PN09L564

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

REVISED VERSION

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
19 June 2008 (19.06.2008)

PCT

(10) International Publication Number
WO 2008/073830 A9

(51) International Patent Classification:
A61B 17/70 (2006.01) *A61B 17/88* (2006.01)

(21) International Application Number:
PCT/US2007/086800

(22) International Filing Date:
7 December 2007 (07.12.2007)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/869,342 10 December 2006 (10.12.2006) US
60/914,360 27 April 2007 (27.04.2007) US

(71) Applicant *(for all designated States except US)*: PARADIGM SPINE, LLC [US/US]; 505 Park Avenue, 14th Floor, New York, NY 10022 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: TRAUTWEIN, Frank, T. [DE/DE]; Ludwigstr. 26, 70794 Filderstadt (DE). HOLTKAMP, Bernhard [DE/DE]; Leopold-messmer-weg 14, D-78166 Donaueschingen (DE). SALVERMOSER, Markus [DE/DE]; Am Muhlberg 14, 75832 Tuttlingen-Mohringen (DE). BERTAGNOLI, Rudolf [AT/AT]; Chimanistr, 21-23, A-1190 Vienna (AT). LOWERY, Gary, L. [US/US]; 5635 Clifton Lane, Jacksonville, FL 32211 (US). EISEN, Guntmar, H. [DE/DE]; Heubergweg 8, 78532 Tuttlingen (DE).

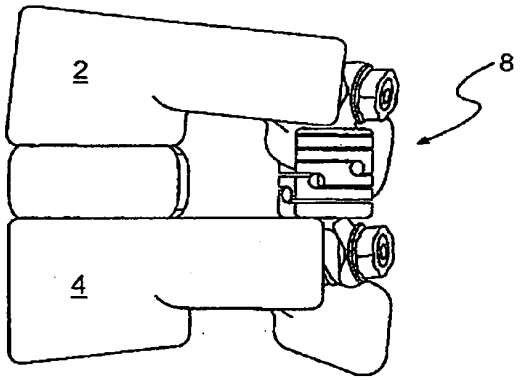
(74) Agent: MCDONELL, Leslie, A.; Finnegan Henderson Farabow, Garrett & Dunner LLP, 901 New York Avenue, Washington, DC 20001-4413 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, 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, 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,

[Continued on next page]

(54) Title: POSTERIOR FUNCTIONALLY DYNAMIC STABILIZATION SYSTEM



(57) Abstract: A functionally dynamic stabilization unit (10) and system for treatment of spinal instability are provided. Each unit, and collectively, the system, is configured to control flexion, extension and translation of the affected unstable vertebral area, thereby stabilizing the vertebral segments by restoring normal function. This is achieved by providing a unit and system that allow for lateral bending, axial compression, rotation, anterior segmental height adjustment, and posterior segmental height adjustment. The unit and system provide sufficient segmental stiffness, while also limiting, or controlling, the range of motion (i.e., sufficient stiffness in the neutral or active zone, while limiting or preventing motion outside of the active zone) to stabilize the vertebral segments. In use, the system mimics the natural movement of the normal spine. Furthermore, the system includes a rigid, fusion-promoting coupler (20) configured for use in an adjacent level, or as a substitute for the functionally dynamic unit. The modularity of the system allows adjustment over time and easier revision surgery, and is configured for minimally-invasive, delivery or implantation.

WO 2008/073830 A9

WO 2008/073830 A9

FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report*

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

(88) **Date of publication of the revised international search report:** 15 January 2009

(15) **Information about Correction:** see Notice of 15 January 2009

POSTERIOR FUNCTIONALLY DYNAMIC STABILIZATION SYSTEM

This application claims priority to United States Provisional Patent Application Number 60/869,342, which was filed on December 10, 2006, and United States Provisional Patent Application Number 60/914,360, which was filed on April 27, 2007, both of which are herein incorporated by reference in their entirety.

FIELD

[0001] The present invention relates to devices and methods for treating spinal conditions, and specifically to spinal stabilization systems for controlling or restricting relative motion between vertebrae.

BACKGROUND

[0002] The spine includes a series of joints known as motion segment units. Each unit represents the smallest component of the spine that exhibits a kinematic behavior characteristic of the entire spine. The motion segment unit is capable of flexion, extension, lateral bending, and translation. The components of each motion segment unit include two adjacent vertebrae, the corresponding apophyseal joints, an intervertebral disc, and/connecting ligamentous tissue, with each component of the motion segment unit contributing to the mechanical stability of the joint. For example, the intervertebral discs that separate adjacent vertebrae provide stiffness that helps to restrain relative motion of the vertebrae in flexion, extension, axial rotation, and lateral bending.

[0003] When the components of a motion segment unit move out of position or become damaged due to trauma, mechanical injury or disease, severe pain and further destabilizing injury to other components of the spine may result. In a patient with degenerative disc disease (DDD), a damaged disc may provide inadequate stiffness, which may result in excessive relative vertebral motion when the spine is under a given load, causing pain and further damage to the disc. Depending upon the severity of the structural changes that occur, treatment may include fusion, discectomy, and/or a laminectomy.

[0004] Current surgical treatments often involve fusion of unstable motion segment units with removal of adjacent tissue. For numerous reasons, fusion may be an undesirable treatment option. For instance, fusion results in a permanent, rigid fixation with irreversible loss of range of motion at fused vertebral levels. In addition, loss of mobility at the fused levels causes stress to be transferred to other neighboring motion segments, which can cause or accelerate degeneration of those segments. Moreover, fusion often does not alleviate some or all of the pain.

[0005] It would thus be desirable to provide a spinal stabilization system that is sufficiently functionally dynamic to manage the load sharing characteristics of the treated spine. It would further be desirable to provide a system that would allow close-to-normal motion, mimicking the physiological response of a healthy motion segment and providing pain relief.

SUMMARY

[0006] The present disclosure provides a functionally dynamic stabilization unit and system for treatment of spinal instability due to, for example, injury, trauma, or degenerative disc disease (DDD). Each unit, and collectively, the system, is configured to control flexion, extension, and translation of affected vertebrae, thereby stabilizing the vertebral segments by restoring normal function. This is achieved by providing a unit and system that allow for lateral bending, axial compression, rotation, anterior segmental height adjustment, and posterior segmental height adjustment. The unit and system provide sufficient segmental stiffness, while also controlling the range of motion to stabilize the vertebral segments. In use, the system mimics the natural movement of the normal spine. Furthermore, the system is configured to allow adjustment over time, revision surgery (e.g., fusion), and percutaneous implantation.

[0007] In accordance with one exemplary embodiment, a functionally dynamic spinal stabilization system is provided. The system may comprise a flexible coupler and can include a cylindrical body portion including one or more slots in the wall of the cylindrical body. The system can further

include a pair of gripping arms for attachment to bone anchors, the arms being located at opposed ends of the coupler. The flexible coupler may also include an internal range-of-motion limiting mechanism configured to limit motion of the flexible coupler in bending, compression, and tension. The system can further comprise a pair of bone anchors configured to cooperate with the gripping arms for attachment to bone tissue.

[0008] In accordance with another exemplary embodiment, the system further includes a rigid coupler having a pair of gripping arms for attachment to bone anchors. Like the flexible coupler, the arms can be located at opposed ends of the coupler. However, unlike the flexible coupler, this coupler does not allow extension or compression. Rather, the coupler promotes fusion by preventing motion at this segment.

[0009] Also provided is a method of treating a spine. The method can comprise attaching a first bone anchor to a vertebra and attaching a second bone anchor to an adjacent vertebrae. A flexible coupler may then be attached to the first and second bone anchors. The flexible coupler can include a cylindrical body portion having one or more slots in the wall of the cylindrical body and an internal range-of-motion limiting mechanism configured to limit motion of the flexible coupler in bending, compression, and tension.

[0010] Also provided is a method of percutaneous implantation of the system that minimizes tissue damage and eases insertion, as well as an instrument set for performing this method. The method can include producing at least one incision over at least two adjacent vertebrae to be treated and positioning at least two wires such that each wire separately contacts a pedicle of one the at least two vertebrae. A screw may be secured to each vertebrae, and the distance between the screws inserted into two adjacent vertebrae is measured. A flexible coupler to be attached to the screws is selected, and the length of the flexible coupler is adjusted based on the distance measured.

[0011] It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory only and are not restrictive of the disclosure, as claimed.

[0012] The accompanying drawings, which are incorporated in and constitute a part of this specification, illustrate several embodiments of the disclosure and together with the description, serve to explain the principles of the disclosure.

[0013] Additional objects and advantages of the disclosure will be set forth in part in the description which follows or may be learned by practice of the disclosure. The objects and advantages of the disclosure will be realized and attained by means of the elements and combinations particularly pointed out in the appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] FIG. 1 illustrates a side perspective view of an implanted functionally dynamic stabilization system.

[0015] FIG. 2 illustrates a top view of the implanted functionally dynamic stabilization system of Fig 1, including two stabilization units on opposite sides of the spine.

[0016] FIG. 3 illustrates a posterior view of the system of FIGS. 1-2.

[0017] FIG. 4A illustrates a perspective view of one stabilization unit of the system of FIGS. 1-3.

[0018] FIG. 4B illustrates a side view of a portion of a flexible coupler used in the stabilization unit of FIG. 4A.

[0019] FIG. 4C illustrates a top view of the flexible coupler of FIG. 4B.

[0020] FIG. 5A illustrates a cross-sectional view of the unit of FIG. 4A.

[0021] FIG. 5B illustrates an exploded view of a portion of the stabilization unit of FIG. 4A.

[0022] FIG. 6 illustrates an exploded view of the flexible coupler of FIGS. 4B-4C.

[0023] FIG. 7A illustrates a perspective view of a portion of the flexible coupler of FIGS 4B and 4C.

[0024] FIG. 7B illustrates a perspective view of a section of the portion of the flexible coupler of FIG. 7A.

[0025] FIG. 8A illustrates a cross-sectional view of the flexible coupler of FIG. 4B in a resting state.

[0026] FIG. 8B illustrates a cross-sectional view of the flexible coupler of FIG. 4B in a fully expanded state.

[0027] FIG. 8C illustrates a cross-sectional view of the flexible coupler of FIG. 4B in a fully compressed state.

[0028] FIG. 8D illustrates an enlarged view of a portion of the flexible coupler of FIG. 8A in a resting state.

[0029] FIG. 9A illustrates a perspective view of another embodiment of an implanted functionally dynamic stabilization system.

[0030] FIG. 9B illustrates an enlarged view of the implanted system of FIG. 9A.

[0031] FIG. 10 illustrates a side view of a portion of the system of FIGS. 9A-9B.

[0032] FIG. 11A illustrates a perspective view of a rigid coupler that may be used with the stabilization systems of the present disclosure.

[0033] FIG. 11B illustrates a cross-sectional view of the rigid coupler of FIG. 11A, taken along line A—A.

[0034] FIG. 11C illustrates a side cross-sectional view of an alternative embodiment of a rigid coupler that may be used with the stabilization systems of the present disclosure.

[0035] FIG. 12 illustrates a perspective view of a modular, multi-segmental stabilization system, according to another embodiment of the disclosure.

[0036] FIG. 13 illustrates a perspective view of a wire template and K-wires used to facilitate implantation of the spinal stabilization systems of the present disclosure.

[0037] FIG. 14A illustrates a perspective view of a set of extension rods used to facilitate implantation of bone anchors using the methods of the present disclosure.

[0038] FIG. 14B illustrates a partial cutaway view of one of the extension rods of FIG. 14A connected to a bone anchor.

[0039] FIG. 15 illustrates a perspective view of a caliper.

[0040] FIG. 16 illustrates a perspective view of an alternative set of extension rods according to the present disclosure.

[0041] FIG. 17 illustrates a perspective view of an instrument for adjusting the length of a flexible coupler.

[0042] FIG. 18A illustrates a perspective view of a nut that may be used to secure stabilization units of the present disclosure.

[0043] FIG. 18B illustrates a partial cutaway view of the nut of FIG. 18B coupled to the insertion tool of FIG. 19.

[0044] FIG. 19 illustrates a perspective view of an insertion tool.

DESCRIPTION OF THE EMBODIMENTS

[0045] The present disclosure provides a functionally dynamic stabilization unit and a system incorporating functionally dynamic stabilization units for treatment of spinal instability. The present disclosure further provides

minimally-invasive methods for implanting spinal stabilization systems, as well as instruments that will facilitate these methods.

[0046] The unit, system, and methods of the present disclosure may be used to treat spinal pathologies caused by, for example, injury, trauma, or degenerative disc disease (DDD). The stabilization unit and systems comprising such units are configured to control flexion, extension and translation of an affected unstable vertebral area, thereby stabilizing vertebral segments and restoring normal function. This is achieved by providing a unit and system that allow for lateral bending, axial compression, rotation, anterior segmental height adjustment, and posterior segmental height adjustment on the spine. The unit and system provide sufficient segmental stiffness within a patient's neutral or active zone, while also limiting or controlling range of motion outside a desired zone. In use, the system mimics the natural movement of the normal spine. Furthermore, the system is configured to allow adjustment over time, revision surgery, and percutaneous delivery or implantation.

[0047] Turning now to the drawings, FIG. 1 shows an embodiment of a functionally dynamic stabilization system 8, implanted between adjacent vertebrae 2, 4. FIG. 2 illustrates a top view of an implanted functionally dynamic stabilization system, and FIG. 3 illustrates a posterior view of the system 8 of FIGS. 1-2. As shown, the system 8 can include one or more flexible stabilization units 10 that can be implanted on a posterior portion of the spine to stabilize affected vertebrae 2, 4.

[0048] As shown in FIG. 4A, each functionally dynamic stabilization unit 10 may comprise a flexible coupler 20 connected to at least one bone anchor 50, such as a pedicle screw or bone screw. The coupler 20 may comprise a flexible body 22 including slots 24 and openings 26. As shown in FIGS. 4B-4C, the flexible body 22 may include, at one end, a gripping arm 30 having an opening 32 for insertion of a bone anchor 50, and at an opposite end a second gripping arm 40, also having an opening 33 for receiving a bone anchor 50. The gripping arms 30, 40 may be integrally formed with the body 22 or may be detachably connected to the body 22. For example, one end of the gripping arm

40 may be threaded for connection to the flexible body 22 via, for example, a sleeve 90 in the flexible body 22, as shown in Fig 6.

[0049] Each gripping arm 30, 40 of the coupler 20 can include, on one side, a concavely-shaped cavity 34, 44 configured to seat against a semi-spherical ball bearing 60, shown in FIGS. 5A-5B, and 6. The ball bearing 60 can have a through-hole, allowing it to fit over the bone anchor 50. In one embodiment, the bone anchor 50 may have an elongate, threaded shaft 52 extending into a flange 56 that connects to a head portion 54 upon which the ball bearing 60 may be placed. The flange 56 may further include serrations 57 to facilitate anchorage to bone tissue and reduce loosening of the anchor 50 over time. The bone anchor 50 may be, for example, a pedicle screw. Preferably, the bone anchor 50 can be cannulated to enable the unit 10 or system 8 to be percutaneously delivered. The concavely-shaped cavities 34, 44 allow the gripping arms to slide or rotate with respect to the bearing 60, thereby enabling the gripping arms 30, 40 to move relative to the bone anchor 50. Other appropriate structures may be used to connect the flexible body 22 to the bone anchors 50 while permitting relative movement between the two.

[0050] As further shown in FIGS. 5A, 5B and 10, a washer 70 may be placed onto the screw 50 and against the flange 56 or nut 80. The washer 70 can be configured and shaped to lie against the ball bearing 60. An assembled functionally dynamic stabilization unit 10 would further include a nut 80 screwed onto the head portion 54 of the screw 50 to secure the components to one another, as illustrated in FIGS. 4A and 5A.

[0051] Each functionally dynamic stabilization unit 10 is configured to allow a range of motion or displacement of between 1.5 and 3.0 mm, where displacement may be measured from the center of a first pedicle screw connected to a first gripping arm 30 to the center of a second pedicle screw connected to the second gripping arm 40. This displacement or range of motion may be achieved, for example, through rotation, extension, or translation.

[0052] FIG. 6 illustrates an exploded view of the flexible coupler of FIGS. 4A-4C. As shown, in some embodiments, one of the gripping arms 40

may be removably attached to the coupler 20. In one embodiment, the coupler 20 can include a threaded opening 28 for securing the second gripping arm 40, and other components, to the coupler 20. Within the flexible coupler 20, there may be a sleeve 90 having an opening 92 at one end and including a threaded rim 94 around the opening 92 for threadably connecting to the coupler body 22. The sleeve 90 can be configured to reside within the coupler body 22 and to receive and cooperate with a pin 100. The pin 100 can comprise an elongate body 102 with a threaded end, the body 102 extending into a semispherical head region 104 and including a skirt or shoulder region 106. Collectively, the sleeve 90 and pin 100 form an extension and compression stop within the coupler body 22, functioning to limit range of motion of the flexible coupler 20 to the patient's neutral or active zone.

[0053] The rim 92 of the sleeve 90 may be threaded to engage the threaded end 46 of the detachable second gripping arm 40. The overall length of the coupler 20 may be adjusted by varying the amount of threading of the second gripping arm 40 into the sleeve 90 (i.e., varying the number of rotations of the arm 40 into the sleeve 90). As shown, the threaded end 46 of the detachable second gripping arm 40 may extend into a plurality of compressible finger projections 43, each projection 43 terminating at a flanged lip 47. The flanged lip 47 serves as a locking mechanism, preventing the second gripping arm 40 from being unscrewed from the sleeve 90 after assembly. The threaded end 46 may also include a well 48 for receiving an elastomeric plug 110, as shown in FIG. 8C. The elastomeric plug 110 may be formed of a soft, compliant plastic material such as, for example, silicone, polyethylene, or polyethyletherketone (PEEK). As the second detachable gripping arm 40 is threaded onto the sleeve 90, the plug 110 interacts with the threaded opening 92, reducing the slack or play between the arm 40 and the sleeve 90. Other suitable structures that permit adjustment of the length of the flexible body while providing control of the amount of compression and extension of the flexible body may also be used. For example, a gripping arm can be attached at a friction fit, a telescoping connection, or using a ratchet mechanism.

[0054] As shown in detail in FIGS. 7A and 7B, in one exemplary embodiment, the coupler body 22 may include a cylindrical body comprised of a series of coil units 22A. The series of coil units 22, when connected to one another to form a stepwise series of slots 24, whereby each slot 24 terminates at an opening 26 of the flexible body 22. In some embodiments, the series of coil units 22A can be formed from a single piece of material such that the units 22A are integrally connected with one another. For example, in one embodiment, the coil units 22A can be etched or cut from a single, tubular piece of material. In other embodiments, one or more coil units 22A can be formed individually and stacked upon one another. The stacked coil units 22A can be connected to one another, for example, by welding or through mechanical connections.

[0055] It is contemplated that the coupler body 22 may vary in degree of stiffness based on the height, width, distance or angle between two adjacent slots 24 and the number of units 22A forming the coupler body 22. Further, one or more units 22A may be formed from different materials so as to vary the mechanical properties of the body 22. In addition, the dimensions of the units 22A, slots 24, and openings 26 can be varied within a single body 22.

[0056] FIGS. 8A—8D show an embodiment of the fully assembled flexible coupler 20 in a resting state (FIGS. 8A and 8D), fully-expanded or distracted state (FIG. 8B), and a fully compressed state (FIG. 8C). In the resting state, shown in FIG. 8A and an expanded view in FIG. 8D, the pin 100 and sleeve 90 are not engaged (i.e., free of resistive forces or encumbrances). In the fully-expanded or distracted state (FIG. 8B), the pin head 104, having a dimension that is larger than the width of the narrowed opening 98, abuts the narrowed opening 98 of the sleeve 90, preventing the flexible coupler body 22 from over expanding. In the fully-compressed state (FIG. 8C), the end of the sleeve 90 with the narrowed opening 98 abuts the inner edge of the first gripping arm 30, as shown. The cooperation of the sleeve 90 and pin 100 inside the coupler body 22 provides a distraction-compression stopping mechanism to control or limit the range of motion that can be offered, preventing not only injury or damage to the affected vertebral segments but also to the functionally dynamic stabilization unit itself. Other types of cooperating elements, such as, for

example, a telescoping element or internal piston, may be sued to control or limit the range of motion of the coupler body 22.

[0057] As previously mentioned, the functionally dynamic stabilization unit 10 may be used alone to stabilize a pair of vertebral segments. Further, if desired, more than one unit 10 may be used in combination to form a multi-level, functionally dynamic stabilization system 12, as shown in FIGS. 9A and 9B. The multi-level, functionally dynamic stabilization system 12 may include two or more of the units 10 connected to one another.

[0058] FIG. 10 illustrates a side view of the system shown in FIGS. 9A-9B. As shown, the system 12 includes a pair of flexible couplers 20 connected in series. The couplers 20 are positioned such that the first gripping arm 30 of each coupler 20 is placed around one ball bearing 60, with a bone anchor 50 and nut 80 securing the combination together. It is understood that more than two couplers 20 may be connected in this manner, and either the first 30 or second 40 gripping arm of any single coupler may be combined with the first 30 or second 40 gripping arm of another coupler 20 on a bone anchor 50. Any number of couplers 20 may be implanted either along one side, or on both sides, of a patient's spine. Further, the units 10 may have differing mechanical properties according to the patient's pathology and anatomy.

[0059] In some embodiments, the stabilization systems of the present disclosure can allow fusion of one or more vertebral motion segments, along with functionally dynamic stabilization of other motion segments. To this end, the stabilization system may include a rigid, fusion-promoting coupler 101, such as the one shown in FIG. 11A. The rigid coupler 101 can be configured for use with the bone anchors 50, ball bearings 60, and washers 70 described previously. As illustrated, the rigid coupler 101 comprises two components 122, 124, each of which extends to a gripping arm 130, 140, respectively, in a manner similar to that in the flexible coupler 20 previously described. Each of the arms 130, 140 includes an opening 132 for attachment to a bone anchor 50, in a manner similar to that described with respect to the flexible coupler 20.

[0060] As further shown in FIG. 11B, the two components 122, 124 may be attached to one another to allow adjustment of the length of the rigid coupler 101. For example, the components 122, 124 can include threaded surfaces, and the length of the rigid coupler 101 can be adjusted by twisting one component 122 with respect to the other component 124, much like the manner previously described for adjusting the length of the flexible coupler 20. Each of the gripping arms 130, 140 can also include, on an underside, a concave cavity 134, 144, respectively, configured to seat against a semi-spherical ball bearing 60. Hence, the implantation of the rigid coupler 101 to the bone anchors 50 is similar to that for the flexible coupler 20, as previously described.

[0061] As shown in FIG. 11C, an alternative embodiment of a rigid, fusion-promoting coupler 201 may be provided. The rigid, fusion-promoting coupler 201 is similar to rigid coupler 101 except that it may not utilize threaded surfaces of components for adjusting a length of the coupler 201. The rigid coupler 201 can be configured for use with the bone anchors 50, ball bearings 60, and washers 70 described previously. As illustrated, the rigid coupler 201 comprises two components 222, 224, each of which extends to a gripping arm 230, 240, respectively, in a manner similar to that in the flexible coupler 20 previously described. Each of the arms 230, 240 includes an opening (not shown) for attachment to a bone anchor 50, in a manner similar to that described with respect to the flexible coupler 20. Each of the gripping arms 230, 240 can also include, on an underside, a concave cavity 234, 244, respectively, configured to seat against a semi-spherical ball bearing 60.

[0062] The first component 222 and the second component 224 may be movable relative to one another to facilitate adjustment of the length of the coupler 201. Instead of threaded surfaces, the component 222 may include a cavity 226 configured to receive a fastening element 230 to secure the first component 222 relative to the second component 224. Because the first and second components do not include threaded surfaces, they may be moved relative to one another by sliding the components rather than twisting. Such an embodiment permits the surgeon to adjust the length of the rigid coupler 201 in situ as necessary.

[0063] The fastening element 230 may be any suitable fastening element such as a screw or a nut. For example, the fastening element 230 may comprise a break-away nut having a first portion configured to fixingly engage the portion 226 of component 222 to fix the position of the first component 222 relative to the second component and a second portion configured to engage an insertion tool for tightening of the first portion to the rigid coupler. The second portion of the break-away nut may be a break-away portion that has a thinner wall or area of lower yield-strength material, and is configured to break when a sufficient torque is applied (i.e., when the nut 230 has been sufficiently tightened). An internal surface of cavity 226 and an external surface of the fastening element 230 may be provided with threads to facilitate engagement of the cavity 226 with the fastening element 230.

[0064] As noted, the stabilization system may include both functionally dynamic, flexible couplers 20 and rigid couplers 101, thereby providing a modular system that allows the combination of motion preservation and fusion at discrete segments of the patient's spine. By permitting interchangeability of the rigid coupler 101 and a flexible coupler 20, in the system, the surgeon will have greater flexibility to address the specific needs of the patient. Therefore, one spinal segment may have functionally dynamic stabilization (i.e., non-fusion), while an adjacent segment may have rigid, segmental fixation (i.e., fusion).

[0065] FIG. 12 illustrates a multi-segmental system 12 comprising three discreet stabilization units 10a, 10b, 10c utilizing flexible couplers 20a, 20b and a rigid coupler 101. The flexible couplers 20a, 20b of units 10a and 10c increase the segmental stiffness of the affected motion segment and restrict the range of motion in flexion, extension, lateral bending and rotation, while preserving motion. By selecting an appropriately-sized coupler 20a, 20b, the posterior segmental height can be adjusted as well. In addition, the rigid, fusion-promoting coupler 101 of unit 10b provides rigid, segmental fixation, thereby promoting fusion, while utilizing the same type of bone anchors 50 and instruments.

[0066] The modular system 12 provides a number of advantages. For example, initially, an implanted system may include only functionally dynamic, flexible couplers 20 connected to vertebra with bone anchors 50, as described above. However, subsequently, due to progression in disease, unabated pain, other symptoms, or other changes in a patient's condition, it may be desirable to fuse one or more previously-treated levels. Therefore, in subsequent surgeries, a surgeon can simply replace a previously-implanted flexible coupler with a rigid coupler 101, while likely using the same bone anchors.

[0067] As noted previously, the units and systems of the present disclosure can be implanted using a minimally-invasive, muscle-sparing approach. Such approaches can include percutaneous methods or a series of small incisions that minimize tissue damage.

[0068] FIGS. 13-19 illustrate exemplary embodiments of insertion instruments that may be provided separately or as a set along with the system. In one exemplary method of the present system, a series of K-wires 200 are inserted into the pedicles of the patient's spine. The K-wires 200 may be inserted through a series of small incisions in the patient's back. Further, as shown in FIG. 13, a wire template 202 may be provided to assist the surgeon in placement of the incisions and K-wires 200. The wire template 202 may include predetermined openings 204 that align with the pedicles of the patient's spine, as illustrated. The openings 204 may be bilaterally located in line with both pedicles of vertebrae to be treated. The template may be provided in various sizes to accommodate patients having variations in pedicle spacing.

[0069] After insertion of the K-wires 200, the cannulated bone anchors 50 may be passed over the K-wires 200, and using a series of extension rods 220a, 220b, 220c, shown in FIG. 14A, the bone anchors can be implanted within selected vertebra. As shown in FIG. 14B, the extension rods can attach to the head portions 54 of the bone anchors 50 to allow manipulation of the anchors 50. In addition, a dilatation sleeve (not shown) can be provided, and the extension rods can be passed through the dilation sleeve to access the implantation site. After or during implantation of the bone anchors 50, the

extension rods 220 can be used to manipulate the anchors 50 and the attached vertebrae to ascertain the full range of motion in a static condition and with an applied load. Such information may be useful to the surgeon to predict the possible range of corrective motion desirable for that spine segment.

[0070] A caliper 240, as illustrated in FIG. 15, may also be provided with the instrument set. The caliper 240 can comprise a pair of pivoting arms 242, 244, each arm extending to a finger engaging opening 246, 248, respectively, and terminating at an opposite end into a gripping end 250, 252, respectively. The pivoting arms 242, 244 can be connected via a leaf spring 254. As shown, the ends of the arms 242, 244 are configured to provide a reading or measurement of the distance between a pair of adjacent bone anchors 50 using the indicia markings 258 on a backboard 256. The gripping ends 250, 252 can be configured to hold a portion of the ball bearing 60 of each bone anchor 50. This enables the caliper 240 to function even when the bone anchors 50 are situated in a nonparallel or unique angle relative to one another.

[0071] FIG. 16 illustrates various rod extensions 260 that are configured to connect to other components of the anchor , such as the ball bearing 60, washer 70, or nut 80. Each of these rod extensions 260 enables minimally-invasive or percutaneous manipulation of the respective component.

[0072] Once the bone anchors 50 are in place and the distance between a pair of adjacent bone anchors 50 has been determined, a surgeon may then select a suitably-sized functionally dynamic, flexible coupler 20 or a rigid, fusion-promoting coupler 101 for placement between the anchors 50. A coupler length adjuster 270, similar to the one shown in FIG. 17, may be provided to ensure that the coupler length is correct prior to insertion. As illustrated, the length adjuster 270 may include a body 272 having a pair of grips 271, between which a coupler 20, 101 can be held. The pair of grips 271 form the insertion area 274 for the coupler. Within the body 272 is a spring-loaded mechanism that exerts biased force against one of the grips 271. The spring-loaded mechanism may be controlled by turning a knob 280, thereby twisting the coupler 20,101, and consequently adjusting its length. The body 272 may further include a window 278 within which there appear indicia 276 indicating the length of the coupler.

Although a flexible coupler 20 is illustrated, it is understood that the length adjuster 270 is also applicable for use with a rigid coupler 101.

[0073] The appropriately-sized coupler 20, 101 is then slid down the K-wires 200 and onto the ball bearings 60 of the bone anchors 50. Subsequently, nuts 80 may be used to secure the coupler 20, 101 in place. In some embodiments, the nuts 80 may have features that prevent over- or under tightening. For example, FIG. 18A illustrates an exemplary embodiment of a suitable nut 180 having a break-away portion 182, connecting an anchor-engaging lower portion 186 to an upper portion 184. The break-away portion 182, having a thinner wall or area of lower yield-strength material, is configured to break when a sufficient torque is applied (i.e., when the nut 180 has been sufficiently tightened).

[0074] The nut 180 can be inserted through the minimally-invasive approach used to implant the bone anchors 50 and couplers 20, 101. For example, FIG. 19 shows an exemplary insertion tool 290 useful for insertion of the nut 180. The insertion tool 290 comprises an elongate body 292 extending from a handle portion 294 to a nut coupling end 296 at an opposite end. The coupling end 296 may be configured to securely attach to the nut at the upper portion 184, as shown in FIG. 18B, and the elongate body 292, with a nut coupled thereto, can be inserted into a previously defined access site to secure the nut 180 to a bone anchor 50. With sufficient tightening, the nut 180 will break at break-away portion 182, leaving the lower portion 186 on a bone anchor and allowing the upper portion 184 to be withdrawn.

[0075] The surgeon may elect to repeat this process at an adjacent level until all the affected levels of the patient's spine have been treated. The entire process may be done percutaneously and/or with minimal disruption to the surrounding tissue.

[0076] Other embodiments of the invention will be apparent to those skilled in the art from consideration of the specification and practice of the disclosure provided herein. It is intended that the specification and examples be

considered as exemplary only, with a true scope and spirit of the disclosure being indicated by the following claims.

CLAIMS

1. A spinal stabilization unit, comprising:

a flexible coupler having a body portion, a pair of arms,, the arms being located at opposed ends of the coupler, and a range-of-motion limiting mechanism configured to control an amount of bending, an amount of compression, and an amount of extension of the coupler; and

an anchoring system including a plurality of bone anchors configured to cooperate with the arms of the flexible coupler to attach the coupler to bone.

2. The unit of claim 1, wherein at least one of the arms is connected to the body of the flexible coupler at a threaded connection.

3. The unit of claim 1, wherein the body is flexible.

4. The unit of claim 1, wherein the body is extendable and compressible along a longitudinal axis of the body.

5. The unit of claim 1, wherein the body is bendable relative to a long axis of the body.

6. The unit of claim 1, wherein the body is cylindrical and includes a plurality of elements forming slots within the body.

7. The unit of claim 1, wherein a length of the flexible coupler is adjustable.

8. The unit of claim 7, wherein one of the arms is attached to the coupler at a threaded connection, and the length of the coupler can be adjusted by rotation of the arm with respect to the threaded connection.

9. The unit of claim 1, wherein range-of-motion limiting mechanism includes:

a sleeve extending internally from a first end of the coupler towards a second end of the coupler and having a narrowed distal opening; and

an elongated body extending internally from the second end of the coupler towards the first end of the coupler and having an enlarged end disposed within the sleeve and dimensioned such that the enlarged end abuts the wall of

the narrowed opening when the coupler is elongated or bent, and the sleeve abuts the second end of the coupler when the coupler is compressed.

10. The unit of claim 1, wherein the range-of-motion limiting device includes

a first element; and

second element cooperatively and movably positioned within the first element, such that movement of the first element relative to the second element in a first direction defines a range of extension of the coupler, and movement of the first element relative to the second element in a second direction, opposite to the first direction, defines a range of compression of the coupler.

11. The unit of claim 1, wherein the bone anchoring system further includes at least one ball bearing and at least one nut.

12. The unit of claim 5, wherein each arm includes a concave portion having an opening, and the anchoring system further includes a semispherical ball bearing for each bone anchor.

13. The unit of claim 12, wherein the flexible coupler is movable relative to the plurality of bone anchors.

14. The unit of claim 1, wherein the flexible coupler is configured to be movable relative to the anchoring system.

15. The unit of claim 1, wherein the anchoring system further includes a plurality of nuts, each nut having a narrowed break-away portion configured to break when sufficient torque is applied to the nut.

16. The unit of claim 1, wherein the range-of-motion limiting mechanism is located within the body.

17. A modular spinal stabilization system, comprising:

a flexible coupler including a pair of arms, the arms being located at opposed ends of the flexible coupler, and a range-of-motion limiting mechanism configured to control an amount of bending, an amount of compression, and an amount of extension of the flexible coupler;

a rigid coupler including a pair of arms, the arms being located at opposed ends of the rigid coupler; and

a fixation system including a plurality of bone anchors configured to cooperate with the arms of the flexible and rigid couplers to attach the couplers to bone.

18. The system of claim 17, wherein the flexible coupler includes a cylindrical body portion including one or more slots in the wall of the cylindrical body.

19. The system of claim 17, wherein the flexible coupler includes a flexible body.

20. The system of claim 19, wherein the body is extendable and compressible along a longitudinal axis of the body.

21. The system of claim 19, wherein the body is bendable relative to a longitudinal axis of the body.

22. The system of claim 17, wherein at least one of the flexible coupler arms is attached to the flexible coupler at a threaded connection.

23. The system of claim 17, wherein a length of the flexible coupler is adjustable.

24. The system of claim 23, wherein an arm of the flexible coupler is attached to the flexible coupler at a threaded connection, and the length of the flexible coupler is adjustable through rotation of the arm with respect to the flexible coupler.

25. The system of claim 17, wherein the range-of-motion limiting mechanism is positioned within a flexible body of the flexible coupler.

26. The system of claim 17, wherein the range-of-motion limiting device includes

a first element, and

second element cooperatively and movably positioned within the first element, such that movement of the first element relative to the second element in a first direction defines a range of extension of the flexible coupler, and

movement of the first element relative to the second element in a second direction, opposite to the first direction, defines a range of compression of the flexible coupler.

27. The system of claim 17, wherein the fixation system further includes a plurality of ball bearings and a plurality of nuts

28. The system of claim 27, wherein the flexible coupler is configured to be movable relative to the plurality of bone anchors.

29. The system of claim 17, wherein the flexible coupler is configured to be movable relative to the fixation system.

30. The system of claim 17, wherein the range-of-motion limiting mechanism includes:

a sleeve extending internally from a first end of the flexible coupler towards a second end of the flexible coupler and having a narrowed distal opening; and

an elongated body extending internally from the second end of the flexible coupler towards the first end of the flexible coupler and having an enlarged end disposed within the sleeve and dimensioned such that the enlarged end abuts the wall of the narrowed opening when the flexible coupler is elongated or bent, and the sleeve abuts the second end of the flexible coupler when the flexible coupler is compressed.

31. The system of claim 17, wherein the rigid coupler is adjustable in length.

32. The system of claim 31, wherein an arm of the rigid coupler is attached to the rigid coupler at a threaded connection, and the length of the rigid coupler is adjustable through rotation of the arm with respect to the rigid coupler.

33. The system of claim 17, wherein the fixation system further includes a plurality of semi-spherical ball bearings, and wherein the arms of the flexible coupler and the arms of the rigid coupler each include a concave portion having an opening configured to engage a semispherical ball bearing.

34. The system of claim 17, wherein the fixation system further includes a plurality of nuts for securing the rigid coupler or flexible coupler to a respective

bone anchor, each nut having a narrowed break-away portion configured to break when sufficient torque is applied to the nut.

35. The system of claim 17, further comprising a second flexible coupler.

36. The system of claim 17, further comprising a second rigid coupler.

37. The system of claim 17, further comprising a second flexible coupler and a second rigid coupler.

38. A method of treating a spine, comprising:

attaching a first bone anchor to a first vertebra;

attaching a second bone anchor to a second vertebra adjacent the first vertebrae;

connecting first and second arms of a flexible coupler to the first and second bone anchors, respectively, the flexible coupler having a body portion, a pair of arms, and a range-of-motion limiting mechanism configured to control an amount of bending, an amount of compression, and an amount of extension of the coupler.

39. The method of claim 38, further including adjusting a length of the flexible coupler prior to attaching the flexible coupler to the bone anchors.

40. The method of claim 39, wherein adjusting the length of the flexible coupler includes rotating one of the flexible coupler arms relative to the body portion to adjust an amount that the arm extends from the body portion. .

41. The method of claim 38, further including attaching a third bone anchor to a third vertebra; and

attaching a rigid coupler to the third bone anchor and one of the first bone anchor and second bone anchor, wherein the rigid coupler is configured to prevent movement between two of the vertebrae.

42. The method of claim 41, further including adjusting a length of the rigid coupler prior to attaching the rigid coupler to the bone anchors.

43. The method of claim 42, wherein adjusting the length of the rigid coupler includes rotating an arm of the rigid coupler to adjust an amount that the rigid coupler arm extends from the rigid coupler..

44. The method of claim 38, further including disconnecting the flexible coupler from the first and second bone anchors attached to the first and second vertebrae; and

replacing the flexible coupler with a rigid coupler.

45. The method of claim 44, wherein replacing the flexible coupler includes connecting the rigid coupler to the first bone anchor and second bone anchors attached to the first and second vertebrae.

46. The method of claim 38, wherein the range-of-motion limiting mechanism includes an internal range-of-motion limiting mechanism disposed within the coupler body configured to limit motion of the body in bending, compression, and expansion.

47. The method of claim 46, further comprising controlling an amount of expansion and an amount of bending of the flexible coupler, wherein controlling expansion and bending includes providing a sleeve extending internally from a first end of the flexible coupler towards a second end of the flexible coupler and having a narrowed distal opening and positioning a elongated body having an enlarged distal end and extending from the second flexible coupler such that the enlarged end abuts the wall of the narrowed opening when the flexible coupler is elongated or bent.

48. The method of claim 46, further comprising controlling an amount of compression of the flexible body, wherein controlling compression includes providing a sleeve extending internally from a first end of the flexible coupler towards a second end of the flexible coupler and having a narrowed distal opening and positioning a elongated body having an enlarged distal end and extending from the second flexible coupler such that the sleeve abuts the second end of the flexible coupler when the flexible coupler is compressed.

49. A method of implanting a spinal stabilization unit, comprising:

producing at least one incision over at least two adjacent vertebrae to be treated;

positioning at least two wires such that each wire separately contacts a pedicle of one the at least two vertebrae;

securing a screw to first and second adjacent vertebrae to be treated; and

attaching a flexible coupler to the two screws of the first and second adjacent vertebrae.

50. The method of claim 49, further including measuring the distance between the screws inserted into the two adjacent vertebrae.

51. The method of claim 50, further adjusting a length of the flexible coupler to fit between two of the screws.

52. The method of claim 51, wherein adjusting the length of the flexible coupler includes rotating an arm of flexible coupler to adjust an amount the arm extends from a body portion of the flexible coupler.

53. The method of claim 49, further comprising producing at least one incision over a third vertebrae to be treated;

positioning at least one wire such that the wire separately contacts a pedicle of the third vertebrae;

securing a screw to the third vertebrae to be treated; and

attaching a rigid coupler to the third screw and to one of the first and second screws.

54. The method of claim 53, further including measuring the distance between the third screw and the one of the first and second screws.

55. The method of claim 54, further adjusting a length of the rigid coupler to fit between the third screw and the one of the first and second screws.

56. The method of claim 55, wherein adjusting the length of the rigid coupler includes rotating an arm of the rigid coupler to adjust an amount the arm extends from the rigid coupler.

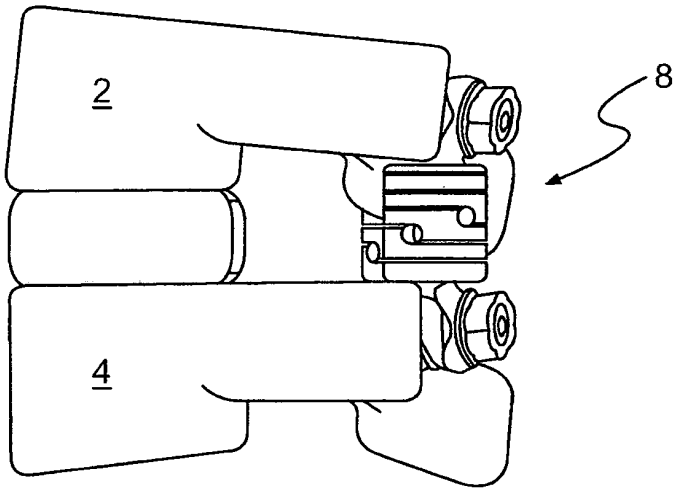


FIG. 1

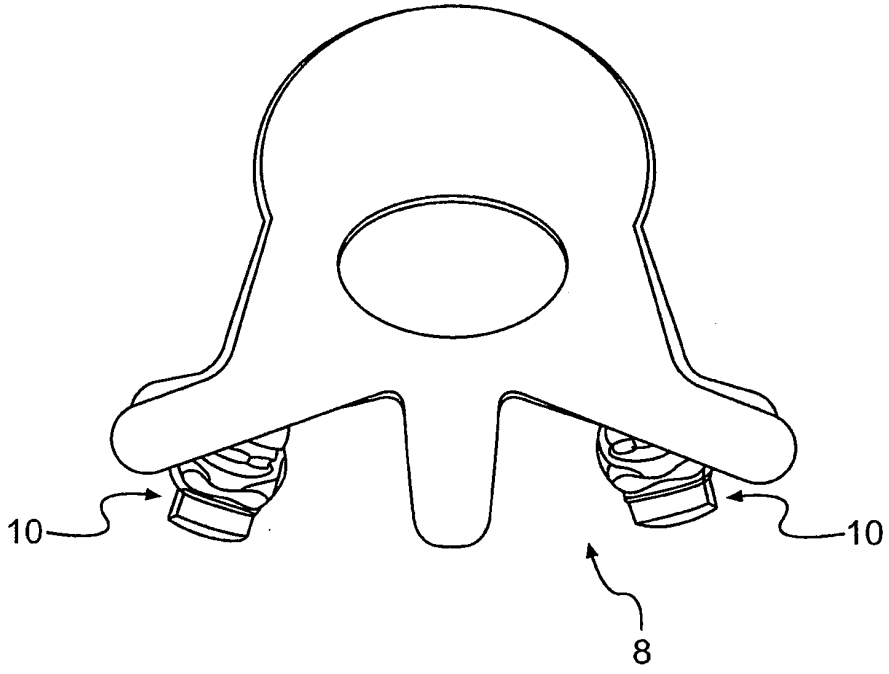


FIG. 2

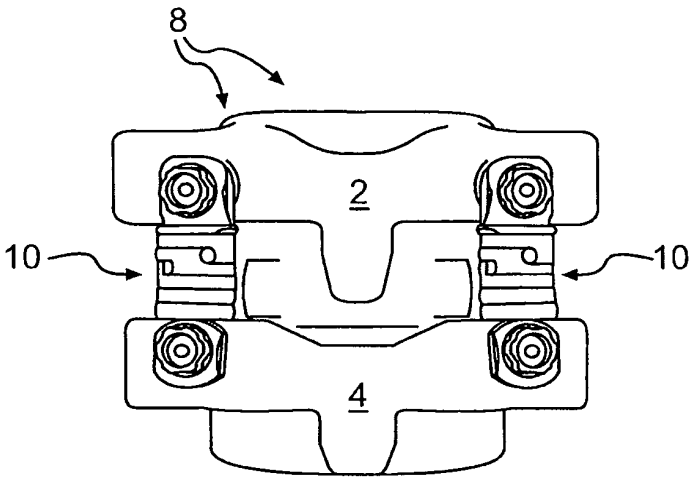


FIG. 3

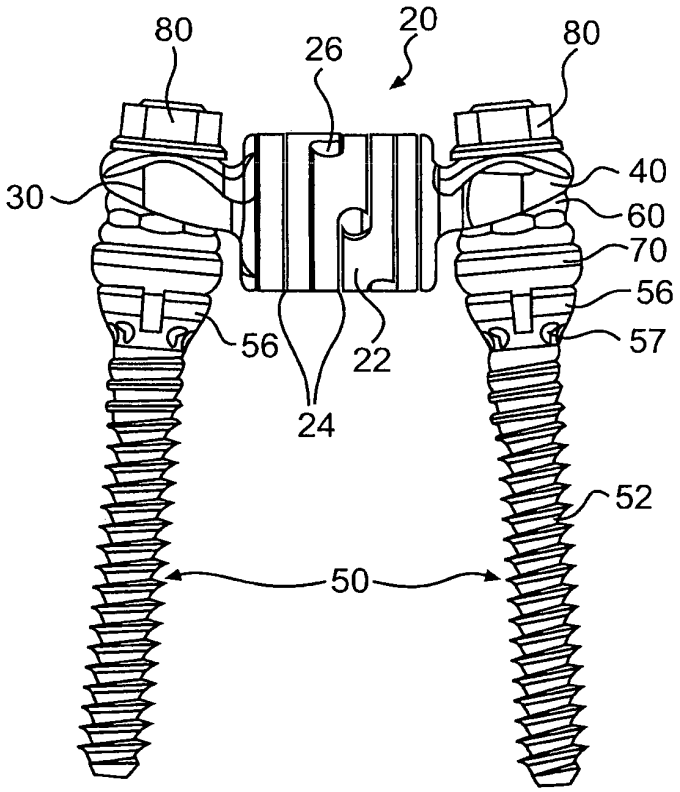


FIG. 4A

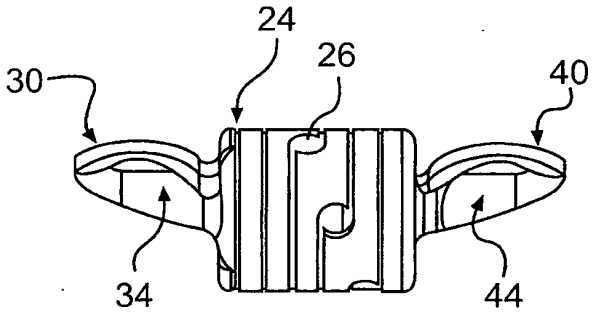


FIG. 4B

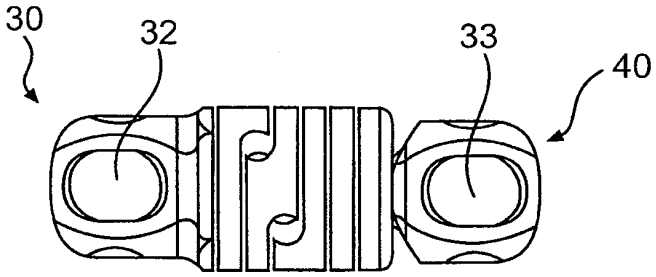


FIG. 4C

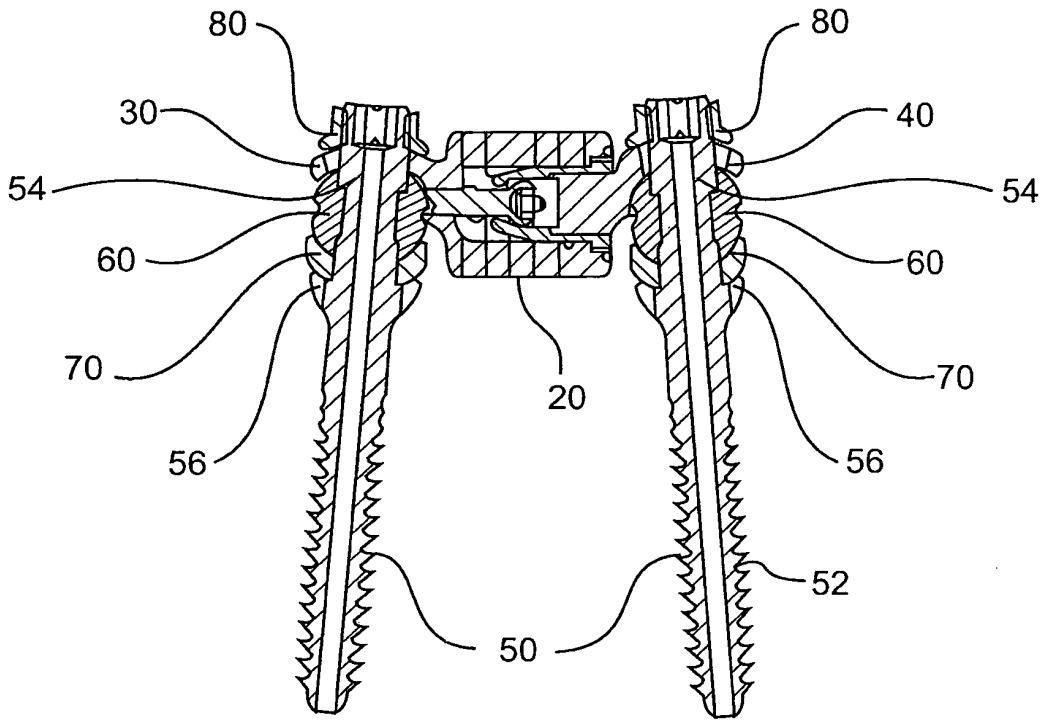

80
80
30
40
54
54
60
60
70
70
20
56
56
52
50

FIG. 5A

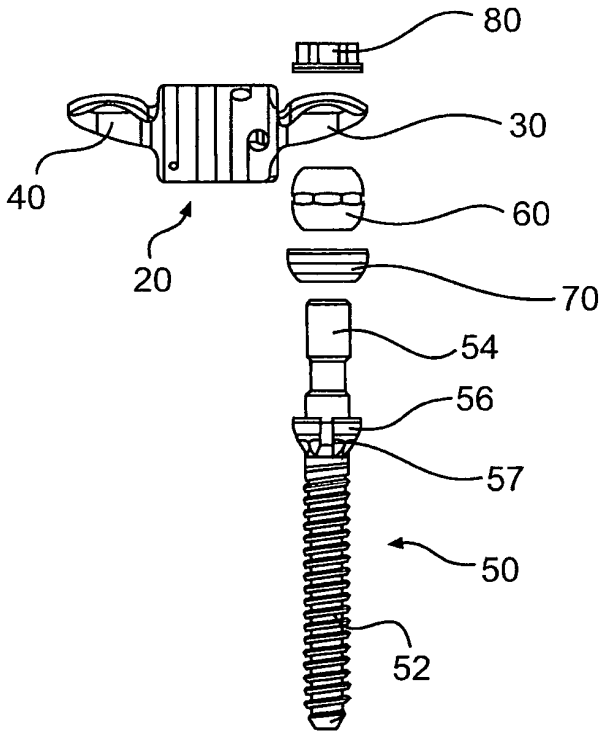

80
30
40
60
20
70
54
56
57
50
52

FIG. 5B

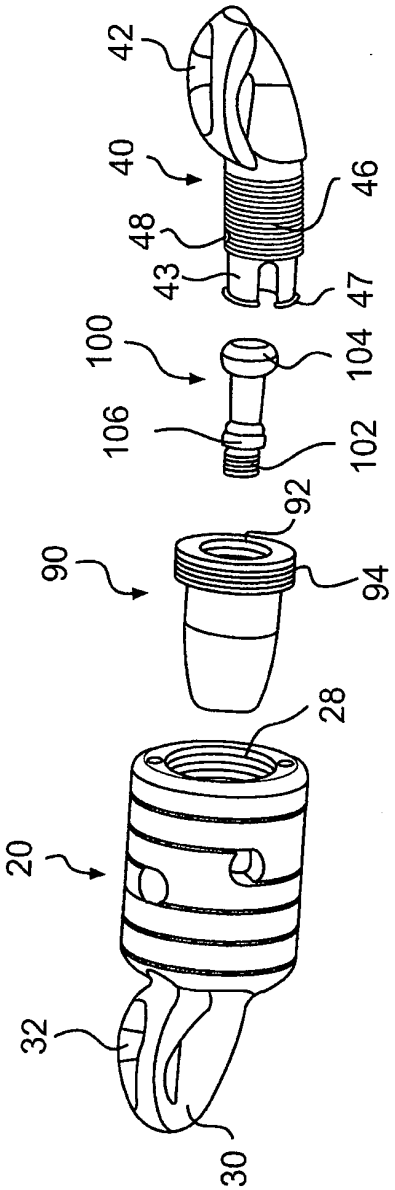


FIG. 6

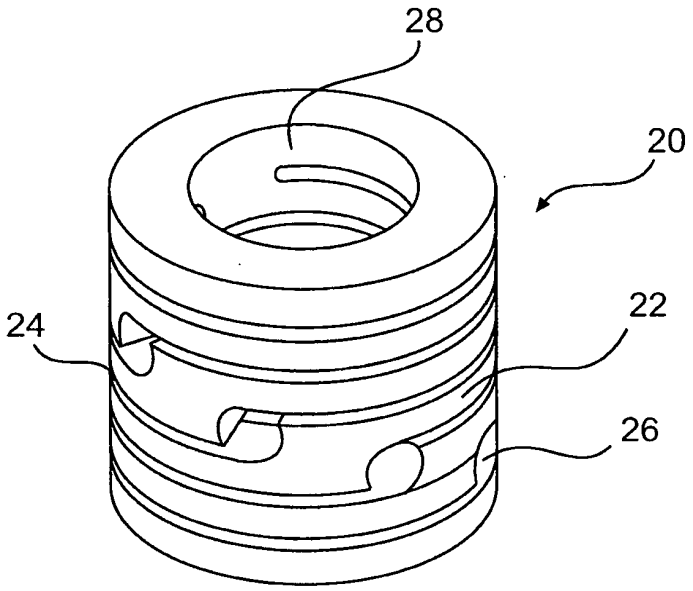


FIG. 7A

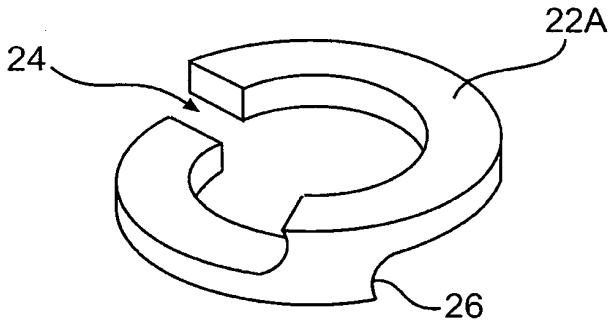


FIG. 7B

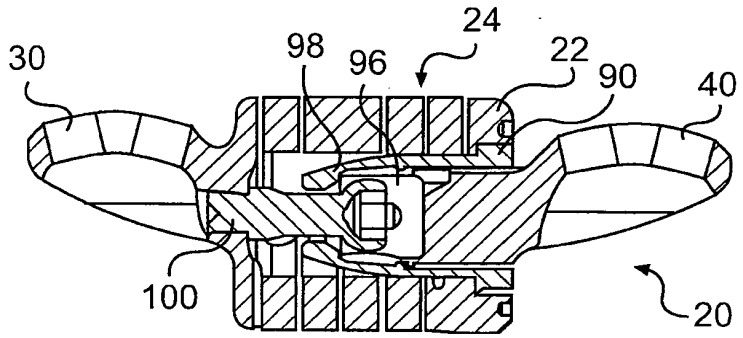


FIG. 8A

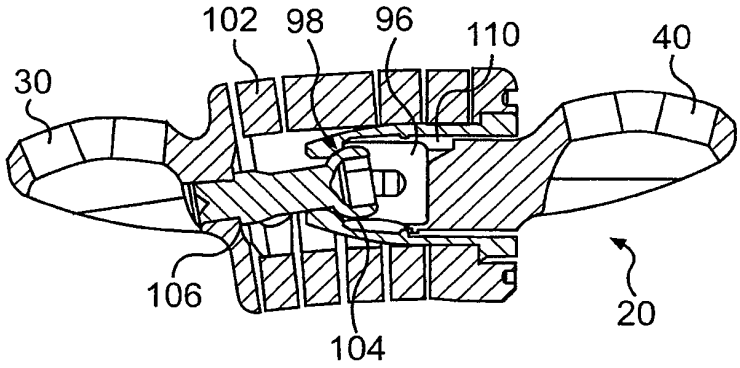


FIG. 8B

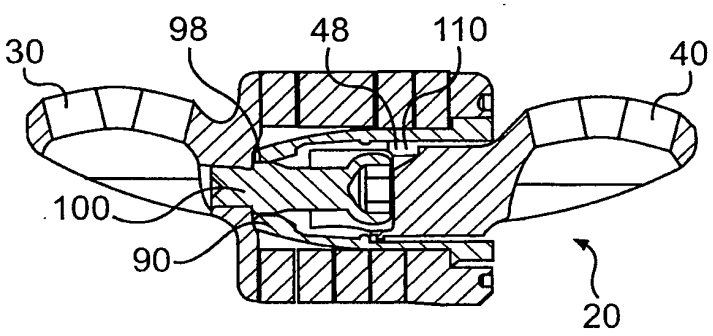


FIG. 8C

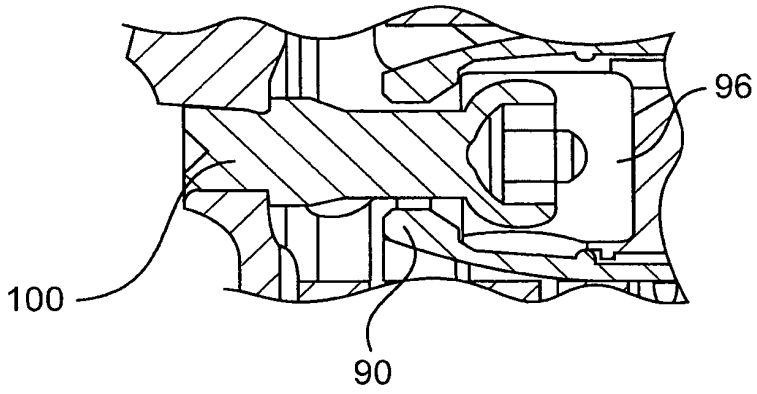


FIG. 8D

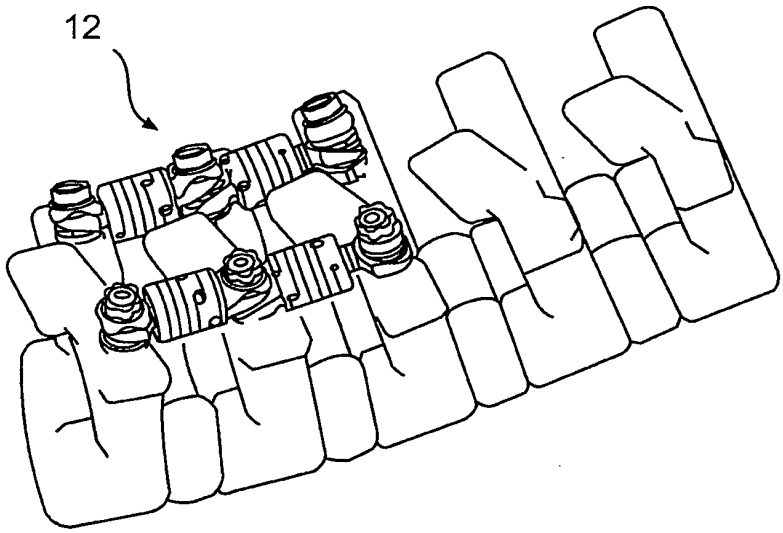


FIG. 9A

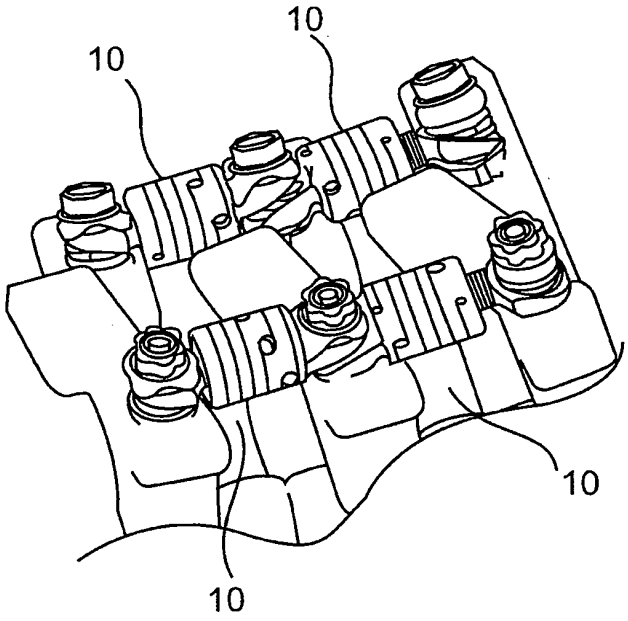


FIG. 9B

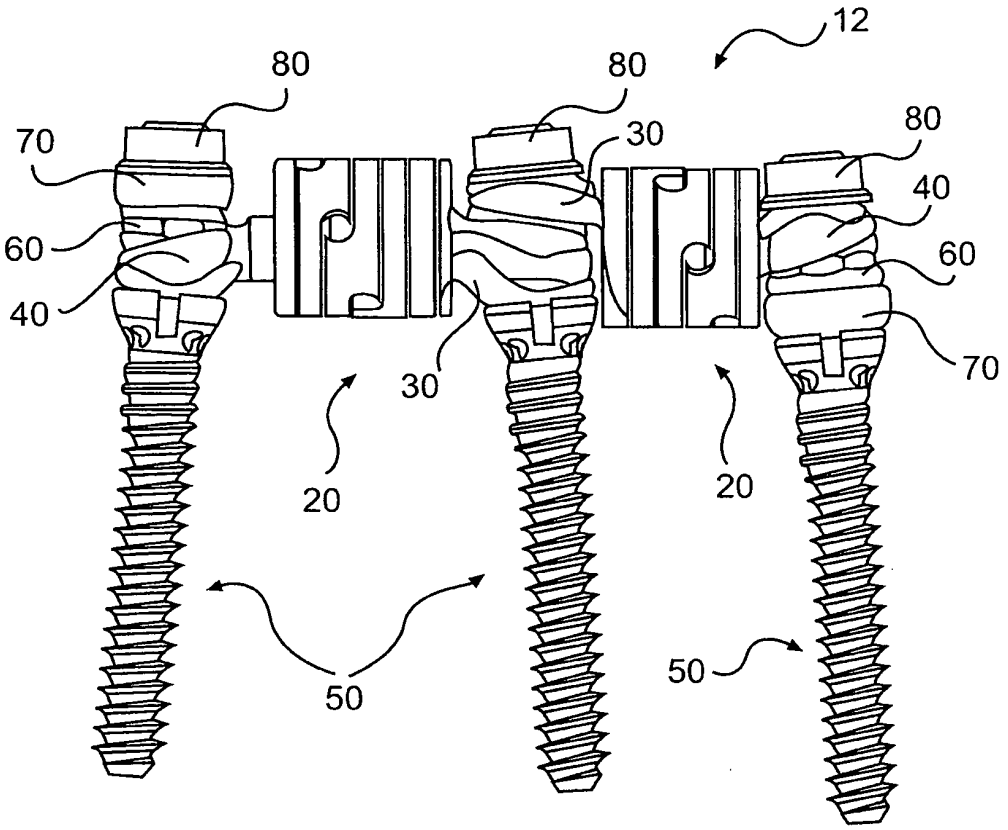


FIG. 10

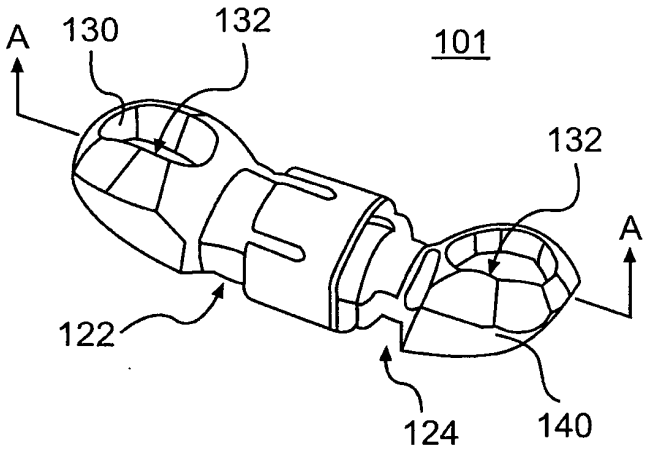


FIG. 11A

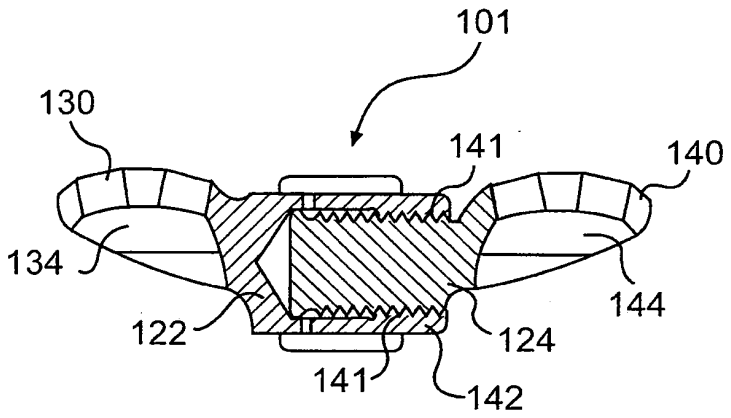


FIG. 11B

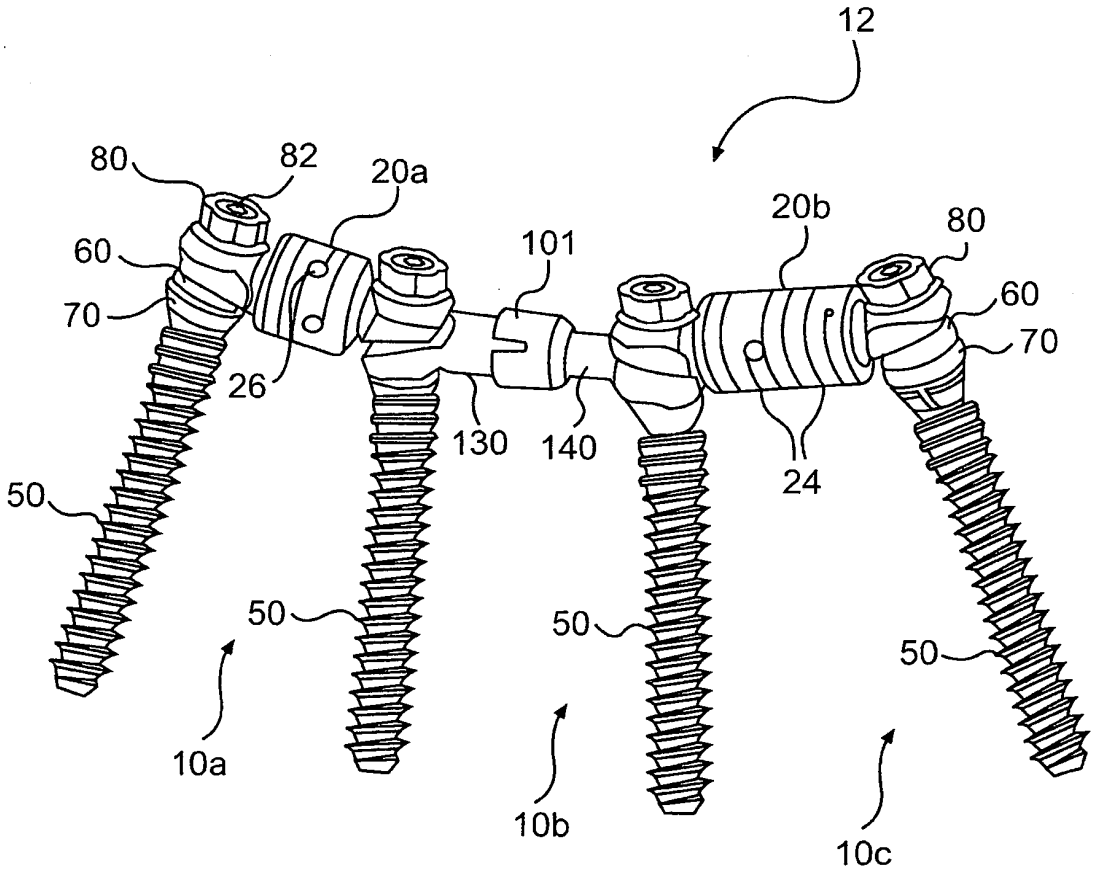


FIG. 12

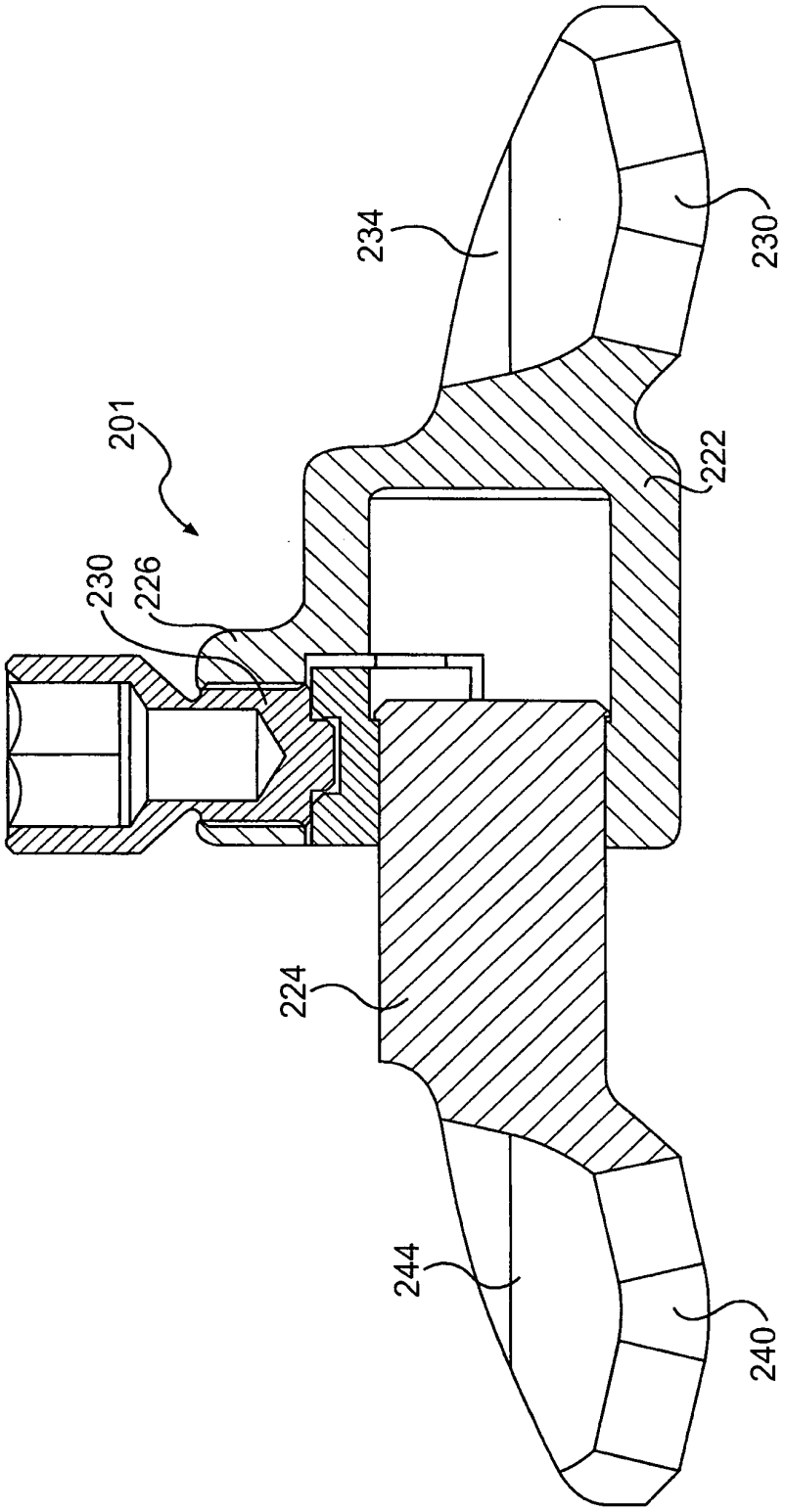


FIG. 11C

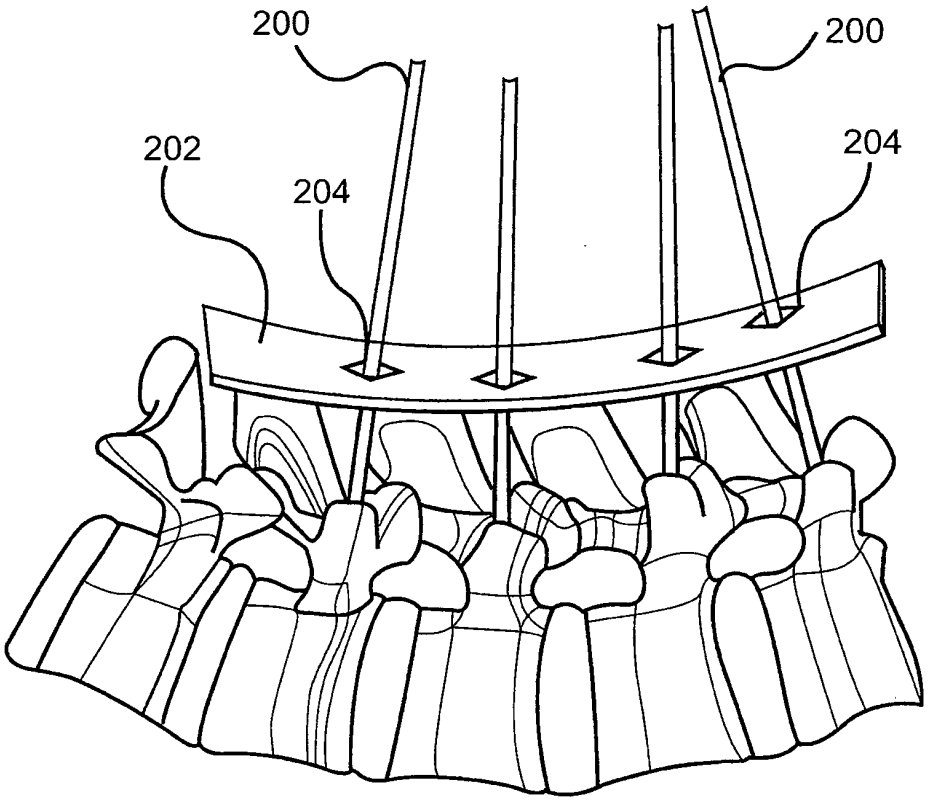


FIG. 13

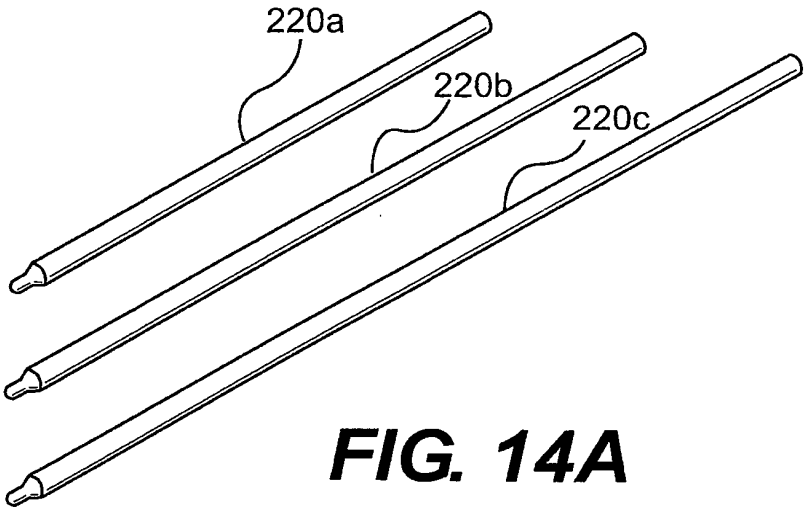


FIG. 14A

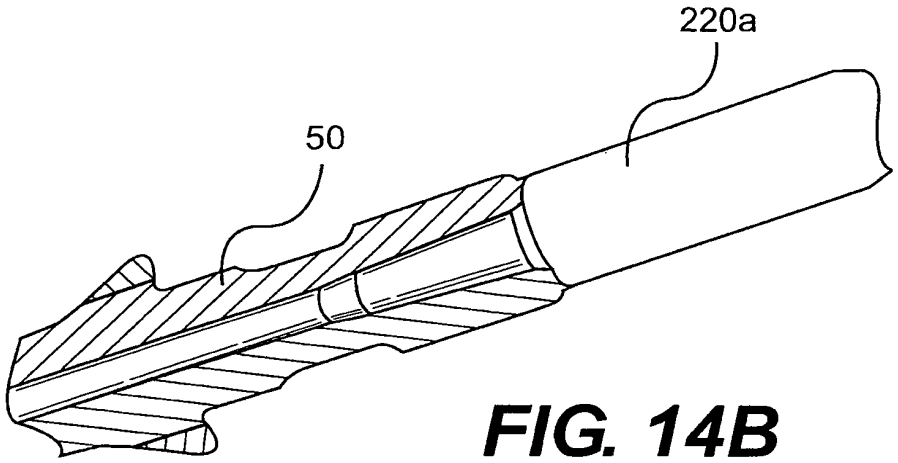


FIG. 14B

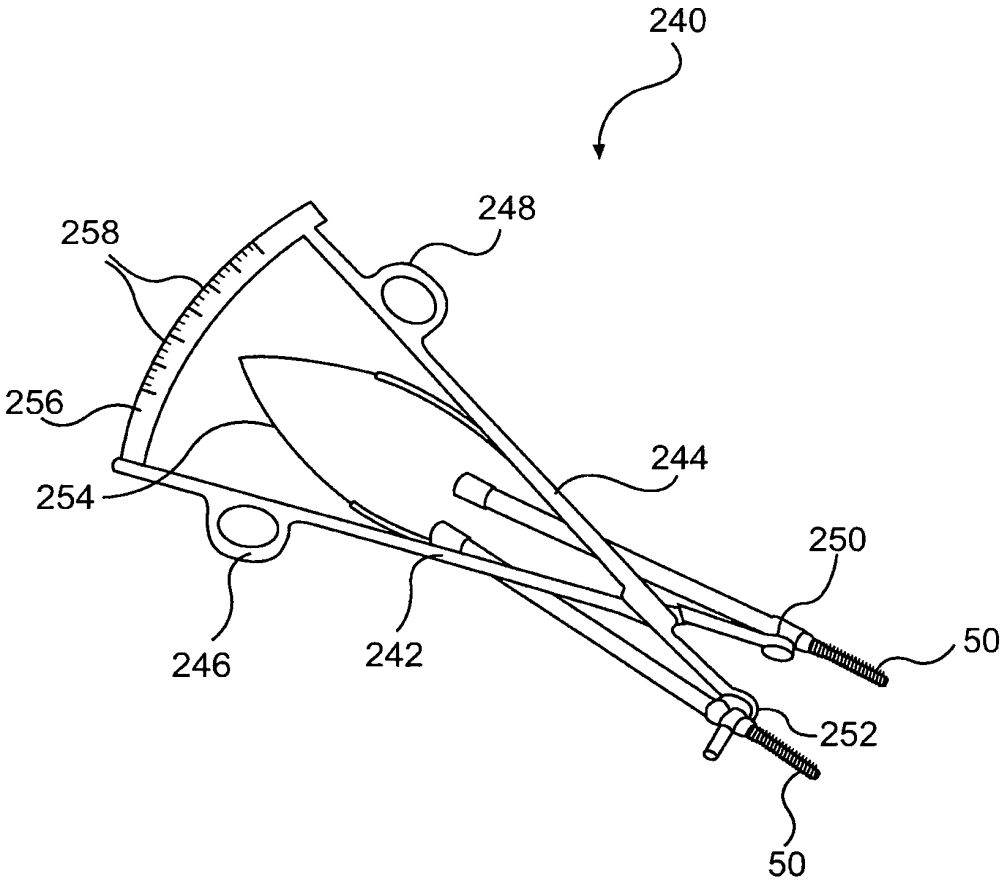


FIG. 15

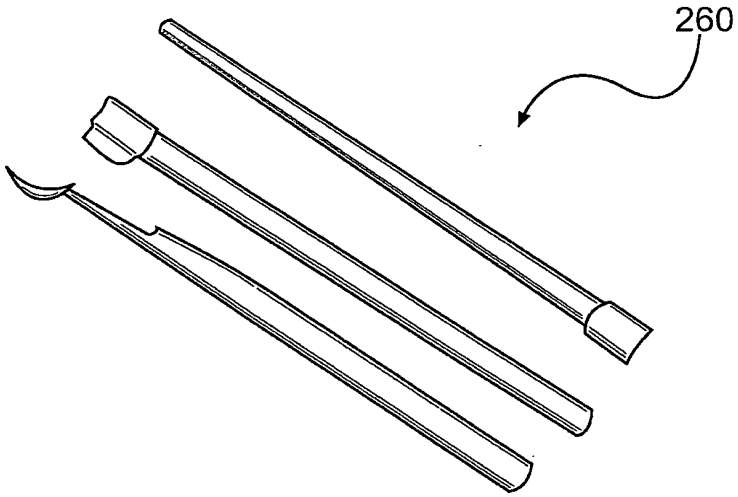


FIG. 16

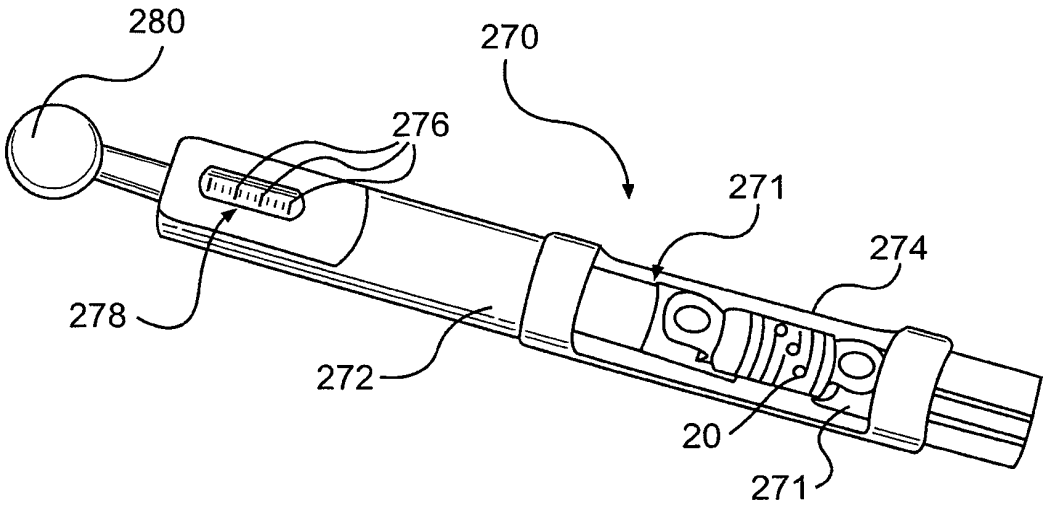


FIG. 17

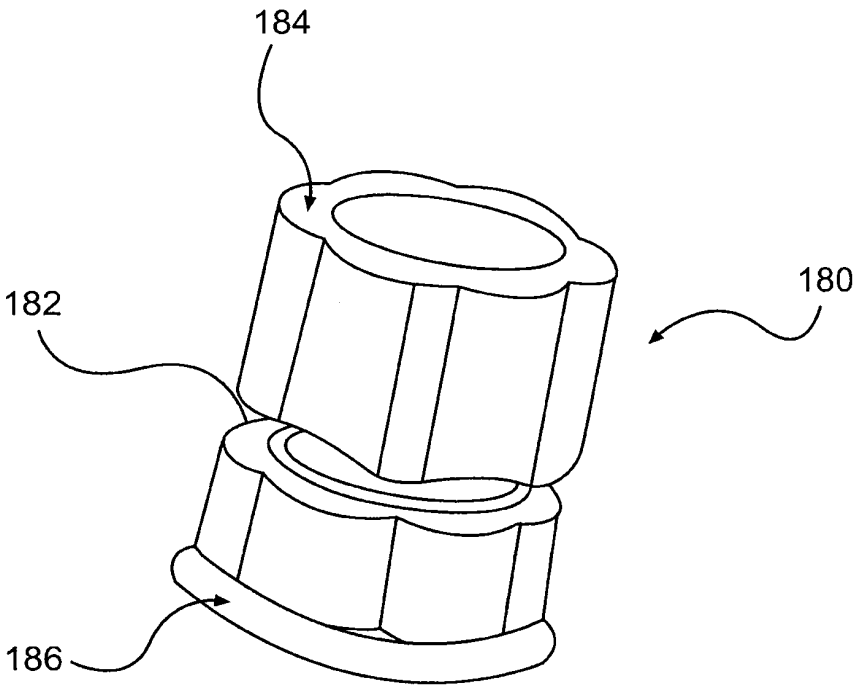


FIG. 18A

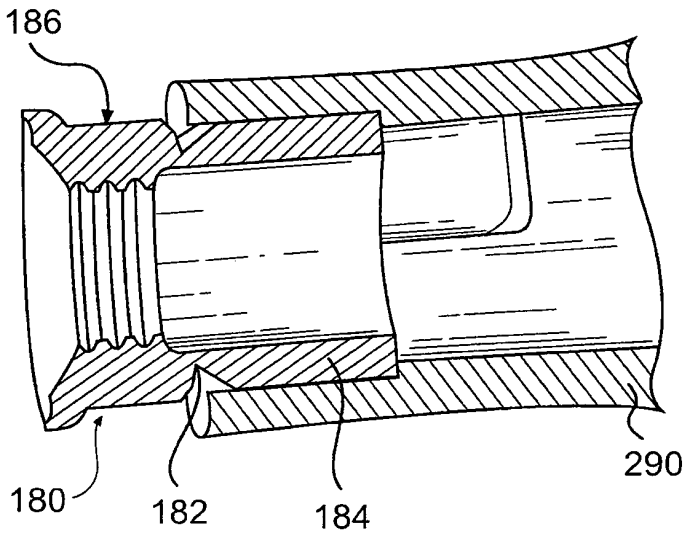


FIG. 18B

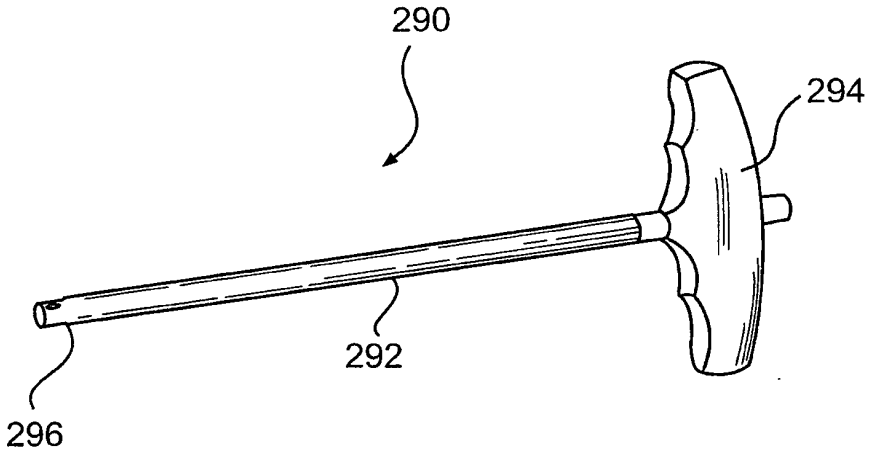


FIG. 19

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2007/086800

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/70
ADD. A61B17/88

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	EP 0 919 199 A (SCIENT X SARL [FR]) 2 June 1999 (1999-06-02) figures 1,3,4 paragraphs [0024], [0026], [0030] - [0032]	1,3-10
Y		2
X	US 2006/189983 A1 (FALLIN T W [US] ET AL FALLIN T WADE [US] ET AL) 24 August 2006 (2006-08-24) figures 2-4,8-10 paragraphs [0032], [0033], [0038], [0040] paragraphs [0084], [0087] paragraphs [0077], [0080]	1,3-6, 9-14

-/--

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

[X] 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
5 May 2008	20/05/2008

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	Fourcade, Olivier

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2007/086800

Box No. 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. [X] Claims Nos.: 38-56
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 No. 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 allsearchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search reportcovers 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 and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2007/086800

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2006/045091 A (UNIV THE BOARD OF TRUSTEES OF [US]; KIM DANIEL H [US] UNIV LELAND STAN) 27 April 2006 (2006-04-27) paragraph [0104]; figures 23A,23B	1,3-6,9, 10
X	EP 1 072 228 A (DEV S E D SOC ET [FR]; MULTI POLES CONSEILS [FR]) 31 January 2001 (2001-01-31) figures 1,6,7 paragraphs [0023], [0042], [0054] - [0057] claims 1,11	1,4,7,8, 10-14
Y		17-24, 26-33,35
Y	US 2006/025770 A1 (SCHLAPFER FRIDOLIN [CH] ET AL) 2 February 2006 (2006-02-02) paragraph [0038]; figures 1,5	17,23, 24, 26-33,35
Y	WO 03/047442 A (MATHYS MEDIZINALTECHNIK AG [CH]; STUDER ARMIN [CH]; FRIGG ROBERT [CH]) 12 June 2003 (2003-06-12) claim 1; figures 1-3	2,18-22

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2007/086800

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 0919199 A	02-06-1999	DE 69828745 D1	03-03-2005
		DE 69828745 T2	29-12-2005
		ES 2238089 T3	16-08-2005
		FR 2771280 A1	28-05-1999
		US 6241730 B1	05-06-2001
US 2006189983 A1	24-08-2006	US 2006189984 A1	24-08-2006
		WO 2006091572 A2	31-08-2006
		WO 2006101655 A1	28-09-2006
WO 2006045091 A	27-04-2006	AU 2005295209 A1	27-04-2006
		CA 2582118 A1	27-04-2006
		EP 1802240 A2	04-07-2007
		US 2006084984 A1	20-04-2006
		US 2006084987 A1	20-04-2006
		US 2006084982 A1	20-04-2006
EP 1072228 A	31-01-2001	FR 2796828 A1	02-02-2001
		US 6626904 B1	30-09-2003
US 2006025770 A1	02-02-2006	AU 2002368445 A1	30-06-2004
		BR 0215930 A	09-08-2005
		CA 2508661 A1	24-06-2004
		WO 2004052218 A1	24-06-2004
		EP 1567073 A1	31-08-2005
		JP 2006508748 T	16-03-2006
WO 03047442 A	12-06-2003	AT 373994 T	15-10-2007
		AT 378011 T	15-11-2007
		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 03047441 A1	12-06-2003
		CN 1578644 A	09-02-2005
		CN 1599580 A	23-03-2005
		CZ 20040691 A3	16-02-2005
		EP 1450707 A1	01-09-2004
		EP 1450708 A1	01-09-2004
		EP 1880684 A2	23-01-2008
		ES 2293963 T3	01-04-2008
		ES 2296901 T3	01-05-2008
		HU 0402255 A2	30-05-2005
		HU 0402275 A2	30-05-2005
		JP 2005511974 T	28-04-2005
		JP 2005511133 T	28-04-2005
		MX PA04005398 A	23-03-2005
		NZ 533300 A	25-02-2005
		NZ 533301 A	24-03-2005
		US 2005056979 A1	17-03-2005
		US 2005065514 A1	24-03-2005
		US 2008033435 A1	07-02-2008

[19] 中华人民共和国国家知识产权局

[51] Int. Cl.
A61B 17/70 (2006.01)
A61B 17/88 (2006.01)

[12] 发明专利申请公布说明书

[21] 申请号 200780045505.8

[43] 公开日 2009 年 11 月 4 日

[11] 公开号 CN 101573081A

[22] 申请日 2007.12.7
[21] 申请号 200780045505.8
[30] 优先权
[32] 2006.12.10 [33] US [31] 60/869,342
[32] 2007. 4.27 [33] US [31] 60/914,360
[86] 国际申请 PCT/US2007/086800 2007.12.7
[87] 国际公布 WO2008/073830 英 2008.6.19
[85] 进入国家阶段日期 2009.6.9
[71] 申请人 帕拉迪格脊骨有限责任公司
地址 美国纽约州
[72] 发明人 F·T·特劳特魏因
B·霍尔特坎普 M·萨尔韦尔莫泽
R·贝尔塔尼奥利 G·L·洛韦里
G·H·艾森

[74] 专利代理机构 北京市中咨律师事务所
代理人 吴 鹏 马江立

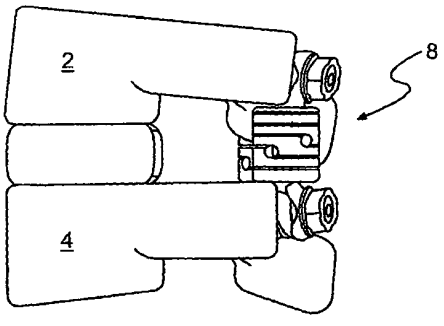
权利要求书 7 页 说明书 12 页 附图 17 页

[54] 发明名称

后路机能动态稳定系统

[57] 摘要

提供了一种用于治疗脊柱失稳的机能动态稳定单元(10)和系统。 各单元和共同的系统构造成控制患病的不稳定椎骨区域的屈曲、伸展和平移，从而通过恢复正常功能来稳定椎骨节段。 这通过提供一种允许侧向弯曲、轴向压缩、转动、前路节段高度调节和后路节段高度调节的单元和系统来实现。该单元和系统提供足够的节段刚度，同时还限制或控制运动范围(即，在中性区或活动区内有足够的刚度，同时又限制或防止活动区外部的运动)以便稳定椎骨节段。 在使用中，该系统模拟正常椎骨的自然运动。 此外，该系统包括刚性的、促进融合的联接器(20)，该联接器(20)构造成用于相邻的水平，或作为机能动态单元的替换物。 该系统的模块性允许随时间进行调节和更简便地进行翻修手术，且构造成用于微创的输送或植入。



1. 一种脊柱稳定单元，包括:

柔性联接器，该柔性联接器具有体部、一对臂、和运动范围限制机构，所述臂设置在所述联接器的相对端，所述运动范围限制机构构造成控制所述联接器的弯曲量、压缩量和伸展量；和

锚固系统，该锚固系统包括多个骨锚固件，该骨锚固件构造成与所述柔性联接器的臂协作以将该联接器附装到骨上。

2. 根据权利要求 1 所述的单元，其特征在于，所述臂中的至少一个在螺纹连接部连接到所述柔性联接器的体部。

3. 根据权利要求 1 所述的单元，其特征在于，所述体部是柔性的。

4. 根据权利要求 1 所述的单元，其特征在于，所述体部沿所述体部的纵向轴线可伸展和可压缩。

5. 根据权利要求 1 所述的单元，其特征在于，所述体部相对于所述体部的长轴线可弯曲。

6. 根据权利要求 1 所述的单元，其特征在于，所述体部是筒形的，且包括在所述体部中形成槽口的多个元件。

7. 根据权利要求 1 所述的单元，其特征在于，所述柔性联接器的长度是可调节的。

8. 根据权利要求 7 所述的单元，其特征在于，所述臂中的一个在螺纹连接部附装到所述联接器上，所述联接器的长度可通过使所述臂相对于所述螺纹连接部转动而进行调节。

9. 根据权利要求 1 所述的单元，其特征在于，所述运动范围限制机构包括:

套管，该套管在内部从所述联接器的第一端朝所述联接器的第二端延伸，且具有窄缩的末端开口；和

长形体，该长形体在内部从所述联接器的第二端朝所述联接器的第一端延伸，并具有设置在所述套管中的扩大的端部，且尺寸设定为使得当所

述联接器伸长或弯曲时，该扩大的端部靠接在所述窄缩开口的壁上，而当所述联接器被压缩时，所述套管抵靠所述联接器的第二端。

10. 根据权利要求 1 所述的单元，其特征在于，所述运动范围限制装置包括:

第一元件；和

第二元件，该第二元件协作性地和可运动地安设在所述第一元件内，使得所述第一元件相对于所述第二元件在第一方向上的运动限定所述联接器的伸展范围，而所述第一元件相对于所述第二元件在与所述第一方向相反的第二方向上的运动限定所述联接器的压缩范围。

11. 根据权利要求 1 所述的单元，其特征在于，所述骨锚固系统还包括至少一个球支承件和至少一个螺母。

12. 根据权利要求 5 所述的单元，其特征在于，每个所述臂包括凹部，该凹部具有开口，所述锚固系统还包括用于每个骨锚固件的半球形的球支承件。

13. 根据权利要求 12 所述的单元，其特征在于，所述柔性联接器可相对于所述多个骨锚固件运动。

14. 根据权利要求 1 所述的单元，其特征在于，所述柔性联接器构造成可相对于所述锚固系统运动。

15. 根据权利要求 1 所述的单元，其特征在于，所述锚固系统还包括多个螺母，每个螺母具有窄缩的可断部分，该可断部分构造成在有足够大的转矩施加到所述螺母上时断裂。

16. 根据权利要求 1 所述的单元，其特征在于，所述运动范围限制机构设置在所述体部内。

17. 一种模块化的脊柱稳定系统，包括:

柔性联接器，该柔性联接器包括一对臂、和运动范围限制机构，所述臂设置在所述柔性联接器的相对端，所述运动范围限制机构构造成控制所述柔性联接器的弯曲量、压缩量和伸展量;

刚性联接器，该刚性联接器包括一对臂，所述臂设置在所述刚性联接

器的相对端；和

固定系统，该固定系统包括多个骨锚固件，所述骨锚固件构造成与所述柔性和刚性联接器的臂协作以将所述联接器附装在骨上。

18. 根据权利要求 17 述的系统，其特征在于，所述柔性联接器包括筒形体部，该筒形体部在其壁中包括一个或多个槽口。

19. 根据权利要求 17 述的系统，其特征在于，所述柔性联接器包括柔性体部。

20. 根据权利要求 19 所述的系统，其特征在于，所述体部沿所述体部的纵向轴线可伸展和可压缩。

21. 根据权利要求 19 所述的系统，其特征在于，所述体部相对于体部的纵向轴线可弯曲。

22. 根据权利要求 17 所述的系统，其特征在于，所述柔性联接器的臂中的至少一个在螺纹连接部连接到所述柔性联接器。

23. 根据权利要求 17 所述的系统，其特征在于，所述柔性联接器的长度是可调节的。

24. 根据权利要求 23 所述的系统，其特征在于，所述柔性联接器的臂在螺纹连接部附装到所述柔性联接器上，所述柔性联接器的长度可通过使所述臂相对于所述柔性联接器转动而进行调节。

25. 根据权利要求 17 述的系统，其特征在于，所述运动范围限制机构设置在所述柔性联接器的柔性体部内。

26. 根据权利要求 17 所述的系统，其特征在于，所述运动范围限制装置包括:

第一元件；和

第二元件，该第二元件协作性地和可运动地安设在所述第一元件内，使得所述第一元件相对于所述第二元件在第一方向上的运动限定所述柔性联接器的伸展范围，而所述第一元件相对于所述第二元件在与所述第一方向相反的第二方向上的运动限定所述柔性联接器的压缩范围。

27. 根据权利要求 17 所述的系统，其特征在于，所述固定系统还包

括多个球支承件和多个螺母。

28. 根据权利要求 27 所述的系统，其特征在于，所述柔性联接器构造成可相对于所述多个骨锚固件运动。

29. 根据权利要求 17 所述的系统，其特征在于，所述柔性联接器构造成可相对于所述固定系统运动。

30. 根据权利要求 17 所述的系统，其特征在于，所述运动范围限制机构包括:

套管，该套管在内部从所述柔性联接器的第一端朝所述柔性联接器的第二端延伸，且具有窄缩的末端开口；和

长形体，该长形体在内部从所述柔性联接器的第二端朝所述柔性联接器的第一端延伸，并具有设置在所述套管中的扩大的端部，且尺寸设定为使得当所述柔性联接器伸长或弯曲时，该扩大的端部靠接在所述窄缩开口的壁上，而当所述柔性联接器被压缩时，所述套管抵靠所述柔性联接器的第二端。

31. 根据权利要求 17 述的系统，其特征在于，所述刚性联接器的长度可调节。

32. 根据权利要求 31 所述的系统，其特征在于，所述刚性联接器的臂在螺纹连接部附装到所述刚性联接器上，所述刚性联接器的长度可通过使所述臂相对于所述刚性联接器转动而进行调节。

33. 根据权利要求 17 所述的系统，其特征在于，所述固定系统还包括多个半球形的球支承件，所述柔性联接器的臂和所述刚性联接器的臂都包括具有开口的凹部，该凹部构造成与所述半球形的球支承件接合。

34. 根据权利要求 17 所述的系统，其特征在于，所述固定系统还包括多个用于将所述刚性联接器或柔性联接器固定到相应的骨锚固件上的螺母，每个螺母具有窄缩的可断部分，该可断部分构造成在有足够大的转矩施加到所述螺母上时断裂。

35. 根据权利要求 17 所述的系统，其特征在于，还包括第二柔性联接器。

36. 根据权利要求 17 所述的系统，其特征在于，还包括第二刚性联接器。

37. 根据权利要求 17 所述的系统，其特征在于，还包括第二柔性联接器和第二刚性联接器。

38. 一种治疗脊柱的方法，包括:

将第一骨锚固件附装于第一椎骨;

将第二骨锚固件附装于与所述第一椎骨邻近的第二椎骨;

将柔性联接器的第一和第二臂分别连接到所述第一和第二骨锚固件，所述柔性联接器具有体部、一对臂、和运动范围限制机构，该运动范围限制机构构造成控制所述联接器的弯曲量、压缩量和伸展量。

39. 根据权利要求 38 所述的方法，其特征在于，还包括在将所述柔性联接器附装到所述骨锚固件之前调节所述柔性联接器的长度。

40. 根据权利要求 39 所述的方法，其特征在于，调节所述柔性联接器的长度包括使所述柔性联接器的臂之一相对于所述体部转动以调节所述臂从所述体部延伸的量。

41. 根据权利要求 38 所述的方法，其特征在于，还包括将第三骨锚固件附装于第三椎骨; 和

将刚性联接器附装到所述第三骨锚固件以及所述第一骨锚固件和所述第二骨锚固件中的一个，其中所述刚性联接器构造成防止两个椎骨之间的运动。

42. 根据权利要求 41 所述的方法，其特征在于，还包括在将所述刚性联接器附装到所述骨锚固件之前调节所述刚性联接器的长度。

43. 根据权利要求 42 所述的方法，其特征在于，调节所述刚性联接器的长度包括转动所述刚性联接器的臂以调节所述刚性联接器的臂从所述刚性联接器延伸的量。

44. 根据权利要求 38 所述的方法，其特征在于，还包括使所述柔性联接器与附装在所述第一和第二椎骨上的所述第一和第二骨锚固件拆分; 和

用刚性联接器替换所述柔性联接器。

45. 根据权利要求 44 所述的方法，其特征在于，替换所述柔性联接器包括将所述刚性联接器连接到附装在所述第一和第二椎骨上的所述第一骨锚固件和第二骨锚固件。

46. 根据权利要求 38 所述的方法，其特征在于，所述运动范围限制机构包括设置在所述联接器体部内的内部运动范围限制机构，该运动范围限制机构构造成限制所述体部的弯曲、压缩和伸展运动。

47. 根据权利要求 46 所述的方法，其特征在于，还包括控制所述柔性联接器的伸展量和弯曲量，其中控制伸展和弯曲包括提供套管和安设长形体，该套管在内部从所述柔性联接器的第一端朝所述柔性联接器的第二端延伸且具有窄缩的末端开口，该长形体具有扩大的末端部并从第二柔性联接器延伸，使得当所述柔性联接器伸长或弯曲时，该扩大的端部靠接在所述窄缩开口的壁上。

48. 根据权利要求 46 所述的方法，其特征在于，还包括控制所述柔性体部的压缩量，其中控制压缩包括提供套管和安设长形体，该套管在内部从所述柔性联接器的第一端朝所述柔性联接器的第二端延伸且具有窄缩的末端开口，该长形体具有扩大的末端部并从第二柔性联接器延伸，使得当所述柔性联接器被压缩时，所述套管抵靠所述柔性联接器的第二端。

49. 一种植入脊柱稳定单元的方法，包括:

在至少两个相邻的待治疗的椎骨上方产生至少一个切口;

将至少两根丝安置成使得每根丝单独地接触所述至少两个椎骨之一的椎弓根;

将螺钉固定在所述待治疗的第一和第二相邻椎骨上; 和

将柔性联接器附装在所述第一和第二相邻椎骨的两个螺钉上。

50. 根据权利要求 49 所述的方法，其特征在于，还包括测量插入到所述两个相邻椎骨中的螺钉之间的距离。

51. 根据权利要求 50 所述的方法，其特征在于，还包括调节所述柔性联接器的长度以配合在两个螺钉之间。

52. 根据权利要求 51 所述的方法，其特征在于，调节所述柔性联接器的长度包括转动所述柔性联接器的臂以调节所述臂从所述柔性联接器的体部延伸的量。

53. 根据权利要求 49 所述的方法，其特征在于，还包括在待治疗的第三椎骨上方产生至少一个切口；

将至少一根丝安置成使得所述丝单独地接触所述第三椎骨的椎弓根；

将螺钉固定在所述待治疗的第三椎骨上；和

将刚性联接器附装于所述第三螺钉以及所述第一和第二螺钉中的一个螺钉。

54. 根据权利要求 53 所述的方法，其特征在于，还包括测量所述第三螺钉与所述第一和第二螺钉中的所述一个螺钉之间的距离。

55. 根据权利要求 54 所述的方法，其特征在于，还包括调节所述刚性联接器的长度以配合在所述第三螺钉与所述第一和第二螺钉中的所述一个螺钉之间。

56. 根据权利要求 55 所述的方法，其特征在于，调节所述刚性联接器的长度包括转动所述刚性联接器的臂以调节所述臂从所述刚性联接器延伸的量。

后路机能动态稳定系统

本申请要求 2006 年 12 月 10 日提交的美国临时专利申请 No. 60/869,342 和 2007 年 4 月 27 日提交的美国临时专利申请 No. 60/914,360 的优先权，这两篇申请的全部内容并入本文作为参考。

技术领域

本发明涉及用于治疗脊柱疾病的装置和方法，具体地涉及用于控制或限制椎骨之间的相对运动的脊柱稳定系统。

背景技术

脊柱包括一系列已知为运动节段单元的关节。每个单元代表展现整个脊柱的运动学行为特征的脊柱最小组成部分。运动节段单元能够屈曲、伸展、侧向弯曲和平移。每个运动节段单元的组成部分包括两个相邻的椎骨、相应的小面关节、椎间盘和连接韧带组织，其中运动节段单元的每个组成部分都对关节的机械稳定性起作用。例如，将相邻的椎骨分开的椎间盘提供刚度，该刚度有助于约束椎骨在屈曲、伸展、轴向转动和侧向弯曲中的相对运动。

当运动节段单元的组成部分由于创伤、机械性损伤或疾病而错位或受损时，会导致剧烈疼痛和对脊柱的其它组成部分的进一步的失稳性损伤。对于具有椎间盘退变性疾病（DDD）的患者来说，受损的椎间盘提供的刚度可能不足，这在脊柱处于给定荷载下时会导致过度的椎骨相对运动，从而引发疼痛并进一步损坏椎间盘。根据所发生的结构改变的严重程度，治疗可包括融合、椎间盘切除术和/或椎板切除术。

现有的外科治疗常常涉及通过去除邻近组织而对不稳定的运动节段单

元进行融合。由于多种原因，融合是一种不希望的治疗选择。例如，融合将导致永久性的刚性固定，在被融合的椎骨水平/层面（vertebral level）上产生不可逆/不可还原的运动范围损失。此外，在被融合水平上的活动度的损失使得应力被传递到其它邻近的运动节段，这会导致或加速这些节段的退变。此外，融合常常不能减轻部分或全部的疼痛。

因此，希望提供这样一种脊柱稳定系统，其是充分地机能动态的（functionally dynamic），以便控制被治疗脊柱的载荷分配特性。还希望提供一种允许进行接近正常的运动、模拟健康运动节段的生理反应并减轻疼痛的系统。

发明内容

本发明提供一种用于治疗例如由于损伤、创伤或椎间盘退变性疾病（DDD）而导致的脊柱失稳的机能动态稳定单元和系统。各单元和共同的系统构造成控制患病椎骨的屈曲、伸展和平移，从而通过恢复正常功能来稳定椎骨节段。这通过提供一种允许侧向弯曲、轴向压缩、转动、前路节段高度调节及后路节段高度调节的单元和系统来实现。该单元和系统提供足够的节段刚度，同时还控制运动的范围以使椎骨节段稳定。在使用中，该系统模拟正常脊柱的自然运动。此外，该系统构造成允许随时间进行调节、翻修手术（例如融合）和经皮植入。

根据一个示例性实施例，提供一种机能动态脊柱稳定系统。该系统可包括柔性联接器，以及可包括筒形体部，该筒形体部在其壁上包括一个或多个槽口。该系统还可包括一对用于附装到骨锚固件的夹持臂，所述臂设置在联接器的相对端。柔性联接器还可包括内部运动范围限制机构，该限制机构构造成限制柔性联接器的弯曲、压缩和拉伸运动。该系统还可包括一对骨锚固件，该骨锚固件构造成与夹持臂协作以附装到骨组织。

根据另一示例性实施例，所述系统还包括具有一对用于附装到骨锚固件的夹持臂的刚性联接器。与柔性联接器一样，所述臂可设置在联接器的相对端。但是，与柔性联接器不同，这种联接器不允许伸展或压缩。而是，

该联接器通过防止此节段处的运动而促进融合。

还提供一种治疗脊柱的方法。该方法可包括将第一骨锚固件附装于椎骨和将第二骨锚固件附装于邻近的椎骨。然后可将柔性联接器附装于第一和第二骨锚固件。柔性联接器可包括筒形体部和内部运动范围限制机构，所述筒形体部在其壁中具有一个或多个槽口，所述内部运动范围限制机构构造成限制柔性联接器的弯曲、压缩和拉伸运动。

还提供一种将所述系统经皮植入的方法及用于执行此方法的器械组，所述方法对组织的损害最小且便于插入。该方法可包括在至少两个相邻的待治疗的椎骨上方产生至少一个切口，并将至少两根丝（针，wire）安置成使得每根丝单独地接触所述至少两个椎骨之一的椎弓根（pedicle）。可将螺钉固定于各个椎骨，并测量插入到两个相邻椎骨中的螺钉之间的距离。选择待附装于螺钉的柔性联接器，并基于所测得的距离调节柔性联接器的长度。

应当理解，上述一般性说明和下面的详细说明都仅为示例性和说明性的，而非对权利要求所要求保护的本发明构成限制。

结合在本说明书中并构成本说明书一部分的附图示出本发明的数个实施例，并与所作说明一起用于解释本发明的原理。

本发明的其它目的和优点将在下面的说明中部分阐述，或者可通过本发明的实施而被认识到。通过在所附权利要求中特别指出的要素及组合可实现和获得本发明的目的和优点。

附图说明

图 1 示出被植入的机能动态稳定系统的侧面透视图；

图 2 示出图 1 的被植入的机能动态稳定系统的俯视图，该机能动态稳定系统在脊柱的相对两侧包括两个稳定单元；

图 3 示出图 1-2 的系统的后视图；

图 4A 示出图 1-3 的系统的一个稳定单元的透视图；

图 4B 示出图 4A 的稳定单元中使用的柔性联接器的一部分的侧视图；

图 4C 示出图 4B 的柔性联接器的俯视图;

图 5A 示出图 4A 的单元的剖视图;

图 5B 示出图 4A 的稳定单元的一部分的分解图;

图 6 示出图 4B-4C 的柔性联接器的分解图;

图 7A 示出图 4B 和 4C 的柔性联接器的一部分的透视图;

图 7B 示出图 7A 的柔性联接器的所述部分的一个部段的透视图;

图 8A 示出图 4B 的柔性联接器处于非工作状态的剖视图;

图 8B 示出图 4B 的柔性联接器处于完全伸展状态的剖视图;

图 8C 示出图 4B 的柔性联接器处于完全压缩状态的剖视图;

图 8D 示出图 8A 的处于非工作状态的柔性联接器的一部分的放大图;

图 9A 示出被植入的机能动态稳定系统的另一实施例的透视图;

图 9B 示出图 9A 的被植入的系统的放大图;

图 10 示出图 9A-9B 的系统的一部分的侧视图;

图 11A 示出可与本发明的稳定系统一起使用的刚性联接器的透视图;

图 11B 示出图 11A 的刚性联接器沿线 A-A 截取的剖视图;

图 11C 示出可与本发明的稳定系统一起使用的刚性联接器的替换实施例的侧面剖视图;

图 12 示出根据本发明另一实施例的模块化的多节段稳定系统的透视图;

图 13 示出用来便于本发明的脊柱稳定系统植入的针模板和克氏针（K-wire）的透视图;

图 14A 示出用于通过使用本发明的方法便于骨锚固件植入的一组延伸杆的透视图;

图 14B 示出图 14A 的连接到骨锚固件的延伸杆之一的部分切除视图;

图 15 示出卡尺的透视图;

图 16 示出根据本发明的一组可选延伸杆的透视图;

图 17 示出用于调节柔性联接器长度的器械的透视图;

图 18A 示出可用于固定本发明的稳定单元的螺母的透视图;

图 18B 示出图 18A 的联接到图 19 的插入工具的螺母的部分切除视图；

图 19 示出插入工具的透视图。

具体实施方式

本发明提供一种用于治疗脊柱失稳的机能动态稳定单元和结合了机能动态稳定单元的系统。本发明还提供用于植入脊柱稳定系统的微创方法，以及便于执行这些方法的器械。

本发明的单元、系统和方法可用于治疗例如由于损伤、创伤或椎间盘退变性疾病（DDD）而引起的脊柱病变。稳定单元和包括这种单元的系统构造成控制患病的不稳定的椎骨区域的屈曲、伸展和平移，从而稳定椎骨节段并恢复正常功能。这通过提供一种允许对脊柱进行侧向弯曲、轴向压缩、转动、前路节段高度调节和后路节段高度调节的单元和系统来实现。该单元和系统在患者的中性区或活动区（neutral or active zone）内提供足够的节段刚度，同时又限制或控制期望区域外部的运动范围。在使用中，该系统模拟正常脊柱的自然运动。此外，该系统构造成允许随时间进行调节、翻修手术以及经皮输送或植入。

现在转到附图，图 1 示出植入到相邻的椎骨 2、4 之间的机能动态稳定系统 8 的实施例。图 2 示出被植入的机能动态稳定系统的俯视图，图 3 示出图 1-2 的系统 8 的后视图。如图所示，系统 8 可包括一个或多个柔性稳定单元 10，该柔性稳定单元 10 可被植入在脊柱的后部上以便稳定患病的椎骨 2、4。

如图 4A 所示，每个机能动态稳定单元 10 可包括柔性联接器 20，该柔性联接器 20 连接到至少一个骨锚固件 50，例如椎弓根螺钉或接骨螺钉。联接器 20 可包括柔性体部 22，该柔性体部 22 包括槽口 24 和开口 26。如图 4B-4C 所示，柔性体部 22 在一端可包括夹持臂 30，在相对端可包括第二夹持臂 40，夹持臂 30 具有供骨锚固件 50 插入的开口 32，第二夹持臂 40 也具有用于接纳骨锚固件 50 的开口 33。夹持臂 30、40 可与体部 22 一体地形成或可拆分地连接到体部 22。例如，如图 6 所示，夹持臂 40 的一

端可具有螺纹以通过例如柔性体部22中的套管90连接到柔性体部22。

联接器20的每个夹持臂30、40可在一侧包括凹形腔穴34、44，该凹形腔穴34、44构造成支靠在半球形的球支承件60上，如图5A-5B和图6所示。球支承件60可具有通孔，从而允许其装配在骨锚固件50上。在一个实施例中，骨锚固件50可具有长形的螺纹轴52，该螺纹轴52延伸到凸缘56中，该凸缘56连接到头部54，球支承件60可置于该头部54上。凸缘56还可包括锯齿形突起57以便于锚固到骨组织上并减少锚固件50随时间的松动。骨锚固件50例如可以是椎弓根螺钉。优选地，骨锚固件50可以是中空的以使得单元10或系统8能够经皮输送。凹形腔穴34、44允许夹持臂相对于支承件60滑动或转动，从而使得夹持臂30、40能够相对于骨锚固件50运动。也可使用其它适当的结构将柔性体部22连接到骨锚固件50，同时允许二者之间的相对运动。

如图5A、图5B和图10进一步所示，一衬垫70可安置于螺钉50上并靠住凸缘56或螺母80。衬垫70可构造和成形为靠在球支承件60上。如图4A和图5A所示，组装好的机能动态稳定单元10还可包括螺母80，该螺母旋拧在螺钉50的头部54上以便将部件相互固定。

每个机能动态稳定单元10构造成允许运动范围或位移在1.5mm至3.0mm之间，这里位移可从连接至第一夹持臂30的第一椎弓根螺钉的中央到连接至第二夹持臂40的第二椎弓根螺钉的中央进行测量。此位移或运动范围可例如通过转动、伸展或平移来实现。

图6示出图4A-4C的柔性联接器的分解图。如图所示，在一些实施例中，夹持臂40中的一个能可拆除地附装于联接器20。在一个实施例中，联接器20可包括用于将第二夹持臂40和其它部件固定于联接器20的螺纹开口28。在柔性联接器20中可具有套管90，该套管90在一端具有开口92并包括围绕开口92的螺纹边缘94，该螺纹边缘94用于螺纹连接到联接器体部22。套管90可构造成容纳于联接器体部22内，并且接纳销钉100和与销钉100协作。销钉100可包括具有螺纹端部的长形体部102，体部102延伸到半球形头部区域104中并包括裙边或台肩区域106。套管90和

销钉100共同形成联接器体部22内的伸展和压缩阻止装置，该阻止装置的功能是将柔性联接器20的运动范围限制在患者的中性区或活动区。

套管90的边缘92可具有螺纹以便与可拆卸的第二夹持臂40的螺纹端部46接合。联接器20的总长度可通过改变第二夹持臂40旋入套管90中的旋入量（即，改变夹持臂40进入套管90的转动圈数）来进行调节。如图所示，可拆分的第二夹持臂40的螺纹端部46可延伸为多个可压缩的指形突出部43，各个突出部43在凸缘唇47处终止。凸缘唇47用作锁定机构，防止在组装后第二夹持臂40从套管90旋开。如图8C所示，螺纹端部46还可包括用于接纳弹性体插塞110的凹槽48。弹性体插塞110可由软的、顺应性的塑性材料形成，例如硅树脂、聚乙烯或聚醚醚酮（PEEK）。当第二可拆分夹持臂40旋拧在套管90上时，插塞110与螺纹开口92相互作用，从而减少臂40和套管90之间的松弛或间隙。也可使用允许调节柔性体部的长度并同时提供对柔性体部的压缩和伸展量的控制的其它适当的结构。例如，夹持臂可通过摩擦配合、伸缩式连接或使用棘齿机构来进行附装。

如图7A和7B详细示出，在一个示例性实施例中，联接器体部22可包括筒形体部，该筒形体部由一系列盘绕单元22A构成。所述一系列盘绕单元22A在相互连接时形成梯级式的一系列槽口24，其中每个槽口24在柔性体部22的开口26处终止。在一些实施例中，所述一系列盘绕单元22A可由单独一件材料形成，使得单元22A彼此一体地相连。例如，在一个实施例中，盘绕单元22A可由单独一件管状材料刻蚀或切割而成。在其它实施例中，一个或多个盘绕单元22A可分别单独形成且彼此叠置。叠置的盘绕单元22A例如可通过焊接或通过机械连接部而相互连接。

可设想，联接器体部22可根据两个相邻槽口24之间的高度、宽度、距离或角度以及形成联接器体部22的单元22A的数量来改变刚度。此外，一个或多个单元22A可由不同的材料形成以便改变体部22的机械特性。此外，单个体部22内的单元22A、槽口24和开口26的尺寸可变。

图8A-8D示出完全组装好的柔性联接器20处于非工作状态（图8A和

图 8D）、完全伸展或分散状态（图 8B）和完全压缩状态（图 8C）的实施例。如图 8A 及图 8D 中的放大图所示，在非工作状态，销钉 100 和套管 90 未接合（即，没有阻力或阻碍）。在完全伸展或分散状态（图 8B），尺寸比窄缩开口 98 的宽度大的销钉头部 104 靠接于套管 90 的窄缩开口 98，从而防止柔性联接器体部 22 过度伸展。在完全压缩状态（图 8C），套管 90 的带有窄缩开口 98 的端部抵靠在第一夹持臂 30 的内边缘上，如图所示。套管 90 和销钉 100 在联接器体部 22 内的协作提供了分散-压缩阻止机构以便控制或限制所能提供的运动的范围，从而不仅可防止对患病椎骨节段的损伤或损害，还可防止对机能动态稳定单元自身的损伤或损害。也可使用其它类型的协作元件，例如伸缩元件或内部活塞，以控制或限制联接器体部 22 的运动范围。

如上所述，机能动态稳定单元 10 可单独用来稳定一对椎骨节段。此外，如果需要的话，也可组合使用多于一个的单元 10 来形成多个水平的机能动态稳定系统 12，如图 9A 和 9B 所示。多个水平的机能动态稳定系统 12 可包括两个或更多个相互连接的单元 10。

图 10 示出图 9A-9B 所示的系统的侧视图。如图所示，系统 12 包括一对串联连接的柔性联接器 20。联接器 20 设置成使得每个联接器 20 的第一夹持臂 30 围绕一个球支承件 60 安置，其中骨锚固件 50 和螺母 80 将此组合体固定在一起。应当理解，可通过这种方式连接多于两个的联接器 20，且任意单个联接器的第一夹持臂 30 或第二夹持臂 40 可与另外的联接器 20 的第一夹持臂 30 或第二夹持臂 40 在骨锚固件 50 上组合。任意数量的联接器 20 可沿患者脊柱的一侧或两侧植入。此外，根据患者的病理和身体构造，单元 10 可具有不同的机械特性。

在一些实施例中，本发明的稳定系统可允许连同其它运动节段的机能动态稳定一起使一个或多个椎骨运动节段融合。为此，稳定系统可包括例如如图 11A 所示的刚性的、促进融合的联接器 101。刚性联接器 101 可构造成与前文描述的骨锚固件 50、球支承件 60 和衬垫 70 一起使用。如图所示，刚性联接器 101 包括两个部件 122、124，每个部件都以与前文描述的

柔性联接器 20 类似的方式分别延伸到夹持臂 130、140。每个臂 130、140 都包括开口 132，该开口 132 用于以与关于柔性联接器 20 所述类似的方式附装于骨锚固件 50。

如图 11B 进一步所示，两个部件 122、124 可彼此附装以允许对刚性联接器 101 的长度进行调节。例如，部件 122、124 可包括螺纹表面，刚性联接器 101 的长度可通过使一个部件 122 相对于另一部件 124 扭转而进行调节，与前面描述的用于调节柔性联接器 20 的长度的方式很相似。夹持臂 130、140 的每一个还可分别在下侧包括凹形腔穴 134、144，该凹形腔穴构造成支靠在半球形的球支承件 60 上。这样，刚性联接器 101 到骨锚固件 50 上的植入类似于上文描述的柔性联接器 20 的植入。

如图 11C 所示，可提供刚性的、促进融合的联接器 201 的替换实施例。刚性的、促进融合的联接器 201 类似于刚性联接器 101，不同之处在于它可不使用用于调节联接器 201 的长度的部件螺纹表面。刚性联接器 201 可构造成与前述骨锚固件 50、球支承件 60 和衬垫 70 一起使用。如图所示，刚性联接器 201 包括两个部件 222、224，该部件的每一个通过与前述柔性联接器 20 类似的方式分别延伸到夹持臂 230、240。臂 230、240 中的每一个包括用于通过与关于柔性联接器 20 所述类似的方式附装到骨锚固件 50 上的开口（未示出）。每个夹持臂 230、240 还可分别在下侧包括凹形腔穴 234、244，该腔穴构造成支靠在半球形的球支承件 60 上。

第一部件 222 和第二部件 224 可相对于彼此运动以便于调节联接器 201 的长度。作为螺纹表面的替换，部件 222 可包括腔穴 226，该腔穴 226 构造成接纳紧固元件 230 以使第一部件 222 相对于第二部件 224 固定。因为第一部件和第二部件不包括螺纹表面，所以它们可通过使部件滑动而非扭转来相对于彼此运动。这个实施例允许外科医生在需要时现场调节刚性联接器 201 的长度。

紧固元件 230 可以是任何适当的紧固元件，例如螺钉或螺母。例如，紧固元件 230 可包括可断式螺母（break-away nut），该可断式螺母具有第一部分和第二部分，该第一部分构造成与部件 222 的部分 226 牢固地接

合以固定第一部件 222 相对于第二部件的位置，第二部分构造成与用于将第一部分拧紧于刚性联接器的插入工具接合。可断式螺母的第二部分可以是可断部分，该可断部分具有较薄的壁或具有由较低屈服强度的材料制成的区域，且构造成在施加足够大的转矩时（即，当螺母 230 被充分拧紧时）断裂。腔穴 226 的内表面和紧固元件 230 的外表面可设置螺纹以有利于腔穴 226 与紧固元件 230 的接合。

如上所述，稳定系统可包括机能动态柔性联接器 20 和刚性联接器 101，从而提供一种允许在患者脊柱的分离节段使运动保留和融合结合的模块化系统。通过允许刚性联接器 101 和柔性联接器 20 的可互换性，在该系统中，外科医生在满足患者的具体需求时将具有较大的灵活性。因此，一个脊柱节段可具有机能动态稳定（即，非融合），而相邻的节段可具有刚性的节段固定（即，融合）。

图 12 示出包括使用了柔性联接器 20a、20b 和刚性联接器 101 的三个分离的稳定单元 10a、10b、10c 的多节段系统 12。单元 10a 和 10c 的柔性联接器 20a、20b 增加了患病运动节段的节段刚度并限制了屈曲、伸展、侧向弯曲和转动的运动范围，同时保留了运动。通过选择适当地设定尺寸的联接器 20a、20b，后路节段高度也可被调节。此外，单元 10b 的刚性的、促进融合的联接器 101 提供刚性的节段固定，从而促进融合，同时使用了相同类型的骨锚固件 50 和器械。

模块化系统 12 具有多个优点。例如，如上所述，最初，被植入的系统可仅包括机能动态的柔性联接器 20，该联接器 20 通过骨锚固件 50 连接到椎骨。但是，后来，由于疾病的发展、未减弱的疼痛、其它症状或患者病情的其它改变，可能需要融合一个或多个先前治疗过的（椎骨）水平。因此，在随后的外科手术中，外科医生可简单地用刚性联接器 101 代替先前植入的柔性联接器，同时仍能使用相同的骨锚固件。

如前文所述，本发明的单元和系统可使用微创的、肌肉非损伤的方法植入。这些方法可包括经皮方法或一系列使得组织受损最小化的小切割。

图 13-19 示出插入器械的示例性实施例，该插入器械可单独提供或与

该系统一起作为一组提供。在本系统的一种示例性方法中，一系列克氏针200被插入到患者脊柱的椎弓根中。克氏针200可通过患者背部中的一系列小的切口插入。此外，如图13所示，可设置针模板202以辅助外科医生安置切口和克氏针200。如图所示，针模板202可包括与患者脊柱的椎弓根对准的预定开口204。开口204可在两侧设置成与待治疗的椎骨的两个椎弓根对齐。可设置不同尺寸的模板以与椎弓根间距有变化的患者相适应。

在插入克氏针200后，中空的骨锚固件50可从克氏针200上穿过，并且通过利用如图14A所示的一系列延伸杆220a、220b、220c，骨锚固件可植入选定的椎骨内。如图14B所示，延伸杆可附装于骨锚固件50的头部54以允许操纵锚固件50。此外，可设置扩张套管（dilatation sleeve）（未示出），延伸杆可穿过扩张套管以接近植入部位。在植入骨锚固件50后或在植入骨锚固件50期间，可利用延伸杆220来操纵骨锚固件50和所连接的椎骨以确定静态状况和加有载荷的情况下的总运动范围。这些信息有助于外科医生预测该脊柱节段所需的修正运动的可能范围。

如图15所示，可与器械组一起提供卡尺240。卡尺240可包括一对枢转臂242、244，各个臂分别延伸到指部接合开口246、248，且在相对端分别终止于夹持端250、252。枢转臂242、244可通过板簧254连接。如图所示，臂242、244的端部构造成利用底板256上的刻度标记258提供一对相邻的骨锚固件50之间的距离的读数或测量值。夹持端250、252可构造成保持每个骨锚固件50的球支承件60的一部分。这使得即使在骨锚固件50未平行安置或相对于彼此成特定角度时卡尺240也能起作用。

图16示出各种杆延伸部260，这些杆延伸部260构造成连接到锚固件的其它部件，例如球支承件60、衬垫70或螺母80。这些杆延伸部260的每一个都使得能对各个部件进行微创或经皮操纵。

一旦骨锚固件50就位且一对相邻骨锚固件50之间的距离已被确定时，外科医生便可选择用于安置在骨锚固件50之间的适当尺寸的机能动态柔性联接器20或刚性的促进融合的联接器101。可设置类似于图17示出的联接器长度调节器270以确保在插入前联接器的长度是适当的。如图所示，

长度调节器 270 可包括体部 272，该体部 272 具有一对夹持部 271，在该对夹持部之间可保持联接器 20、101。该对夹持部 271 形成联接器的插入区域 274。在体部 272 内具有弹性加载机构，该弹性加载机构向夹持部 271 之一施加偏压力。可通过转动握把 280 来控制弹性加载机构，从而扭转联接器 20、101 并由此调节其长度。体部 272 还可包括窗口 278，在该窗口内显示表示联接器长度的刻度标记 276。尽管示出的是柔性联接器 20，但是应当理解长度调节器 270 也可用于刚性联接器 101。

然后，适当地设定尺寸的联接器 20、101 将沿克氏针 200 滑下并到达骨锚固件 50 的球支承件 60 上。随后，螺母 80 可用于将联接器 20、101 固定就位。在一些实施例中，螺母 80 可具有防止过度拧紧或未拧紧的特征。例如，图 18A 示出具有可断部分 182 的适当的螺母 180 的示例性实施例，可断部分将与骨锚固件接合的下部 186 连接到上部 184。具有较薄的壁或具有由较低屈服强度的材料制成的区域的可断部分 182 构造成在施加了足够大的转矩时（即，当螺母 180 已被充分拧紧时）断裂。

螺母 180 可通过用于植入骨锚固件 50 和联接器 20、101 的微创方法插入。例如，图 19 示出用于插入螺母 180 的示例性插入工具 290。该插入工具 290 包括长形体部 292，该长形体部 292 从手柄部分 294 延伸至相对端的螺母联接端部 296。如图 18B 所示，联接端部 296 可构造成在上部 184 牢固地附接到螺母，且与螺母相联的长形体部 292 可插入到先前限定的进入位置以将螺母 180 固定到骨锚固件 50 上。在被充分拧紧的情况下，螺母 180 将在可断部分 182 断裂，从而将下部 186 留在骨锚固件上并允许上部 184 移开。

外科医生可选择在邻近的（椎骨）水平重复此过程，直到患者脊柱的所有患病水平都被治疗。整个过程可经皮地和/或对周围组织微创地完成。

考虑到本说明书和本文所公开的本发明的实践，本发明的其它实施例对于本领域技术人员而言是显而易见的。本说明书和示例应被看作仅仅是示例性的，本发明的真正范围和精神由所附权利要求来限定。

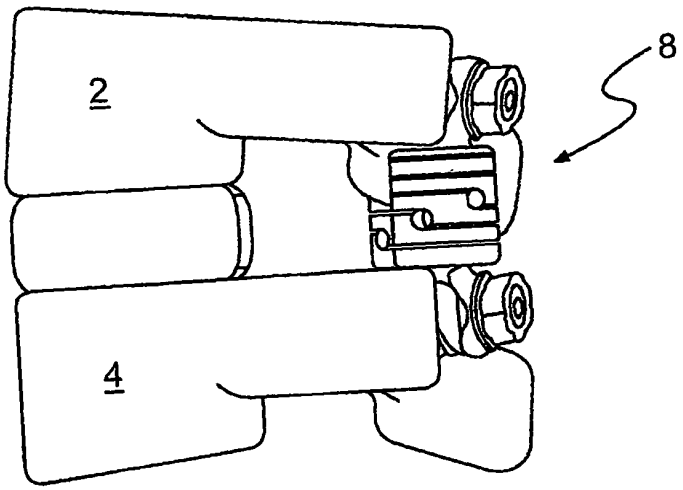


图 1

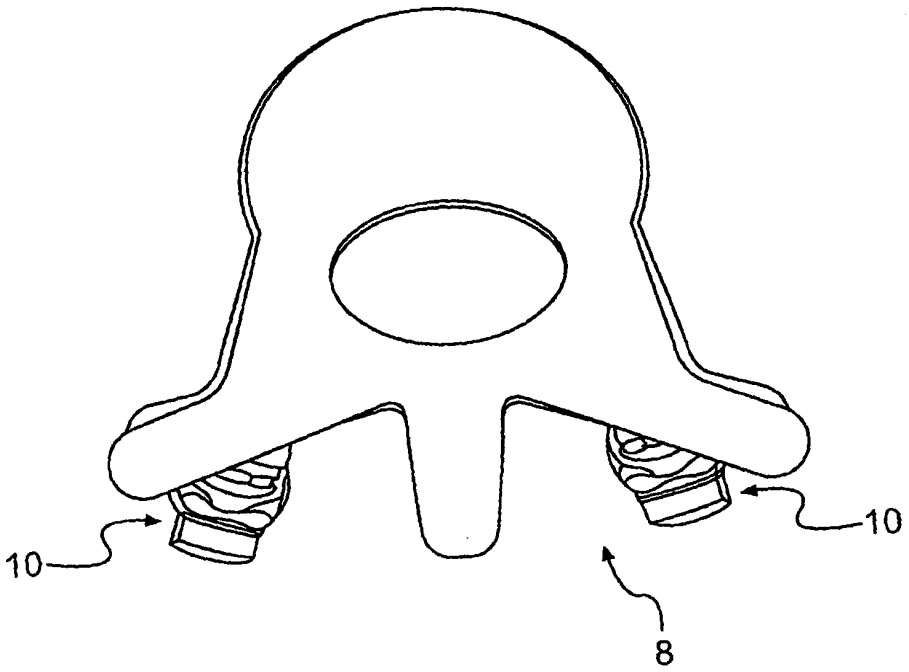


图 2

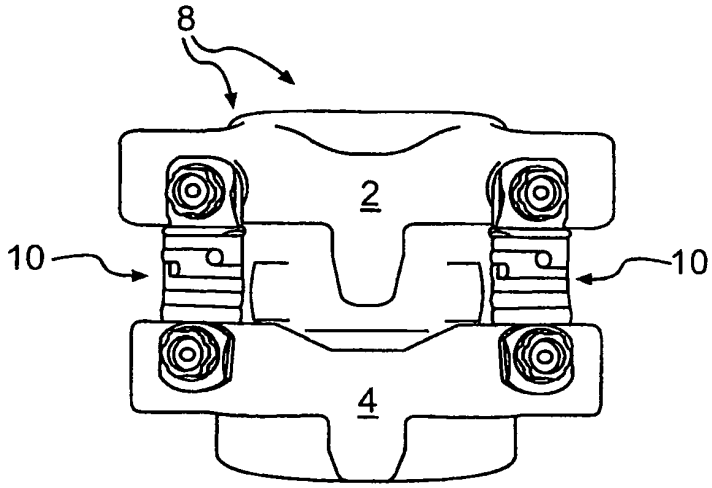


图 3

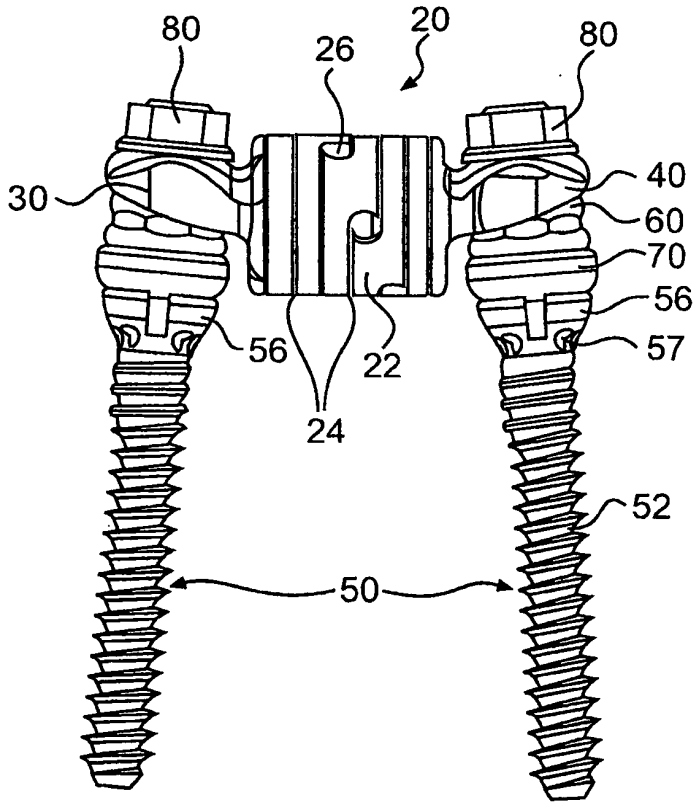


图 4A

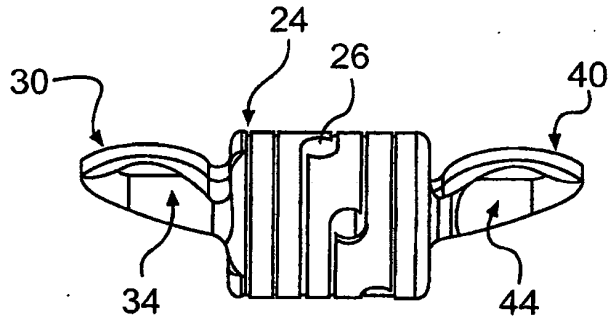


图 4B

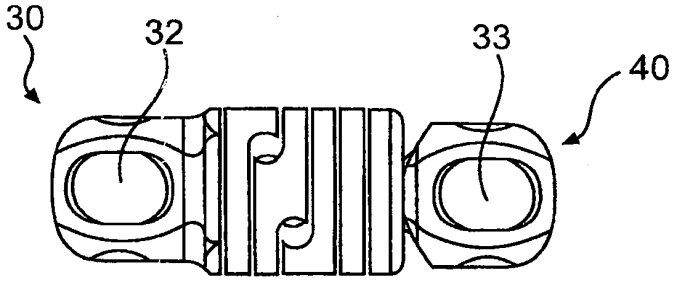


图 4C

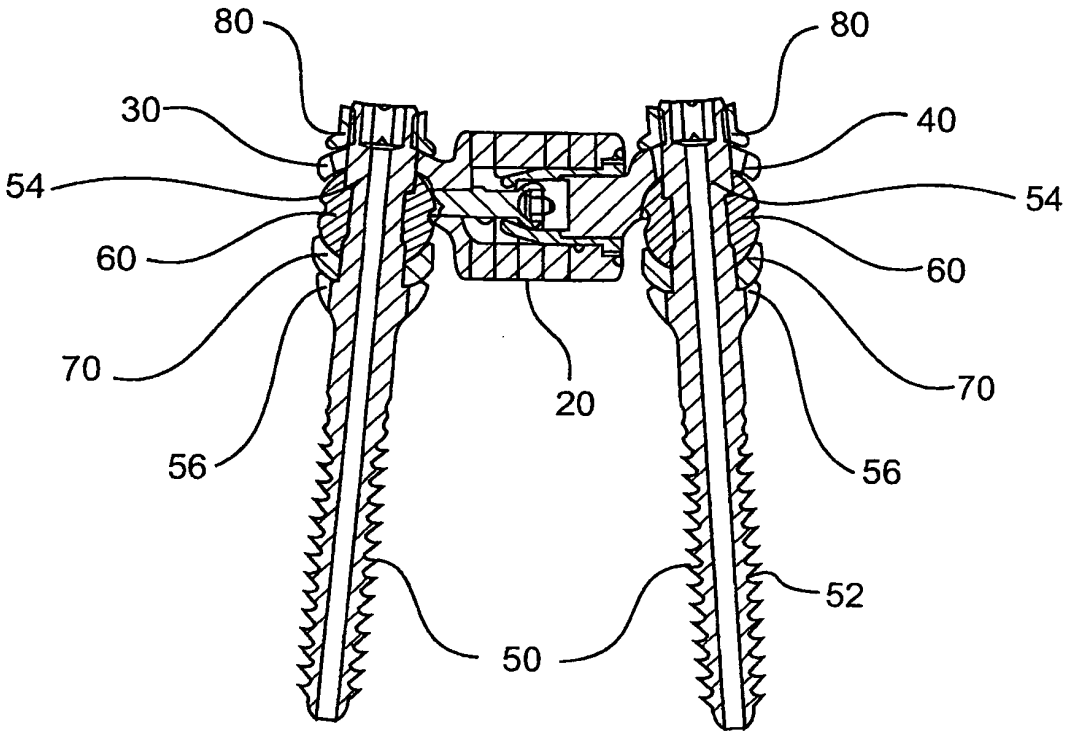

80
80
30
40
54
54
60
60
70
70
20
56
56
52
50

图 5A

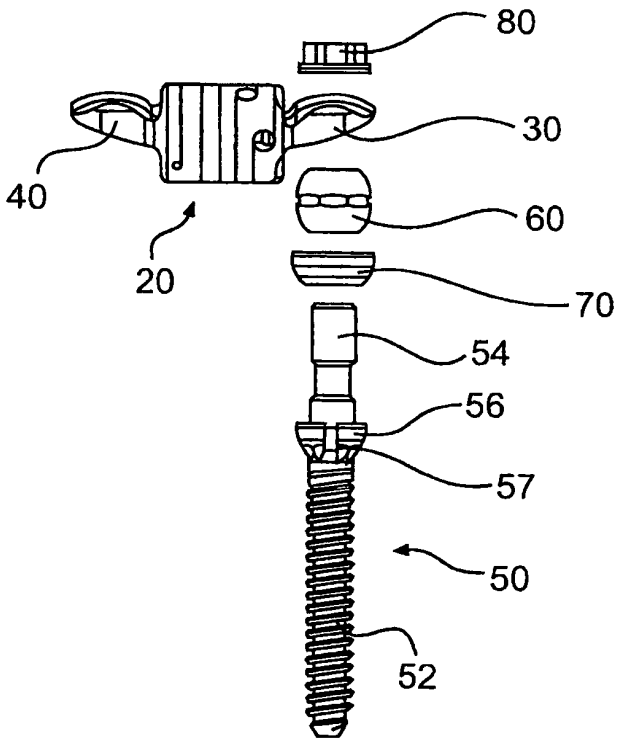

80
30
40
60
20
70
54
56
57
50
52

图 5B

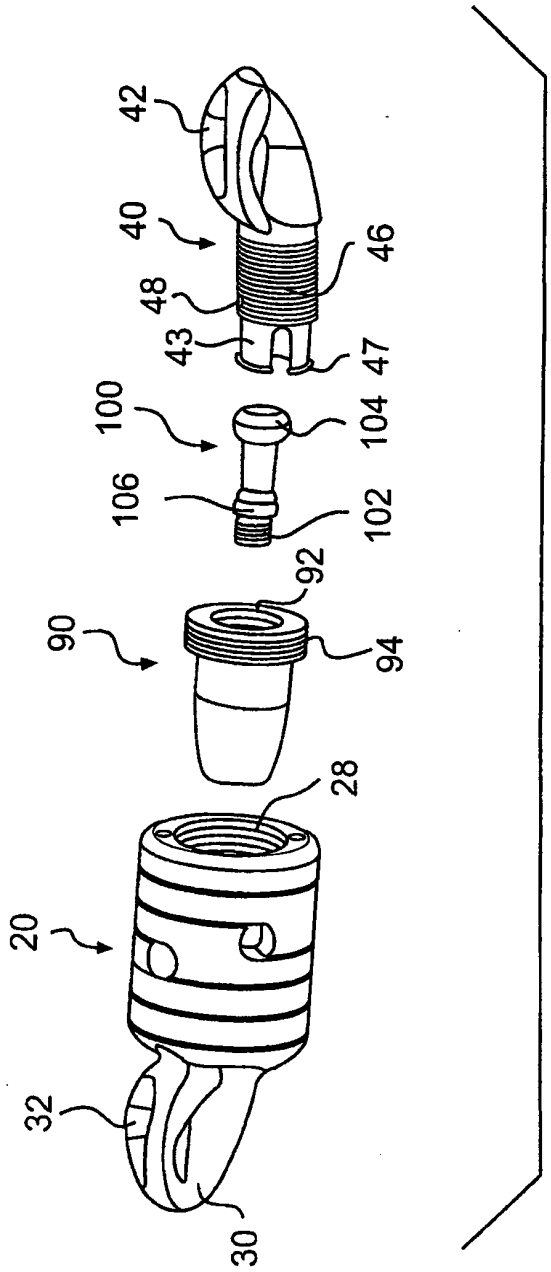


图 6

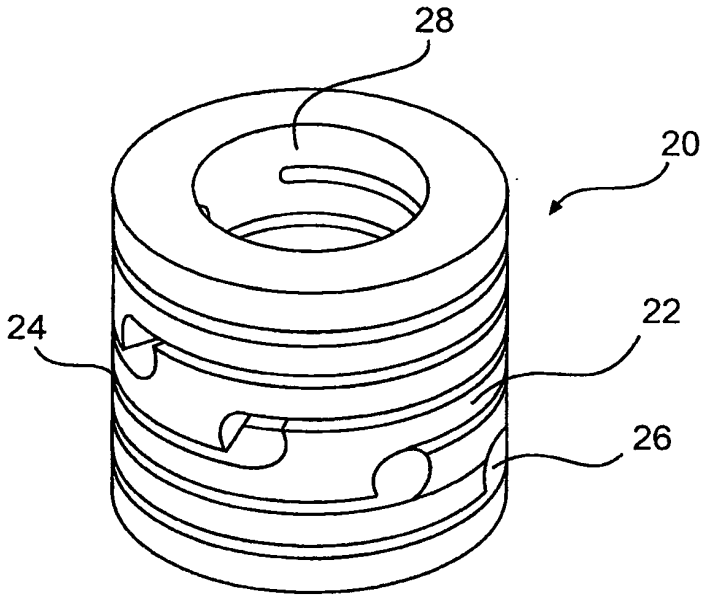


图 7A

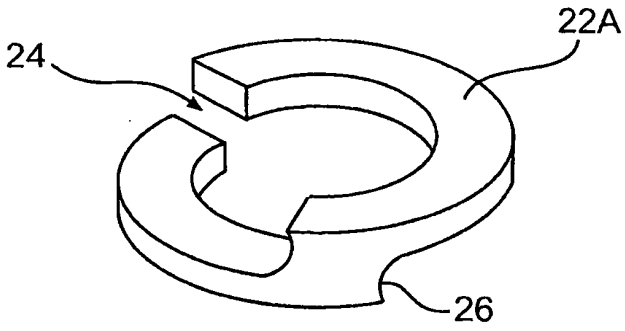


图 7B

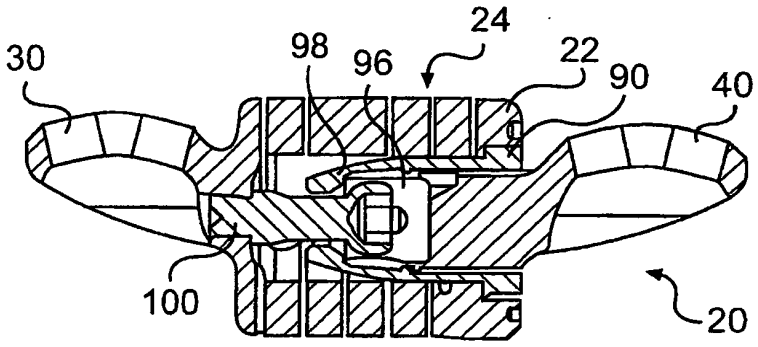


图 8A

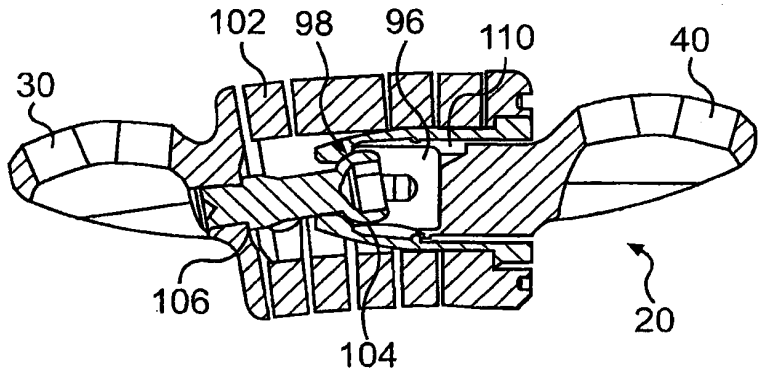


图 8B

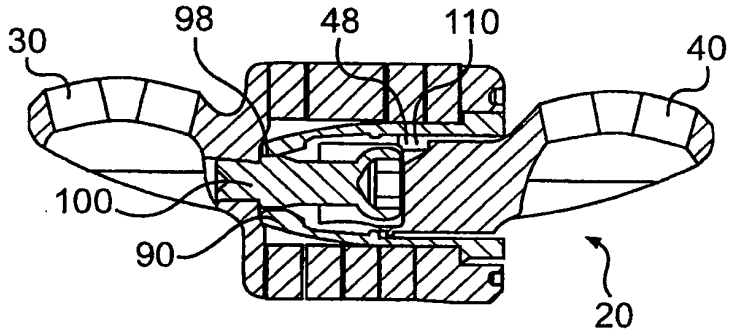


图 8C

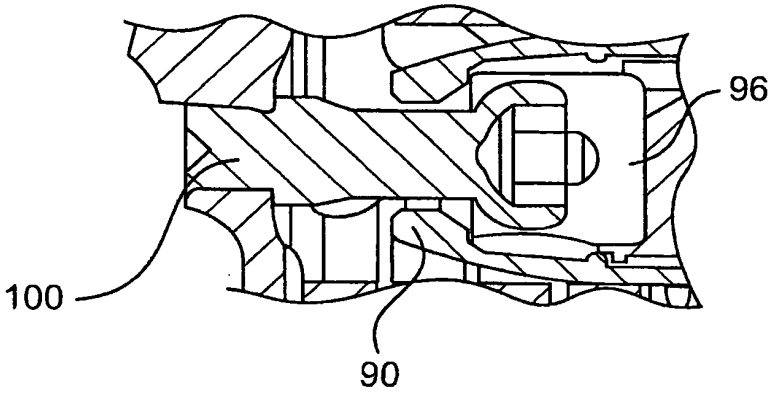


图 8D

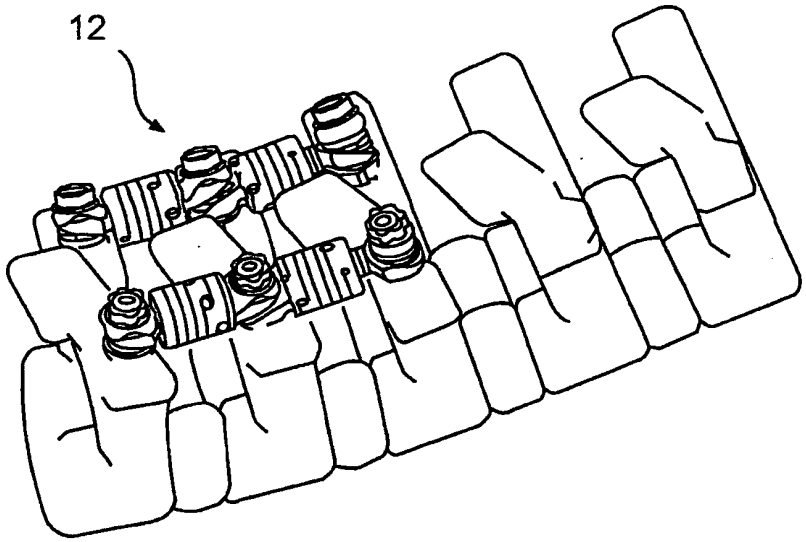


图 9A

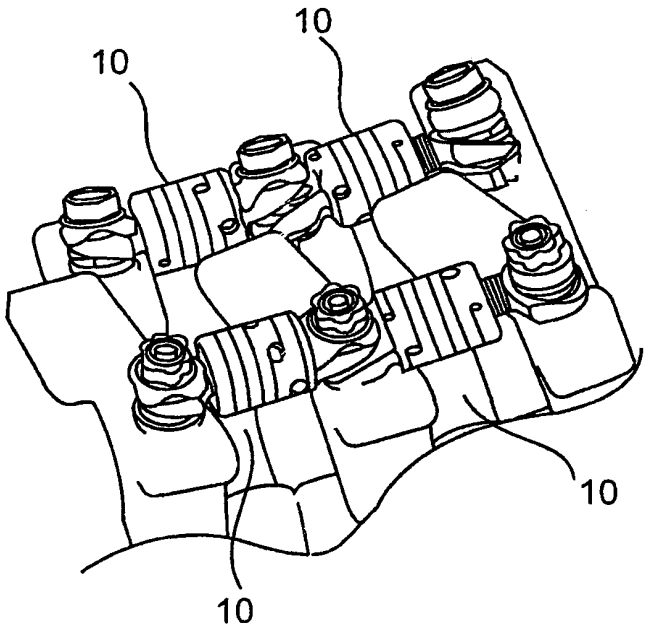


图 9B

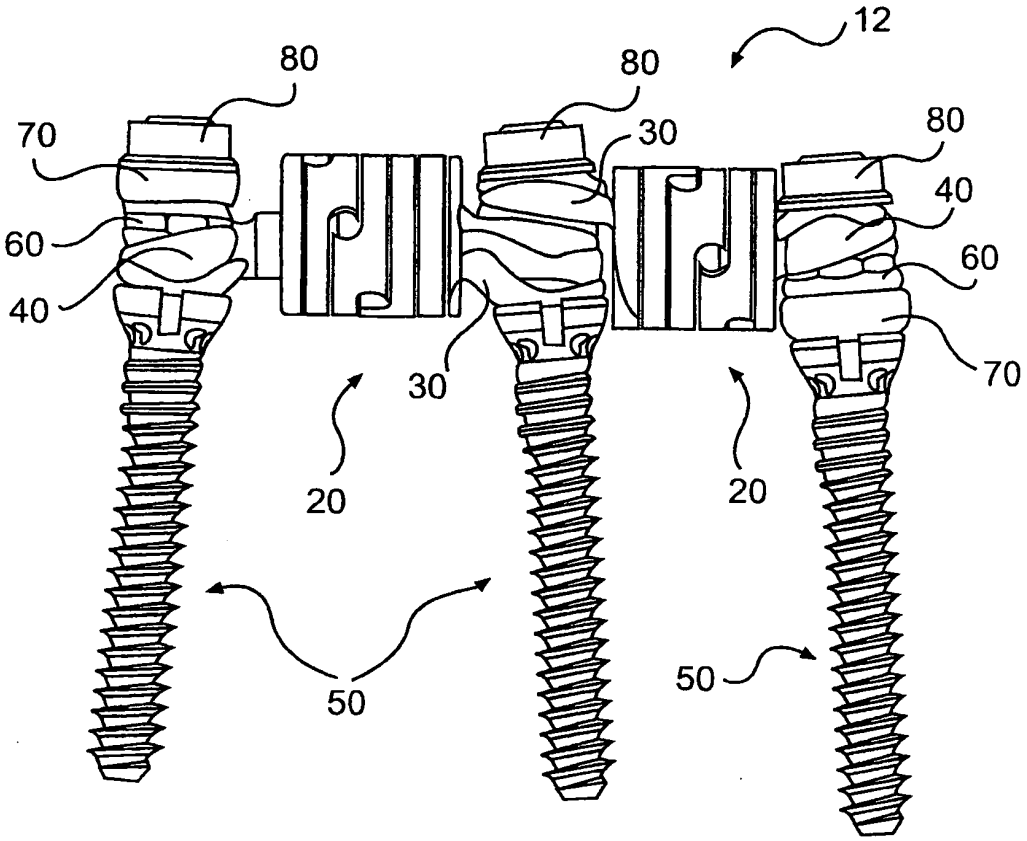

12
80
80
80
70
30
40
60
40
60
70
30
20
20
50
50

图 10

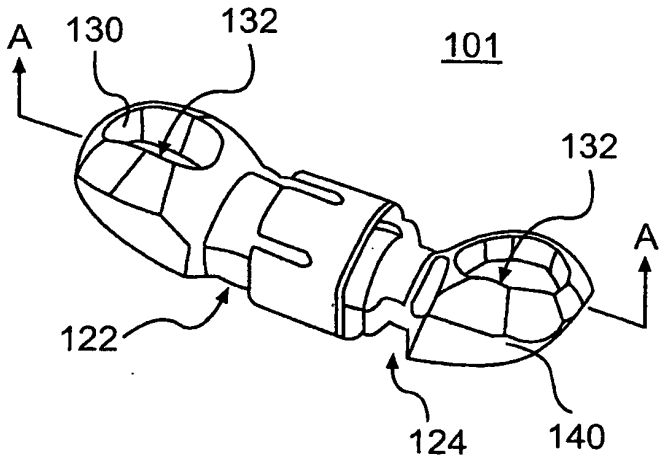

A
130
132
101
132
A
122
124
140

图 11A

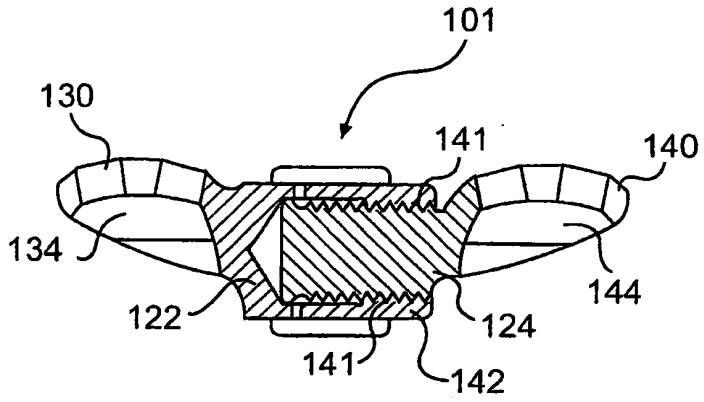

101
130
141
140
134
144
122
124
141
142

图 11B

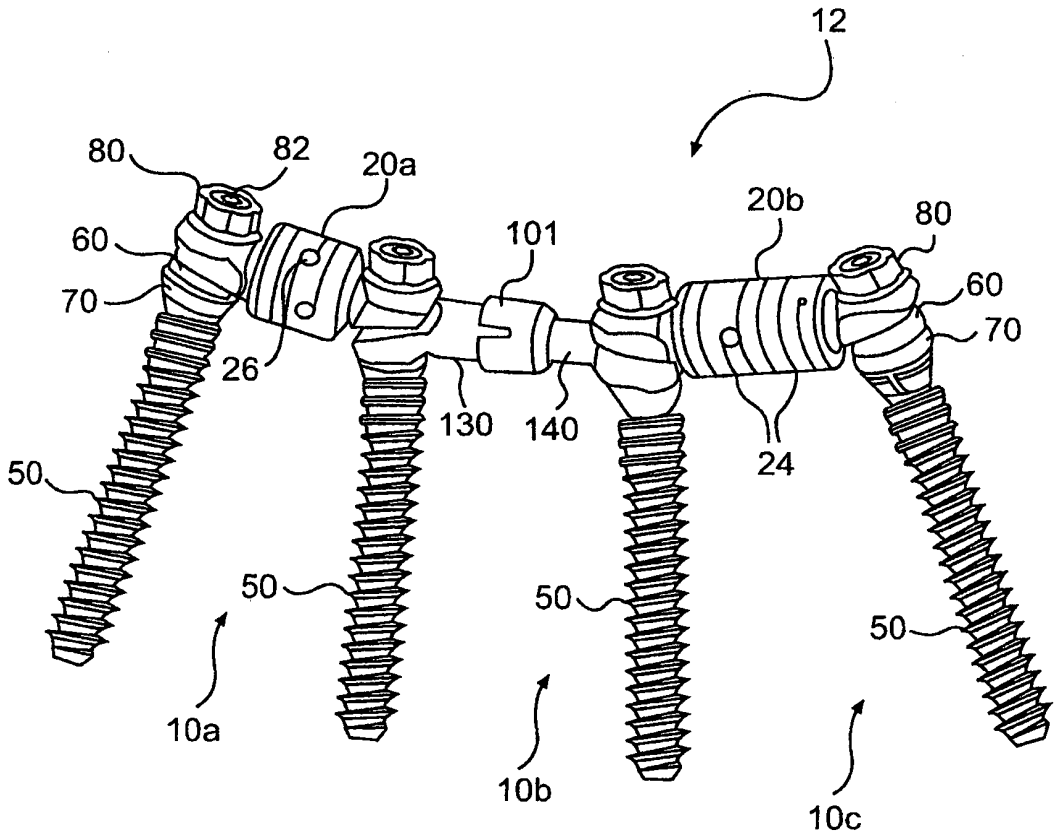

12
80
82
20a
20b
80
60
101
60
70
70
26
130
140
24
50
50
50
50
10a
10b
10c

图 12

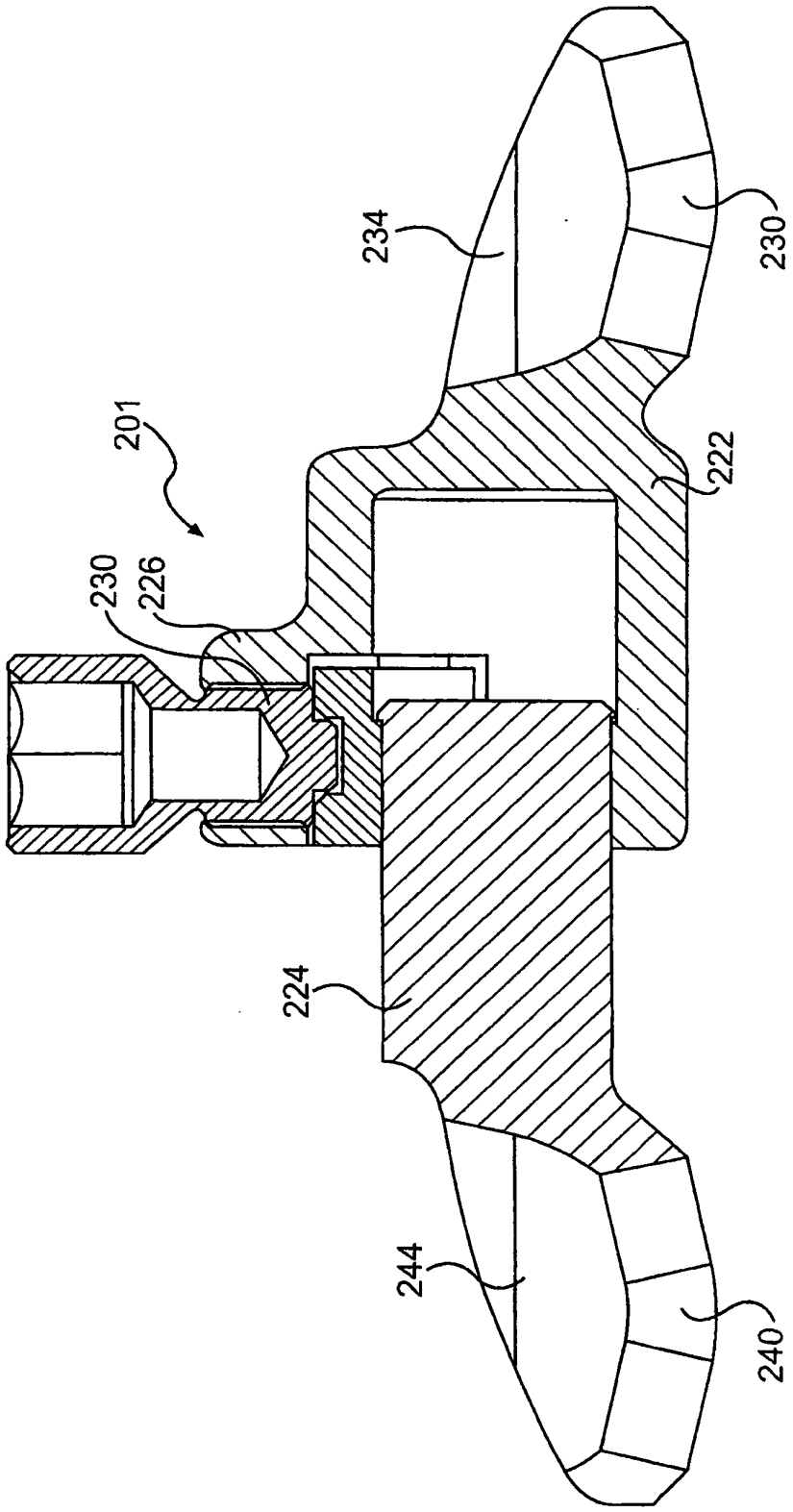


图 11C

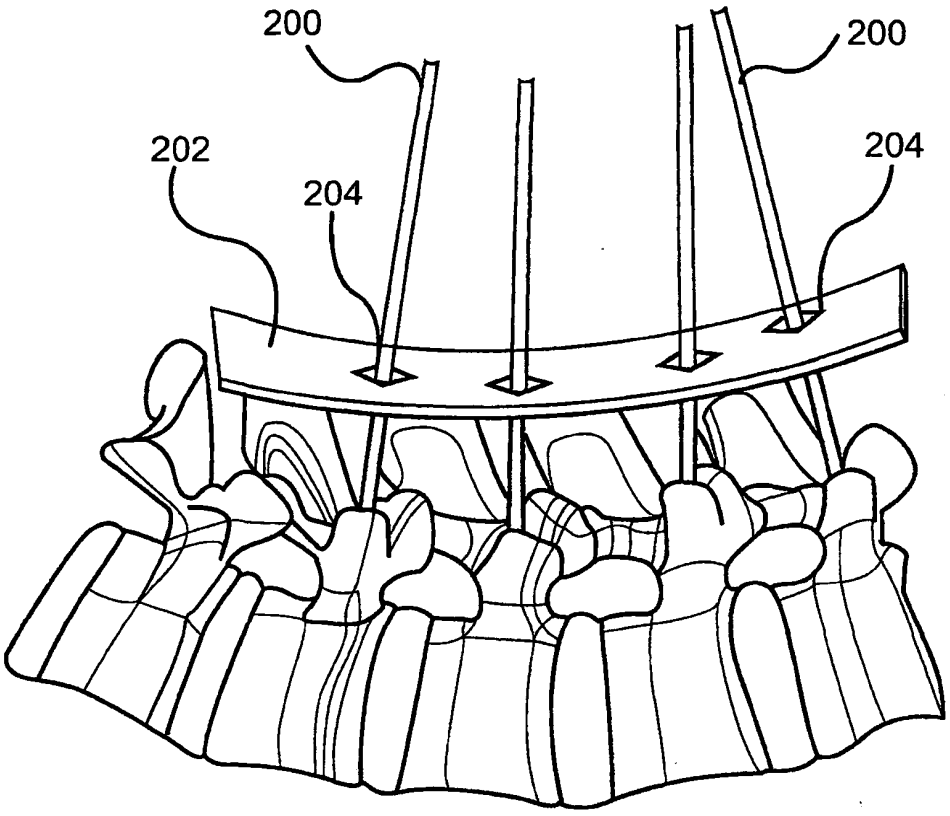


图 13

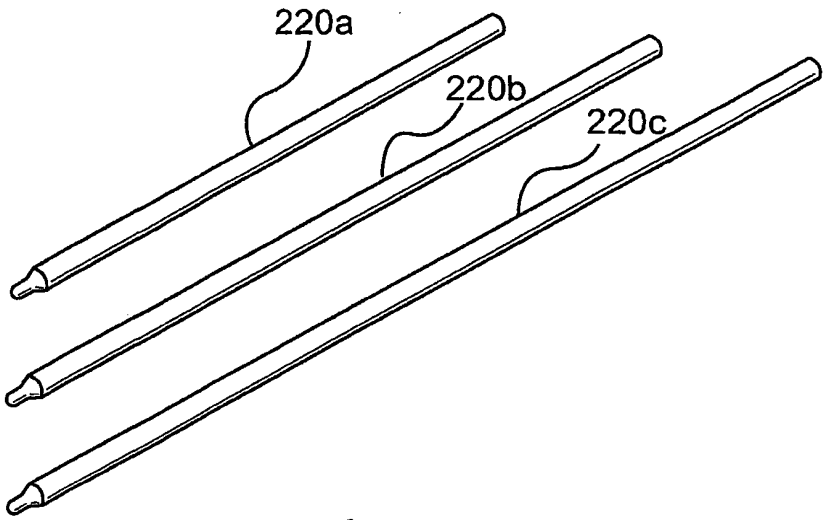


图 14A

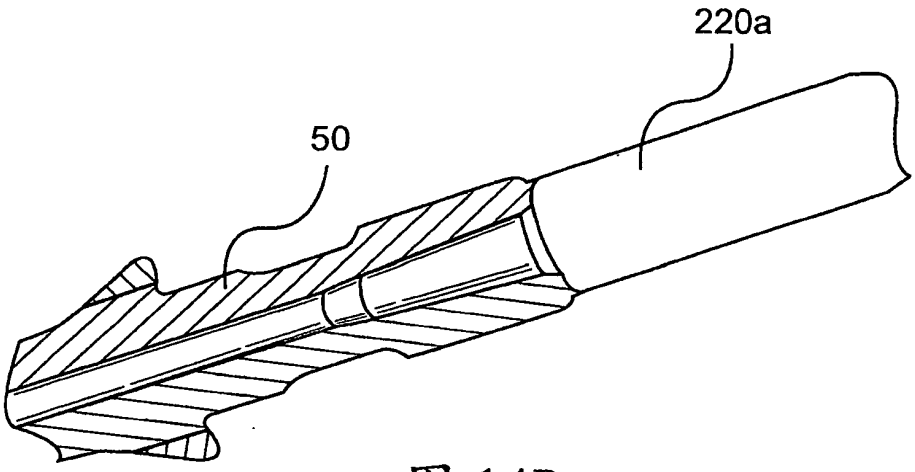


图 14B

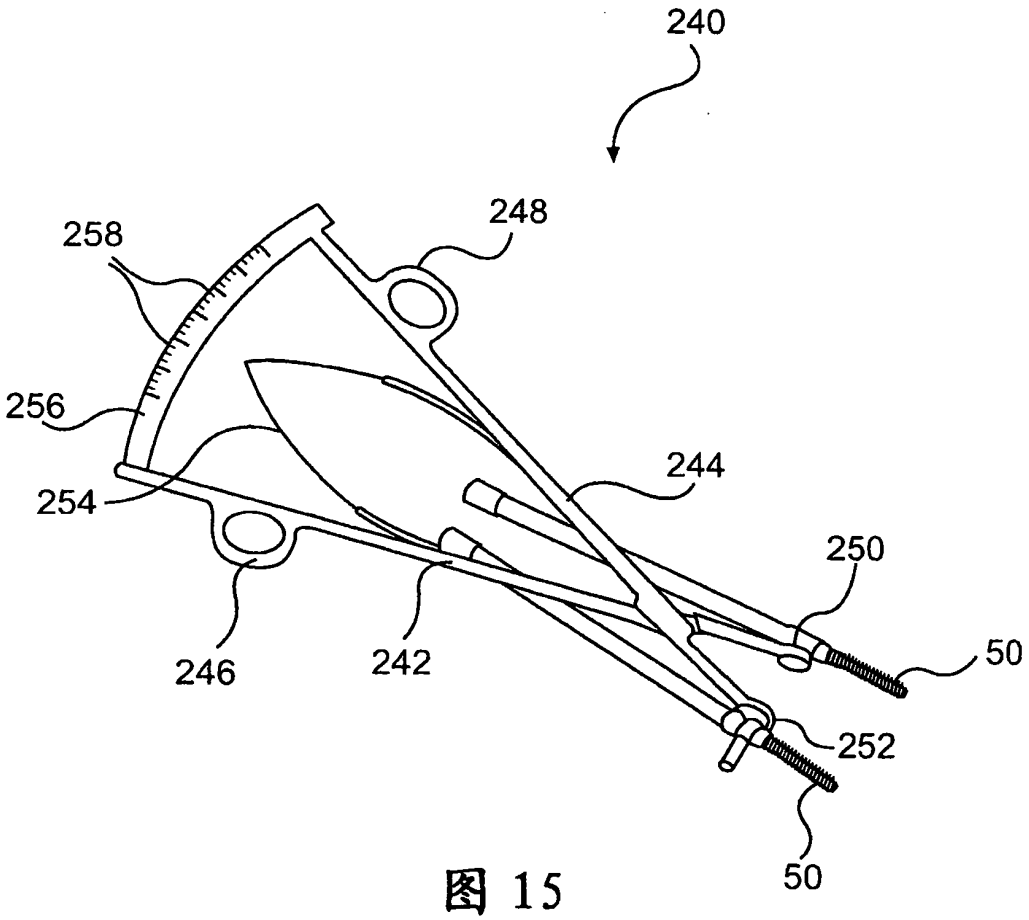


图 15

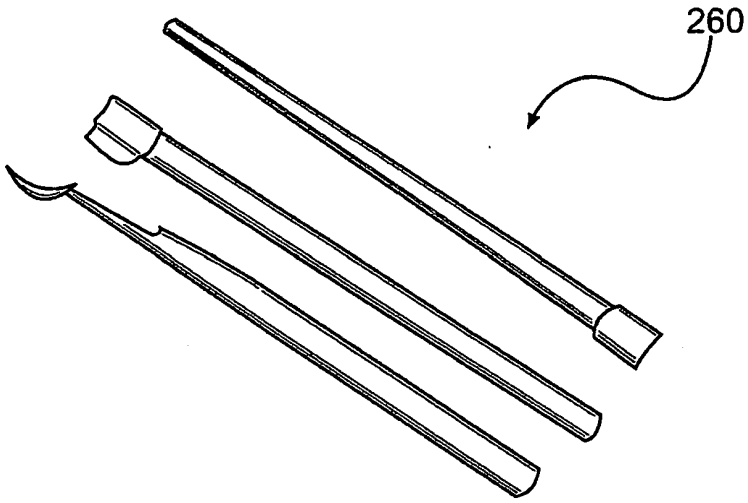


图 16

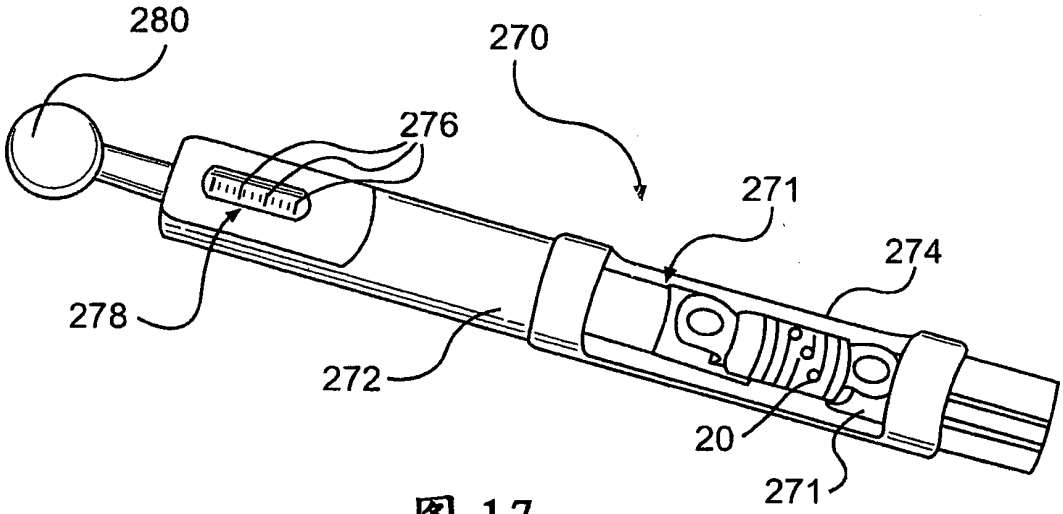


图 17

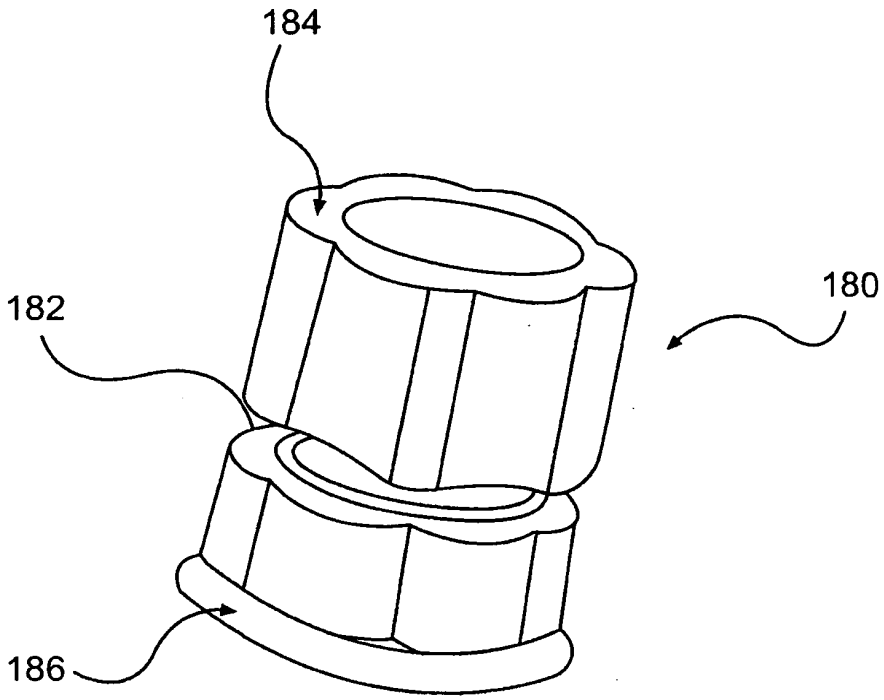


图 18A

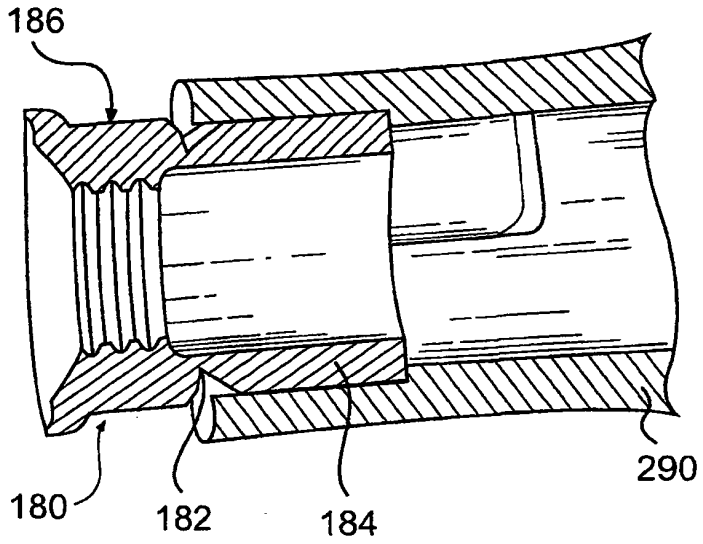


图 18B

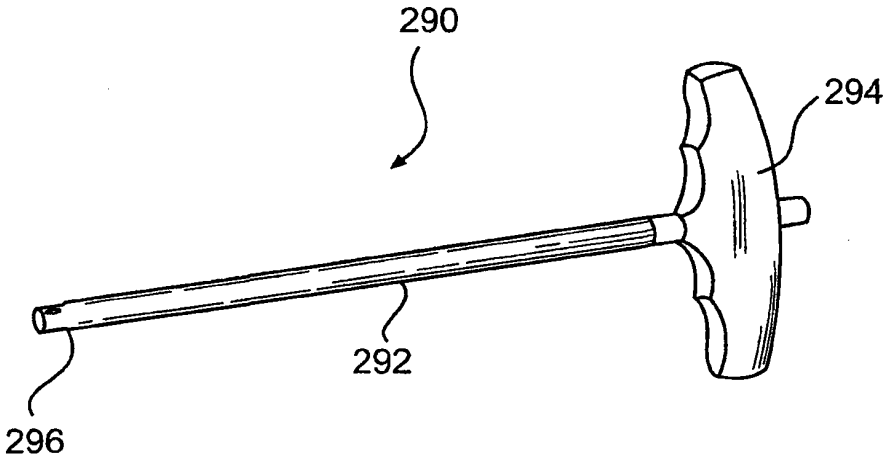


图 19

A functionally dynamic stabilization unit (10) and system for treatment of spinal instability are provided. Each unit, and collectively, the system, is configured to control flexion, extension and translation of the affected unstable vertebral area, thereby stabilizing the vertebral segments by restoring normal function. This is achieved by providing a unit and system that allow for lateral bending, axial compression, rotation, anterior segmental height adjustment, and posterior segmental height adjustment. The unit and system provide sufficient segmental stiffness, while also limiting, or controlling, the range of motion (i.e., sufficient stiffness in the neutral or active zone, while limiting or preventing motion outside of the active zone) to stabilize the vertebral segments. In use, the system mimics the natural movement of the normal spine. Furthermore, the system includes a rigid, fusion-promoting coupler (20) configured for use in an adjacent level, or as a substitute for the functionally dynamic unit. The modularity of the system allows adjustment over time and easier revision surgery, and is configured for minimally-invasive, delivery or implantation.