



Office de la Propriété

Intellectuelle
du Canada

Un organisme
d'Industrie Canada

Canadian
Intellectual Property
Office

An agency of
Industry Canada

CA 2671868 A1 2008/06/19

(21) **2 671 868**

(12) **DEMANDE DE BREVET CANADIEN**
CANADIAN PATENT APPLICATION

(13) **A1**

(86) Date de dépôt PCT/PCT Filing Date: 2007/12/07
(87) Date publication PCT/PCT Publication Date: 2008/06/19
(85) Entrée phase nationale/National Entry: 2009/06/04
(86) N° demande PCT/PCT Application No.: US 2007/086800
(87) N° publication PCT/PCT Publication No.: 2008/073830
(30) Priorités/Priorities: 2006/12/10 (US60/869,342);
2007/04/27 (US60/914,360)

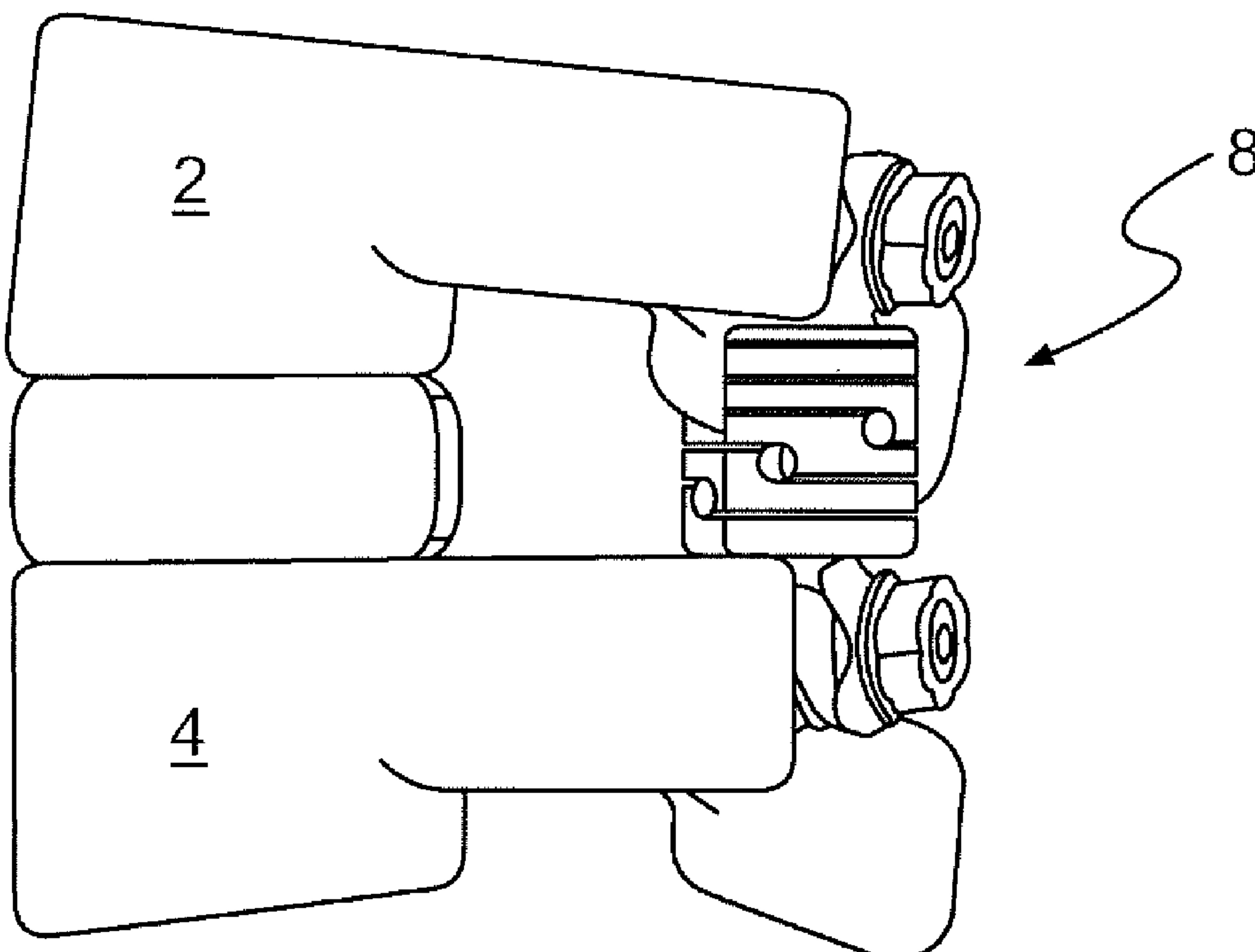
(51) Cl.Int./Int.Cl. *A61B 17/70* (2006.01),
A61B 17/88 (2006.01)

(71) **Demandeur/Applicant:**
PARADIGM SPINE, LLC, US

(72) **Inventeurs/Inventors:**
TRAUTWEIN, FRANK T., DE;
HOLTKAMP, BERNHARD, DE;
SALVERMOSER, MARKUS, DE;
BERTAGNOLI, RUDOLF, AT;
LOWERY, GARY L., US;
EISEN, GUNTMAR H., DE

(74) **Agent:** TORYS LLP

(54) Titre : SYSTEME DE STABILISATION POSTERIEURE FONCTIONNELLEMENT DYNAMIQUE
(54) Title: POSTERIOR FUNCTIONALLY DYNAMIC STABILIZATION SYSTEM



(57) **Abrégé/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.

(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). HOLT Kamp, Bernhard [DE/DE]; Leopold-messmer-weg 14, D-78166 Donaueschingen (DE). SALVER-MOSER, 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).

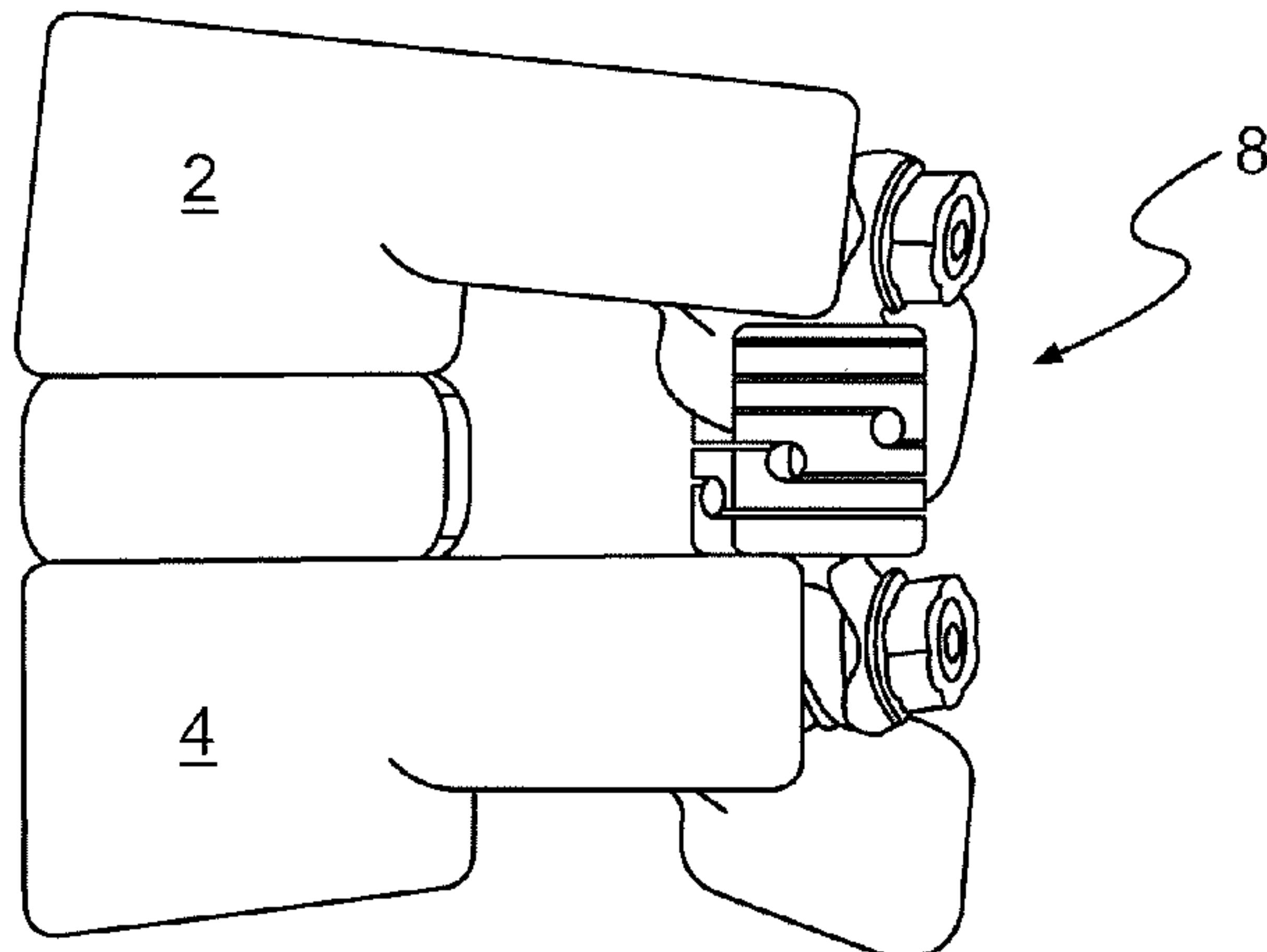
(74) Agent: McDONELL, Leslie, A.; Finnegan Henderson Farabow, Garrett & Dunner LLP, 901 New York Avenue, Washington, DC 20001-4413 (US).

(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



WO 2008/073830 A9

(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



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).

(88) Date of publication of the revised international search report:

15 January 2009

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*

(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 5 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 10 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 15 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 20 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. 25 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 5 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 10 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.

15 **SUMMARY**

[0006] The present disclosure provides a functionally dynamic stabilization unit and system for treatment of spinal instability due to, for example, 20 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 25 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 30 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 5 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 10 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 15 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.

20 [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 25 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 30 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.

5 [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.

10 BRIEF DESCRIPTION OF THE DRAWINGS

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

15 [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.

20 [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.

25 [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.

5 [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.

10 [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.

15 [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.

20 [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.

25 [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 5 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.

10 [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.

15 [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.

20 [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 25 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 5 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 10 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 15 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 20 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 25 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 30 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 5 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 10 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 15 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 20 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 25 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, 30 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 used 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. 5 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. 10 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 15 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.

20 [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 25 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 30 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 5 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 10 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 15 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 20 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 25 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 30 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,

5 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.

10 [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.

15 [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 20 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.

25 [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 30. 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.

5 [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.

10 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

15 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.

20 [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 25 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 30 278 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.

5 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 10 182, 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 15 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 20 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 25 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 30 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

10 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

15 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.

20 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:

25 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

5 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 10 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 15 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.

20 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.

25 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

5 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.

10 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.

15 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.

20 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

30 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
5 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.

10 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

15 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
20 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
25 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.

30 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.

5 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;

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

15 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

25 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 5 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 10 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 15 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 20 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 25 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;

5 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.

10 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.

15 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

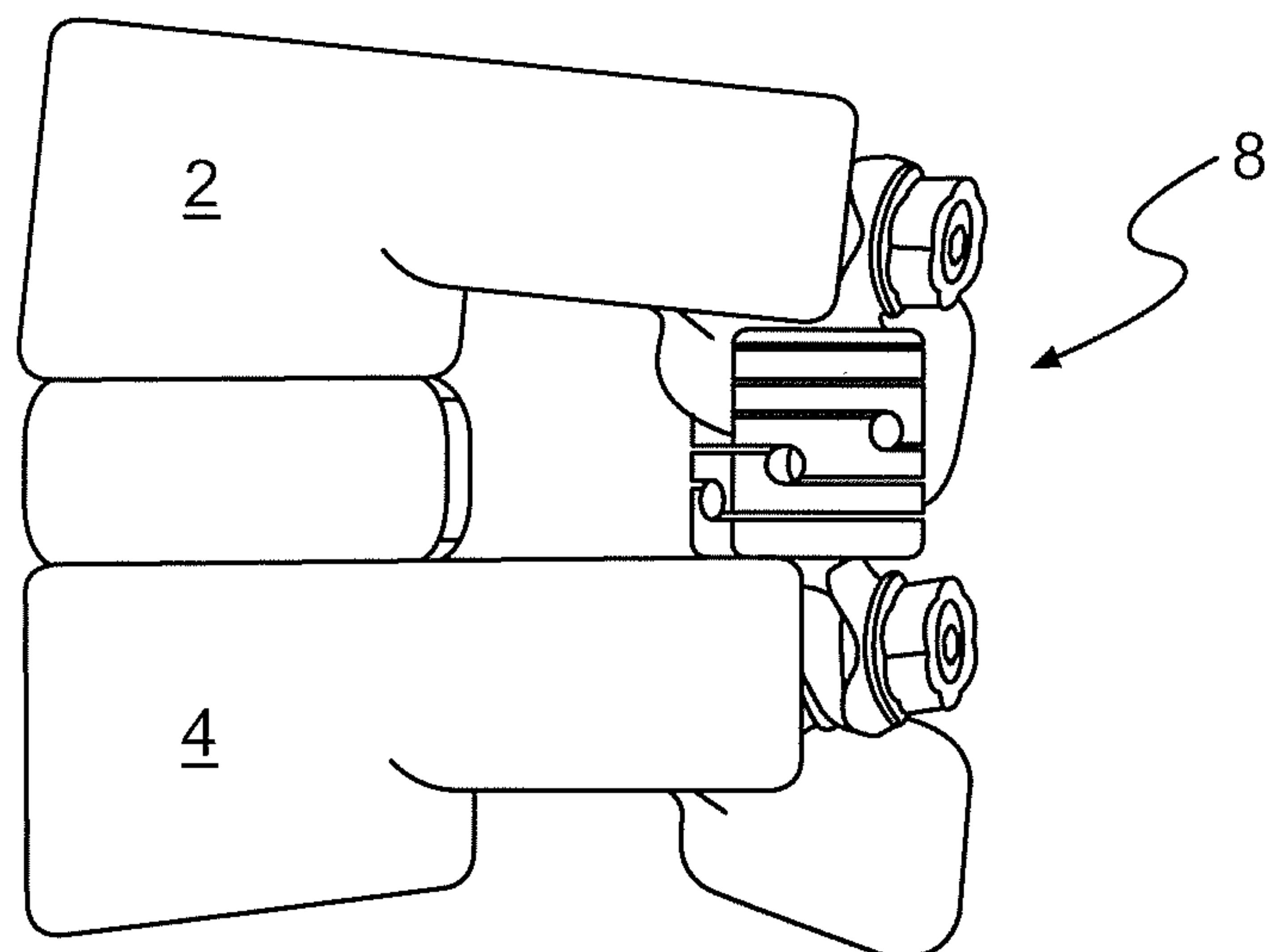
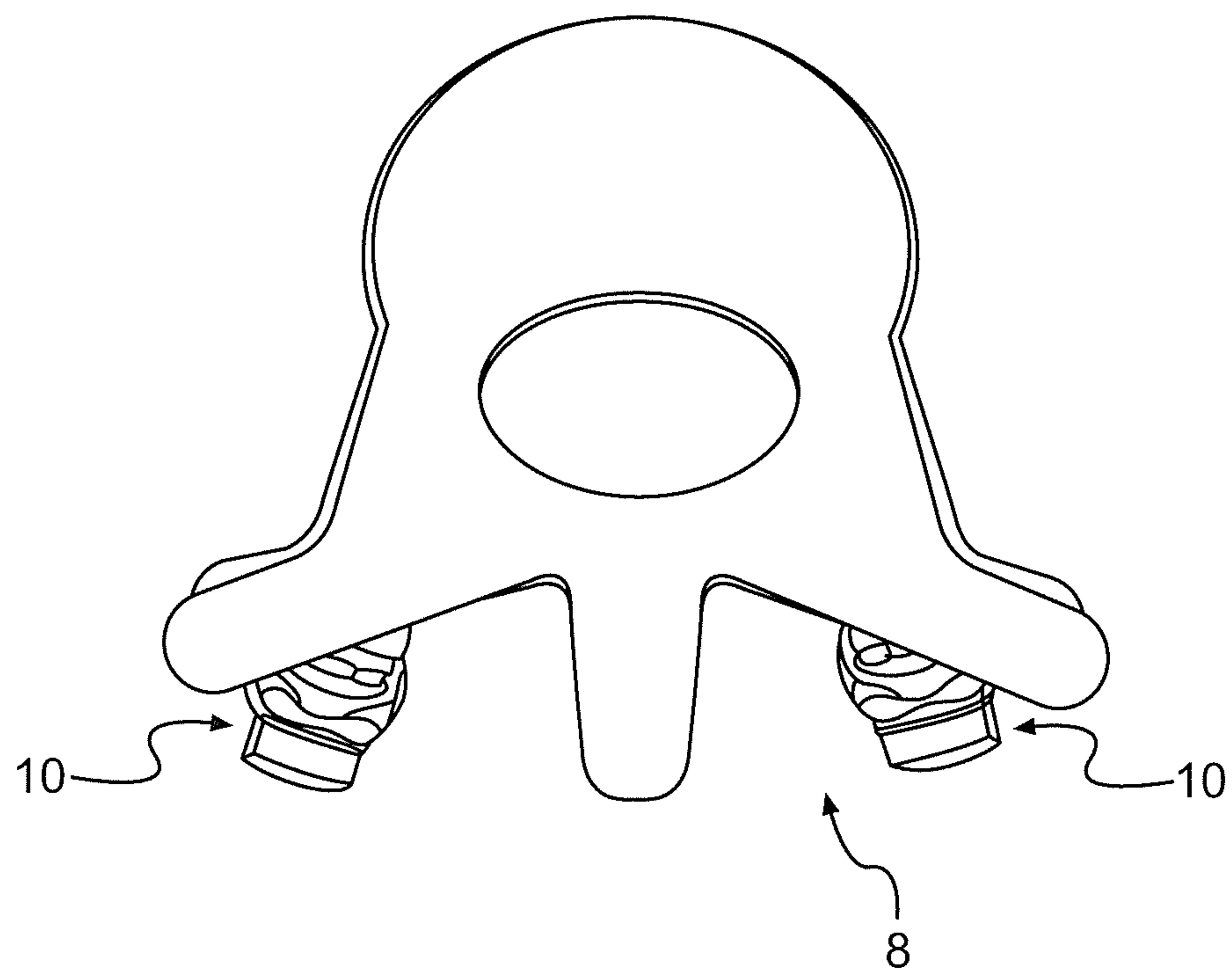
20 attaching a rigid coupler to the third screw and to one of the first and second screws.

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

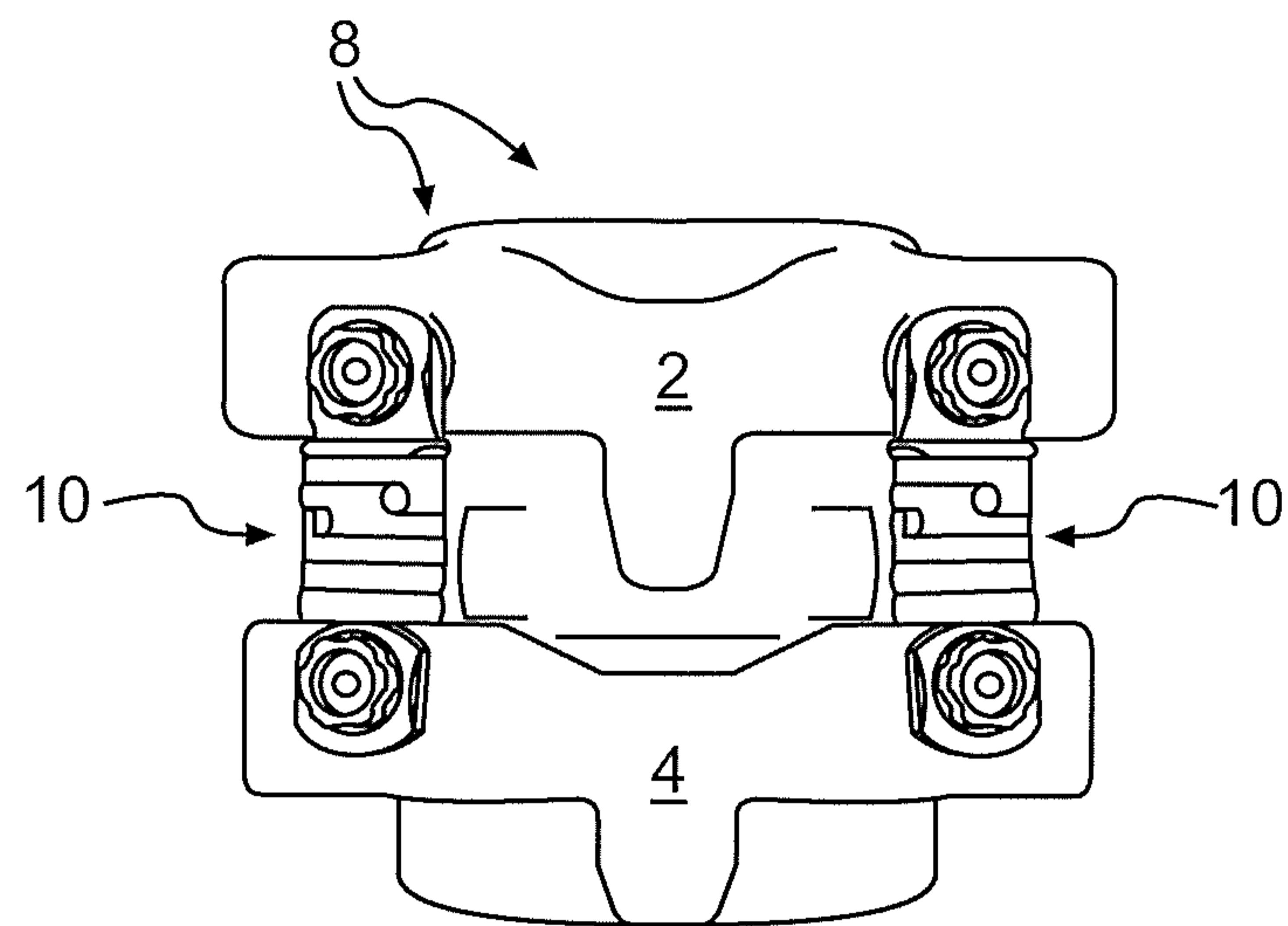
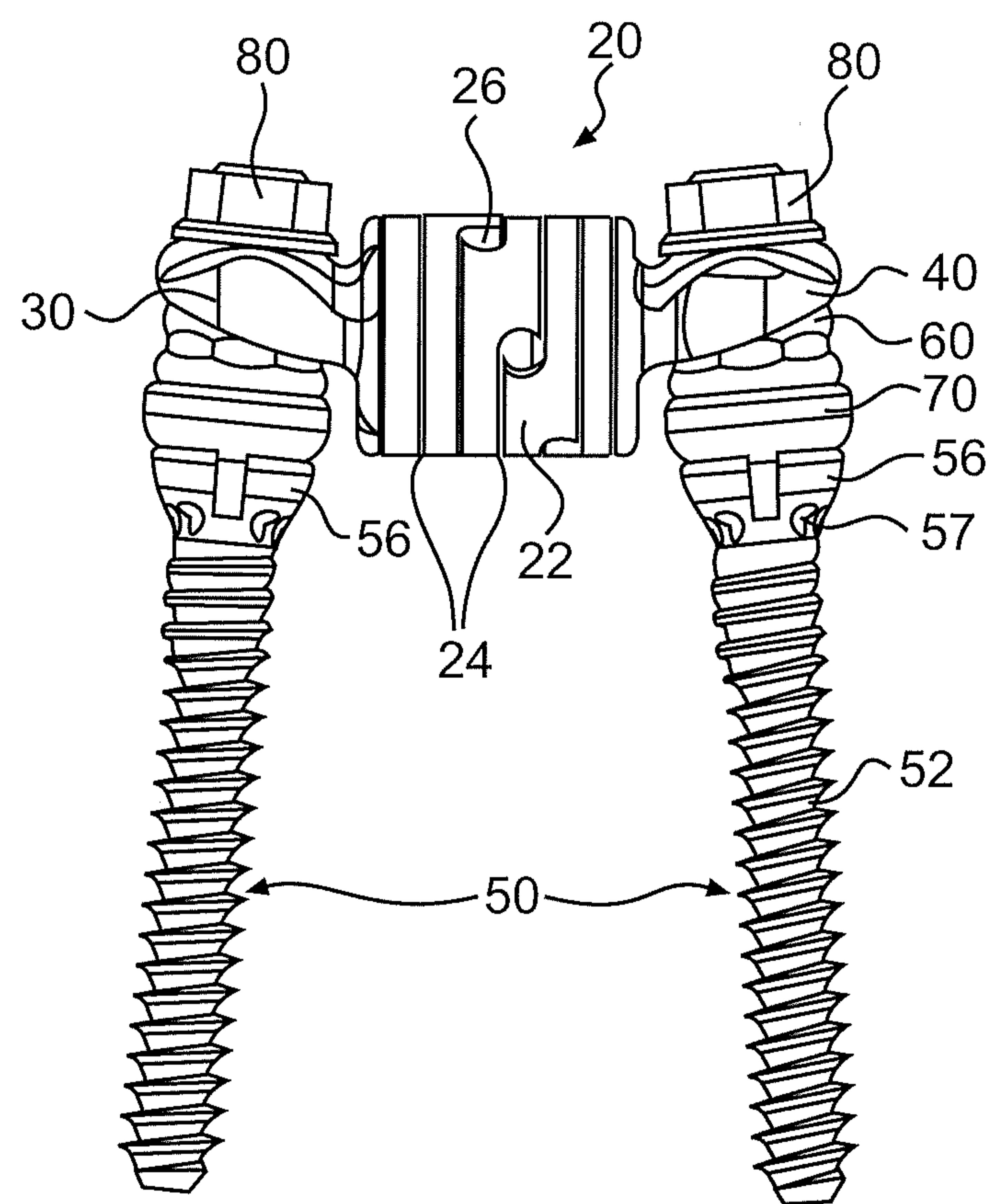
25 55. The method of claim 54, further adjusting a length of the rigid coupler to fit between the third screw and the one of the first and second screws.

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.

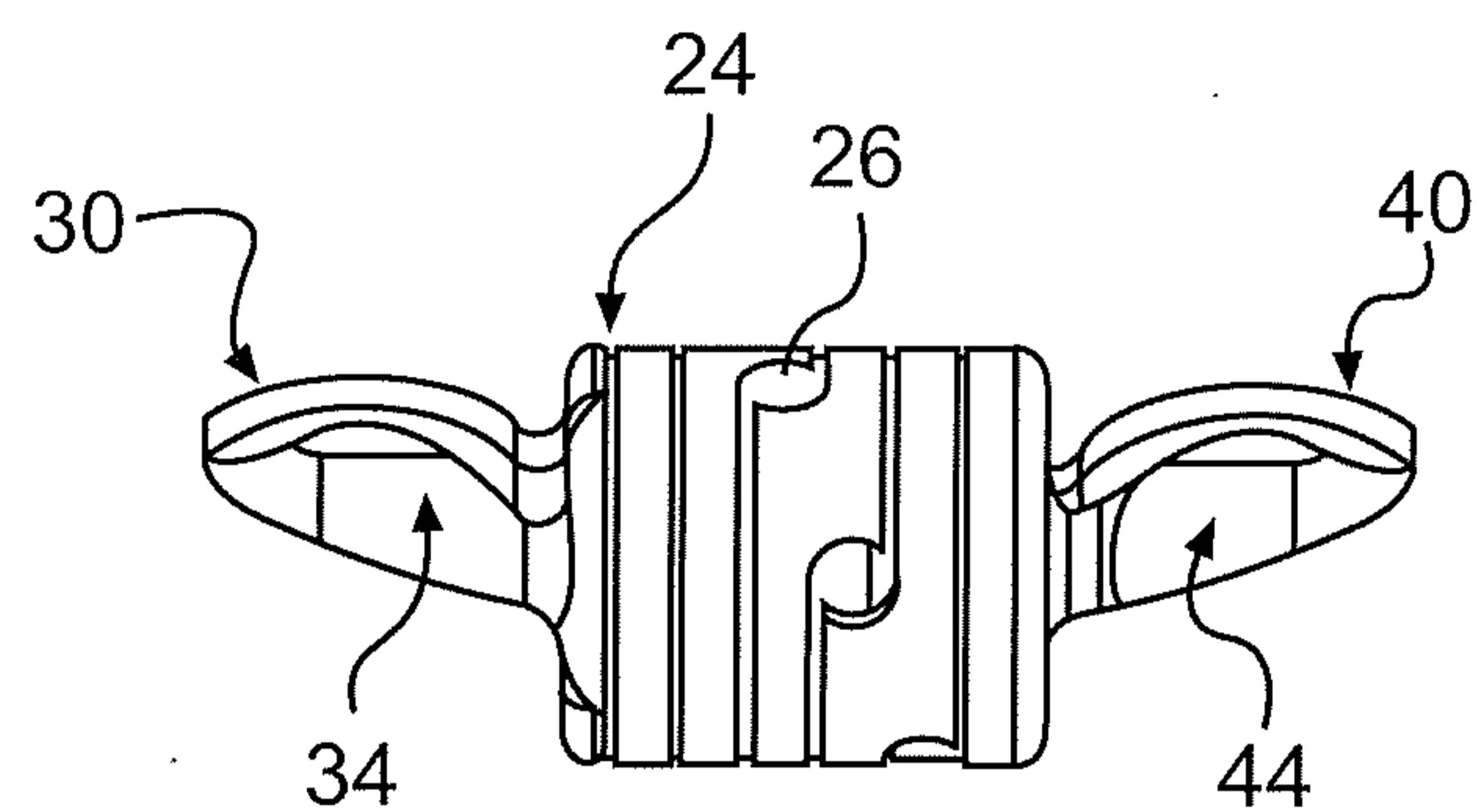
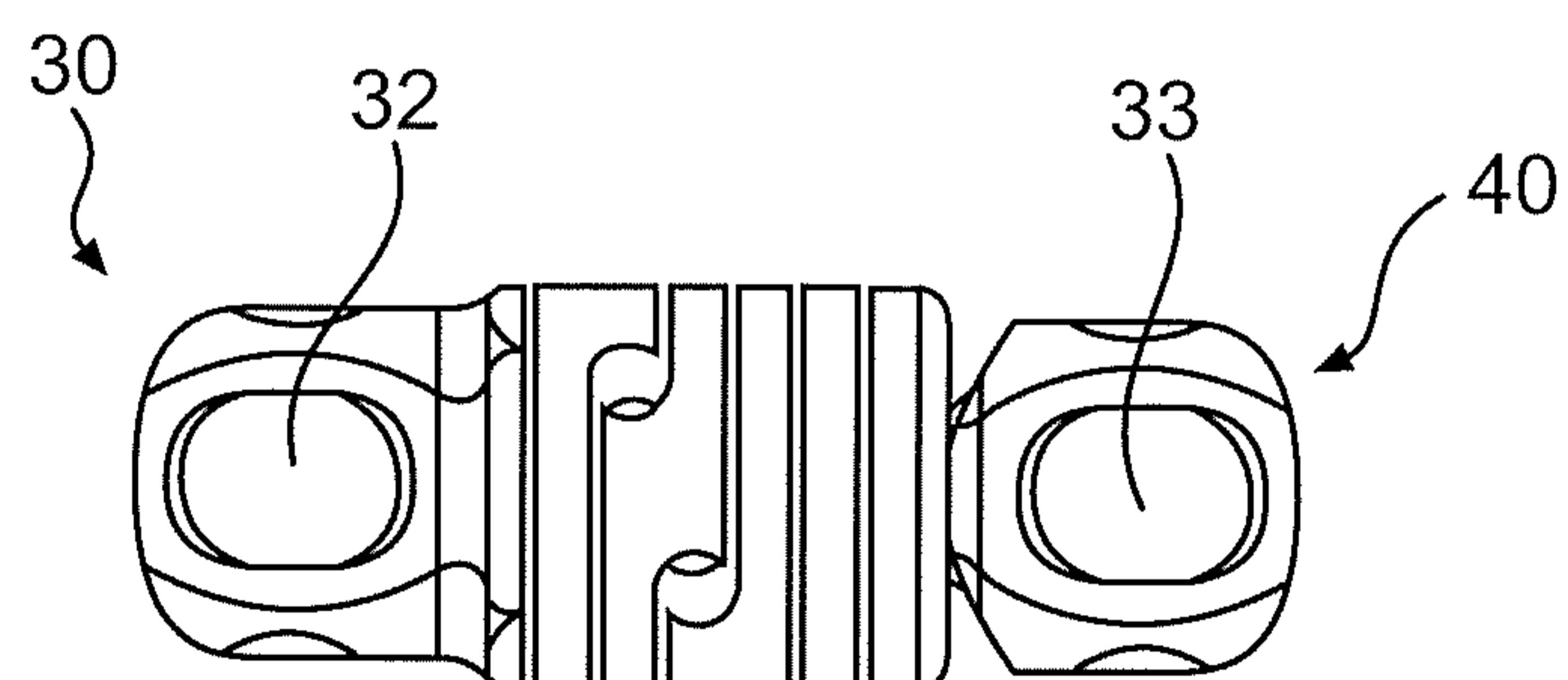
1/17

**FIG. 1****FIG. 2**

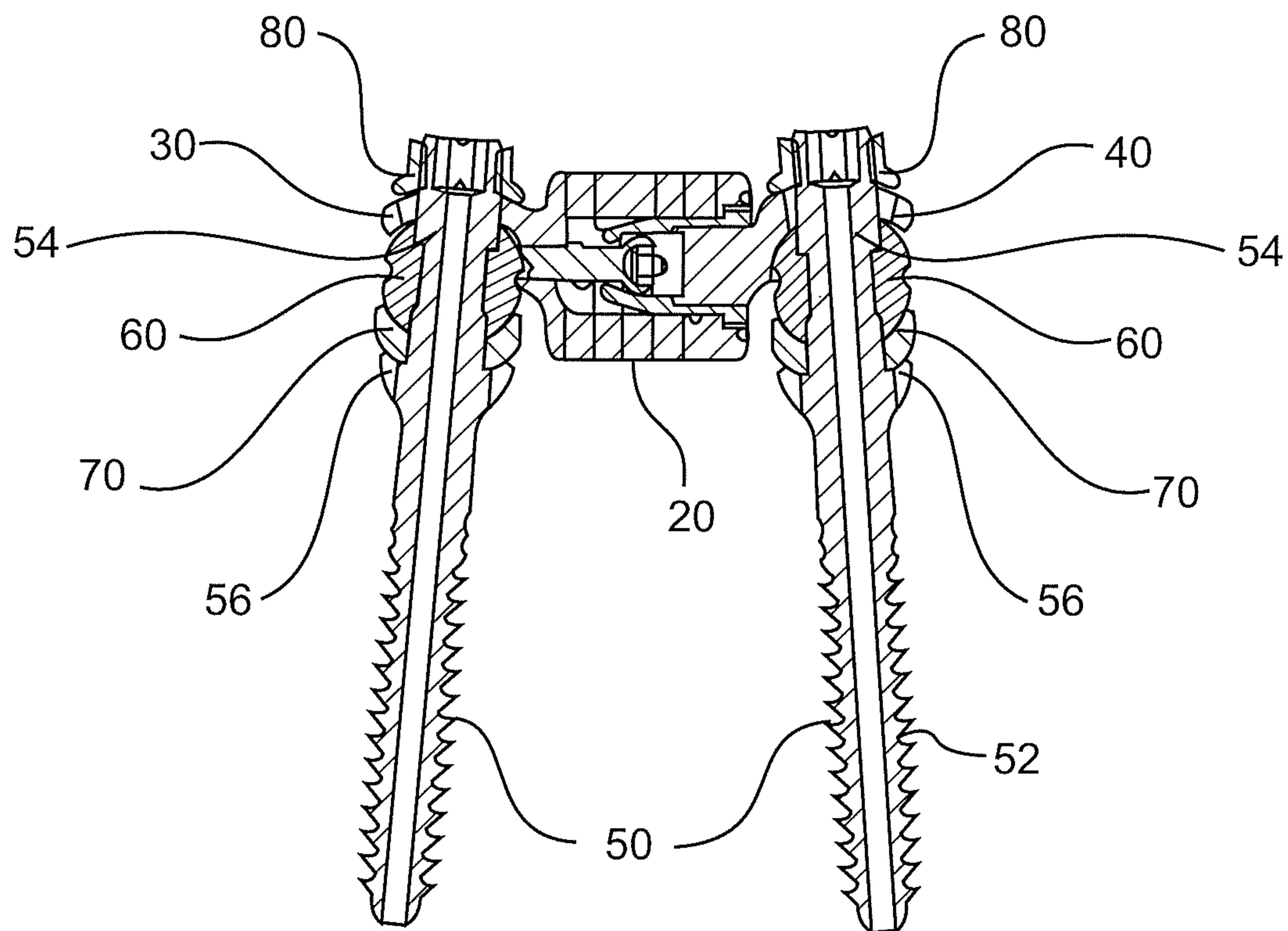
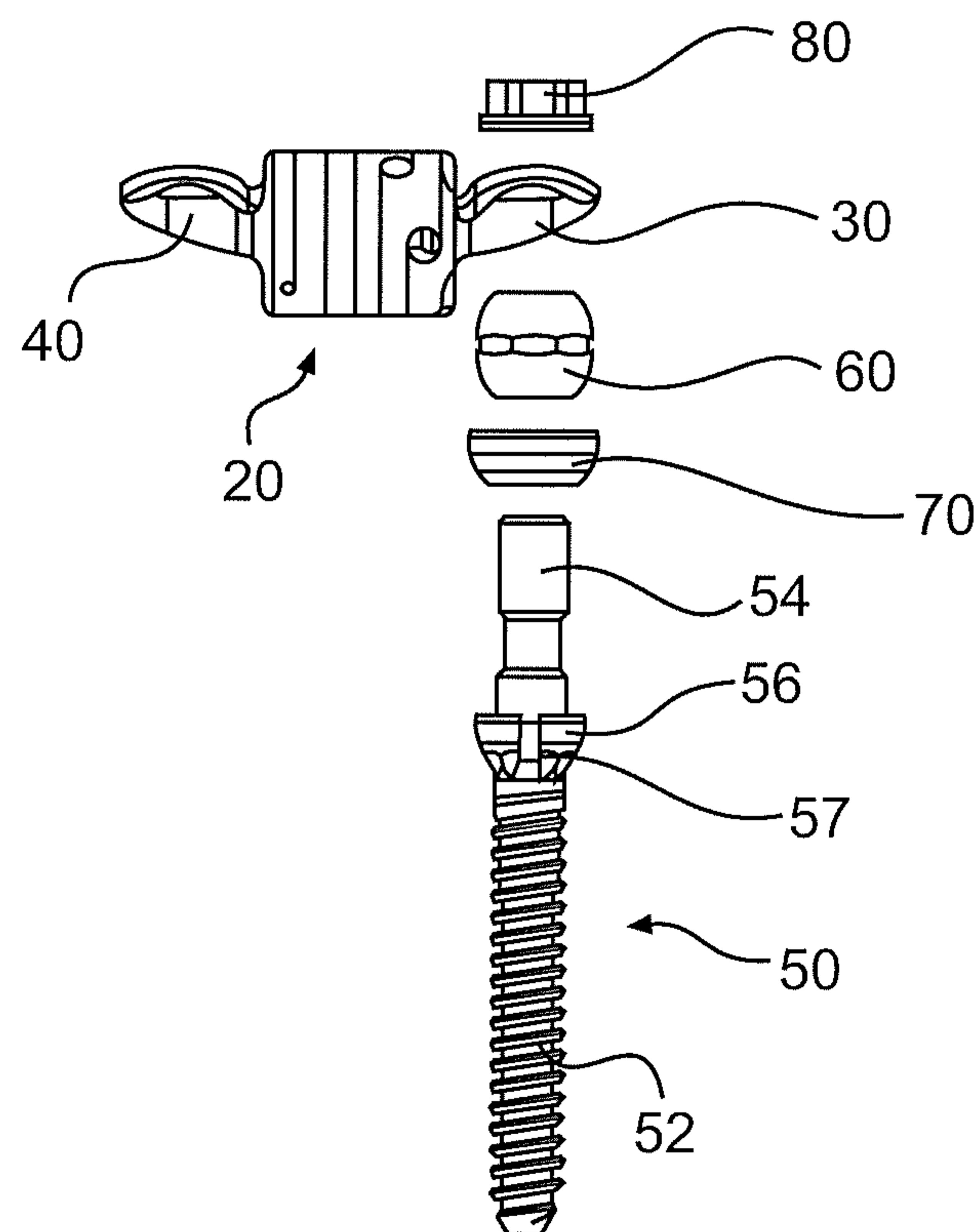
2/17

**FIG. 3****FIG. 4A**

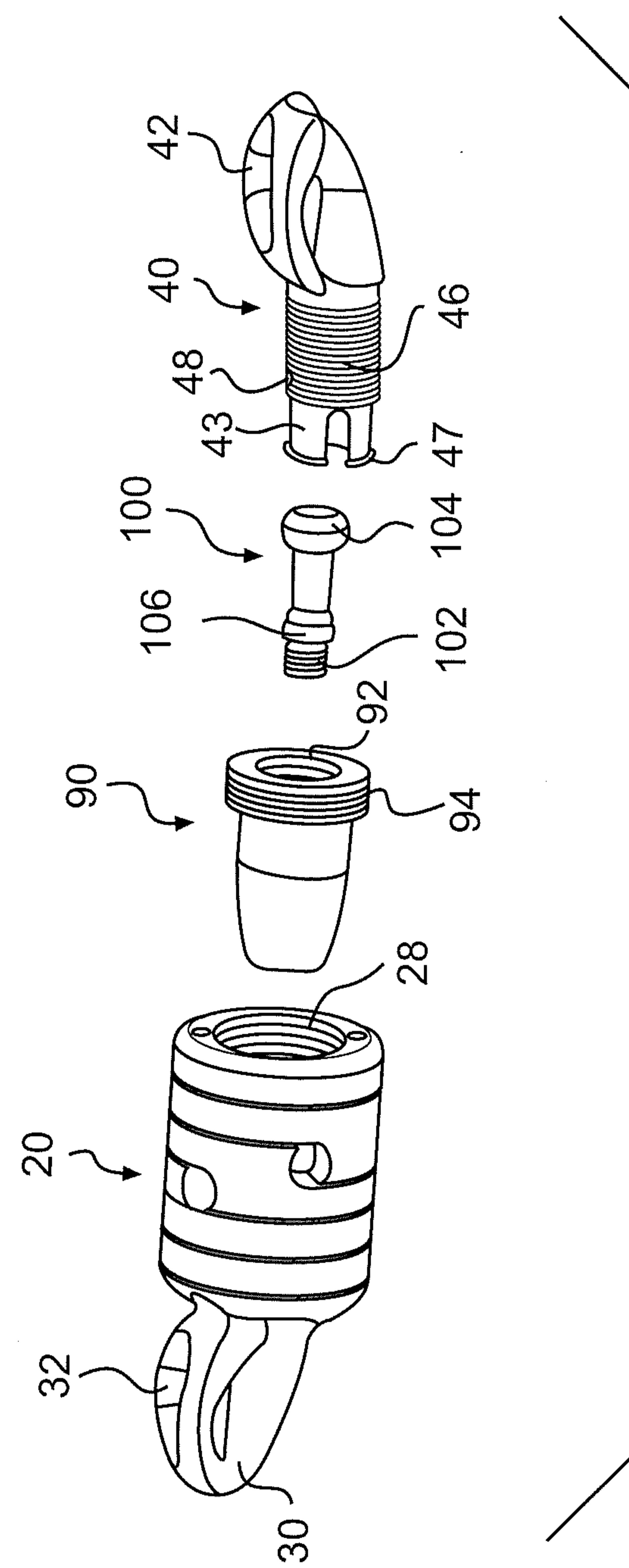
3/17

**FIG. 4B****FIG. 4C**

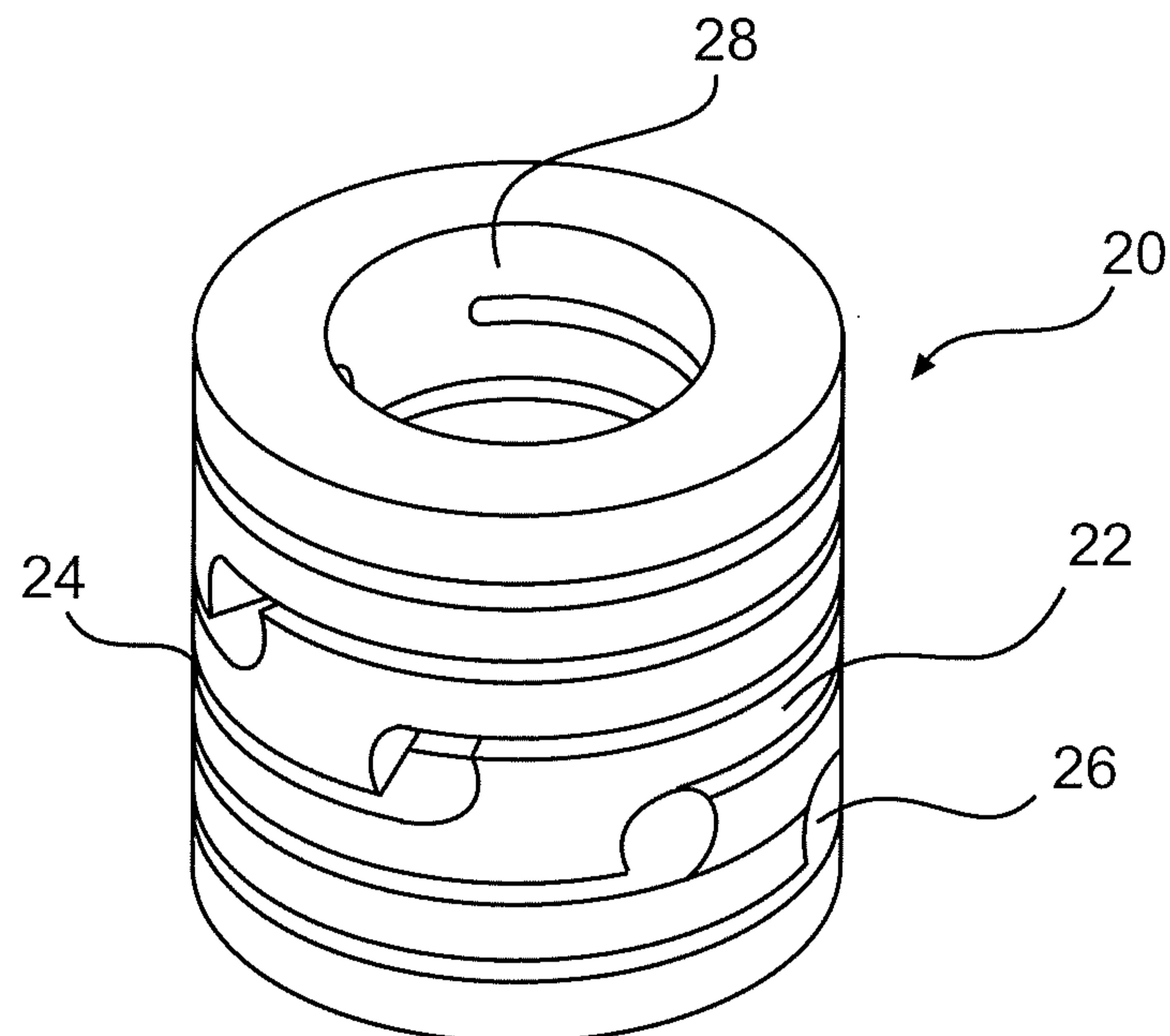
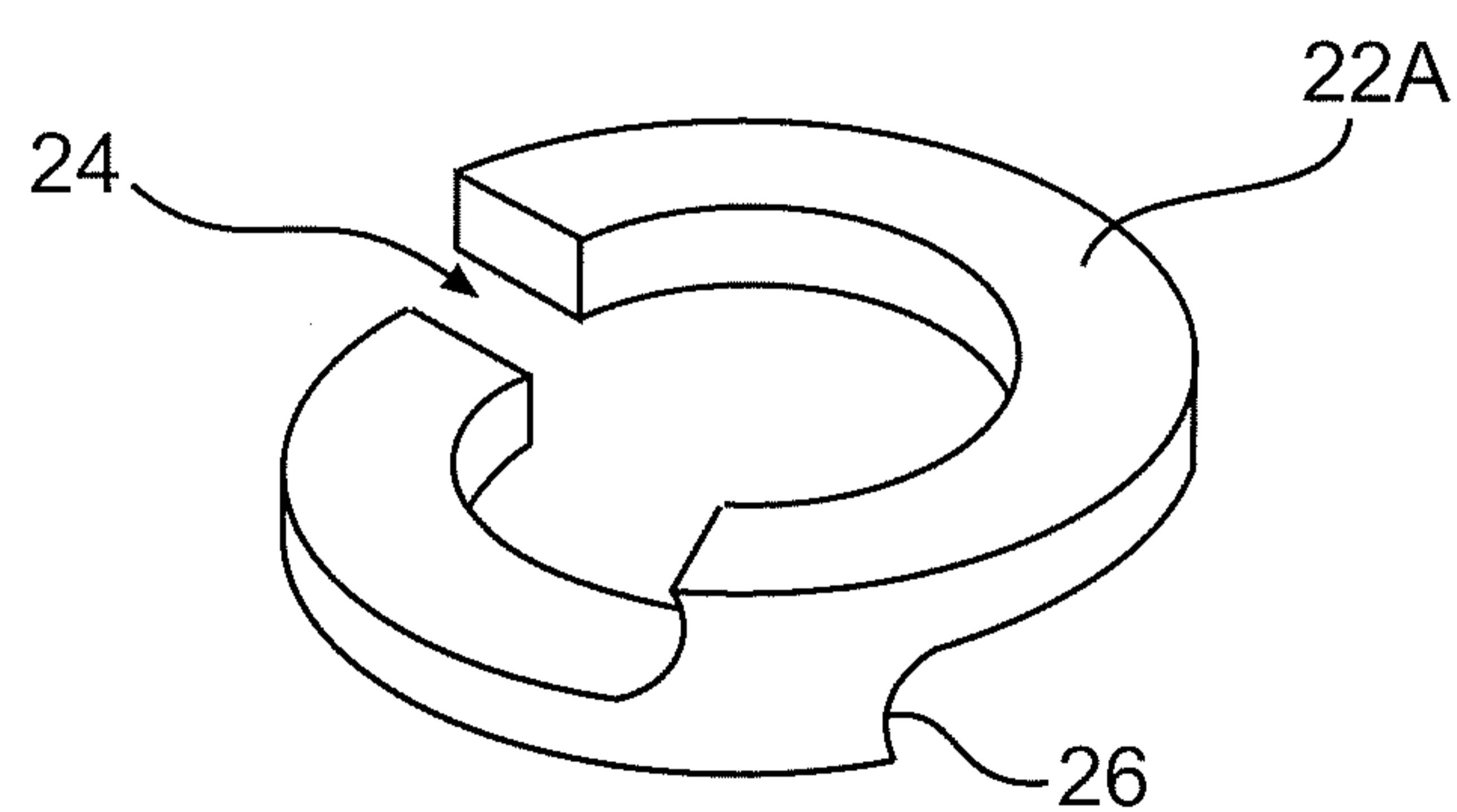
4/17

**FIG. 5A****FIG. 5B**

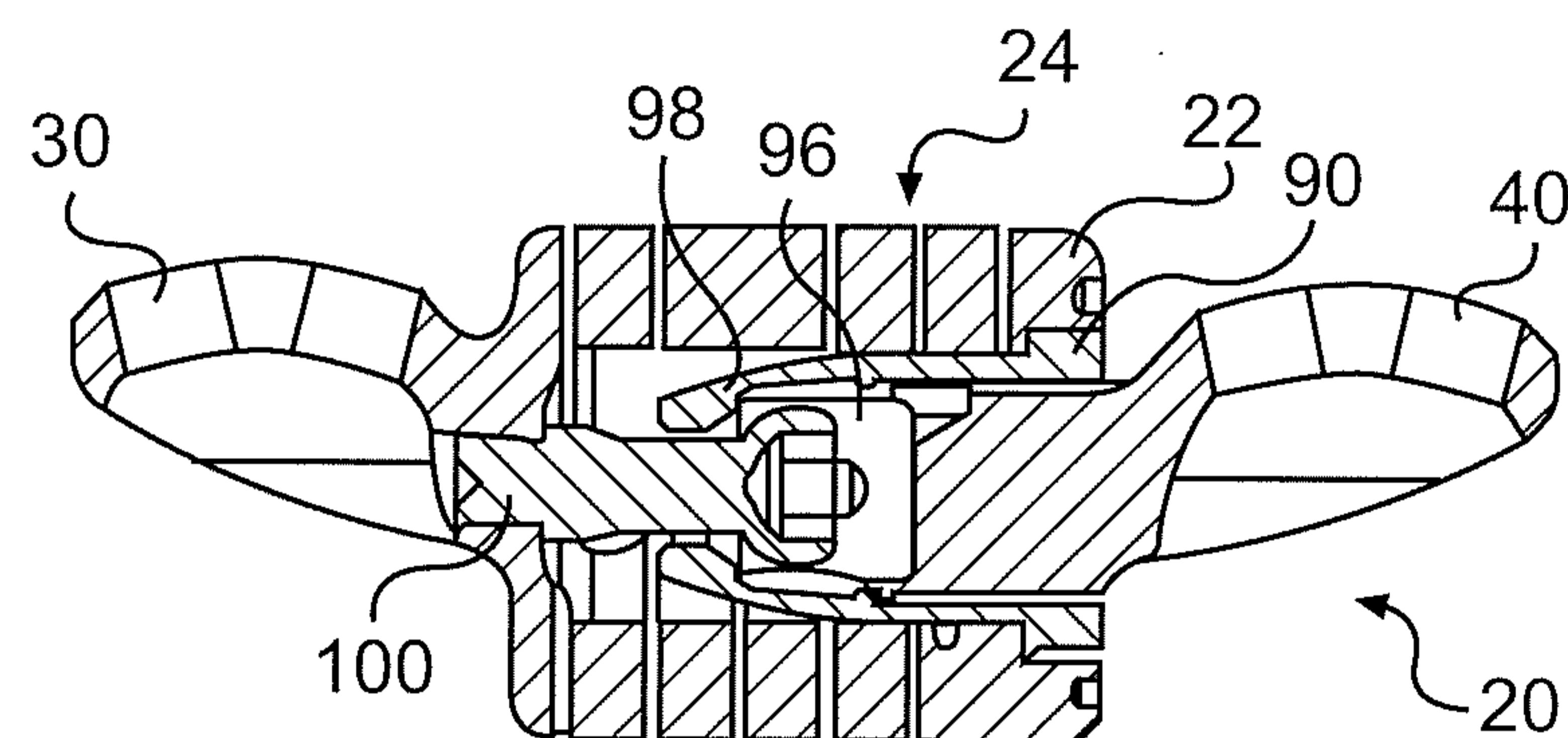
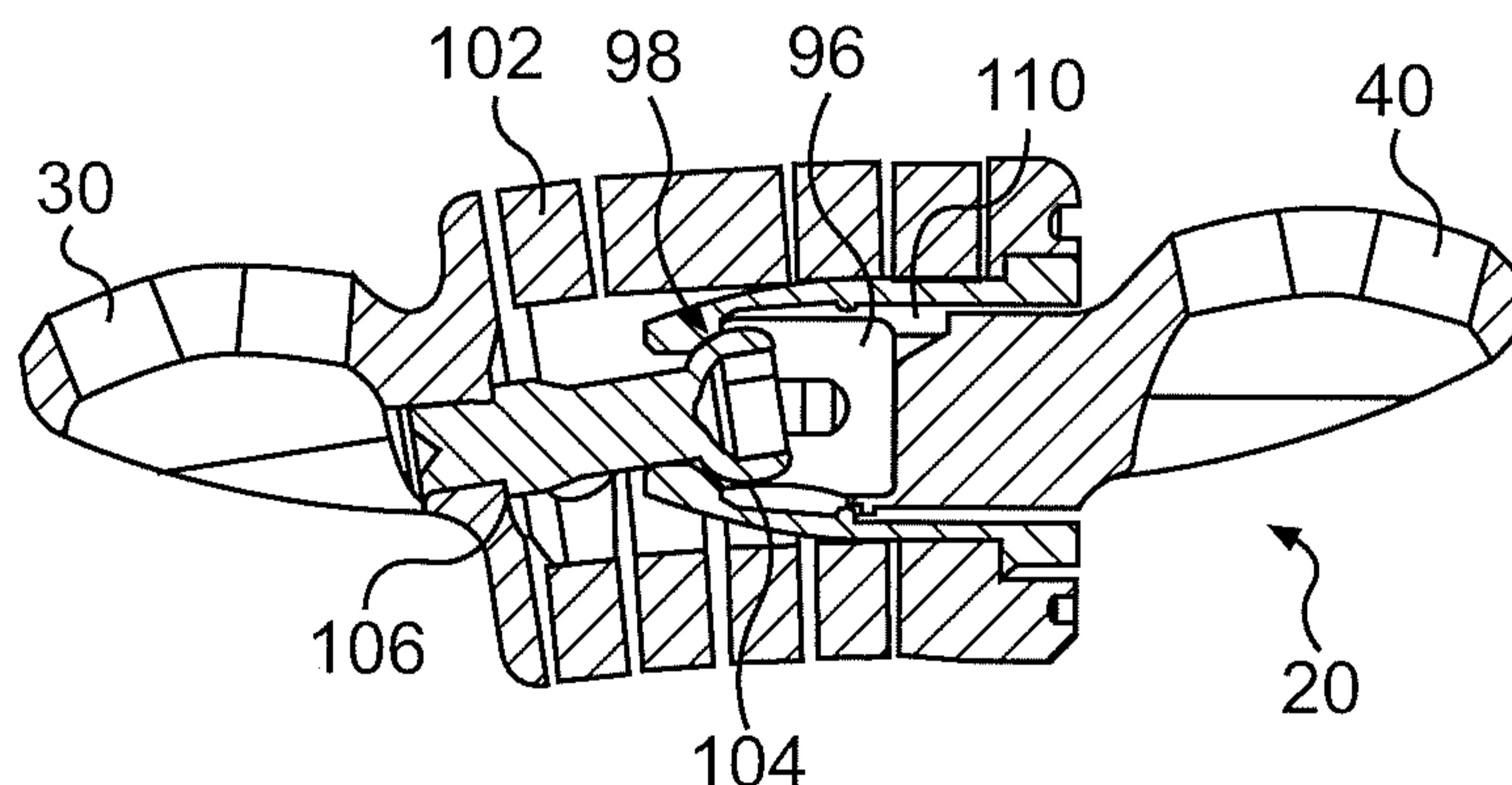
5/17

**FIG. 6**

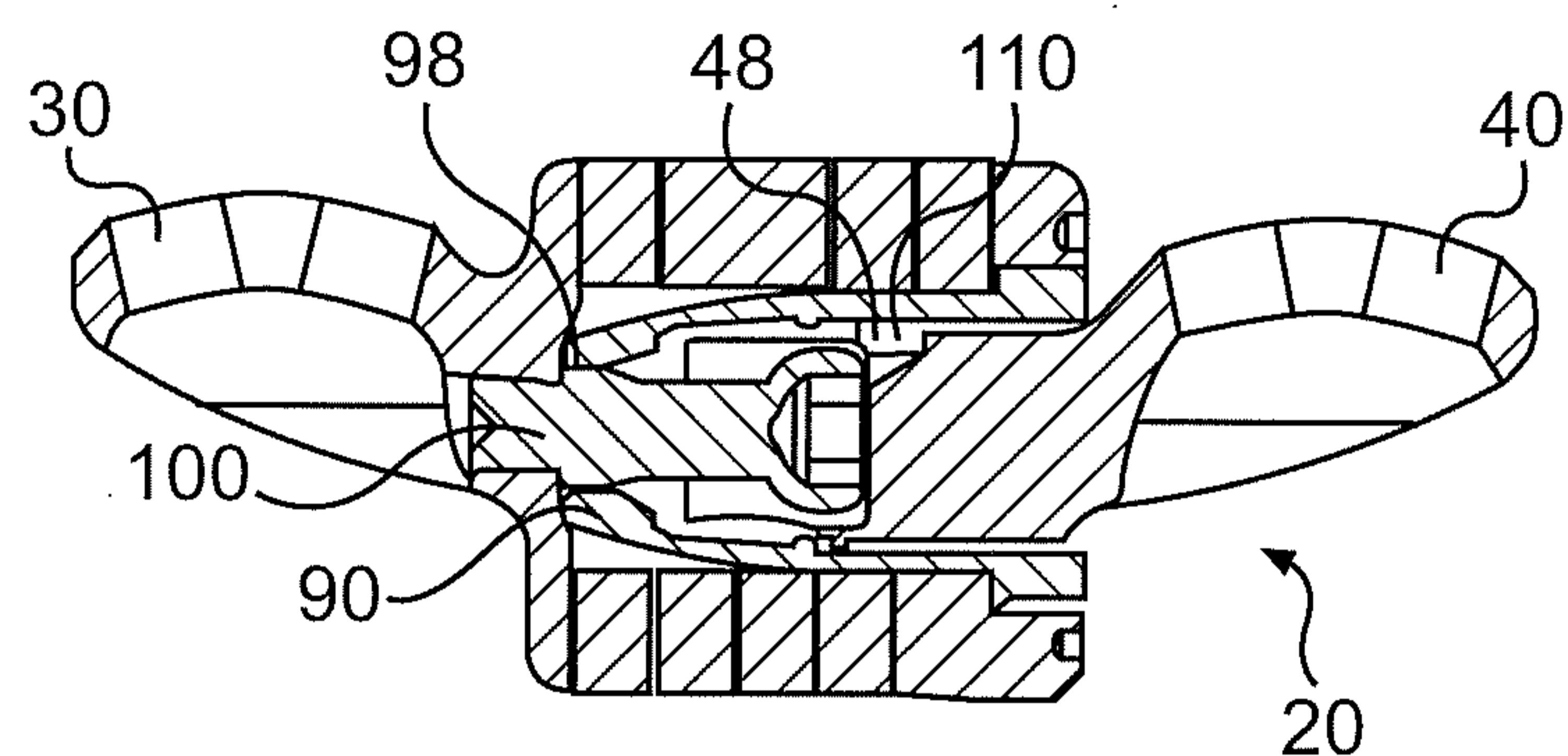
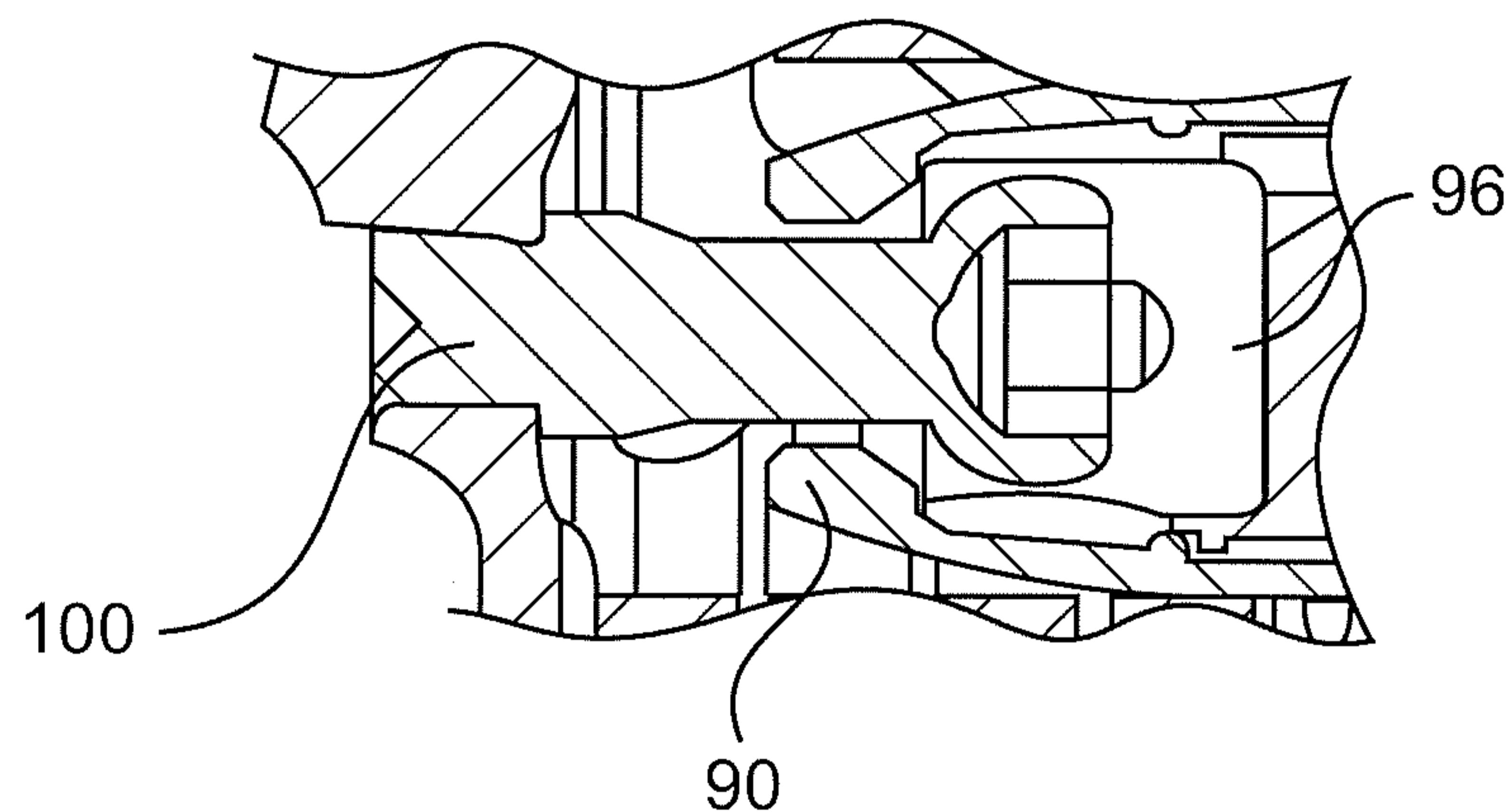
6/17

**FIG. 7A****FIG. 7B**

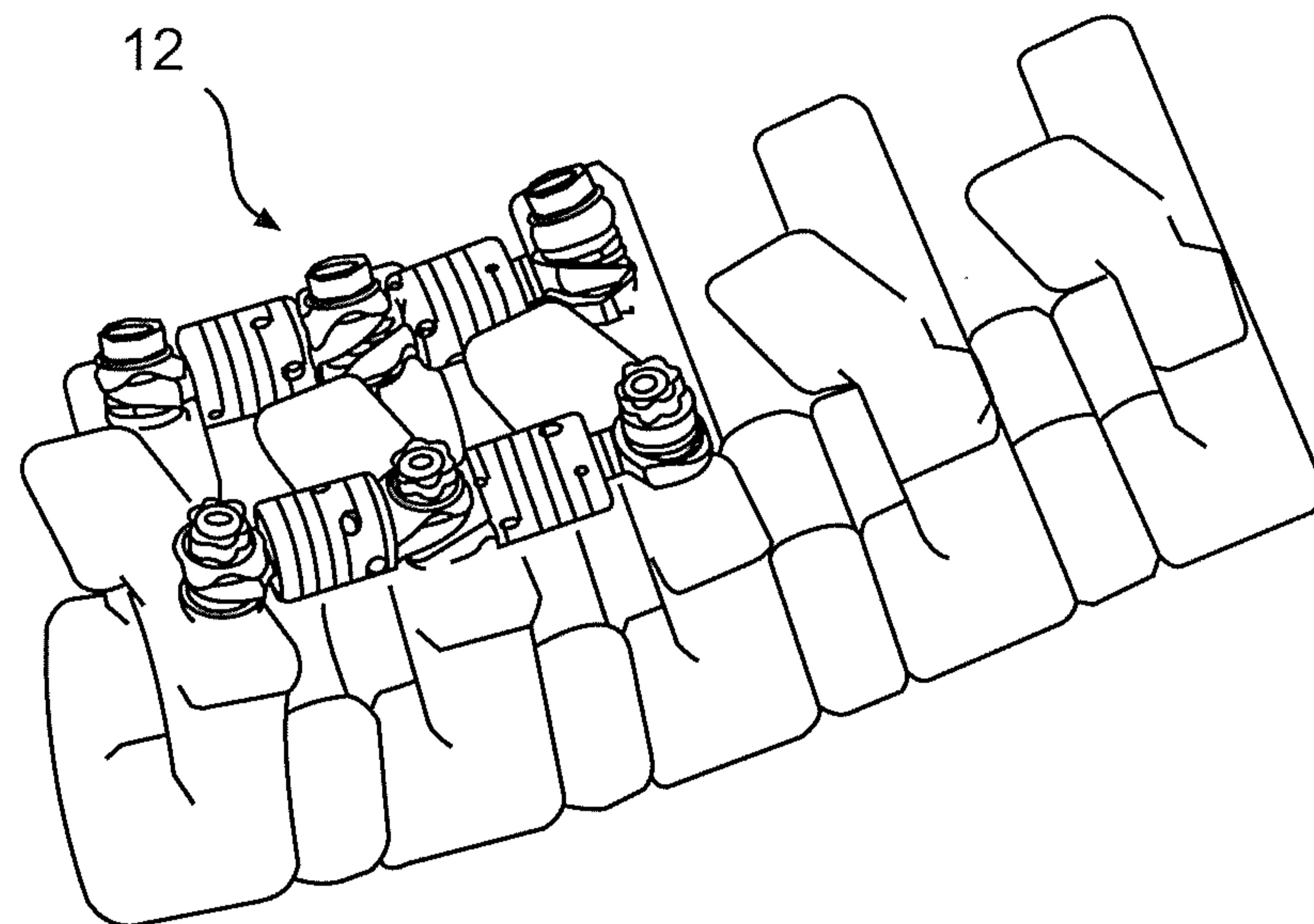
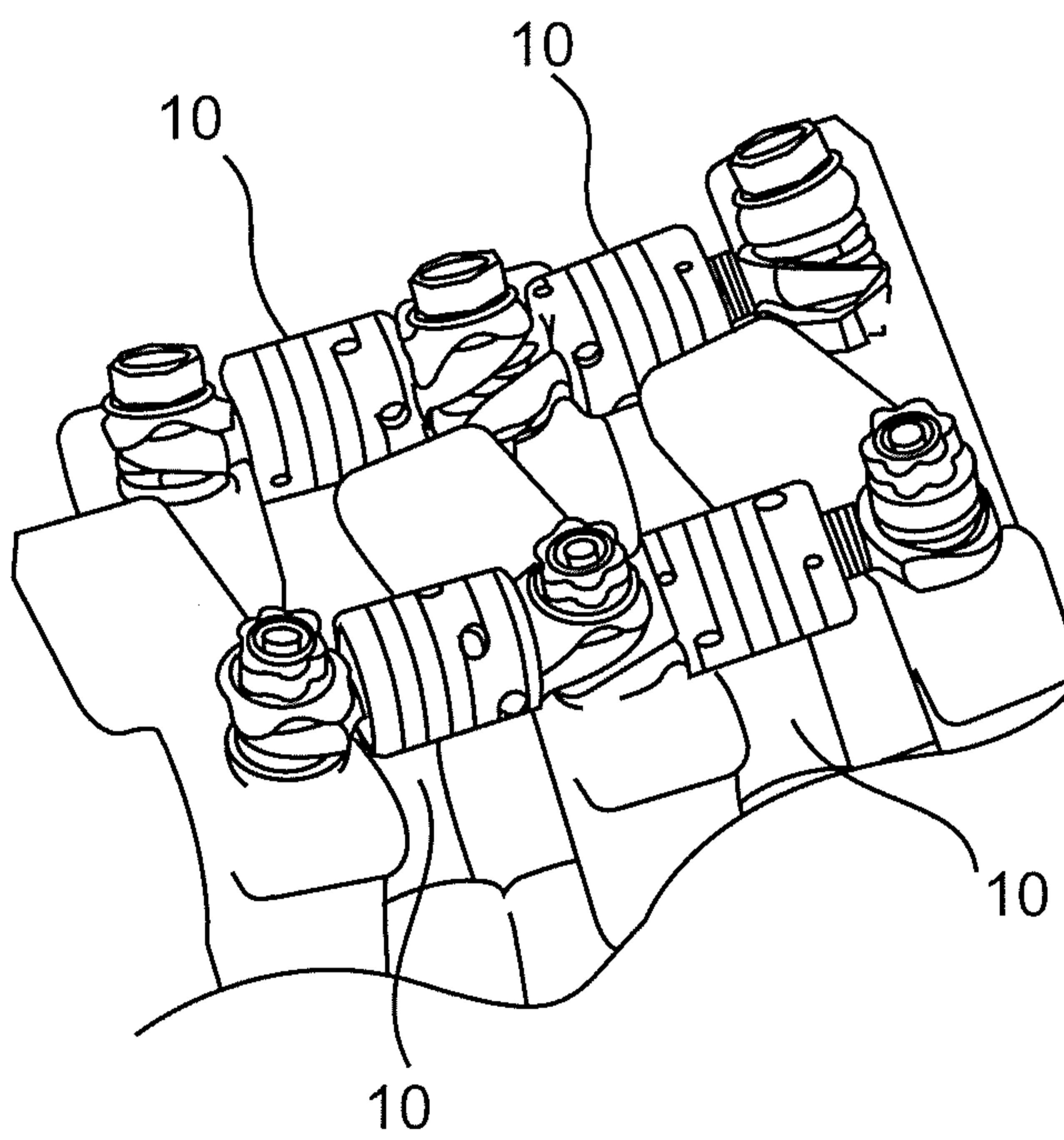
7/17

**FIG. 8A****FIG. 8B**

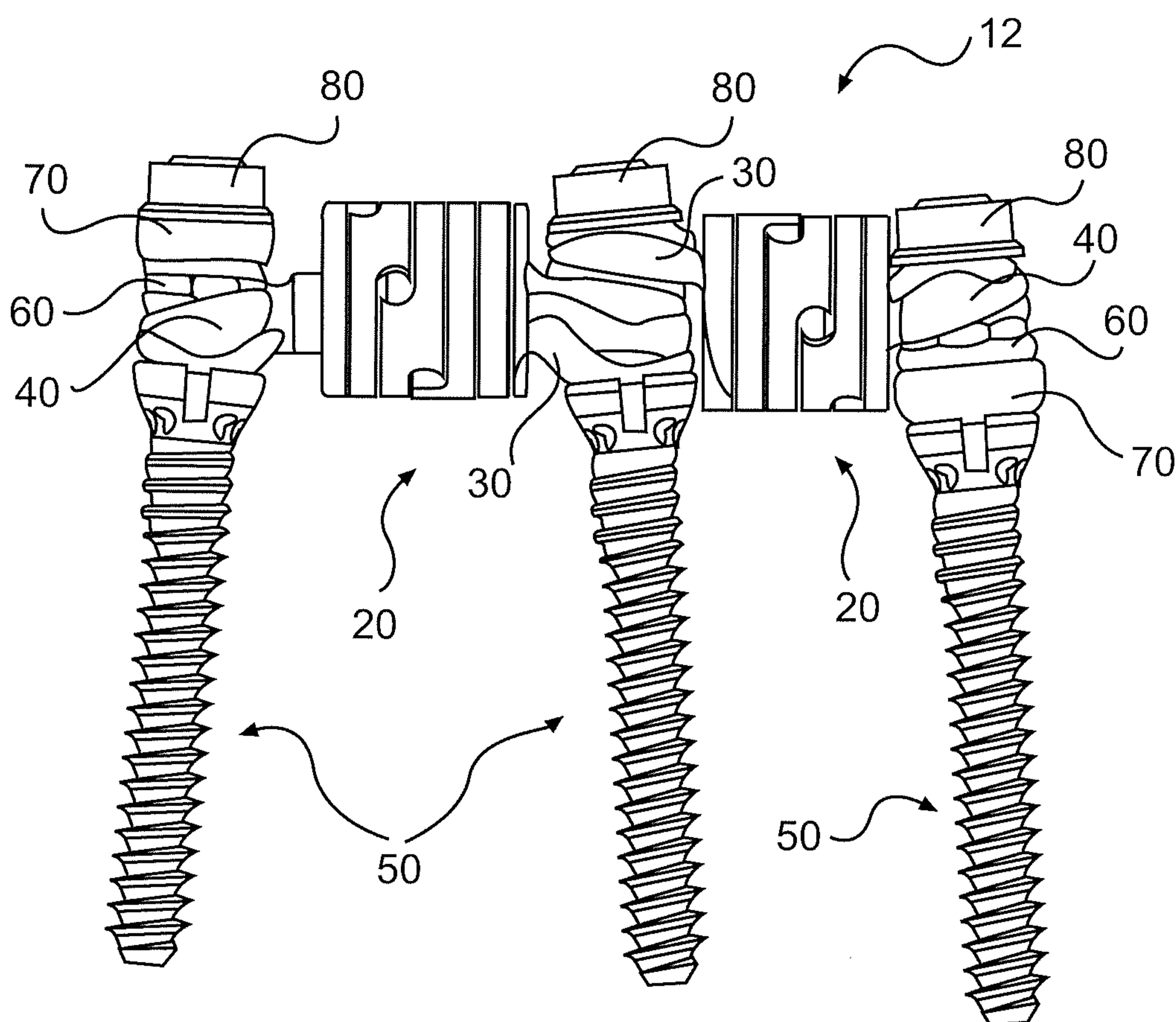
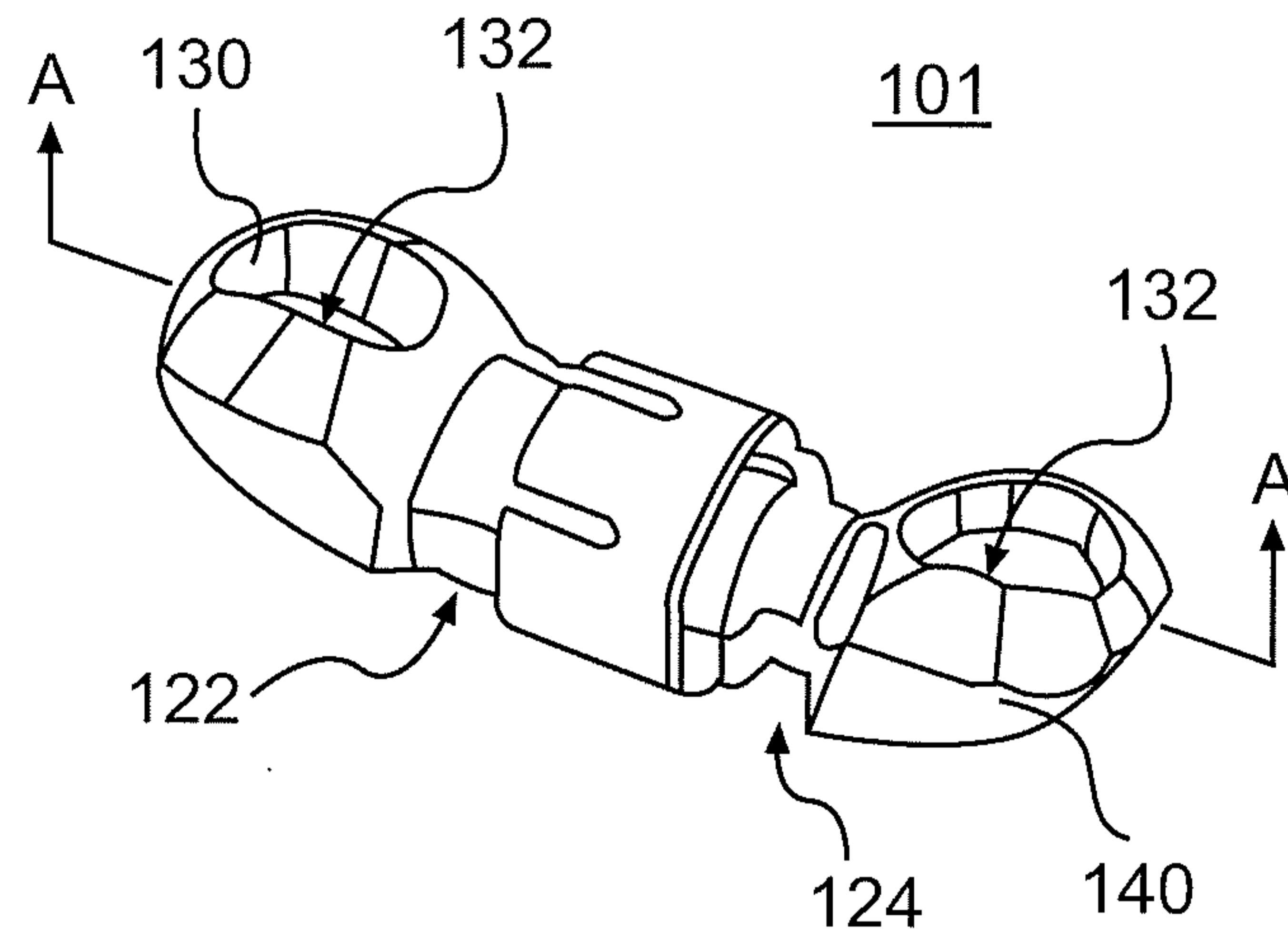
8/17

**FIG. 8C****FIG. 8D**

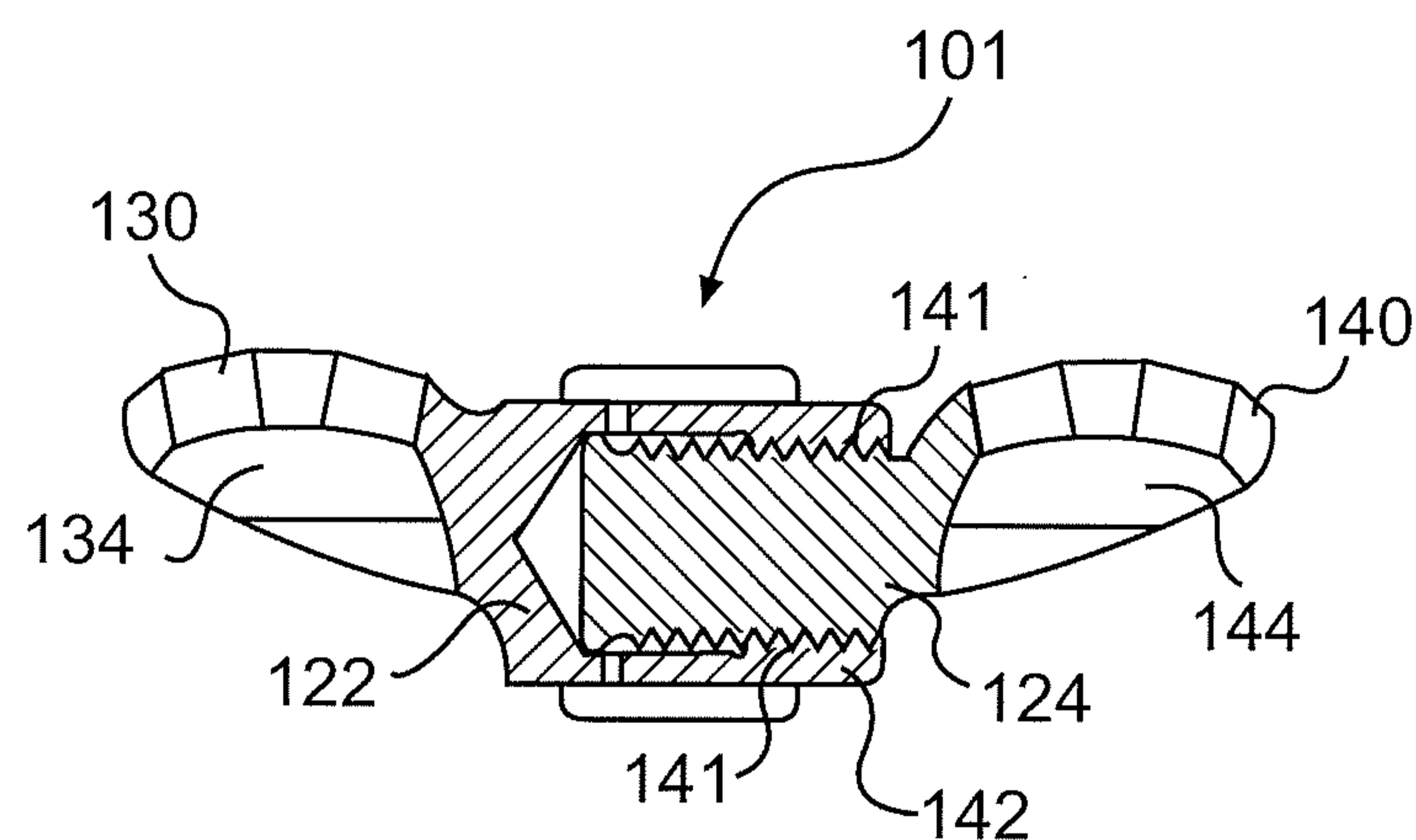
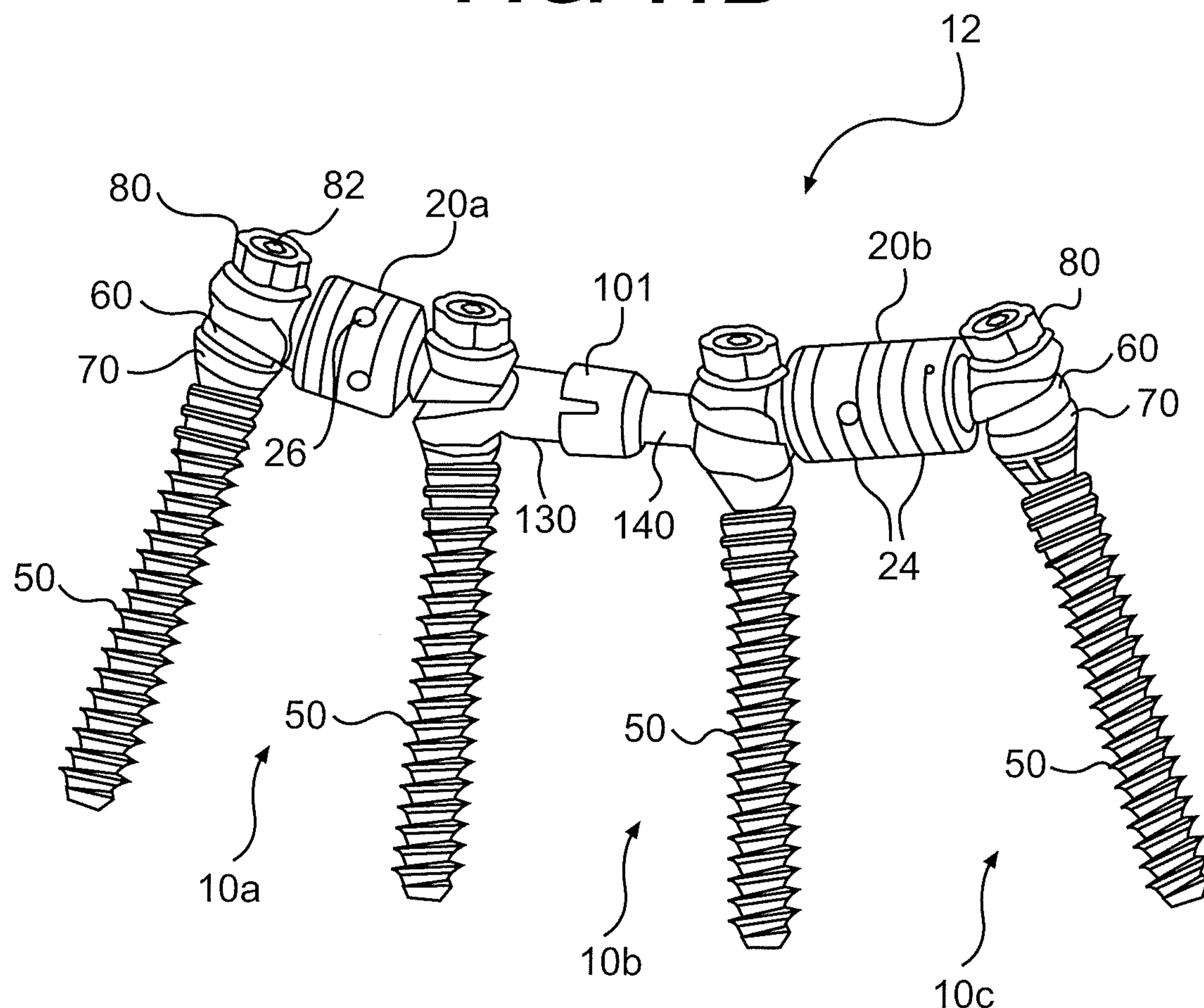
9/17

**FIG. 9A****FIG. 9B**

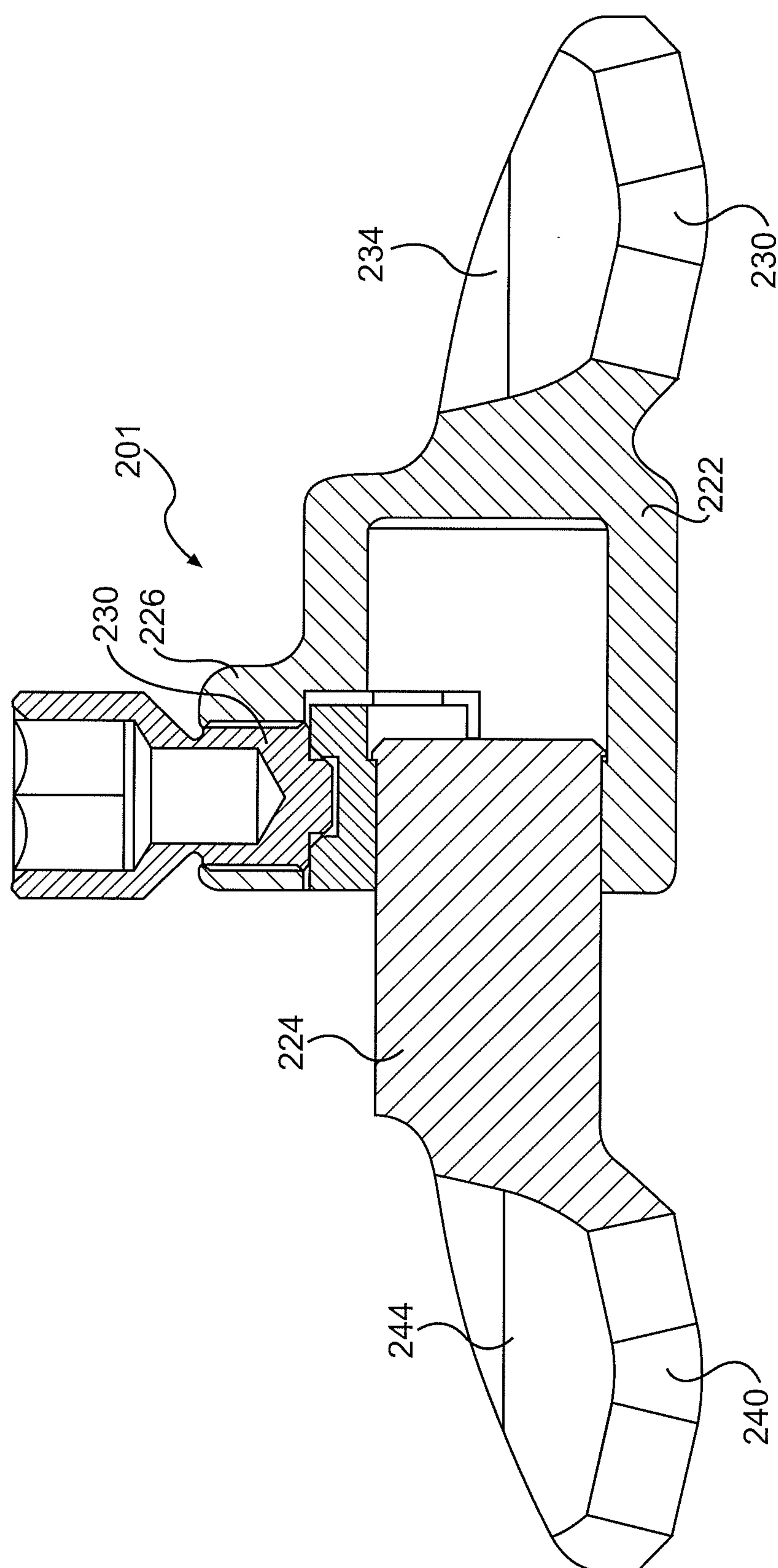
10/17

**FIG. 10****FIG. 11A**

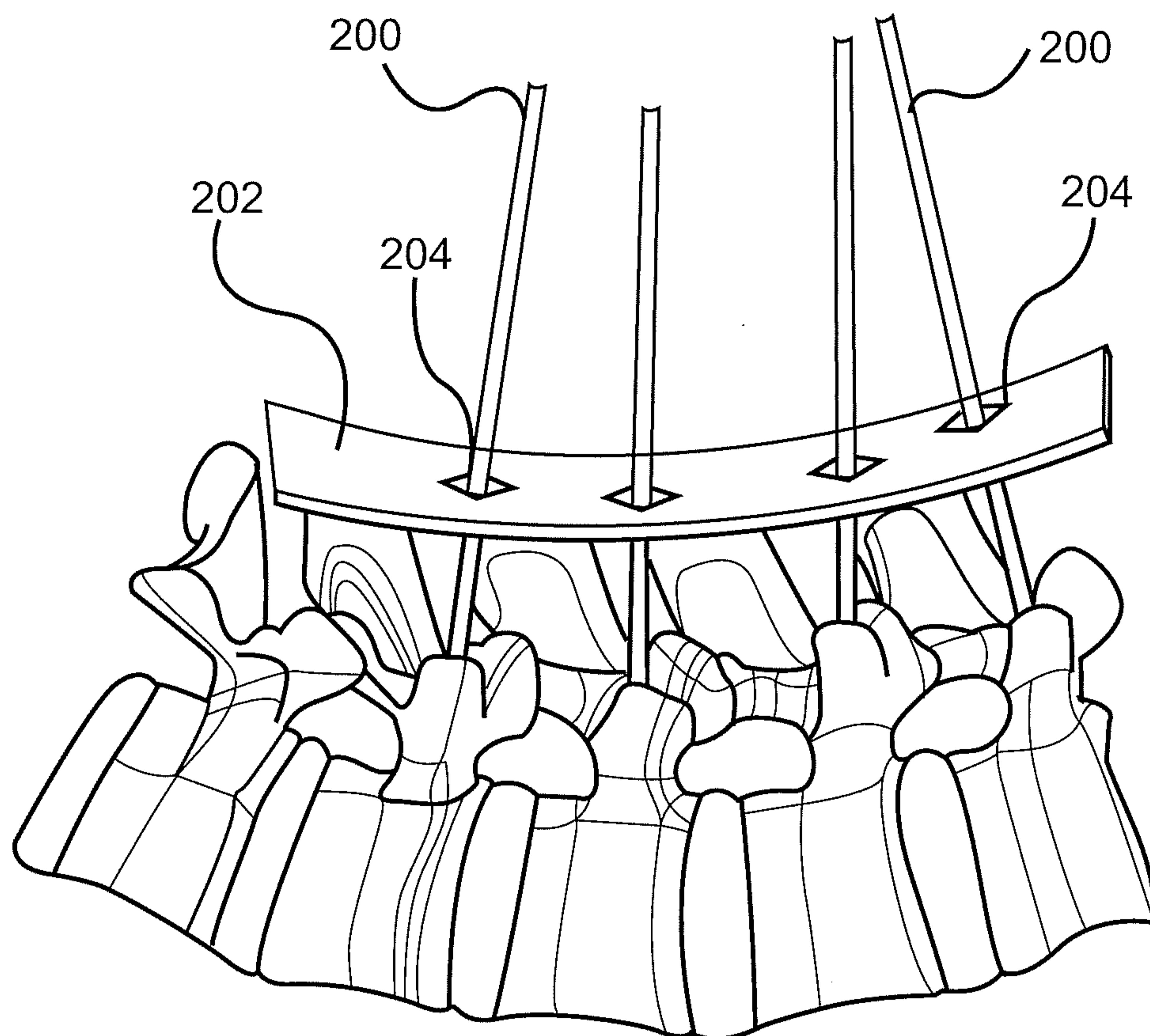
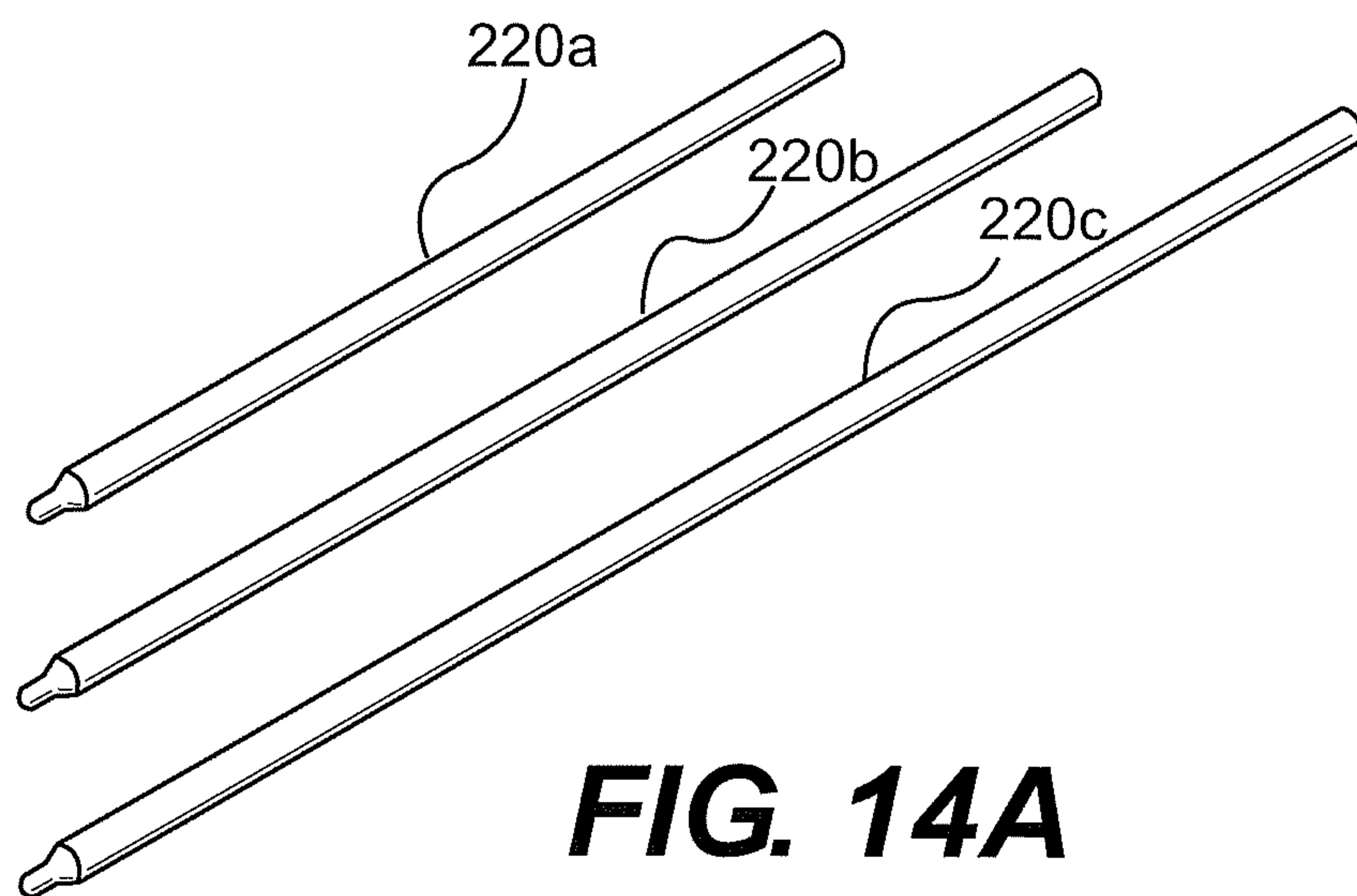
11/17

**FIG. 11B****FIG. 12**

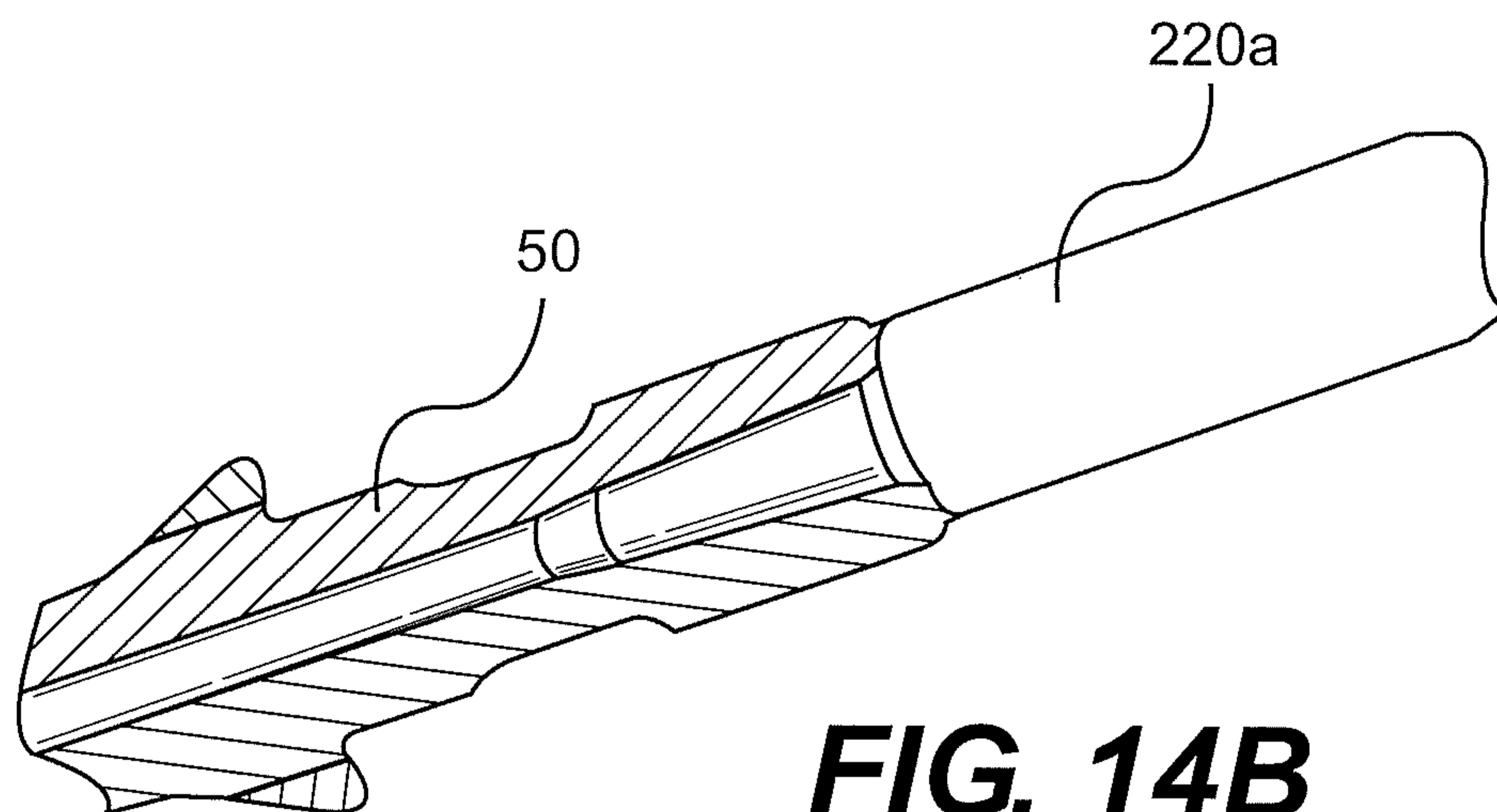
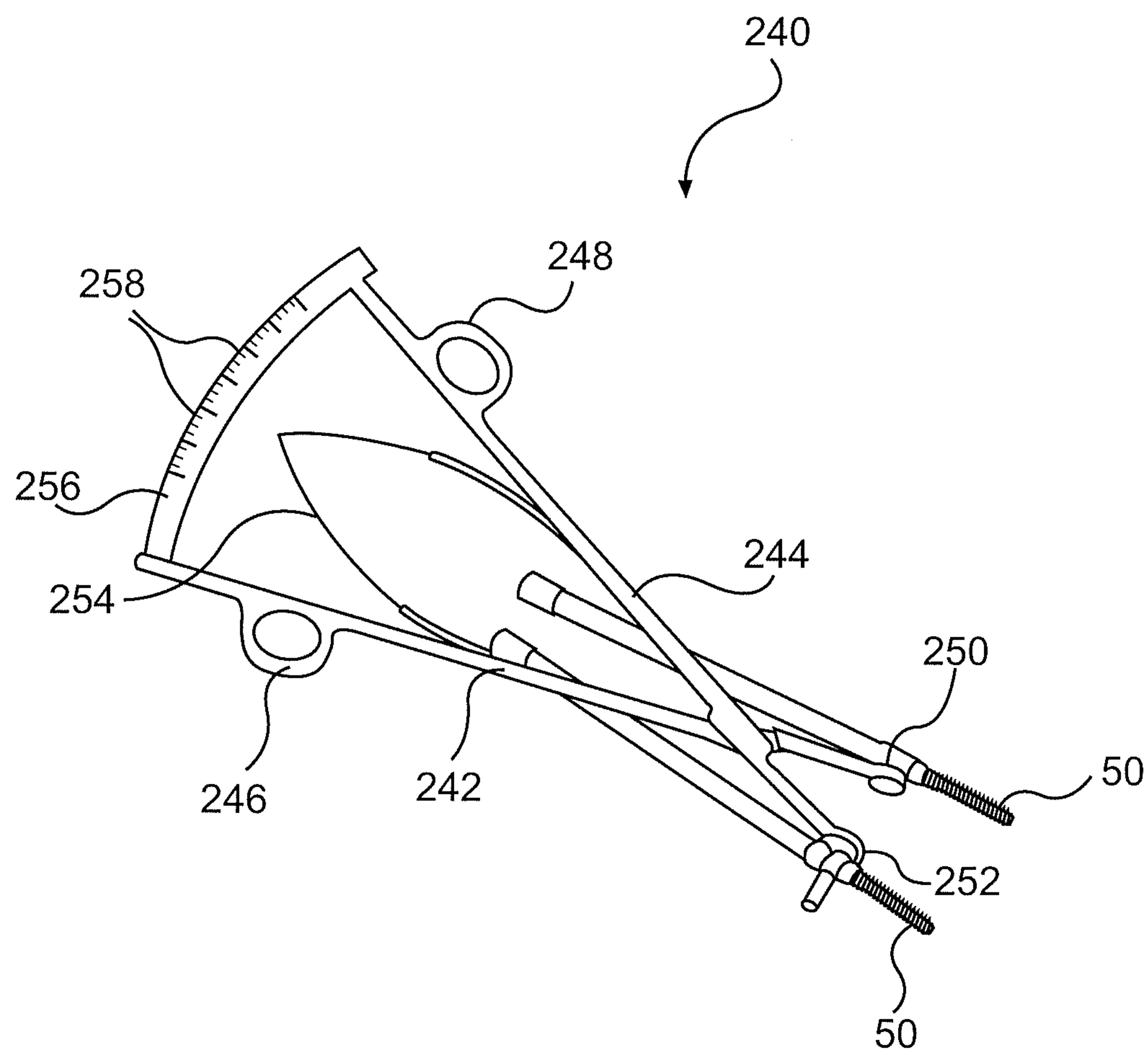
12/17

**FIG. 11C**

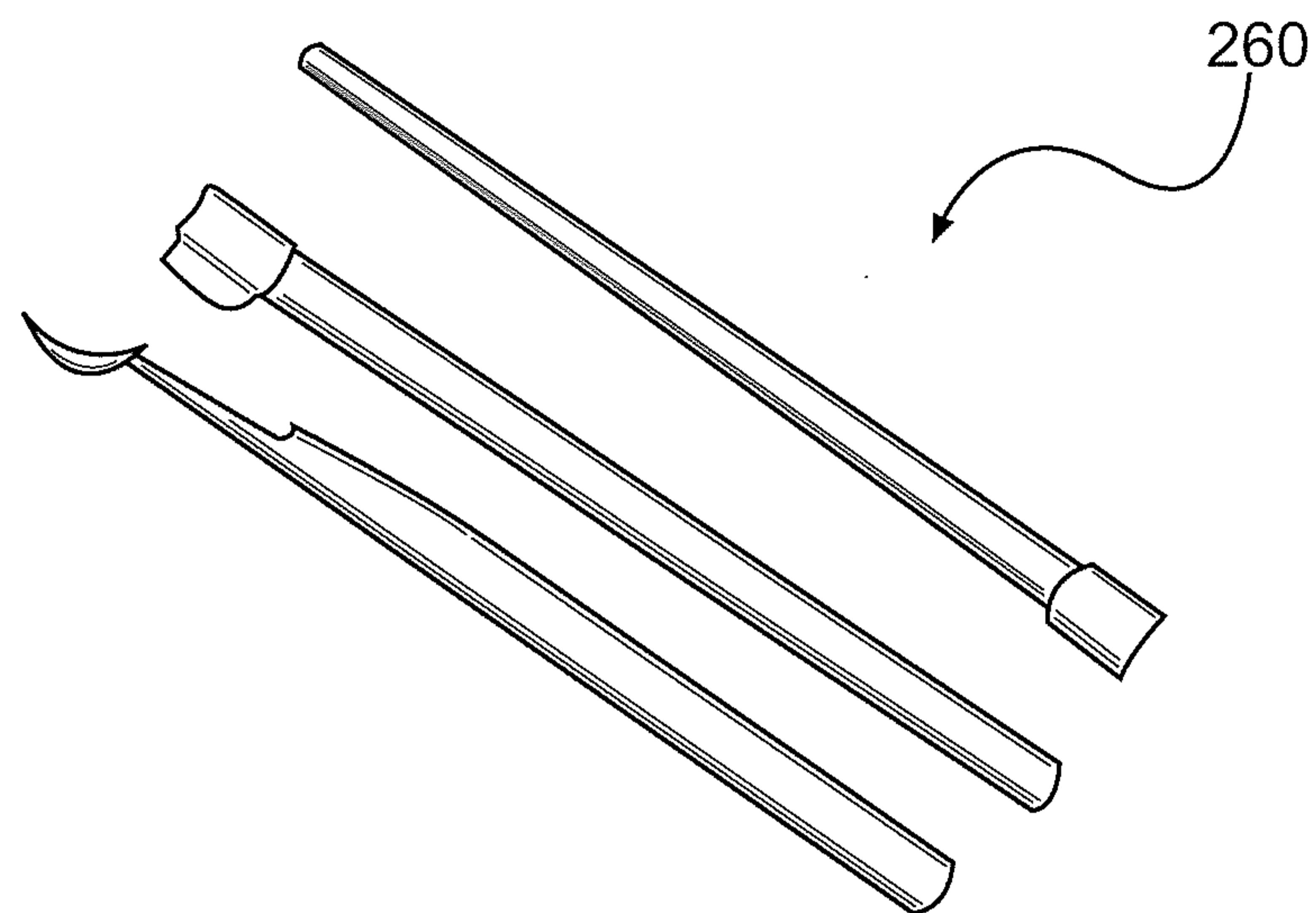
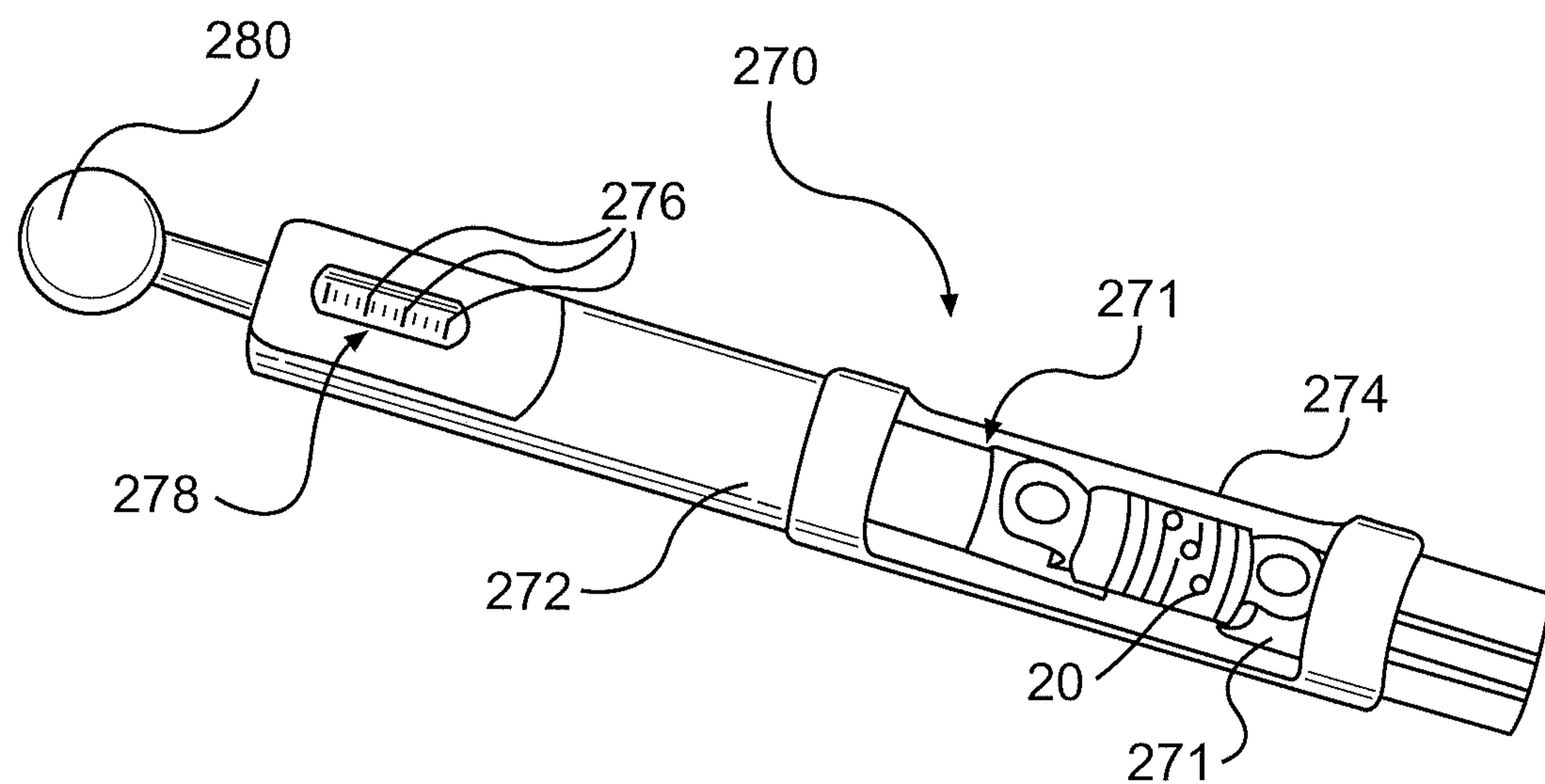
13/17

**FIG. 13****FIG. 14A**

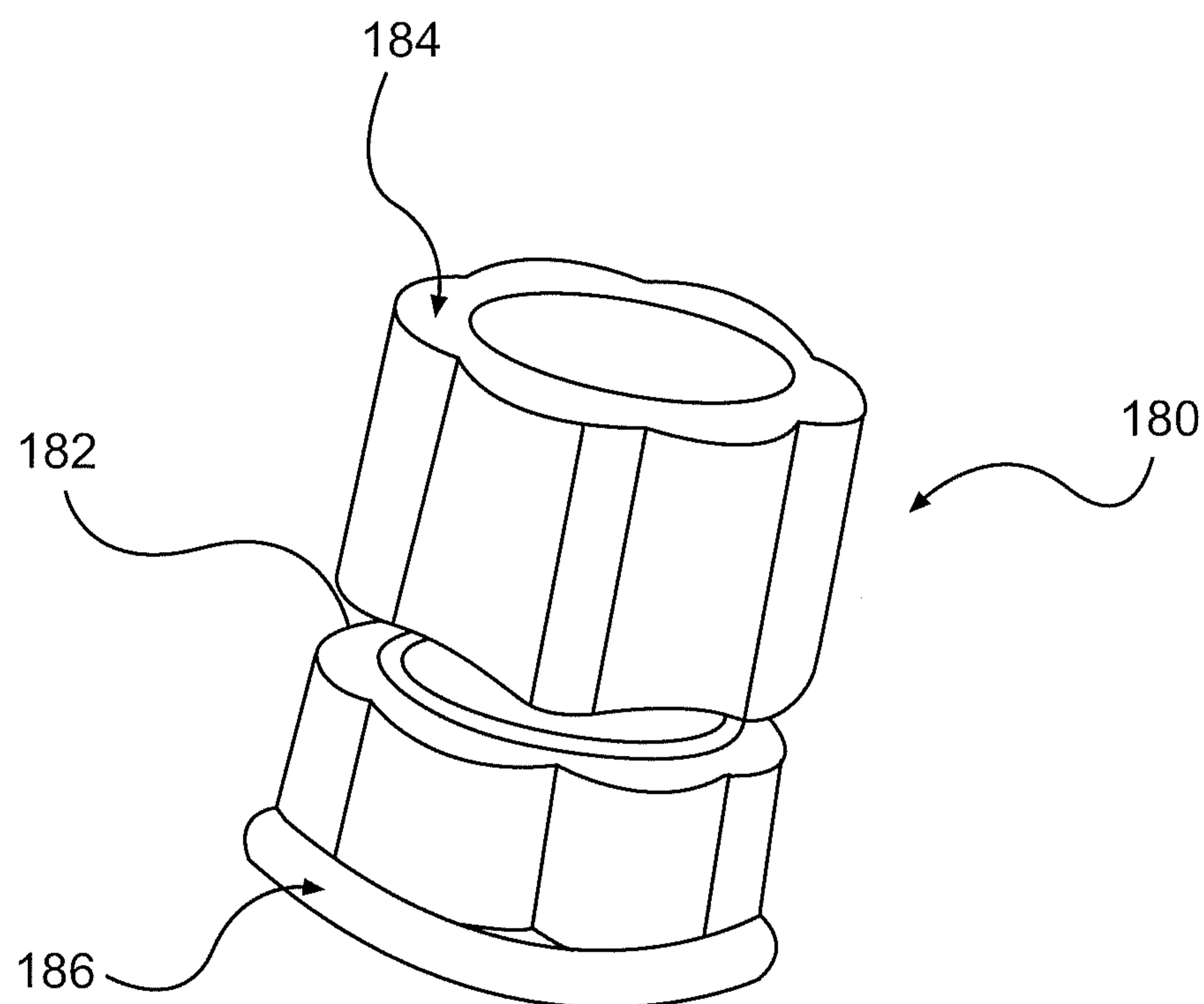
14/17

**FIG. 14B****FIG. 15**

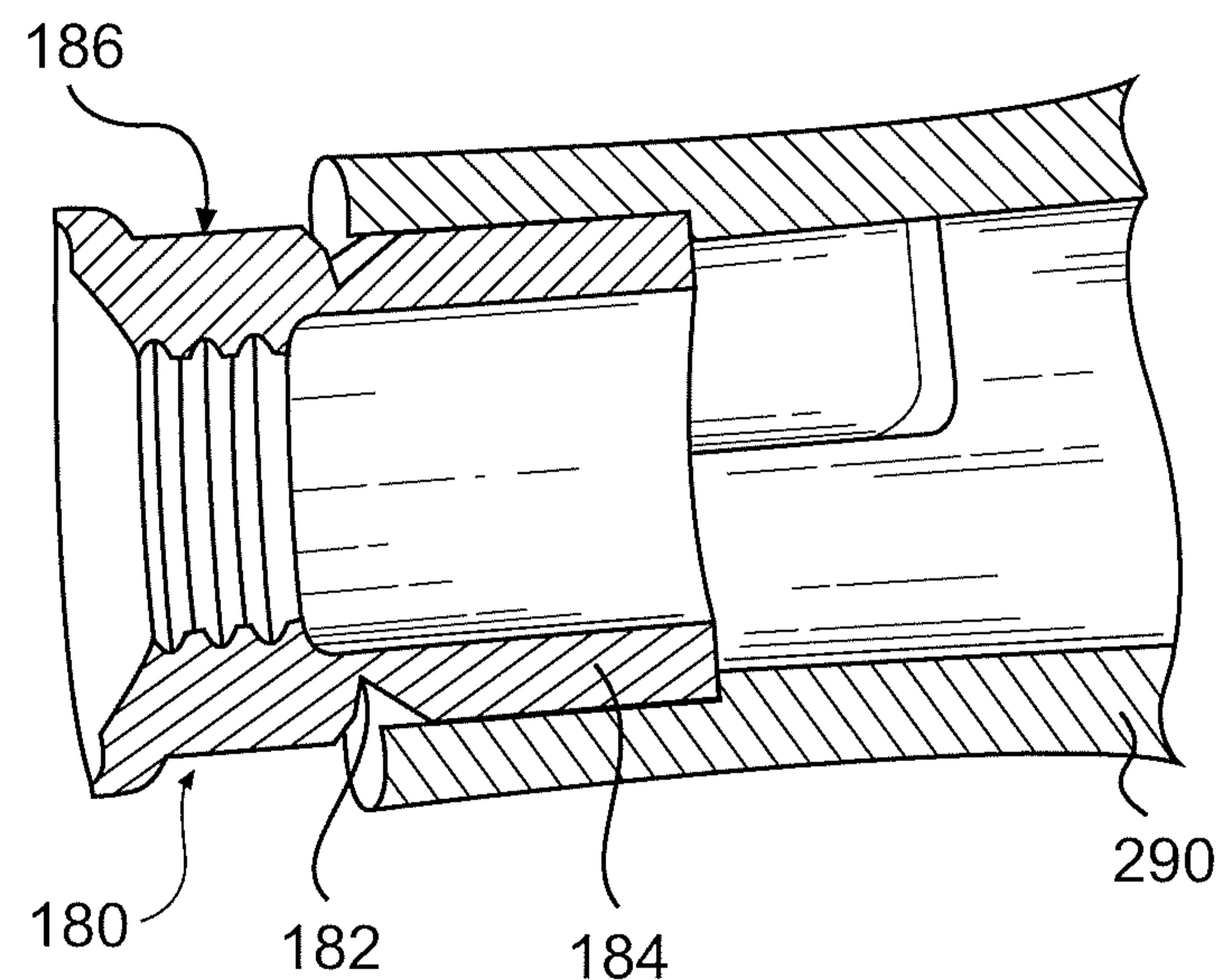
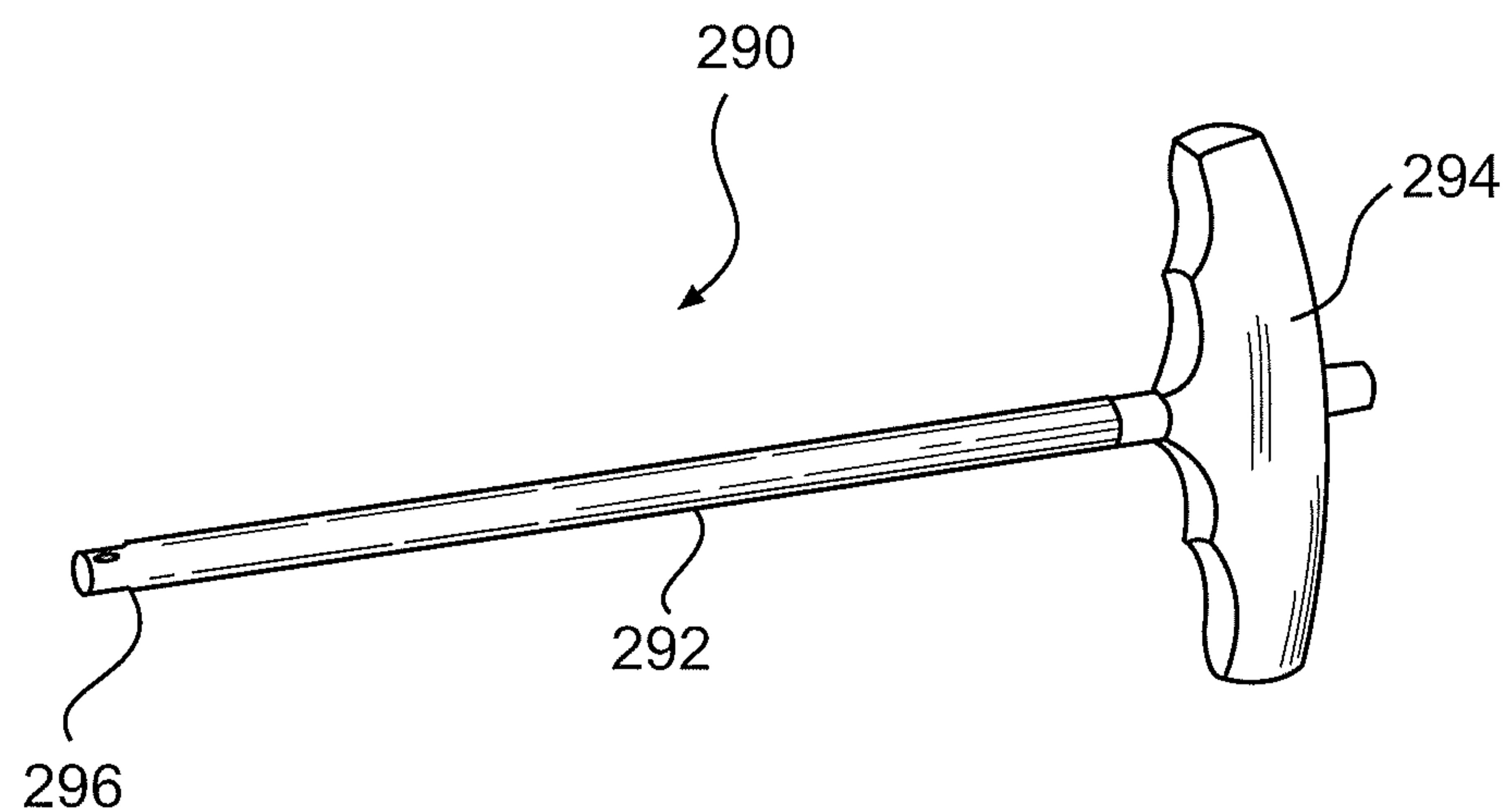
15/17

**FIG. 16****FIG. 17**

16/17

**FIG. 18A**

17/17

**FIG. 18B****FIG. 19**

