

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
2 August 2007 (02.08.2007)

PCT

(10) International Publication Number
WO 2007/087628 A1

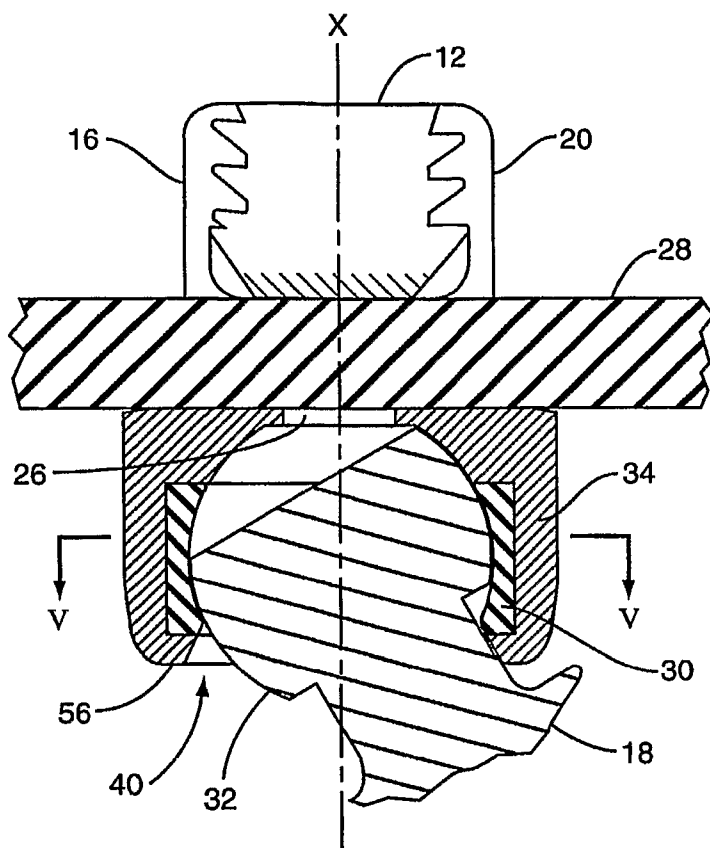
- (51) International Patent Classification:
A61B 17/70 (2006.01)
- (21) International Application Number:
PCT/US2007/061131
- (22) International Filing Date: 26 January 2007 (26.01.2007)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
11/341,188 27 January 2006 (27.01.2006) US
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- (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, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.
- (84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— with international search report

[Continued on next page]

(54) Title: PIVOTING JOINTS FOR SPINAL IMPLANTS INCLUDING DESIGNED RESISTANCE TO MOTION AND METHODS OF USE



(57) Abstract: A pivoting connector (10) couples a vertebral member to a longitudinal member (28). An anchor (18) is pivotally attached to a body by positioning a head (32) of the anchor within a cavity (34) in the body. A longitudinal rod is inserted into a channel also positioned within the body and axially aligned with the cavity. A retainer (12) applies a force to maintain the longitudinal rod within the channel, however the force may be isolated from the anchor. The cavity is adjustable between a plurality of sizes that apply different resistances to pivoting movement of the anchor relative to the body. The adjustment may be performed before or during a surgical procedure. The adjustment may be performed by inserting different components or by rotating a threaded element to create more or less rotational interference.

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**PIVOTING JOINTS FOR SPINAL IMPLANTS INCLUDING DESIGNED
RESISTANCE TO MOTION AND METHODS OF USE**

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Background

Longitudinal members, such as spinal rods, are often used in the surgical treatment of spinal disorders such as degenerative disc disease, disc herniations, scoliosis or other curvature abnormalities, and fractures. Different types of surgical treatments are used. In some cases, spinal fusion is indicated to inhibit relative motion between vertebral bodies. In other cases, dynamic implants are used to preserve motion between vertebral bodies. For either type of surgical treatment, longitudinal members may be attached to the exterior of two or more vertebrae, whether it is at a posterior, anterior, or lateral side of the vertebrae. In other embodiments, longitudinal members are attached to the vertebrae without the use of dynamic implants or spinal fusion.

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Longitudinal members may provide a stable, rigid column that encourages bones to fuse after spinal-fusion surgery. Further, the longitudinal members may redirect stresses over a wider area away from a damaged or defective region. Also, rigid longitudinal members may restore the spine to its proper alignment. In some cases, flexible longitudinal members may be appropriate. Flexible longitudinal members may provide other advantages, such as increasing loading on interbody constructs, decreasing stress transfer to adjacent vertebral elements while bone-graft healing takes place, and generally balancing strength with flexibility.

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Conventionally, longitudinal members are secured to vertebral members using rigid clamping devices. These clamping devices may be multi-axial in the sense that they are adjustable prior to securing. However, once secured, the clamping devices are locked in place. A surgeon may wish to implant a flexible rod system and have more freedom to control pivot points or the nature of the pivoting motion. At present, a surgeon might only have a choice between rigid and flexible longitudinal members, which may not necessarily provide the desired degree of flexibility.

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Summary

Illustrative embodiments disclosed herein are directed to a pivoting connector that couples a vertebral member to a longitudinal member. An anchor is pivotally attaching to a body by positioning a head of the anchor within a cavity in the body. The body may also include a channel that is also positioned within the body and axially aligned with the cavity. The channel may be disposed on an opposite side of the cavity. An intermediate section may separate the channel and cavity. A longitudinal member may be placed within the channel and a retainer applies a force to maintain the longitudinal rod within the channel. The retaining force applied to the longitudinal member may be isolated from the anchor. The cavity may be adjustable between a plurality of sizes that apply different resistances to pivoting movement of the anchor relative to the body. The adjustment may be performed before or during a surgical procedure. According to one or more embodiment, inserting different components into the cavity may achieve the varying rotational resistances. According to one or more embodiments, rotating a threaded element into or onto the body may create more or less rotational interference or rotational resistance.

Brief Description of the Drawings

Figures 1A and 1B are perspective views of a pivoting head assembly according to one or more embodiments comprising a longitudinal member attached to the spine;
Figures 2A and 2B are perspective views of a pivoting head coupled to an anchor member according to one embodiment;
Figure 3 is a side section view of a pivoting head coupled to an anchor member and securing a longitudinal member according to one embodiment;
Figure 4 is a perspective view of an anchor member for use with a pivoting head according to one embodiment;
Figures 5A-C are top section views of a pivoting head with an anchor member and wear member inserted therein according to different embodiments;
Figure 6 is a perspective view of a wear member for use with a pivoting head according to one embodiment;

Figure 7 is a side view, including a partial section view, of an assembled anchor member and wear member for use with a pivoting head according to one embodiment;

Figure 8 is a side section view of a pivoting head with an anchor member and wear member inserted therein according to one embodiment;

5 Figure 9 is a side section view of an assembled pivoting head with an anchor member and wear member constrained therein according to one embodiment;

Figure 10 is a detailed section view of the bottom region of a pivoting head according to one embodiment;

10 Figure 11 is a side section view of a pivoting head and various wear members that may be used with the pivoting head according to one embodiment;

Figure 12 is a side section view of an assembled pivoting head with an anchor member and wear member constrained therein according to one embodiment;

Figure 13 is a detailed section view of the bottom region of a pivoting head according to one embodiment;

15 Figure 14 is a detailed section view of the bottom region of a pivoting head according to one embodiment;

Figure 15 is a detailed section view of an interference snap ring that may be used with the pivoting head according to one embodiment;

20 Figure 16 is a perspective view of a pivoting head coupled to an anchor member according to one embodiment;

Figure 17 is a side section view of an assembled pivoting head with an anchor member and wear member constrained therein according to one embodiment;

Figure 18 is a side section view of an assembled pivoting head with an anchor member and wear member constrained therein according to one embodiment;

25 Figure 19 is a perspective view of a wear member for use with a pivoting head according to one embodiment;

Figure 20 is a side section view of an assembled pivoting head with an anchor member and wear member constrained therein according to one embodiment; and

30 Figure 21 is a side section view of an assembled pivoting head with an anchor member and wear member constrained therein according to one embodiment.

Detailed Description

The various embodiments disclosed herein are directed to pivoting mechanisms and methods for securing longitudinal members in a spinal implant. Various types of longitudinal members are contemplated, including spinal rods that may be secured
5 between multiple vertebral bodies. Figures 1A and 1B show another type of longitudinal member 15 that is secured between the sacrum S and a vertebral member V (i.e., L5). In one embodiment, the longitudinal member 15 is a flexible member, such as a resin or polymer compound. Some flexible non-metallic longitudinal members 15 are constructed from materials such as PEEK and UHMWPE. Other types of flexible longitudinal
10 members 15 may comprise braided metallic structures. In one embodiment, the longitudinal member 15 is rigid or semi-rigid and may be constructed from metals, including for example stainless steels, cobalt-chrome, titanium, and shape memory alloys. Further, the longitudinal member 15 may be straight, curved, or comprise one or more curved portions along its length.

15 In Figures 1A and 1B, the longitudinal member 15 is secured to the vertebral member V with one embodiment of a pivoting head 10 in accordance with the teachings provided herein. In the embodiment shown, the longitudinal member 15 is secured to a saddle 16 within the pivoting head 10 with a securing member 12. The securing member 12 shown
20 in Figures 1A and 1B features a snap-off driving member 14. The driving member 14 is integrally formed with the securing member 12 and allows a surgeon to drive the securing member 12 into contact with the longitudinal member 15 to achieve a certain installation torque. Above that torque, the driving member 14 will snap off, separating from the
25 securing member 12. In this manner, the securing member 12 may provide the desired clamping force to secure the longitudinal member 15.

Figure 1A shows a first orientation for the pivoting head 10 identified by the centerline labeled X. By contrast, Figure 1B shows a second position representing a different spatial
30 relationship between the sacrum S and the vertebra V. As compared to Figure 1A, the vertebra V in Figure 1B exhibits some amount of angular and torsional displacement relative to the sacrum S. Consequently, the pivoting head 10 is illustrated in a second orientation identified by the centerline labeled Y. The pivoting head 10 may provide some or all of this rotation. The illustrations provided in Figures 1A and 1B show the pivoting head 10 as part of a spinal implant that is coupled between a vertebral body V and a

sacrum S. It should be understood that the pivoting head 10 may be used in constructs that are coupled to vertebral bodies V alone. Further, a vertebral implant may be construed to mean implants that are coupled to any or all portions of a spine, including the sacrum, vertebral bodies, and the skull.

5 Figures 2A and 2B illustrate perspective views of the illustrative embodiment of the pivoting head 10 coupled to an anchor member 18. A head 32 of the anchor member 18 is pivotally coupled to a base portion 34 of the pivoting head 10. In one embodiment, the anchor member 18 comprises threads for insertion into a vertebral member V as shown in Figures 1A and 1B. In one embodiment, the anchor member 18 is a pedicle screw. The
10 exemplary saddle 16 is comprised of opposed upright portions forming a U-shaped channel within which a longitudinal member 15 is placed. A seating surface 24 forms the bottom of the U-shaped channel. In one embodiment, the seating surface 24 is curved to substantially match the radius of a longitudinal member 15 that is positioned within the saddle 16. An aperture 26 within the seating surface provides access to a driving feature
15 used to insert the anchor member 18 into a vertebral member V.

In Figure 2A, the pivoting head 10 is shown substantially aligned with the anchor member 18 along the centerline labeled X. In Figure 2B, the anchor member 18 is shown pivoted relative to the pivoting head 10. That is, the pivoting head 10 is shown still aligned with the centerline labeled X while the anchor member 18 is shown aligned with the centerline
20 labeled Y. The pivoted displacement of the pivoting head 10 relative to the anchor member 18 achieved in Figure 2B is provided by an articulation mechanism that is more clearly visible in the section view provided in Figure 3.

Figure 3 shows a section view of the pivoting head 10 holding a different type of longitudinal member 28. In this embodiment, the longitudinal member 28 is a spinal rod.
25 The spinal rod 28 is secured within the saddle 16 with a securing member 12. In the embodiment shown, the securing member 12 is an externally threaded set screw, though other types of securing members such as externally threaded caps and nuts may be used. In the embodiment shown, an articulation mechanism 40 is disposed below the saddle 16 and generally aligned with the central axis X. The articulation mechanism 40 comprises
30 an anchor head 32 of the anchor member 18 that is pivotally coupled to a wear member 30 within the base portion 34 of the pivoting head 10. Since the anchor head 32 is configured to pivot within the wear member 30, the wear member 30 and the outer surface of the

anchor head 32 may be constructed of a wear resistance material. Some suitable examples may include hardened metals, titanium carbide, cobalt chrome, polymers, and ceramics. In other embodiments, a wear resistant layer may be coated onto the anchor head 32 and the wear member 30. In one embodiment, the wear member 30 may be integrally formed into or form a part of the base portion 34. In one embodiment, the wear member 30 may be bonded to the base portion 34 using a biocompatible adhesive such as PMMA or other known adhesives. In these alternative embodiments, the part of the base portion 34 in contact with the anchor head 32 may be coated with a wear resistant layer. Coating processes that include, for example, vapor deposition, dip coating, diffusion bonding, and electron beam welding may be used to coat the above indicated materials onto a similar or dissimilar substrate. Diffusion bonding is a solid-state joining process capable of joining a wide range of metal and ceramic combinations. The process may be applied over a variety of durations, applied pressure, bonding temperature, and method of heat application. The bonding is typically formed in the solid phase and may be carried out in vacuum or a protective atmosphere, with heat being applied by radiant, induction, direct or indirect resistance heating. Electron beam welding is a fusion welding process in which a beam of high-velocity electrons is applied to the materials being joined. The workpieces melt as the kinetic energy of the electrons is transformed into heat upon impact. Pressure is not necessarily applied, though the welding is often done in a vacuum to prevent the dispersion of the electron beam.

The articulation mechanism 40 is spatially and functionally isolated from the clamping forces that are applied between the securing member 12, the rod 28, and the seating surface 24 (see Figures 2A, 2B). That is, since the compression forces applied by the securing member 12 are not transmitted to the articulation mechanism 40, the anchor member 18 rotates about the central axis X under the influence of the sliding resistance provided by the various embodiments disclosed herein. In this manner, the articulation mechanism 40 is not only spatially isolated from the securing member 12, but also physically isolated from the forces provided by the securing member 12.

Figure 4 shows a perspective view of the anchor head 32 of the exemplary anchor member 18. The anchor head 32 includes a driving feature 42 that allows a surgeon to attach the anchor member 18 to a vertebra V. In the embodiment shown, a hex recess driving feature 42 is shown. Other types of driving features 42 may be appropriate, including for

example, slotted, star, Torx, and cross-shaped features. The driving feature 42 may be accessed through the aperture 26 shown in Figures 2A, 2B, and 3.

In the embodiment illustrated in Figure 4, the anchor head 32 is substantially spherical to allow multi-axial pivoting of the anchor member 18 relative to the pivoting head 10. In other embodiments, the anchor head 32 has other shapes to allow motion in fewer directions. For instance, a disc-shaped anchor head 32 may provide motion within a desired plane. Figures 5A, 5B, and 5C illustrate some of these alternative embodiments. Specifically, Figures 5A-5C are top section views according to the section line X-X shown in Figure 3. Figure 5A shows one embodiment where the anchor head 32 and wear member 30 are substantially spherical as previously described. With this configuration, the pivoting head 10 may pivot about a plurality of axes, including axes A, B, C, and D as shown in Figure 5A. Figure 5B shows an alternative embodiment where the anchor head 132 and wear member 130 are substantially disc-shaped. As disclosed above, this configuration may allow pivoting motion about axis B, but not other axes, including axis A. Figure 5C depicts another embodiment that is characterized by at least two different spherical radii R1, R2. This configuration may provide a different resistance to rotation about axes A and B. A somewhat pronounced difference in radii R1, R2 is shown in Figure 5C, though in practice, a fairly small difference may produce the desired result. Figure 6 shows a perspective view of a wear member 30 according to one embodiment. As depicted, the wear member 30 is cylindrically shaped and includes an outer surface 44 and an inner surface 46 extending between a top surface 50 and a bottom surface 52. Generally, the inner surface 46 is constructed to match the shape of the anchor head 32 of the threaded anchor member 18. The outer surface 44 may be configured as desired to fit within the base portion 34 of the pivoting head 10 as shown in Figure 3. In one embodiment, the outer surface 44 is substantially cylindrical. The exemplary wear member 30 also includes a gap 48. The gap 48 in the present embodiment may be used to spread open the wear member 30 by an amount sufficient to slip the wear member 30 over the anchor head 32 of the anchor member 18.

The wear member 30 is shown installed on the anchor head 32 in Figure 7. Figure 7 also shows relevant dimensions of the wear member 30 and the anchor head 32. Dimension L represents a width of the anchor head 32 at its widest point. The width may comprise a diameter, a spherical diameter, or other linear dimension. Dimensions M and N

respectively represent an interior width at the top 50 and bottom 52 of the wear member 30. Notably, dimension L is larger than both M and N. Thus, the gap 48 allows the anchor head 32 to fit within the wear member 30 as shown in Figure 7.

Figure 8 shows the assembled wear member 30 and anchor member 18 inserted into the base portion 34 of the pivoting head 10. The anchor member 18 and wear member 30 are retained within the base portion 34 by deforming the lower lip 56 in the direction of the arrow labeled F. The deforming step may be performed using a variety of techniques, including but not limited to mechanical pressing, swaging, and orbital forming. Orbital forming (or orbital forging) is a cold metal forming process during which the workpiece (the base portion 34 in this case) is transformed between upper and lower dies. The process features one or the other of these dies orbiting relative to the other with a compression force applied therebetween. Due to this orbiting motion over the workpiece, the resultant localized forces can achieve a high degree of deformation at a relatively low compression force level. The fully assembled pivoting head 10 is illustrated in Figure 9. In this Figure, the lower lip 56 of the base portion 34 is formed to constrain the wear member 30 and the anchor member 18.

Figure 10 shows a detail view of the lower lip 56 of the base portion 34. The forming technique used to form the lower lip 56 under and around the wear member 30 may be controlled to produce a pivoting head 10 with a desired, predetermined resistance to motion. The dashed lines labeled INT1 and INT2 depict this ability to control the amount of interference between the parts, and hence the amount of resistance to motion. If a greater amount of resistance to motion is desired, the lower lip 56 may be deformed a greater amount as indicated by the dashed line labeled INT2. A lesser amount of deformation indicated by the dashed line INT1 may produce less resistance to motion. In one embodiment, the lower lip 56 is formed to produce a very large resistance to motion such that the pivoting head 10 is, for all practical purposes, fixed. At the opposite end of the spectrum, the lower lip 56 is formed to merely place the relevant parts (base portion 34, wear member 30, and anchor head 32) in contact with one another or in close proximity to one another. In this embodiment, the pivoting head 10 is free to rotate with very little or no resistance to motion. At points between these extremes (indicated by dashed line INT1), a desired amount of interference may produce a desirable resistance to motion.

The resistance to motion may be measured in standard torque units, such as inch-ounces or other units of measure. As the parts are formed, the measurable resistance to motion may be marked on the exterior of the pivoting head 10 to provide surgeons an indication of the relative flexibility of the pivoting head 10. This marking may be provided as an
5 alphanumeric indication as represented by the letter T in Figures 2A and 2B. The marking may be stamped, whether by ink or metal deformation, engraved, or otherwise displayed on the pivoting head 10.

Interference between the base portion 34, the wear member 30, and the anchor head 32 will generally contribute to greater amounts of resistance to motion. Accordingly, the
10 parts may be selected according to size to provide the desired resistance to motion. For instance, Figure 11 shows a pivoting head 10, including a base portion 34 that is defined in part by a dimension D1. This dimension D1 corresponds approximately to the outer dimension of the wear members 30b, 30c, and 30d that are also shown in Figure 10. However, each wear member 30b-d has a slightly different outer dimension D2-D4. As an
15 example, wear member 30b is characterized by the largest outer dimension D2. Wear member 30c is characterized by the smallest outer diameter D3 and wear member 30d is somewhere between, with an outer diameter D4. It is assumed for the sake of this discussion, that the inner surface 46 is the same for all three wear members 30b-d. In an alternative embodiment, the inner surface 46 may be constructed with different sizes to
20 create different amounts of interference with the anchor head 32 of the anchor member 18. In an alternative embodiment, both the inner 46 and outer 44 surfaces may vary between wear members 30. That is, different wear members 30 may have different thicknesses. In an alternative embodiment, the resistance to pivoting motion of the head 32 may be provided by materials having different coefficients of friction.

For the embodiments shown in Figure 11, wear member 30c will result in the least amount
25 of interference when used in the pivoting head 10. Conversely, wear member 30b will result in the greatest amount of interference when used in the pivoting head 10. A measurable resistance to motion of the pivoting head 10 can be determined once the parts are assembled. As indicated above, this measured resistance to motion may be marked on
30 the exterior of the pivoting head 10 to provide surgeons an indication of the relative flexibility of the pivoting head 10.

Figure 12 shows an alternative embodiment of the pivoting head 10a. The section view shows an alternative technique for retaining the wear member 30 and anchor member 18 within the base portion 34a. In this embodiment, a snap ring 58 is inserted into the bottom of the base portion 34a beneath the wear member 30. The snap ring 58 may effectively
5 retain the wear member 30 and anchor member 18 within the pivoting head 10a. A detailed view of the area around the snap ring 58 is shown in Figure 13. Notably, in this embodiment, the snap ring 58 acts as a barrier to prevent the wear member 30 from escaping but does not contribute to any interference between the other parts (30, 32, 34). In an alternative embodiment shown in Figure 14, a snap ring 158 may contribute to the
10 overall resistance to motion of the pivoting head 10b. As with the embodiment shown in Figures 12 and 13, the snap ring 158 is configured to fit within the interior of the base portion 34b. However, the interior portion of the snap ring 158 is modified slightly to create an interference with the wear member 30e. In this embodiment, the wear member
15 30e is slightly modified to include a rounded lower outside corner 60 to facilitate insertion of the snap ring 158. A detailed view of a cross section of the snap ring 158 is shown in Figure 15.

The exemplary snap ring 158 comprises a bottom surface 64, a top surface 66, and an outer surface 62, each of which are configured to fit within the body portion 34b of the pivoting head 10b. A retaining surface 68 further acts to keep the wear member 30e
20 within the pivoting head 10b. This snap ring 158 also includes an interference surface 70 that contacts the wear member 30e to create a force G (shown in Figure 14) that compresses the wear member 158 towards the anchor head 32. The compression force G creates an interference that resists pivoting motion of the anchor head 32 relative to the wear member 30e. Snap rings 158 including different interference surfaces 72, 74 may be
25 selected to create more or less interference as desired. Once the snap ring 158 is assembled to retain and compress the wear member 30e, a measurable resistance to motion of the pivoting head 10b can be determined. As indicated above, this measured resistance to motion may be marked on the exterior of the pivoting head 10b to provide surgeons an indication of the relative flexibility of the pivoting head 10b.

30 Figures 16 and 17 illustrate an alternative embodiment of the pivoting head 10c. In this embodiment, the resistance to motion may be set intra-operatively. The base portion 34 c of the pivoting head 10c includes one or more adjustment members 76 that allow a

surgeon to adjust the amount of interference between the wear member 30 and the anchor head 32. Further, a surgeon may be able to adjust this amount of interference differently about different axes depending upon how many adjustment members 76 are provided. In the embodiments illustrated, there are four total adjustment members 76, disposed
5 approximately 90 degrees apart from one another. More or fewer adjustment members 76 may be provided. Also, in one embodiment, one of the adjustment members 76 is substantially aligned with the orientation in which a longitudinal member 15 lies. For example, in the embodiment shown, one adjustment member 76 is substantially parallel to the seating surface 24. In one embodiment, an adjustment member 76 is substantially
10 transverse to this seating surface. In the embodiment shown, the adjustment members 76 are setscrews that may be screwed in to create a compressive force H that is shown in Figure 17. In another embodiment, the adjustment member 76 may be a pin. The compressive force H may create an increased amount of interference that also creates more resistance to motion.

Figure 18 shows an alternative embodiment of the pivoting head 10d that includes a threaded region 78 disposed towards a bottom of the base portion 34d. An adjustment member 80 having substantially matching threads 84 is threaded onto the threads 78 on the base portion 34d and rotated until the desired resistance to motion is obtained. This procedure may be performed intra-operatively. In one embodiment, the threads 78, 84 are
20 tapered threads to create an increasing amount of inward compression J and corresponding interference. In one embodiment, a lower opening 82 of the adjustment member 80 is smaller than a width of the threaded portion 78 of the base portion 34d. Consequently, the more the adjustment member 80 is threaded onto the base portion 34d, the base portion 34d is compressed an increasing amount.

Figure 19 shows an alternative embodiment of the wear member 30a that may be used in one or more embodiments disclosed herein. The wear member 30a also includes a series of gaps 48a as with the previous embodiment shown in Figure 6. However, gaps 48a do not extend from the bottom surface 52a to the top surface 50a. In this embodiment, the top surface 50a of the wear member 30a is substantially continuous. In one embodiment, the
25 wear member 30a comprises four gaps 48a separated by approximately 90 degrees. In other embodiments, more or fewer numbers of gaps 48a are used. Since the gaps 48a originate at the bottom surface 52a of the wear member 30a, inward deflection of the wear
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member 30a, particularly near the bottom surface 52a, is possible. This feature may be appropriate for one or more embodiments where inward deflection of the wear member 30a is used to create a desired resistance to motion.

Embodiments described above have contemplated an anchor member 18 that comprises threads for insertion into a vertebral member V. Certainly, the pivoting head 10 may be incorporated on other types of bone screws. For example, different types of screws may be used to attach longitudinal members 15 to the sacrum S or to other parts of a vertebral member V. These include, for example, anterior and lateral portions of a vertebral body. In other embodiments, such as those shown in Figures 20 and 21, the pivoting head 10 may be implemented on other types of anchoring members. For example, Figure 20 shows a pivoting head 10 incorporated onto a hook-type anchor member 118. In another embodiment shown in Figure 21, the pivoting head 10 is incorporated onto another type of threaded anchor member 218 that is inserted into a plate 220 instead of a bony member. Spatially relative terms such as "under", "below", "lower", "over", "upper", and the like, are used for ease of description to explain the positioning of one element relative to a second element. These terms are intended to encompass different orientations of the device in addition to different orientations than those depicted in the figures. Further, terms such as "first", "second", and the like, are also used to describe various elements, regions, sections, etc and are also not intended to be limiting. Like terms refer to like elements throughout the description.

As used herein, the terms "having", "containing", "including", "comprising" and the like are open ended terms that indicate the presence of stated elements or features, but do not preclude additional elements or features. The articles "a", "an" and "the" are intended to include the plural as well as the singular, unless the context clearly indicates otherwise.

The present invention may be carried out in other specific ways than those herein set forth without departing from the scope and essential characteristics of the invention. For example, embodiments described above have contemplated a pivoting head 10 having a substantially U-shaped recess in which to hold a longitudinal member 15. Certainly other types of configurations may incorporate the articulation mechanism 40 described herein. For example, alternative embodiments of the pivoting head may have circular apertures, C-shaped clamps, and multi-piece clamps as are known to secure a longitudinal member. The present embodiments are, therefore, to be considered in all respects as illustrative and

not restrictive, and all changes coming within the meaning and equivalency range of the appended claims are intended to be embraced therein.

Claims

What is claimed is:

1. A connector to connect a vertebral member to a longitudinal member, the connector comprising:
 - 5 an anchor comprising a shaft and an anchor head;
 - a body attached to the anchor and comprising a channel and a cavity aligned along a common axis, the channel sized to receive the longitudinal member;
 - a fastener configured to maintain the longitudinal member in the channel; and
 - a first wear member positionable within the cavity and forming a first receiving area sized
10 to accommodate the head of the anchor;
 - a second wear member positionable within the cavity and forming a second receiving area sized to accommodate the head of the anchor;
 - the first wear member producing a first resistance to pivoting of the anchor relative to the body when the first wear member is positioned in the cavity,
 - 15 the second wear member producing a second resistance to pivoting of the anchor relative to the body when the second wear member is positioned in the cavity,
 - the cavity being isolated from the channel when the fastener maintains the longitudinal member in the channel.
- 20 2. The connector of claim 1 wherein the anchor head comprises an outer width, the wear member positioned within the cavity to contact the outer width.
3. The connector of claim 1 wherein the first and second wear members are constructed of different materials.
- 25 4. The connector of claim 1 wherein the first and second wear members have different sizes.
5. The connector of claim 1 further comprising a marking indicative of one of the
30 first and second resistances to pivoting.

6. The connector of claim 1 wherein the first wear member produces different resistances to motion in different pivoting directions.

5 7. A connector to connect a vertebral member to a longitudinal member, the connector comprising:

an anchor comprising a shaft and an anchor head having an outer width;

a body attached to the anchor and comprising a channel and a cavity aligned along a common axis, the channel sized to receive the longitudinal member;

a fastener configured to maintain the longitudinal member in the channel; and

10 a first wear member positionable within the cavity and having a first receiving area sized to accommodate the head of the anchor and having a first width when mounted within the cavity,

15 a second wear member positionable within the cavity and having a second receiving area sized to accommodate the head of the anchor and having a second width when mounted within the cavity,

a first difference between the outer width of the head and the first width of the first wear member being less than a second difference between the outer width of the head and the second width of the second wear member;

20 the cavity being isolated from the channel when the fastener maintains the longitudinal member in the channel.

25 8. The connector of claim 7 wherein the first receiving area has a first size when the first wear member is positioned in the cavity producing a first resistance to pivoting of the anchor relative to the body, the second receiving area having a second size when the first wear member is positioned in the cavity producing a second different resistance to pivoting of the anchor relative to the body.

30 9. The connector of claim 7 wherein the first and second wear members have different outer widths.

10. The connector of claim 7 wherein the first and second wear members have different wall thicknesses.

11. The connector of claim 7 wherein the first and second wear members have different inner widths.

5 12. The connector of claim 7 wherein the first and second wear members are constructed of different materials.

13. The connector of claim 7 wherein the first wear member produces a first resistance to pivoting and the second wear member produces second different resistance to pivoting.

10 14. A connector to connect a vertebral member to a longitudinal member, the connector comprising:

an anchor comprising a shaft and an anchor head;

15 a body attached to the anchor and comprising a channel and a cavity aligned along a common axis, the channel sized to receive the longitudinal member;

a fastener configured to maintain the longitudinal member in the channel, a force applied by the fastener to maintain the longitudinal rod within the channel being isolated from the anchor; and

20 a wear member contained within the cavity and forming a receiving area to accommodate the head of the anchor; and

an adjuster to adjust a size of the receiving area to control an amount of resistance applied to the head of the anchor when the anchor pivots within the body.

25 15. The connector of claim 14 wherein the body comprises a sidewall, the adjuster being a setscrew in the side wall and contacting the wear member.

16. The connector of claim 15 further comprising a plurality of setscrews.

30 17. The connector of claim 14 wherein the body comprises a deformable sidewall having external threads, the adjuster having mating threads and insertable onto the threads to adjust the size of the receiving area.

18. The connector of claim 14 wherein the wear member is positioned between the adjuster and the anchor to space the adjuster from the anchor.

5 19. A connector to connect a vertebral member to a longitudinal member, the connector comprising:

an anchor comprising a shaft and a head;

a body attached to the anchor and comprising a channel and a cavity aligned along a common axis, the channel sized to receive the longitudinal member;

10 a fastener configured to maintain the longitudinal member in the channel, a force applied by the fastener to maintain the longitudinal rod within the channel being isolated from the anchor; and

15 an adjuster to control an amount of resistance applied to the head of the anchor when the anchor pivots within the body, the adjuster selectably positionable between a first position to apply a first amount of resistance and a second position to apply a second different amount of resistance.

20 20. The connector of claim 19 wherein the body comprises a sidewall, the adjuster being a setscrew in the side wall and rotatable to control the amount of resistance applied to the head of the anchor.

21. The connector of claim 20 further comprising a plurality of setscrews.

25 22. The connector of claim 20 wherein the setscrew contacts a wear member that is in contact with the head of the anchor.

23. The connector of claim 19 wherein the body comprises a deformable sidewall having external threads, the adjuster having mating threads and insertable onto the threads to control the amount of resistance applied to the head of the anchor.

30 24. The connector of claim 19 wherein a wear member is positioned between the adjuster and the anchor to space the adjuster from the anchor.

25. A method of connecting a vertebral member to a longitudinal member, the method comprising the steps of:
pivotaly attaching an anchor to a body by positioning a head of the anchor within a cavity positioned within a body;
5 inserting a longitudinal rod into a channel positioned within the body and axially aligned with the cavity;
applying a force to maintain the longitudinal rod within the channel, the force being isolated from the anchor; and
adjusting the cavity to a first size that applies a first resistance to resist pivoting movement
10 of the anchor relative to the body, and
adjusting the cavity to a second size that applies a second resistance to resist pivoting movement of the anchor relative to the body.

26. The method of claim 25 wherein adjusting the cavity to the first size comprises
15 inserting a first wear member within the cavity and adjusting the cavity to the second size comprises inserting a second wear member within the cavity.

27. The method of claim 25 wherein adjusting the cavity to the first size comprises
20 inserting a first interference member within the cavity and adjusting the cavity to the second size comprises inserting a second interference member within the cavity.

28. The method of claim 25 further comprising displaying a marking on the body indicative of one of the first and second resistances to pivoting.

29. A method of connecting a vertebral member to a longitudinal member, the method comprising the steps of:
25 pivotaly attaching an anchor to a body by positioning a head of the anchor within a cavity positioned within a body;
inserting a longitudinal rod into a channel positioned within the body and axially aligned
30 with the cavity;
applying a force to maintain the longitudinal rod within the channel, the force being isolated from the anchor; and

positioning an adjuster to a first position thereby adjusting the cavity to a first size that applies a first resistance to resist pivoting movement of the anchor relative to the body, and

5 positioning an adjuster to a second position thereby adjusting the cavity to a second size that applies a second resistance to resist pivoting movement of the anchor relative to the body.

10 30. The method of claim 29 wherein positioning an adjuster to the first and second positions comprises rotating a setscrew into a sidewall of the body.

31. The method of claim 29 wherein positioning an adjuster to the first and second positions comprises rotating a threaded member onto a sidewall of the body.

15 32. The method of claim 29 further comprising displaying a marking on the body indicative of one of the first and second resistances to pivoting.

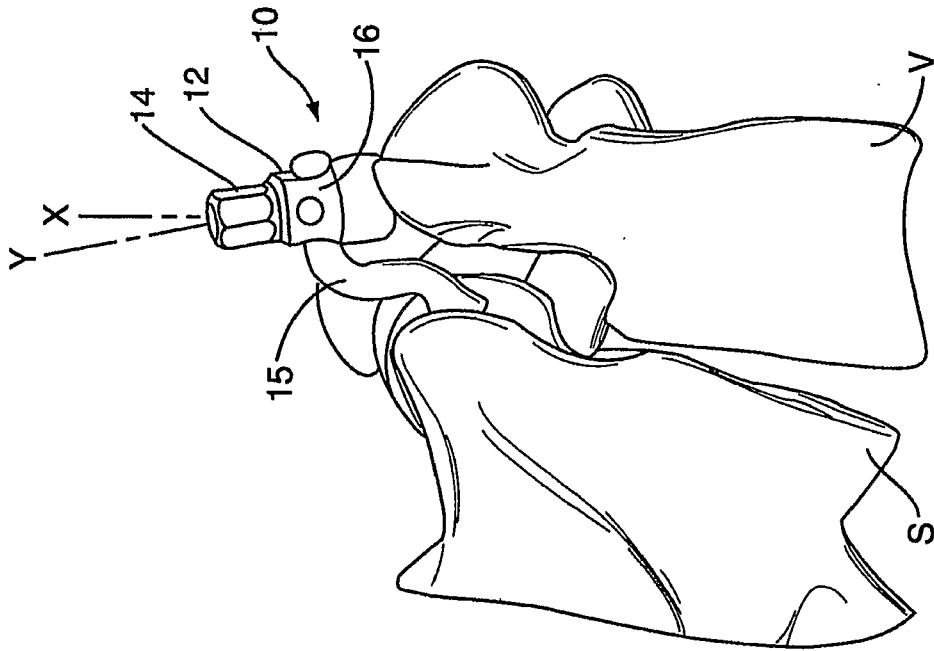


FIG. 1B

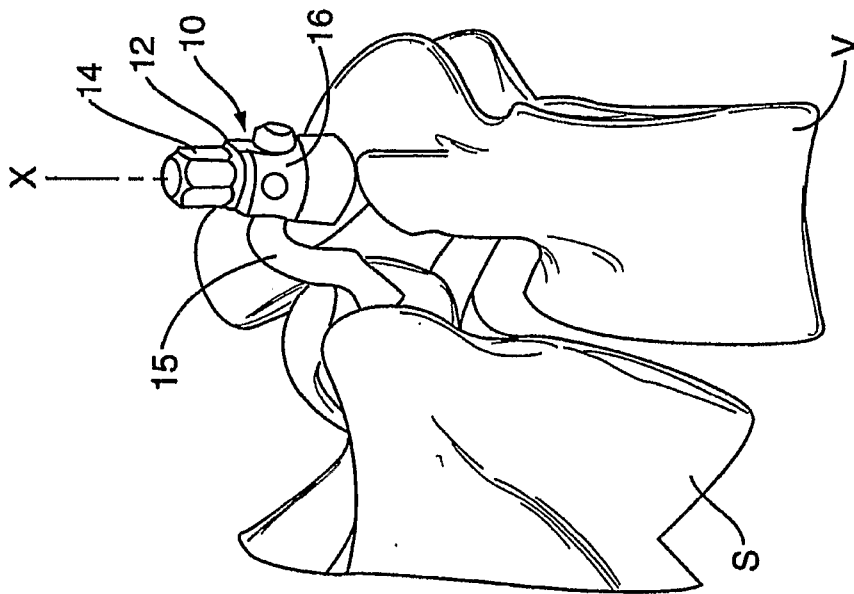


FIG. 1A

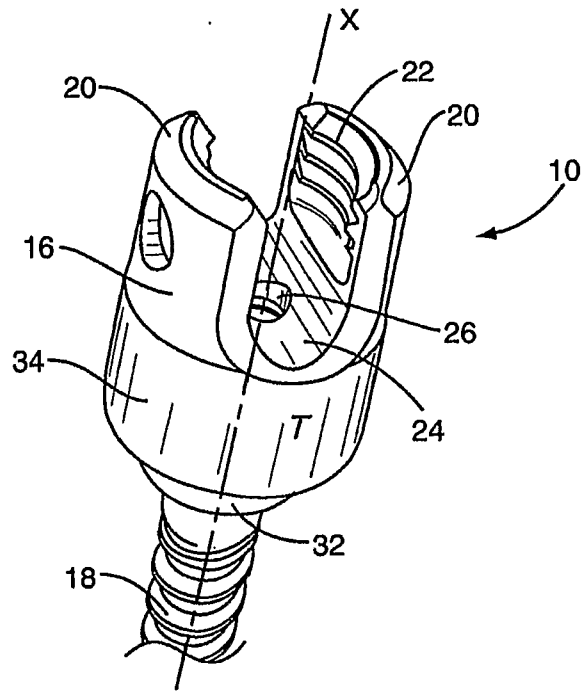


FIG. 2A

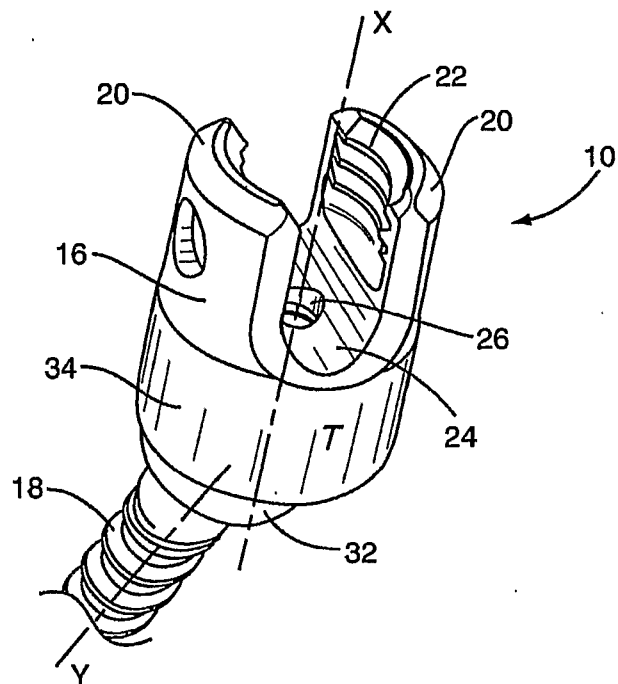


FIG. 2B

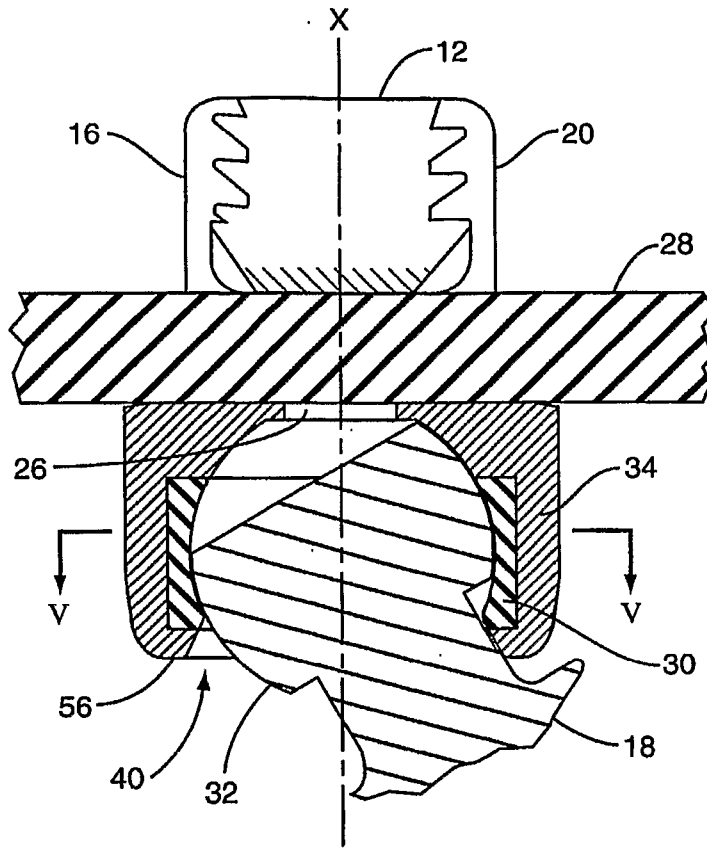


FIG. 3

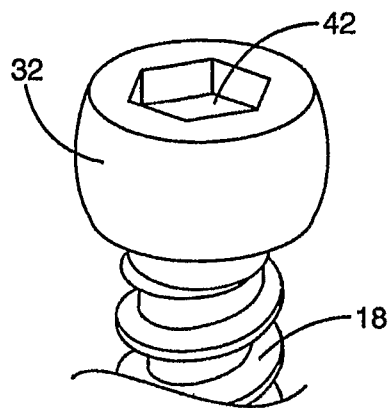


FIG. 4

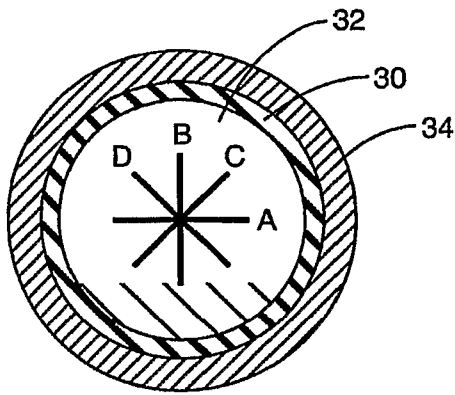


FIG. 5A

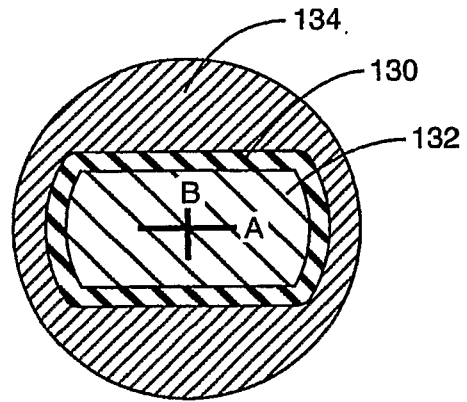


FIG. 5B

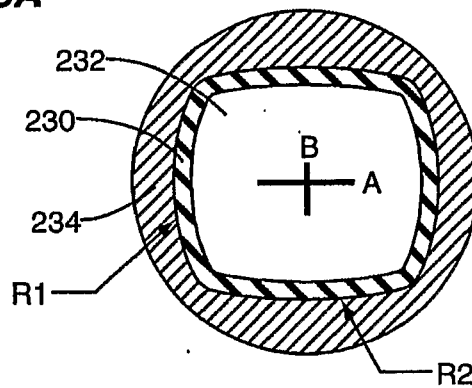


FIG. 5C

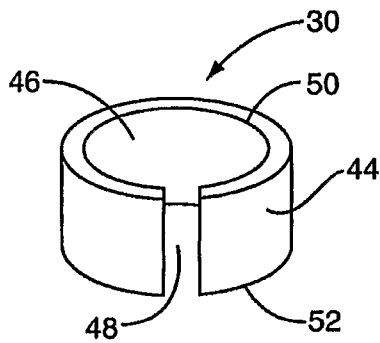


FIG. 6

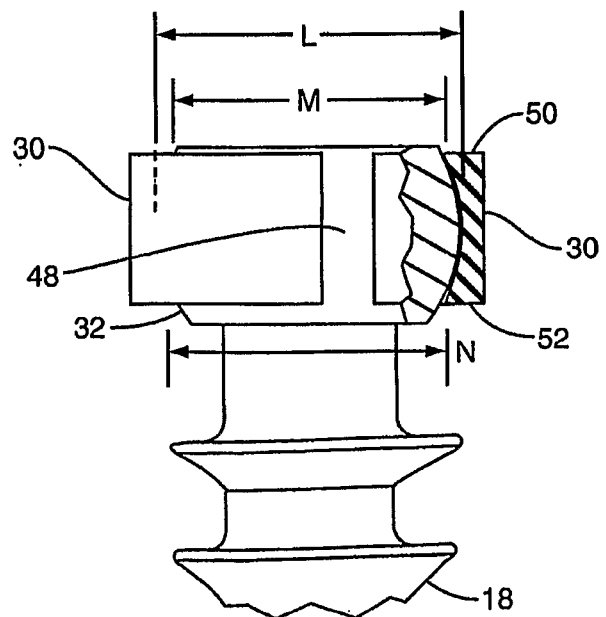


FIG. 7

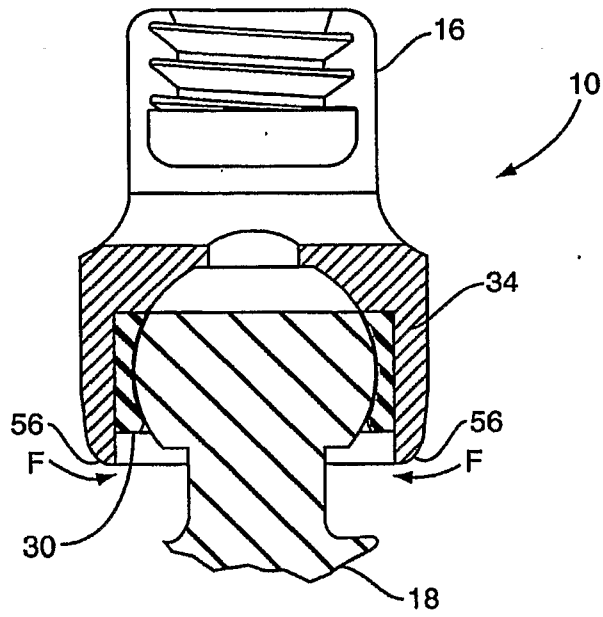


FIG. 8

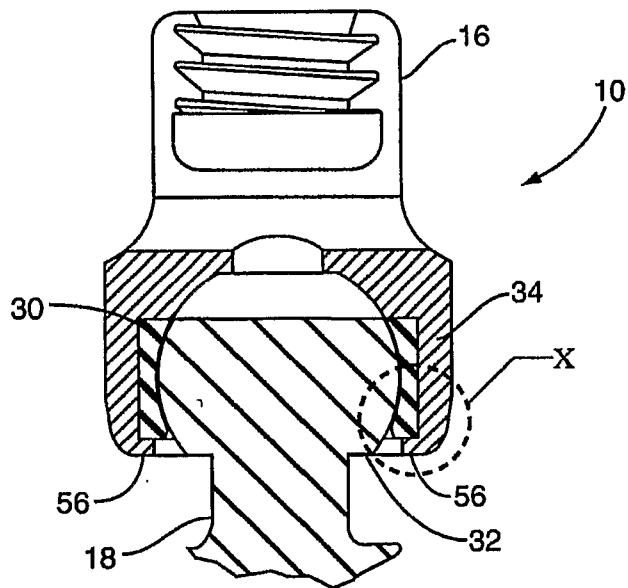


FIG. 9

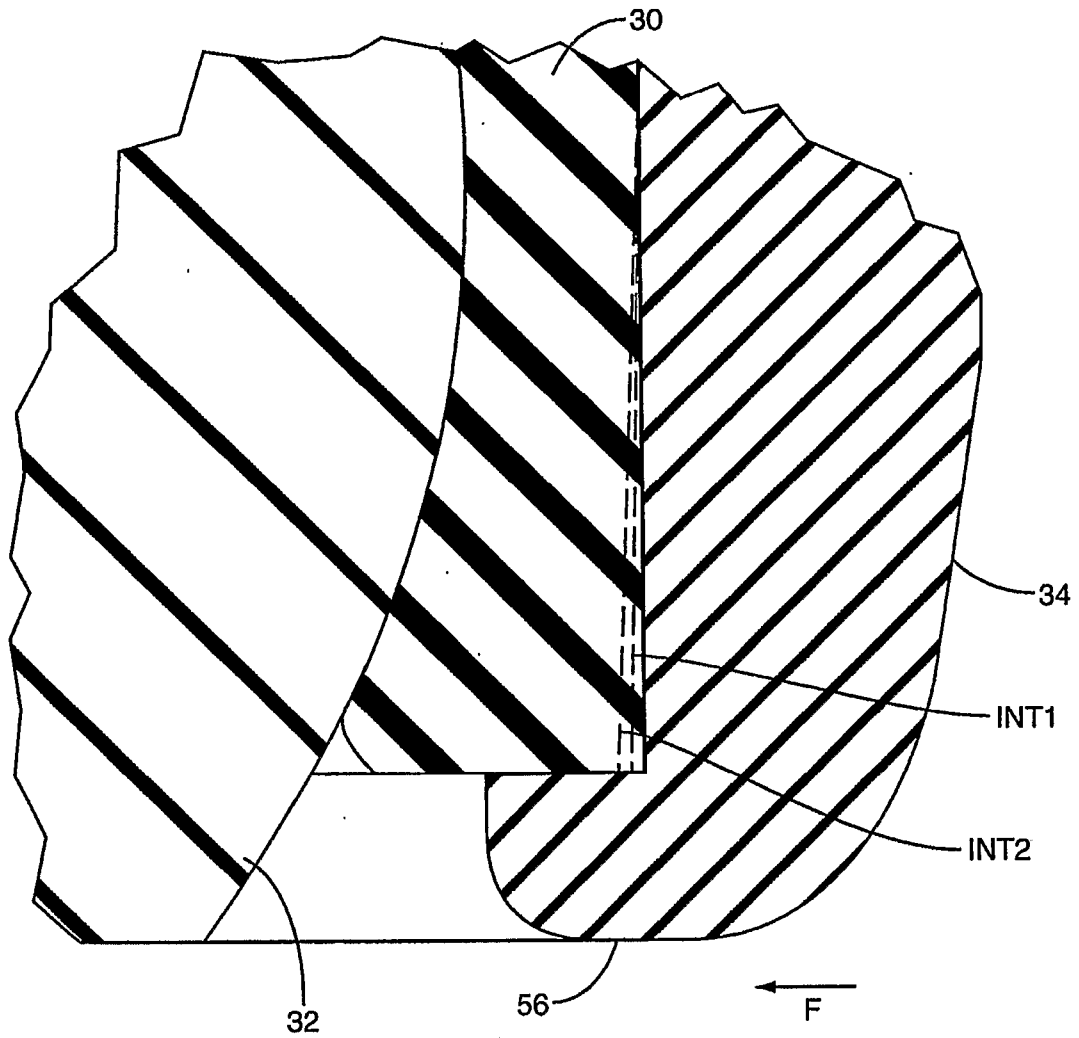


FIG. 10

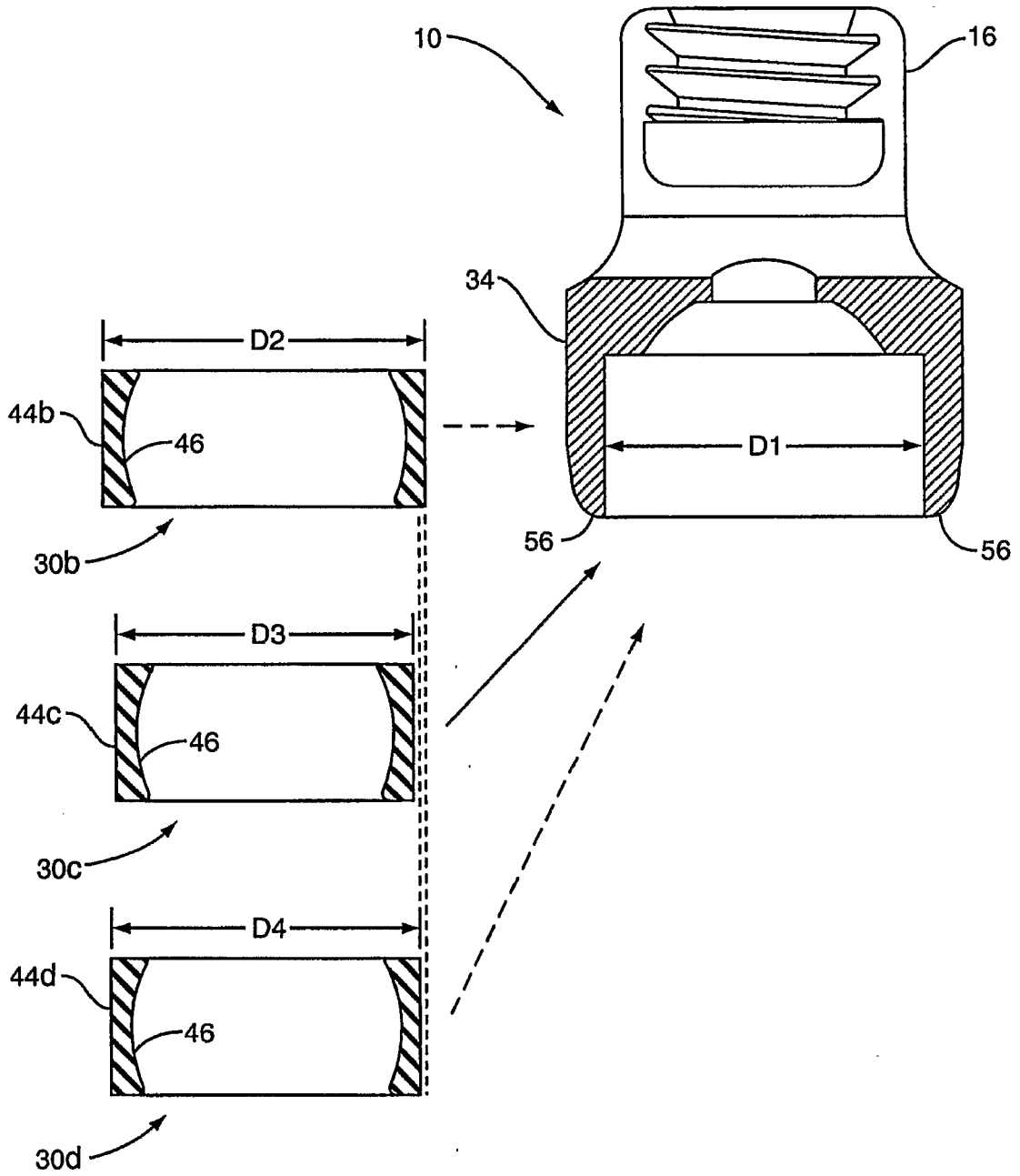


FIG. 11

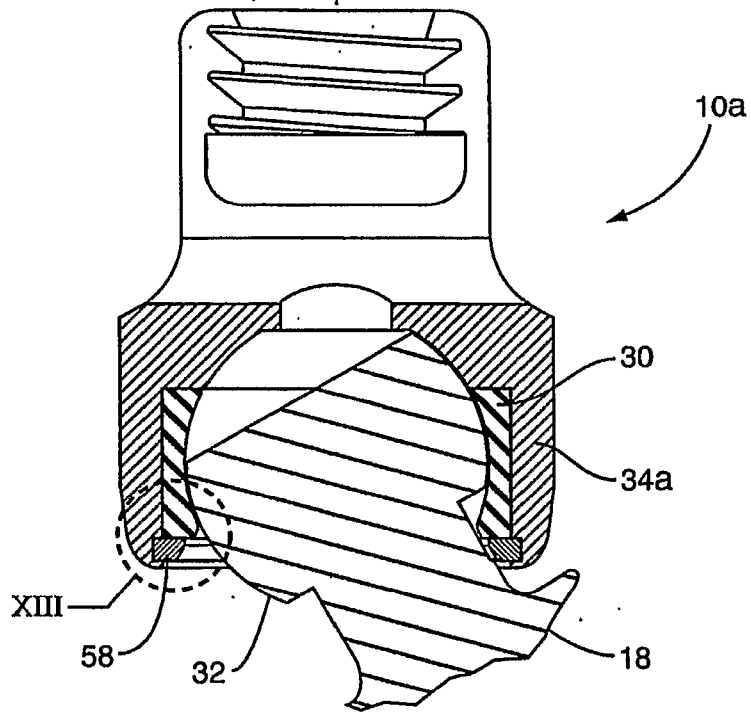


FIG. 12

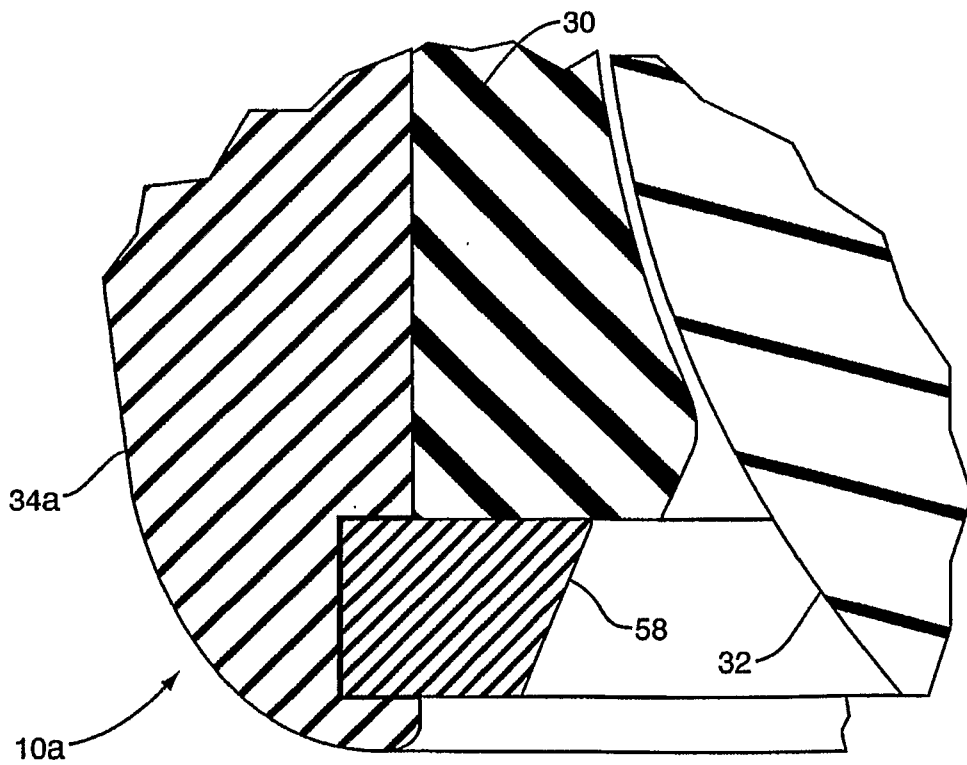


FIG. 13

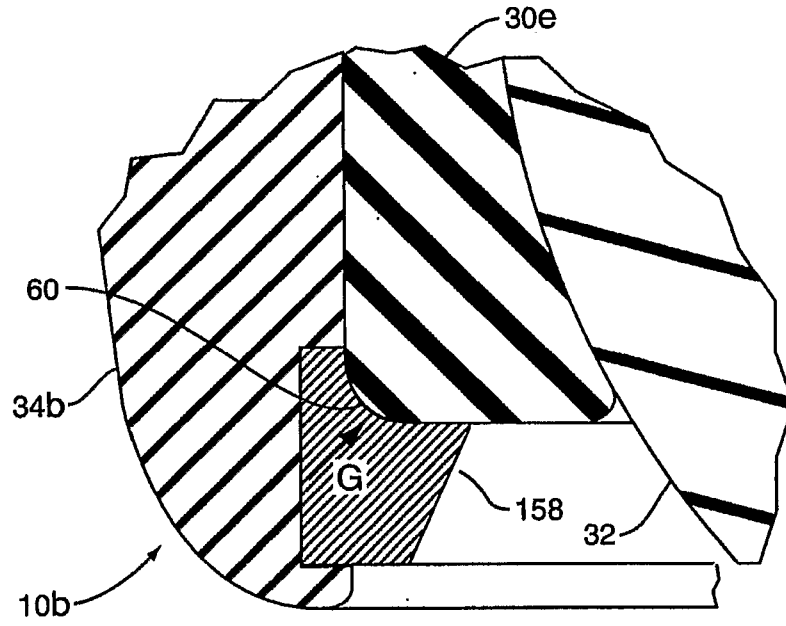


FIG. 14

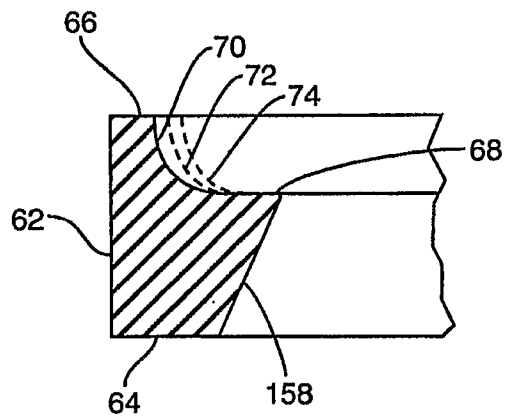


FIG. 15

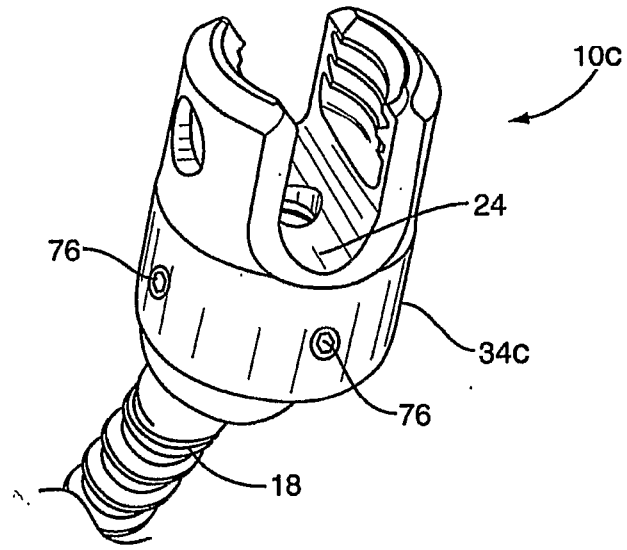


FIG. 16

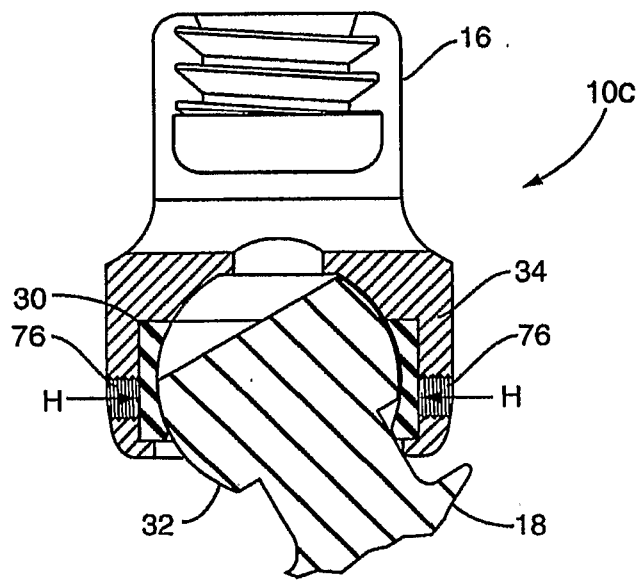


FIG. 17

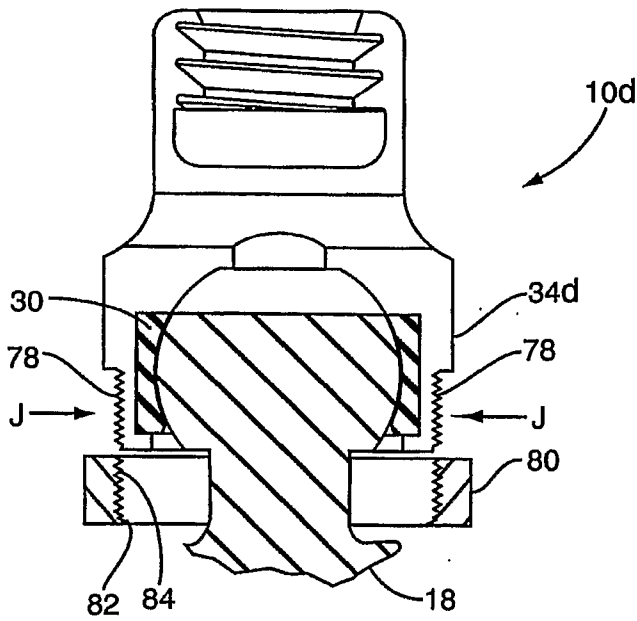


FIG. 18

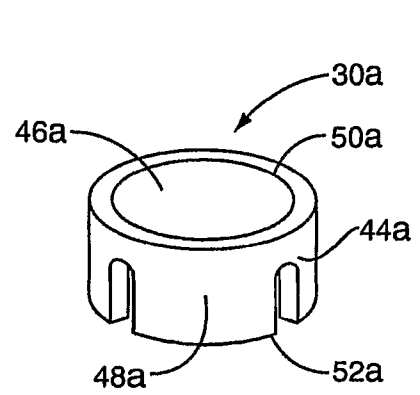


FIG. 19

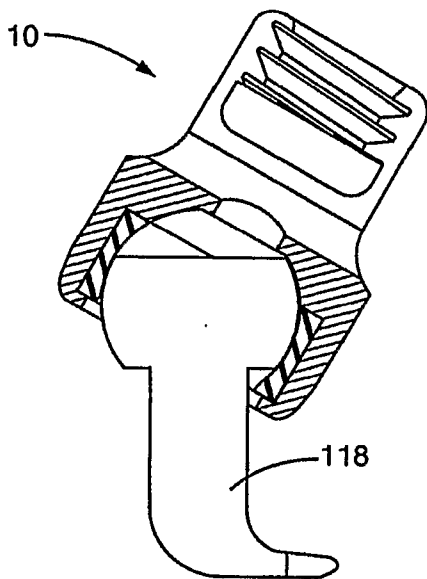


FIG. 20

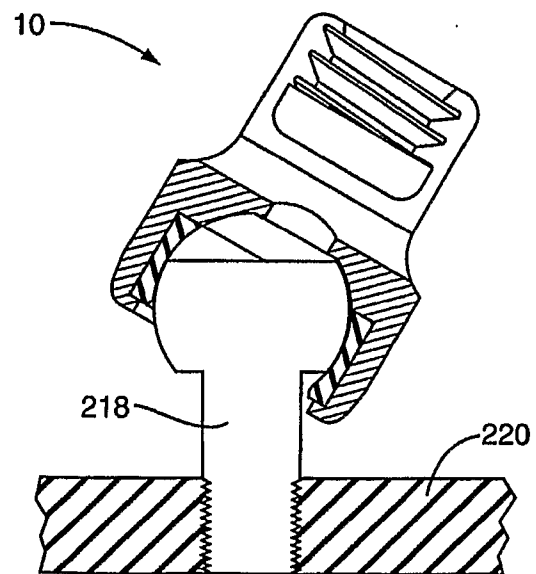


FIG. 21

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2007/061131

A. CLASSIFICATION OF SUBJECT MATTER
INV. 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)
A61B

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

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2004/267264 A1 (KONIECZYNSKI DAVID D [US] ET AL) 30 December 2004 (2004-12-30) figures 2a,2b paragraph [0024] - paragraph [0028]	1,2,4-6
Y	-----	3,7-10, 12,13
Y	US 6 290 703 B1 (GANEM FRANCK [FR]) 18 September 2001 (2001-09-18) figures 9,13,14 column 6, lines 51-56 ----- -/--	3,7-10, 12-14, 17,18

Further documents are listed in the continuation of Box C.

See patent family annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *&* document member of the same patent family

Date of the actual completion of the international search

Date of mailing of the international search report

8 May 2007

14/05/2007

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Louka, Maria

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2007/061131

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2004/176766 A1 (SHLUZAS ALAN E [US]) 9 September 2004 (2004-09-09) figure 9 paragraphs [0062], [0063] figures 4,15	7-11,13
Y		15,16, 20,21
Y	----- US 5 863 293 A (RICHEL SOPH MARC [US]) 26 January 1999 (1999-01-26) figures 3,4 column 5, lines 10-14 column 5, line 50 - column 6, line 11	14-18
X	----- US 6 918 911 B2 (BIEDERMANN LUTZ [DE] ET AL BIEDERMANN LUTZ [DE] ET AL) 19 July 2005 (2005-07-19) figures 8,9 column 7, line 4 - line 27 column 7, lines 52-54	14, 17-19, 22-24
Y		20,21
A	----- US 2005/228385 A1 (IOTT ANDREW [US] ET AL) 13 October 2005 (2005-10-13) paragraphs [0117], [0120]; figures 26,29	1-24
A	----- US 2005/277928 A1 (BOSCHERT PAUL F [US]) 15 December 2005 (2005-12-15) figure 4 paragraphs [0055], [0056] -----	1-24

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2007/061131

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.: 25-32
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

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

1. As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- The additional search fees were accompanied by the applicant's protest.
- No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

information on patent family members

International application No

PCT/US2007/061131

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