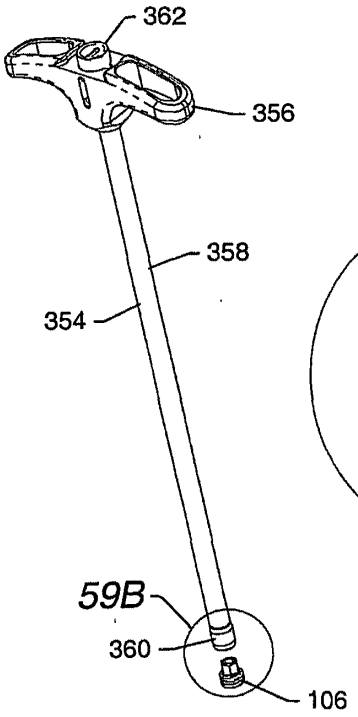


FIG. 59A

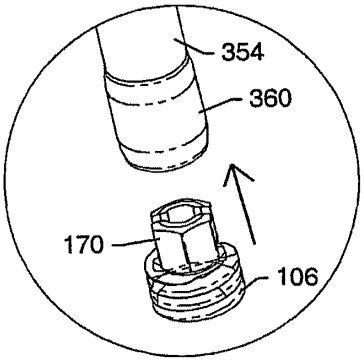


FIG. 59B

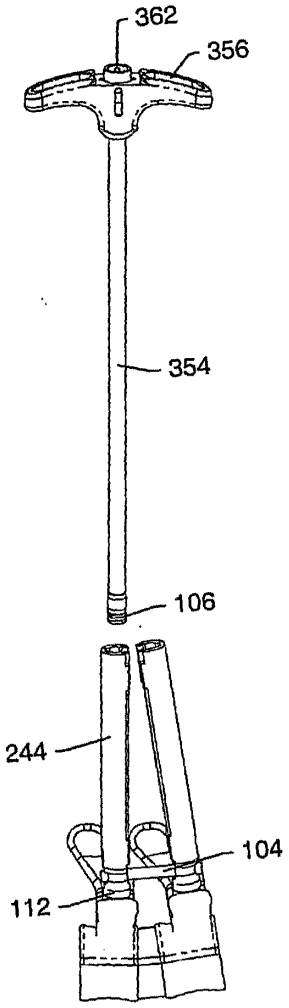


FIG. 60A

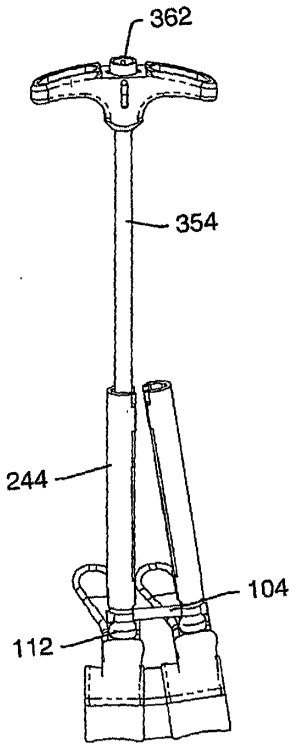


FIG. 60B

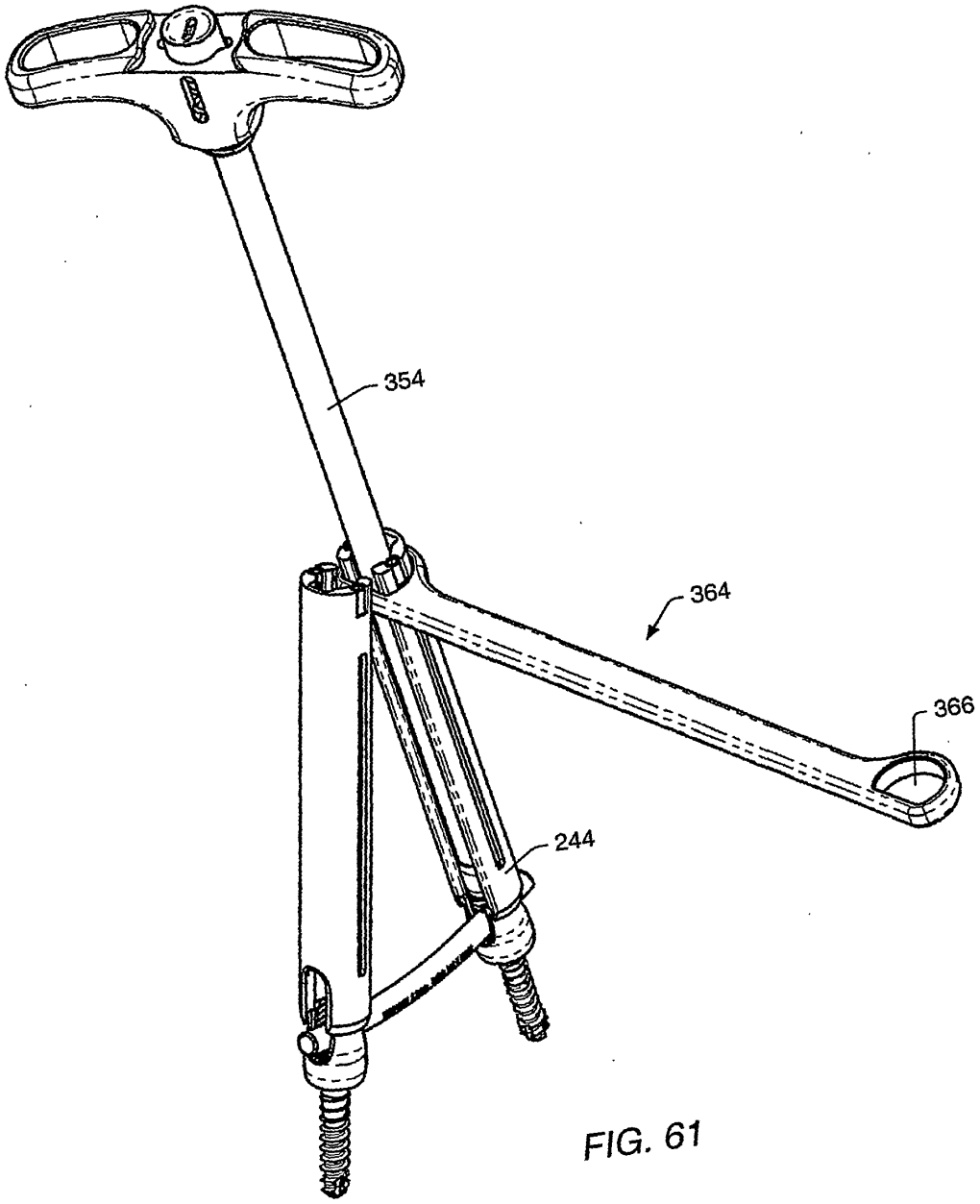


FIG. 61

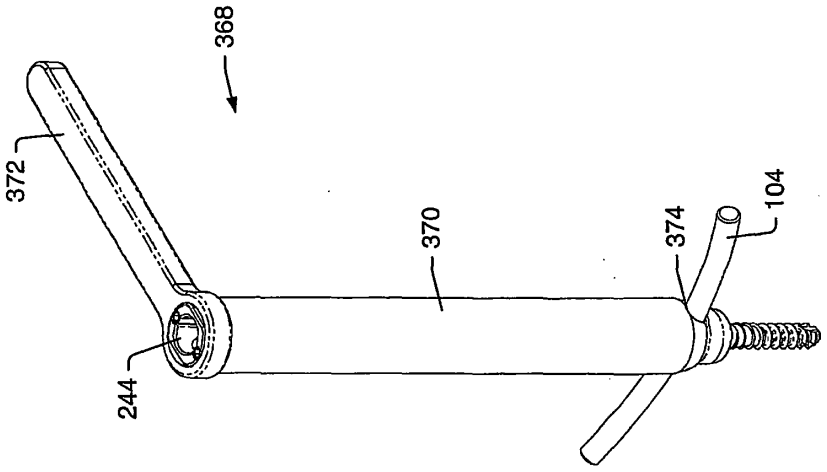


FIG. 63

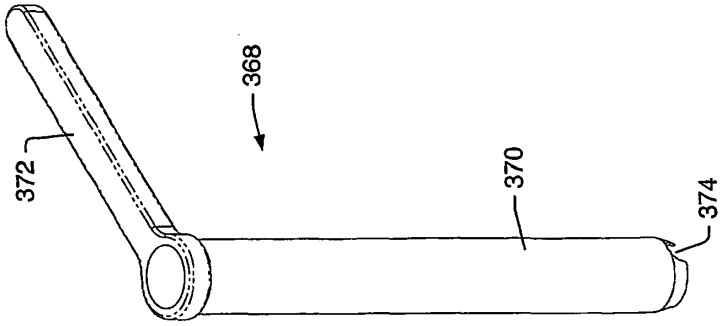


FIG. 62

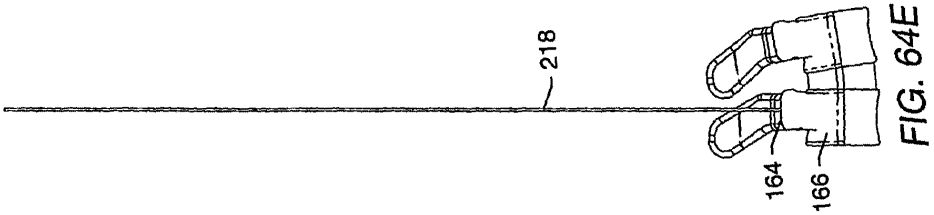


FIG. 64E

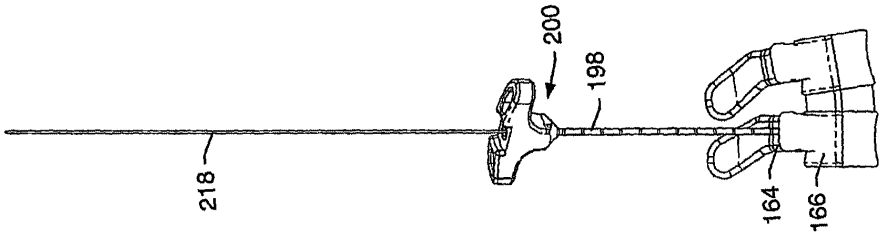


FIG. 64D

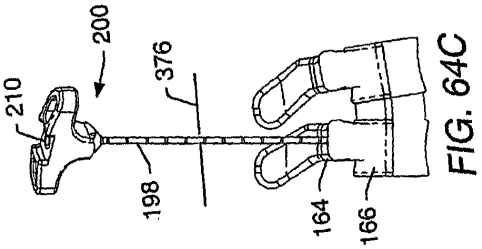


FIG. 64C

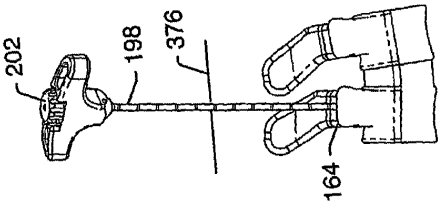


FIG. 64B

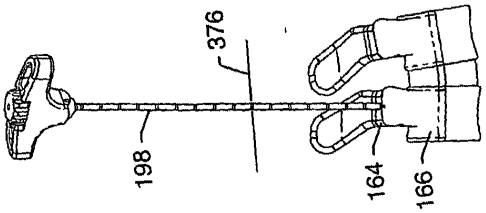


FIG. 64A

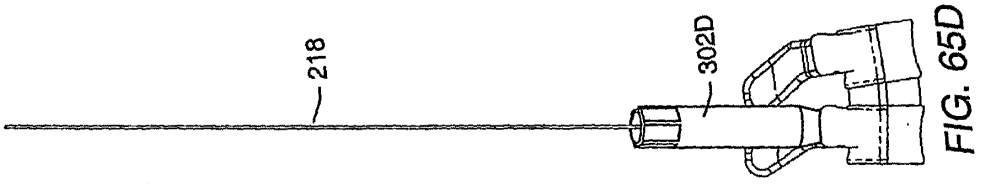


FIG. 65D

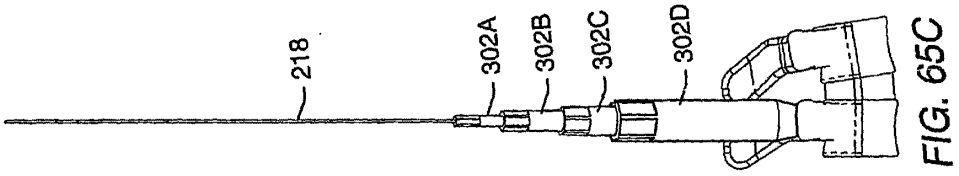


FIG. 65C

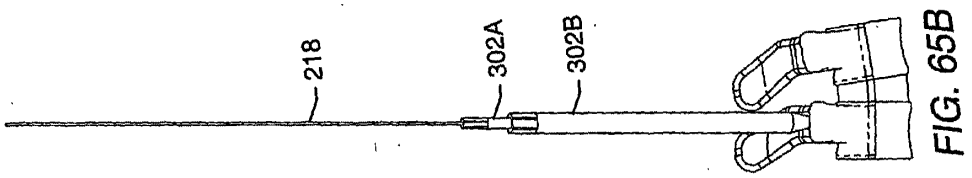


FIG. 65B

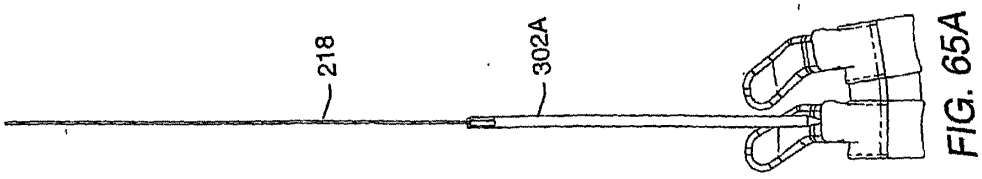


FIG. 65A

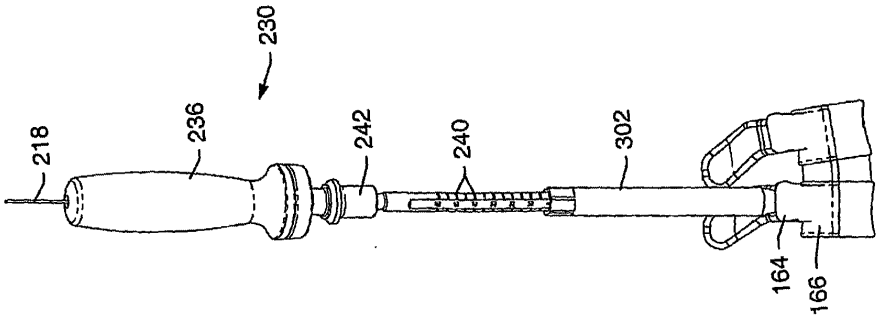


FIG. 66D

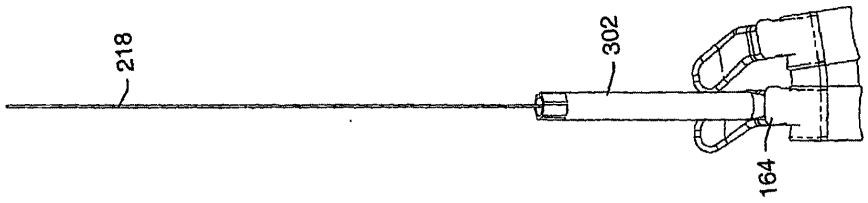


FIG. 66C

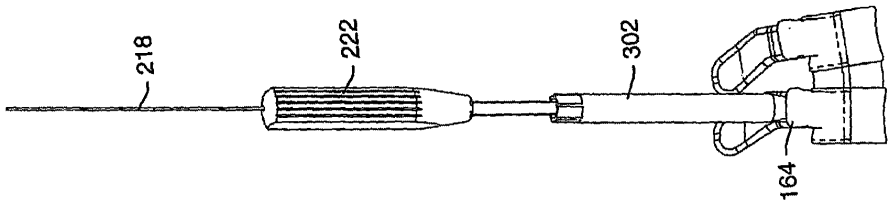


FIG. 66B

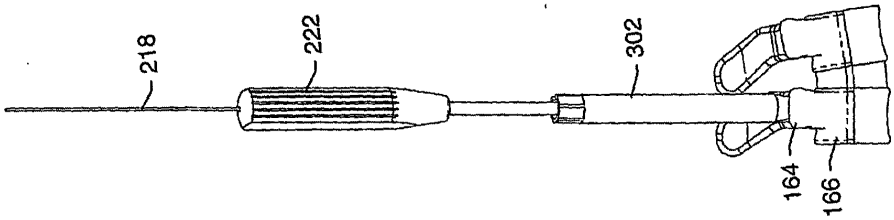


FIG. 66A

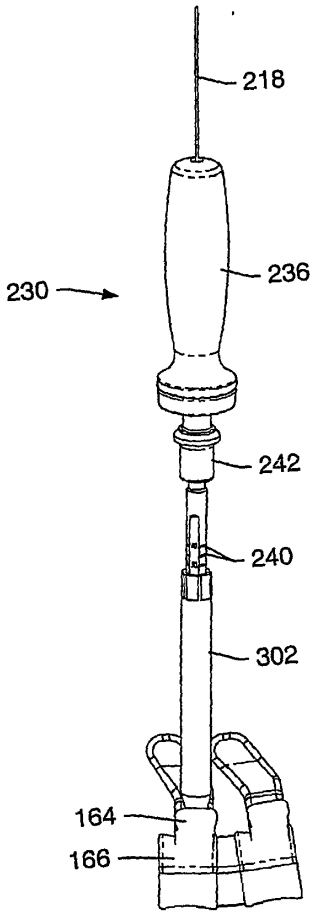


FIG. 66E

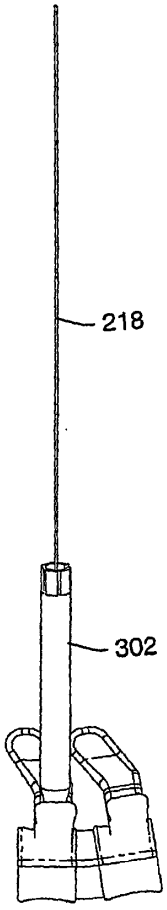
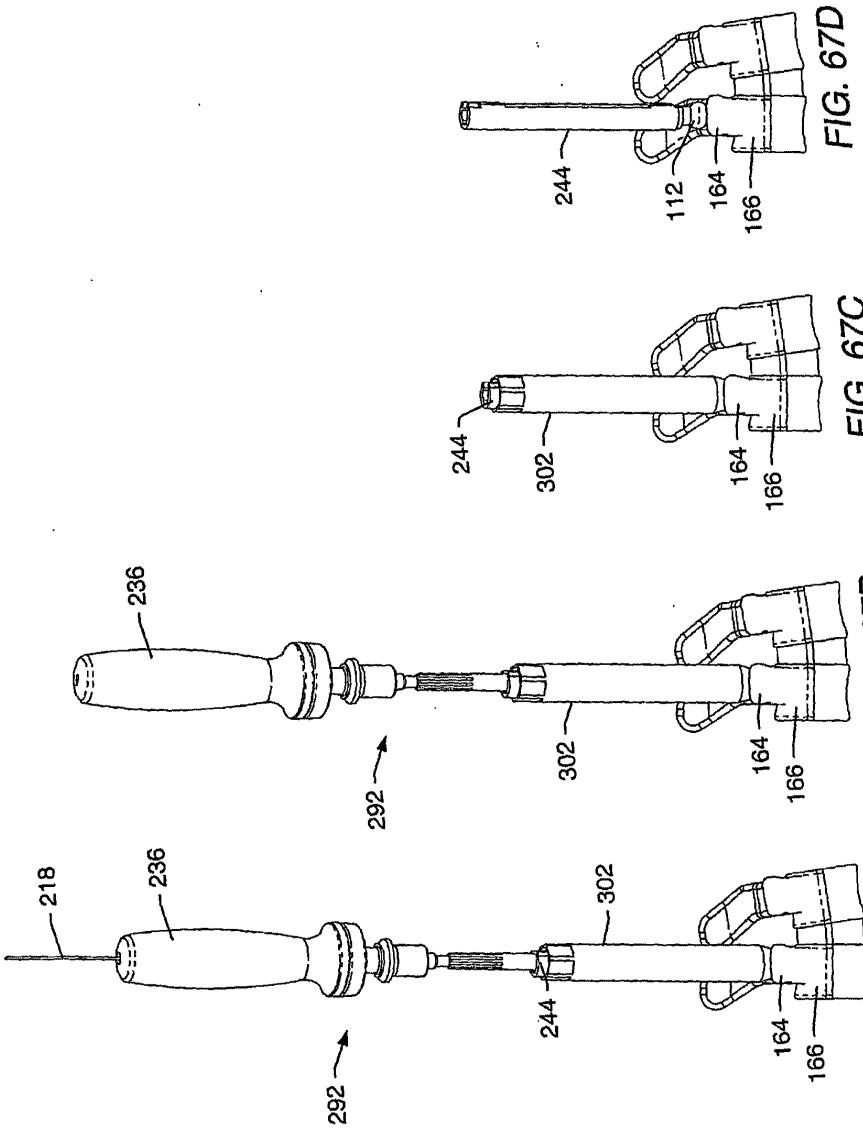


FIG. 66F


244
112
164
166
FIG. 67D
244
302
164
166
FIG. 67C
236
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302
164
166
FIG. 67B
218
236
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292
244
164
166
FIG. 67A

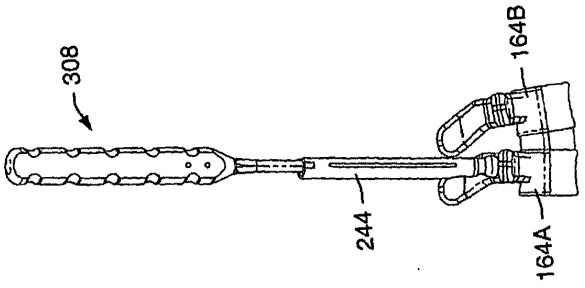


FIG. 68D

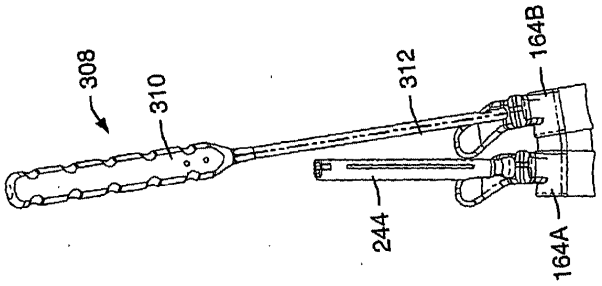


FIG. 68C

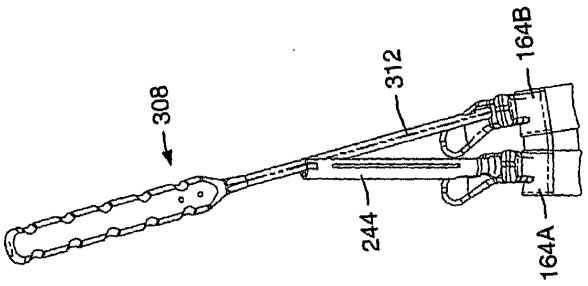


FIG. 68B

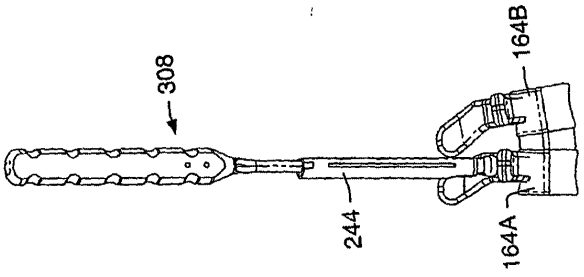


FIG. 68A

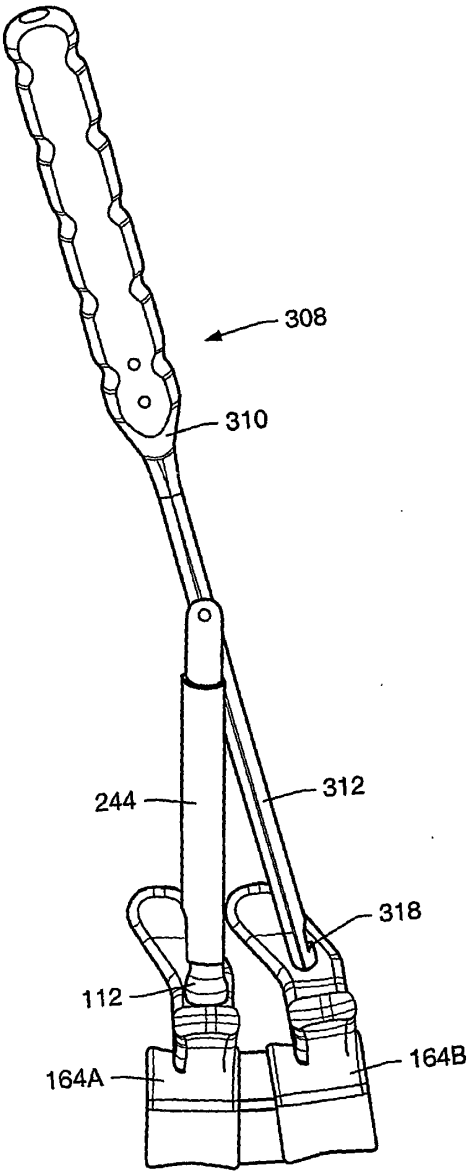


FIG. 69

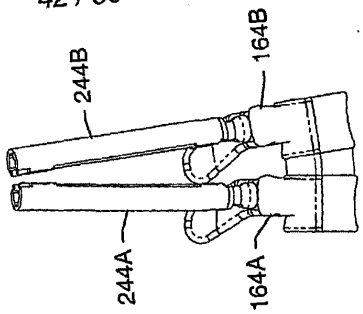


FIG. 70D

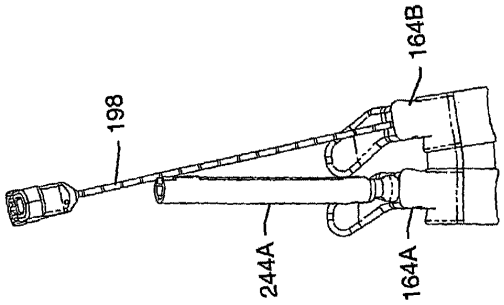


FIG. 70C

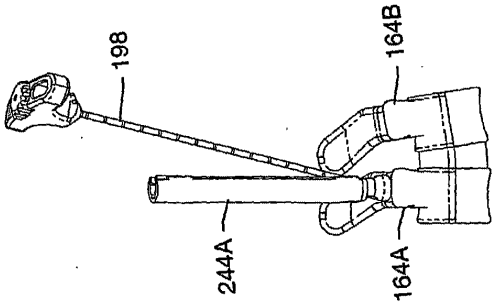


FIG. 70B

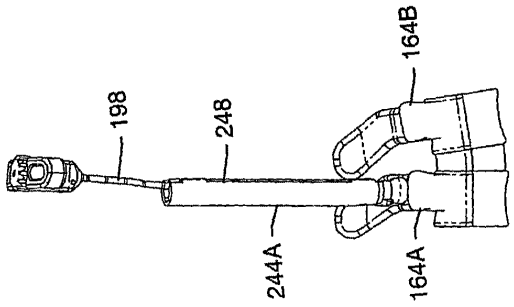


FIG. 70A

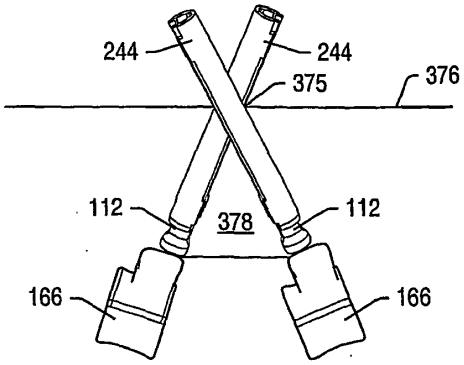


FIG. 71



FIG. 72



FIG. 73

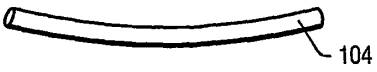


FIG. 74

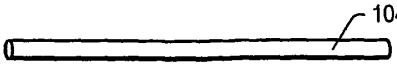


FIG. 75

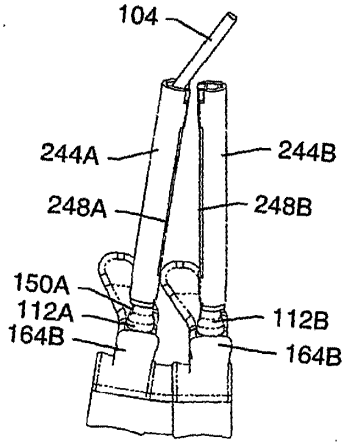


FIG. 76A

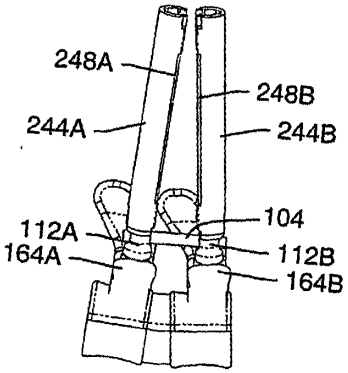


FIG. 76C

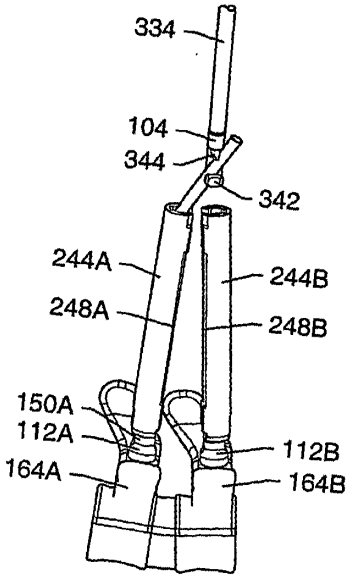


FIG. 76B

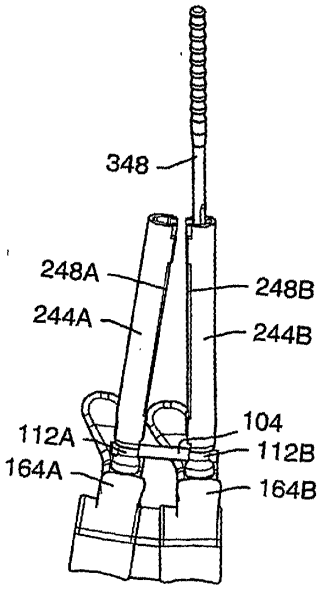


FIG. 76D

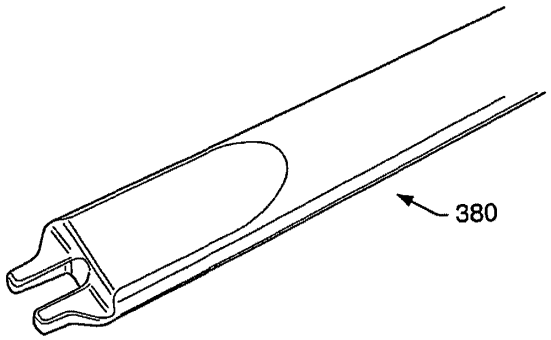


FIG. 77

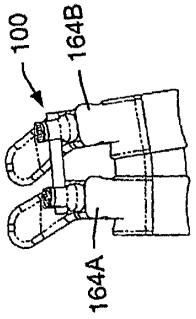


FIG. 78D

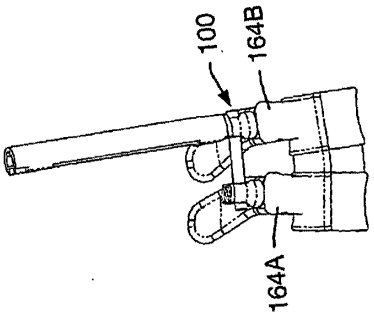


FIG. 78C

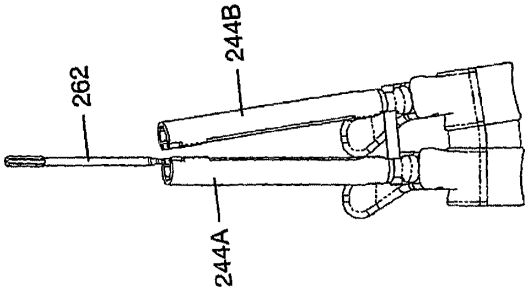


FIG. 78B

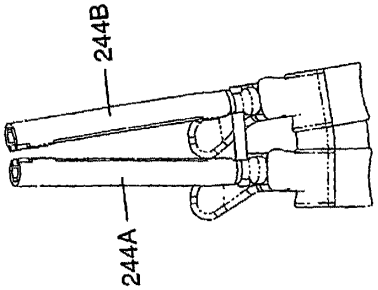


FIG. 78A

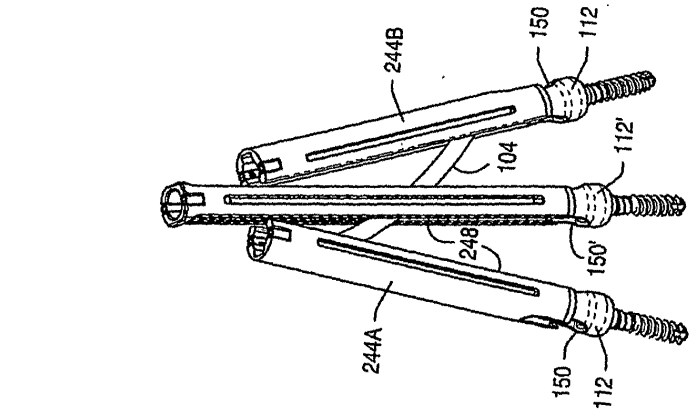


FIG. 79C

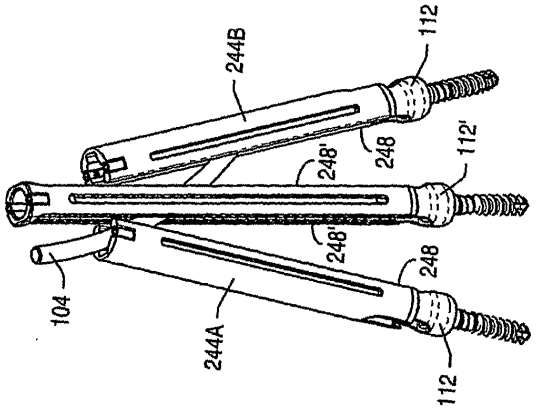


FIG. 79B

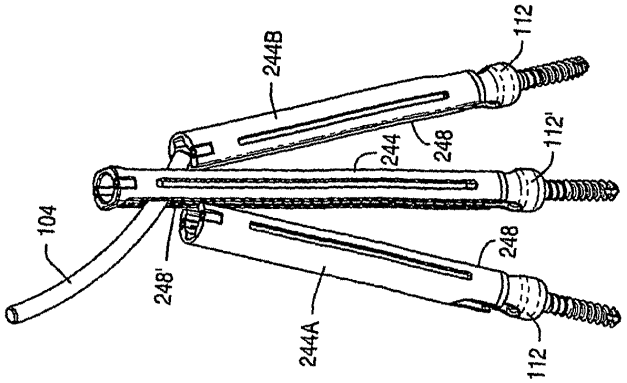


FIG. 79A

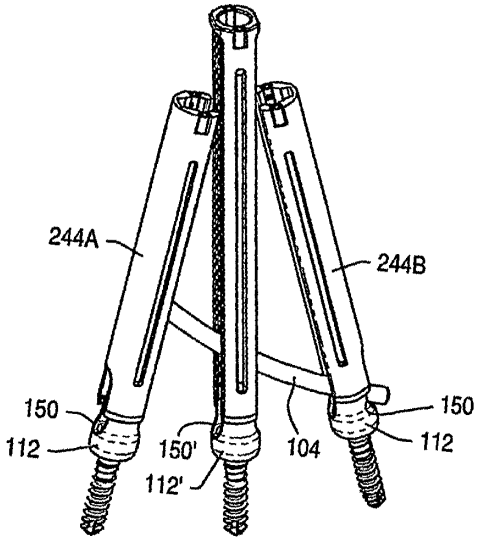


FIG. 79D

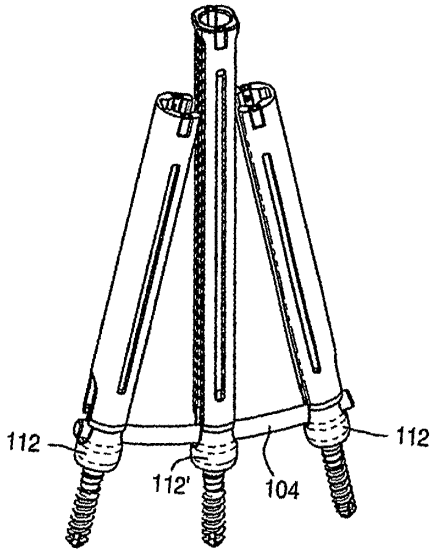


FIG. 79E

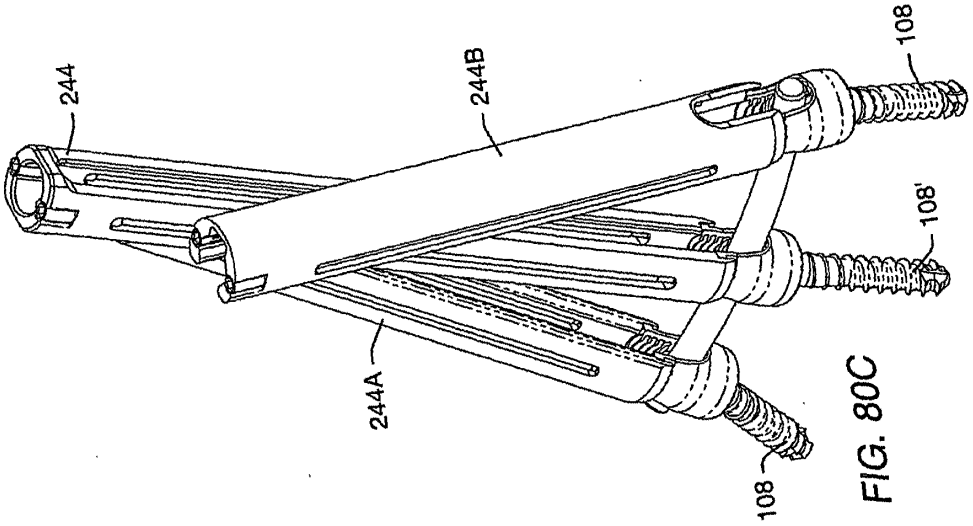


FIG. 80C

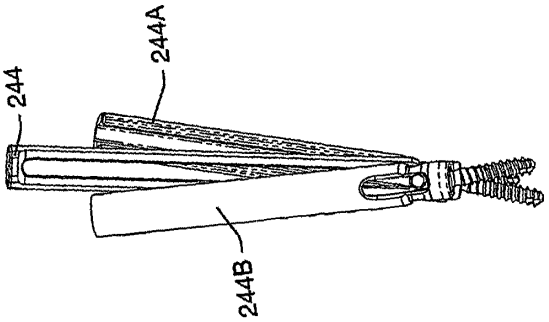


FIG. 80B

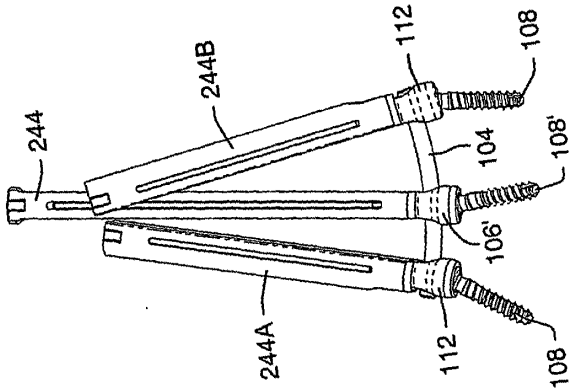


FIG. 80A

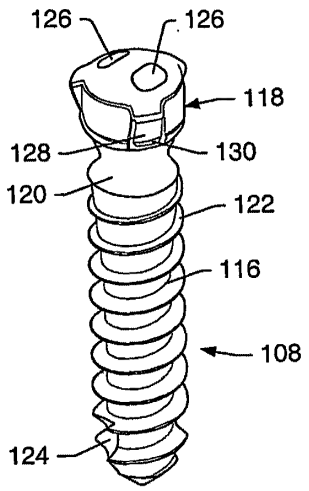


FIG. 81

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 03/34469

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.
Y	US 5 647 873 A (RALPH JAMES D ET AL) 15 July 1997 (1997-07-15) column 5, line 54 - line 65 column 6, line 30 -column 7, line 45 figures 4-6,8 ---	1-9, 11-19,86
Y	US 6 331 179 B1 (FREID JIM ET AL) 18 December 2001 (2001-12-18) column 9, line 61 -column 11, line 65 figures 5-7,10,13,14 ---	1-9, 11-19,86
X	FR 2 796 545 A (DIMSO DISTRIB MEDICALE DU SUD) 26 January 2001 (2001-01-26)	21,23, 24,26, 30,34, 40-44,87
Y	page 4, line 25 -page 10, line 8 figures --- -/--	32,33

[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
18 March 2004	31/03/2004

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

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

INTERNATIONAL SEARCH REPORT

Internatio[illegible] Application No
PCT/US 03/34469

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
Y	DE 298 10 798 U (SCHAEFER MICOMED GMBH) 28 October 1999 (1999-10-28)	32,33
A	page 8, paragraph 4 -page 9, paragraph 1 figure 2	21
X	FR 2 729 291 A (EUROS SA) 19 July 1996 (1996-07-19)	21,22, 24,25, 30,87
Y	the whole document	23,27-29
Y	EP 1 190 678 A (DEPUY ACROMED INC) 27 March 2002 (2002-03-27)	23,27-29
A	column 4, paragraph 16 -column 7, paragraph 26 figures 1-4	21
X	US 6 183 472 B1 (LUTZ CHRISTIAN) 6 February 2001 (2001-02-06)	21,22, 24,25, 30,87
Y	the whole document	35-39
Y	US 2001/001119 A1 (LOMBARDO ALAN) 10 May 2001 (2001-05-10)	35-39
X	the whole document	87
X	US 5 817 094 A (RALPH JAMES D ET AL) 6 October 1998 (1998-10-06) column 5, line 62 -column 10, line 67 figures 4-12	40,87

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

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 03/34469

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 45-85,88
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

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

see additional sheet

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

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

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

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

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 1069 of 2152

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-20,86

   Fixed coupling between the ring and the head of the bone fastener

1.1. Claims: 21-44,87
   Construction of the collar with the connection between the collar and a tool

Please note that all inventions mentioned under item 1, although not necessarily linked by a common inventive concept, could be searched without effort justifying an additional fee.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 03/34469

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Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 1072 of 2152

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

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(71) **Demandeur(s) :** *MEDICREA INTERNATIONAL Société anonyme* — FR.

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

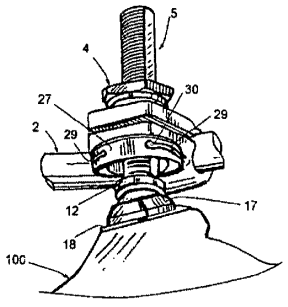
(73) **Titulaire(s) :**

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

(54) MATERIEL D'OSTEOSYNTHESE VERTEBRALE.

(57) Ce matériel comprend des organes d'ancrage osseux, 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 des pièces de connexion (3) de cette ou ces tiges (2) à ces organes d'ancrage; au moins un des organes d'ancrage est du type "polyaxial", c'est-à-dire comprend un pion proximal (5) articulé par rapport à la partie de base (6) de l'organe d'ancrage permettant l'ancrage osseux; des moyens de serrage (4) permettent le montage de la pièce de connexion (3) sur l'organe d'ancrage.

Selon l'invention, le pion proximal (5) comprend une surface (12, 50) formant une butée axiale, contre laquelle la pièce de connexion (3) devant être montée sur l'organe d'ancrage polyaxial est destinée à venir reposer, et lesdits moyens de serrage (4) permettent de serrer cette pièce de connexion (3) contre cette surface (12, 50), ladite surface (12, 50) étant positionnée de telle sorte que la pièce de connexion (3), lorsqu'elle est serrée contre cette surface (12, 50), laisse subsister la possibilité de débattement articulé du pion proximal (5) par rapport à ladite partie de base (6).



FR 2 857 850 - A1

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 1073 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 et/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, au moins un organe d'ancrage comprend une partie de base permettant son ancrage osseux et un pion proximal fileté articulé par rapport à cette partie de base, sur lequel peut être vissé un écrou. Chaque pièce de connexion comprend alors 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 la partie de base, 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 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 ou des segments vertébraux traités, qui peuvent conduire à des dégénérescences précoces 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 et/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 à ces organes d'ancrage ; au moins un des organes d'ancrage est du type "polyaxial", c'est-à-dire comprend un pion proximal articulé par rapport à une partie de base permettant l'ancrage osseux ; des moyens de serrage permettent le montage de la pièce de connexion sur l'organe d'ancrage.

Selon l'invention, le pion proximal comprend une surface formant une butée axiale, contre laquelle la pièce de connexion devant être montée sur l'organe d'ancrage polyaxial est destinée à venir reposer, et lesdits moyens de serrage permettent de serrer cette pièce de connexion contre cette surface, ladite surface étant positionnée de telle sorte que la pièce de connexion, lorsqu'elle est serrée contre cette surface, laisse subsister la possibilité de débattement articulé du pion proximal par rapport à ladite partie de base.

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.

La pièce de connexion comprend de préférence une partie arrondie destinée à entourer une tige de liaison et deux ailes parallèles percées de trous, destinées à être engagées sur ledit pion proximal et à être serrées l'une vers l'autre de manière à réaliser le serrage de ladite partie arrondie autour dune tige de liaison.

Avantageusement, 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 base ou l'os, 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 base, avec amortissement.

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 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.

Le pion proximal et ladite surface formant butée axiale peuvent être conformés de manière à permettre le réglage de la position axiale de cette surface par rapport au pion proximal, et cette surface peut être conformée pour réaliser un serrage de ladite pièce ou partie de pièce à structure élastiquement déformable entre elle et une surface d'appui contre laquelle repose cette pièce ou partie de pièce.

Ladite surface formant butée axiale permet alors, selon le serrage qu'elle réalise, de régler l'amortissement produit par ladite pièce ou partie de pièce à structure élastiquement déformable.

Selon une forme de mise en œuvre de l'invention dans ce cas, le pion proximal est fileté et ladite surface formant butée axiale est réalisée sous forme d'une collerette à trou taraudé pouvant être vissée sur ce pion.

Ladite surface d'appui contre laquelle repose la pièce ou partie de pièce à structure élastiquement déformable peut être une surface de la partie de base ou l'os vertébral.

Avantageusement, les parois du pion proximal et de ladite partie de base 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.

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 de pièces que comprend le matériel qu'elle concerne.

La figure 1 est une de ces pièces, avant montage, selon une forme de réalisation ;

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, et

la figure 8 est une vue desdites pièces, avant montage, selon une autre forme de réalisation.

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.

Dans cette position de serrage de chaque pièce 3 contre la collerette 12 correspondante, la paroi 27 ne repose contre la paroi 17 que par une surface

très réduite, comme le montre la figure 2. Ce serrage laisse subsister la possibilité de débattement articulé du pion proximal 5 par rapport au corps de vis 6, ce débattement 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 (cf. figure 5). 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.

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.

La figure 8 représente des pièces 2 à 5 identiques ou 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 pièce 3 est dépourvue de la paroi 27, et le matériel comprend, pour au moins un organe d'ancrage 1, une pièce 31 sous forme d'une rondelle en matériau à structure élastiquement déformable, notamment en silicone ou en PMMA, et 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.

La rondelle 50 peut être vissée sur le pion 5 jusqu'à réaliser un serrage de la pièce 31 en fonction de d'un amortissement recherché pour le débattement du pion 5. 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 2 par rapport à la pièce 3.

Comme cela apparaît de ce qui précède, l'invention fournit un matériel d'ostéosynthèse vertébrale permettant un jeu 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) et/ou des crochets, une ou deux tiges de liaison (2), destinées à être reliées à ces organes d'ancrage, et des pièces de connexion (3) de cette ou ces tiges (2) à ces organes d'ancrage ; au moins un des organes d'ancrage est du type "polyaxial", c'est-à-dire comprend un pion proximal (5) articulé par rapport à la partie de base (6) de l'organe d'ancrage permettant l'ancrage osseux ; des moyens de serrage (4) permettent le montage de la pièce de connexion (3) sur l'organe d'ancrage ;

matériel caractérisé en ce que le pion proximal (5) comprend une surface (12, 50) formant une butée axiale, contre laquelle la pièce de connexion (3) devant être montée sur l'organe d'ancrage polyaxial est destinée à venir reposer, et en ce que lesdits moyens de serrage (4) permettent de serrer cette pièce de connexion (3) contre cette surface (12, 50), ladite surface (12, 50) étant positionnée de telle sorte que la pièce de connexion (3), lorsqu'elle est serrée contre cette surface (12, 50), laisse subsister la possibilité de débattement articulé du pion proximal (5) par rapport à ladite partie de base (6).

2 – Matériel selon la revendication 1, caractérisé en ce que la pièce de connexion (3) comprend une partie arrondie (20) destinée à entourer une tige de liaison (2) et deux ailes parallèles (21) percées de trous, destinées à être engagées sur ledit pion proximal (5) et à être serrées l'une vers l'autre de manière à réaliser le serrage de ladite partie arrondie (20) autour dune tige de liaison (2).

3 – Matériel selon la revendication 1 ou la revendication 2, caractérisé en ce que ledit organe d'ancrage polyaxial (1) 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 ladite partie de base (6) ou l'os, 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 la partie de base (6), avec amortissement.

4 – Matériel selon la revendication 3, caractérisé en ce que ladite pièce ou partie de pièce (31) à structure élastiquement déformable est conformée de manière à réaliser un amortissement du mouvement du pion proximal (5) sur l'ensemble du débattement de ce pion (5).

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 l'une des revendications 3 à 5, caractérisé en ce que le pion proximal (5) et ladite surface (50) formant butée axiale sont conformés de manière à permettre le réglage de la position axiale de cette surface (50) par rapport au pion proximal (5), et en ce que cette surface (50) est conformée pour réaliser un serrage de ladite pièce ou partie de pièce (31) à structure élastiquement déformable entre elle et une surface d'appui (17, 18) contre laquelle repose cette pièce ou partie de pièce (31).

7 – Matériel selon la revendication 6, caractérisé en ce que le pion proximal (5) est fileté et en ce que ladite surface formant butée axiale est réalisée sous forme d'une collerette (50) à trou taraudé pouvant être vissée sur ce pion (5).

8 – Matériel selon la revendication 6 ou la revendication 7, caractérisé en ce que ladite surface d'appui contre laquelle repose la pièce ou partie de pièce (31) à structure élastiquement déformable est une surface (17, 18) de la partie de base (6) ou l'os vertébral.

9 – Matériel selon l'une des revendications 1 à 8, caractérisé en ce que les parois (11, 17) du pion proximal (5) et de ladite partie de base (6) 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.

10 – Matériel selon l'une des revendications 1 à 9, 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 (5), notamment au moins du double du diamètre de ce pion.

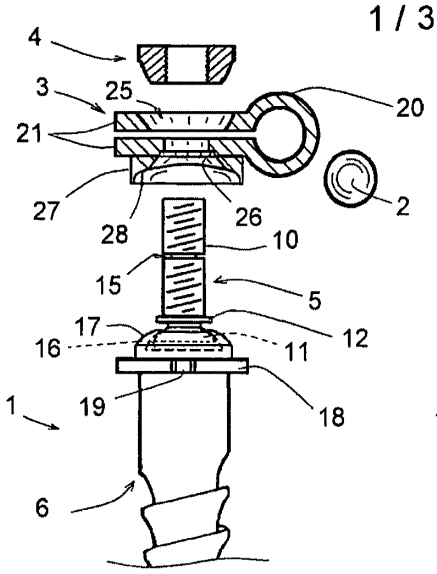


FIG. 1

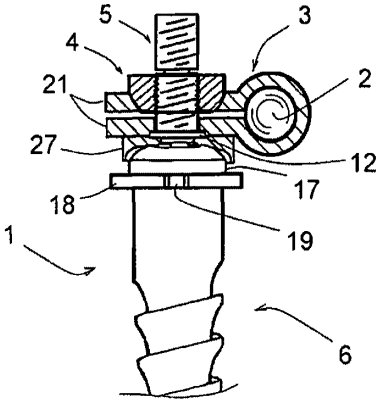


FIG. 2

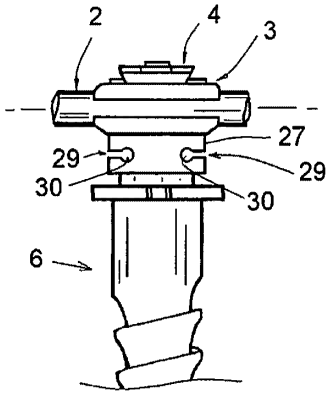


FIG. 3

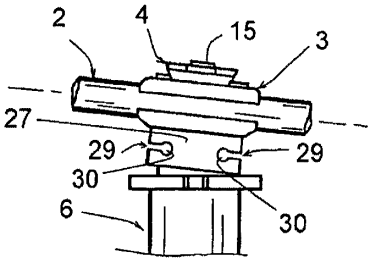


FIG. 4

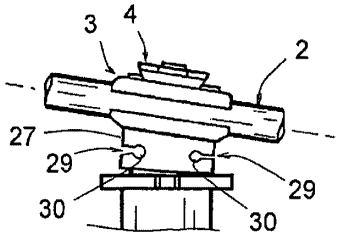


FIG. 5

FIG. 6

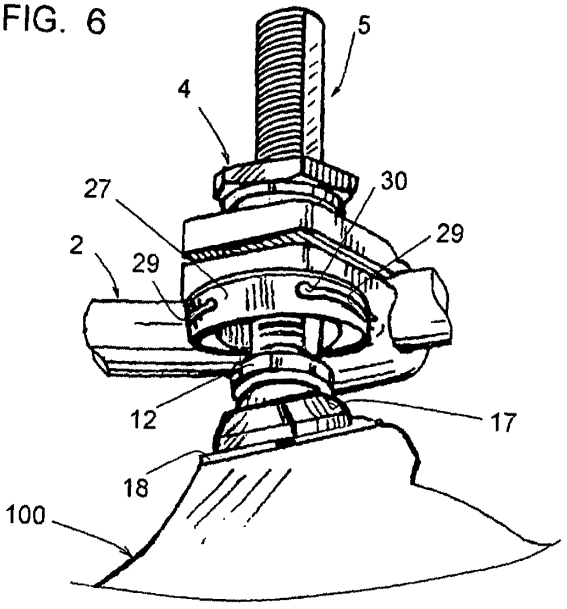


FIG. 7

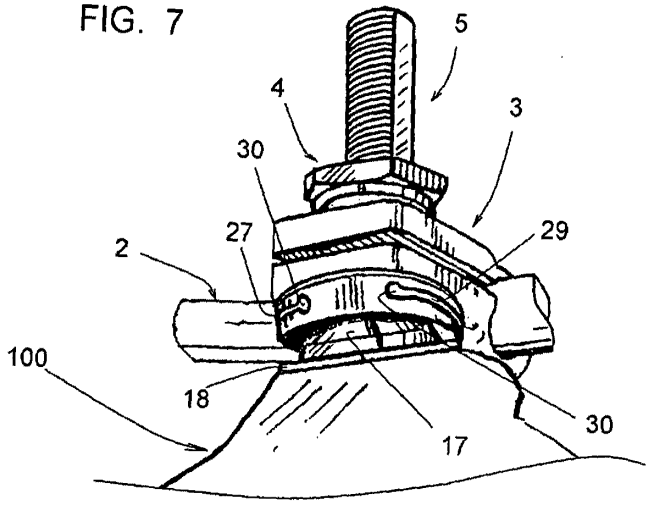
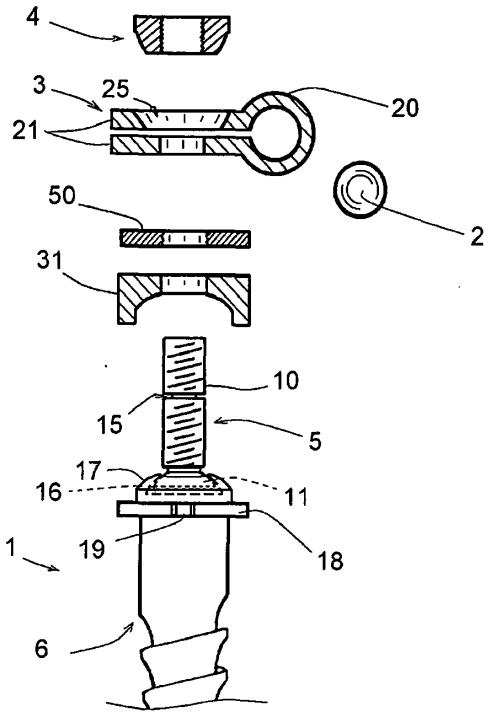


FIG. 8



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RAPPORT DE RECHERCHE PRÉLIMINAIRE

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

N° d'enregistrement national

FA 647137
FR 0403413

DOCUMENTS CONSIDÉRÉS COMME PERTINENTS		Revendication(s) concernée(s)	Classement attribué à l'invention par l'INPI
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A	US 5 735 851 A (ERRICO J.P.ET AL) 7 avril 1998 (1998-04-07) * figure 10a * -----	1	
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A	WO 91/06254 A (BIEDERMANN L. & HARMS J.) 16 mai 1991 (1991-05-16) * page 7, ligne 2 - ligne 10; figures 5-8 * * page 7, ligne 37 - page 8, ligne 13 * -----	1	DOMAINES TECHNIQUES RECHERCHÉS (Int.CL.7) A61B

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

2

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Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 1088 of 2152

ANNEXE AU RAPPORT DE RECHERCHE PRÉLIMINAIRE
RELATIF A LA DEMANDE DE BREVET FRANÇAIS NO. FR 0403413 FA 647137

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

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 1089 of 2152

ANNEXE AU RAPPORT DE RECHERCHE PRÉLIMINAIRE
RELATIF A LA DEMANDE DE BREVET FRANÇAIS NO. FR 0403413 FA 647137

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 1090 of 2152

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

INFORMATION DISCLOSURE STATEMENT

Applicant: Roger P. Jackson, et al.

Date: 1-10-13

For: MULTI-START CLOSURES FOR OPEN IMPLANTS

Docket No.: 11,433

* *

Shawnee, Kansas

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

Sir:

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

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Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 1091 of 2152

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Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 1092 of 2152

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Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 1093 of 2152

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Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 1094 of 2152

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Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 1095 of 2152

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Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 1096 of 2152

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Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 1097 of 2152

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Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 1098 of 2152

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Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 1099 of 2152

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Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 1100 of 2152

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Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 1101 of 2152

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Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 1102 of 2152

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Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 1103 of 2152

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Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 1104 of 2152

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Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 1105 of 2152

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Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 1106 of 2152

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Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 1107 of 2152

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Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 1108 of 2152

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Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 1109 of 2152

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Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 1110 of 2152

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Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 1111 of 2152

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Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 1112 of 2152

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Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 1113 of 2152

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Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 1114 of 2152

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Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 1115 of 2152

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Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 1116 of 2152

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Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 1117 of 2152

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Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 1118 of 2152

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Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 1119 of 2152

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Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 1120 of 2152

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Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 1121 of 2152

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Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 1122 of 2152

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Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 1123 of 2152

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Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 1124 of 2152

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Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 1125 of 2152

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Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 1126 of 2152

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Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 1127 of 2152

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Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 1128 of 2152

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Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 1129 of 2152

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Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 1130 of 2152

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Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 1131 of 2152

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Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 1132 of 2152

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Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 1133 of 2152

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Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 1134 of 2152

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Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 1135 of 2152

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Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
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Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 1137 of 2152

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

Respectfully submitted,

1-8-13
Date

Roger P. Jackson, Inventor

Respectfully submitted,

1-9-2013
Date

James L. Surber, Inventor

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01433; Petitioners' EX1035
Page 1139 of 2152

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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

Sheet 1 of 50

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Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code [2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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				Art Unit	
				Examiner Name	
Sheet	2	of	50	Attorney Docket Number	11,433

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Sheet	3	of	50	Attorney Docket Number	11,433

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Sheet	4	of	50	Docket No.	11,433

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Sheet	7	of	50	Attorney Docket Number	11,433

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Sheet	8	of	50	Attorney Docket Number	11,433

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Sheet	9	of	50	Attorney Docket Number	11,433

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Sheet	10	of	50	Attorney Docket Number	11,433

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Sheet	11	of	50	Attorney Docket Number	11,433

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

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				Art Unit	
				Examiner Name	
Sheet	14	of	50	Attorney Docket Number	11,433

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Examiner Initials*	Cite No.[7]	Document Number Number-Kind Code [2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-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.	
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		US-6,689,134	02/10/04	Ralph, et al.	
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		FR2865377	01/27/04	Clement, et al.		
		FR2865375	01/27/04	Sournac, et al.		
		FR2865373	01/27/04	Sournac, et al.		
		WO03/068088	08/21/03	Altarac, et al.		
		FR2856578	06/27/03	Clement, et al.		
		WO02/054966	07/18/02	Glascott		

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Sheet	15	of	50	Attorney Docket Number	11,433

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		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.	
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		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.		

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		US-6,610,063	08/26/03	Kumar, et al.	
		US-6,595,992	07/22/03	Wagner, et al.	
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		WO2008/088731	07/24/2008	Hawkins		
		EP1925263	05/28/2008	Matthis, et al.		
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		US-6,488,681	12/03/02	Martin, et al.	
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Sheet	18	of	50	Attorney Docket Number	11,433

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		US-6,248,105	06/19/01	Schlapfer, et al.	
		US-RE37,161	05/01/01	Michelson, et al.	
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		US-5,782,833	07/21/98	Haider	
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