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
IPR2023-01430; Petitioners' EX1002
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.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 859 of 2152

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
IPR2023-01430; Petitioners' EX1002
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)

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 861 of 2152

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
IPR2023-01430; Petitioners' EX1002
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
IPR2023-01430; Petitioners' EX1002
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).

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 864 of 2152

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.

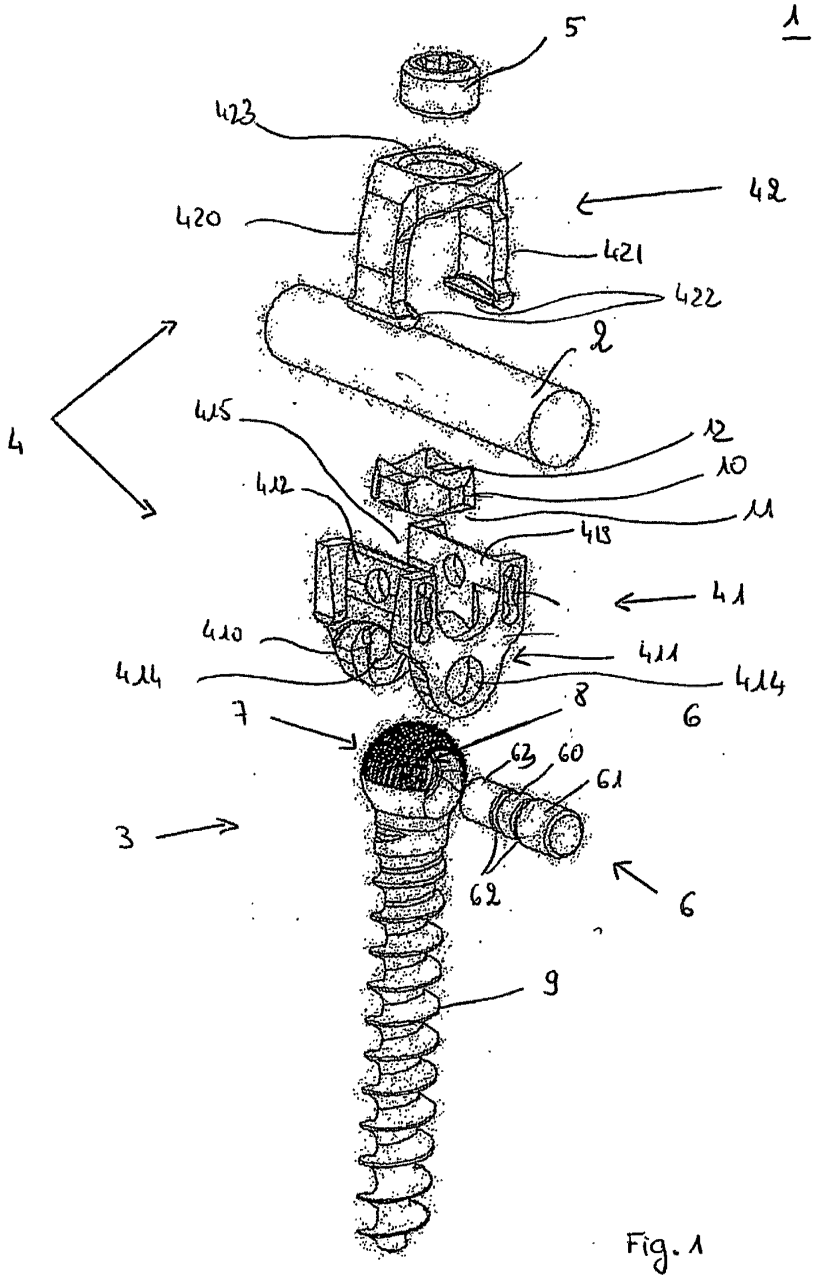

1
5
423
42
420
421
422
2
4
425
12
10
412
11
413
41
410
411
414
414
6
7
8
63
60
61
3
62
6
9

Fig. 1

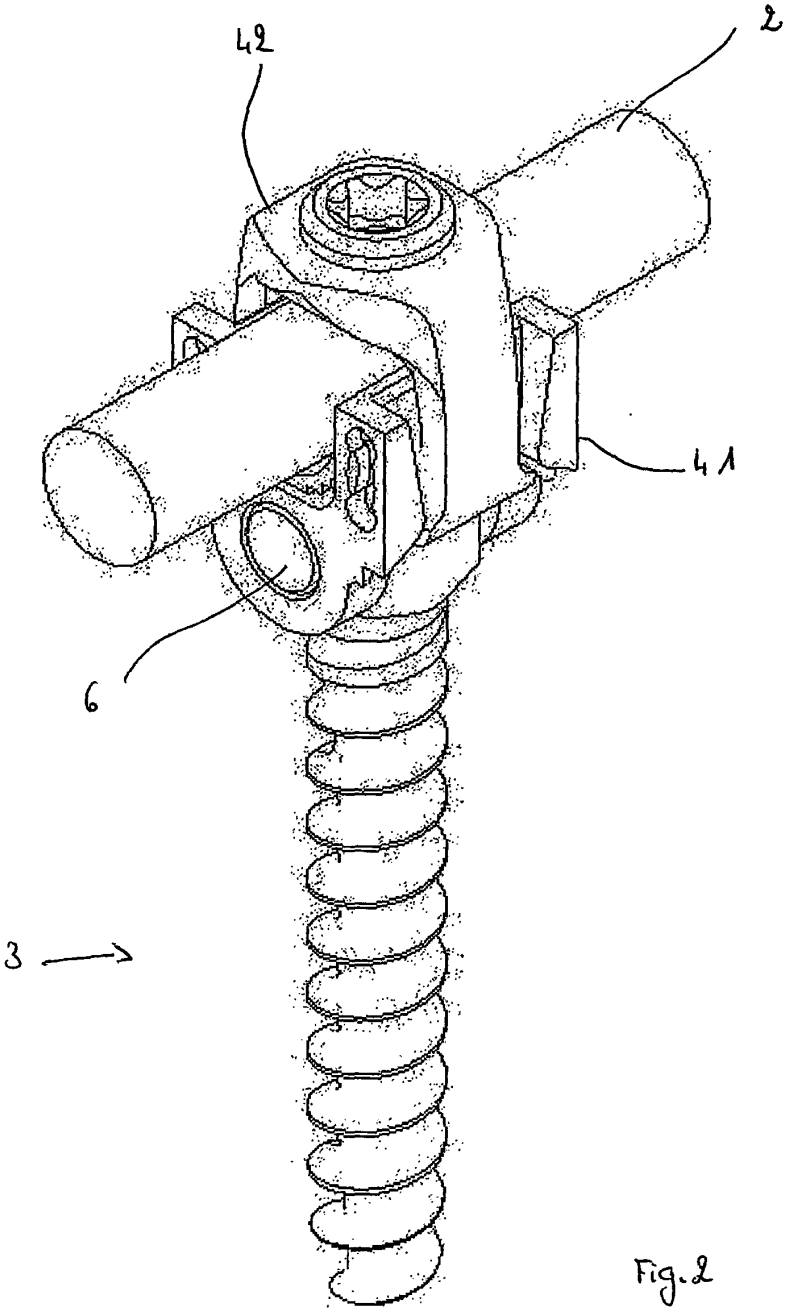


Fig. 2

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 867 of 2152

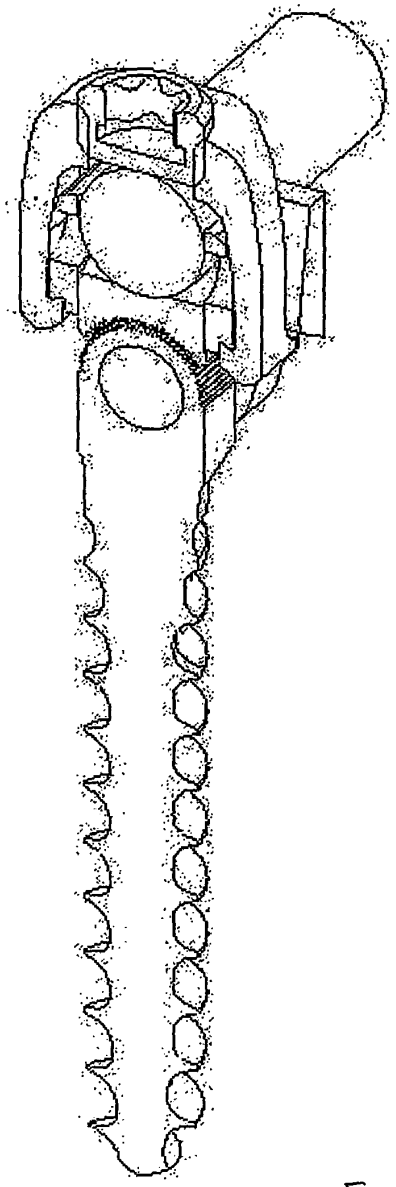


Fig. 3

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 868 of 2152

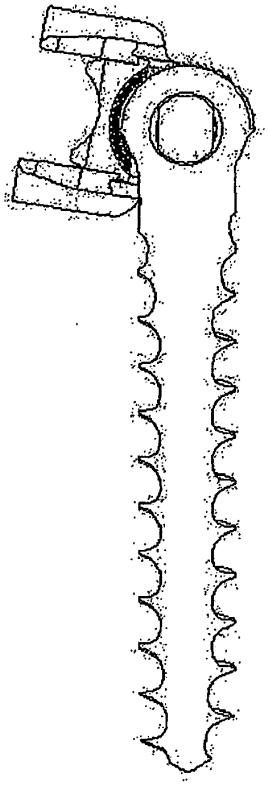


Fig. 4

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 869 of 2152

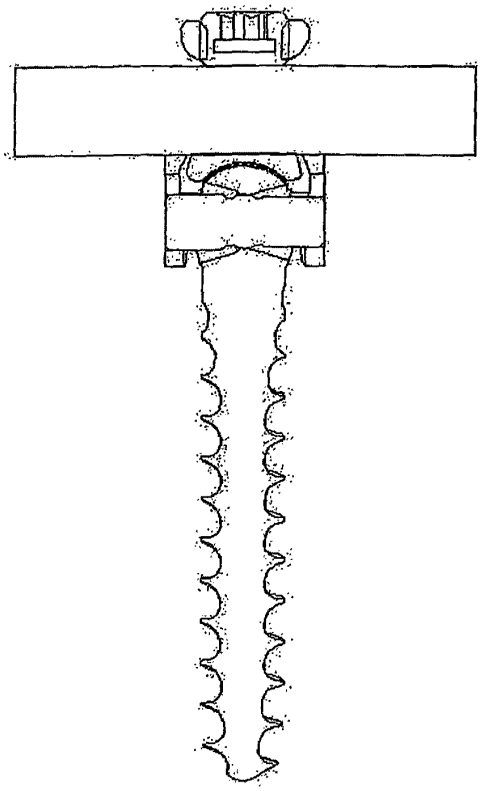


Fig. 5

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 870 of 2152

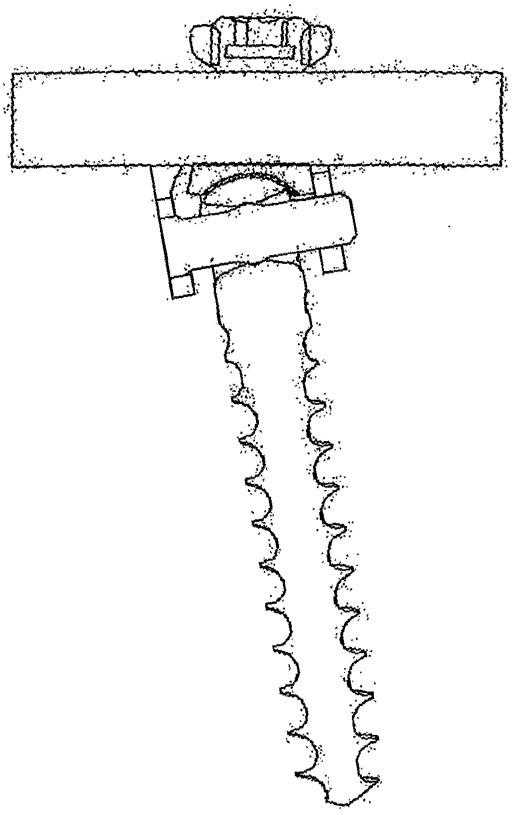


Fig. 6

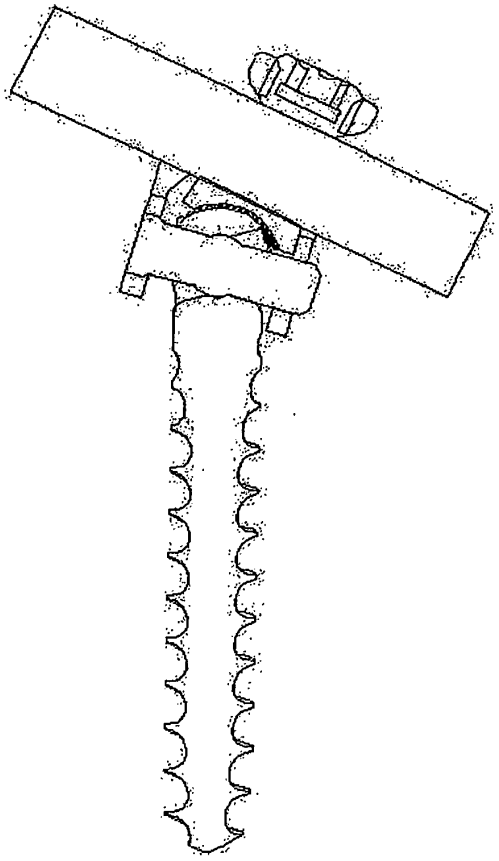


Fig. 7

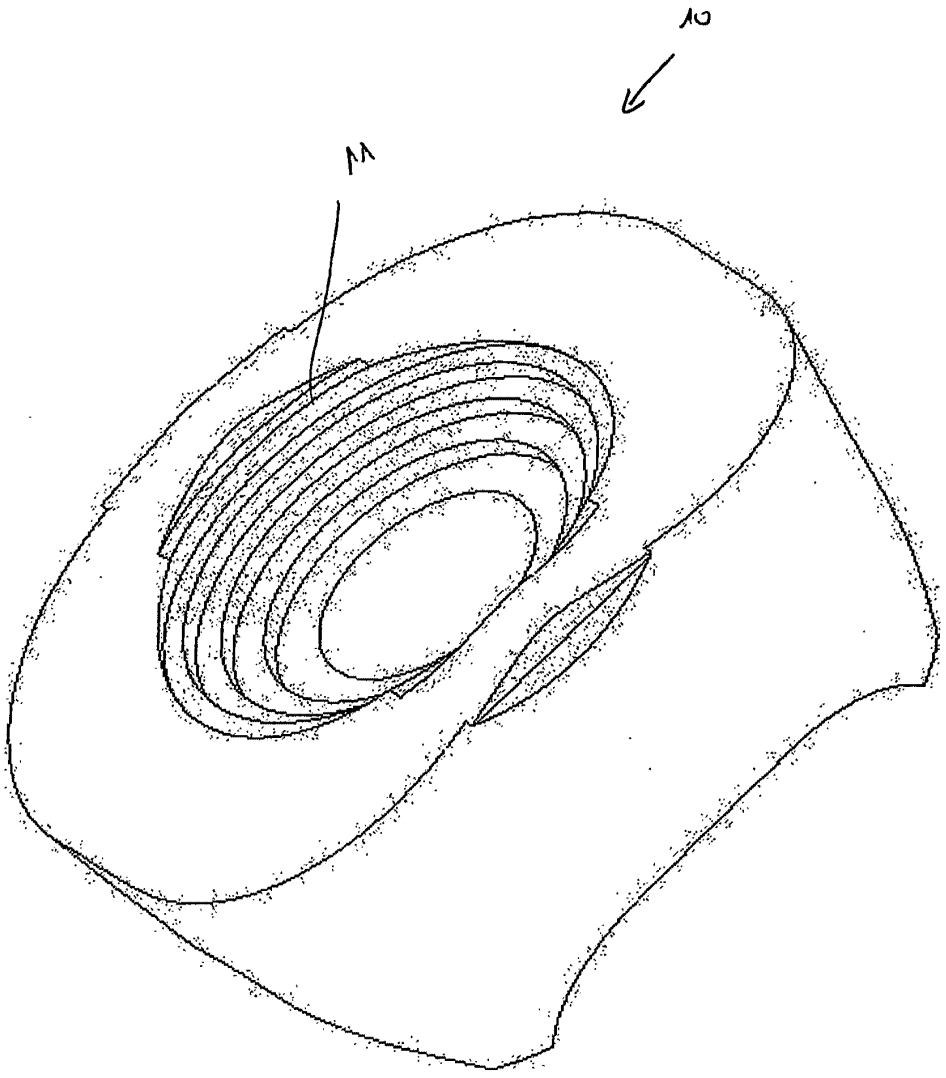


Fig. 8

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 873 of 2152

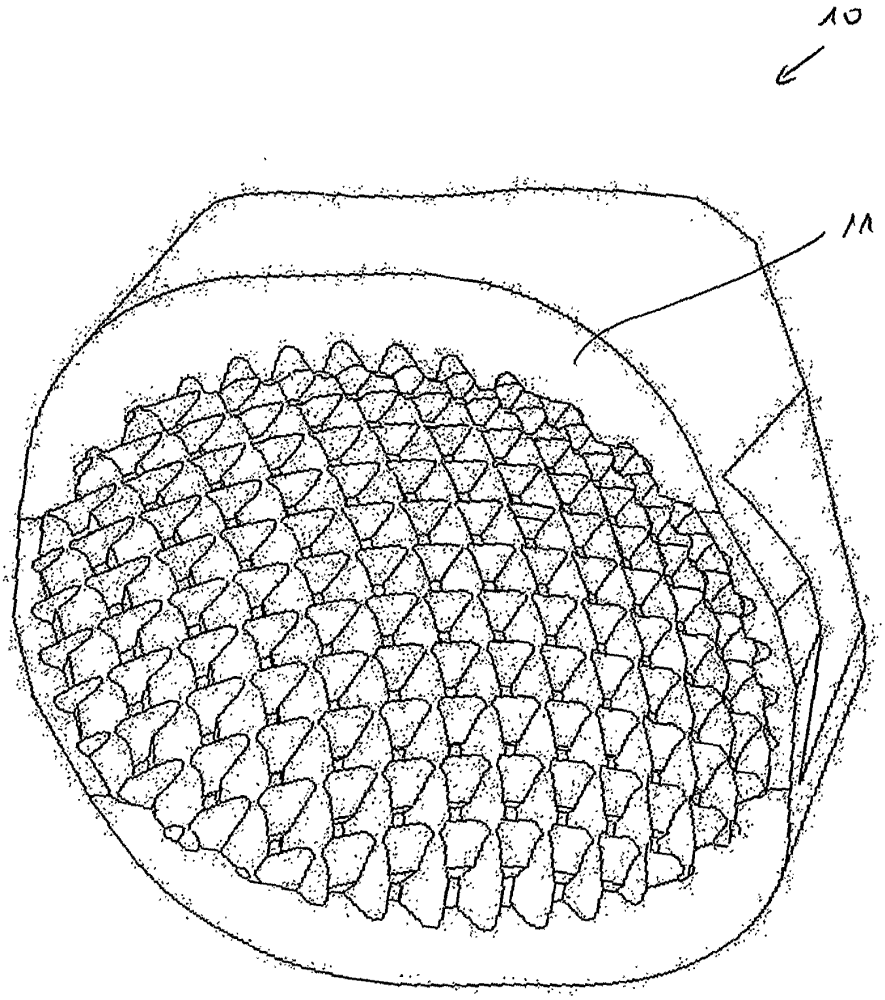


Fig. 9

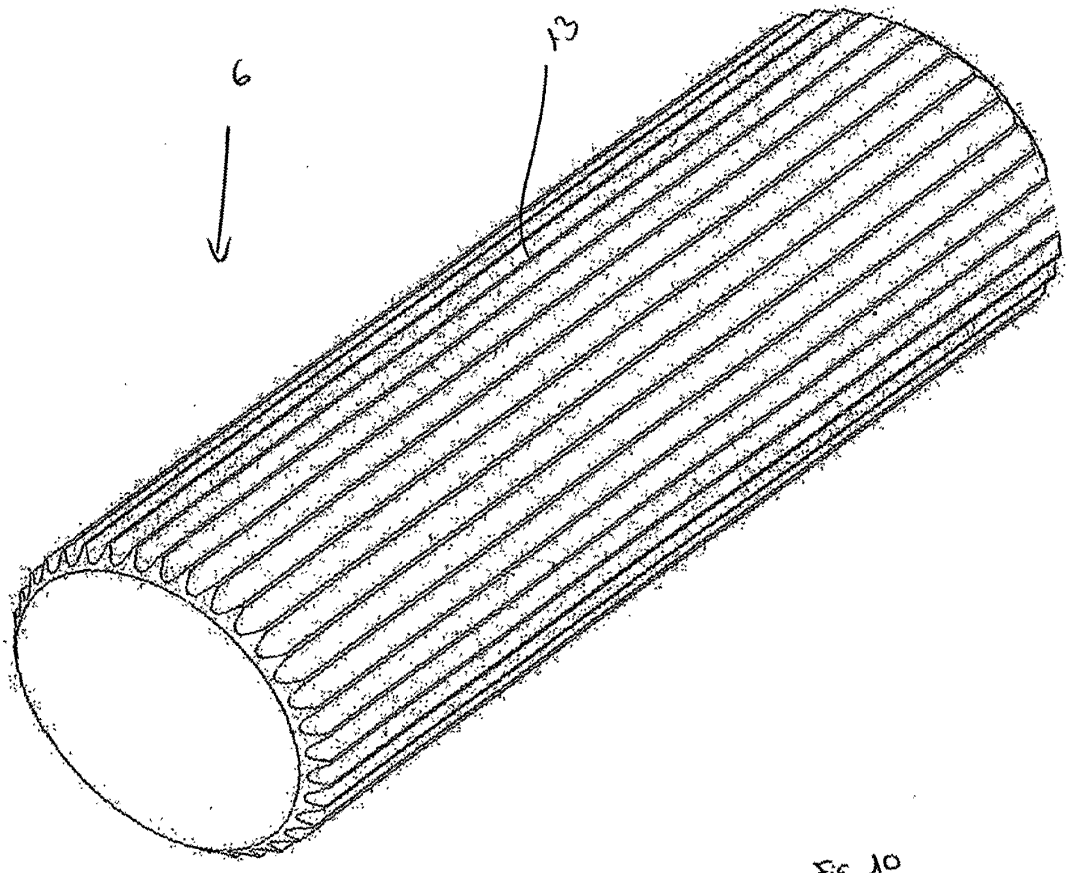


Fig. 10

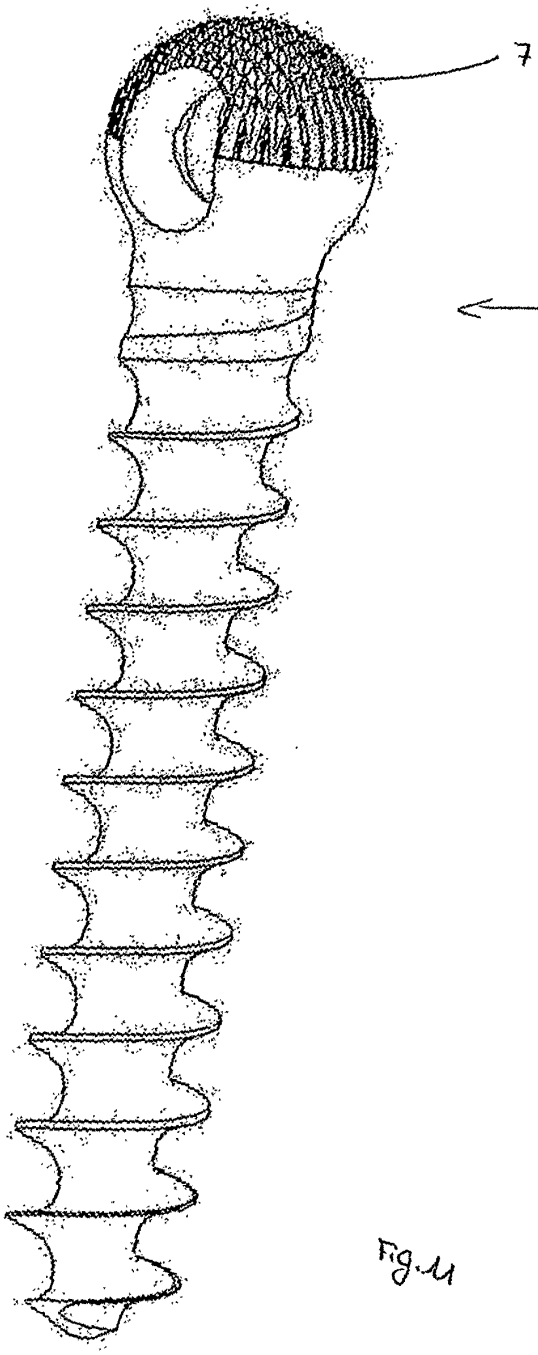


Fig.11

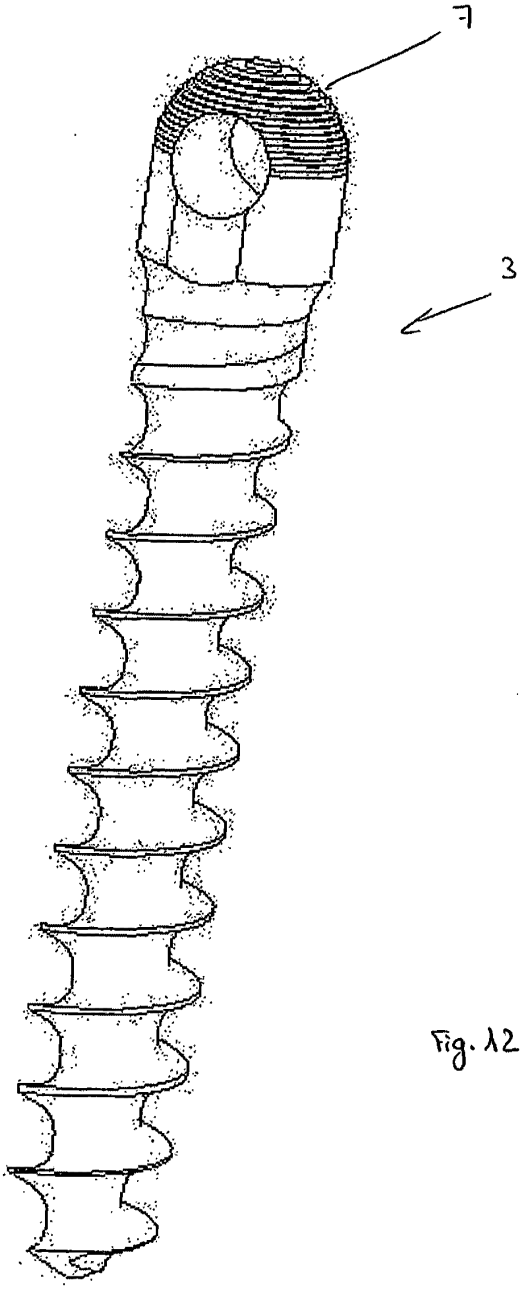


Fig. 12

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 877 of 2152

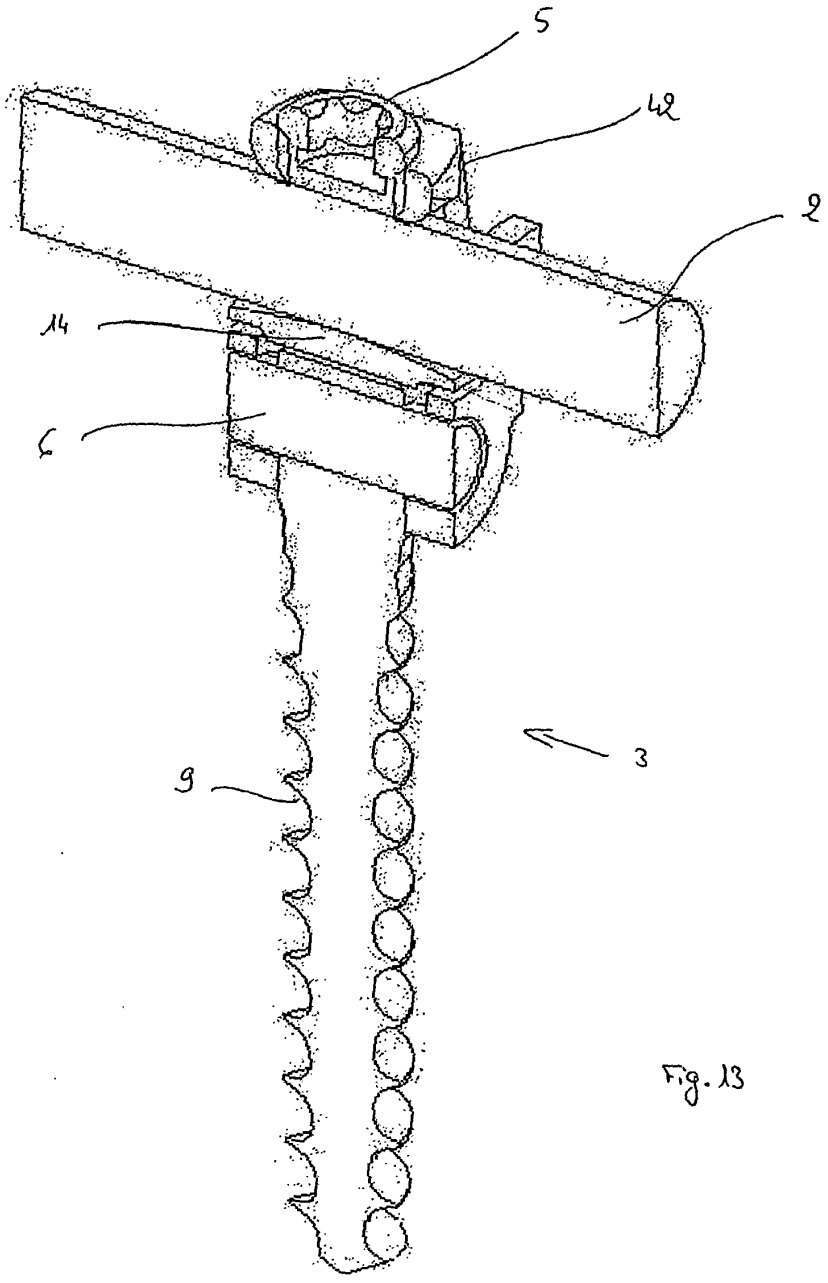


Fig. 13

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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
21 October 2004 (21.10.2004)

PCT

(10) International Publication Number
WO 2004/089245 A2

(51) International Patent Classification[7]: A61F

(21) International Application Number: PCT/US2004/010319

(22) International Filing Date: 2 April 2004 (02.04.2004)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/460,616 4 April 2003 (04.04.2003) US

(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).

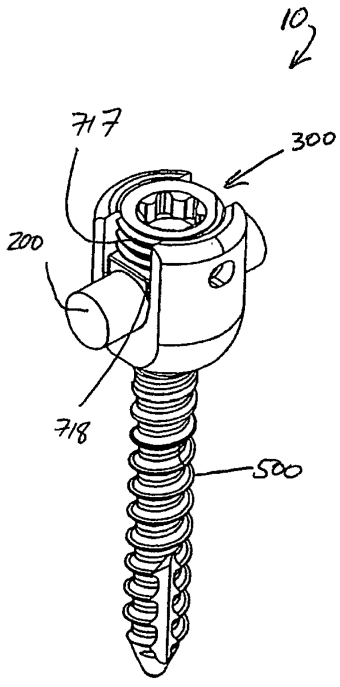
(74) Agent: **EICHENBERGER, Robert**; Frost Brown Todd LLC, 120 West Spring Street, Suite 400, New Albany, IN 47150 (US).

(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.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW),

[Continued on next page]

(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)*

— *of inventorship (Rule 4.17(iv)) for US only*

Published:

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

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

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

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 890 of 2152

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
IPR2023-01430; Petitioners' EX1002
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

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.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 896 of 2152

[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,

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 is:

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
IPR2023-01430; Petitioners' EX1002
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
IPR2023-01430; Petitioners' EX1002
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.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 908 of 2152

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.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 910 of 2152

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.

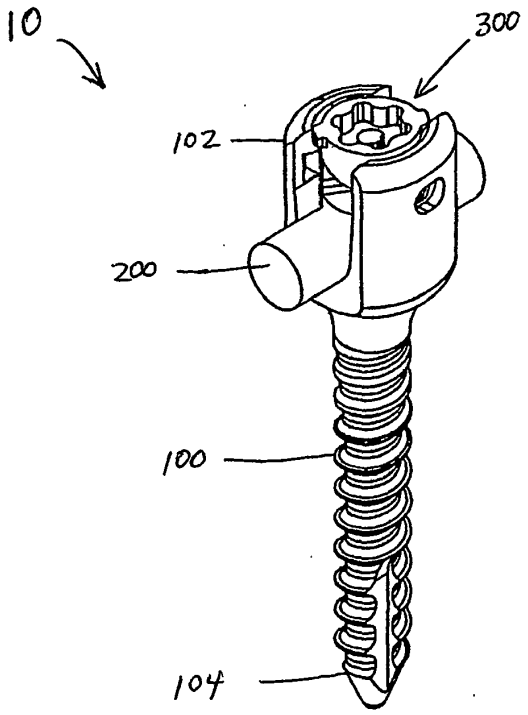


Fig 1

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 913 of 2152

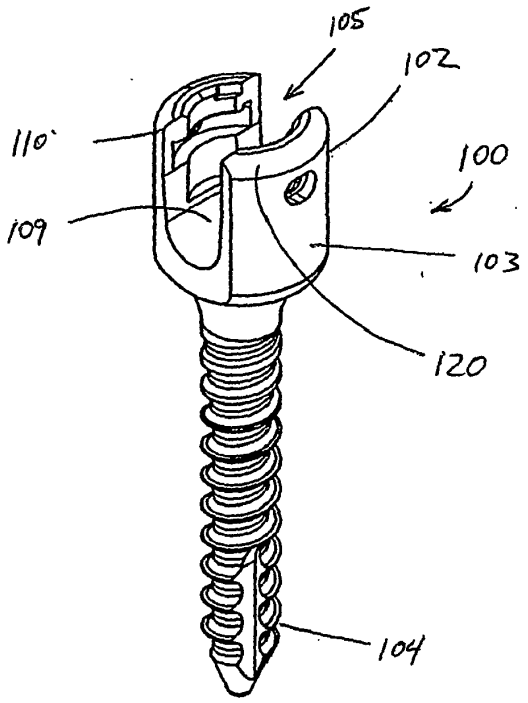
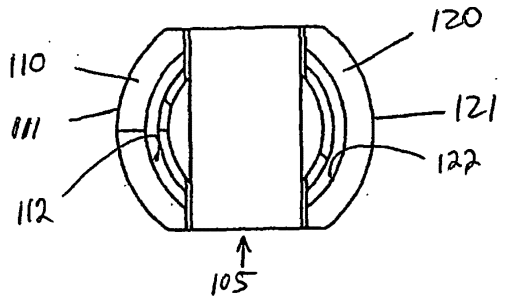


Fig. 2

Fig. 3



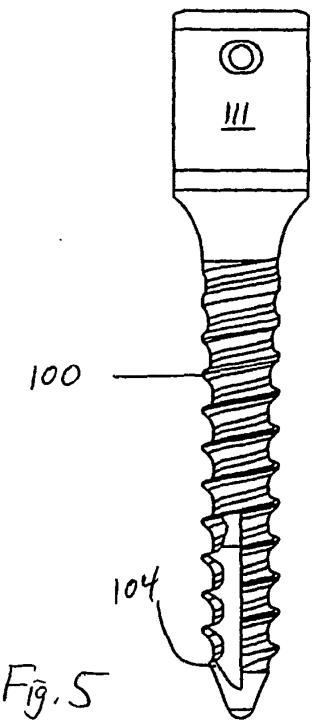


Fig. 5

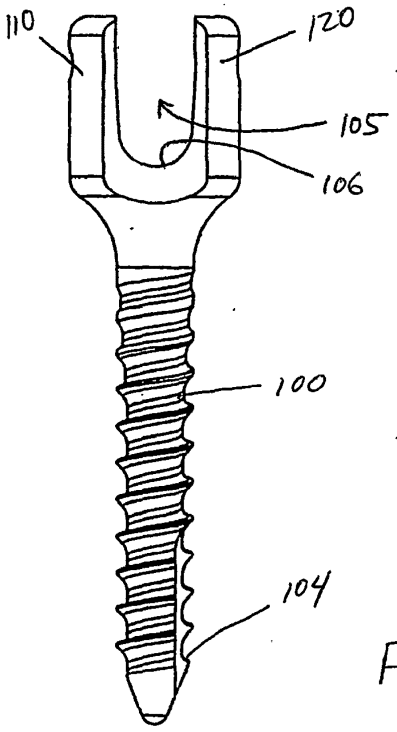


Fig. 4

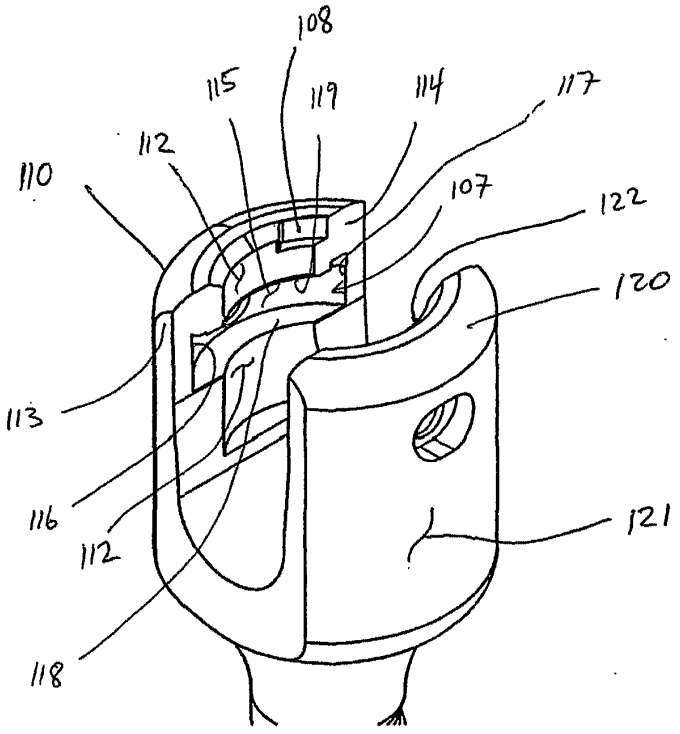


Fig. 6

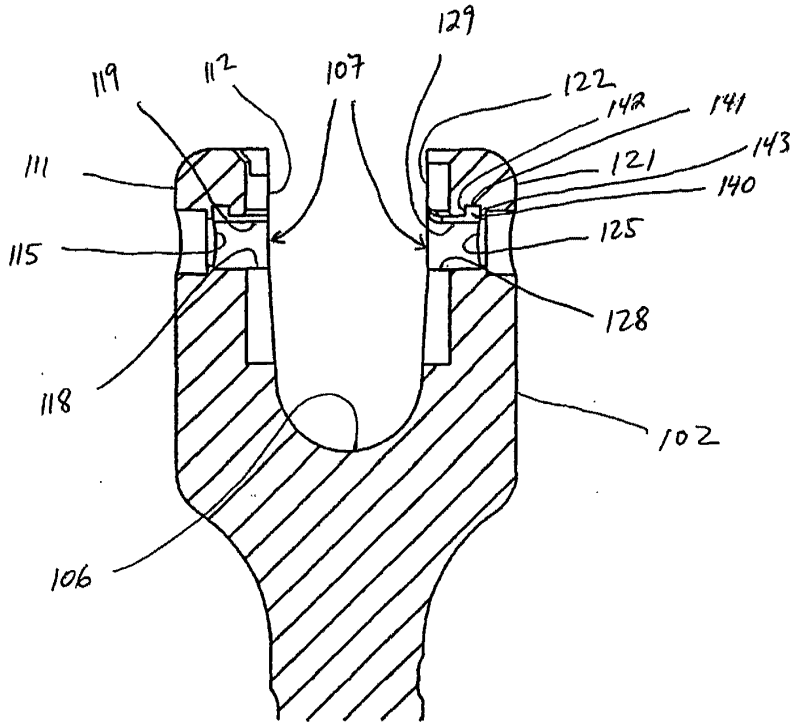

129
119
112
107
122
142
141
111
121
143
140
115
125
128
118
102
106

Fig. 7

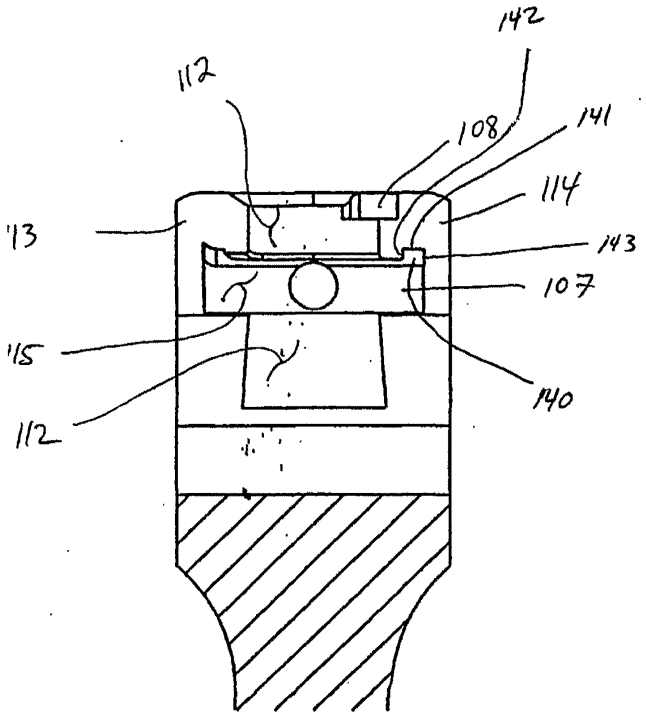
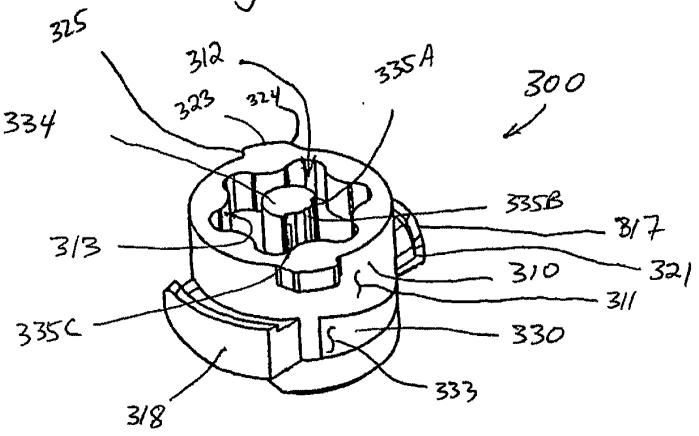


Fig. 8

Fig. 9



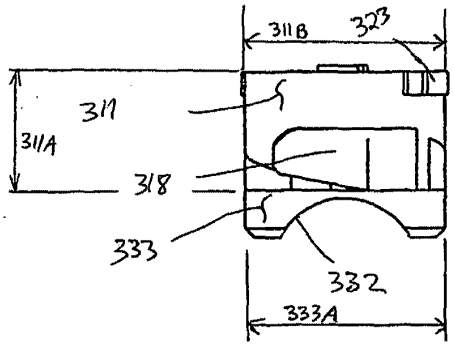


Fig. 10

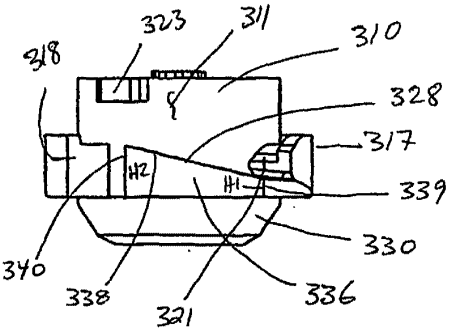
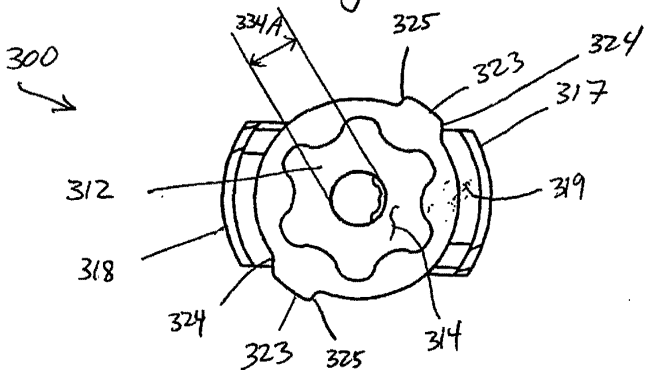


Fig. 11

Fig. 12



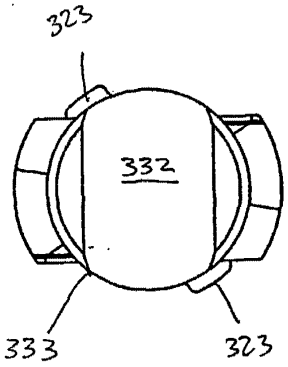


Fig. 13

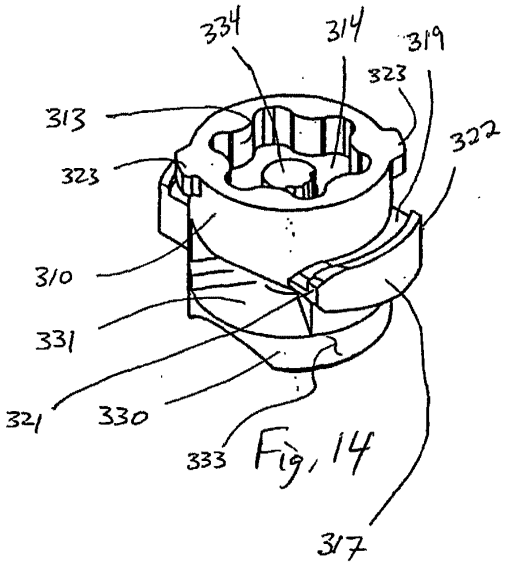


Fig. 14

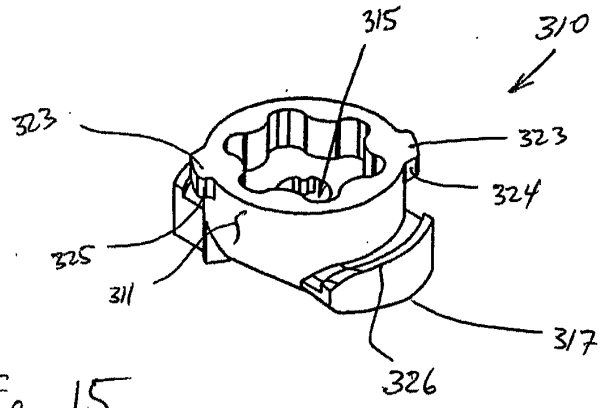

315
310
323
323
324
325
311
317
326

Fig. 15

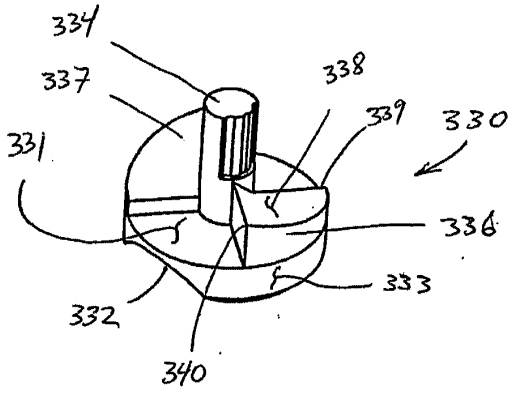

334
337
338
339
330
331
336
333
332
340

Fig. 16

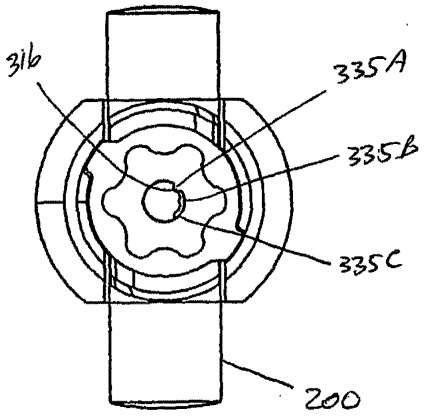


Fig. 17

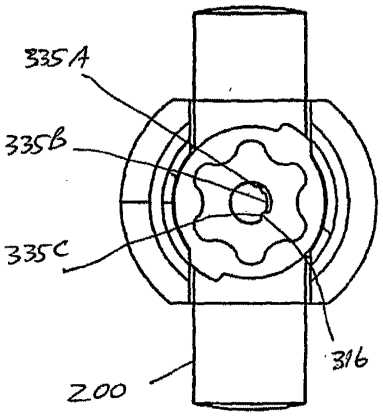


Fig. 18

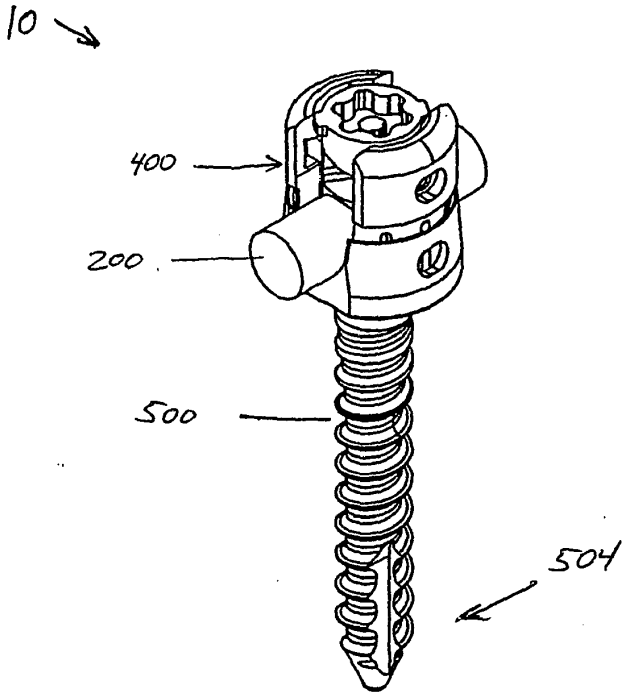


Fig. 19

Fig. 20

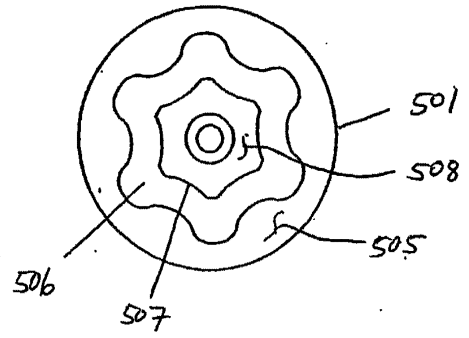


Fig. 21

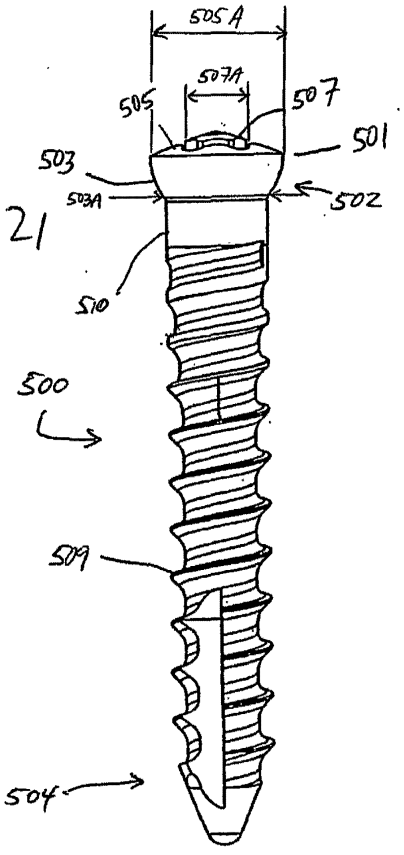
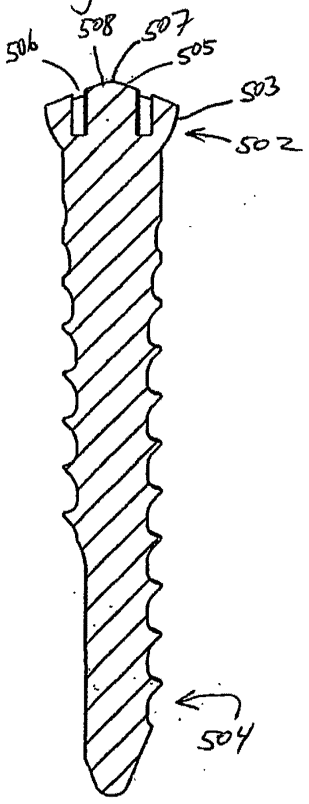


Fig. 22



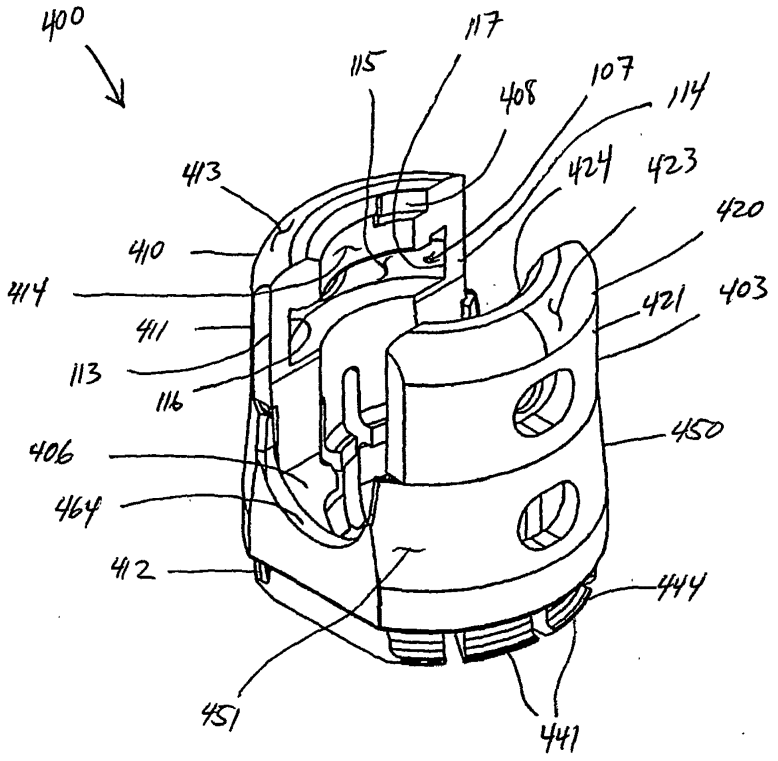
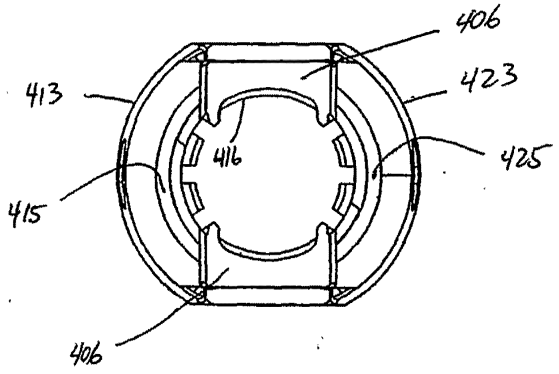

400
117
115
107
408
114
413
424
423
420
410
414
421
403
411
113
116
450
406
464
412
444
451
441

Fig. 23

Fig. 24



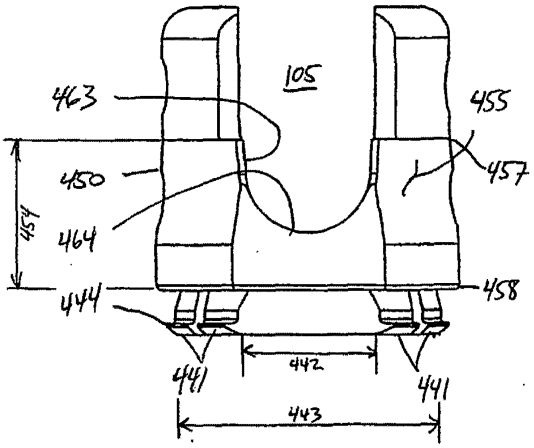


Fig. 25

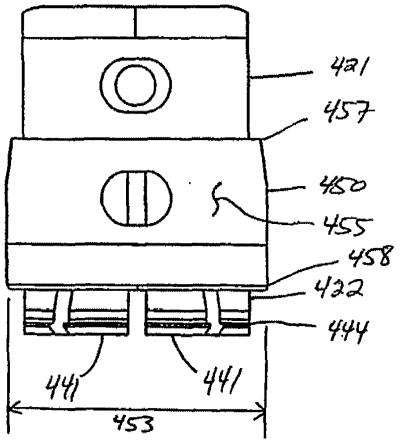


Fig. 26

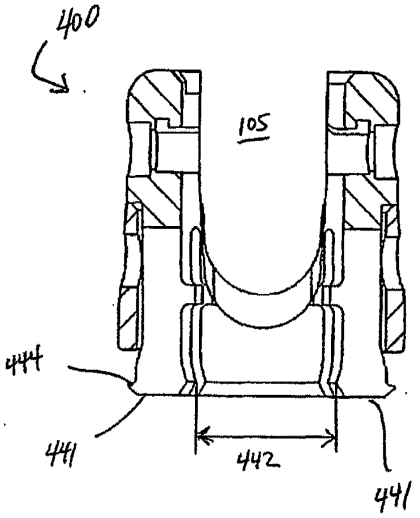


FIG. 25A

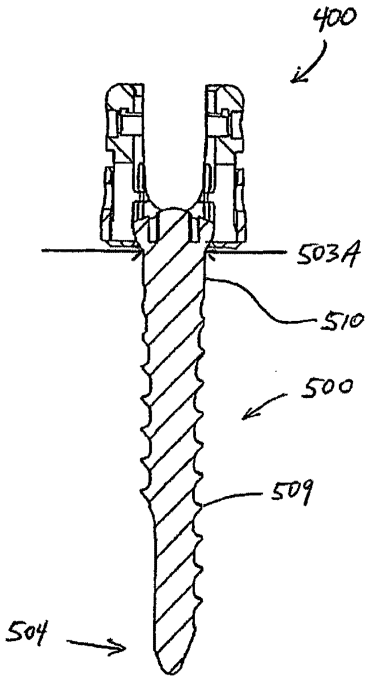


FIG. 25B

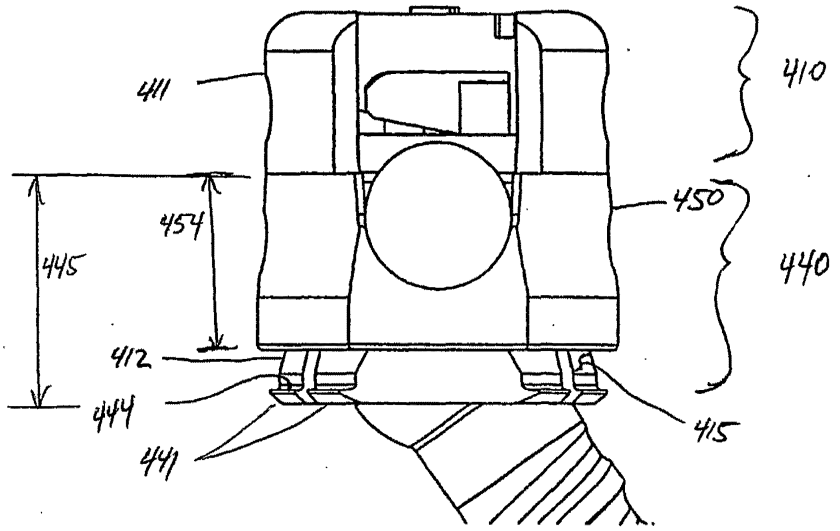


Fig. 27

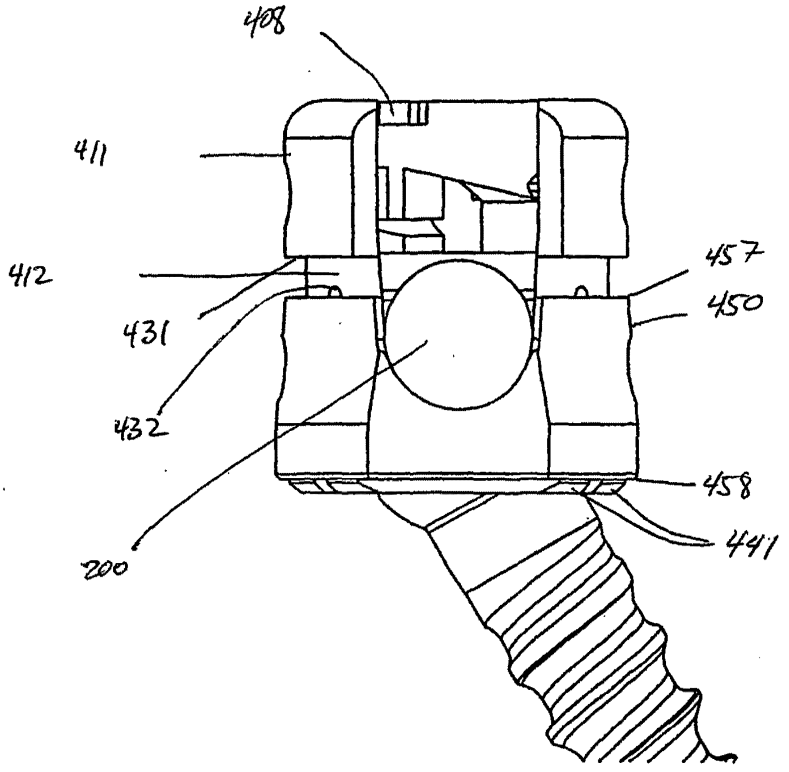


Fig. 28

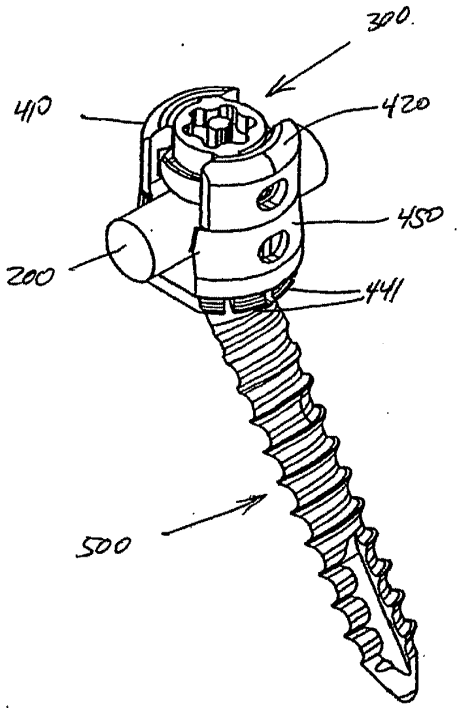


Fig. 29

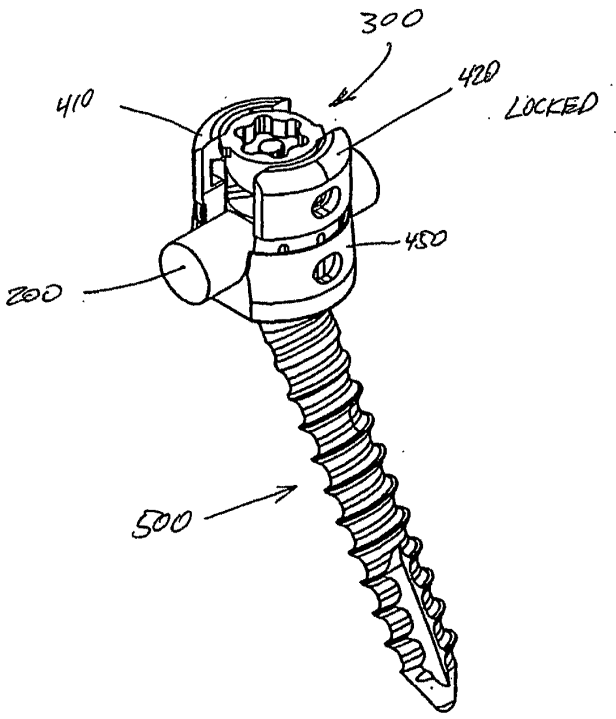


Fig. 30

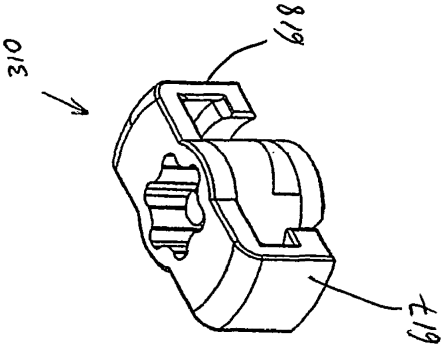


FIG. 33

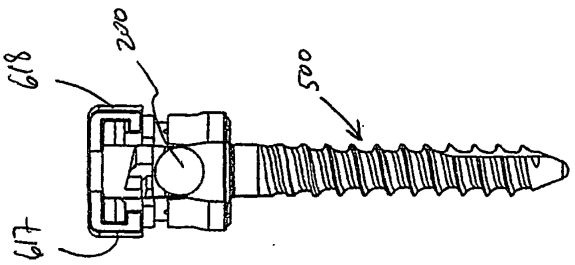


FIG. 32

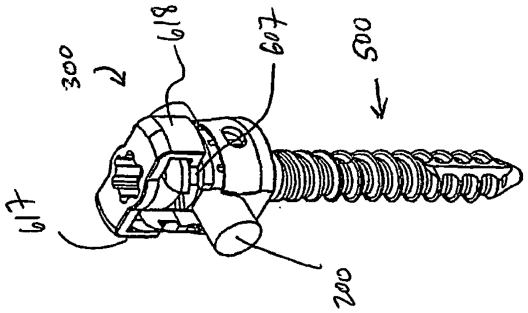


FIG. 31

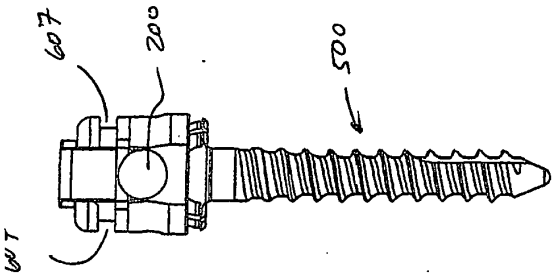


FIG. 36

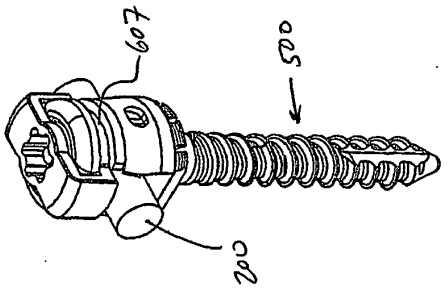


FIG. 35

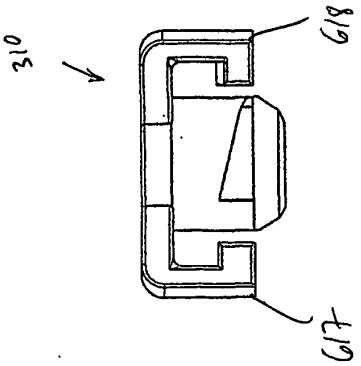


FIG. 34

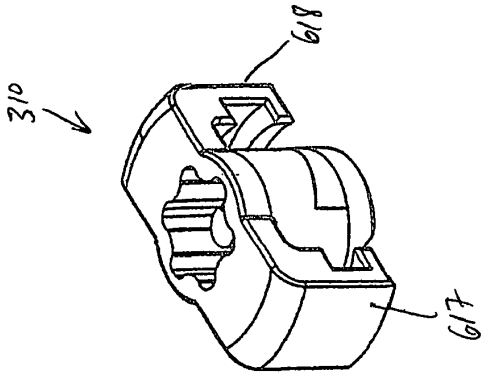


FIG. 39

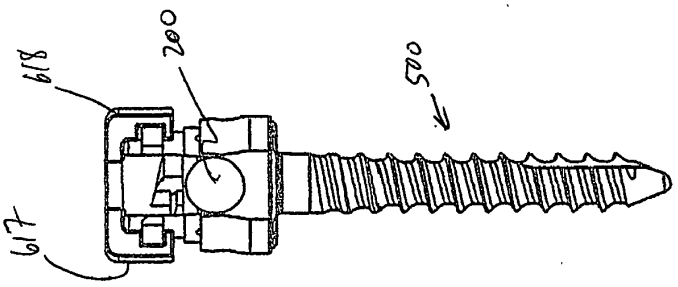


FIG. 38

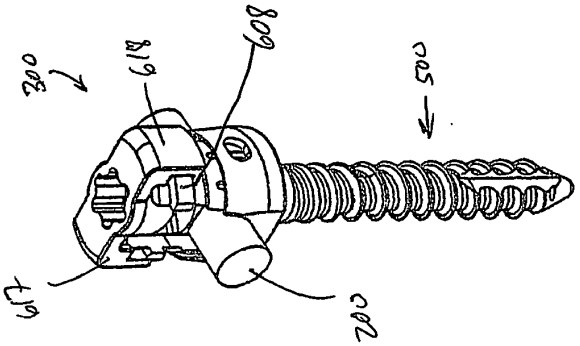


FIG. 37

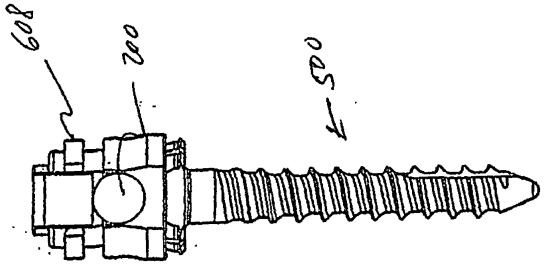


FIG. 42

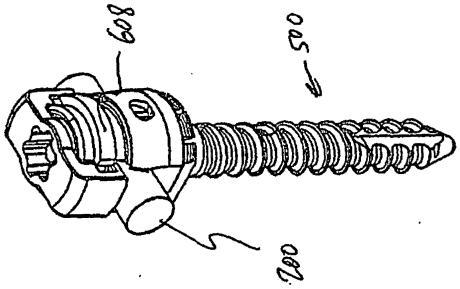


FIG. 41

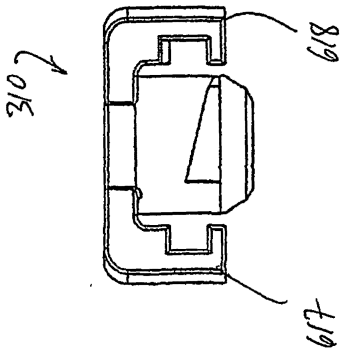


FIG. 40

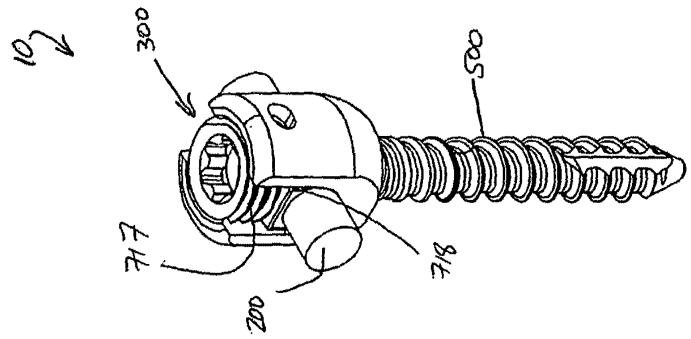


FIG. 43

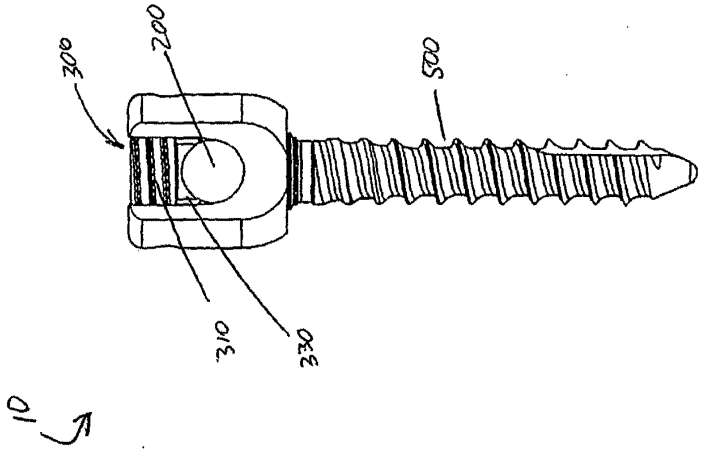


FIG. 44

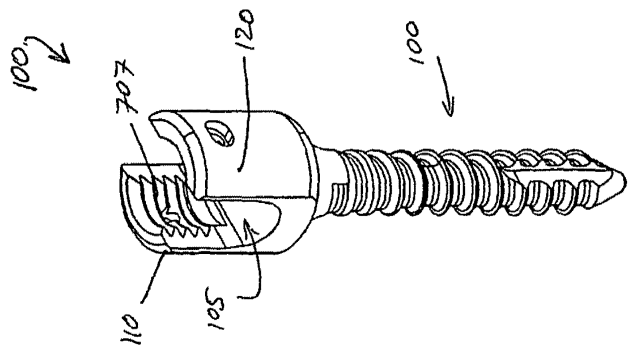


FIG. 45

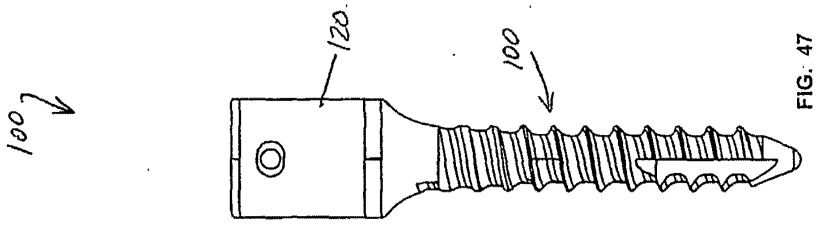


FIG. 47

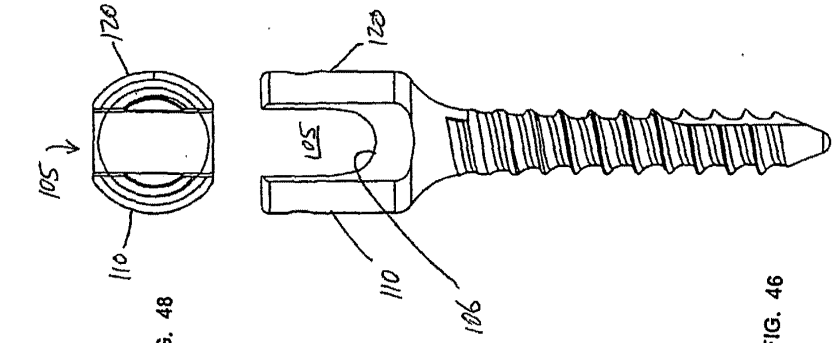


FIG. 48

FIG. 46

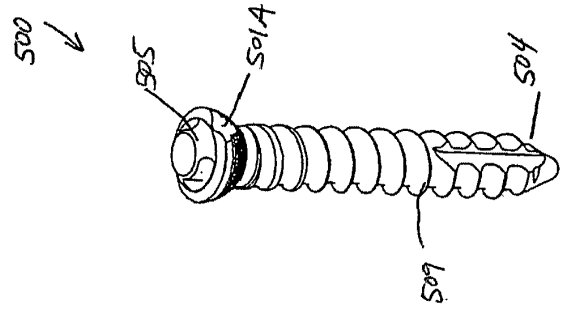


FIG. 49

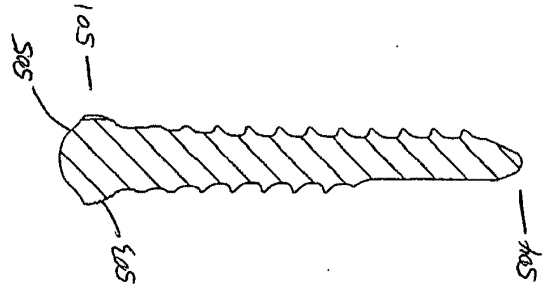


FIG. 51

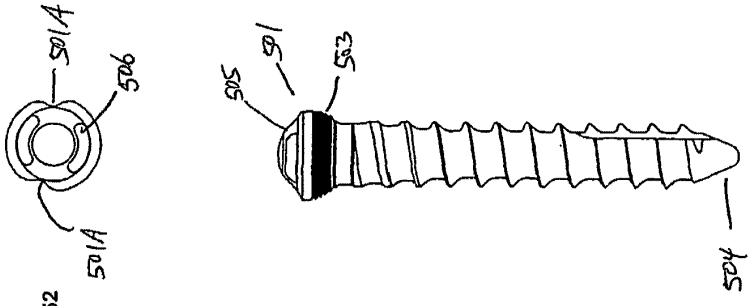


FIG. 52

FIG. 50

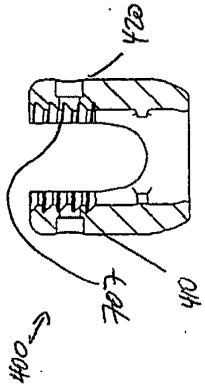


FIG. 55

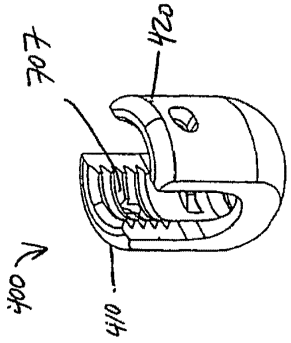


FIG. 53

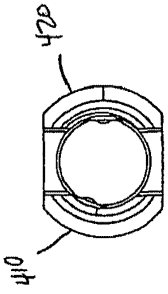


FIG. 56

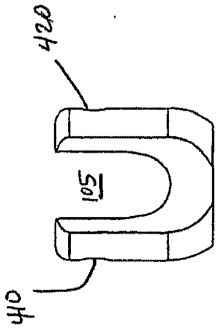
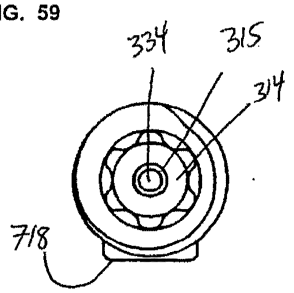


FIG. 54

FIG. 59



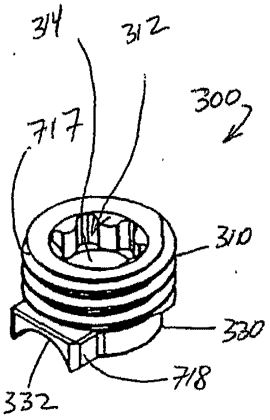


FIG. 57

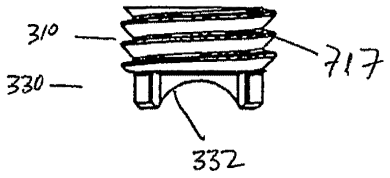


FIG. 58

(19) RÉPUBLIQUE FRANÇAISE

INSTITUT NATIONAL
DE LA PROPRIÉTÉ INDUSTRIELLE

PARIS

(11) N° de publication : **2 865 378**
(à n'utiliser que pour les commandes de reproduction)

(21) N° d'enregistrement national : **04 11266**

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

(12) DEMANDE DE BREVET D'INVENTION A1

(22) **Date de dépôt :** 22.10.04.

(30) **Priorité :** 27.01.04 FR 0400745.

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

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

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

(71) **Demandeur(s) :** *MEDICREA INTERNATIONAL Société anonyme* — FR.

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

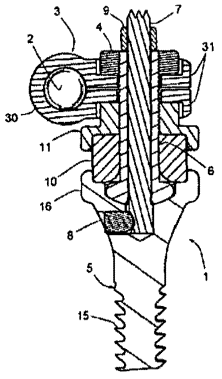
(73) **Titulaire(s) :**

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

(54) MATERIEL D'OSTEOSYNTHESE 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
IPR2023-01430; Petitioners' EX1002
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

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.

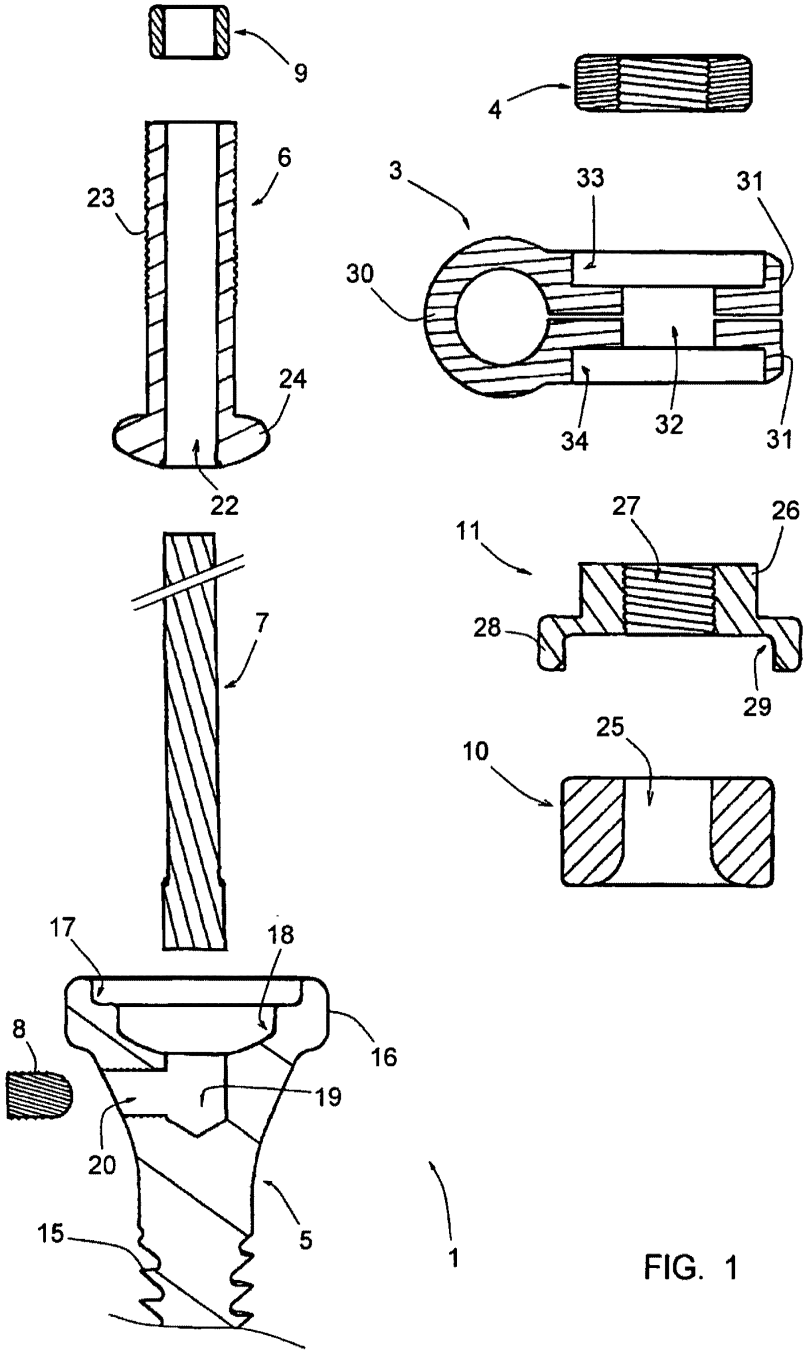
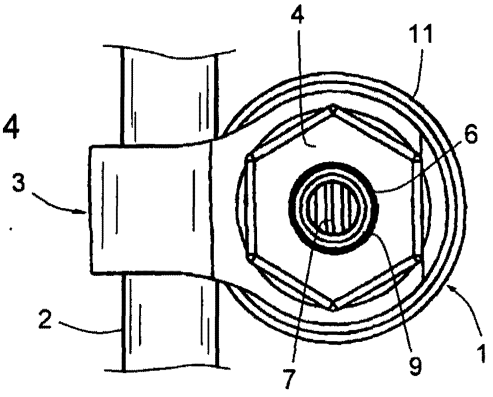

9
4
6
23
3
33
31
30
24
34
32
31
22
27
26
11
7
28
29
25
10
17
18
8
16
19
20
5
15
1

FIG. 1

FIG. 4



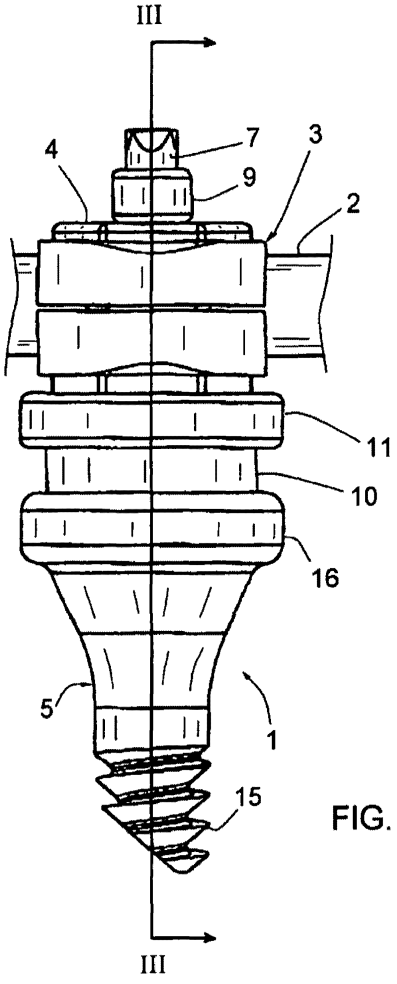


FIG. 2

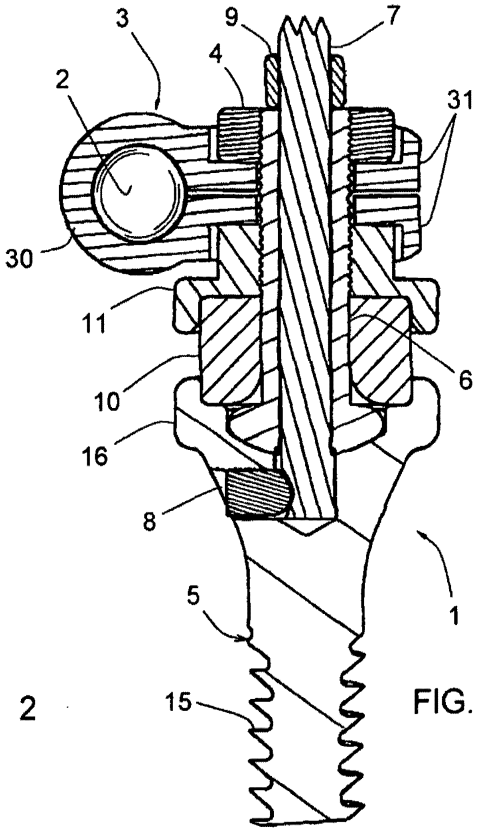


FIG. 3

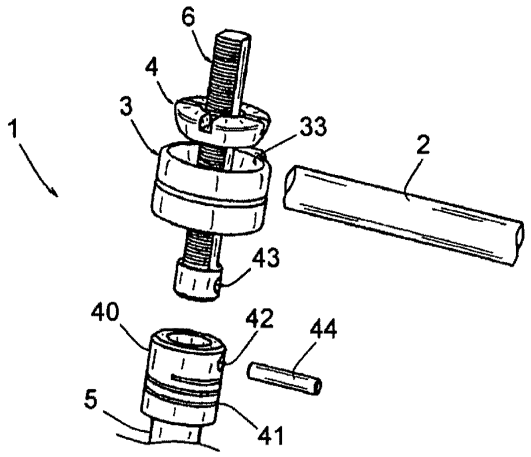


FIG. 5

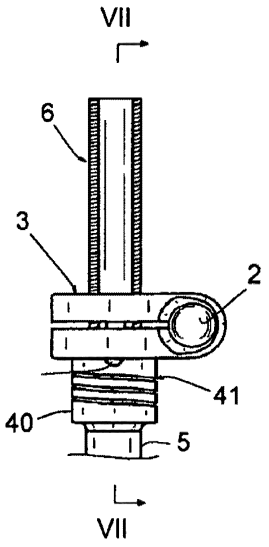


FIG. 6

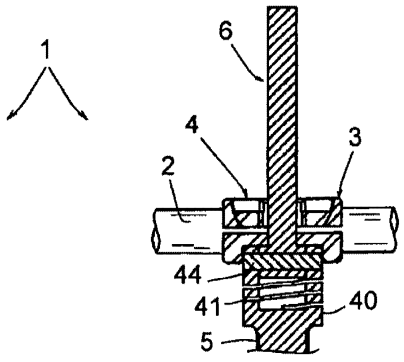


FIG. 7

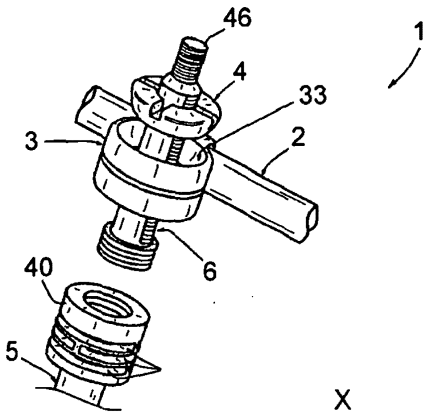


FIG. 8

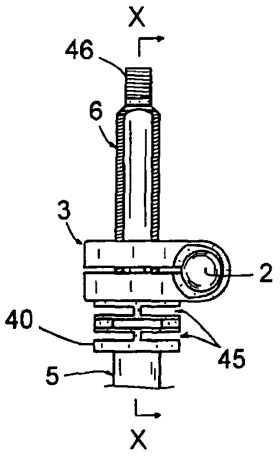


FIG. 9

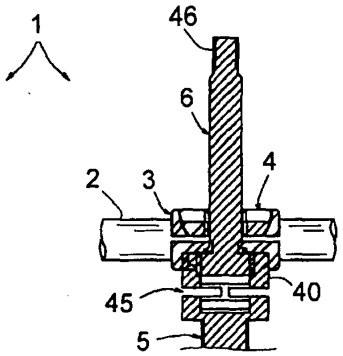


FIG. 10

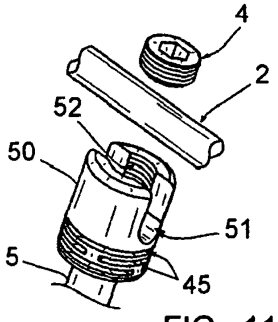


FIG. 11

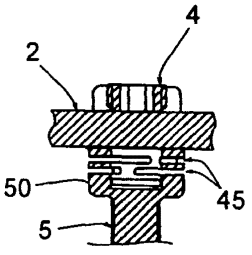


FIG. 12

RÉPUBLIQUE FRANÇAISE

2865378

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
Y		4,5,8,9	

Y	WO 03/047441 A1 (MATHYS MEDIZINALTECHNIK AG; STUDER, ARMIN) 12 juin 2003 (2003-06-12) * figures 3-5 *	4,5	

Y	WO 03/068088 A (CROSS MED PROD INC) 21 août 2003 (2003-08-21) * page 5, ligne 3 - page 6, ligne 9; figures 1,2 *	8,9	

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	DOMAINES TECHNIQUES RECHERCHÉS (Int.CL.7) A61B

X	WO 00/15125 A (SYNTHES AG ; BRACE MICHAEL (US); SYNTHES USA (US); LANGE ERIC (US)) 23 mars 2000 (2000-03-23) * page 4, alinéa 8 - page 5, alinéa 3; figures 1,2 *	1	

A	FR 2 827 498 A1 (FORTIN FREDERIC) 24 janvier 2003 (2003-01-24) * abrégé; figures 1-3 *	1,3	

A	FR 2 697 742 A1 (BIOMAT) 13 mai 1994 (1994-05-13) * page 11, ligne 14 - page 12, ligne 9; figure 1 *	1	

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

EPO FORM 1503 12.99 (P04C14)

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 959 of 2152

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

Document brevet cité au rapport de recherche		Date de publication	Membre(s) de la famille de brevet(s)		Date de publication
US 4946458	A	07-08-1990	DE	3614101 C1	22-10-1987
			AT	82484 T	15-12-1992
			CA	1328591 C	19-04-1994
			DE	3782678 D1	24-12-1992
			EP	0242708 A2	28-10-1987
			ES	2035826 T3	01-05-1993
			JP	1802142 C	26-11-1993
			JP	5008011 B	01-02-1993
			JP	62277954 A	02-12-1987
			KR	9506929 B1	26-06-1995
WO 03047441	A1	12-06-2003	AU	2002218099 A1	17-06-2003
			AU	2002242566 A1	17-06-2003
			BR	0117188 A	09-11-2004
			BR	0214584 A	03-11-2004
			CA	2469005 A1	12-06-2003
			CA	2469008 A1	12-06-2003
			WO	03047442 A1	12-06-2003
			EP	1450707 A1	01-09-2004
			EP	1450708 A1	01-09-2004
WO 03068088	A	21-08-2003	US	2004006342 A1	08-01-2004
			US	2003163133 A1	28-08-2003
			AU	2003210964 A1	04-09-2003
			EP	1474053 A1	10-11-2004
			WO	03068088 A1	21-08-2003
US 5882350	A	16-03-1999	US	5669911 A	23-09-1997
			US	5520690 A	28-05-1996
			US	RE37665 E1	16-04-2002
			AT	250393 T	15-10-2003
			AU	714659 B2	06-01-2000
			AU	5539796 A	30-10-1996
			CA	2216955 A1	17-10-1996
			DE	69630117 D1	30-10-2003
			DE	69630117 T2	09-06-2004
			EP	1364623 A1	26-11-2003
			EP	0828459 A1	18-03-1998
			JP	3497865 B2	16-02-2004
			JP	11503351 T	26-03-1999
			US	2002045899 A1	18-04-2002
			WO	9632071 A1	17-10-1996
			US	5531746 A	02-07-1996
			US	5643265 A	01-07-1997
			US	5647873 A	15-07-1997
			US	5607426 A	04-03-1997

EPO FORM P0465

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 960 of 2152

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

Document brevet cité au rapport de recherche	Date de publication	Membre(s) de la famille de brevet(s)	Date de publication
US 5882350 A		US 5876402 A	02-03-1999
		US 5725588 A	10-03-1998
		US 5690630 A	25-11-1997
		US 5817094 A	06-10-1998
WO 0015125 A	23-03-2000	AU 751174 B2	08-08-2002
		AU 5404799 A	03-04-2000
		CA 2343327 A1	23-03-2000
		WO 0015125 A1	23-03-2000
		EP 1109502 A1	27-06-2001
		JP 2002524188 T	06-08-2002
		US 6187005 B1	13-02-2001
		ZA 200100673 A	28-08-2001
FR 2827498 A1	24-01-2003	CA 2453989 A1	30-01-2003
		EP 1408860 A1	21-04-2004
		WO 03007828 A1	30-01-2003
FR 2697742 A1	13-05-1994	AT 146064 T	15-12-1996
		CA 2109457 A1	07-05-1994
		DE 69306536 D1	23-01-1997
		DE 69306536 T2	28-05-1997
		EP 0596788 A1	11-05-1994
		ES 2096249 T3	01-03-1997
		GR 3022754 T3	30-06-1997
		JP 2666683 B2	22-10-1997
		JP 6165789 A	14-06-1994
		US 5380325 A	10-01-1995

EPO FORM P0465

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 961 of 2152

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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
21 May 2004 (21.05.2004)

PCT

(10) International Publication Number
WO 2004/041100 A1

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

(21) International Application Number:
PCT/US2003/034469

(22) International Filing Date: 30 October 2003 (30.10.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

60/422,455	30 October 2002 (30.10.2002)	US
60/466,091	28 April 2003 (28.04.2003)	US
60/471,254	16 May 2003 (16.05.2003)	US

(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).

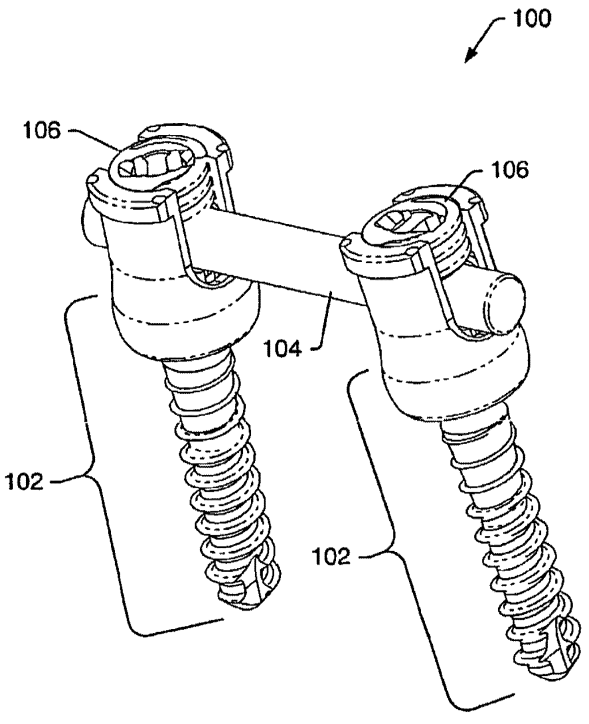
(74) Agent: MEYERTONS, Eric, B.; Meyertons, Hood, Kivlin, Kowert & Goetzel, P.C., P.O. Box 398, Austin, TX 78767-0398 (US).

(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, 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, 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.

(84) Designated States *(regional)*: ARIPO patent (BW, GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW),

[Continued on next page]

(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
IPR2023-01430; Petitioners' EX1002
Page 962 of 2152

Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report*

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

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

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
IPR2023-01430; Petitioners' EX1002
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
IPR2023-01430; Petitioners' EX1002
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
IPR2023-01430; Petitioners' EX1002
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
IPR2023-01430; Petitioners' EX1002
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
IPR2023-01430; Petitioners' EX1002
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
IPR2023-01430; Petitioners' EX1002
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
IPR2023-01430; Petitioners' EX1002
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
IPR2023-01430; Petitioners' EX1002
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
IPR2023-01430; Petitioners' EX1002
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
IPR2023-01430; Petitioners' EX1002
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
IPR2023-01430; Petitioners' EX1002
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
IPR2023-01430; Petitioners' EX1002
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
IPR2023-01430; Petitioners' EX1002
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
IPR2023-01430; Petitioners' EX1002
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
IPR2023-01430; Petitioners' EX1002
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
IPR2023-01430; Petitioners' EX1002
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
IPR2023-01430; Petitioners' EX1002
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
IPR2023-01430; Petitioners' EX1002
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
IPR2023-01430; Petitioners' EX1002
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
IPR2023-01430; Petitioners' EX1002
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
IPR2023-01430; Petitioners' EX1002
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
IPR2023-01430; Petitioners' EX1002
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
IPR2023-01430; Petitioners' EX1002
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
IPR2023-01430; Petitioners' EX1002
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
IPR2023-01430; Petitioners' EX1002
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
IPR2023-01430; Petitioners' EX1002
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
IPR2023-01430; Petitioners' EX1002
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
IPR2023-01430; Petitioners' EX1002
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
IPR2023-01430; Petitioners' EX1002
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
IPR2023-01430; Petitioners' EX1002
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
IPR2023-01430; Petitioners' EX1002
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
IPR2023-01430; Petitioners' EX1002
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
IPR2023-01430; Petitioners' EX1002
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
IPR2023-01430; Petitioners' EX1002
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
IPR2023-01430; Petitioners' EX1002
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
IPR2023-01430; Petitioners' EX1002
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
IPR2023-01430; Petitioners' EX1002
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
IPR2023-01430; Petitioners' EX1002
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
IPR2023-01430; Petitioners' EX1002
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
IPR2023-01430; Petitioners' EX1002
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
IPR2023-01430; Petitioners' EX1002
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
IPR2023-01430; Petitioners' EX1002
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
IPR2023-01430; Petitioners' EX1002
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
IPR2023-01430; Petitioners' EX1002
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
IPR2023-01430; Petitioners' EX1002
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
IPR2023-01430; Petitioners' EX1002
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
IPR2023-01430; Petitioners' EX1002
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
IPR2023-01430; Petitioners' EX1002
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
IPR2023-01430; Petitioners' EX1002
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
IPR2023-01430; Petitioners' EX1002
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
IPR2023-01430; Petitioners' EX1002
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
IPR2023-01430; Petitioners' EX1002
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
IPR2023-01430; Petitioners' EX1002
Page 1016 of 2152

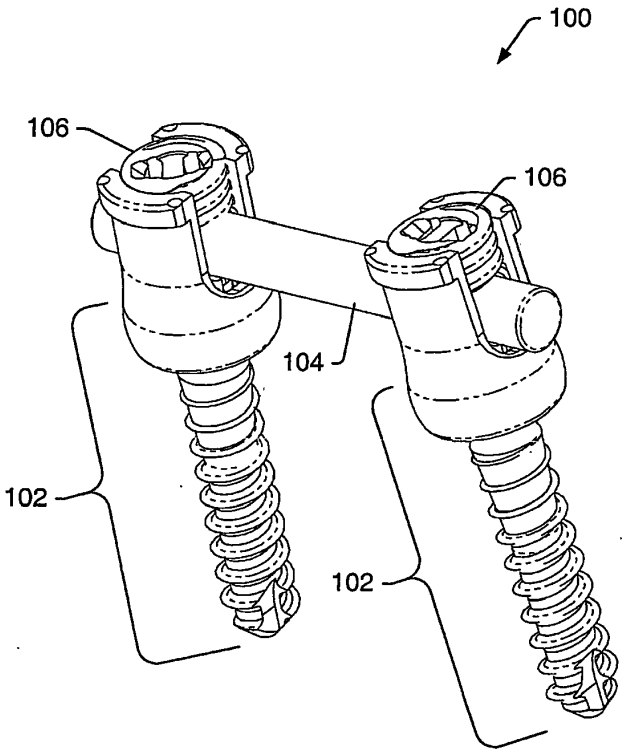


FIG. 1

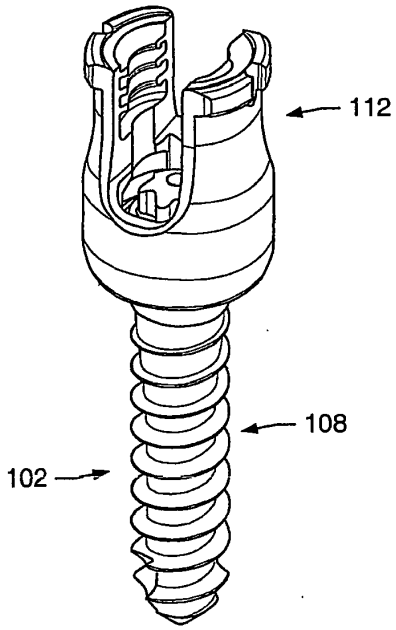


FIG. 2

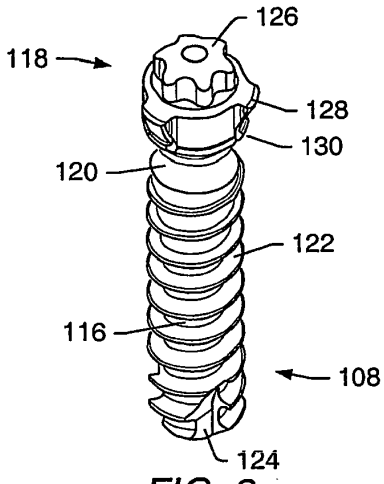


FIG. 3

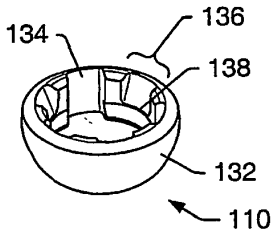


FIG. 4A

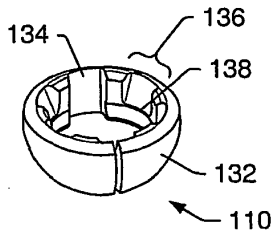


FIG. 4B

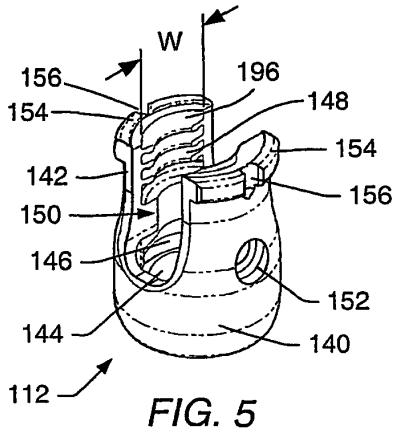


FIG. 5

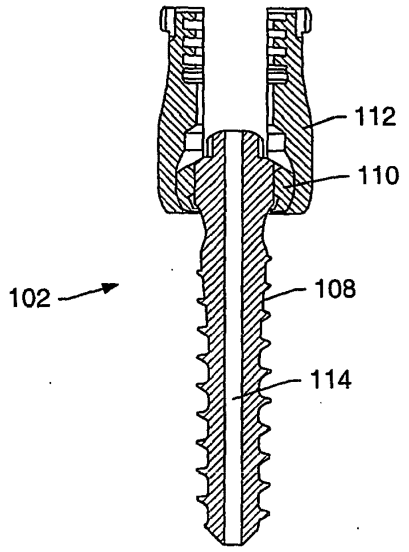


FIG. 6

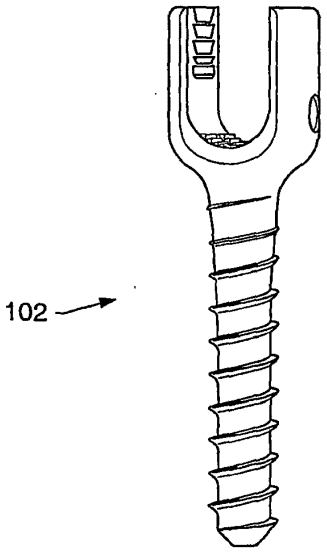


FIG. 7

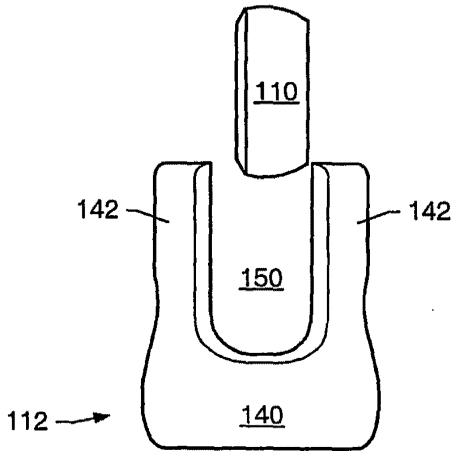


FIG. 8A

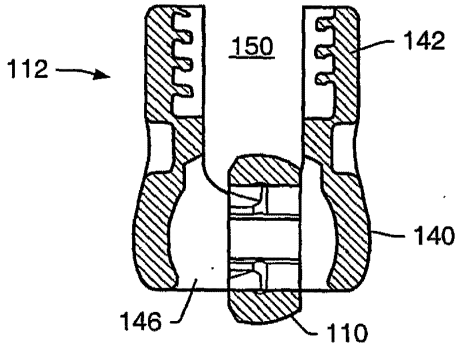


FIG. 8B

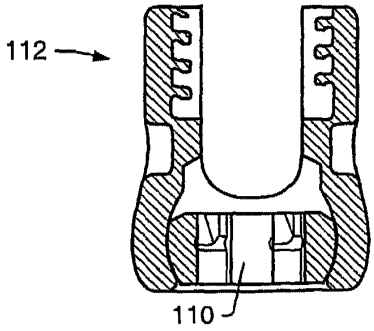


FIG. 8C

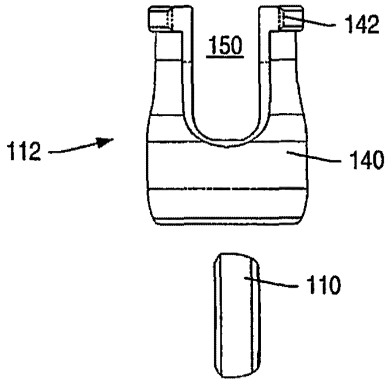


FIG. 9A

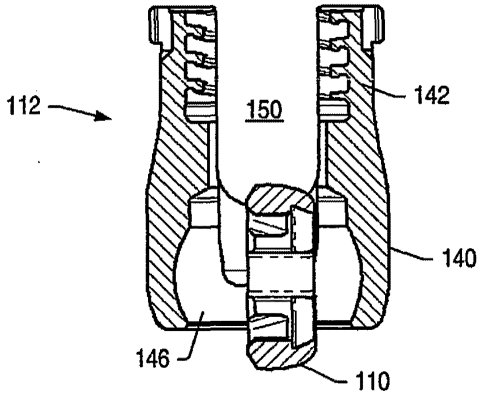


FIG. 9B

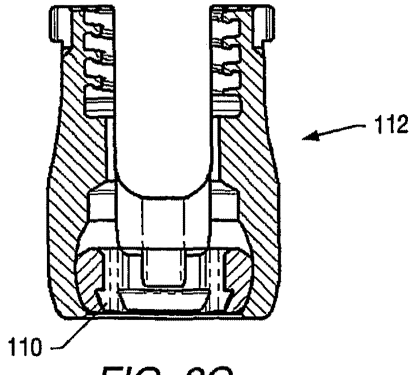


FIG. 9C

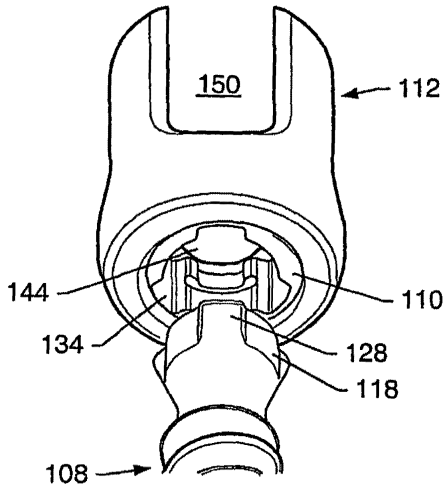


FIG. 10A

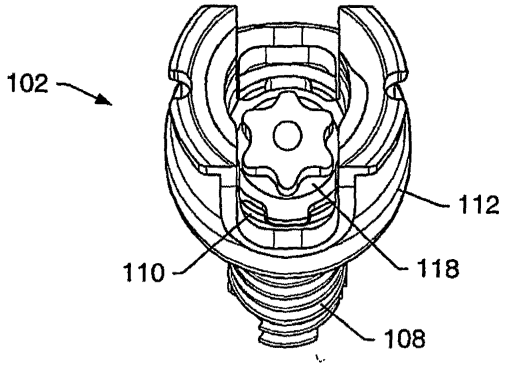


FIG. 10B

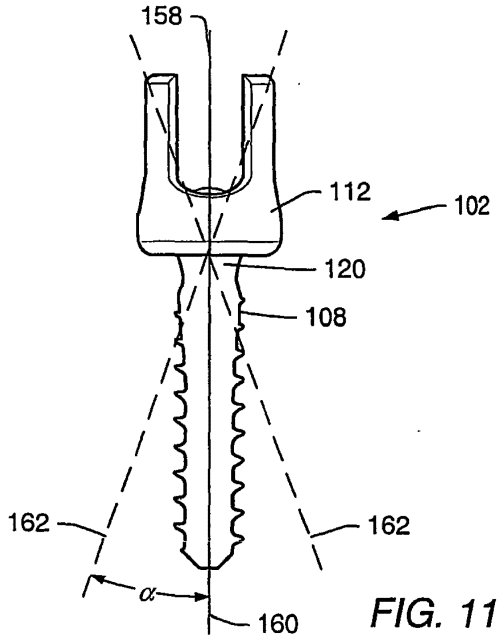


FIG. 11

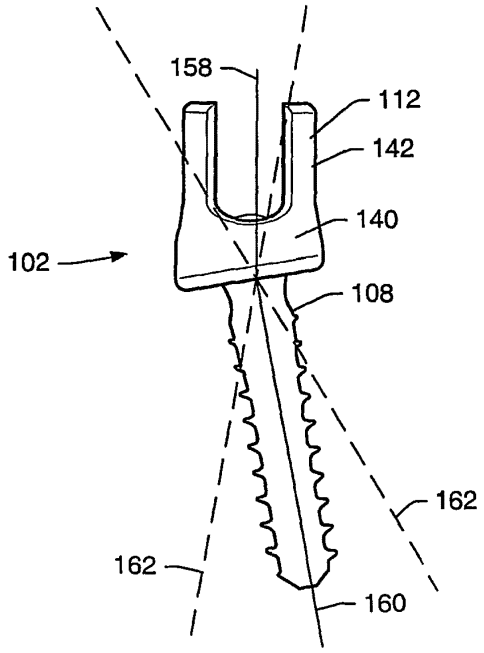


FIG. 12A

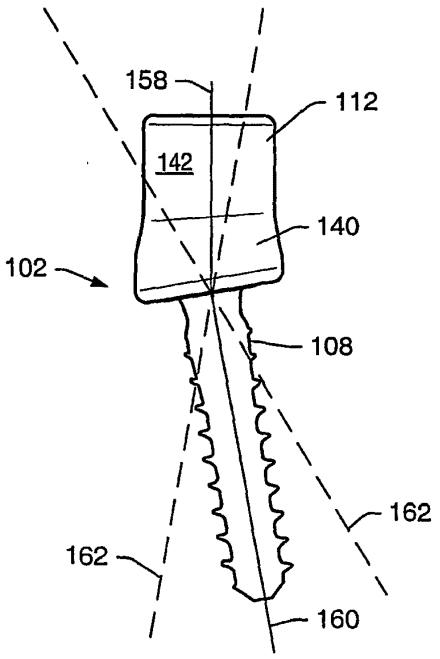


FIG. 12B

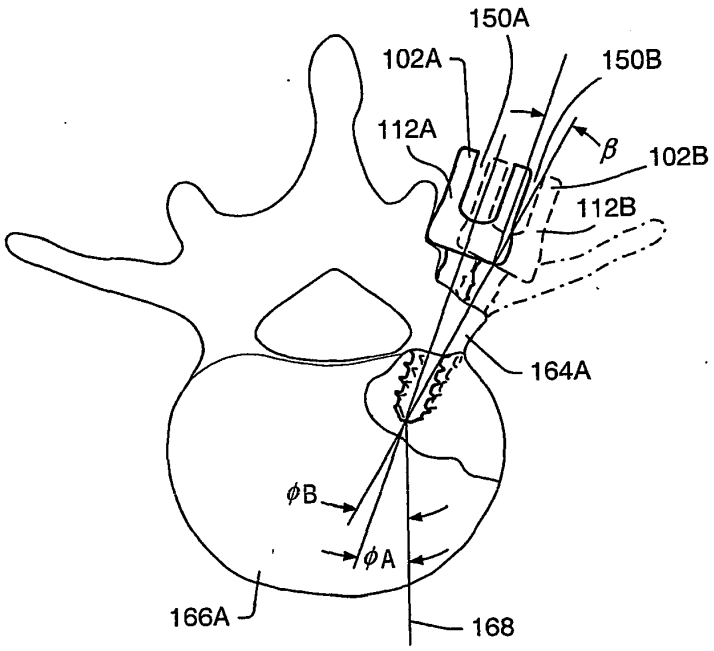


FIG. 13A

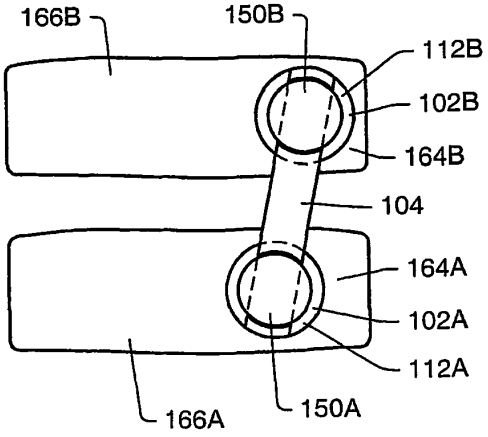


FIG. 13B

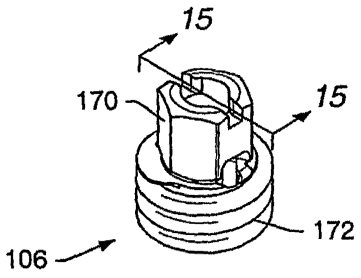


FIG. 14

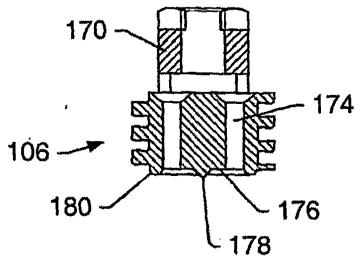


FIG. 15

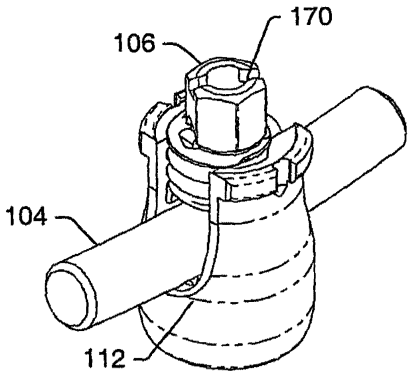


FIG. 16

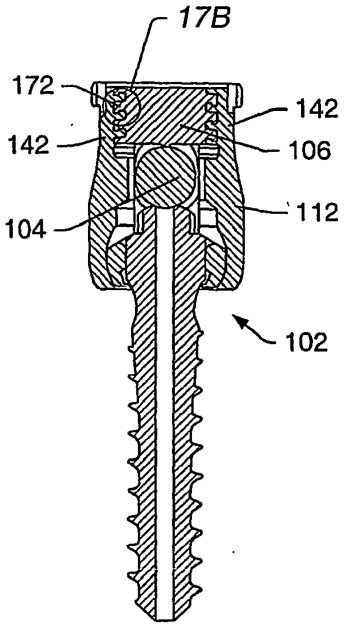


FIG. 17A

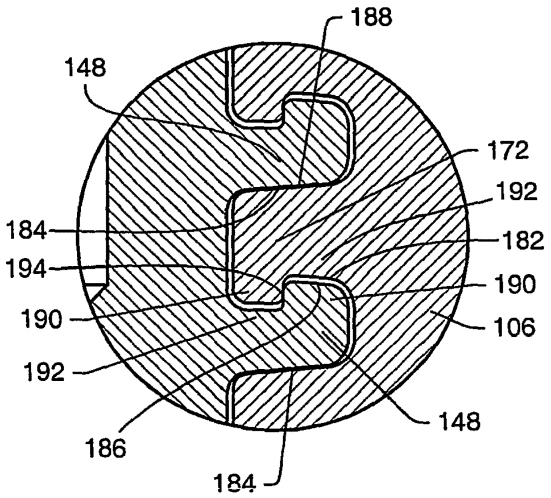


FIG. 17B

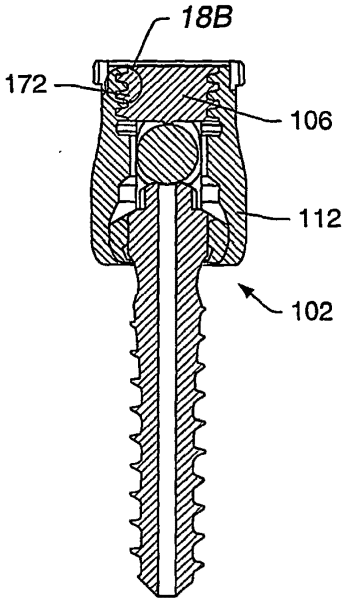


FIG. 18A

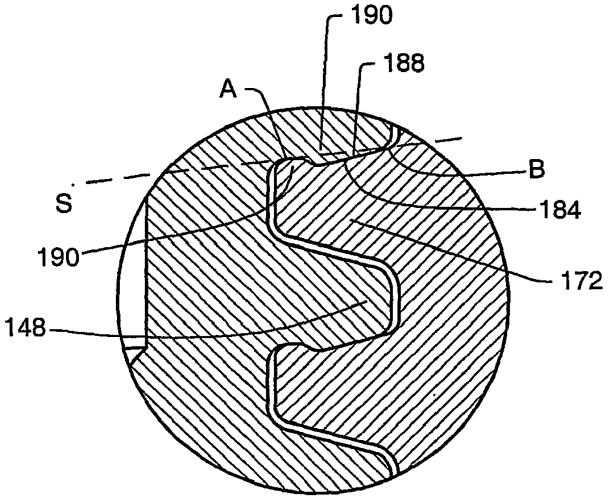


FIG. 18B

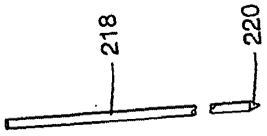


FIG. 22

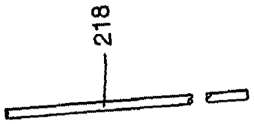


FIG. 23

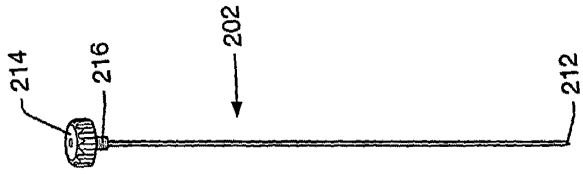


FIG. 21

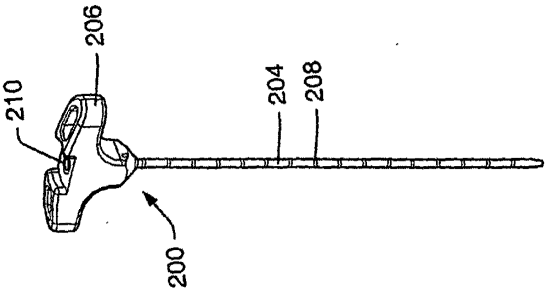


FIG. 20

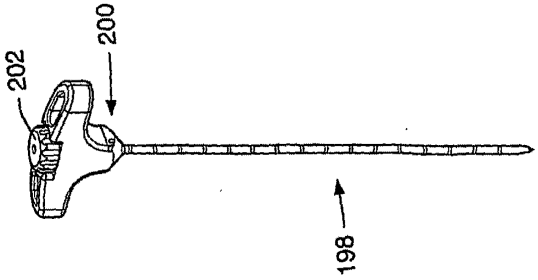


FIG. 19

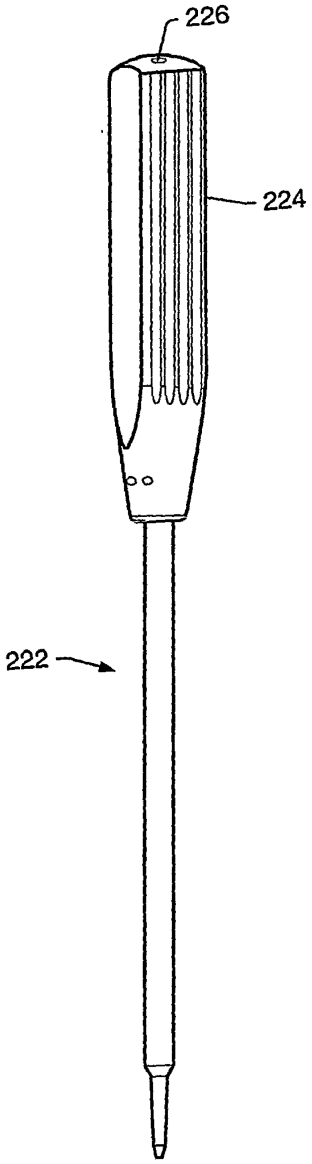


FIG. 24

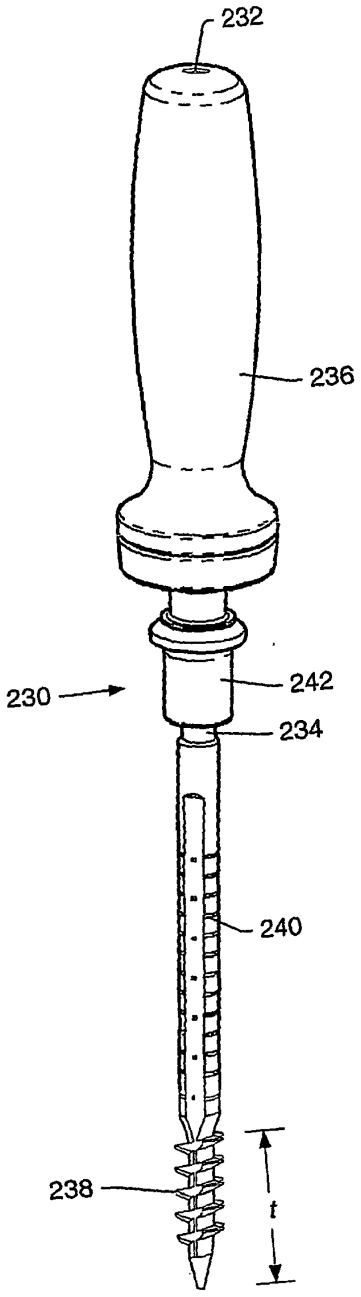


FIG. 25

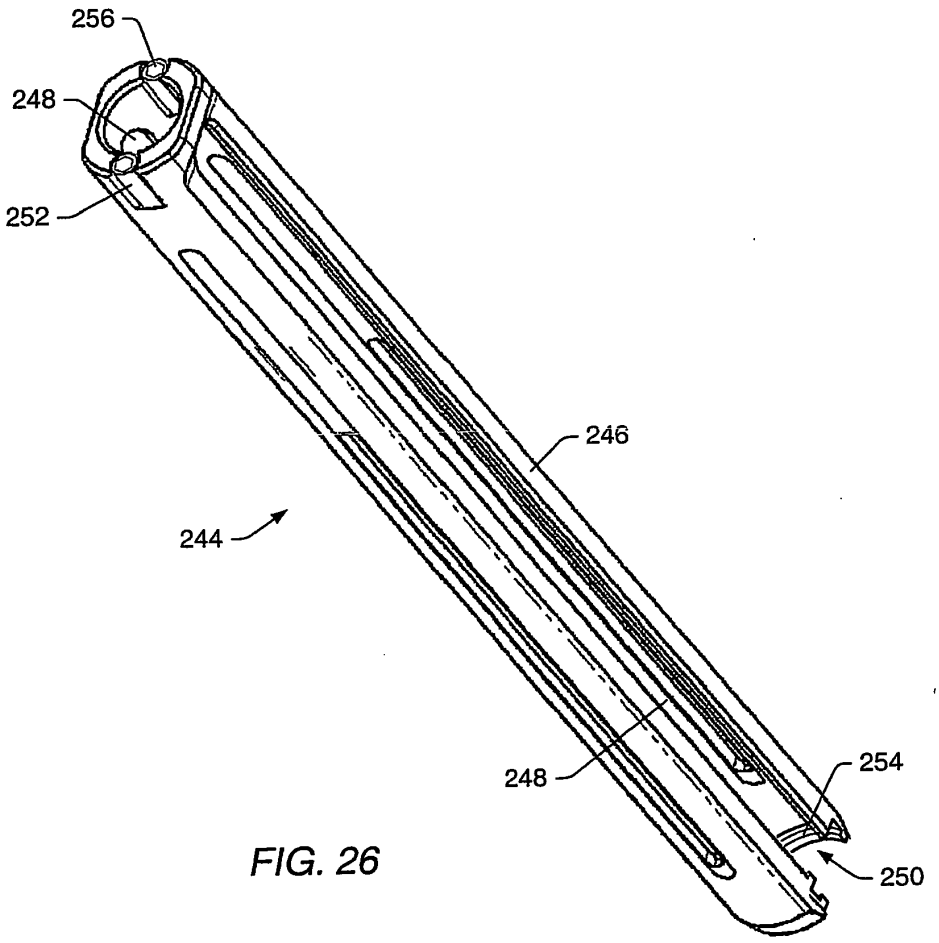


FIG. 26

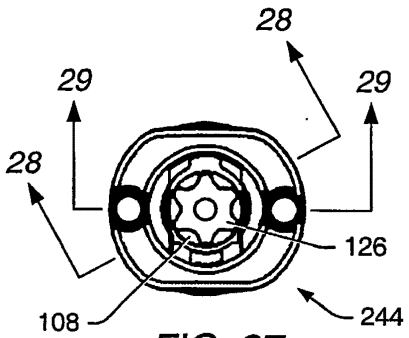


FIG. 27

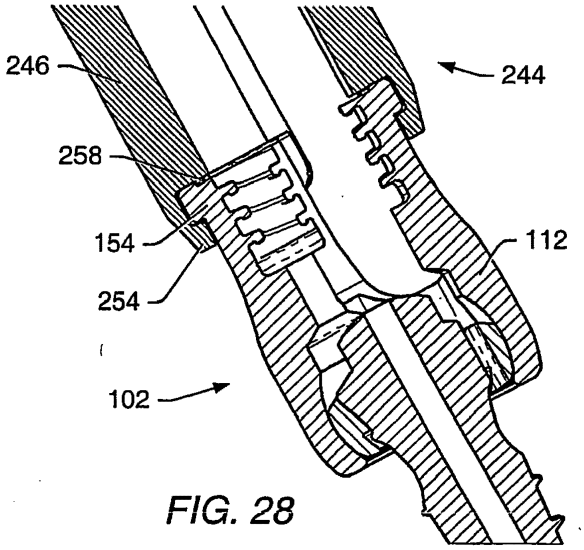


FIG. 28

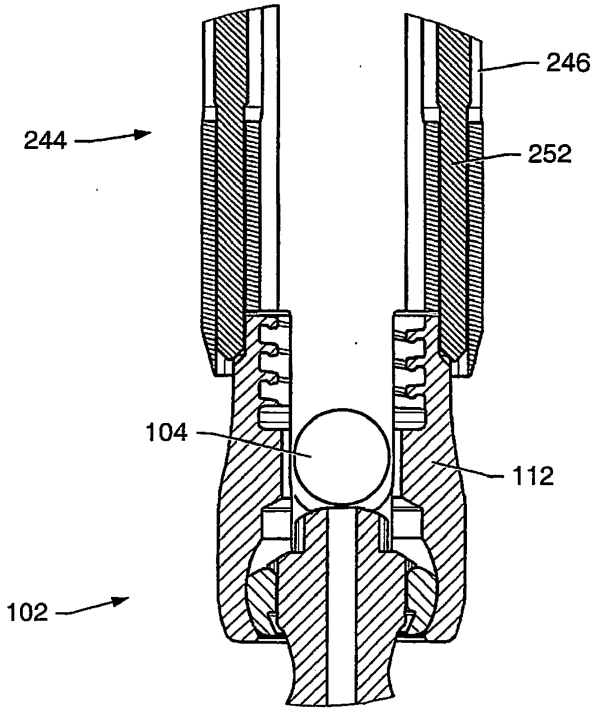


FIG. 29

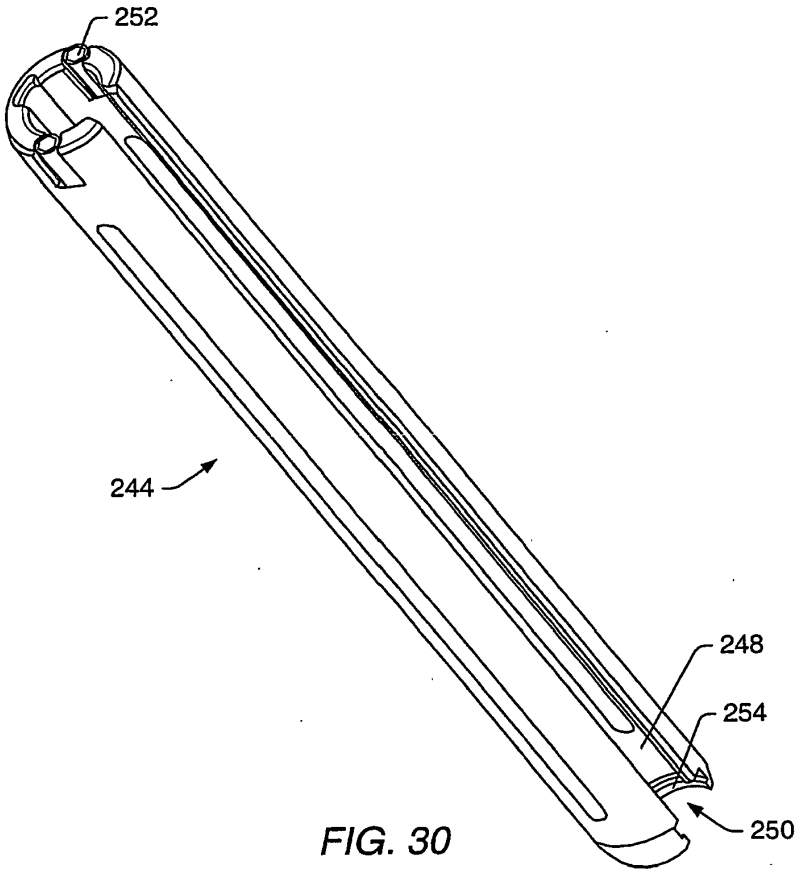


FIG. 30

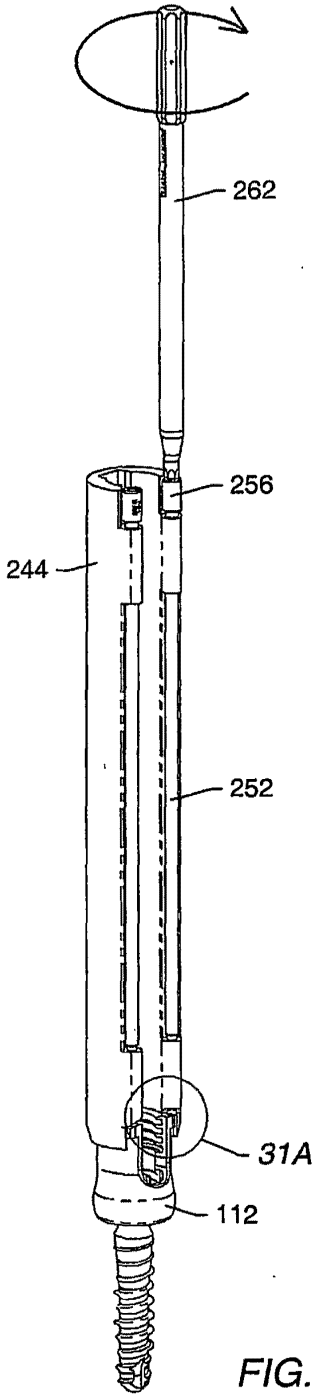


FIG. 31

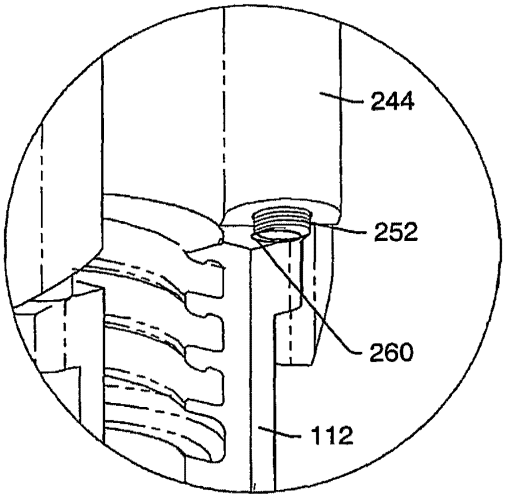


FIG. 31A

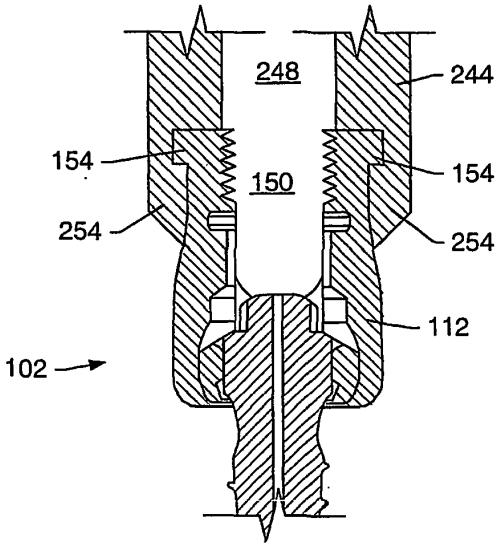


FIG. 32

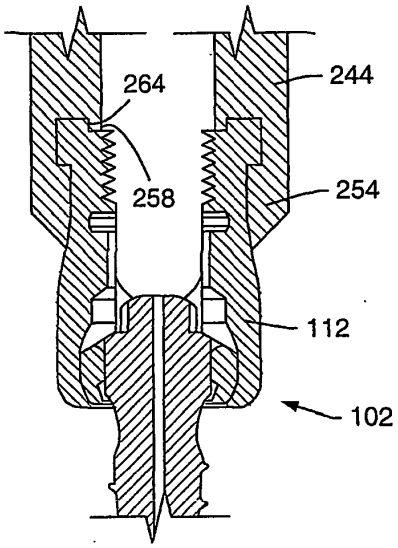


FIG. 33

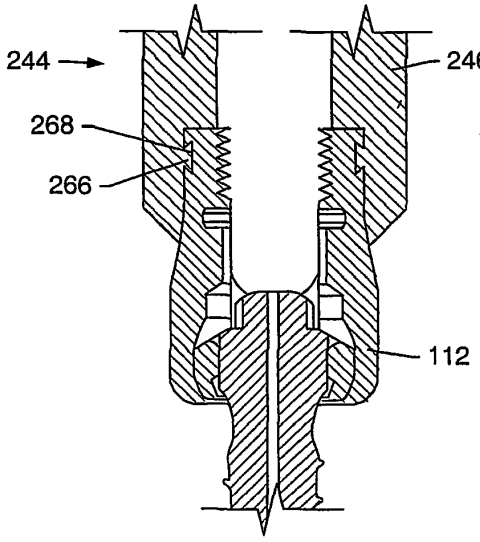


FIG. 34

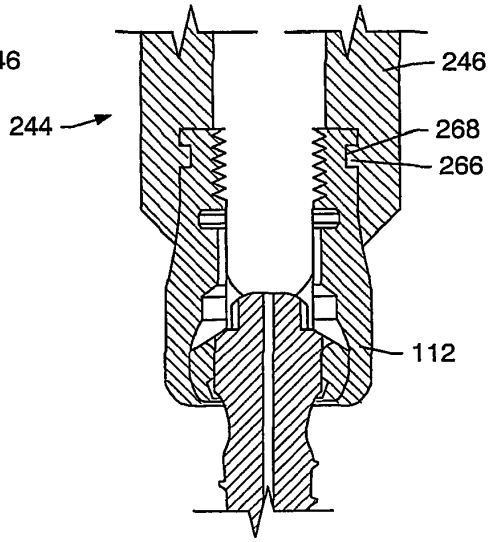


FIG. 35

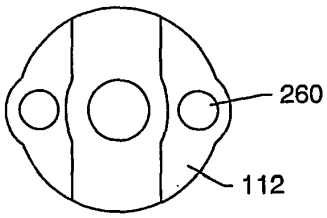


FIG. 36

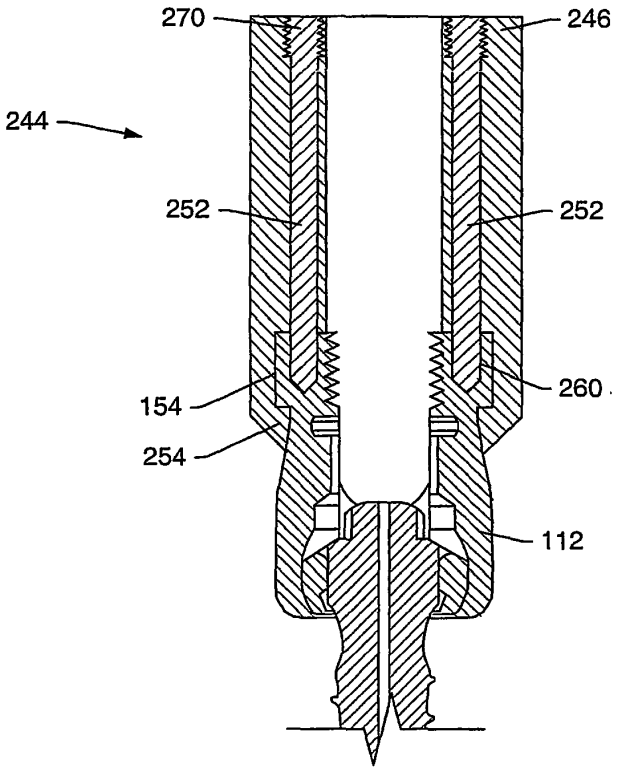


FIG. 37

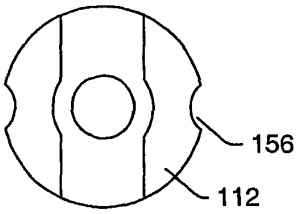


FIG. 38

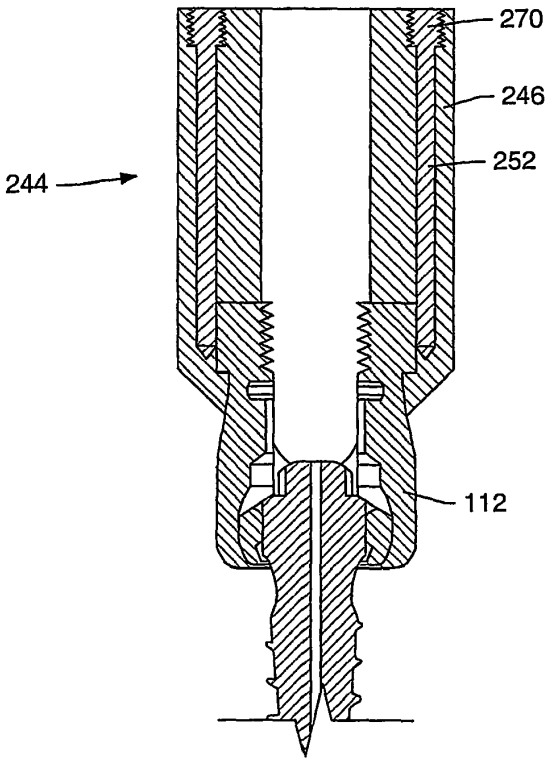


FIG. 39

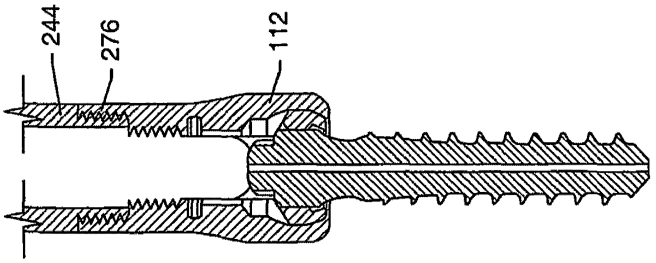


FIG. 43

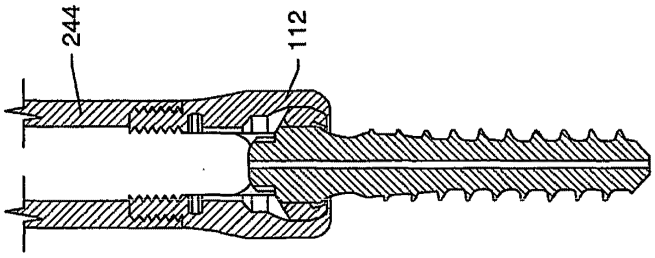


FIG. 42

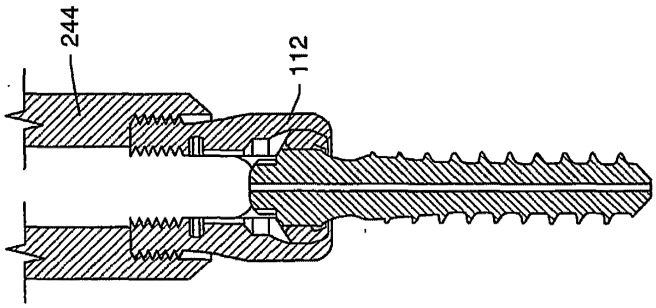


FIG. 41

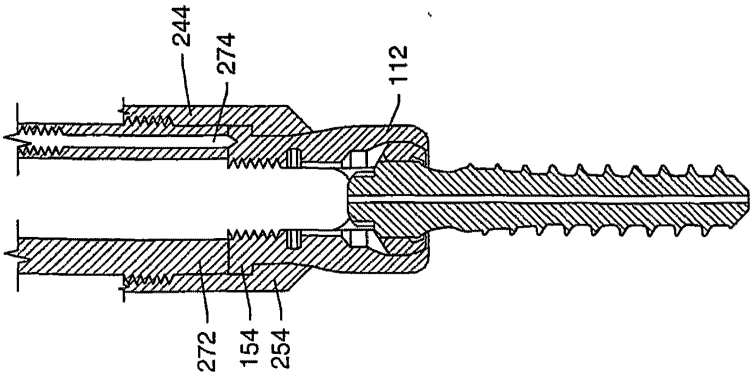


FIG. 40

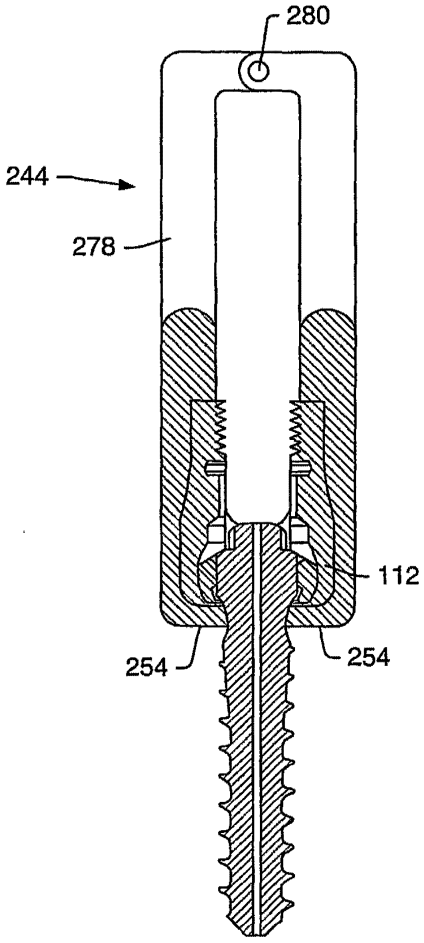


FIG. 44

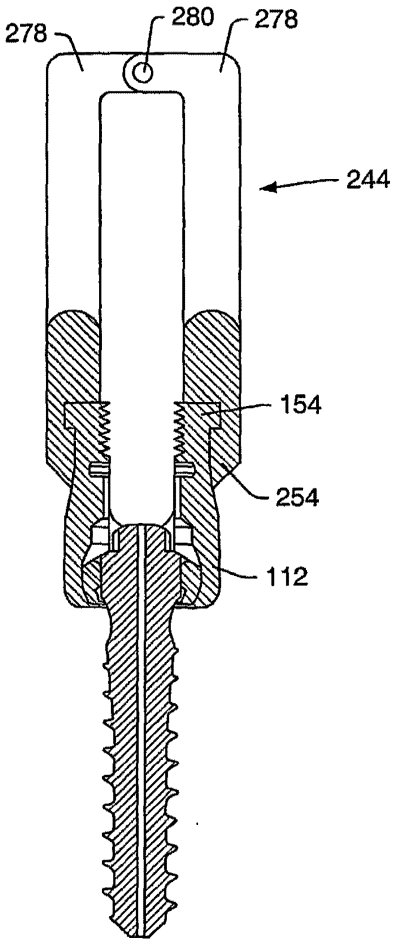


FIG. 45

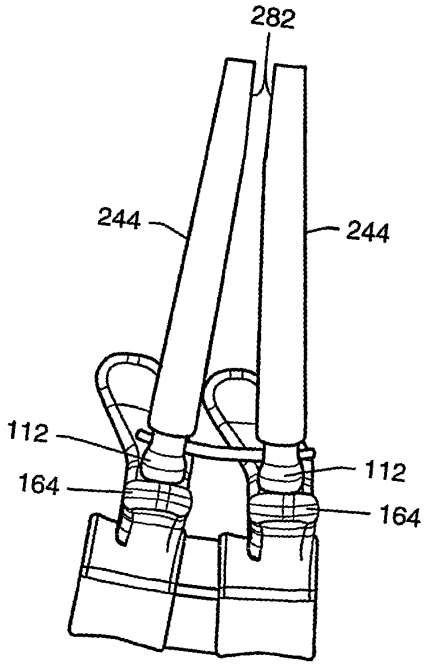


FIG. 46

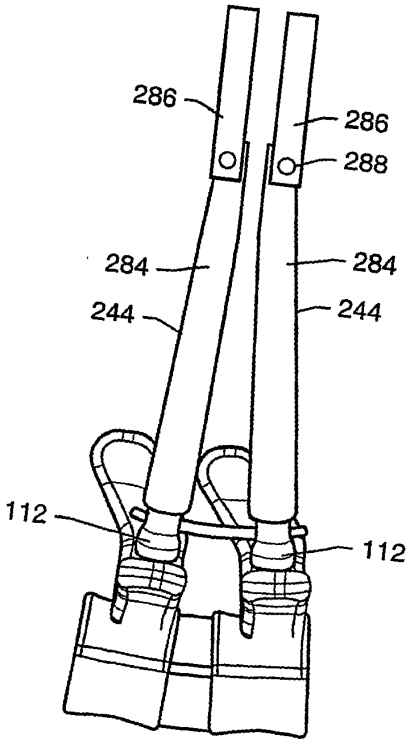


FIG. 47

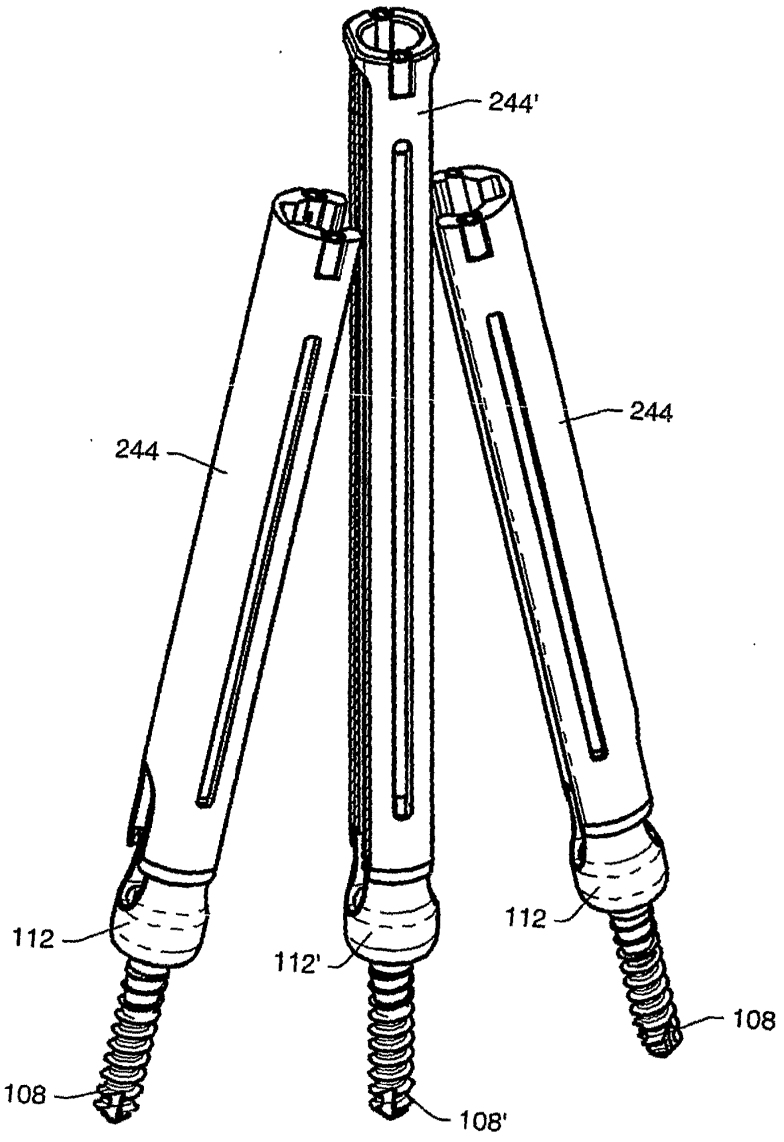


FIG. 48

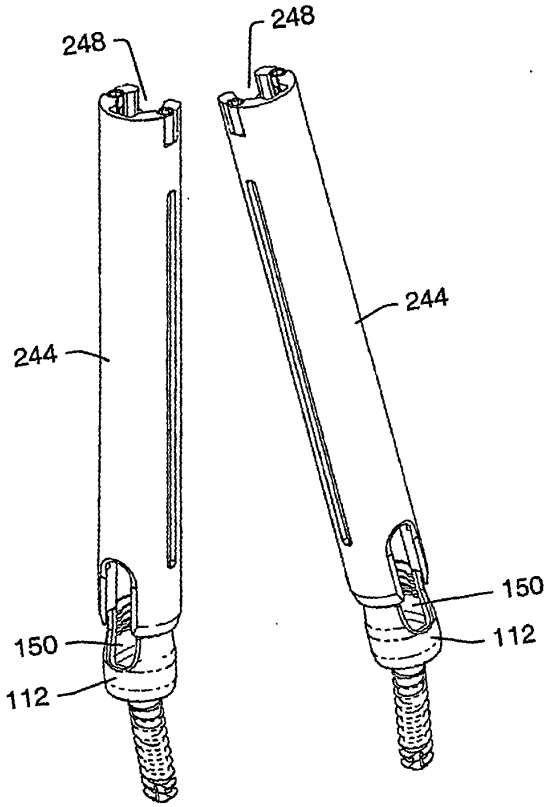


FIG. 49

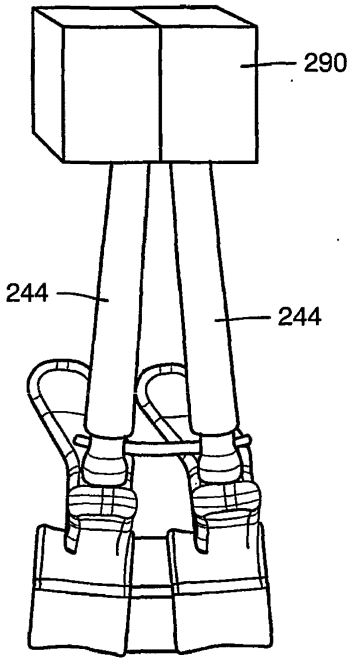


FIG. 50

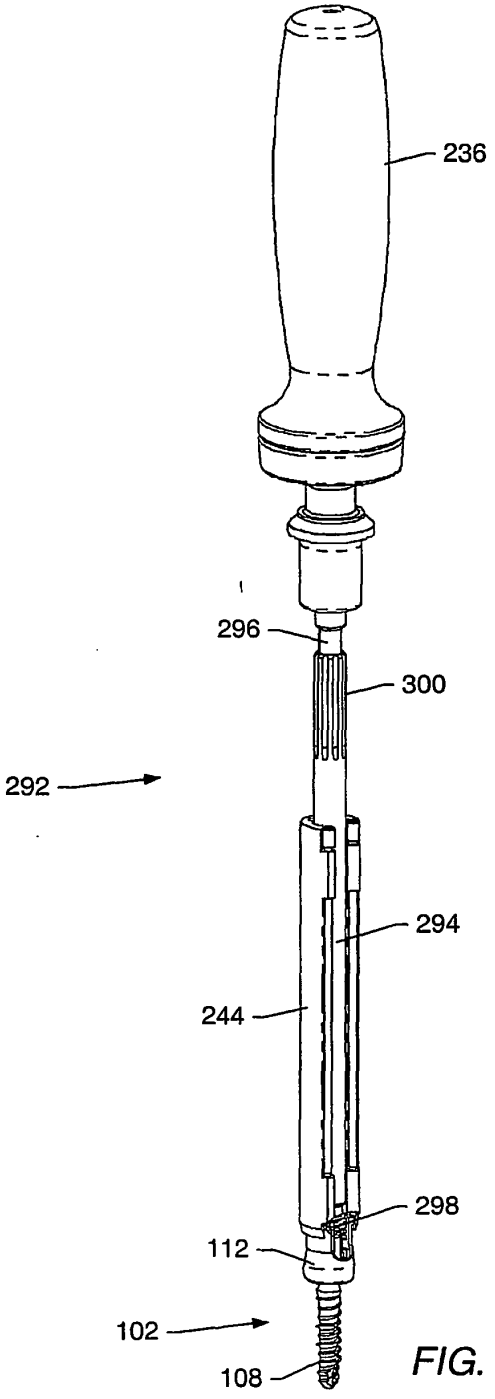


FIG. 51

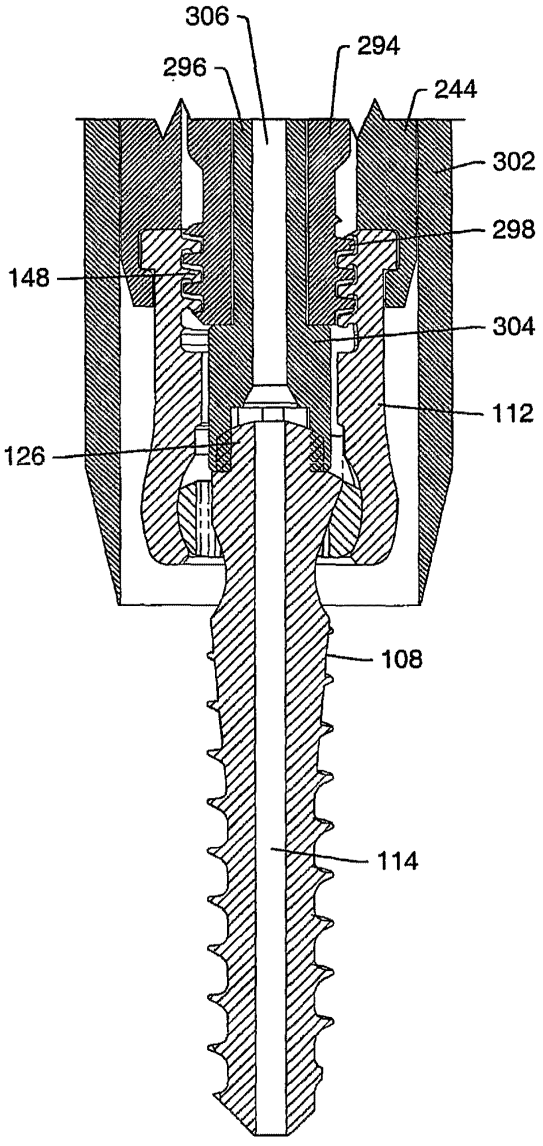


FIG. 52

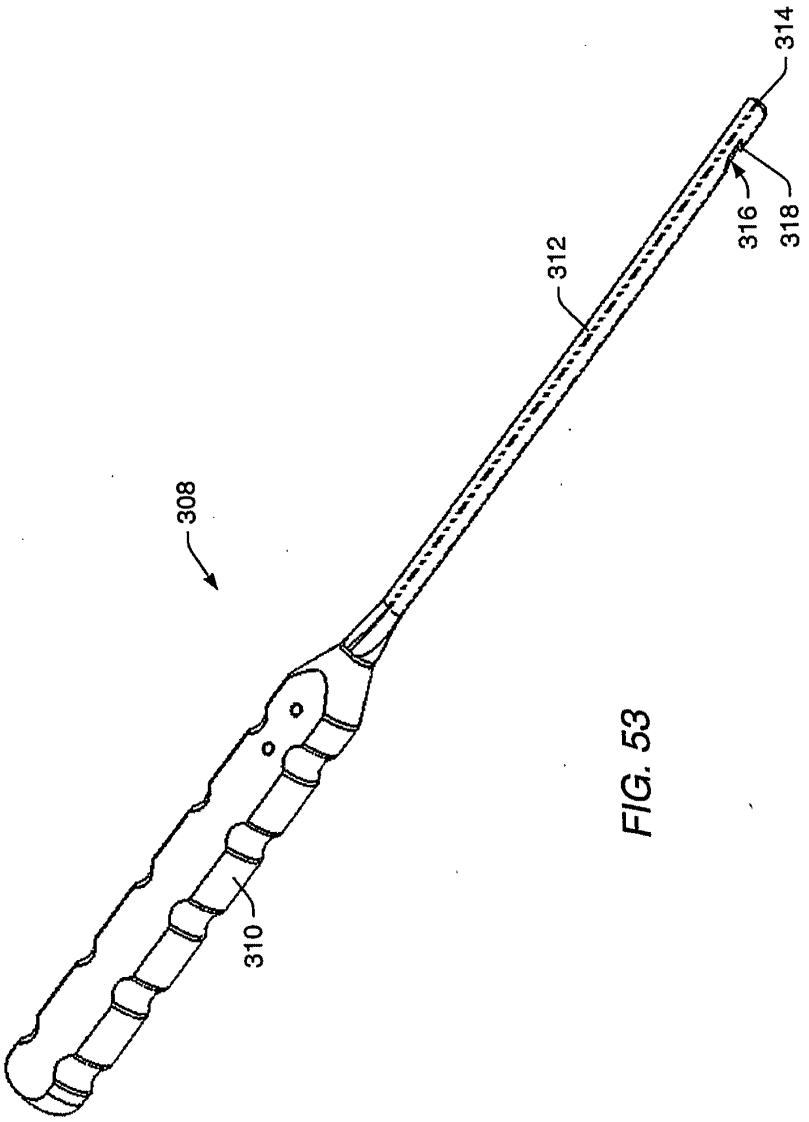


FIG. 53

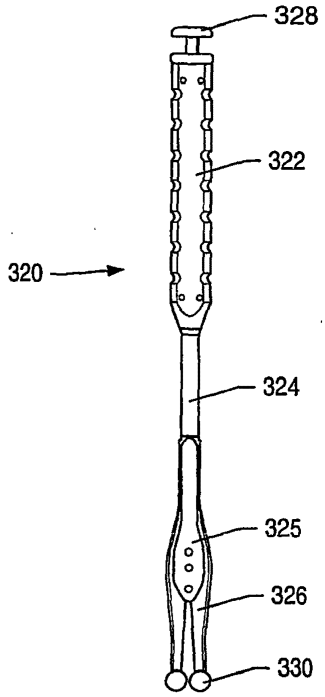


FIG. 54

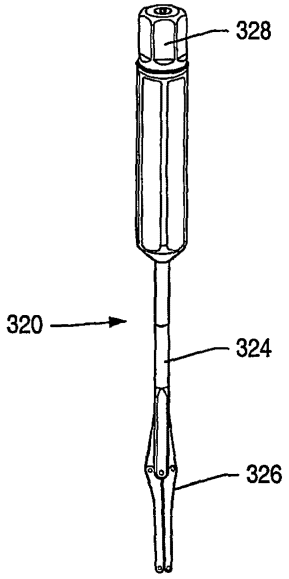


FIG. 55

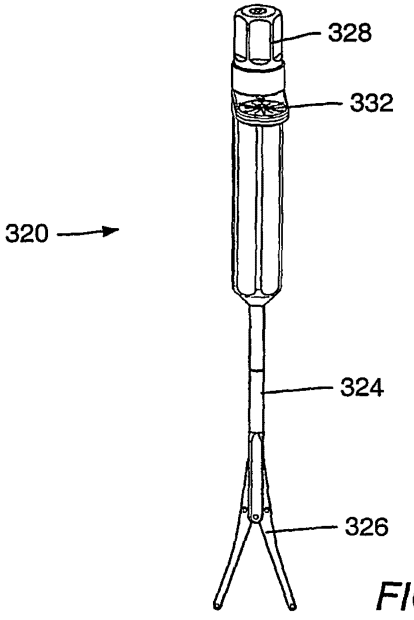


FIG. 56

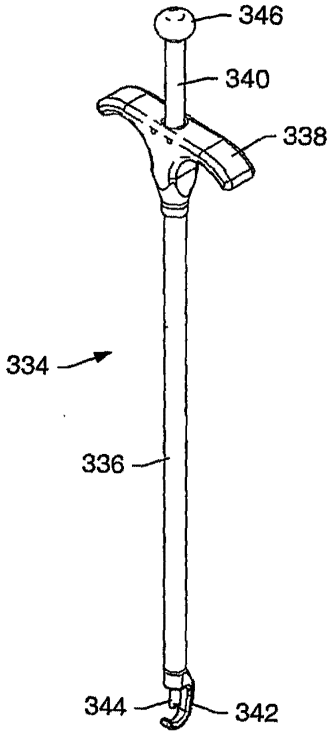


FIG. 57

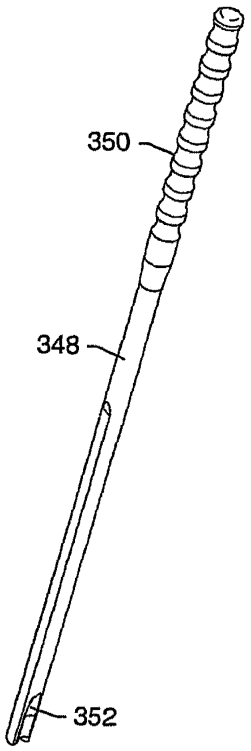


FIG. 58

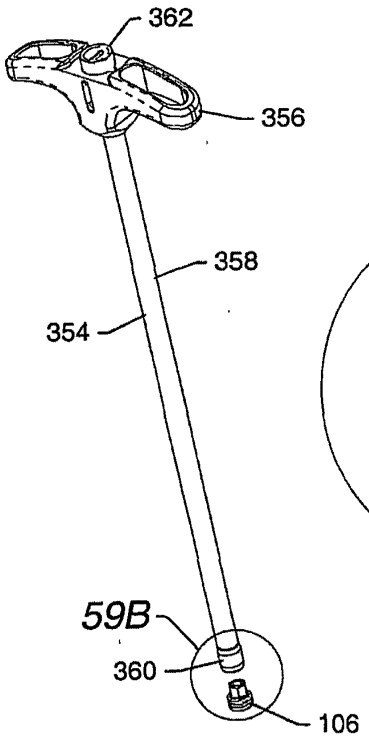


FIG. 59A

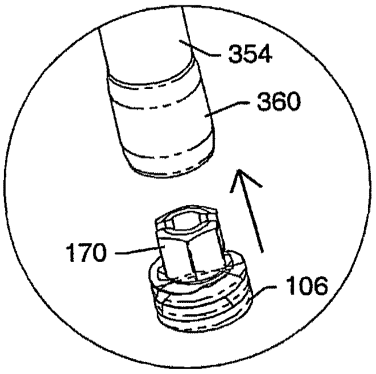


FIG. 59B

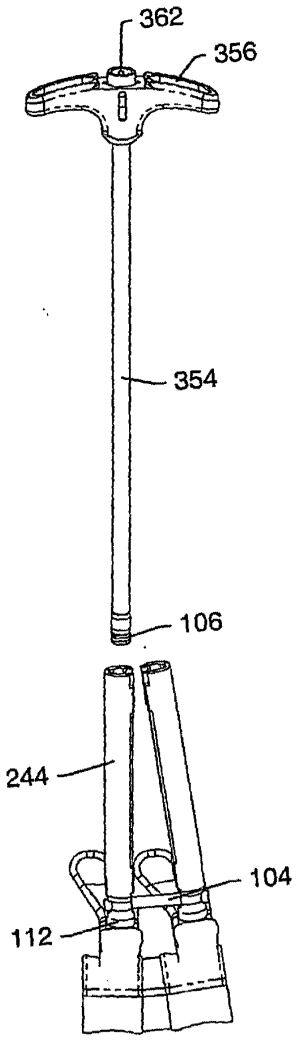


FIG. 60A

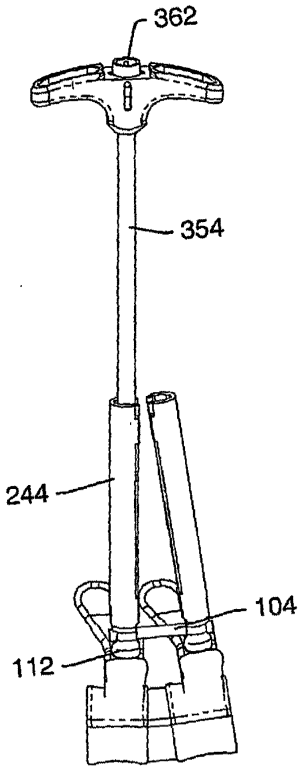


FIG. 60B

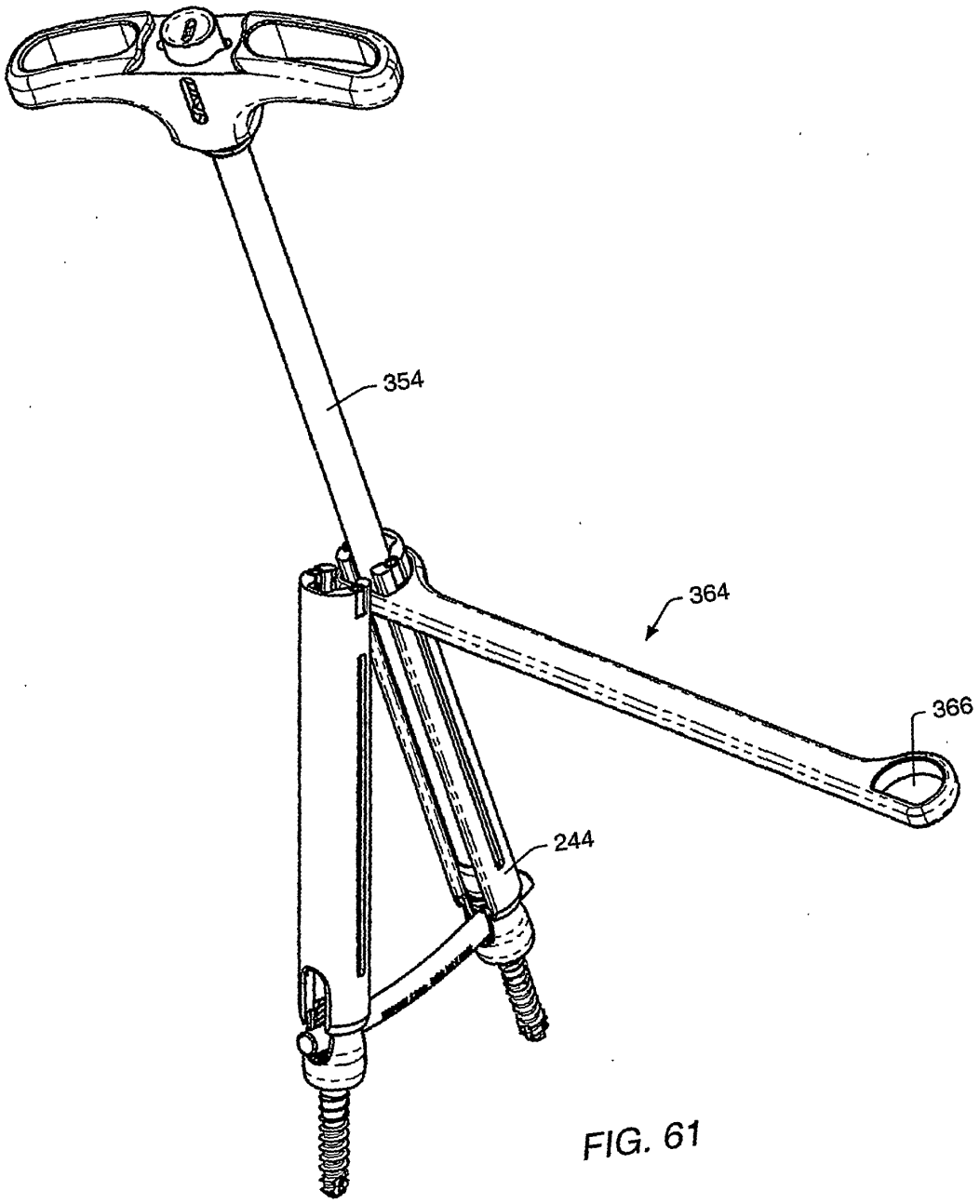


FIG. 61

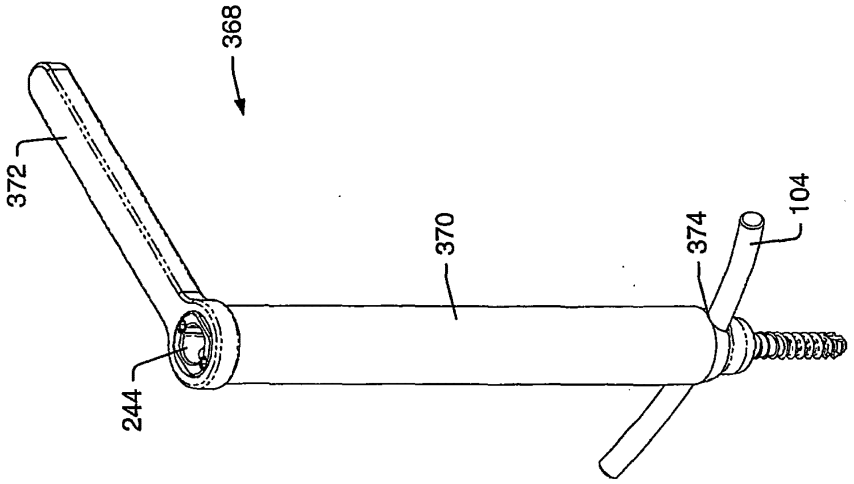


FIG. 63

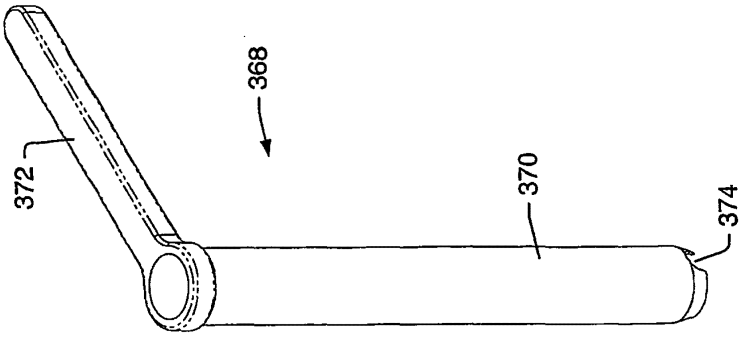


FIG. 62

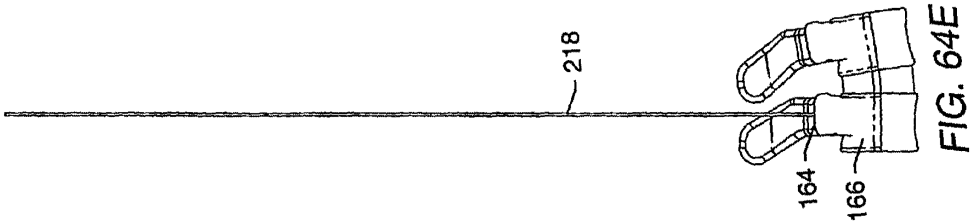


FIG. 64E

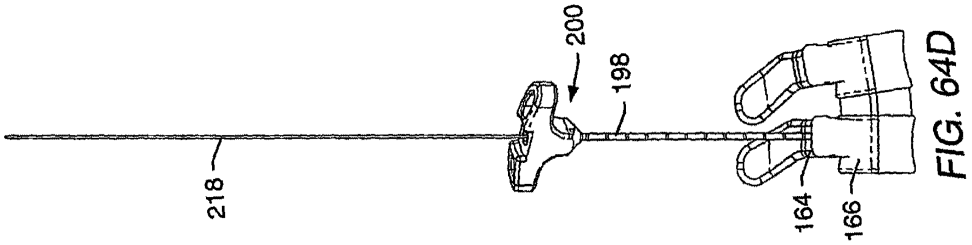


FIG. 64D

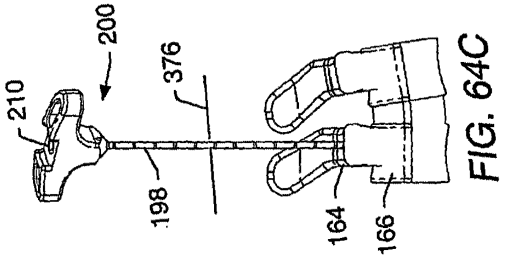


FIG. 64C

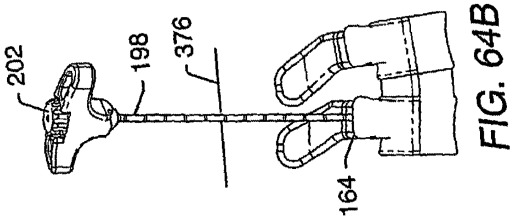


FIG. 64B

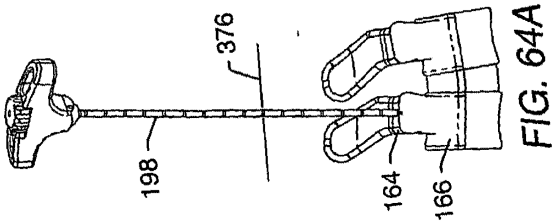


FIG. 64A

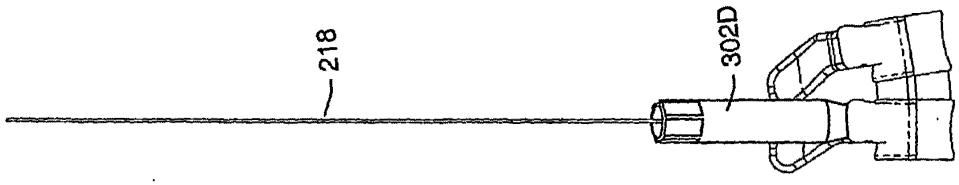


FIG. 65D

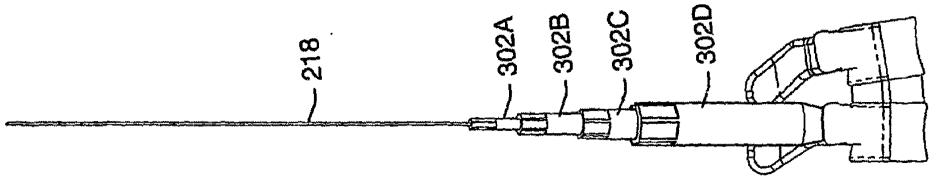


FIG. 65C

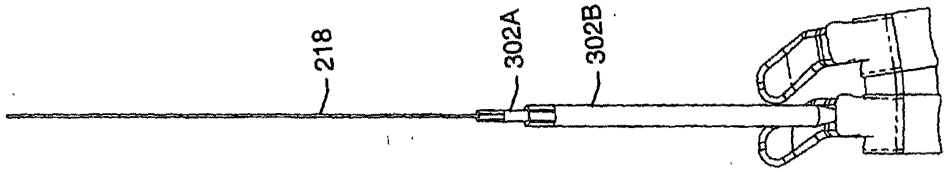


FIG. 65B

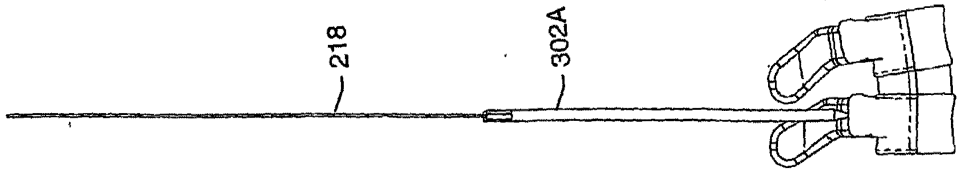


FIG. 65A

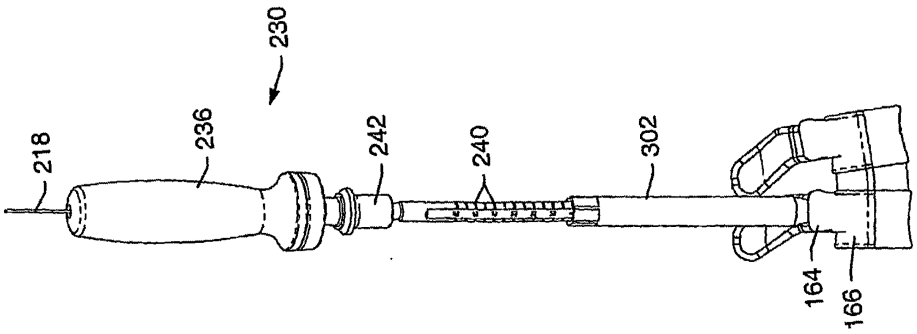


FIG. 66D

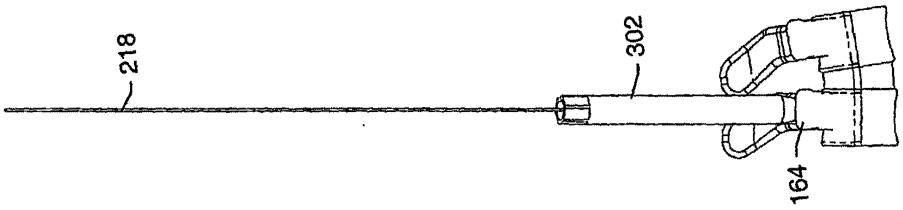


FIG. 66C

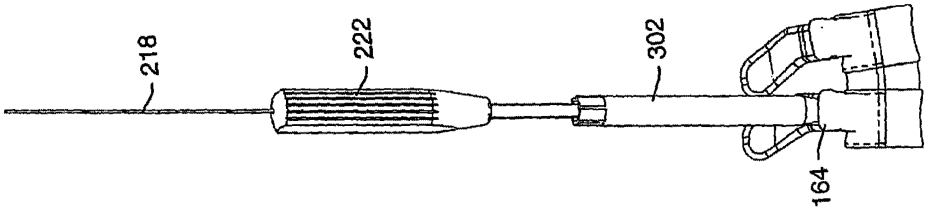


FIG. 66B

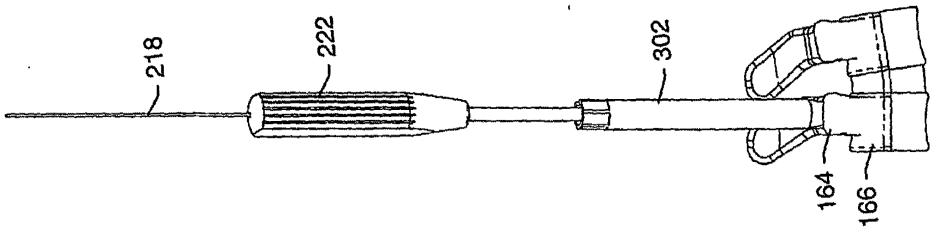


FIG. 66A

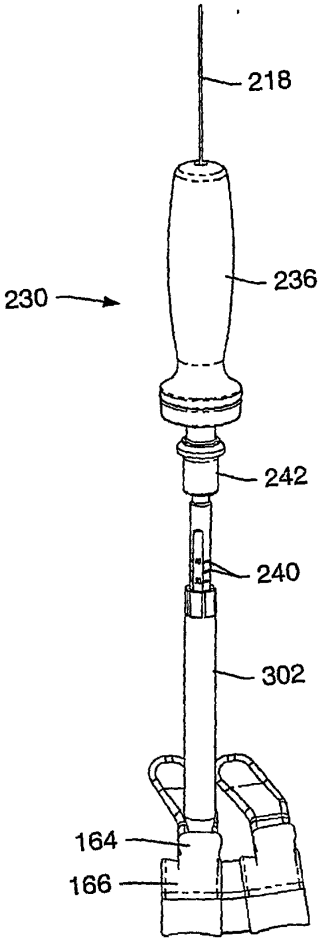


FIG. 66E

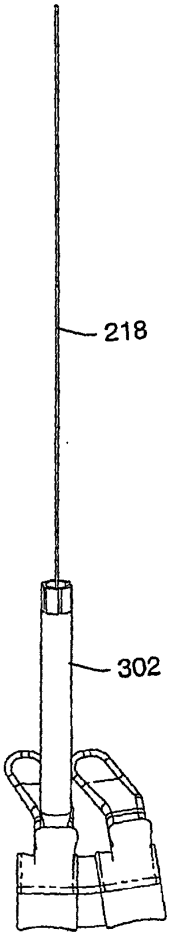
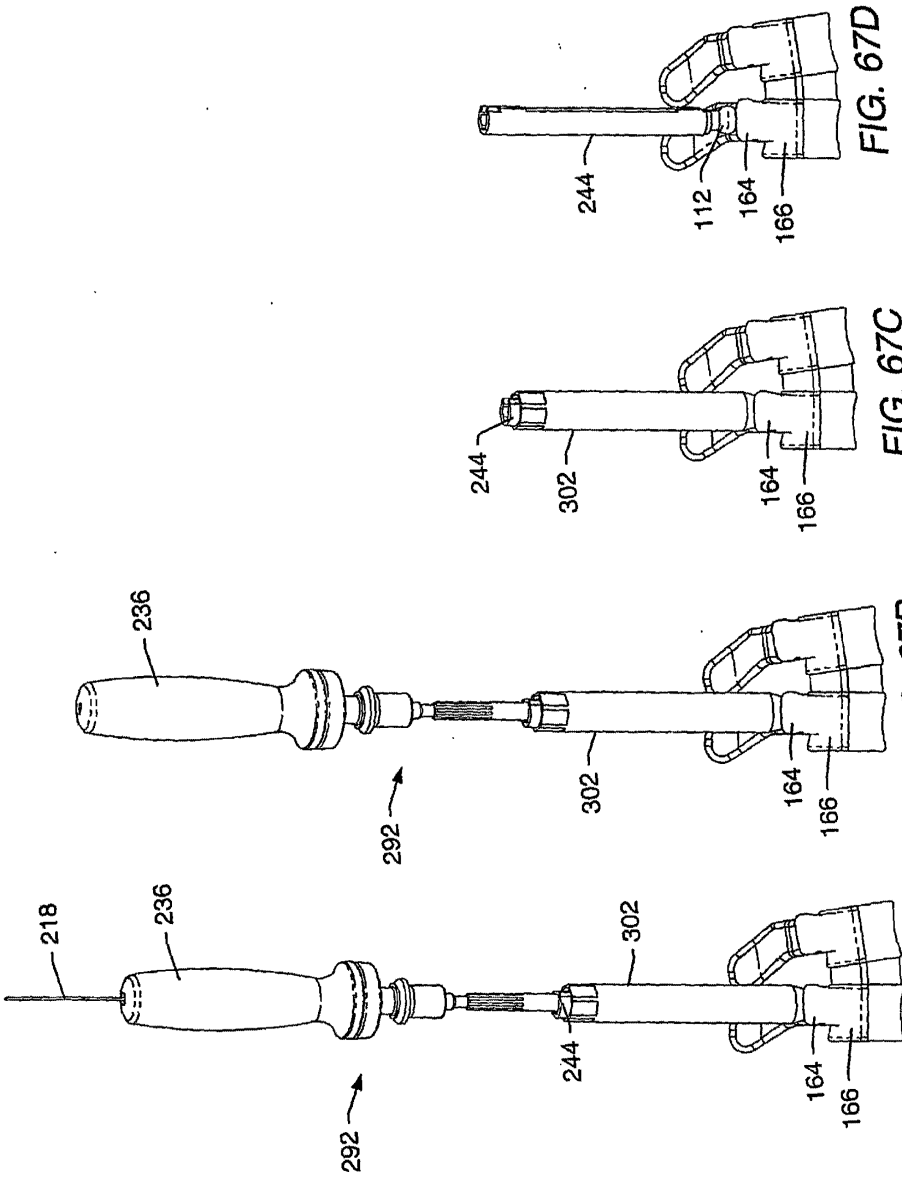


FIG. 66F


244
112
164
166
FIG. 67D
244
302
164
166
FIG. 67C
236
292
302
164
166
FIG. 67B
218
236
302
292
244
164
166
FIG. 67A

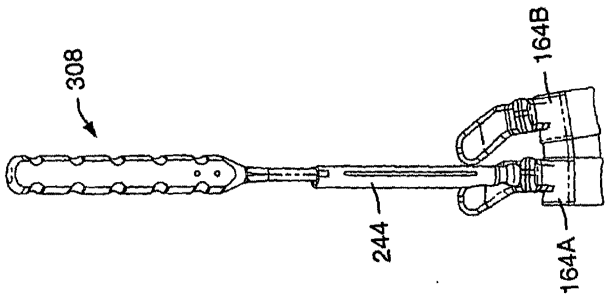


FIG. 68D

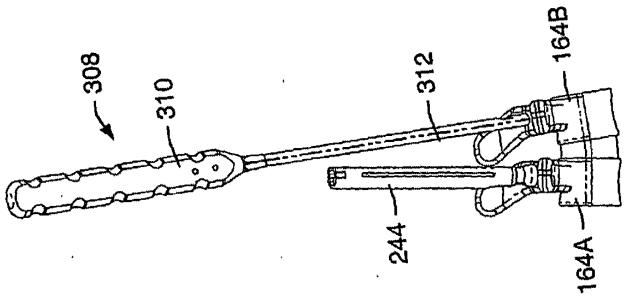


FIG. 68C

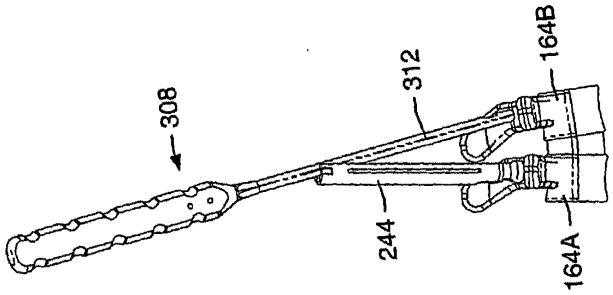


FIG. 68B

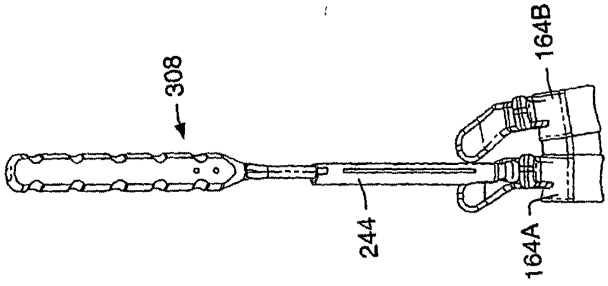


FIG. 68A

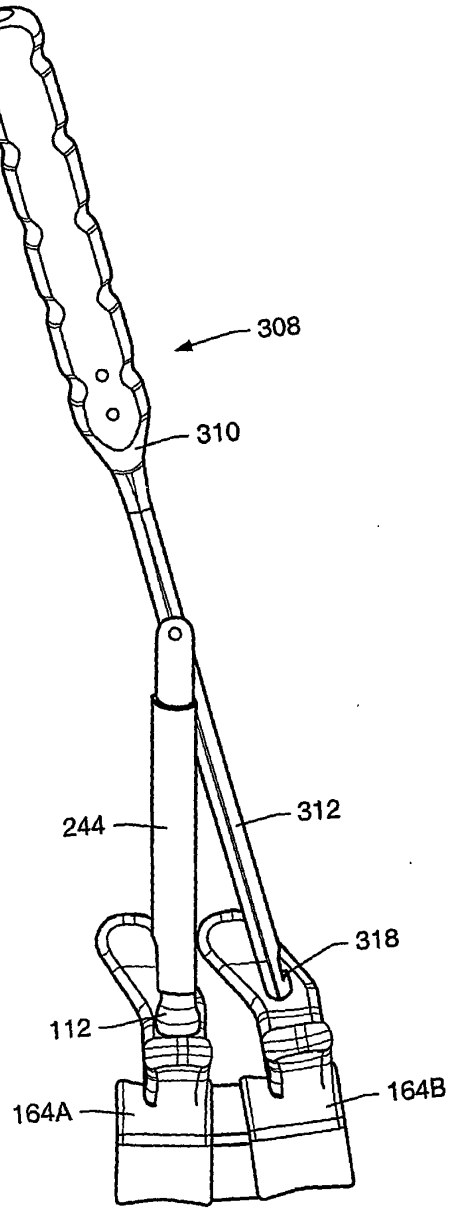


FIG. 69

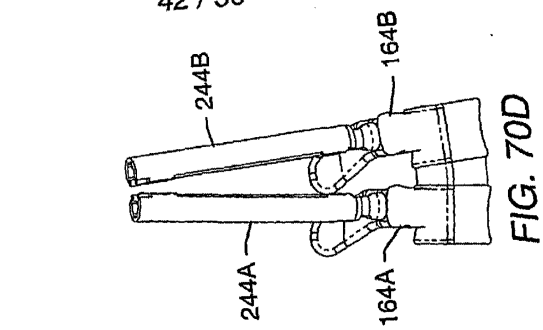


FIG. 70D

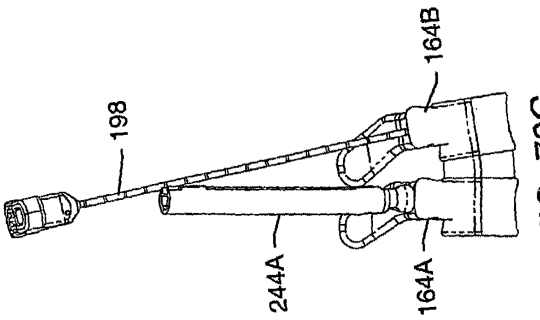


FIG. 70C

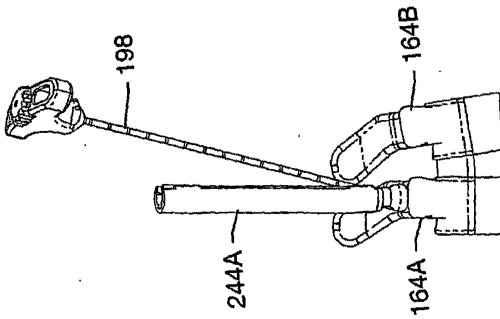


FIG. 70B

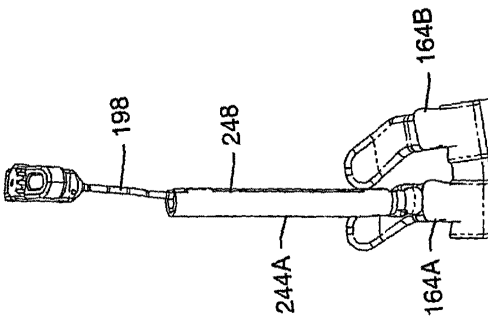


FIG. 70A

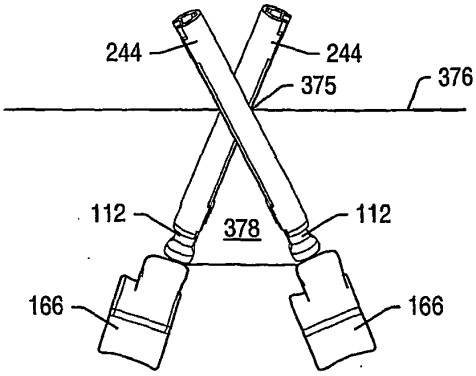


FIG. 71



FIG. 72



FIG. 73

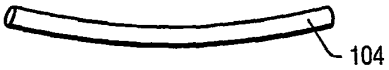


FIG. 74

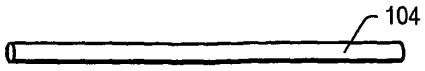


FIG. 75

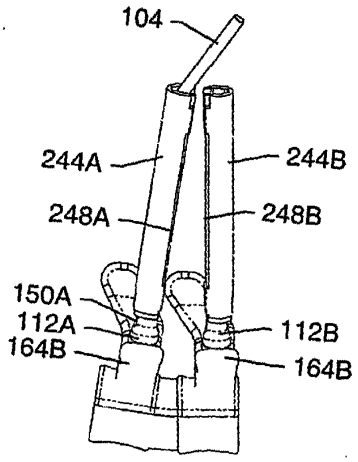


FIG. 76A

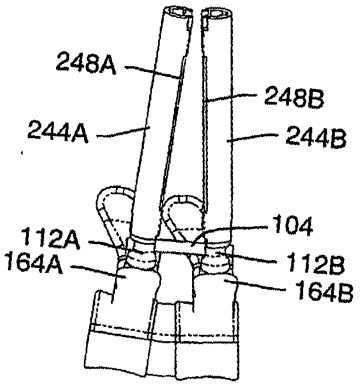


FIG. 76C

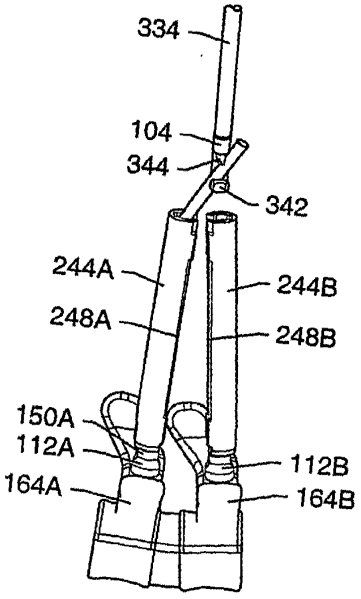


FIG. 76B

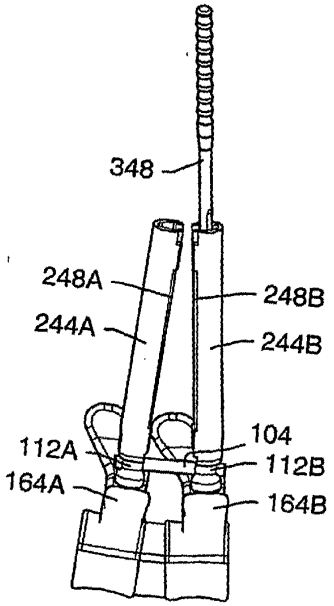


FIG. 76D

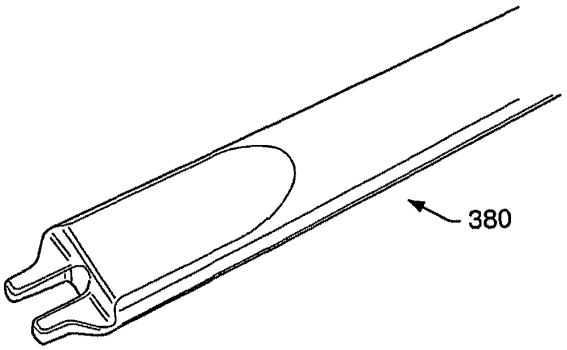


FIG. 77

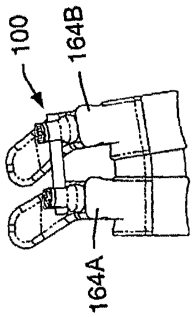


FIG. 78D

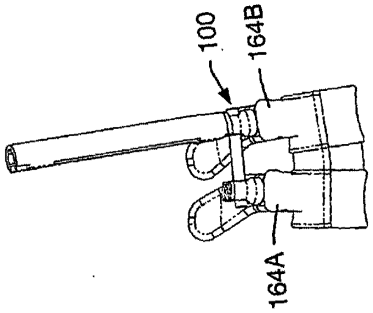


FIG. 78C

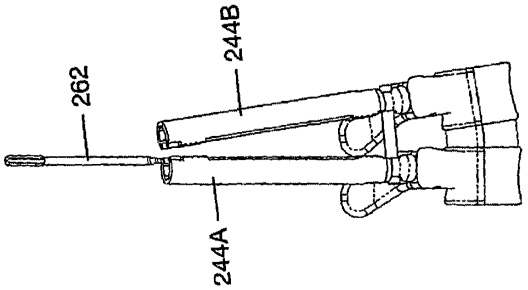


FIG. 78B

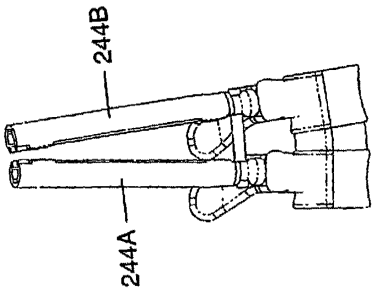


FIG. 78A

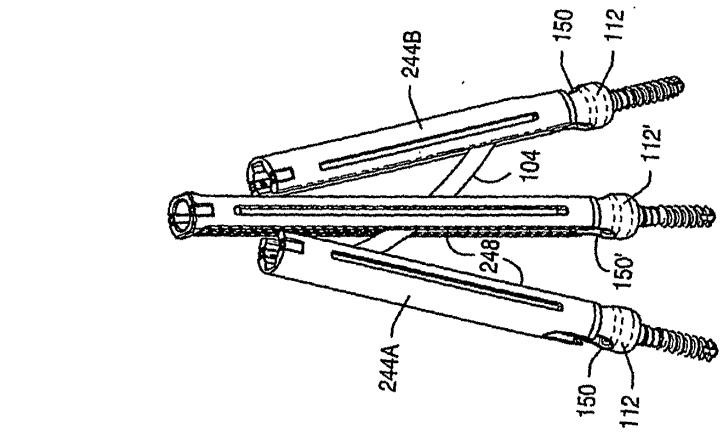


FIG. 79C

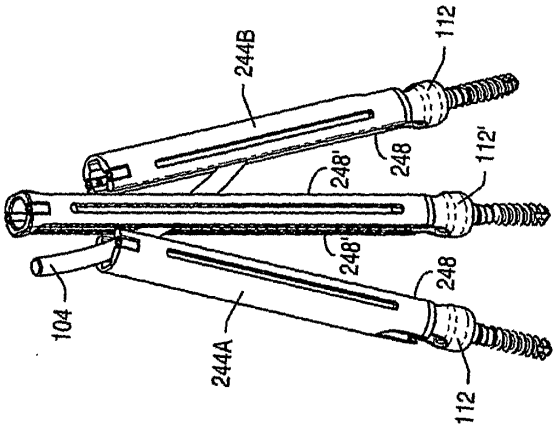


FIG. 79B

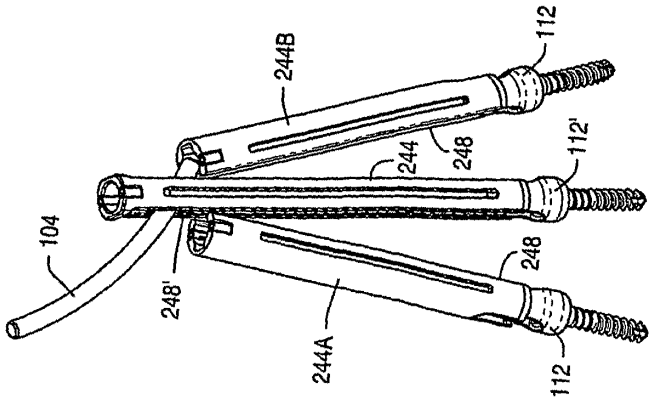


FIG. 79A

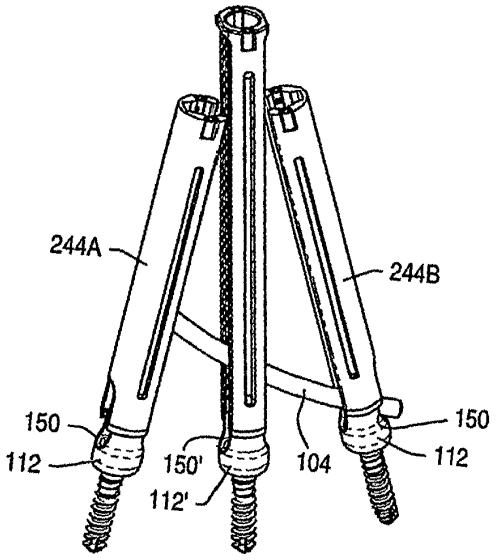


FIG. 79D

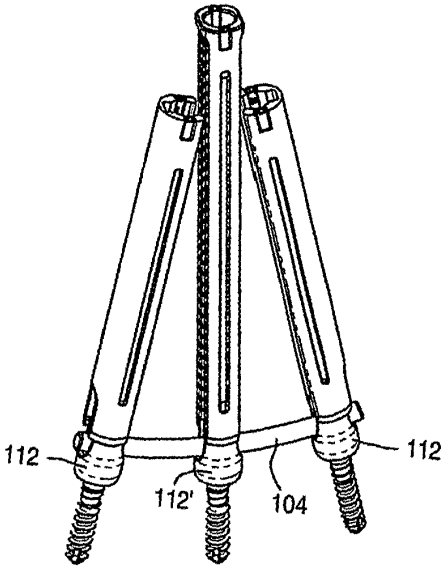


FIG. 79E

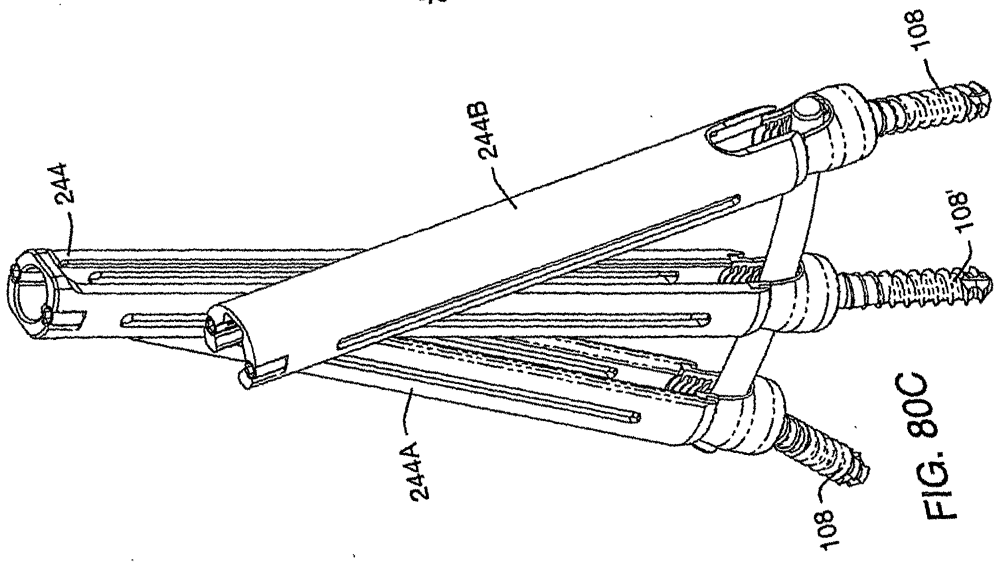


FIG. 80C

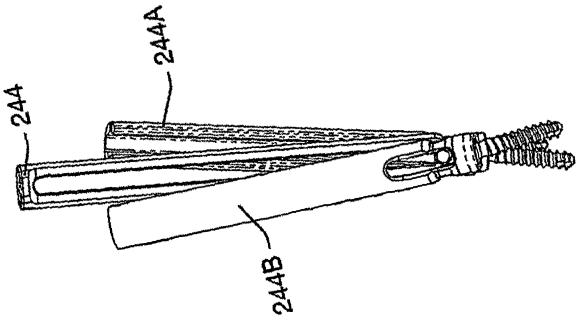


FIG. 80B

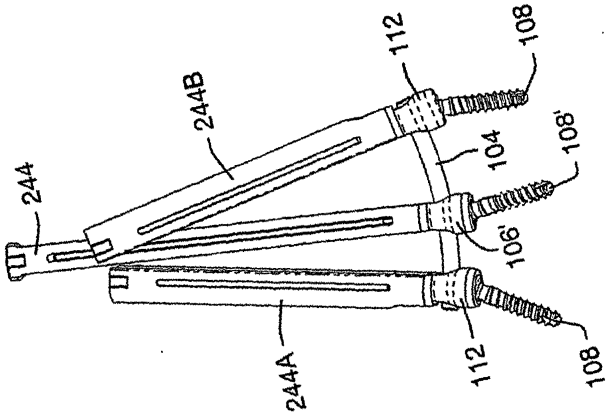


FIG. 80A

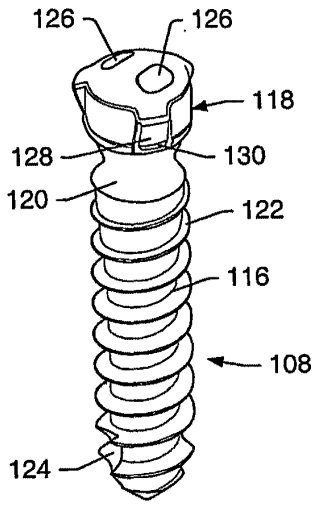


FIG. 81

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
IPR2023-01430; Petitioners' EX1002
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

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5647873 A	15-07-1997	US 5520690 A	28-05-1996
		AT 250393 T	15-10-2003
		AU 714659 B2	06-01-2000
		AU 5539796 A	30-10-1996
		CA 2216955 A1	17-10-1996
		DE 69630117 D1	30-10-2003
		EP 1364623 A1	26-11-2003
		EP 0828459 A1	18-03-1998
		JP 11503351 T	26-03-1999
		US 5882350 A	16-03-1999
		WO 9632071 A1	17-10-1996
		US 5531746 A	02-07-1996
		US 5643265 A	01-07-1997
		US 5607426 A	04-03-1997
		US 5876402 A	02-03-1999
		US 5725588 A	10-03-1998
		US 5669911 A	23-09-1997
		US 5690630 A	25-11-1997
		US RE37665 E1	16-04-2002
		US 5817094 A	06-10-1998
US 6331179 B1	18-12-2001	AU 2777001 A	16-07-2001
		CA 2396535 A1	12-07-2001
		EP 1259176 A1	27-11-2002
		JP 2003518977 T	17-06-2003
		WO 0149191 A1	12-07-2001
		US 2002045898 A1	18-04-2002
FR 2796545 A	26-01-2001	FR 2796545 A1	26-01-2001
		AU 6846000 A	13-02-2001
		DE 1198205 T1	14-11-2002
		EP 1198205 A1	24-04-2002
		ES 2171366 T1	16-09-2002
		WO 0106940 A1	01-02-2001
		JP 2003505138 T	12-02-2003
DE 29810798 U	28-10-1999	DE 29810798 U1	28-10-1999
FR 2729291 A	19-07-1996	FR 2729291 A1	19-07-1996
		EP 0802772 A1	29-10-1997
		ES 2125712 T3	01-03-1999
		WO 9621396 A1	18-07-1996
EP 1190678 A	27-03-2002	AU 756121 B2	02-01-2003
		AU 5992101 A	28-03-2002
		CA 2357606 A1	22-03-2002
		EP 1190678 A2	27-03-2002
		JP 2002136524 A	14-05-2002
US 6183472 B1	06-02-2001	DE 29806563 U1	18-06-1998
		AU 748182 B2	30-05-2002
		AU 2365899 A	21-10-1999
		CA 2268513 A1	09-10-1999
		EP 0948939 A2	13-10-1999
		JP 3431069 B2	28-07-2003
		JP 2000023992 A	25-01-2000
		ZA 9902516 A	05-10-1999

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

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 03/34469

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2001001119 A1	10-05-2001	AU 1493301 A	30-04-2001
		CA 2423973 A1	05-04-2001
		WO 0122893 A1	05-04-2001
US 5817094 A	06-10-1998	US 5520690 A	28-05-1996
		US 2002045899 A1	18-04-2002
		US 5669911 A	23-09-1997
		US 5690630 A	25-11-1997
		AT 250393 T	15-10-2003
		AU 714659 B2	06-01-2000
		AU 5539796 A	30-10-1996
		CA 2216955 A1	17-10-1996
		DE 69630117 D1	30-10-2003
		EP 1364623 A1	26-11-2003
		EP 0828459 A1	18-03-1998
		JP 11503351 T	26-03-1999
		US 5882350 A	16-03-1999
		WO 9632071 A1	17-10-1996
		US 5531746 A	02-07-1996
		US 5643265 A	01-07-1997
		US 5647873 A	15-07-1997
		US 5607426 A	04-03-1997
		US 5876402 A	02-03-1999
		US 5725588 A	10-03-1998
		US RE37665 E1	16-04-2002

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

(19) RÉPUBLIQUE FRANÇAISE

INSTITUT NATIONAL
DE LA PROPRIÉTÉ INDUSTRIELLE

PARIS

(11) N° de publication : **2 857 850**
(à n'utiliser que pour les commandes de reproduction)

(21) N° d'enregistrement national : **04 03413**

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

(12) DEMANDE DE BREVET D'INVENTION A1

(22) **Date de dépôt :** 01.04.04.

(30) **Priorité :** 27.06.03 FR 0307776; 27.01.04 FR 0400747.

(43) **Date de mise à la disposition du public de la demande :** 28.01.05 Bulletin 05/04.

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

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

(71) **Demandeur(s) :** *MEDICREA INTERNATIONAL Société anonyme* — FR.

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

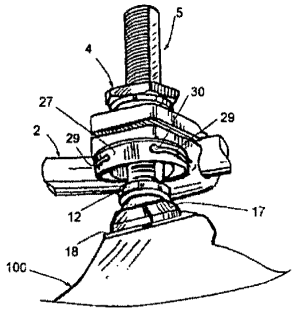
(73) **Titulaire(s) :**

(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
IPR2023-01430; Petitioners' EX1002
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.

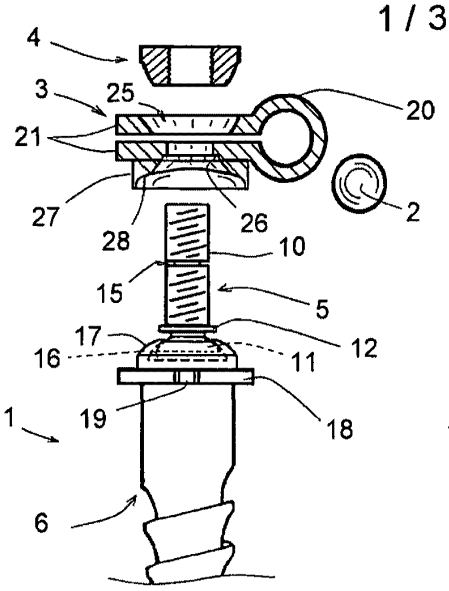


FIG. 1

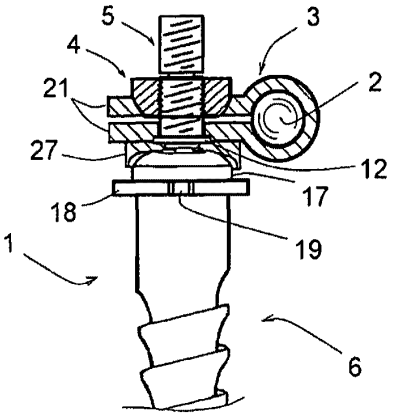


FIG. 2

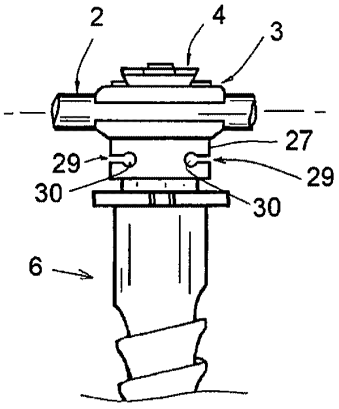


FIG. 3

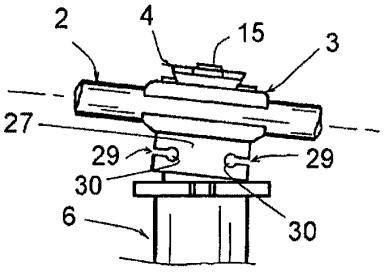


FIG. 4

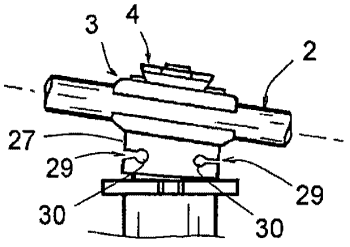


FIG. 5

FIG. 6

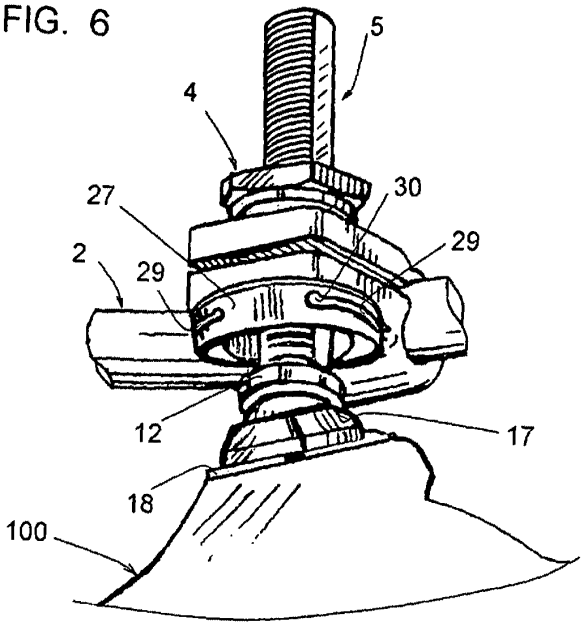


FIG. 7

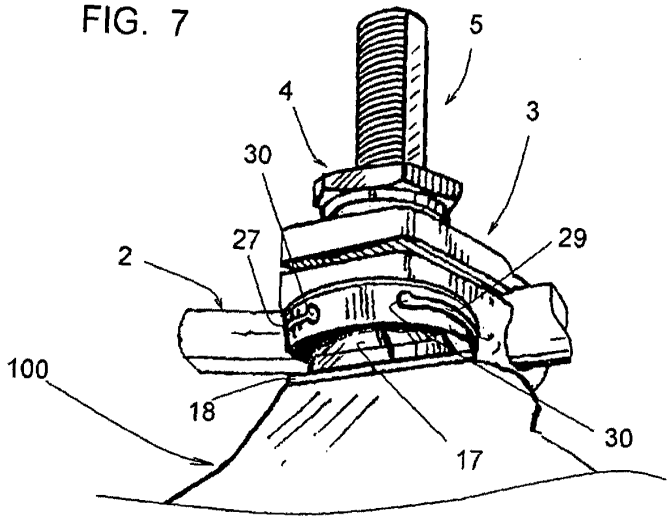
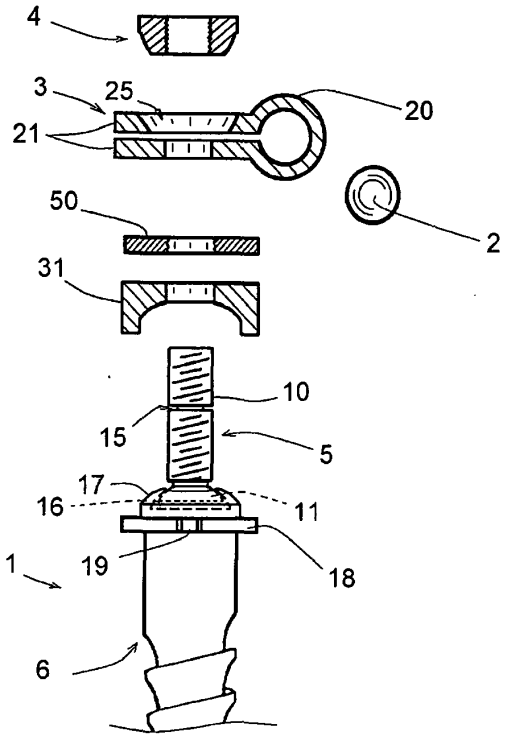


FIG. 8



RÉPUBLIQUE FRANÇAISE

2857850

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 647137
FR 0403413

DOCUMENTS CONSIDÉRÉS COMME PERTINENTS		Revendication(s) concernée(s)	Classement attribué à l'invention par l'INPI
Catégorie	Citation du document avec indication, en cas de besoin, des parties pertinentes		
A	WO 98/55038 A (TAYLOR J.) 10 décembre 1998 (1998-12-10) * figures 1-3 * -----	1	A61B17/70
A	US 5 735 851 A (ERRICO J.P.ET AL) 7 avril 1998 (1998-04-07) * figure 10a * -----	1	
A	FR 2 697 742 A (BIOMAT) 13 mai 1994 (1994-05-13) * page 11, ligne 14 - page 12, ligne 9; figure 1 * -----	1	
A	EP 0 242 708 A (HARMS J. & BIEDERMANN L.) 28 octobre 1987 (1987-10-28) * colonne 3, ligne 6 - ligne 10; figures 1,3 * * colonne 3, ligne 55 - colonne 44, ligne 15 * -----	1	
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

EPO FORM 1503 12.99 (P04C14)

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

Document brevet cité au rapport de recherche		Date de publication	Membre(s) de la famille de brevet(s)		Date de publication
WO 9855038	A	10-12-1998	IE	970411 A2	03-12-1997
			CA	2292748 A1	10-12-1998
			EP	1415602 A2	06-05-2004
			EP	1415603 A2	06-05-2004
			EP	0986339 A1	22-03-2000
			WO	9855038 A1	10-12-1998
			JP	2002510998 T	09-04-2002
			US	6267765 B1	31-07-2001
US 5735851	A	07-04-1998	AU	731811 B2	05-04-2001
			AU	4673197 A	05-05-1998
			CA	2268152 A1	16-04-1998
			EP	0949887 A1	20-10-1999
			JP	2002515792 T	28-05-2002
			KR	2000048988 A	25-07-2000
			WO	9815233 A1	16-04-1998
			US	5800435 A	01-09-1998
FR 2697742	A	13-05-1994	FR	2697742 A1	13-05-1994
			AT	146064 T	15-12-1996
			CA	2109457 A1	07-05-1994
			DE	69306536 D1	23-01-1997
			DE	69306536 T2	28-05-1997
			EP	0596788 A1	11-05-1994
			ES	2096249 T3	01-03-1997
			GR	3022754 T3	30-06-1997
			JP	2666683 B2	22-10-1997
			JP	6165789 A	14-06-1994
			US	5380325 A	10-01-1995
EP 0242708	A	28-10-1987	DE	3614101 C1	22-10-1987
			AT	82484 T	15-12-1992
			CA	1328591 C	19-04-1994
			DE	3782678 D1	24-12-1992
			EP	0242708 A2	28-10-1987
			ES	2035826 T3	01-05-1993
			JP	1802142 C	26-11-1993
			JP	5008011 B	01-02-1993
			JP	62277954 A	02-12-1987
			KR	9506929 B1	26-06-1995
			US	4946458 A	07-08-1990
WO 9106254	A	16-05-1991	DE	3936702 A1	08-05-1991
			AT	139103 T	15-06-1996
			CA	2045502 A1	04-05-1991
			DE	59010378 D1	18-07-1996

EPO FORM P0465

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1089 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

Document brevet cité au rapport de recherche	Date de publication	Membre(s) de la famille de brevet(s)	Date de publication
WO 9106254 A		WO 9106254 A1	16-05-1991
		EP 0452451 A1	23-10-1991
		JP 4502568 T	14-05-1992
		US 5196013 A	23-03-1993

EPO FORM P0465

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1090 of 2152

Express Mail EM626520557US

U.S. PTO
13694849
011013



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

INFORMATION DISCLOSURE STATEMENT

Applicant: Roger P. Jackson, et al.

Date: 1-10-13

For: MULTI-START CLOSURES FOR OPEN IMPLANTS

Docket No.: 11,433

* *

Shawnee, Kansas

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

Sir:

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

U. S. Patents

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1091 of 2152

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1092 of 2152

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1093 of 2152

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1094 of 2152

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1095 of 2152

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1096 of 2152

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1097 of 2152

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1098 of 2152

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1099 of 2152

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1100 of 2152

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1101 of 2152

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1102 of 2152

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1103 of 2152

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1104 of 2152

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1105 of 2152

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1106 of 2152

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1107 of 2152

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1108 of 2152

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1109 of 2152

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1110 of 2152

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1111 of 2152

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

U.S. Published Applications

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1112 of 2152

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1113 of 2152

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1114 of 2152

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1115 of 2152

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1116 of 2152

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1117 of 2152

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1118 of 2152

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1119 of 2152

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1120 of 2152

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1121 of 2152

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1122 of 2152

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1123 of 2152

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1124 of 2152

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1125 of 2152

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1126 of 2152

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1127 of 2152

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1128 of 2152

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1129 of 2152

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1130 of 2152

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1131 of 2152

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1132 of 2152

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1133 of 2152

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1134 of 2152

Foreign Patents

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1135 of 2152

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1136 of 2152

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1137 of 2152

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

Other Documents

EBI Omega 21 Brochure, EBI Spine Systems, pub. 1999

Claris Instrumentation Brochure, G Med, pub. 1997

VLS System Variable Locking Screw Brochure, Interpore Cross International,1999

CD Horizon M8 Multi Axial Screw Spinal System Brochure, Medtronic Sofamor Danek, no publish date

Contour Spinal System Brochure, Ortho Development, no publish date

Xia Spinal System Brochure, Stryker Howmedica Osteonics, no publish date

The Rod Plate System Brochure, Stryker Howmedica Osteonics, pub. Oct., 1999

Silhouette Spinal Fixation System Brochure, Sulzer Medica Spine-

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1138 of 2152

Tech, no publish date

SDRS Surgical Dynamics Rod System Brochure, Surgical Dynamics, pub. 1998-99

Versalok Low Back Fixation System Brochure, Wright Medical Technology, Inc., pub. 1997

The Strength of Innovation Advertisement, Blackstone Medical Inc., no publish date

The Moss Miami 6.0mm System Advertisement, author unknown, no publish date

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

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

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

Respectfully submitted,

1-8-13
Date

Roger P. Jackson, Inventor

Respectfully submitted,

1-9-2013
Date

James L. Surber, Inventor

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1139 of 2152

OIPAP
JAN 10 2013
IAP11
PATENT & TRADEMARK OFFICE

EXPRESS MAIL EM626520557US

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

Substitute for form 1449/PTO				*Complete if Known*	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	
				Filing Date	
(Use as many sheets as necessary)				First Named Inventor	Roger P. Jackson
				Art Unit	
				Examiner Name	
Sheet	1	of	50	Attorney Docket Number	11,433

U. S. PATENT DOCUMENTS					
Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code [2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		us-7,572,279	08/11/2009	Jackson	
		US-7,479,156	01/20/2009	Lourdel, et al.	
		US-7,476,228	01/13/2009	Abdou	
		US-7,445,627	11/04/2008	Hawkes, et al.	
		US-7,491,218	02/17/2009	Landry, et al.	
		US-7,491,221	02/17/2009	David	
		US-7,503,924	03/17/2009	Lee, et al.	
		US-7,503,918	03/17/2009	Baccelli, et al.	
		US-7,530,992	05/12/2009	Biedermann, et al.	
		US-7,527,640	05/05/2009	Ziolo, et al.	
		US-7,524,323	04/28/2009	Malandain	
		US-7,559,943	07/14/2009	Mjuwid	
		US-7,563,264	07/21/2009	Landry, et al.	
		US-7,563,275	07/21/2009	Falahee, et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Cite No.[1]	Foreign Patent Document Country Code [3] Number[4] Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
		WO2009/015100	01/29/2009	Keyer, et al.		
		WO95/01132	01/12/1995	Schlapfer, et al.		
		FR2,925,288	06/26/2009	Timoteo		
		WO01/10317	02/15/2001	Marquez-Alverez		
		EP1210914	06/05/2002	Marquez Alverez		

Examiner Signature		Date Considered	

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

[1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: **Commissioner for Patents, Washington, DC 20231.**

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

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

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

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

Sheet 2 of 50

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[7]	Document Number Number-Kind Code [2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-7,569,061	08/04/2009	Colleran	
		US-7,572,280	08/11/2009	Dickinson, et al.	
		US-7,575,587	08/18/2009	Rezach, et al.	
		US-7,588,575	08/15/2009	Colleran, et al.	
		US-7,588,588	09/12/2009	Spitler, et al.	
		US-7,588,593	09/15/2009	Aferzon	
		US-7,591,839	09/22/2009	Biedermann, et al.	
		US-7,601,166	10/13/2009	Biedermann, et al.	
		US-7,604,656	10/20/2009	Shluzas	
		US-7,611,518	11/03/2009	Walder, et al.	
		US-7,615,068	11/10/2009	Timm, et al.	
		US-7,621,941	11/24/2009	Schlapfer, et al.	
		US-7,625,394	12/01/2009	Molz, IV, et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.[1]	Foreign Patent Document Country Code [3] Number[4] Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
		EP2380513	10/26/11	Biedermann, et al.		
		DE29903342	06/02/99	Grzibek		

Examiner Signature		Date Considered	

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

[1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, Washington, DC 20231.**

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

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

Substitute for form 1449/PTO				*Complete if Known*	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	
				Filing Date	
(Use as many sheets as necessary)				First Named Inventor	Roger P. Jackson
				Art Unit	
				Examiner Name	
Sheet	3	of	50	Attorney Docket Number	11,433

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[7]	Document Number Number-Kind Code [2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-7,641,674	01/05/2010	Young	
		US-7,645,294	01/12/1010	Kalfaseld	
		US-7,648,522	01/19/2010	David	
		US-2009/0018591	01/15/2009	Hawkes, et al.	
		US-2009/0012567	01/08/2009	Biedermann, et al.	
		US-2009/0005814	01/01/2009	Miller, et al.	
		US-2009/0005813	01/01/2009	Crall, e tal.	
		US-2009/0005787	01/01/2009	Crall, et al.	
		US-2008/0312701	12/18/2008	Batters, et al.	
		US-2008/0312696	12/18/2008	Battlers, et al.	
		US-2008/0312692	12/18/2008	Brennan, et al.	
		US-2008/0312655	12/18/2008	Kirschman, et al.	
		US-2008/0154315	06/26/2008	Jackson	
		US-2009/0024169	01/22/2009	Triplett, et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.[1]	Foreign Patent Document Country Code [3] Number[4] Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
		WO2012/088890	07/05/2012	Li, Lei, et al.		
		WO2012/075827	06/14/2012	Jin, Hangjun, et al.		

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: **Commissioner for Patents, Washington, DC 20231.**
If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

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

Substitute for form 1449/PTO				*Complete if Known*	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	
				Filing Date	
(Use as many sheets as necessary)				First Named Inventor	Roger P. Jackson
				Art Unit	
				Examiner Name	
Sheet	4	of	50	Docket No.	11,433

U. S. PATENT DOCUMENTS					
Examiner Initials*	Cite No.[7]	Document Number Number-Kind Code [2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-2008/0200956	08/21/2008	Beckwith, et al.	
		US-2008/0215095	09/04/2008	Biedermann, et al.	
		US-2008/0228229	09/18/2008	Walder, et al.	
		US-2008/0234734	09/25/2008	Walder, et al.	
		US-2008/0234756	09/25/2008	Sutcliffe, et al.	
		US-2008/0234759	09/25/2008	Marino	
		US-2008/0249570	10/09/2008	Carson, et al.	
		US-2008/0262548	10/23/2008	Lange, et al.	
		US-2008/0262556	10/23/2008	Jacofsky, et al.	
		US-2008/0269742	10/30/2008	Levy, et al.	
		US-2008/0269809	10/30/2008	Garamszegi	
		US-2008/0287994	11/20/2008	Perez-Cruet, et al.	
		US-2008/0288002	11/20/2008	Crall, et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Cite No.[1]	Foreign Patent Document Country Code [3] Number[4] Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.
This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: **Commissioner for Patents, Washington, DC 20231.**
If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

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

Substitute for form 1449/PTO				*Complete if Known*	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	
				Filing Date	
(Use as many sheets as necessary)				First Named Inventor	Roger P. Jackson
				Art Unit	
				Examiner Name	
Sheet	5	of	50	Attorney Docket Number	11,433

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[7]	Document Number Number-Kind Code [2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-2008/0306528	12/11/2008	Winslow, et al.	
		US-2008/0306533	12/11/2008	Winslow, et al.	
		US-2008/0306539	12/11/2008	Cain, et al.	
		US-2006/0166535	07/27/2006	Brumfiled, et al.	
		US-2006/0276789	12/07/2006	Jackson	
		US-2007/0055244	03/08/2007	Jackson	
		US-2009/0030457	01/29/2009	Janowski, et al.	
		US-2009/0036929	02/05/2009	Reglos, et al.	
		US-2009/0036932	02/05/2009	Rouyer, et al.	
		US-2009/0036934	02/05/2009	Biedermann, et al.	
		US-2009/0062860	03/05/2009	Fraiser, et al.	
		US-2009/0062865	03/05/2009	Schumacher	
		US-2009/0062867	03/05/2009	Schumacher	

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.[1]	Foreign Patent Document Country Code [3] Number[4] Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.usplo.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.
This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: **Commissioner for Patents, Washington, DC 20231.**
If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

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

Substitute for form 1449/PTO				*Complete if Known*	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	
				Filing Date	
(Use as many sheets as necessary)				First Named Inventor	Roger P. Jackson
				Art Unit	
				Examiner Name	
Sheet	6	of	50	Attorney Docket Number	11,433

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[7]	Document Number Number-Kind Code [2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-2009/0062914	03/05/2009	Marino	
		US-2009/0069853	03/12/2009	Schumacher	
		US-2009/0069849	03/12/2009	Oh, et al.	
		US-2009/0069852	03/12/2009	Farris, et al.	
		US-2006/0217716	09/28/2006	Baker, et al.	
		US-2009/0076550	03/19/2009	Bernhardt, Jr., et al.	
		US-2009/0076552	03/19/2009	Tornier	
		US-2009/0082809	03/26/2009	Nguyen, et al.	
		US-2009/0082815	03/26/2009	Zylber, et al.	
		US-2009/0082819	03/26/2009	Blain, et al.	
		US-2009/0088799	04/02/2009	Yeh	
		US-2009/0088807	04/02/2009	Castaneda, et al.	
		US-2009/0082812	03/26/2009	Lewis	

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.[1]	Foreign Patent Document Country Code [3] Number[4] Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]

Examiner Signature		Date Considered	

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

[1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, Washington, DC 20231.**

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

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

Substitute for form 1449/PTO				*Complete if Known*	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	
				Filing Date	
(Use as many sheets as necessary)				First Named Inventor	Roger P. Jackson
				Art Unit	
				Examiner Name	
Sheet	7	of	50	Attorney Docket Number	11,433

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[7]	Document Number Number-Kind Code [2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-2009/0005813	01/01/2009	Crall, et al.	
		US-2009/0093843	04/09/2009	Lemoine, et al.	
		US-2009/0105769	04/23/2009	Rock, et al.	
		US-2009/0105770	04/23/2009	Berrevoets, et al.	
		US-2009/0105771	04/23/2009	Lei, et al.	
		US-2009/0118772	05/07/2009	Diederich, et al.	
		US-2009/0131983	05/21/2009	Biedermann	
		US-2009/0138044	05/28/2009	Bergeron, et al.	
		US-2009/0138052	05/28/2009	Biedermann, et al.	
		US-2009/0143827	06/04/2009	Levy, et al.	
		US-2009/0143829	06/04/2009	Shluzas	
		US-2009/0149887	06/11/2009	Schlaepfer, et al.	
		US-2009/0163955	06/25/2009	Moumene, et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.[1]	Foreign Patent Document Country Code [3] Number[4] Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: **Commissioner for Patents, Washington, DC 20231.**
If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

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

Substitute for form 1449/PTO				*Complete if Known*	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	
				Filing Date	
(Use as many sheets as necessary)				First Named Inventor	Roger P. Jackson
				Art Unit	
				Examiner Name	
Sheet	8	of	50	Attorney Docket Number	11,433

U. S. PATENT DOCUMENTS					
Examiner Initials*	Cite No.[7]	Document Number Number-Kind Code [2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-2009/0163956	06/25/2009	Biedermann, et al.	
		US-2009/0163961	06/25/2009	Kirschman	
		US-2009/0163963	06/25/2009	Berrevoets	
		US-2009/0182380	07/16/2009	Abdelgany	
		US-2009/0192548	07/30/2009	Jeon, et al.	
		US-2009/0192551	07/30/2009	Cianfrani, et al.	
		US-2009/0198280	08/06/2009	Spratt, et al.	
		US-2009/0198289	08/06/2009	Manderson	
		US-2009/0198291	08/06/2009	Kevin, et al.	
		US-2009/0204155	08/13/2009	Aschmann	
		US-2009/0216280	08/27/2009	Hutchinson	
		US-2009/0248030	10/01/2009	Butler, et al.	
		US-2009/0248075	10/01/2009	Ogilvie, et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Cite No.[1]	Foreign Patent Document Country Code [3] Number[4] Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.
If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

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

Substitute for form 1449/PTO				*Complete if Known*	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	
				Filing Date	
(Use as many sheets as necessary)				First Named Inventor	Roger P. Jackson
				Art Unit	
				Examiner Name	
Sheet	9	of	50	Attorney Docket Number	11,433

U. S. PATENT DOCUMENTS					
Examiner Initials*	Cite No.[7]	Document Number Number-Kind Code [2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-2009/0248088	10/01/2009	Biedermann	
		US-2009/0254125	10/08/2009	Predick	
		US-2009/0259254	10/15/2009	Pisharodi	
		US-2009/0264896	10/22/2009	Biedermann, et al.	
		US-2009/0264933	10/22/2009	Carls, et al.	
		US-2009/0270916	10/29/2009	Ramsay, et al.	
		US-2009/0270917	10/29/2009	Boehm	
		US-2009/0281571	11/12/2009	Weaver, et al.	
		US-2009/0281572	11/12/2009	White	
		US-2009/0281573	11/12/2009	Biedermann,e t al.	
		US-2009/0287253	11/19/2009	Felix, et al.	
		US-2009/0299415	12/03/2009	Pimenta	
		US-2009/0306719	12/10/2009	Meyer, III, et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Cite No.[1]	Foreign Patent Document Country Code [3] Number[4] Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.
This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, Washington, DC 20231.**
If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

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

Substitute for form 1449/PTO				*Complete if Known*	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	
				Filing Date	
(Use as many sheets as necessary)				First Named Inventor	Roger P. Jackson
				Art Unit	
				Examiner Name	
Sheet	10	of	50	Attorney Docket Number	11,433

U. S. PATENT DOCUMENTS					
Examiner Initials*	Cite No.[7]	Document Number Number-Kind Code [2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-2009/0306720	12/10/2009	Doubler, et al.	
		US-2009/0312804	12/17/2009	Gamache, et al.	
		US-2009/0326582	12/31/2009	Songer, et al.	
		US-2009/0326587	12/31/2009	Matthis, et al.	
		US-2010/0004692	01/07/2010	Biedermann,e t al.	
		US-2010/0010540	01/14/2010	Park	
		US-2010/0016898	01/21/2010	Shluzas	
		US-2006/0276789	07/12/2006	Jackson	
		US-			
		US-			
		US-			
		US-			
		US-			

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Cite No.[1]	Foreign Patent Document Country Code [3] Number[4] Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, Washington, DC 20231.**
If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

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

Substitute for form 1449/PTO				*Complete if Known*	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	
				Filing Date	
(Use as many sheets as necessary)				First Named Inventor	Roger P. Jackson
				Art Unit	
				Examiner Name	
Sheet	11	of	50	Attorney Docket Number	11,433

U. S. PATENT DOCUMENTS					
Examiner Initials*	Cite No.[7]	Document Number Number-Kind Code [2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-7,445,627	11/04/08	Hawkes, et al.	
		US-7,018,379	03/28/06	Drewry, et al.	
		US-7,018,378	03/28/06	Biedermann, et al.	
		US-RE39,035	03/21/06	Finn, et al.	
		US-6,981,973	01/03/06	McKinley	
		US-6,979,334	12/27/05	Dalton	
		US-6,974,460	12/13/05	Carbone, et al.	
		US-6,964,664	11/15/05	Freid, et al.	
		US-6,964,665	11/15/05	Thomas, et al.	
		US-6,958,065	10/25/05	Ueyama, et al.	
		US-6,955,677	10/18/05	Dahners	
		US-6,953,462	10/11/05	Lieberman	
		US-6,945,972	09/20/05	Frigg, et al.	
		US-6,932,817	08/23/05	Baynham, et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Cite No.[1]	Foreign Patent Document Country Code [3] Number[4] Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
		WO2006/028537	03/16/06	Thramann, et al.		
		EP 1634537	03/15/06	Errico, et al.		
		WO2006/017616	02/16/06	Doubler, et al.		
		WO2006/012088	02/02/06	Kingsley		
		WO2005/099400	10/27/05	Iott, et al.		

Examiner Signature		Date Considered	

PTO/SB/08A (04-03)

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.
This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: **Commissioner for Patents, Washington, DC 20231.**

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

Substitute for form 1449/PTO				*Complete if Known*	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	
				Filing Date	
(Use as many sheets as necessary)				First Named Inventor	Roger P. Jackson
				Art Unit	
				Examiner Name	
Sheet	12	of	50	Attorney Docket Number	11,433

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[7]	Document Number Number-Kind Code [2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-6,872,208	03/29/05	McBride, et al.	
		US-6,869,432	03/22/05	Schlapfer, et al.	
		US-6,869,433	03/22/05	Glascott	
		US-6,858,031	02/22/05	Morrison, et al.	
		US-6,843,791	01/18/05	Serhan	
		US-6,840,940	01/11/05	Ralph, et al.	
		US-6,835,196	12/28/04	Biedermann, et al.	
		US-6,830,571	12/14/04	Lenke, et al.	
		US-6,827,719	12/07/04	Ralph, et al.	
		US-6,790,209	09/14/04	Beale, et al.	
		US-6,780,186	08/24/04	Errico, et al.	
		US-6,770,075	08/03/04	Howland	
		US-6,767,351	07/27/04	Orbay, et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.[1]	Foreign Patent Document Country Code [3] Number[4] Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
		WO2005/082262	09/09/05	Sournac, et al.		
		WO2005/072632	08/11/05	Sournac, et al.		
		EP1579816	09/28/05	Harms, et al.		
		EP1570795	09/07/05	Harms, et al.		
		WO2005/020829	03/10/05	Renaud, et al.		
		WO2005/000136	01/06/05	Clement, et al.		

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.
This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

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

Substitute for form 1449/PTO				*Complete if Known*	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	
				Filing Date	
(Use as many sheets as necessary)				First Named Inventor	Roger P. Jackson
				Art Unit	
				Examiner Name	
Sheet	13	of	50	Attorney Docket Number	11,433

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[7]	Document Number Number-Kind Code [2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-6,761,723	07/13/04	Buttermann, et al.	
		US-6,755,836	06/29/04	Lewis	
		US-6,755,835	06/29/04	Schultheiss, et al.	
		US-6,755,829	06/29/04	Bono, et al.	
		US-6,746,449	06/08/04	Jones, et al.	
		US-6,740,086	05/25/04	Richelsoph	
		US-6,736,820	05/18/04	Biedermann, et al.	
		US-6,736,816	05/18/04	Ritland	
		US-6,733,502	05/11/04	Altarac, et al.	
		US-6,730,127	05/04/04	Michelson	
		US-6,730,093	05/04/04	Saint Martin	
		US-6,723,100	04/20/04	Biedermann, et al.	
		US-6,716,213	04/06/04	Shitoto	

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.[1]	Foreign Patent Document Country Code [3] Number[4] Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
		WO2005/000137	01/06/05	Clement, et al.		
		WO2004/107997	12/16/04	Bette, et al.		
		WO2004/089245	10/21/04	Mueller		
		FR 2865378	10/22/04	Sournac, et al.		
		WO2004/041100	05/21/04	Landry, et al.		
		FR 2857850	04/01/04	Clement, et al.		

Examiner Signature		Date Considered	

PTO/SB/08A (04-03)
Approved for use through 04/30/2003. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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

[1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, Washington, DC 20231.**

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

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

Substitute for form 1449/PTO				*Complete if Known*	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	
				Filing Date	
(Use as many sheets as necessary)				First Named Inventor	Roger P. Jackson
				Art Unit	
				Examiner Name	
Sheet	14	of	50	Attorney Docket Number	11,433

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[7]	Document Number Number-Kind Code [2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-6,716,247	04/06/04	Michelson	
		US-6,716,214	04/06/04	Jackson	
		US-6,712,818	03/30/04	Michelson	
		US-6,706,045	03/16/04	Lin, et al.	
		US-6,699,249	03/02/04	Schlapfer, et al.	
		US-6,695,843	02/24/04	Biedermann, et al.	
		US-6,695,851	02/24/04	Zdeblick, et al.	
		US-6,695,843	02/24/04	Biedermann, et al.	
		US-6,689,134	02/10/04	Ralph, et al.	
		US-6,689,133	02/10/04	Morrison, et al.	
		US-6,682,529	01/27/04	Stahurski	
		US-6,679,833	01/20/04	Smith, e tal.	
		US-6,676,661	01/13/04	Martin Benlloch, et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.[1]	Foreign Patent Document Country Code [3] Number[4] Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
		FR2865377	01/27/04	Clement, et al.		
		FR2865375	01/27/04	Sournac, et al.		
		FR2865373	01/27/04	Sournac, et al.		
		WO03/068088	08/21/03	Altarac, et al.		
		FR2856578	06/27/03	Clement, et al.		
		WO02/054966	07/18/02	Glascott		

Examiner Signature		Date Considered	

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

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.
This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, Washington, DC 20231.**
If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Substitute for form 1449/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	
				Filing Date	
(Use as many sheets as necessary)				First Named Inventor	Roger P. Jackson
				Art Unit	
				Examiner Name	
Sheet	15	of	50	Attorney Docket Number	11,433

U. S. PATENT DOCUMENTS					
Examiner Initials*	Cite No.[2]	Document Number Number-Kind Code [2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-6,673,073	01/06/04	Schafer	
		US-6,663,635	12/16/03	Frigg, et al.	
		US-6,663,632	12/16/03	Frigg	
		US-6,660,004	12/09/03	Barker, et al.	
		US-6,656,179	12/02/03	Schaefer, et al.	
		US-6,656,181	12/02/03	Dixon, et al.	
		US-6,648,885	11/18/03	Friesem	
		US-6,648,887	11/18/03	Ashman	
		US-6,635,059	10/21/03	Randall, et al.	
		US-6,626,907	09/30/03	Campbell, et al.	
		US-6,626,908	09/30/03	Cooper, et al.	
		US-6,623,485	09/23/03	Doubler, et al.	
		US-6,613,050	09/02/03	Wagner, et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Cite No.[1]	Foreign Patent Document Country Code [3] Number[4] Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
		EP1190678	03/27/02	Bono, et al.		
		GB2365345	02/20/02	Cooper, et al.		
		EP1121902	08/08/01	Schaffler, et al.		
		FR2796545	01/26/01	Saint Martin, et al.		
		DE19507141	09/12/96	Gleich, et al.		
		FR2729291	07/19/96	Gennari		
		G9202745.8	04/30/92	Hauck, et al.		

Examiner Signature		Date Considered	

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

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.
This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

Substitute for form 1449/PTO				*Complete if Known*	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	
				Filing Date	
(Use as many sheets as necessary)				First Named Inventor	Roger P. Jackson
				Art Unit	
				Examiner Name	
Sheet	16	of	50	Attorney Docket Number	11,433

U. S. PATENT DOCUMENTS					
Examiner Initials*	Cite No.[7]	Document Number Number-Kind Code [2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-6,610,063	08/26/03	Kumar, et al.	
		US-6,595,992	07/22/03	Wagner, et al.	
		US-6,595,993	07/22/03	Donno, et al.	
		US-6,585,740	07/01/03	Schlapfer, et al.	
		US-6,582,436	06/24/03	Schlapfer, et al.	
		US-6,582,466	06/24/03	Gauchet	
		US-6,565,567	05/20/03	Haider	
		US-6,565,565	05/20/03	Yuan, et al.	
		US-6,562,040	05/13/03	Wagner	
		US-6,558,387	05/06/03	Errico, et al.	
		US-6,554,834	04/29/03	Crozet, et al.	
		US-6,554,832	04/29/03	Shluzas	
		US-6,551,320	04/22/03	Liebermann	
		US-6,547,790	04/15/03	Harkey, III, et al.	
		US-6,533,786	03/18/03	Needham, et al.	
		US-6,530,929	03/11/03	Jusis, et al.	
		US-6,527,804	03/04/03	Gauchet, et al.	
		US-6,520,962	02/18/03	Taylor, et al.	
		US-6,508,818	01/21/03	Steiner, et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Cite No.[1]	Foreign Patent Document Country Code [3] Number[4] Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
		WO2008/088731	07/24/2008	Hawkins		
		EP1925263	05/28/2008	Matthis, et al.		
Examiner Signature			Date Considered			

PTO/SB/08A (04-03)

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

[1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

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

Substitute for form 1449/PTO				*Complete if Known*	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	
				Filing Date	
(Use as many sheets as necessary)				First Named Inventor	Roger P. Jackson
				Art Unit	
				Examiner Name	
Sheet	17	of	50	Attorney Docket Number	11,433

U. S. PATENT DOCUMENTS					
Examiner Initials*	Cite No.[7]	Document Number Number-Kind Code [2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-6,488,681	12/03/02	Martin, et al.	
		US-6,485,494	11/26/02	Haider	
		US-6,471,705	10/29/02	Biedermann, et al.	
		US-6,471,703	10/29/02	Ashman	
		US-6,451,021	09/17/02	Ralph, et al.	
		US-6,440,137	08/27/02	Horvath, et al.	
		US-6,402,752	06/11/02	Schaffler-Wachter, et al.	
		US-RE37,665	04/16/02	Ralph, et al.	
		US-6,368,321	04/09/02	Jackson	
		US-6,355,040	03/12/02	Richelsoph, et al.	
		US-6,309,391	10/30/01	Crandall, et al.	
		US-6,331,179	12/18/01	Freid, et al.	
		US-6,302,888	10/16/01	Mellinger, et al.	
		US-6,287,308	09/11/01	Betz, et al.	
		US-6,287,311	09/11/01	Sherman, et al.	
		US-6,280,445	08/28/01	Morrison, et al.	
		US-6,280,442	08/28/01	Barker, et al.	
		US-6,273,888	08/14/01	Justis	
		US-6,254,602	07/03/01	Justis	

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Cite No.[1]	Foreign Patent Document Country Code [3] Number[4] Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]

Examiner Signature		Date Considered	

PTO/SB/08A (04-03)
Approved for use through 04/30/2003. OMB 0651-0031

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.
This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

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

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

Substitute for form 1449/PTO				*Complete if Known*	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	
				Filing Date	
(Use as many sheets as necessary)				First Named Inventor	Roger P. Jackson
				Art Unit	
				Examiner Name	
Sheet	18	of	50	Attorney Docket Number	11,433

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[7]	Document Number Number-Kind Code [2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-6,248,105	06/19/01	Schlapfer, et al.	
		US-RE37,161	05/01/01	Michelson, et al.	
		US-6,224,596	05/01/01	Jackson	
		US-6,187,005	02/13/01	Brace, et al.	
		US-6,183,472	02/06/01	Lutz	
		US-6,146,383	11/14/00	Studer, et al.	
		US-6,132,434	10/17/00	Sherman, et al.	
		US-6,132,432	10/17/00	Richelsoph	
		US-6,132,431	10/17/00	Nilsson, et al.	
		US-6,113,601	09/05/00	Tatar	
		US-6,110,172	08/29/00	Jackson	
		US-6,099,528	08/08/00	Saurat	
		US-6,090,111	07/18/00	Nichols	
		US-6,090,110	07/18/00	Metz-Stavenhagen	
		US-6,086,588	07/11/00	Ameil, et al.	
		US-6,077,262	06/20/00	Schlapfer, et al.	
		US-6,074,391	06/13/00	Metz-Stavenhagen, et al.	
		US-6,063,090	05/16/00	Schlapfer	
		US-6,053,917	04/25/00	Sherman, et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.[1]	Foreign Patent Document Country Code [3] Number[4] Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]

Examiner Signature		Date Considered	

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

[1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

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

Substitute for form 1449/PTO				*Complete if Known*	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	
				Filing Date	
(Use as many sheets as necessary)				First Named Inventor	Roger P. Jackson
				Art Unit	
				Examiner Name	
Sheet	19	of	50	Attorney Docket Number	11,433

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[7]	Document Number Number-Kind Code [2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-6,022,350	02/08/00	Ganem	
		US-6,019,759	02/01/00	Rogozinski	
		US-6,010,503	01/04/00	Richelsoph, et al.	
		US-5,964,760	10/12/99	Richelsoph	
		US-5,961,517	10/05/99	Biedermann, et al.	
		US-5,954,725	09/21/99	Sherman, et al.	
		US-5,891,145	04/06/99	Morrison, et al.	
		US-5,885,286	03/23/99	Sherman, et al.	
		US-5,882,350	03/16/99	Ralph, et al.	
		US-5,879,351	03/09/99	Viart	
		US-5,879,350	03/09/99	Sherman, et al.	
		US-5,876,402	03/02/99	Errico, et al.	
		US-5,863,293	01/26/99	Richelsoph	
		US-5,817,094	10/06/98	Errico, et al.	
		US-5,800,435	09/01/98	Errico, et al.	
		US-5,797,911	08/25/98	Sherman, et al.	
		US-5,782,833	07/21/98	Haider	
		US-5,738,685	04/14/98	Halm, et al.	
		US-5,733,286	03/31/98	Errico, et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.[1]	Foreign Patent Document Country Code [3] Number[4] Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T*

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.
This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: **Commissioner for Patents, Washington, DC 20231.**

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

Substitute for form 1469/PTO				*Complete if Known*	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	
				Filing Date	
(Use as many sheets as necessary)				First Named Inventor	Roger P. Jackson
				Art Unit	
				Examiner Name	
Sheet	20	of	50	Attorney Docket Number	11,433

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[7]	Document Number Number-Kind Code [2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-5,728,098	03/17/98	Sherman, et al.	
		US-5,725,528	03/10/98	Errico, et al.	
		US-5,716,356	02/10/98	Biedermann, et al.	
		US-5,690,630	11/25/97	Errico, et al.	
		US-5,681,319	10/28/97	Biedermann, et al.	
		US-5,672,176	09/30/97	Biedermann, et al.	
		US-5,669,911	09/23/97	Errico, et al.	
		US-5,647,873	07/15/97	Errico, et al.	
		US-7,186,255	03/06/2007	Baynham, et al.	
		US-5,607,426	03/04/97	Ralph, et al.	
		US-5,601,553	02/11/97	Trebing, et al.	
		US-5,591,166	01/07/97	Bernhardt, et al.	
		US-5,586,984	12/24/96	Errico, et al.	
		US-5,584,834	12/17/96	Errico, et al.	
		US-5,569,247	10/29/96	Morrison	
		US-5,554,157	09/10/96	Errico, et al.	
		US-5,496,321	03/05/96	Puno, et al.	
		US-5,476,464	12/19/95	Metz-Stavenhagen, et al.	
		US-5,476,462	12/19/95	Allard, et al.	
		US-5,474,555	12/12/95	Puno, et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.[1]	Foreign Patent Document Country Code [3] Number[4] Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.usplo.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

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

Substitute for form 1449/PTO				*Complete if Known*	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	
				Filing Date	
(Use as many sheets as necessary)				First Named Inventor	Roger P. Jackson
				Art Unit	
				Examiner Name	
Sheet	21	of	50	Attorney Docket Number	11,433

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[7]	Document Number Number-Kind Code [2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-5,466,237	11/14/95	Byrd, III, et al.	
		US-5,443,467	08/22/95	Biedermann, et al.	
		US-5,429,639	07/04/95	Judet	
		US-5,395,371	03/07/95	Miller, et al.	
		US-5,360,431	11/01/94	Puno, et al.	
		US-5,312,404	05/17/94	Asher, et al.	
		US-5,261,912	11/16/93	Frigg	
		US-5,207,678	05/04/93	Harms, et al.	
		US-5,129,388	07/14/92	Vignaud, et al.	
		US-4,946,458	08/07/90	Harms, et al.	
		US-2006/0058788	03/16/06	Hammer, et al.	
		US-2006/0052786	03/09/06	Dant, et al.	
		US-2006/0052784	03/09/06	Dant, et al.	
		US-2006/0052783	03/09/06	Dant, et al.	
		US-2006/0036252	02/16/06	Baynham, et al.	
		US-2006/0036242	02/16/06	Nilsson, et al.	
		US-2006/0025770	02/02/06	Schlapfer, et al.	
		US-2006/0025767	02/02/06	Khalili	
		US-2006/0025768	02/02/06	Iott, et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.[1]	Foreign Patent Document Country Code [3] Number[4] Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

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

Substitute for form 1449/PTO				*Complete if Known*	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	
				Filing Date	
(Use as many sheets as necessary)				First Named Inventor	Roger P. Jackson
				Art Unit	
				Examiner Name	
Sheet	22	of	50	Attorney Docket Number	11,433

U. S. PATENT DOCUMENTS					
Examiner Initials*	Cite No.[7]	Document Number Number-Kind Code [2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-2006/0015104	01/16/06	Dalton	
		US-2006/0009769	01/12/06	Liebermann	
		US-2006/0009770	01/12/06	Speirs, et al.	
		US-2006/0004359	01/05/06	Kramer, et al.	
		US-2006/0004357	01/05/06	Lee, et al.	
		US-2006/0004363	01/05/06	Brockmeyer, et al.	
		US-2006/0004360	01/05/06	Kramer, et al.	
		US-2005/0288669	12/29/05	Abdou	
		US-2005/0288671	12/29/05	Yuan, et al.	
		US-2005/0288673	12/29/05	Catbagan, et al.	
		US-2005/0283238	12/22/05	Reiley	
		US-2005/0283152	12/22/05	Lindemann, et al.	
		US-2005/0283157	12/22/05	Coates, et al.	
		US-2005/0277925	12/15/05	Mujwid	
		US-2005/0277928	12/15/05	Boschert	
		US-2005/0277919	12/15/05	Slivka, et al.	
		US-2005/0273101	12/08/05	Schumacher	
		US-2005/0273099	12/08/05	Baccelli, et al.	
		US-2005/0267474	12/01/05	Dalton	

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Cite No.[1]	Foreign Patent Document Country Code [3] Number[4] Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

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

Substitute for form 1449/PTO				*Complete if Known*	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	
				Filing Date	
(Use as many sheets as necessary)				First Named Inventor	Roger P. Jackson
				Art Unit	
				Examiner Name	
Sheet	23	of	50	Attorney Docket Number	11,433

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[7]	Document Number Number-Kind Code [2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-2005/0261687	11/24/05	Garamszegi, et al.	
		US-2005/0251141	11/10/05	Frigg, et al.	
		US-2005/0251137	11/10/05	Ball	
		US-2005/0240183	10/27/05	Vaughan	
		US-2005/0240181	10/27/05	Boomer, et al.	
		US-2005/0234450	10/20/05	Barker	
		US-2005/0234452	10/20/05	Malandain	
		US-2005/0234451	10/20/05	Markworth	
		US-2005/0228501	10/13/05	Miller, et al.	
		US-2005/0216003	09/29/05	Beidermann, et al.	
		US-2005/0203516	09/15/05	Biedermann, et al.	
		US-2005/0192580	09/01/05	Dalton	
		US-2005/0187555	08/25/05	Beidermann, et al.	
		US-2005/0187548	08/25/05	Butler, et al.	
		US-2005/0171540	08/04/05	Lim, et al.	
		US-2005/0165400	07/28/05	Fernandez	
		US-2005/0159750	07/21/05	Doherty	
		US-2005/0154391	07/14/05	Doherty, et al.	
		US-2005/0154389	07/14/05	Selover, et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.[1]	Foreign Patent Document Country Code [3] Number[4] Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

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

Substitute for form 1449/PTO				*Complete if Known*	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	
				Filing Date	
(Use as many sheets as necessary)				First Named Inventor	Roger P. Jackson
				Art Unit	
				Examiner Name	
Sheet	24	of	50	Attorney Docket Number	11,433

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[7]	Document Number Number-Kind Code [2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-2005/0149023	07/07/05	Ritland	
		US-2005/0131404	06/16/05	Mazda, et al.	
		US-2005/0131413	06/16/05	O'Driscoll, et al.	
		US-2005/0113927	05/26/05	Malek	
		US-2005/0107788	05/19/05	Beaurain, et al.	
		US-2005/0080415	04/14/05	Keyer, et al.	
		US-2005/0070899	03/31/05	Doubler, et al.	
		US-2005/0055026	03/10/05	Biedermann, et al.	
		US-2005/0027296	02/03/05	Thramann, et al.	
		US-2004/0267264	12/30/04	Konieczynski, et al.	
		US-2004/0249380	12/09/04	Glascott	
		US-2004/0225289	11/11/04	Biedermann, et al.	
		US-2004/0236330	11/25/04	Purcell, et al.	
		US-2004/0210216	10/21/04	Farris, et al.	
		US-2004/0176766	09/09/04	Shluzas	
		US-2004/0186473	09/23/04	Cournoyer, et al.	
		US-2004/0172022	09/02/04	Landry, et al.	
		US-2004/0158247	08/12/04	Sitiso, et al.	
		US-2004/0147929	07/29/04	Biedermann, et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.[1]	Foreign Patent Document Country Code [3] Number[4] Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

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

Substitute for form 1449/PTO				*Complete if Known*	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	
				Filing Date	
(Use as many sheets as necessary)				First Named Inventor	Roger P. Jackson
				Art Unit	
				Examiner Name	
Sheet	25	of	50	Attorney Docket Number	11,433

U. S. PATENT DOCUMENTS					
Examiner Initials*	Cite No.[7]	Document Number Number-Kind Code [2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-2004/0143265	07/22/04	Landry, et al.	
		US-2004/0138662	07/15/04	Landry, et al.	
		US-2004/0116929	06/17/04	Barker, et al.	
		US-2004/0097933	05/20/04	Lourdel, et al.	
		US-2004/0092934	05/13/04	Howland	
		US-2004/0006342	01/08/04	Altarac, et al.	
		US-2003/0216735	11/20/03	Altarac, et al.	
		US-2003/0208204	11/06/03	Bailey, et al.	
		US-2003/0199873	10/23/03	Richelsoph	
		US-2003/0176862	09/18/03	Taylor, et al.	
		US-2003/0163133	08/28/03	Altarac, et al.	
		US-2003/0149432	08/07/03	Frigg, et al.	
		US-2003/0125741	07/03/03	Biedermann, et al.	
		US-2003/0105460	06/05/03	Crandall, et al.	
		US-2003/0100896	05/29/03	Biedermann, et al.	
		US-2003/0093078	05/15/03	Ritland	
		US-2003/0073996	04/17/03	Doubler, et al.	
		US-2003/0023243	01/30/03	Biedermann, et al.	
		US-2002/0193795	12/19/02	Gertzbein, et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Cite No.[1]	Foreign Patent Document Country Code [3] Number[4] Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.
This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: **Commissioner for Patents, Washington, DC 20231.**

Substitute for form 1449/PTO				*Complete if Known*	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	
				Filing Date	
(Use as many sheets as necessary)				First Named Inventor	Roger P. Jackson
				Art Unit	
				Examiner Name	
Sheet	26	of	50	Attorney Docket Number	11,433

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[7]	Document Number Number-Kind Code [2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-2002/0173789	11/21/02	Howland	
		US-2002/0143341	10/03/02	Biedermann, et al.	
		US-2002/0203511	09/15/02	Wilson-MacDonald, et al.	
		US-2002/0111626	08/15/02	Ralph, et al.	
		US-2002/0082602	06/27/02	Biedermann, et al.	
		US-2002/0045898	04/18/02	Freid, et al.	
		US-2002/0035366	03/21/02	Walder, et al.	
		US-2001/0001119	05/10/01	Lombardo	
		US-2006/0106383	05/18/06	Biedermann, eta l.	
		US-2006/0084995	04/20/06	Biedermann, et al.	
		US-2007/0073291	03/29/07	Cordaro, et al.	
		US-2007/0078460	04/05/07	Frigg, et al.	
		US-2007/0083199	04/12/07	Baccelli	

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.[1]	Foreign Patent Document Country Code [3] Number[4] Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
		WO2006/005198	01/19/06	Schlapfer		
		WO2007/0130835	11/15/07	Dewey, et al.		
		WO2007/130840	11/15/07	Moore		
		WO2007/130941	11/15/07	Wisnewski		
		WO2007/124222	11/01/07	Malandain, et al.		
		WO2006/119241	11/09/06	Dickinson, et al.		
		WO2007/118045	10/18/07	Melkent, et al.		

Examiner Signature		Date Considered	

PTO/SB/08A (04-03)

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.
This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED [illegible] Commissioner for Patents, Washington, DC 20231.

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

Substitute for form 1449/PTO				*Complete if Known*	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	
				Filing Date	
(Use as many sheets as necessary)				First Named Inventor	Roger P. Jackson
				Art Unit	
				Examiner Name	
Sheet	27	of	50	Attorney Docket Number	11,433

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[7]	Document Number / Number-Kind Code [2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-2007/0088357	04/19/07	Johnson, et al.	
		US-2007/0093817	04/26/07	Barrus, et al.	
		US-2007/0093818	04/26/07	Biedermann, et al.	
		US-2007/0093819	04/26/07	Albert	
		US-2007/0093826	04/26/07	Hawkes, et al.	
		US-2007/0093827	04/26/07	Warnick	
		US-2007/0093831	04/26/07	Abdelgany, et al.	
		US-2007/0055242	03/08/07	Bailly	
		US-2006/0235389	10/19/06	Albert, et al.	
		US-2006/0235392	10/19/06	Hammer, et al.	
		US-2006/0235393	10/19/06	Bono, et al.	
		US-2006/0241593	10/26/06	Sherman, et al.	
		US-2006/0241595	10/26/06	Molz, IV., et al.	
		US-2006/0241599	10/26/06	Konieczynski, et al.	
		US-2006/0241600	10/26/06	Ensign, et al.	
		US-2006/0247631	11/02/06	Ahn, et al.	
		US-2006/0247624	11/02/06	Banouskou, et al.	
		US-2006/0247636	11/02/06	Yuan, et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.[1]	Foreign Patent Document / Country Code [3] Number[4] Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

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

Substitute for form 1449/PTO				*Complete if Known*	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	
				Filing Date	
(Use as many sheets as necessary)				First Named Inventor	Roger P. Jackson
				Art Unit	
				Examiner Name	
Sheet	28	of	50	Attorney Docket Number	11,433

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[7]	Document Number Number-Kind Code [2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-2006/0264933	11/23/06	Baker, et al.	
		US-2006/0264936	11/23/06	Partin et al.	
		US-2006/0276787	12/07/06	Zubok, et al.	
		US-2006/0276791	12/07/06	Shluzas	
		US-2006/0276792	12/07/06	Ensign, eta l.	
		US-2006/0282074	12/14/06	Renaud, et al.	
		US-2006/0293659	12/28/06	Alvarez	
		US-2006/0293666	12/28/06	Matthis, et al.	
		US-2006/0293665	12/28/06	Shluzas	
		US-2006/0247779	11/02/06	Gordon, et al.	
		US-2007/0016188	01/18/07	Boehm, Jr., et al.	
		US-2007/0049933	03/01/07	Ahn, et al.	
		US-2007/0043364	02/22/07	Cawley, et al.	
		US-2007/0043359	02/22/07	Altarac, et al.	
		US-2007/0043358	02/22/07	Molz, IV., et al.	
		US-2007/0043357	02/22/07	Kirschman	

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.[1]	Foreign Patent Document Country Code [3] Number[4] Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.
This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED [illegible] TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

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

Substitute for form 1449/PTO				*Complete if Known*	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	
				Filing Date	
(Use as many sheets as necessary)				First Named Inventor	Roger P. Jackson
				Art Unit	
				Examiner Name	
Sheet	29	of	50	Attorney Docket Number	11,433

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[7]	Document Number Number-Kind Code [2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-2007/0016198	01/18/07	Boehm, Jr., et al.	
		US-2007/0021750	01/25/07	Shluzas, et al.	
		US-2007/0043355	02/22/07	Bette, et al.	
		US-2007/0055235	03/08/07	Janowski, et al.	
		US-2007/0055238	03/08/07	Biedermann, et al.	
		US-2007/0055239	03/08/07	Sweeney, et al.	
		US-2007/0055240	03/08/07	Matthis, et a902	
		US-2007/0055241	03/08/07	Matthis, et al.	
		US-2007/0073291	03/29/07	Cordaro, et al.	
		US-2006/0106380	05/18/06	Colleran, et al.	
		US-2006/0095037	05/04/06	Jones, et al.	
		US-2006/0089644	04/27/06	Felix	
		US-2006/0089643	04/27/06	Mujwid	
		US-2006/0084993	04/20/06	Landry, et al.	
		US-2006/0084989	04/20/06	Dickinson, et al.	
		US-2006/0084981	04/20/06	Shluzas	
		US-2006/0079899	04/13/06	Ritland	
		US-2006/0079895	04/13/06	McLeer	

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.[1]	Foreign Patent Document Country Code [3] Number[4] Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.
This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

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

Substitute for form 1449/PTO				*Complete if Known*	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	
				Filing Date	
(Use as many sheets as necessary)				First Named Inventor	Roger P. Jackson
				Art Unit	
				Examiner Name	
Sheet	30	of	50	Attorney Docket Number	11,433

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[7]	Document Number Number-Kind Code [2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-2006/0079894	04/13/06	Colleran, et al.	
		US-2006/0074419	04/06/06	Taylor, et al.	
		US-2006/0212034	09/21/06	Triplett, et al.	
		US-2006/0229614	10/12/06	Foley, et al.	
		US-2006/0229615	10/12/06	Abdou	
		US-2006/0200123	09/07/06	Mueller	
		US-2006/0200149	09/07/06	Hoy, et al.	
		US-2006/0200131	09/07/06	Chao, et al.	
		US-2006/0195198	08/31/06	Schumacher	
		US-2006/0173456	08/03/06	Hawkes, et al.	
		US-2006/0173454	08/03/06	Spitler, et ak,	
		US-2006/0167455	07/27/06	Clement, et al.	
		US-2006/0161152	07/20/06	Ensign, et al.	
		US-2006/0155278	07/13/06	Warnick	
		US-2006/0155277	07/13/06	Metz-Stavenhagen	
		US-2006/0149244	07/06/06	Amrein, et al.	
		US-2006/0149241	07/06/06	Richelsoph, et al.	
		US-2006/0149232	07/06/06	Sasing	

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.[1]	Foreign Patent Document Country Code [3] Number[4] Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]

Examiner Signature		Date Considered	

PTO/SB/08A (04-03)
Approved for use through 04/30/2003. OMB 0651-0031

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.
This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED

Substitute for form 1449/PTO				*Complete if Known*	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	
				Filing Date	
(Use as many sheets as necessary)				First Named Inventor	Roger P. Jackson
				Art Unit	
				Examiner Name	
Sheet	31	of	50	Attorney Docket Number	11,433

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[7]	Document Number Number-Kind Code [2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-2006/0142761	06/29/06	Landry, eta l.	
		US-2006/0129149	06/15/06	Iott, et al.	
		US-2006/0129147	06/15/06	Biedermann, et al.	
		US-2006/0116677	06/01/06	Burd, et al.	
		US-2007/0260243	11/08/07	Biedermann	
		US-2007/0100341	05/03/07	Reglos, et al.	
		US-2007/0118117	05/24/07	Altarac, et al.	
		US-2007/0118118	05/24/07	Kwak, et al.	
		US-2007/0118123	05/24/07	Strausbaugh, et al.	
		US-2007/0118124	05/24/07	Biedermann, et al.	
		US-2007/0123862	05/31/07	Warnick	
		US-2007/0123864	05/31/07	Walder, et al.	
		US-2007/0123867	05/31/07	Kirschman	
		US-2007/0161986	07/12/07	Levy	
		US-2007/0161994	07/12/07	Lowrey, et al.	
		US-2007/0161995	07/12/07	Trautwein, et al.	
		US-2007/0161996	07/12/07	Biedermann, et al.	
		US-2007/0161999	07/12/07	Biedermann, et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.[1]	Foreign Patent Document Country Code [3] Number[4] Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.
This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

Substitute for form 1449/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	
				Filing Date	
(Use as many sheets as necessary)				First Named Inventor	Roger P. Jackson
				Art Unit	
				Examiner Name	
Sheet	32	of	50	Attorney Docket Number	11,433

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[7]	Document Number Number-Kind Code [2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-2007/0167948	07/19/07	Abdou	
		US-2007/0167949	07/19/07	Altarac, et al.	
		US-2007/0123870	05/31/07	Jeon, et al.	
		US-2007/0173819	07/26/07	Sandlin	
		US-2007/0173820	07/26/07	Trieu	
		US-2007/0173828	07/26/07	Firkins, et al.	
		US-2007/0191839	08/16/07	Justis, et al.	
		US-2007/0198014	08/23/07	Graf, et al.	
		US-2007/0208344	09/06/07	Young	
		US-2007/0225707	09/27/07	Wisnewski, eta l.	
		US-2007/0225711	09/27/07	Ensign	
		US-2007/0233078	10/04/07	Justis, et al.	
		US-2007/0233080	10/04/07	Na, et al.	
		US-2007/0233086	10/04/07	Harms, et al.	
		US-2007/0233087	10/04/07	Schlapfer	
		US-2007/0250061	10/25/07	Chin, et al.	
		US-2005/0260058	11/2005	Casagne, III	
		US-2005/0096654	05/2005	Lin	

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.[1]	Foreign Patent Document Country Code [3] Number[4] Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]

Examiner Signature		Date Considered	

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

[1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED [illegible] SEND TO: Commissioner for Patents, Washington, DC 20231.

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

Substitute for form 1449/PTO				*Complete if Known*	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	
				Filing Date	
(Use as many sheets as necessary)				First Named Inventor	Roger P. Jackson
				Art Unit	
				Examiner Name	
Sheet	33	of	50	Attorney Docket Number	11,433

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code [2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-2006/0217716	09/2006	Baker, et al.	
		US-2003/0153911	08/2003	Shluzas	
		US-2002/0072751	06/2002	Jackson	
		US-2002/0133159	09/2002	Jackson	
		US-2003/0023240	01/2003	Amrein, et al.	
		US-7,211,086	05/01/07	Biedermann, et al.	
		US-7,186,255	03/06/07	Baynham, et al.	
		US-7,121,755	10/17/06	Schlapfer, et al.	
		US-7,125,426	10/24/06	Moumene, et al.	
		US-7,128,743	10/31/06	Metz-Stavenhagen	
		US-7,141,051	11/28/06	Janowski, et al.	
		US-7,144,396	12/05/06	Shluzas	
		US-7,163,538	1/16/07	Altarac, et al.	
		US-7,163,539	1/16/07	Abdelgany, et al.	
		US-7,166,108	1/23/07	Mazda, et al.	
		US-7,090,674	8/15/06	Doubler, et al.	
		US-7,087,057	08/08/06	Konieczynski, et al.	
		US-7,066,937	06/27/06	Shluzas	

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.[1]	Foreign Patent Document Country Code [3] Number[4] Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED [illegible] TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

Substitute for form 1449/PTO				*Complete if Known*	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	
				Filing Date	
(Use as many sheets as necessary)				First Named Inventor	Roger P. Jackson
				Art Unit	
				Examiner Name	
Sheet	34	of	50	Attorney Docket Number	11,433

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[7]	Document Number Number-Kind Code [2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-7,081,116	07/25/06	Carly	
		US-RE39,089	05/02/06	Ralph, et al.	
		US-7,022,122	04/04/06	Amrein, et al.	
		US-7,083,621	08/01/06	Shaolian, et al.	
		US-7,066,937	06/27/06	Shluzas	
		US-7,211,087	05/01/07	Young	
		US-7,223,268	05/29/07	Biedermann	
		US-7,264,621	09/04/07	Coates, et al.	
		US-7,270,665	09/18/07	Morrison, et al.	
		US-7,291,151	11/06/07	Alvarez	
		US-7,291,153	11/06/07	Glascott	
		US-7,294,128	11/13/07	Alleyne, et al.	
		US-7,294,129	11/13/07	Hawkins, et al.	
		US-2,346,346	04/11/1944	Anderson	
		US-4,759,672	07/1988	Nilsen, et al.	
		US-2,813,450	11/1957	Dzus	
		US-2,362,999	11/1944	Elmer	
		US-7,066,062	06/2006	Flesher	

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.[1]	Foreign Patent Document Country Code [3] Number[4] Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.
This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

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

Substitute for form 1449/PTO				*Complete if Known*	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	
				Filing Date	
(Use as many sheets as necessary)				First Named Inventor	Roger P. Jackson
				Art Unit	
				Examiner Name	
Sheet	35	of	50	Attorney Docket Number	11,433

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[7]	Document Number Number-Kind Code [2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-5,019,080	05/1991	Hemer	
		US-4,033,139	07/1977	Frederick	
		US-6,186,718	02/2001	Fogard	
		US-6,214,012	04/2001	Karpman, et al.	
		US-2,531,892	11/1950	Reese	
		US-3,013,244	12/1961	Rudy	
		US-7,214,227	05/2007	Colleran, et al.	
		US-6,296,642	10/2001	Morrison, et al.	
		US-6,896,677	05/2005	Lin	
		US-5,938,663	08/1999	Petreto	
		US-5,873,878	02/1999	Harms, et al.	
		US-6,652,526	11/2003	Arafiles	
		US-6,296,642	10/2001	Morrison, et al.	
		US-6,371,957	04/2002	Amrein, et al.	
		US-4,790,297	12/1988	Luque	
		US-7,699,872	04/20/2010	Farris, et al.	
		US-7,699,875	04/20/2010	Timm	
		US-7,699,876	04/20/2010	Barry, et al.	
		US-7,704,271	04/27/2010	Abdou	
		US-7,713,288	05/11/2010	Timm, et al.	
		US-7,717,941	05/18/2010	Petit	
		US-7,717,942	05/18/2010	Schumacher	
		US-7,717,943	05/18/2010	Kirschman	

Examiner Signature		Date Considered	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.usplo.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.
This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

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

Substitute for form 1449/PTO				*Complete if Known*	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	
				Filing Date	
(Use as many sheets as necessary)				First Named Inventor	Roger P. Jackson
				Art Unit	
				Examiner Name	
Sheet	36	of	50	Attorney Docket Number	11,433

U. S. PATENT DOCUMENTS					
Examiner Initials*	Cite No.[8]	Document Number Number-Kind Code [2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-7,294,128	11/13/2007	Alleyne, et al.	
		US-7,294,127	11/13/2007	Hawkins, et al.	
		US-7,306,603	12/11/2007	Boehm, Jr., et al.	
		US-7,306,604	12/11/2007	Carli	
		US-7,306,606	12/11/2007	Sasing	
		US-7,314,467	01/01/2008	Howland	
		US-7,316,684	01/08/2008	Baccelli, et al.	
		US-7,322,979	01/29/2008	Crandall, et al.	
		US-7,335,201	02/26/2008	Doubler, et al.	
		US-7,335,202	02/26/2008	Matthis, et al.	
		US-7,338,490	03/04/2008	Ogilvie, et al.	
		US-7,338,4911	03/04/2008	Baker, et al.	
		US-2007/0270806	11/22/2007	Foley, et al.	
		US-2007/0270807	11/22/2007	Armstrong, et al.	
		US-2007/0270810	11/22/2007	Sanders	
		US-2007/0270813	11/22/2007	Garamszegi	
		US-2007/0270815	11/22/2007	Johnson, et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Cite No.[1]	Foreign Patent Document Country Code [3] Number[4] Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]

Examiner Signature		Date Considered	

PTO/SB/08A (04-03)
Approved for use through 04/30/2003. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.
This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED [illegible] SEND TO: Commissioner for Patents, Washington, DC 20231.

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

Substitute for form 1449/PTO				*Complete if Known*	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	
				Filing Date	
(Use as many sheets as necessary)				First Named Inventor	Roger P. Jackson
				Art Unit	
				Examiner Name	
Sheet	37	of	50	Attorney Docket Number	11,433

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[7]	Document Number Number-Kind Code [2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-2007/0270830	11/22/2007	Morrison	
		US-2007/0270831	11/22/2007	Dewey, et al.	
		US-2007/0270832	11/22/2007	Moore	
		US-2007/0270835	11/22/2007	Wisnewski	
		US-2007/0270839	11/22/2007	Jeon, et al.	
		US-2007/0288004	12/13/2007	Alvarez	
		US-2008/0009862	01/10/2008	Hoffman	
		US-2008/0009864	01/10/2008	Forton, et al.	
		US-2008/0015578	01/17/2008	Erickson, et al.	
		US-2008/0015579	01/17/2008	Whipple	
		US-2008/0015580	01/17/2008	Chao	
		US-2008/0015584	01/17/2008	Richelsoph	
		US-2008/0015586	01/17/2008	Krishna, et al.	
		US-7,722,646	05/25/2010	Ralph, et al.	
		US-7,722,649	05/25/2010	Biedermann, et al.	
		US-7,722,651	05/25/2010	Kwak, et al.	
		US-7,722,652	05/25/2010	Justis, et al.	
		US-7,722,654	05/25/2010	Taylor, et al.	
		US-7,727,261	06/01/2010	Barker, et al.	
		US-7,731,736	06/08/2010	Guenther, et al.	
		US-7,731,749	06/08/2010	Biedermann, et al.	
		US-7,749,258	07/06/2010	Biedermann, et al.	
		US-7,758,618	07/20/2010	Walder, et al.	
		US-2010/0094343	04/15/2010	Pham, et al.	

Examiner Signature		Date Considered	

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

[1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

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

Substitute for form 1449/PTO				*Complete if Known*	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	
				Filing Date	
(Use as many sheets as necessary)				First Named Inventor	Roger P. Jackson
				Art Unit	
				Examiner Name	
Sheet	38	of	50	Attorney Docket Number	11,433

U. S. PATENT DOCUMENTS					
Examiner Initials*	Cite No.[8]	Document Number Number-Kind Code [2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-2008/0021454	01/24/2008	Chao, et al.	
		US-2008/0021455	01/24/2008	Chao, et al.	
		US-2008/0021462	01/24/2008	Trieu	
		US-2008/0021464	01/24/2008	Morin, et al.	
		US-2008/0021473	01/24/2008	Butler, et al.	
		US-2008/0027432	01/31/2008	Strauss, et al.	
		US-2008/0039838	02/14/2008	Landry, et al.	
		US-2008/0039843	02/14/2008	Abdou	
		US-2008/0045951	02/21/2008	Fanger, et al.	
		US-2008/0045955	02/21/2008	Berrevoets, et al.	
		US-2008/0045957	02/21/2008	Landry, et al.	
		US-2008/0051780	02/28/2008	Vaidya, et al.	
		US-2008/0058811	03/06/2008	Alleyne, et al.	
		US-2010/0094348	04/15/2010	Biedermann, et al.	
		US-2010/0094349	04/15/2010	Hammer, et al.	
		US-2010/0094352	04/15/2010	Iott, et al.	
		US-2010/0094353	04/15/2010	Shim, et al.	
		US-2010/0100136	04/22/2010	Won, et al.	
		US-2010/0100137	04/22/2010	Justis, et al.	
		US-2010/0106189	04/29/2010	Miller	
		US-2010/0114170	05/06/2010	Barrus, et al.	
		US-2010/0114171	05/06/2010	Boachie-Adjei, et al.	
		US-2010/0114180	05/06/2010	Rock, et al.	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.
This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

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

Substitute for form 1449/PTO				*Complete if Known*	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	
				Filing Date	
(Use as many sheets as necessary)				First Named Inventor	Roger P. Jackson
				Art Unit	
				Examiner Name	
Sheet	39	of	50	Attorney Docket Number	11,433

U. S. PATENT DOCUMENTS					
Examiner Initials*	Cite No.[9]	Document Number Number-Kind Code [2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-2008/0058812	03/06/2008	Zehnder	
		US-2008/0065073	03/13/2008	Perriello, et al.	
		US-2008/0065077	03/13/2008	Ferree	
		US-2008/0071273	03/20/2008	Hawkes, et al.	
		US-2008/0071277	03/20/2008	Warnick	
		US-2008/0071274	03/20/2008	Enisgn	
		US-2008/0065075	03/13/2008	Dant	
		US-2008/0077139	03/27/2008	Landry, et al.	
		US-2008/0086131	04/10/2008	Daly, eta l.	
		US-2008/0086132	04/10/2008	Biedermann, eta l.	
		US-2008/0097441	04/24/2008	Hayes, et al.	
		US-2008/0097457	04/24/2008	Warnick	
		US-2008/0108992	05/08/2008	Barry, et al.	
		US-2008/0119858	05/22/2008	Potash	
		US-2008/0140075	06/12/2008	Ensign, et al.	
		US-2010/0125302	05/20/2010	Hammill, Sr., et al.	
		US-2010/0131017	05/27/2010	Farris, et al.	
		US-2010/0131018	05/27/2010	Konieczynski, et al.	
		US-2010/0137918	06/03/2010	Wilcox, et al.	
		US-2010/0137920	06/03/2010	Hammill, Sr., et al.	
		US-2010/0145390	06/10/2010	McCarthy, et al.	
		US-2010/0152776	06/10/2010	Keyer, et al.	
		US-2010/0152785	06/17/2010	Forton, et al.	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.
This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

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

Substitute for form 1449/PTO				*Complete if Known*	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	
				Filing Date	
(Use as many sheets as necessary)				First Named Inventor	Roger P. Jackson
				Art Unit	
				Examiner Name	
Sheet	40	of	50	Attorney Docket Number	11,433

U. S. PATENT DOCUMENTS

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

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.
This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: **Commissioner for Patents, Washington, DC 20231.**

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

Substitute for form 1449/PTO				*Complete if Known*	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	
				Filing Date	
(Use as many sheets as necessary)				First Named Inventor	Roger P. Jackson
				Art Unit	
				Examiner Name	
Sheet	41	of	50	Attorney Docket Number	11,433

U. S. PATENT DOCUMENTS					
Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code [2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-2008/0249570	10/09/2008	Carson, et al.	
		US-2008/0262548	10/23/2008	Lange, et al.	
		US-2008/0262556	10/23/2008	Jacofsky, et al.	
		US-2008/0269742	10/30/2008	Levy, et al.	
		US-2008/0269809	10/30/2008	Garamszegi	
		US-2008/0287994	11/20/2008	Perez-Cruet, et al.	
		US-2008/0288002	11/20/2008	Crall, et al.	
		US-2008/0306528	12/11/2008	Winslow, et al.	
		US-2008/0306533	12/11/2008	Winslow, et al.	
		US-2008/0306539	12/11/2008	Cain, et al.	
		US-2006/0166535	07/27/2006	Brumfield, et al.	
		US-2006/0276789	12/07/2006	Jackson	
		US-2007/0055244	03/08/2007	Jackson	
		US-2010/0168800	07/01/2010	Biedermann, et al.	
		US-2010/0168801	07/01/2010	Biedermann, et al.	
		US-2010/0174322	07/08/2010	Abdelgany, et al.	
		US-2010/0179603	07/15/2010	Warnick	
		US-2010/0063553	03/11/2010	Warnick	
		US-2008/0249576	10/09/2008	Wawkes, et al.	
		US-5,683,392	11/04/1997	Richelsoph	
		US-7,604,655	10/20/2009	Warnick	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.
This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

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

Substitute for form 1449/PTO				*Complete if Known*	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	
				Filing Date	
(Use as many sheets as necessary)				First Named Inventor	Roger P. Jackson
				Art Unit	
				Examiner Name	
Sheet	42	of	50	Attorney Docket Number	11,433

U. S. PATENT DOCUMENTS					
Examiner Initials*	Cite No.[1,2]	Document Number Number-Kind Code [2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-7,695,498	04/13/2010	Rilland	
		US-7,695,497	04/13/2010	Cordaro, et al.	
		US-7,691,132	04/06/2010	Landry, et al.	
		US-7,691,131	04/06/2010	Graf	
		US-7,691,129	04/06/2010	Felix	
		US-7,686,835	03/30/2010	Warnick	
		US-7,686,834	03/30/2010	Saint Martin	
		US-7,686,833	03/30/2010	Muhanna, et al.	
		US-7,682,377	03/23/2010	Konieczynski, et al.	
		US-7,678,139	03/16/2010	Garamszegi, et al.	
		US-7,678,136	03/16/2010	Doubler, et al.	
		US-7,674,277	03/09/2010	Burd, et al.	
		US-2010/0094353	04/15/2010	Shim, et al.	
		US-2010/0094352	04/15/2010	Iott, et al.	
		US-2010/0094349	04/15/2010	Hammer, et al.	
		US-2010/0094348	04/15/2010	Biedermann, et al.	
		US-2010/0094345	04/15/2010	Saidha, et al.	
		US-2010/0094343	04/15/2010	Pham, et al.	
		US-2010/0087865	04/08/2010	Biedermann, et al.	
		US-2010/0087861	04/08/2010	Lechmann, et al.	
		US-7,087,057	08/08/2006	Konieczynski, et al.	
		US-2006/0217716	09/28/2006	Baker, et al.	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.
This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

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

Substitute for form 1449/PTO				*Complete if Known*	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	
				Filing Date	
(Use as many sheets as necessary)				First Named Inventor	Roger P. Jackson
				Art Unit	
				Examiner Name	
Sheet	43	of	50	Attorney Docket Number	11,433

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[13]	Document Number Number-Kind Code [2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-2009/0082819	03/26/2009	Blain, et al.	
		US-2009/0076552	03/19/2009	Tornier	
		US-2010/0069969	03/18/2010	Ampuero, et al.	
		US-2010/0069963	03/18/2010	Eckman	
		US-2010/0063551	03/11/2010	Richelsoph	
		US-2010/0063550	03/11/2010	Felix, et al.	
		US-2010/0063546	03/11/2010	Miller, et al.	
		US-2010/0063545	03/11/2010	Richelsoph	
		US-2010/0057126	03/04/2010	Hestad	
		US-2010/0057125	03/04/2010	Viker	
		US-			
		US-			
		US-			

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.[1]	Foreign Patent Document Country Code [3] Number[4] Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

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

Substitute for form 1449/PTO				*Complete if Known*	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	
				Filing Date	
(Use as many sheets as necessary)				First Named Inventor	Roger P. Jackson
				Art Unit	
				Examiner Name	
Sheet	44	of	50	Attorney Docket Number	11,433

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[7]	Document Number Number-Kind Code [2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-7,819,902	10/26/10	Abdelgany, et al.	
		US-7,811,310	10/12/10	Baker, et al.	
		US-7,811,288	10/12/10	Jones, et al.	
		US-7,806,913	10/05/10	Fanger, et al.	
		US-7,794,480	09/14/10	Gordon, et al.	
		US-7,794,477	09/14/10	Melkent, et al.	
		US-7,789,900	09/07/10	Levy, et al.	
		US-7,785,354	08/31/10	Biedermann, et al.	
		US-7,785,351	08/31/10	Gordon,e t al.	
		US-7,780,706	08/24/10	Marino, et al.	
		US-7,766,945	08/03/10	Nilsson, et al.	
		US-7,766,944	08/03/10	Metz-Stavenhagen	
		US-7,766,946	08/03/10	Bailly	
		US-7,766,943	08/03/10	Fallin, et al.	
		US-7,763,057	07/27/10	Abdelgany, et al.	
		US-8,021,097	09/20/11	Farris, et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.[1]	Foreign Patent Document Country Code [3] Number[4] Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]

Examiner Signature		Date Considered	

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

[1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

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

Substitute for form 1449/PTO				*Complete if Known*	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Application Number	
				Filing Date	
				First Named Inventor	Roger P. Jackson
				Art Unit	
				Examiner Name	
Sheet	45	of	50	Attorney Docket Number	11,433

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[2]	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-2010/0262196	10/14/10	Barrus, et al.	
		US-2010/0256682	10/07/10	Fallin, et al.	
		US-2010/0256681	10/07/10	Hammer, et al.	
		US-2010/0249856	09/30/10	Iott, et al.	
		US-2010/0249846	09/30/10	Simonson	
		US-2010/0241170	09/23/10	Cammisa, et al.	
		US-2010/0234891	09/16/10	Freeman, et al.	
		US-2010/0228293	09/09/10	Courtney, et al.	
		US-2010/0222822	09/02/10	Farris, et al.	
		US-2010/0204735	08/12/10	Gephart, et al.	
		US-2010/0198272	08/05/10	Keyer, et al.	
		US-2010/0198270	08/05/10	Barker, et al.	
		US-2010/0198269	08/05/10	Taylor, et al.	
		US-2010/0191290	07/29/10	Felix	
		US-2010/0185247	07/22/10	Richelsoph	
		US-7,572,279	08/11/2009	Jackson	
		US-7,186,255	03/06/2007	Baynham, et al.	
		US-2008/0154315	06/26/2008	Jackson	

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.[1]	Foreign Patent Document Country Code [3] Number[4] Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

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

Substitute for form 1449/PTO				*Complete if Known*	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	
				Filing Date	
(Use as many sheets as necessary)				First Named Inventor	Roger P. Jackson
				Art Unit	
				Examiner Name	
Sheet	46	of	50	Attorney Docket Number	11,433

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[7]	Document Number Number-Kind Code [2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-7,972,364	07/05/11	Biedermann, et al.	
		US-RE42,545	07/12/11	Ralph, et al.	
		US-7,985,242	07/26/11	Forton, et al.	
		US-7,985,248	07/26/11	Walder, et al.	
		US-7,988,694	08/02/11	Barrus, et al.	
		US-7,988,711	08/02/11	Errickson, et al.	
		US-RE42,626	08/16/11	Taylor, et al.	
		US-8,022,806	08/23/11	Justis	
		US-8,012,183	09/06/11	Alain	
		US-8,012,186	09/06/11	Pham, et al.	
		US-8,012,188	09/06/11	Mettent, et al.	
		US-8,016,862	09/13/11	Felix, et al.	
		US-8,016,866	09/13/11	Warnick	
		US-8,021,397	09/20/11	Farris, et al.	
		US-8,025,681	09/27/11	Colleran, et al.	
		US-8,029,539	01/04/11	Kirschman	
		8,034,084	10/11/11	Landry, et al.	
		8,043,340	10/25/11	Law	
		US-2011/0166606	07/07/11	Stihl, et al.	
		US-2011/0172715	07/14/11	Pond, Jr., et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.[1]	Foreign Patent Document Country Code [3] Number[4] Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.
This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

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

Substitute for form 1449/PTO				*Complete if Known*	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	
				Filing Date	
(Use as many sheets as necessary)				First Named Inventor	
				Art Unit	
				Examiner Name	
	47	of	50	Attorney Docket Number	11,433

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[7]	Document Number Number-Kind Code [2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-2011/0178558	07/21/11	Barry	
		US-2011/0184471	07/28/11	Foley, et al.	
		US-2011/0190822	08/04/11	Spitler, et al.	
		US-2011/0190823	08/04/11	Bergeron, et al.	
		US-2011/0190826	08/04/11	Ogilvie, et al.	
		US-2011/0196427	08/11/11	Trautwein, et al.	
		US-2011/0202095	08/18/11	Semler, et al.	
		US-2011/0208251	08/25/11	Hammill, Sr., et al.	
		US-2011/0230917	09/22/11	Carson, et al.	
		US-2011/0251644	10/13/11	Hestad, et al.	
		US-2011/0257687	10/20/11	Trieu, et al.	
		US-2011/0257689	10/20/11	Fiechter, et al.	
		US-2011/0257690	10/20/11	Rezach	

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.[1]	Foreign Patent Document Country Code [3] Number[4] Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

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

Substitute for form 1449/PTO				*Complete if Known*	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	
				Filing Date	
(Use as many sheets as necessary)				First Named Inventor	Roger P. Jackson
				Art Unit	
				Examiner Name	
Sheet	48	of	50	Attorney Docket Number	11,433

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[7]	Document Number Number-Kind Code [2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-8,048,124	11/01/2011	Chin, et al.	
		US-8,048,126	11/01/2011	A Harac, et al.	
		US-8,052,720	11/08/2011	Kuester, et al.	
		US-8,057,519	11/15/2011	Justis, et al.	
		US-8,062,339	11/22/2011	Hammer, et al.	
		US-8,066,744	11/29/2011	Justis, et al.	
		US-8,075,599	12/13/2011	Johnson, et al.	
		US-8,075,603	12/13/2011	Hammill, Sr., et al.	
		US-8,083,776	12/27/2011	Alvarez	
		US-8,100,946	01/24/2012	Strausbaugh, et al.	
		US-8,100,947	01/24/2012	Ensign, et al.	
		US-8,100,948	01/24/2012	Ensign, et al.	
		US-8,137,387	03/20/2012	Garamszegi	
		US-8,162,990	04/24/2012	Potash, et al.	
		US-8,162,991	04/24/2012	Strauss, et al.	
		US-8,167,913	05/01/2012	Albert, et al.	
		US-8,167,914	05/01/2012	Hunt, et al.	
		US-8,197,517	06/12/2012	Lab, et al.	
		US-8,197,518	06/12/12	Hammill, Sr., et al.	
		US-8,221,471	07/17/2012	Kovach, et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.[1]	Foreign Patent Document Country Code [3] Number[4] Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
Examiner Signature			Date Considered			

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.
This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED [illegible] TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

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

Substitute for form 1449/PTO				*Complete if Known*	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Application Number	
				Filing Date	
				First Named Inventor	Roger P. Jackson
				Art Unit	
				Examiner Name	
Sheet	49	of	50	Attorney Docket Number	11,433

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[7]	Document Number Number-Kind Code [2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-8,221,472	07/17/2012	Peterson, et al.	
		US-8,236,032	08/07/2012	Ramsay, eta l.	
		US-8,236,035	08/07/2012	Bedor	
		US-7,878,351	02/01/2011	Falzoni, et al.	
		US-4,771,905	09/20/1988	Perne, et al.	
		US-6,968,966	11/29/2005	Gregory	
		US-6,726,689	04/27/2004	Jackson	
		US-7,008,228	03/07/2006	Bjorn, et al.	
		US-7,582,107	09/01/2009	Trail, et al.	
		US-US-			
		US-			
		US-			

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.[1]	Foreign Patent Document Country Code [3] Number[4] Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
Examiner Signature			Date Considered			

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.
This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED

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

Substitute for form 1449/PTO				*Complete if Known*	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Application Number	
				Filing Date	
				First Named Inventor	Roger P. Jackson
				Art Unit	
				Examiner Name	
Sheet	50	of	50	Attorney Docket Number	11,433

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue numbers(s), publisher, city and/or country where published.	T[2]
		EBI Omega 21 Brochure, EBI Spine Systems, pub. 1999	
		Claris Instrumentation Brochure, G Med, pub. 1997	
		VLS System Variable Locking Screw Brochure, Interpore Cross International,1999	
		CD Horizon M8 Multi Axial Screw Spinal System Brochure, Medtronic Sofamor Danek, no publish date	
		Contour Spinal System Brochure, Ortho Development, no publish date	
		Xia Spinal System Brochure, Stryker Howmedica Osteonics, no publish date	
		The Rod Plate System Brochure, Stryker Howmedica Osteonics, pub. Oct., 1999	
		Silhouette Spinal Fixation System Brochure, Sulzer Medica Spine-Tech, no publish date	
		SDRS Surgical Dynamics Rod System Brochure, Surgical Dynamics, pub. 1998-99	
		Versalok Low Back Fixation System Brochure, Wright Medical Technology, Inc., pub. 1997	
		The Strength of Innovation Advertisement, Blackstone Medical Inc., no publish date	
		The Moss Miami 6.0mm System Advertisement, author unknown, no publish date	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[1] Applicant's unique citation designation number (optional). [2] Applicant is to place a check mark here if English language Translation is attached.
This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, Washington, DC 20231.**
If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

(12) 按照专利合作条约所公布的国际申请

(19) 世界知识产权组织
国 际 局

(43) 国际公布日
2012 年 7 月 5 日 (05.07.2012)

WIPO | PCT

(10) 国际公布号
WO 2012/088890 A1

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

(21) 国际申请号: PCT/CN2011/078297

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

(25) 申请语言: 中文

(26) 公布语言: 中文

(30) 优先权:
201010623046.0 2010 年 12 月 31 日 (31.12.2010) CN

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

(72) 发明人; 及

(75) 发明人/申请人 (仅对美国): **李雷 (LI, Lei)** [CN/CN]; 中国上海市浦东新区天雄路 588 弄上海国际医学园区医谷现代商务园 23 号楼, Shanghai 201318 (CN)。 **田芳 (TIAN, Fang)** [CN/CN]; 中国上海市浦东新区天雄路 588 弄上海国际医学园区医谷现代商务园 23 号楼, Shanghai 201318 (CN)。 **刘道志 (LIU, Daozhi)** [CN/CN]; 中国上海市浦东新区天雄路 588 弄上海国际医学园区医谷现代商务园 23 号楼, Shanghai 201318 (CN)。 **冯勇 (FENG, Yong)** [CN/CN]; 中国上海市浦东新区天雄路 588 弄上海国际医学园区医谷现代商务园 23 号楼, Shanghai 201318 (CN)。

(74) 代理人: **中原信达知识产权代理有限责任公司 (CHINA SINDA INTELLECTUAL PROPERTY LTD.)**; 中国北京市西城区金融街 19 号富凯大厦 B 座 11 层, Beijing 100033 (CN)。

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

[见续页]

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

(54) 发明名称 : 动态椎弓根螺钉植入物

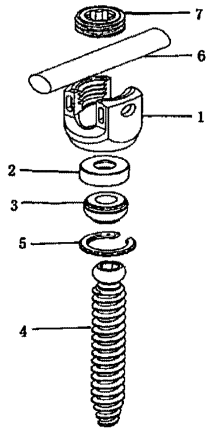


图2 / Fig.2

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

[见续页]

WO 2012/088890 A1

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1190 of 2152

(84) **指定国** (除另有指明，要求每一种可提供的地区保护): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), 欧亚 (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), 欧洲 (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)。

本国际公布:

— 包括国际检索报告(条约第 21 条(3))。

(57) **摘要**:

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1191 of 2152

说 明 书

动态椎弓根螺钉植入物

技术领域

本发明涉及技术领域为骨科内植物技术领域，特别地涉及动态椎弓根螺钉植入物。

背景技术

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

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

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

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1192 of 2152

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

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

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

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

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1193 of 2152

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

发明内容

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

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

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

其特征在于：

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

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

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1194 of 2152

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

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

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

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

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

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

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

优选的是，所述螺钉头套的外周具有多个条形开槽。

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1195 of 2152

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

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

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

优选的是，所述挡圈中设置有开口。

根据上述的结构，挡圈设置有开口，从而可以方便挡圈的嵌入组装。

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

从下面参考附图所描述的优选实施例中很容易理解本发明的上述特征和优点。

附图说明

图1是本发明的动态椎弓根螺钉植入物的整体透视图。

图2是本发明的动态椎弓根螺钉植入物的分解透视图。

图3是本发明的动态椎弓根螺钉植入物的横剖视图。

图4是本发明的动态椎弓根螺钉植入物的螺钉的示意图，其中图4

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1196 of 2152

（a）是螺钉的透视图，图4（b）是螺钉的横剖视图。

图5是本发明的动态椎弓根螺钉植入物的挡圈的透视图。

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

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

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

具体实施方式

以下参考附图来详细描述本发明的优选实施例。

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

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

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

图5是本发明的动态椎弓根螺钉植入物的挡圈5的透视图。挡圈5

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1197 of 2152

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

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

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

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

图8是本发明的动态椎弓根螺钉植入物的螺钉座1的示意图，其中

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1198 of 2152

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

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

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

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

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

而且，根据本发明，所述螺钉头套的下部具有唇结构，该唇结构

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1199 of 2152

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

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

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

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

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1200 of 2152

权 利 要 求 书

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

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

其特征在于：

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

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

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

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

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1201 of 2152

压环（2）能够沿所述螺钉座（1）轴向运动。

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

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

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1202 of 2152

说 明 书 附 图

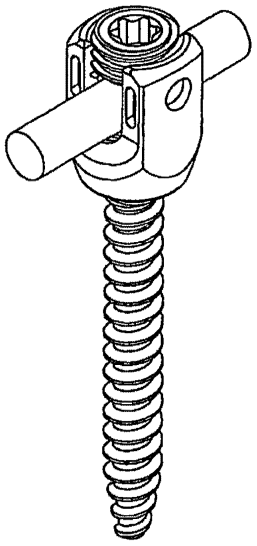


图1

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1203 of 2152

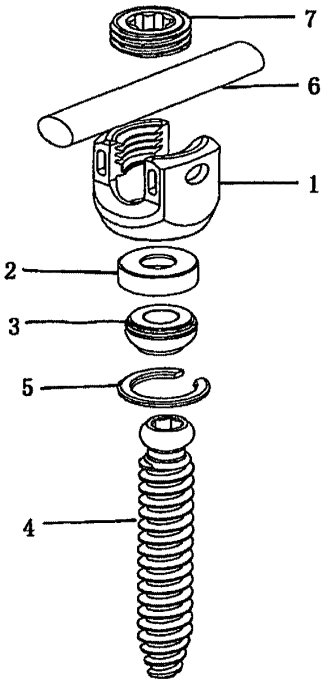


图2

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1204 of 2152

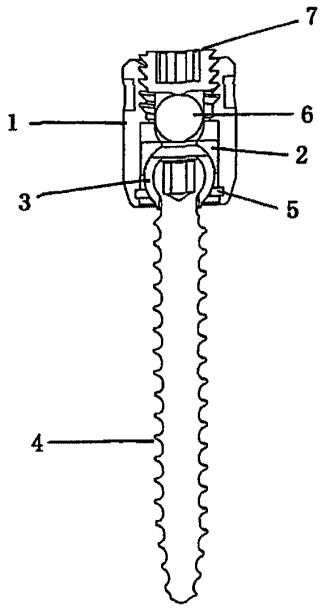


图3

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1205 of 2152

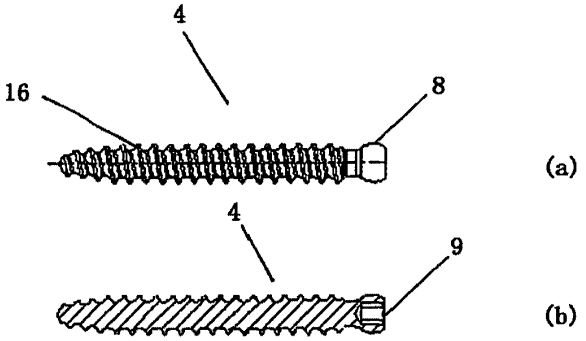


图4

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1206 of 2152

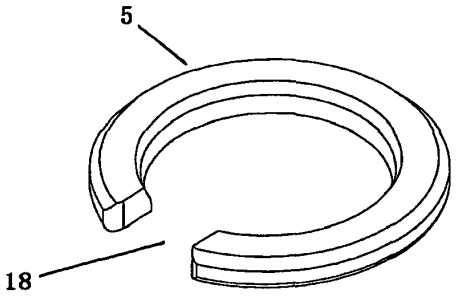


图5

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1207 of 2152

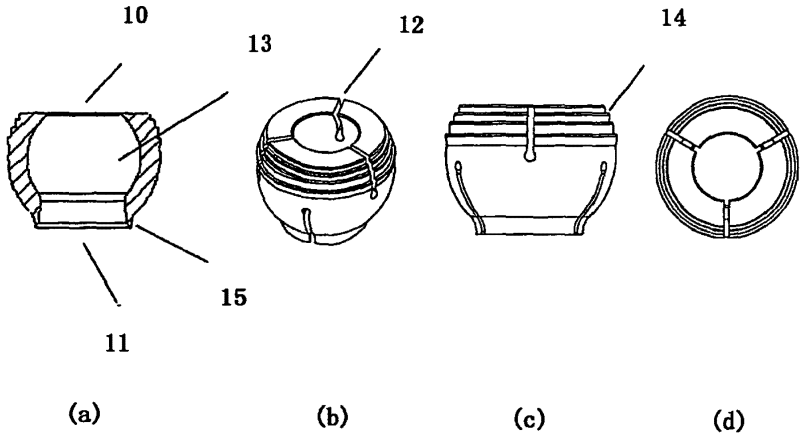


图6

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1208 of 2152

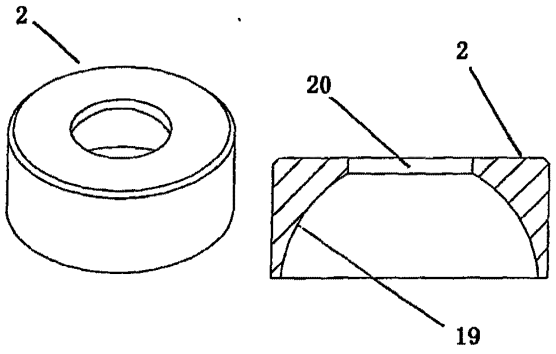


图7

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1209 of 2152

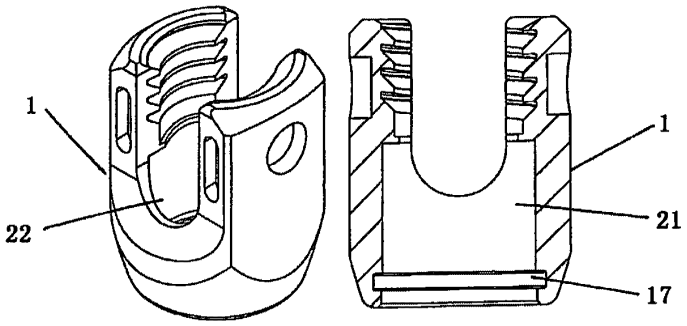


图8

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1210 of 2152

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CN2011/078297

A. CLASSIFICATION OF SUBJECT MATTER

See extra sheet

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC: A61B17

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

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

CPRSABS, CNTXT, EPODOC, CNKI

head, screw, rod, shank

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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

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

* Special categories of cited documents:

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

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

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

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

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

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

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

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

"&" document member of the same patent family

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

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

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CN2011/078297

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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

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

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/CN2011/078297

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1213 of 2152

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CN2011/078297

A. CLASSIFICATION OF SUBJECT MATTER(second sheet)

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

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

国际检索报告

国际申请号
PCT/CN2011/078297

A. 主题的分类

参见附加页

按照国际专利分类(IPC)或者同时按照国家分类和 IPC 两种分类

B. 检索领域

检索的最低限度文献(标明分类系统和分类号)

IPC: A61B17

包含在检索领域中的除最低限度文献以外的检索文献

在国际检索时查阅的电子数据库(数据库的名称，和使用的检索词（如使用）)

CPRSABS, CNTXT, EPODOC, CNKI

套，螺钉，头，head, screw, rod, shank

C. 相关文件

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

☒ 其余文件在 C 栏的续页中列出。　　☒ 见同族专利附件。

* 引用文件的具体类型：

"A" 认为不特别相关的表示了现有技术一般状态的文件

"E" 在国际申请日的当天或之后公布的在先申请或专利

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

"O" 涉及口头公开、使用、展览或其他方式公开的文件

"P" 公布日先于国际申请日但迟于所要求的优先权日的文件

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

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

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

"&" 同族专利的文件

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

PCT/ISA/210 表(第 2 页) (2009 年 7 月)

国际检索报告

国际申请号
PCT/CN2011/078297

C(续). 相关文件

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1216 of 2152

国际检索报告
关于同族专利的信息

国际申请号
PCT/CN2011/078297

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1217 of 2152

国际检索报告

国际申请号
PCT/CN2011/078297

A. 主题的分类(第 2 页)

A61B17/70 (2006.01) i

A61B17/86 (2006.01) i

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1218 of 2152

(12) 按照专利合作条约所公布的国际申请

(19) 世界知识产权组织
国 际 局

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

WIPO | PCT

(10) 国际公布号
WO 2012/075827 A1

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

(21) 国际申请号: PCT/CN2011/078277

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

(25) 申请语言: 中文

(26) 公布语言: 中文

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

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

(72) 发明人; 及

(75) 发明人/申请人 (仅对美国): **金航军 (JIN, Hangjun)** [CN/CN]; 中国上海市浦东新区天雄路 588 弄上海国际医学园区医谷现代商务园 23 号楼, Shanghai 201318 (CN)。 **向勇刚 (XIANG, Yonggang)** [CN/CN]; 中国上海市浦东新区天雄路 588 弄上海国际医学园区医谷现代商务园 23 号楼, Shanghai 201318 (CN)。 **吕振杰 (LV, Zhenjie)** [CN/CN]; 中国上海市浦东新区天雄路 588 弄上海国际医学园区医谷现代商务园 23 号楼, Shanghai 201318 (CN)。 **黄加春 (HUANG, Jiachun)** [CN/CN]; 中国上海市浦东新区天雄路 588 弄上海国际医学园区医谷现代商务园 23 号楼, Shanghai 201318 (CN)。 **杨天兵 (YANG, Tianbing)** [CN/CN]; 中国上海市浦东新区天雄路 588 弄上海国际医学园区医谷现代商务园 23 号楼, Shanghai 201318 (CN)。 **刘道志 (LIU, Daozhi)** [CN/CN]; 中国上海市浦东新区天雄路 588 弄上海国际医学园区医谷现代商务园 23 号楼, Shanghai 201318 (CN)。

(74) 代理人: **中原信达知识产权代理有限责任公司 (CHINA SINDA INTELLECTUAL PROPERTY LTD.)**; 中国北京市西城区金融街 19 号富凯大厦 B 座 11 层, Beijing 100033 (CN)。

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

[见续页]

(54) Title: POLYAXIAL PEDICLE SCREW

(54) 发明名称 : 一种万向椎弓根螺钉

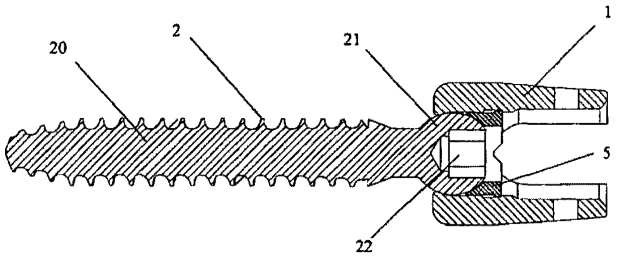


图 3/ Fig.3

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

[见续页]

WO 2012/075827 A1

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1219 of 2152

(84) **指定国** (除另有指明，要求每一种可提供的地区保护): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), 欧亚 (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), 欧洲 (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)。

本国际公布:

— 包括国际检索报告(条约第 21 条(3))。

(57) **摘要**:

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1220 of 2152

说 明 书

一种万向椎弓根螺钉

技术领域

本申请涉及医疗器械领域，特别是涉及一种万向椎弓根螺钉。

背景技术

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

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

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

发明内容

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

一种万向椎弓根螺钉，包括：螺钉座、螺钉头和压环，

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1221 of 2152

其中:

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

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

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

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

优选地，所述压环与所述球状结构相接触一端的结构为弧形结构。

优选地，所述压环设置有凸块一端的端面上还设置有两个相对称的 V 型扩张槽。

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

优选地，所述螺钉头球状结构顶端设置有内六角形槽。

优选地，所述螺钉座上设置有凸棱的一端的断面上设置有多个万向槽。

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

此外，弹性卡圈对材料弹性要相当的要求，而目前植入物螺钉通常采用

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1222 of 2152

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

附图说明

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

图1为现有的万向椎弓根螺钉的结构示意图；

图2为图1的爆炸图；

图3为本申请实施例提供的万向椎弓根螺钉的剖视结构示意图；

图4为图3的爆炸图；

图5为本申请实施例提供的螺钉座的结构示意图；

图6为本申请实施例提供的螺钉座的剖视结构示意图；

图7为本申请实施例提供的压环的结构示意图；

图8为本申请实施例提供的压环的侧视图；

图9为图8的仰视图。

图10为本申请实施例提供的压环在组装时的结构示意图。

具体实施方式

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1223 of 2152

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

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

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

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

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

图 7 为本申请实施例提供的压环的结构示意图。图 8 为本申请实施例提

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1224 of 2152

供的压环的侧视图。图 9 为图 8 的仰视图。

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

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

下面结合该万向椎弓根螺钉的装配过程对其结构进行进一步描述。

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

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1225 of 2152

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

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

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1226 of 2152

1、一种万向椎弓根螺钉，其特征在于，包括：螺钉座、螺钉头和压环，其中：

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

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

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

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

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

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

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

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

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1227 of 2152

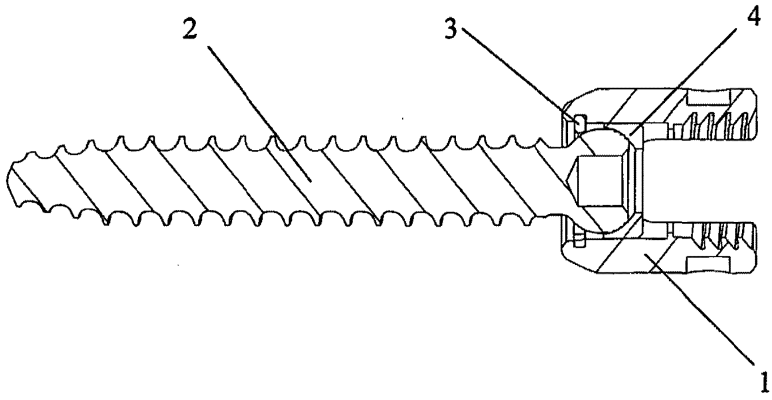


图 1

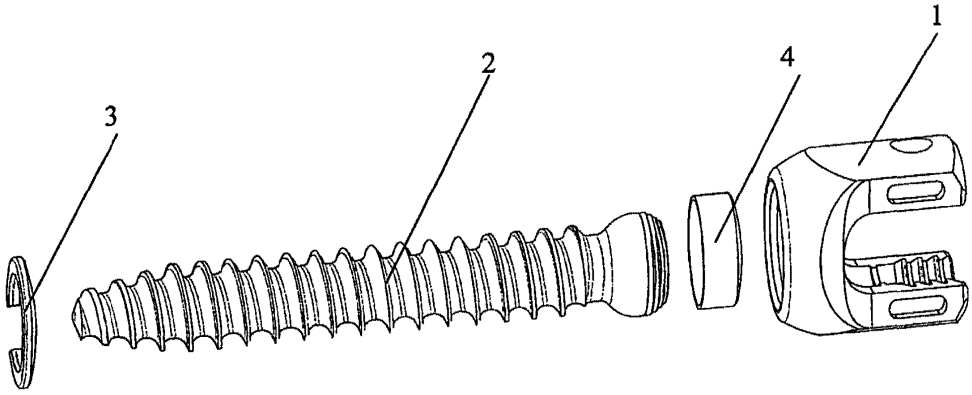


图 2

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1228 of 2152

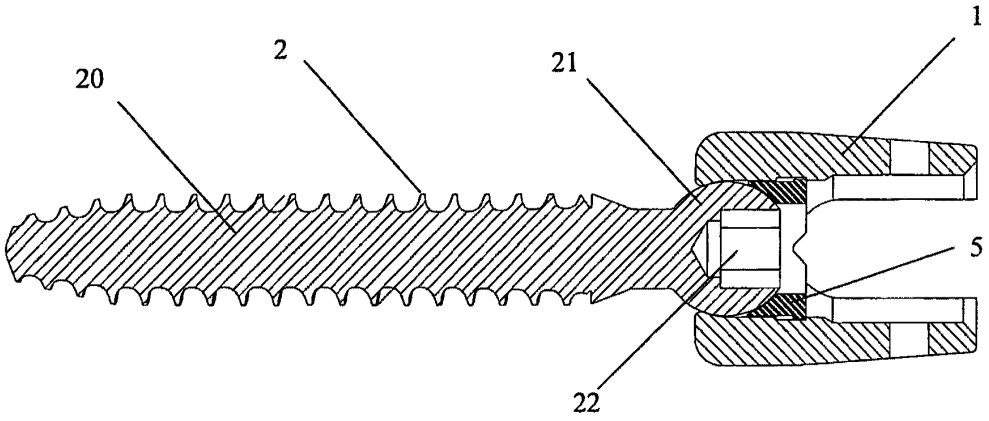


图 3

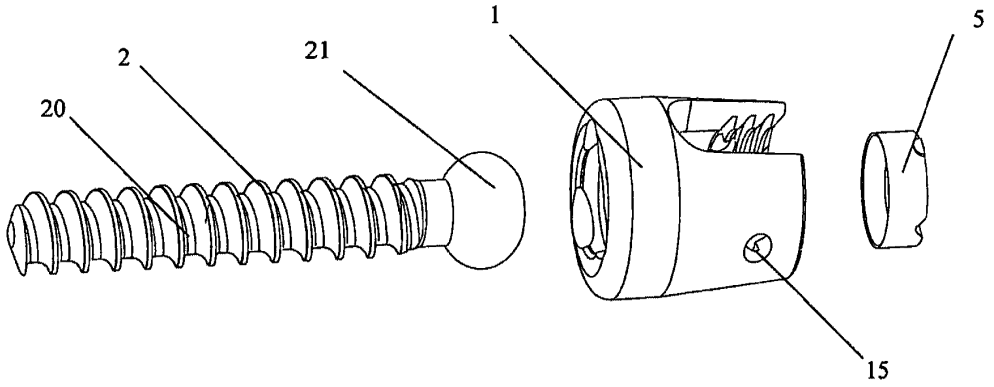


图 4

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1229 of 2152

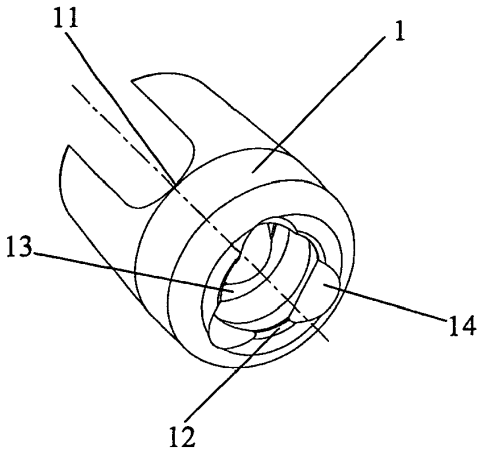


图 5

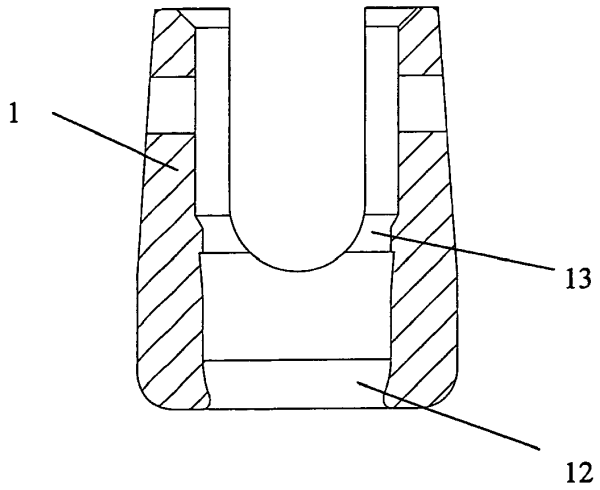


图 6

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1230 of 2152

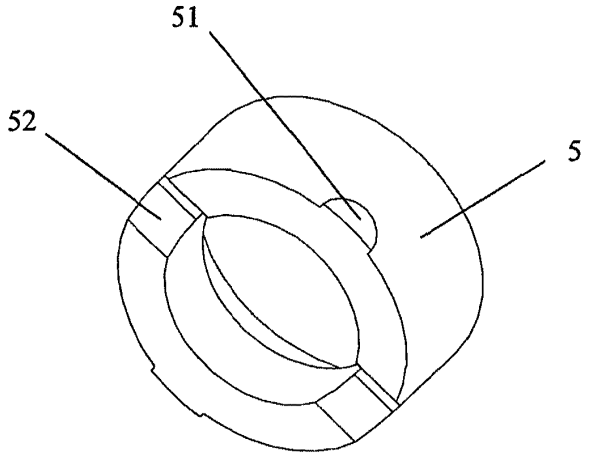


图 7

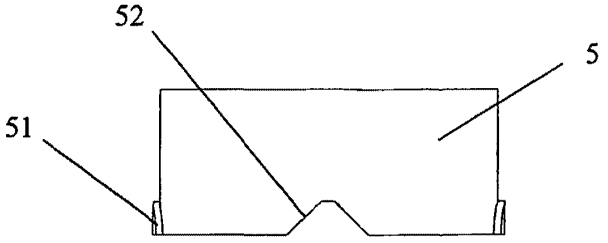


图 8

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1231 of 2152

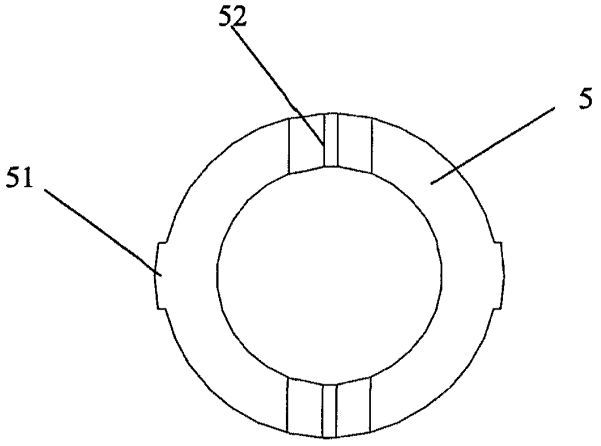


图 9

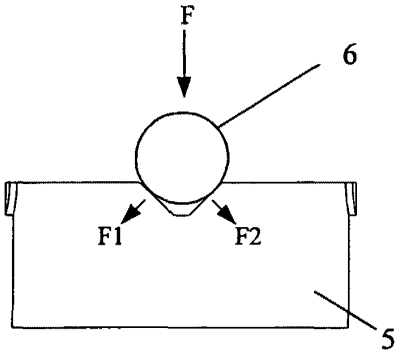


图 10

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1232 of 2152

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CN2011/078277

A. CLASSIFICATION OF SUBJECT MATTER

See the extra sheet

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC: A61B 17

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

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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

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

* Special categories of cited documents:

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

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

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

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

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

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

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

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

"&" document member of the same patent family

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

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

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/CN2011/078277

Patent Documents referred in the Report	Publication Date	Patent Family	Publication Date
CN 101389279 A	18.03.2009	US 2005283157 A1	22.12.2005
		US 7264621 B2	04.09.2007
		EP 1768587 A1	04.04.2007
		WO 2006009753 A1	26.01.2006
		KR 20070041722 A	19.04.2007
		KR 100816975 B1	25.03.2008
		CN 101389279 B	25.05.2011
		CA 2572794 A1	26.01.2006
		AU 2005265015 A1	26.01.2006
		AU 2005265015 B2	23.09.2010
		JP 2008503260 A	07.02.2008
WO 2009124196 A2	08.10.2009	US 2009254125 A1	08.10.2009
US 2007088357 A1	19.04.2007	EP 1945118 A2	23.07.2008
		WO 2007047074 A2	26.04.2007
		KR 20080072848 A	07.08.2008
		CA 2625230 A1	26.04.2007
		AU 2006303883 A1	26.04.2007
		JP 2009511227 A	19.03.2009
US 2004102781 A1	27.05.2004	KR 20040045628 A	02.06.2004
		KR 100495876 B1	16.06.2005
US 5443467 A	22.08.1995	EP 0614649 A1	14.09.1994
		EP 0614649 B1	08.05.1996
		DE 4307576 C1	21.04.1994
		JP 6296621 A	25.10.1994
		JP 2510476 B2	26.06.1996
		CA 2118562 A1	11.09.1994
		CA 2118562 C	05.05.1998
		KR 0128371 B1	01.04.1998
		ES 2089867 T3	01.10.1996

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

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CN2011/078277

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

A61B 17/70 (2006.01) i

A61B 17/86 (2006.01) i

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

国际检索报告

国际申请号
PCT/CN2011/078277

A. 主题的分类

参见附加页

按照国际专利分类(IPC)或者同时按照国家分类和 IPC 两种分类

B. 检索领域

检索的最低限度文献(标明分类系统和分类号)

IPC: A61B17

包含在检索领域中的除最低限度文献以外的检索文献

在国际检索时查阅的电子数据库(数据库的名称，和使用的检索词（如使用）)

EPODOC, CPRSABS, VEN, CNKI

螺钉，万向，head, screw

C. 相关文件

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

☐ 其余文件在 C 栏的续页中列出。　　☒ 见同族专利附件。

* 引用文件的具体类型：

"A" 认为不特别相关的表示了现有技术一般状态的文件

"E" 在国际申请日的当天或之后公布的在先申请或专利

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

"O" 涉及口头公开、使用、展览或其他方式公开的文件

"P" 公布日先于国际申请日但迟于所要求的优先权日的文件

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

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

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

"&" 同族专利的文件

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

PCT/ISA/210 表(第 2 页) (2009 年 7 月)

国际检索报告
关于同族专利的信息

国际申请号
PCT/CN2011/078277

检索报告中引用的专利文件	公布日期	同族专利	公布日期
CN101389279A	18.03.2009	US2005283157 A1	22.12.2005
		US7264621 B2	04.09.2007
		EP1768587 A1	04.04.2007
		WO2006009753 A1	26.01.2006
		KR20070041722 A	19.04.2007
		KR100816975 B1	25.03.2008
		CN101389279 B	25.05.2011
		CA2572794 A1	26.01.2006
		AU2005265015 A1	26.01.2006
		AU2005265015 B2	23.09.2010
		JP2008503260A	07.02.2008
WO2009124196A2	08.10.2009	US2009254125 A1	08.10.2009
US2007088357A1	19.04.2007	EP1945118 A2	23.07.2008
		WO2007047074 A2	26.04.2007
		KR20080072848 A	07.08.2008
		CA2625230 A1	26.04.2007
		AU2006303883 A1	26.04.2007
		JP2009511227 A	19.03.2009
US2004102781A1	27.05.2004	KR20040045628 A	02.06.2004
		KR100495876 B1	16.06.2005
US5443467A	22.08.1995	EP0614649 A1	14.09.1994
		EP0614649 B1	08.05.1996
		DE4307576 C1	21.04.1994
		JP6296621 A	25.10.1994
		JP2510476 B2	26.06.1996
		CA2118562 A1	11.09.1994
		CA2118562 C	05.05.1998
		KR0128371 B1	01.04.1998
		ES2089867 T3	01.10.1996

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1237 of 2152

国际检索报告

国际申请号
PCT/CN2011/078277

A. 主题的分类(第 2 页)

A61B17/70 (2006.01) i

A61B17/86 (2006.01) i

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1238 of 2152

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

(11) EP 2 380 513 A1

(12) EUROPEAN PATENT APPLICATION

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

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

(21) Application number: **11174731.7**

(22) Date of filing: **11.10.2007**

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

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

(71) Applicant: **Biedermann Motech GmbH**
78054 VS-Schwenningen (DE)

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

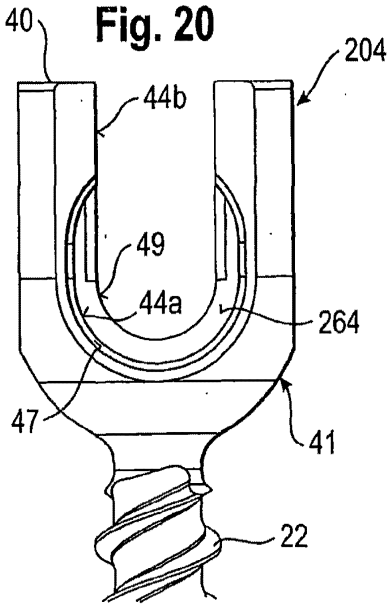
(74) Representative: **Prüfer & Partner GbR**
European Patent Attorneys
Sohnckestraße 12
81479 München (DE)

Remarks:
This application was filed on 20-07-2011 as a divisional application to the application mentioned under INID code 62.

(54) Bone stabilization device

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

Fig. 20



EP 2 380 513 A1

Printed by Jouve, 75001 PARIS (FR)

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1239 of 2152

Description

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[0016] In an alternative aspect related to a monoaxial

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1240 of 2152

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

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

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

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

Fig. 1 shows an illustration of the spinal column;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1241 of 2152

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01430; Petitioners' EX1002
Page 1242 of 2152