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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
28 September 2006 (28.09.2006)

PCT

(10) International Publication Number
WO 2006/102269 A2

(51) International Patent Classification:
A61B 17/56 (2006.01)

(21) International Application Number:
PCT/US2006/010115

(22) International Filing Date: 21 March 2006 (21.03.2006)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

60/663,885	21 March 2005 (21.03.2005)	US
60/663,918	21 March 2005 (21.03.2005)	US
60/664,076	22 March 2005 (22.03.2005)	US
11/377,971	17 March 2006 (17.03.2006)	US
11/378,108	17 March 2006 (17.03.2006)	US
11/378,894	17 March 2006 (17.03.2006)	US

(71) Applicant *(for all designated States except US)*: **ST. FRANCIS MEDICAL TECHNOLOGIES, INC.** [US/US]; 960 Atlantic Avenue, Suite 102, Alameda, California 94501 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **ZUCHERMAN, James, F.** [US/US]; 3035 Pierce Street, San Francisco, California 94123 (US). **HSU, Ken, Y.** [US/US]; 52 Clarendon Avenue, San Francisco, California 94114 (US). **WINSLOW, Charles, J.** [US/US]; 25 Hilton Court, Walnut Creek, California 94595 (US). **FLYNN, John, J.** [US/US]; 18 Baldwin Drive, West Milford, New Jersey 07480 (US). **MITCHELL, Steven, T.** [US/US]; 776 Duke Circle, Pleasant Hill, California 94523 (US). **YERBY, Scott, A.** [US/US]; 1333 Birch Street, Montara, California 94037 (US). **MARKWART, John, A.** [US/US]; 4808 Heyer Avenue, Castro Valley, California 94552 (US).

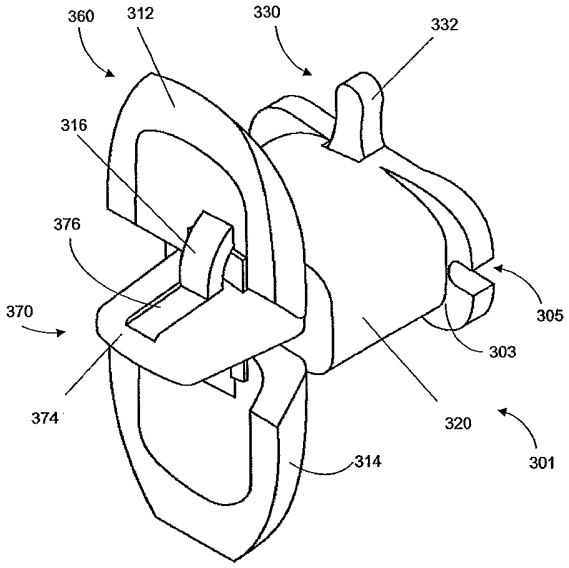
(74) Agents: **MEYER, Sheldon, R.** et al.; FLIESLER MEYER LLP, Four Embarcadero Center, Fourth Floor, San Francisco, California 94111-4156 (US).

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

(84) 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),

[Continued on next page]

(54) Title: INTERSPINOUS PROCESS IMPLANT HAVING DEPLOYABLE WING AND METHOD OF IMPLANTATION



(57) Abstract: Systems and method in accordance with an embodiment of the present invention can includes an implant comprising a first wing, a spacer extending from the first wing, and a distraction guide. The distraction guide is arranged in a first configuration to pierce and/or distract tissue associated with adjacent spinous processes extending from vertebrae of a targeted motion segment. The implant can be positioned between the adjacent spinous processes and once positioned, the distraction guide can be arranged in a second configuration. When arranged in a second configuration, the distraction guide can act as a second wing. The first wing and the second wing can limit or block movement of the implant along a longitudinal axis of the implant.

WO 2006/102269 A2

European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

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

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

INTERSPINOUS PROCESS IMPLANT HAVING DEPLOYABLE WING AND METHOD OF IMPLANTATION

CLAIM OF PRIORITY

U.S. Provisional Patent Application No. 60/663,885 entitled INTERSPINOUS PROCESS IMPLANT HAVING DEPLOYABLE WING AND METHOD OF IMPLANTATION, by James F. Zucherman *et al.*, filed March 21, 2005 (Attorney Docket No. KLYC-01114US0);

U.S. Provisional Patent Application No. 60/663,918 entitled INTERSPINOUS PROCESS IMPLANT HAVING DEPLOYABLE WING AND METHOD OF IMPLANTATION, by James F. Zucherman *et al.*, filed March 21, 2005 (Attorney Docket No. KLYC-01114US1);

U.S. Provisional Patent Application No. 60/664,076 entitled INTERPSINOUS PROCESS IMPLANT HAVING DEPLOYABLE WING AS AN ADJUNCT TO SPINAL FUSION AND METHOD OF IMPLANTATION, by James F. Zucherman *et al.*, filed March 22, 2005 (Attorney Docket No. KLYC-01114US2);

U.S. Patent Application No. 11/___,___ entitled INTERSPINOUS PROCESS IMPLANT HAVING DEPLOYABLE WING AND METHOD OF IMPLANTATION, by James F. Zucherman *et al.*, filed March 17, 2006 (Attorney Docket No. KLYC-01114US3);

U.S. Patent Application No. 11/___,___ entitled INTERSPINOUS PROCESS IMPLANT HAVING DEPLOYABLE WING AND METHOD OF IMPLANTATION, by James F. Zucherman *et al.*, filed March 17, 2006 (Attorney Docket No. KLYC-01114US4); and

U.S. Patent Application No. 11/___,___ entitled INTERSPINOUS PROCESS IMPLANT HAVING DEPLOYABLE WING AS AN ADJUNCT TO SPINAL FUSION AND METHOD OF IMPLANTATION, by James F. Zucherman *et al.*, filed March 17, 2006 (Attorney Docket No. KYLC-01114US5).

TECHNICAL FIELD

This invention relates to interspinous process implants.

BACKGROUND OF THE INVENTION

The spinal column is a bio-mechanical structure composed primarily of ligaments, muscles, vertebrae and intervertebral disks. The bio-mechanical functions of the spine include: (1) support of the body, which involves the transfer of the weight and the bending movements of the head, trunk and arms to the pelvis and legs, (2) complex physiological motion between these parts, and (3) protection of the spinal cord and the nerve roots.

As the present society ages, it is anticipated that there will be an increase in adverse spinal

conditions which are characteristic of older people. By way of example only, with aging comes an increase in spinal stenosis (including, but not limited to, central canal and lateral stenosis), and facet arthropathy. Spinal stenosis results in a reduction foraminal area (*i.e.*, the available space for the passage of nerves and blood vessels) which compresses the nerve roots and causes radicular pain. Humpreys, S.C. *et al.*, *Flexion and traction effect on C5-C6 foraminal space*, Arch. Phys. Med. Rehabil., vol. 79 at 1105 (Sept. 1998). Another symptom of spinal stenosis is myelopathy, which results in neck and back pain and muscle weakness. *Id.* Extension and ipsilateral rotation of the neck and back further reduces the foraminal area and contributes to pain, nerve root compression and neural injury. *Id.*; Yoo, J.U. *et al.*, *Effect of cervical spine motion on the neuroforaminal dimensions of human cervical spine*, Spine, vol. 17 at 1131 (Nov. 10, 1992). In contrast, neck and back flexion increases the foraminal area. Humpreys, S.C. *et al.*, at 1105.

Over time, loss of disk height in the thoracic and lumbar regions, as well as the cervical region can result in a degenerative cascade with deterioration of all components of a motion segment resulting in segment instability and ultimately in spinal stenosis. During the process of deterioration, disks can become herniated and/or become internally torn and chronically painful. When symptoms seem to emanate from both anterior (disk) and posterior (facets and foramen) structures, patients cannot tolerate positions of extension or flexion.

Pain associated with stenosis can be relieved by medication and/or surgery. It is desirable to eliminate the need for major surgery for all individuals, and in particular, for the elderly.

Accordingly, a need exists to develop spine implants that alleviate pain caused by spinal stenosis and other such conditions caused by damage to, or degeneration of, the spine. Such implants would distract, or increase the space between, the vertebrae to increase the foraminal area and reduce pressure on the nerves and blood vessels of the spine.

A further need exists for development of a minimally invasive surgical implantation method for spine implants that preserves the physiology of the spine.

Further, a need exists for an implant that accommodates the distinct anatomical structures of the spine, minimizes further trauma to the spine, and obviates the need for invasive methods of surgical implantation. Additionally, a need exists to address adverse spinal conditions that are exacerbated by spinal extension.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1A is a perspective view of an implant including a spacer having a tear-drop shaped cross-section, a distraction guide, a first wing, and a second wing connectable with the distraction guide.

FIG. 1B is a perspective view of an implant including a rotatable spacer having an elliptical

cross-section, a distraction guide, a first wing, and a second wing connectable with the distraction guide.

FIG. 2A is a perspective view of an implant in accordance with an embodiment of the present invention including a main body and an insert, the main body having a distraction guide, a spacer, and a first wing.

FIG. 2B is a perspective view of the implant of **FIG. 2A** wherein the insert is positioned within the main body, causing the distraction guide associated with the main body to limit or block movement of the implant when positioned between adjacent spinous processes.

FIG. 3A is a side view of the main body of the implant of **FIGs. 2A** and **2B** positioned between adjacent spinous processes.

FIG. 3B is a side view of the implant of **FIG. 3A** wherein the insert is positioned within the main body.

FIG. 4 is a perspective view of an implant in accordance with an alternative embodiment wherein the main body includes hooks to limit relative movement of adjacent spinous processes during flexion motion.

FIG. 5 is a side view of the implant of **FIG. 4** positioned between adjacent spinous processes and arranged so that the hooks confine the adjacent spinous processes.

FIG. 6A is a perspective view of still another embodiment of an implant in accordance with the present invention, wherein a first section and a second section of a distraction guide are deployable to form a second wing.

FIG. 6B is a perspective view of the implant of **FIG. 6A** wherein the insert is positioned within the main body, causing the first section and the second section of the distraction guide to deploy.

FIG. 7A is a perspective view of a still further embodiment of an implant in accordance with the present invention including a rotatable spacer.

FIG. 7B is a perspective view of the implant of **FIG. 7A** wherein the insert is positioned within a central body so that the distraction guide deploys as a second wing.

FIG. 7C is a cross-sectional side view of distraction guide of **FIG. 7A**.

FIG. 7D is a cross-sectional side view of distraction guide of **FIG. 7B**.

FIG. 8 is a side view of the implant of **FIGs. 7A-7D** positioned between adjacent spinous processes.

FIG. 9A is a side view of an alternative embodiment of the implant positioned between adjacent spinous processes.

FIG. 9B is a partial cross-section side view of the implant of **FIG. 9A** showing deployable winglets disposed within a distraction guide of the implant.

FIG. 9C is a partial cross-sectional side view of the implant of **FIG. 9B** wherein the winglets

deployed.

FIG. 10A is a side view of an alternative embodiment of the implant positioned between adjacent spinous processes.

FIG. 10B is a side view of the implant of **FIG. 10A** positioned between adjacent spinous processes wherein the winglets deployed.

FIG. 10C is a partial cross-sectional end view of the implant of **FIG. 10A** showing deployable winglets disposed within a distraction guide of the implant.

FIG. 10D is a partial cross-sectional end view of the implant of **FIGs. 10A-10C** showing the winglets deployed so that the winglets extend from the distraction guide of the implant.

FIG. 10E is an end view of the implant of **FIGs. 10A-10D** showing the distraction guide and the deployed winglets relative to the distraction guide.

FIG. 11A is a partial cross-sectional end view of an alternative embodiment of an implant in accordance with the present invention including an alternative actuator arrangement.

FIG. 11B is an partial cross-sectional end view of the implant of **FIG. 11A** showing the winglets deployed so that the winglets extend from the distraction guide of the implant.

FIG. 12A is a partial cross-sectional end view of still another embodiment of an implant in accordance with the present invention having an alternative actuator arrangement wherein the winglets comprise two hinged portions.

FIG. 12B is a partial cross-sectional end view of the implant of **FIG. 12A** showing the winglets deployed so that the winglets extend from the distraction guide of the implant.

FIG. 13 is a partial cross-sectional end view of a still further embodiment of an implant in accordance with the present invention wherein implants are arranged at adjacent motion segments.

FIG. 14 illustrates an embodiment of a method for implanting the implant of **FIGs. 2A-8** between adjacent spinous processes in accordance with the present invention.

FIG. 15A illustrates an embodiment of a method for implanting the interspinous implant of **FIGs. 2A-8** between adjacent spinous processes in accordance with the present invention.

FIG. 15B illustrates an embodiment of a method for implanting the interspinous implant of **FIGs. 9A-13** between adjacent spinous processes in accordance with the present invention.

DETAILED DESCRIPTION

INTERSPINOUS IMPLANTS

FIG. 1A is a perspective view of an implant as described in U.S. Pat. App. Ser. No. 10/850,267, filed May 20, 2004, incorporated herein by reference. The implant **100** comprises a first wing **130**, a spacer **120**, and a lead-in tissue expander (also referred to herein as a distraction guide) **110**.

The distraction guide **110** in this particular embodiment is wedge-shaped, *i.e.*, the implant has an expanding cross-section from a proximal end of the implant **100** to a region **150** where the guide **110** joins with the spacer **120** (referencing for the figures is based on the point of insertion of the implant between spinous processes). As such, the distraction guide **110** functions to initiate distraction of the soft tissue and the spinous processes when the implant **100** is surgically inserted between the spinous processes. It is to be understood that the distraction guide **110** can be pointed and the like, in order to facilitate insertion of the implant **100** between the spinous processes of adjacent cervical vertebrae. It is advantageous that the insertion technique disturb as little of the bone and surrounding tissue or ligaments as possible in order to reduce trauma to the site and promote early healing, and prevent destabilization of the normal anatomy. For embodiments such as those of **FIGs. 1A** and **1B**, there is no requirement to remove any of the bone of the spinous processes and no requirement to sever, or remove from the body, ligaments and tissues immediately associated with the spinous processes. For example, it is unnecessary to sever the supraspinal ligament of the lower vertebrae or the *ligamentum nuchae* (which corresponds to the supraspinal ligament) which partially cushions the spinous processes of the upper cervical vertebrae.

As can be seen, the spacer **120** can be teardrop-shaped in cross-section perpendicular to a longitudinal axis **125** of the implant **100**. In this way, the shape of the spacer **120** can roughly conform to a wedge-shaped space, or a portion of the space, between adjacent spinous processes within which the implant **100** is to be positioned. As shown in **FIG. 1A**, the spacer **120** (and the first wing **108**) is shaped to accommodate the anatomical form or contour of spinous processes (and/or laminae) of preferably the C6 and C7 vertebra for placement between such spinous processes (i.e., the C6-C7 motion segment). The same shape or variations of this shape can be used to accommodate other motion segments, for example in the thoracic or lumbar regions. In other embodiments the spacer **120** can have alternative shapes such as circular, wedge, oval, ovoid, football, and rectangular with rounded corners, and other shapes. The shape of the spacer **120** can be selected for a particular patient so that the physician can position the implant **100** as close as possible to the anterior portion of the surface of the spinous process. The shape selected for the spacer **120** can affect the contact surface area of the implant **100** and the spinous processes that are to be subject to distraction. Increasing the contact surface area between the implant **100** and the spinous processes can distribute a load force between the spinous frame and the implant **100**.

The first wing **130** is likewise teardrop-shaped in cross-section perpendicular to a longitudinal axis **125** of the spacer **120** and distraction guide **110**. The dimensions of the first wing **130** can be larger than that of the spacer **120**, particularly along the axis of the spine, and can limit or block lateral displacement of the implant **100** in the direction of insertion along the longitudinal axis **125**. As with the

spacer **120**, the first wing **130** can have other cross-sectional shapes, such as elliptical, wedge, circular, oval, ovoid, football, and rectangular with rounded corners and other shapes.

The implant **100** of **FIG. 1A** further includes an adjustable wing **160** (also referred to herein as a second wing) separate from the distraction guide **110**, the spacer **120** and the first wing **130**. The second wing **160** is connectable with the distraction guide **110** (and/or the spacer **120**) once the implant **100** is positioned between adjacent spinous processes. The second wing **160**, similar to the first wing **130**, can limit or block lateral displacement of the implant **100**, however displacement is limited or blocked in the direction opposite insertion. When both the first wing **130** and the second wing **160** are connected with the implant **100** and the implant **100** is positioned between adjacent spinous processes, a portion of the spinous processes can be sandwiched between the first wing **130** and the second wing **160**, limiting displacement along the longitudinal axis **125**. As can be seen, the second wing **160** can be teardrop-shaped in cross-section. A lip **180** defining a space **170** through the second wing **160** allows the second wing **160** to pass over the distraction guide **110** to meet and connect with the distraction guide **110** and/or the spacer **120**. The second wing **160** is then secured to the distraction guide **110** and/or the spacer **120**. The second wing **160**, can be designed to be interference-fit onto the spacer **120** or a portion of the distraction guide **110** adjacent to the spacer **120**. Where the second wing **160** is interference-fit, there is no additional attachment device to fasten the second wing **160** relative to the remainder of the implant **100**.

Alternatively, various fasteners can be used to secure the second wing **160** relative to the remainder of the implant **100**. For example, **FIG. 1A** illustrates an embodiment of an implant **100** including a teardrop-shaped second wing **160** having a tongue **158** at the posterior end of the second wing **160**. A bore **155** is disposed through the tongue **158**, and is aligned with a corresponding bore **156** on the spacer **120** when the second wing **160** is brought into position by surgical insertion relative to the rest of the implant **100**. A threaded screw **154** can be inserted through the aligned bores **155,156** in a posterior-anterior direction to secure the second wing **160** to the spacer **120**. The direction of insertion from a posterior to an anterior direction has the screw **154** engaging the bores **155,156** and the rest of the implant **100** along a direction that is generally perpendicular to the longitudinal axis **125**. This orientation is most convenient when the physician is required to use a screw **154** to secure the second wing **160** to the rest of the implant **100**. The second wing **160** can further be secured to the spacer **120** by some other mechanism, for example such as a flexible hinge (not shown) with a protrusion that engages an indentation of one of the distraction guide **110** and the spacer **120**. Alternatively, the second wing **160** can be secured to one of the distraction guide **110** and the spacer **120** by still some other mechanism.

FIG. 1B is a perspective view of an implant as described in U.S. Pat. 6,695,842 to Zucherman,

et al., incorporated herein by reference. The implant **200** has a main body that includes a spacer **220**, a first wing **230**, a lead-in tissue expander **210** (also referred to herein as a distraction guide) and an alignment track **203**. The main body of the implant **200** is inserted between adjacent spinous processes and remains in place (where desired) without attachment to the bone or ligaments.

The distraction guide **210** includes a tip from which the distraction guide **210** expands, the tip having a diameter sufficiently small such that the tip can pierce an opening in an interspinous ligament and/or can be inserted into a small initial dilated opening. The diameter and/or cross-sectional area of the distraction guide **210** gradually increases until it is substantially similar to the diameter of the spacer **220**. The tapered front end eases the ability of a physician to urge the implant **200** between adjacent spinous processes. When urging the main body of the implant **200** between adjacent spinous processes, the front end of the distraction guide **210** distracts the adjacent spinous processes and dilates the interspinous ligament so that a space between the adjacent spinous processes is approximately the diameter of the spacer **220**.

As shown in **FIG. 1B**, the spacer **220** is elliptically shaped in cross-section, and can swivel so that the spacer **220** can self-align relative to the uneven surfaces of the spinous processes. Self-alignment can ensure that compressive loads are distributed across the surface of the bone. As contemplated in Zucherman '842, the spacer **220** can have, for example, a diameter of six millimeters, eight millimeters, ten millimeters, twelve millimeters and fourteen millimeters. These diameters refer to the height by which the spacer **220** distracts and maintains apart the spinous process. For an elliptically shaped spacer **220**, the selected height (i.e., diameter) is the minor dimension measurement across the ellipse. The major dimension is transverse to the alignment of the spinous process, one above the other.

The first wing **230** has a lower portion **231** and an upper portion **232**. The upper portion **232** is shaped to accommodate the anatomical form or contour of spinous processes (and/or laminae) of preferably the L4 (for an L4-L5 placement) or L5 (for an L5-S1 placement) vertebra. The same shape or variations of this shape can be used to accommodate other motion segments, such as motion segments in the cervical and thoracic regions. The lower portion **231** can also be rounded to accommodate the spinous processes. The lower portion **231** and upper portion **232** of the first wing **230** act as a stop mechanism when the implant **200** is inserted between adjacent spinous processes. The implant **200** cannot be inserted beyond the surfaces of the first wing **230**. Additionally, once the implant **200** is inserted, the first wing **230** can prevent some side-to-side, or posterior-to-anterior movement of the implant **200**.

As with the implant **100** of **FIG. 1A**, the implant **200** of **FIG. 1B** further includes a second wing **260**. Similar to the first wing **230**, the second wing **260** includes a lower portion **261** and an upper portion **262** sized and/or shaped to accommodate the anatomical form or contour of the spinous

processes and/or lamina. The second wing **260** can be secured to the main body of the implant **200** with a fastener **254**. The second wing **260** also has an alignment tab **268**. When the second wing **260** is initially placed on the main body of the implant **200**, the alignment tab **268** engages the alignment track **203**. The alignment tab **268** slides within the alignment track **203** and helps to maintain the adjustable wing **260** substantially parallel with the first wing **230**. When the main body of the implant **200** is inserted into the patient and the second wing **260** has been attached, displacement along the longitudinal axis **225** in either the direction of insertion or the direction opposite insertion can be limited or blocked. Further, the second wing **260** also can prevent some side-to-side, or posterior-to-anterior movement.

For both the implant **100** of **FIG. 1A** and the implant **200** of **FIG. 1B**, where a second wing **160,260** is connected with the implant **100,200** after the implant **100,200** is positioned between the spinous processes, a procedure for positioning such an implant **100,200** and subsequently connecting the second wing **160,260** with the implant **100,200** can require a bilateral approach wherein a physician must access both sides of the interspinous ligament, a first side to pierce and/or distract the interspinous ligament and position the implant **100,200** so that the movement in the direction of insertion is satisfactorily limited by the first wing **130,230**, and a second side to attach the second wing **160,260** such that movement in the direction opposite insertion is satisfactorily limited by the second wing **160,260**.

IMPLANTS HAVING DEPLOYABLE SECOND WING

Referring to **FIGs. 2A** through **3B**, implants **300** and methods for positioning such implants in accordance with the present invention can, in an embodiment, include a deployable second wing **360** associated with a main body **301** such that the second wing **360** can be deployed with a physician needing only to access a first side of spinous processes to limit or block movement along the longitudinal axis **325**.

As shown in **FIG. 2A**, the implant **300** includes a main body **301** having a fixed spacer **320** and a distraction guide **310**. The distraction guide **310** comprises a first winglet (also referred to herein as an upper winglet) **312** and a second winglet (also referred to herein as a lower winglet) **314**, and when arranged in a first configuration can include a tip from which the distraction guide **310** expands, the tip having a diameter sufficiently small such that the tip can pierce an opening in an interspinous ligament and between spinous processes and/or can be inserted into a small initial dilated opening. The diameter and/or cross-sectional area of the distraction guide **310** is then gradually increased until it is substantially similar to the diameter of the spacer **320**. In this respect, the distraction guide **310** of **FIG. 2A** can resemble a distraction guide as described above when arranged in the first configuration. The winglets **312,314** can be hinged or otherwise pivotably connected with the main body **301** such that the winglets

312,314 can be arranged in a second configuration (**FIG. 2B**) once the implant **300** is positioned between spinous processes. In a second configuration one or both of the winglets **312,314** abut at least one of the spinous processes and/or related tissues when urged in a direction opposite from insertion, thereby limiting motion along the longitudinal axis **325**. Thus when arranged in a second configuration, the distraction guide **310** becomes a second wing **360**, as shown in **FIG. 2B**.

The implant **300** includes an insert **370** having an insert body **372** and a first wing **330**. As shown in **FIG. 2B**, the insert **370** can be mated with the main body **301** to arrange the distraction guide **310** of the implant **300** in the second configuration, thereby deploying the second wing **360**. To facilitate mating of the main body **301** and the insert **370**, the spacer **320** includes a cavity sized and shaped for receiving the insert body **372** and accessible from a distal end of the main body **301**. A portion of the upper winglet **312** and the lower winglet **314** can extend at least partially into the cavity so that when the insert body **372** is received within the cavity, the insert body **372** displaces the portions, causing the distraction guide **310** to be arranged in the second configuration. In the embodiment shown, the upper winglet **312** and the lower winglet **314** each include a lever **316,318** comprising a curved protrusion that protrudes into the cavity when the distraction guide **310** is in the first configuration. As the insert body **372** of the insert **370** fills the cavity, the insert body **372** contacts the first lever **316** and the second lever **318**, applying a force to the first lever **316** and the second lever **318** which translates into a pivoting motion of the hinged upper winglet **312** and the hinged lower winglet **314**. The insert body **372** can optionally have a tapered proximal end **374** having a first groove **376** and a second groove **378** corresponding to the first lever **316** and the second lever **318**, respectively. The tapered shape of the proximal end **374** allows the upper winglet **312** and lower winglet **314** to be deployed gradually, fully deploying as the insert body **372** is fully seated within the cavity. The main body **301** is shown including a flange **303** in which is formed notches **305** to receive an insertion tool (not shown), for example. As the insert body **372** is seated within the cavity, an upper tab **332** and a lower tab **331** of the first wing **330** seats within cut-outs **322** of the flange **303**.

Referring to **FIG. 3A**, the main body **301** of the implant **300** is shown positioned between adjacent spinous processes of the targeted motion segment. The motion segment shown is within the lumbar region, but in other embodiments, particularly where a fixed spacer **320** is used, implants **300** in accordance with the present convention can be positioned at motion segments of the thoracic and cervical region. The main body **301** is positioned as shown by initially approaching the interspinous ligament between the upper and lower adjacent spinous processes **2,4** through an opening to the right of the interspinous ligament, roughly posterior to the right inferior articular facet **6** of the vertebrae from which the upper spinous process **2** extends. The main body **301** can be associated with one or more insertion tools (not shown), and the distraction guide **310** can be arranged in the first configuration. The

tip of the distraction guide **310** is positioned roughly adjacent to a point along the interspinous ligament, and the distraction guide **310** is then urged through the interspinous ligament, piercing the interspinous ligament and/or separating and distracting fibers of the interspinous ligaments. The main body **301** is then urged through the interspinous ligament until the spacer **320** is positioned between the adjacent spinous processes **2,4** so that the spacer **320** supports a load applied by the spinous processes **2,4**.

Referring to **FIG. 3B**, once the implant **300** is positioned as desired, the insertion tools can be removed from the opening and the insert **370** can be positioned at the distal end of the main body **301**. The insert body **372** can be urged into the cavity within the main body **301** until the proximal end **374** of the insert body **372** contacts the first lever **316** and the second lever **318**. The insert **370** can then be further urged along the longitudinal axis **325** so that the insert body **372** urges the first lever **316** and the second lever **318** away from the insert body **372**, causing the upper winglet **312** and the lower winglet **314** to pivot about the first hinge **313** and the second hinge **315**, respectively. As the first lever **316** and the second lever **318** are displaced from the cavity, the first lever **316** and the second lever **318** are guided along corresponding grooves **376,378** of the tapered proximal end **374**. As the insert body **372** seats within the cavity of the main body **301**, the upper winglet **312** and the lower winglet **314** deploy as a second wing **360**. The insertion tool can be removed from the incision once the insert body **372** is seated within the main body **301**. As can be seen a portion of the upper spinous process and a portion of the lower spinous process are sandwiched between the first wing **330** and the second wing **360**, limiting motion along the longitudinal axis **325**.

Implants and methods for positioning such implants between spinous processes in accordance with the present invention are not meant to be limited to embodiments as described above and otherwise herein, but rather are meant to include any implant having a second wing deployable by urging an insert within a main body positioned between adjacent spinous processes. Myriad different variations may be readily apparent to one of ordinary skill in the art. For example, in an alternative embodiment, the main body **301** of the implant **300** of **FIGs. 2A** through **3B** can include a lower winglet **314** pivotably associated with the main body **301** while an upper winglet **312** is fixedly associated with the main body **301**. An insert **370** can be adapted to deploy only the lower winglet **314** when seated within the cavity of the main body **301**.

In other embodiments, a first wing **310** can extend from the main body **301** rather than, or in addition to, a first wing extending from the insert **370**. When the main body **301** is initially positioned between the adjacent spinous processes, movement of the main body **301** along the longitudinal axis **325** can be limited in the direction of insertion. As the first wing **310** extending from the main body **301** contacts one or both of the adjacent spinous processes, further movement of the main body **301** in the direction of insertion can be limited or blocked. The first wing **310** can thus act as a hard stop, allowing

the main body **301** to be positioned without requiring a position of the main body **301** along the spinous processes to be estimated, thereby easing implantation.

Referring to **FIG. 4**, in still further embodiments implants **400** in accordance with the present invention can include one or both of a first engagement element (also referred to herein as an upper hook) **480** and a second engagement element (also referred to herein as a lower hook) **482** for limiting flexion motion in a motion segment. For example, similar hooks have been described in greater detail in U.S. Pat. No. 6,451,019 issued Sep. 17, 2002 to Zucherman *et al.* and U.S. Pat. No. 6,652,527 issued Nov. 25, 2003 to Zucherman *et al.*, both incorporated herein by reference. Implants in accordance with the present invention can include such arrangements. The implant **400** shown in **FIGs. 4** and **5** includes an upper hook **480** extending from an upper connection rod **484** rotatably associated with the main body **401** and a lower hook **482** extending from a lower connection rod **486** rotatably associated with the main body **401**. Alternatively, the connection rods **484,486** can be fixedly associated with the main body **401**. The hooks **480,482** include tapered proximal ends **481,483** that act as lead-in tissue expanders to distract interspinous ligaments of the motion segments above and below the targeted motion segment. As the main body **401** is positioned between adjacent spinous processes, the tapered proximal ends **481,483** of the upper and lower hooks **480,482** can likewise pierce and/or distract interspinous ligaments so that the upper and lower hooks **480,482** can be properly positioned to limit or restrain flexion motion of the targeted motion segment when the main body **401** is in place. As shown, the hooks **480,482** can be pivotably associated with the connection rods **484,486** so that the hooks **480,482** can be rotated relative to the connection rods **484,486**, thereby allowing a physician to improve contact and spread loads between the hooks **480,482** and corresponding spinous processes **2,4**. The rotatable upper connection rod **484** and lower connection rod **486** can provide flexibility in placement, so that where an anatomy varies between patients and varies between motion segments such that the arrangement of a minor dimension and major dimension of the implant **400** about the longitudinal axis **425** varies, the implant **400** can be accommodated.

FIG. 5 is a posterior view of the implant **400** positioned between adjacent spinous processes **2,4** and having an upper hook **480** and a lower hook **482** arranged so that both flexion and extension is limited as desired. Further, the second wing **460** is deployed to limit movement of the implant **400** along the longitudinal axis **425**. The upper hook **480** and the lower hook **482** prevent movement along the longitudinal axis **425** in the direction opposite insertion, making a first wing unnecessary.

Referring to **FIGs. 6A** and **6B**, in still other embodiments implants **500** and methods for positioning such implants **500** between spinous processes in accordance with the present invention can include a distraction guide **510** wherein portions of the distraction guide **510** can be extended from the distraction guide **510** to form an upper winglet **512** and a lower winglet **514**, respectively, of a second

wing **560** by positioning an insert **570** within a cavity of the main body **501**. This is in contrast to the above embodiment where the entire distraction guide is formed by the winglets. In this embodiment, the winglet **512,514** extend out the side of the distraction guide **510**. When not extended, as seen in **FIG. 6A**, the winglet **512,514** partially form the sides of the distraction guide **510**. Such embodiments are contemplated to be useful where it is desired that the second wing **560** have a limited height relative to implants **300,400** as described above where the entire distraction guide **310** is deployed (see **FIG. 2A** through **3B**). For example, where implants **500** are to be positioned at adjacent motion segments, it can be desired that the second wings **560** of the implants **500** do not interfere with one another implant, for example during an extension motion when compressive loads are applied to the implants **500**. As with implants described above, one of ordinary skill in the art can appreciate the myriad different variations of the implant **500** of **FIGs. 6A** and **6B**. For example, in alternative embodiments the upper winglet **512** and the lower winglet **514** can have some other shape. For example, the positions of the upper winglet **512** and lower winglet **514** are staggered so that implants **500** positioned at adjacent motion segments can be more easily positioned without interfering with one another. Such staggering can also accommodate anatomies where one of the upper and lower spinal processes is wider than the other. With staggering, for example, the upper winglet **512** can be pivotably mounted on the distraction guide **510** at a position less distant from the distraction end **511** than the location where the lower winglet **514** is pivotably mounted on the distraction guide **510**. In still other embodiments, the upper winglet **512** and the lower winglet **514** can have some other shape.

Referring to **FIGs. 7A** through **8**, in still further embodiments of implants **600** in accordance with the present invention, the main body **601** can include a hollow central body **605** (shown in **FIGs. 7C** and **7D**) extending from a first wing **630**. A rotatable spacer **620** is disposed about the hollow central body **605**. The implant **600** can include a spacer **620** that resembles spacers, for example, as described above in **FIG. 1B**. A distraction guide **610** can extend from the hollow central body **605** and can include an upper winglet **612** and a lower winglet **614**, one or both of which can be pivotably associated with a main portion **611** of the distraction guide **610** so that the upper winglet **612** and/or the lower winglet **614** can be deployed as a second wing **660**. A pin **606** can be inserted into the hollow central body **605** to deploy the second wing **630**. Referring to **FIG. 7B**, once the pin **606** is seated within the main body **601**, the upper winglet **612** and the lower winglet **614** can be pivoted away from each other so that the upper winglet **612** and the lower winglet **614** limit or block motion along the longitudinal axis **625** in the direction opposite from insertion. The upper winglet **612** and the lower winglet **614** thus act as a second wing **660**.

Referring to the partial cross-sections of **FIGs. 7C** and **7D**, in an embodiment the distraction guide **610** can include a cup **616** structure sized and arranged to receive the pin **606**. Bar structures

618,619 can be pivotably connected between the cup structure **616** and one or both of the upper winglet **612** and the lower winglet **614** so that when a force is applied to the cup structure **616** by the pin **606**, the force is further transferred to the upper winglet **612** and the lower winglet **614**, causing the upper winglet **612** and the lower winglet **614** to pivot on hinges **613,615** associated with the main portion **611** of the distraction guide **610** so that the second wing **660** is deployed. As can be seen, the pivot points **613,615** of the upper winglet **612** and the lower winglet **614** are arranged proximally relative to the mount points **617,619** of the bar structures **618,619**, causing the upper winglet **612** and the lower winglet **614** to pivot away from one another when the mount points **617,619** are urged together by the insertion of the pin **606** (as seen in **FIG. 7D**). In other embodiments, the upper winglet **612** and the lower winglet **614** can be caused to pivot away from one another using some other mechanism. Implants in accordance with the present invention are not intended to be limited to such second wing deployment mechanisms as are described in detail herein.

Referring to **FIG. 8**, the implant **600** is shown positioned between adjacent spinous processes **2,4**. The second wing **660** as shown is sized such that when arranged in a first configuration (i.e., as a distraction guide **610**) the upper winglet **612** and the lower winglet **614** do not extend undesirably into the adjacent tissues. However, the upper winglet **612** and the lower winglet **614** can be sized and shaped other than as shown in **FIG. 8**. The upper winglet **612** and the lower winglet **614** need only be sized and shaped such that when arranged in a second configuration, the upper and lower winglets **612,614** limit or block movement along the longitudinal axis **625** in a direction opposite from insertion.

FIGs. 9A through **9C** illustrate a further embodiment of an implant **700** in accordance with the present invention arranged between adjacent spinous processes **2,4**. In such an embodiment, upper and lower winglets **712,714** can be disposed within the distraction guide **710** and can be deployed by actuating an actuator arrangement including a shaft connected with a cam **707**, the shaft having an engageable head **706**, or alternatively including some other mechanism such as a gear. As can be seen in **FIG. 9A** the implant **700** can be disposed between adjacent spinous processes **2,4** as described above in reference to **FIG. 3**. The distraction guide **710** of the implant **700** can be employed to pierce and/or distract an interspinous ligament **6** connected between the adjacent spinous process **2,4**. The implant **700** can then be urged between the spinous processes **2,4** so that the distraction guide **710** further distracts the interspinous ligament **6** to form a space within which a spacer **220** can be disposed. In the embodiment shown, the spacer **220** can pivot about a central body extending from the first wing **230** of the implant **700**. The first wing **230** limits and/or blocks movement along a longitudinal axis **725** of the implant **700** in the direction of insertion.

Once the implant **700** is arranged as desired, the actuator arrangement can be actuated to deploy the upper and lower winglets, **712,714**, thereby forming a second wing **760** as shown in **FIG. 9C**. The

second wing **760** limits and/or blocks movement along the longitudinal axis **725** in a direction opposite the direction of insertion. With the second wing **760** deployed, the adjacent spinous processes **2,4** are at least partially disposed between the wings **730,760**, preventing the implant **800** from becoming undesirably dislodged from the space between the adjacent spinous processes **2,4**. As shown in **FIG. 9C**, the first wing **730** and the second wing **760** can be arranged sufficiently far apart that the adjacent spinous processes **2,4** can move relative to one another slightly (e.g., laterally - such as during a twisting motion), allowing the patient greater flexibility of movement.

FIGs. 9B and **9C** are partial cross-sectional posterior views of the implant **700** shown in **FIG. 9A**. In an embodiment, the deployable winglets **712,714** can be extended from the distraction guide **710** using an actuator arrangement comprising a shaft **707** and cam **716**. The cam **716** can be rotated to force the winglets **712,714** to pivot outward from the distraction guide **710**. As shown, the winglets **712,714** are at least partially disposed within a cavity of the distraction guide **710**.

FIGs. 10A through **10E** illustrate a still further embodiment of an implant **800** in accordance with the present invention arranged between adjacent spinous processes **2,4**. In such an embodiment, upper and lower winglets **812,814** can be disposed within the distraction guide **810** and can be deployed by actuating an actuator arrangement including a screw **807** having an engageable head **806**, or alternatively including some other mechanism such as a gear. As can be seen in **FIG. 10A** the implant **800** can be disposed between adjacent spinous processes **2,4** as described above in reference to **FIG. 3**. The distraction guide **810** of the implant **800** can be employed to pierce and/or distract an interspinous ligament **6** connected between the adjacent spinous process **2,4**. The implant **800** can then be urged between the spinous processes **2,4** so that the distraction guide **810** further distracts the interspinous ligament **6** to form a space within which a spacer **220** can be disposed. In the embodiment shown, the spacer **220** can pivot about a central body extending from the first wing **230** of the implant **800**. The first wing **230** limits and/or blocks movement along a longitudinal axis **825** of the implant **800** in the direction of insertion.

Once the implant **800** is arranged as desired, the actuator arrangement can be actuated to deploy the upper and lower winglets, **812,814**, thereby forming a second wing **860** as shown in **FIG. 9B**. The second wing **860** limits and/or blocks movement along the longitudinal axis **825** in a direction opposite the direction of insertion. With the second wing **860** deployed, the adjacent spinous processes **2,4** are at least partially disposed between the wings **830,860**, preventing the implant **800** from becoming undesirably dislodged from the space between the adjacent spinous processes **2,4**. As shown in **FIG. 9B**, the first wing **830** and the second wing **860** can be arranged sufficiently far apart that the adjacent spinous processes **2,4** can move relative to one another slightly (e.g., laterally - such as during a twisting motion), allowing the patient greater flexibility of movement.

FIGs. 10C and **10D** are partial cross-sectional end views of the implant **800** shown in **FIGs. 10A** and **10B**. In an embodiment, the deployable winglets **812,814** can be extended from the distraction guide **810** using an actuator arrangement comprising a screw **806** and threaded collar **816**. The threaded collar **816** can be driven along the screw **806** to force the winglets **812,814** to pivot outward from the distraction guide **810**. As shown, the winglets **812,814** are at least partially disposed within a cavity of the distraction guide **810**. The winglets **812,814** are pivotably connected with the threaded collar **816** at an upper pivot point **817** and a lower pivot point **819**. Pins **813,815** or other obstruction devices can be disposed within the cavity and arranged so that the pins **813,815** do not interfere with the arrangement of the winglets **812,814** in a nested, or undeployed, position. However, as the threaded collar **816** travels along the screw **806** in a posterior-to-anterior direction, the inner surface of the winglets **812,814** contact the pins **813,815** and the winglets **812,814** pivot away from the distraction guide **810**. If desired the winglets **812,814** can be spring biased against the posts **813,815** such that in the nested positions and in any deployed position the winglets **812,814** are held against the posts **813,815**.

As shown in **FIGs. 10D** and **10E**, when the threaded collar **816** has traveled a distance along the screw **806**, the winglets **812,814** are deployed to form a second wing **860**. The winglets **812,814** extend along a significant portion of the outer surface of the spinous processes **2,4**. When urged along the longitudinal axis **825** in a direction opposite the direction of insertion, the winglets **812,814** contact the adjacent spinous processes **2,4** and resist further movement in said direction. **FIG. 10E** is an end view of the implant **800** with the second wing **860** deployed. As shown, the screw head **806** extends from the distraction guide **810**; however, when implemented, it is preferable for the screw head **806** to be either flush with the surface of the distraction guide **810** or slightly receded from the surface of the distraction guide **810** so that movement of the implant **800** is not obstructed during distraction of the interspinous ligament **6** and/or the spinous processes **2,4**. The screw head **806** is shown extending from the distraction guide **810** to demonstrate possible arrangement relative to the proximal end of the distraction guide **810**.

FIGs. 11A and **11B** illustrate yet another embodiment of the implant **900** having an alternative actuation arrangement. In such an embodiment, the winglets **912,914** can be reversed in arrangement so that the winglets **912,914** are deployed by urging the threaded collar **916** toward the screw head **806**. **FIGs. 12A** and **12B** illustrate a still further embodiment of the implant **1000** having an alternative actuation arrangement. In such embodiments, the winglets **1012,1014** include two hinged portions, each winglet **1012,1014** folding outward to form a portion of a second wing **1060**. The second wing **1060** does not extend as far along the axis of the spine, i.e. the total height of the second wing **1060** along the spine is smaller than previous embodiments. A reduced second wing height can be advantageous where implants are positioned at adjacent motion segments, thereby preventing undesired contact of adjacent

implants.

As mentioned above, in other embodiments in accordance with the present invention, the winglets can be deployed from the distraction guide using a mechanism other than a screw and threaded collar. For example, one or more gears can be employed. Further, in still other embodiments the upper and lower winglets can have a shape along other than those shapes shown in **FIGs. 10A** through **12B**. The invention is not intended to be limited to winglets having shapes such as shown. In still further embodiments, such as shown in **FIG. 13**, the implant **1100** can include only one of the upper and lower winglets. For example, where implants are positioned at adjacent motion segments it can be advantageous to have a lower winglet **814**, thereby preventing undesired contact of adjacent implants **1100**. As will be obvious to one of ordinary skill in the art, myriad different actuation arrangements can be employed to form a second wing. Implants in accordance with the present invention are not intended to be limited to those described in detail herein.

MATERIALS FOR USE IN IMPLANTS OF THE PRESENT INVENTION

In some embodiments, the implant, and components of the implant (i.e., the spacer, the distraction guide, etc.) can be fabricated from medical grade metals such as titanium, stainless steel, cobalt chrome, and alloys thereof, or other suitable implant material having similar high strength and biocompatible properties. Additionally, the implant can be at least partially fabricated from a shape memory metal, for example Nitinol, which is a combination of titanium and nickel. Such materials are typically radiopaque, and appear during x-ray imaging, and other types of imaging. Implants in accordance with the present invention, and/or portions thereof can also be fabricated from somewhat flexible and/or deflectable material. In these embodiments, the implant and/or portions thereof can be fabricated in whole or in part from medical grade biocompatible polymers, copolymers, blends, and composites of polymers. A copolymer is a polymer derived from more than one species of monomer. A polymer composite is a heterogeneous combination of two or more materials, wherein the constituents are not miscible, and therefore exhibit an interface between one another. A polymer blend is a macroscopically homogeneous mixture of two or more different species of polymer. Many polymers, copolymers, blends, and composites of polymers are radiolucent and do not appear during x-ray or other types of imaging. Implants comprising such materials can provide a physician with a less obstructed view of the spine under imaging, than with an implant comprising radiopaque materials entirely. However, the implant need not comprise any radiolucent materials.

One group of biocompatible polymers is the polyaryletherketone group which has several members including polyetheretherketone (PEEK), and polyetherketoneketone (PEKK). PEEK is proven as a durable material for implants, and meets the criterion of biocompatibility. Medical grade PEEK is

available from Victrex Corporation of Lancashire, Great Britain under the product name PEEK-OPTIMA. Medical grade PEKK is available from Oxford Performance Materials under the name OXPEKK, and also from CoorsTek under the name BioPEKK. These medical grade materials are also available as reinforced polymer resins, such reinforced resins displaying even greater material strength. In an embodiment, the implant can be fabricated from PEEK 450G, which is an unfilled PEEK approved for medical implantation available from Victrex. Other sources of this material include Gharda located in Panoli, India. PEEK 450G has the following approximate properties:

Property	Value
Density	1.3 g/cc
Rockwell M	99
Rockwell R	126
Tensile Strength	97 MPa
Modulus of Elasticity	3.5 GPa
Flexural Modulus	4.1 GPa

PEEK 450G has appropriate physical and mechanical properties and is suitable for carrying and spreading a physical load between the adjacent spinous processes. The implant and/or portions thereof can be formed by extrusion, injection, compression molding and/or machining techniques.

It should be noted that the material selected can also be filled. Fillers can be added to a polymer, copolymer, polymer blend, or polymer composite to reinforce a polymeric material. Fillers are added to modify properties such as mechanical, optical, and thermal properties. For example, carbon fibers can be added to reinforce polymers mechanically to enhance strength for certain uses, such as for load bearing devices. In some embodiments, other grades of PEEK are available and contemplated for use in implants in accordance with the present invention, such as 30% glass-filled or 30% carbon-filled grades, provided such materials are cleared for use in implantable devices by the FDA, or other regulatory body. Glass-filled PEEK reduces the expansion rate and increases the flexural modulus of PEEK relative to unfilled PEEK. The resulting product is known to be ideal for improved strength, stiffness, or stability. Carbon-filled PEEK is known to have enhanced compressive strength and stiffness, and a lower expansion rate relative to unfilled PEEK. Carbon-filled PEEK also offers wear resistance and load carrying capability.

As will be appreciated, other suitable similarly biocompatible thermoplastic or thermoplastic polycondensate materials that resist fatigue, have good memory, are flexible, and/or deflectable, have very low moisture absorption, and good wear and/or abrasion resistance, can be used without departing from the scope of the invention. As mentioned, the implant can be comprised of polyetherketoneketone

(PEKK). Other material that can be used include polyetherketone (PEK), polyetherketoneetherketoneketone (PEKEKK), polyetheretherketoneketone (PEEKK), and generally a polyaryletheretherketone. Further, other polyketones can be used as well as other thermoplastics. Reference to appropriate polymers that can be used in the implant can be made to the following documents, all of which are incorporated herein by reference. These documents include: PCT Publication WO 02/02158 A1, dated January 10, 2002, entitled "Bio-Compatible Polymeric Materials;" PCT Publication WO 02/00275 A1, dated January 3, 2002, entitled "Bio-Compatible Polymeric Materials;" and, PCT Publication WO 02/00270 A1, dated January 3, 2002, entitled "Bio-Compatible Polymeric Materials." Other materials such as Bionate®, polycarbonate urethane, available from the Polymer Technology Group, Berkeley, California, may also be appropriate because of the good oxidative stability, biocompatibility, mechanical strength and abrasion resistance. Other thermoplastic materials and other high molecular weight polymers can be used.

METHODS FOR IMPLANTING INTERSPINOUS IMPLANTS

A minimally invasive surgical method for implanting an implant **300** as shown in **FIGs. 2A-8** in the cervical spine is disclosed and taught herein. In this method, as shown in **FIG. 14**, preferably a guide wire **780** is inserted through a placement network **790** into the neck of the implant recipient. The guide wire **780** is used to locate where the implant **300** is to be placed relative to the cervical spine, including the spinous processes. Once the guide wire **780** is positioned with the aid of imaging techniques, an incision is made on the side of the neck so that an implant **300** in accordance with an embodiment of the present invention, can be positioned in the neck thorough an incision and along a line that is about perpendicular to the guide wire **780** and directed at the end of the guide wire **780**. The main body **301** of the implant **300** is inserted into the neck of the patient. Preferably during insertion, the distraction guide **310** pierces or separates the tissue without severing the tissue.

Once the main body **301** is satisfactorily positioned, an insert **370** can be positioned within a cavity of the main body **301**, causing the distraction guide **310** of the main body **301** to be arranged in a second configuration so that at least a portion of the distraction guide **310** forms a second wing. The insert **370** can be inserted along a line that is generally colinear with the line over which the main body **301** is inserted. The anatomy of the neck is such that it is most convenient and minimally invasive to enter the neck from the side with respect to the main body **301** and the insert **370**.

Further, a minimally invasive surgical method for implanting an implant as described in **FIGs. 2A-8** in the lumbar spine is disclosed and taught herein. In this method, as shown in the flowchart of **FIG. 15A**, preferably a unilateral incision or opening can be made using a posterior-anterior approach (Step 102). The unilateral incision can be made, for example, at a location some distance to the left of

an axis along the spinous process. The incision or opening can be enlarged, and a distraction tool can be positioned within the incision so that the proximal end of the distraction tool (Step 104) can access an exposed side of the interspinous ligament. The distraction tool can be urged through the interspinous ligament, thereby distracting the interspinous ligament so as to receive the implant (Step 106). Once the interspinous ligament is sufficiently distracted, the distraction tool can be disengaged and removed from the incision (Step 108).

Once the distraction tool has been removed from the incision, the implant can be positioned at the dilated opening, and the distraction guide of the implant can be urged through the dilated opening (Step 110). The implant can be further urged through the opening until the spacer is positioned as desired between the adjacent spinous processes of the targeted motion segment (Step 112). The spacer is free to rotate so that the load is distributed more evenly over the surface of the spinous processes. Optionally, the implant can be urged through the dilated opening until the first wing contacts the adjacent spinous processes, thereby blocking further movement in the direction of insertion. Once the implant is properly arranged, the insert can be positioned at the distal end of the implant so that the insert can be urged into and through the hollow cavity of the hollow central body (Step 114). As the insert is seated inside of the cavity, the distraction guide splits, and the upper winglet and the lower winglet deploy as a second wing. The remaining tools can be removed from the incision, and the incision can be closed (Step 116). Preferably during insertion, the distraction end pierces or separates the tissue without severing the tissue.

Further, a minimally invasive surgical method for implanting an implant as shown in **FIGs. 9A-13** in the lumbar spine is disclosed and taught herein. In this method, as shown in the flowchart of **FIG. 15B**, an incision or opening can be made using a posterior-anterior approach (Step 202). The incision or opening can be enlarged, and a distraction tool can be positioned within the incision so that the proximal end of the distraction tool (Step 204) can access an exposed side of the interspinous ligament. The distraction guide can be urged through the interspinous ligament and distracted, thereby distracting the interspinous ligament so as to receive the implant (Step 206). Once the interspinous ligament is sufficiently distracted, the distraction tool can be disengaged and removed from the incision (Step 208).

Once the distraction guide has been removed from the incision, the implant can be positioned at the dilated opening, and the distraction guide of the implant can be urged through the dilated opening (Step 210). The implant can be further urged through the opening until the spacer is positioned as desired between the adjacent spinous processes of the targeted motion segment (Step 212). The spacer is free to rotate so that the load is distributed more evenly over the surface of the spinous processes. Optionally, the implant can be urged through the dilated opening until the first wing contacts the adjacent spinous processes, thereby blocking further movement in the direction of insertion. Once the

implant is properly arranged, an actuation tool can be inserted within the incision at an opposite side of the adjacent spinous processes from the point of insertion (Step 214). The actuation tool can engage the actuation arrangement, and can actuate the actuation arrangement so that the upper winglet and the lower winglet deploy as a second wing, as described above (Step 216). The remaining tools can be removed from the incision, and the incision can be closed (Step 218). Preferably during insertion, the distraction end pierces or separates the tissue without severing the tissue.

The foregoing description of the present invention have been presented for purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise forms disclosed. Many modifications and variations will be apparent to practitioners skilled in this art. The embodiments were chosen and described in order to best explain the principles of the invention and its practical application, thereby enabling others skilled in the art to understand the invention for various embodiments and with various modifications as are suited to the particular use contemplated. It is intended that the scope of the invention be defined by the following claims and their equivalents.

WHAT IS CLAIMED:

1. An interspinous implant adapted to be inserted between spinous processes, the implant comprising:

a spacer;

a distraction guide having a first configuration;

wherein the distraction guide is adapted to be arranged in a second configuration; and

wherein when the distraction guide is arranged in the second configuration, the distraction guide limits movement of the interspinous implant when the interspinous implant is positioned between spinous processes.

2. The implant of claim 1, further including a first wing; and

wherein the spacer is disposed between the first wing and the distraction guide.

3. The implant of claim 1, wherein:

the spacer includes a cavity; and

the implant further includes:

an insert adapted to be urged into the cavity; and

wherein when the insert is urged into the cavity, the distraction guide is arranged from the first configuration to the second configuration.

4. The implant of claim 1, further comprising:

a first portion pivotably associated with one of the distraction guide and the spacer,

a first protuberance extending from the first portion,

a second portion pivotably associated with one of the distraction guide and the spacer, and

a second protuberance extending from the second portion; and

wherein the distraction guide is arranged in a second configuration by applying a force to the first protuberance and the second protuberance so that the first portion and the second portion pivot away from each other.

5. The implant of claim 1, wherein:

the distraction guide includes a first winglet and a second winglet;

the second winglet is pivotably associated with the spacer;

wherein the distraction guide is arranged in a second configuration by urging the second winglet to pivot away from the first winglet.

6. The implant of claim 5, wherein when the distraction guide is in the second configuration, the distraction guide is a second wing that limits movement of the interspinous implant when positioned between spinous processes.

7. The implant of claim 1, wherein:

the distraction guide includes a distraction end and a wing pivotably mounted to the distraction guide rearwardly of said distraction end; and

the wing is pivotable from a first position adjacent to the distraction end to a second position away from the distraction end.

8. An interspinous implant adapted to be inserted between spinous processes, the implant comprising:

a spacer;

a distraction guide including a winglet adapted to be extended from the distraction guide;

an actuator operably associated with the winglet so that when the actuator is actuated, the winglet extends from the distraction guide.

9. The implant of claim 8, further comprising:

a first wing;

wherein:

the spacer is disposed between the distraction guide and the first wing;

when the winglet extends from the distraction guide, the winglet is a second wing;

the first wing and the second wing limit movement of the interspinous implant when the implant is positioned between spinous processes.

10. The implant of claim 8, further including:

a central body; and

wherein:

the spacer is rotatably disposed about the central body, and

the distraction guide extends from the central body.

11. The implant of claim 10, wherein:

the distraction guide includes a cavity; and

the winglet and the actuator are at least partially disposed within the cavity.

12. The implant of claim 11, wherein when the actuator is actuated, the winglet pivots so that the winglet extends away from the cavity.

13. The implant of claim 12, wherein:

the actuator is a threaded shaft;

the winglet is pivotably attached to a threaded collar such that the collar travels along the threaded shaft when the actuator is actuated.

14. The implant of claim 8, wherein:

the winglet is a first winglet, and the distraction guide further includes a second winglet;

the second winglet is extendable from the distraction guide; and

when the actuator is actuated, the second winglet extends from the distraction guide.

15. An interspinous implant adapted to be inserted between spinous processes, the implant comprising:

a first wing;

a central body extending from the first wing;

a spacer rotatably disposed about the central body;

a distraction guide extending from the central body, the distraction guide including:

an actuator disposed at least partially within the distraction guide;

a first winglet and a second winglet operably associated with the actuator and adapted to be extended from the distraction guide;

wherein the first winglet and the second winglet are extended by actuating the actuator.

16. The implant of claim 15, further comprising:

a collar having a threaded surface, the collar being associated with the actuator;

wherein the actuator includes a threaded surface; and

wherein the first winglet and the second winglet are pivotably associated with the collar.

17. The implant of claim 15, wherein the first winglet and the second winglet including a first inner surface and a second inner surface; and

further including:

a first pin disposed within the distraction guide, the first pin being adapted to contact the first inner surface to guide the movement of the first winglet; and

a second pin disposed within the distraction guide, the second pin can contact the

second inner surface to guide the movement of the second winglet.

18. An interspinous implant adapted to be inserted between spinous processes, the implant comprising:

a flange;

a spacer extending from the flange;

a first connection rod pivotably associated with the flange at a proximal end of the first connection rod;

a first hook extending from a distal end of the first connection rod;

a second connection rod pivotably associated with the flange at a proximal end of the second connection rod;

a second hook extending from a distal end of the second connection rod; a distraction guide extending from the spacer, the distraction guide having a first configuration;

wherein the distraction guide is adapted to be arranged in a second configuration.

wherein when the distraction guide is arranged in the second configuration, the distraction guide limits movement of the interspinous implant when positioned between spinous processes.

19. The implant of claim 18, further comprising:

a cavity disposed through the flange and the spacer;

an insert adapted to be urged into the cavity.

wherein when the insert is urged into the cavity, the distraction guide is arranged from the first configuration to the second configuration.

20. The implant of claim 18, wherein:

the distraction guide includes a first winglet and a second winglet;

the second winglet includes a protuberance and is pivotably associated with the spacer;

wherein the distraction guide is arranged in a second configuration by urging the second winglet to pivot away from the first winglet;

wherein the second winglet is urged to pivot away from the first winglet by applying a force to the protuberance.

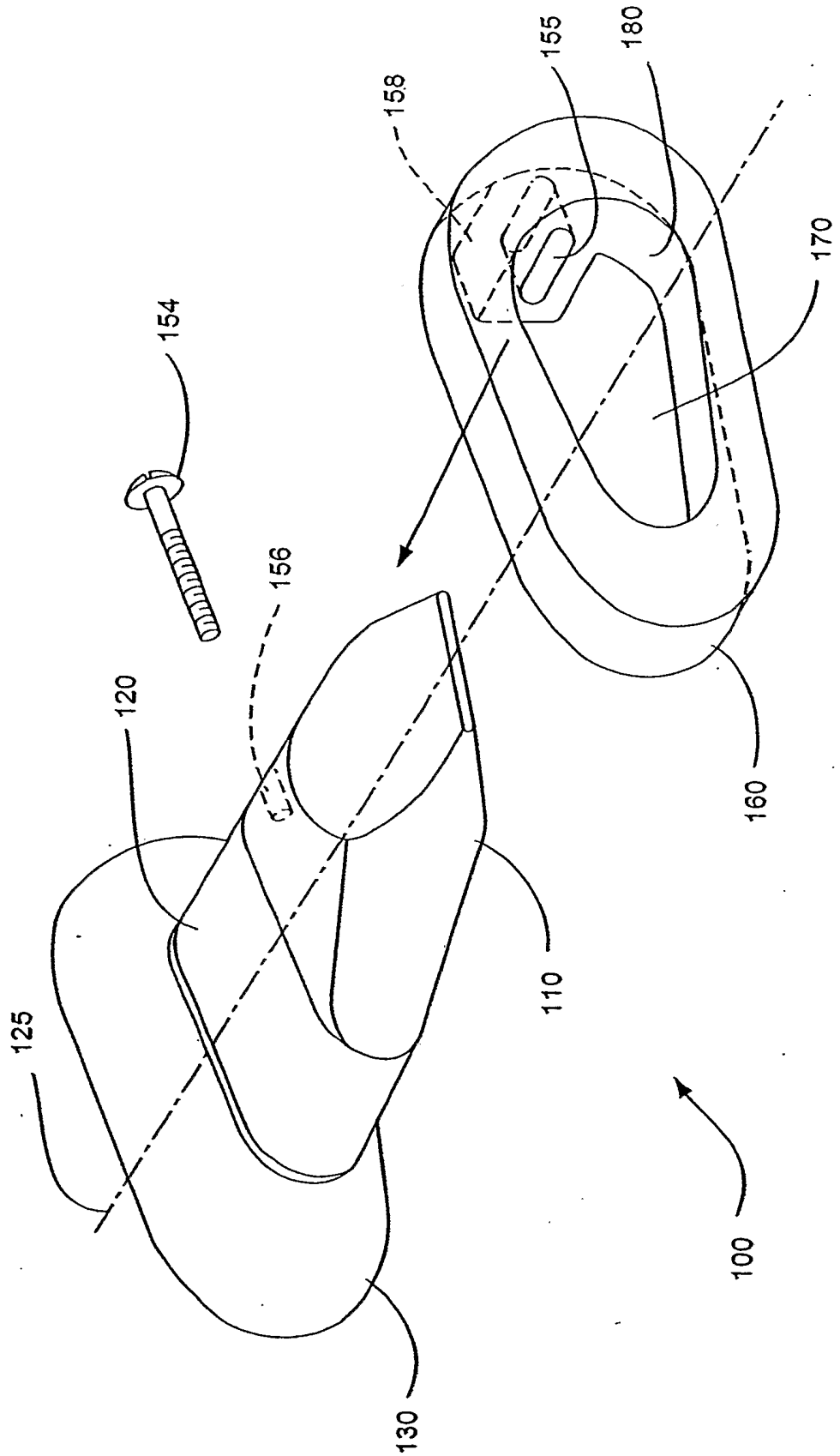


Fig. 1A

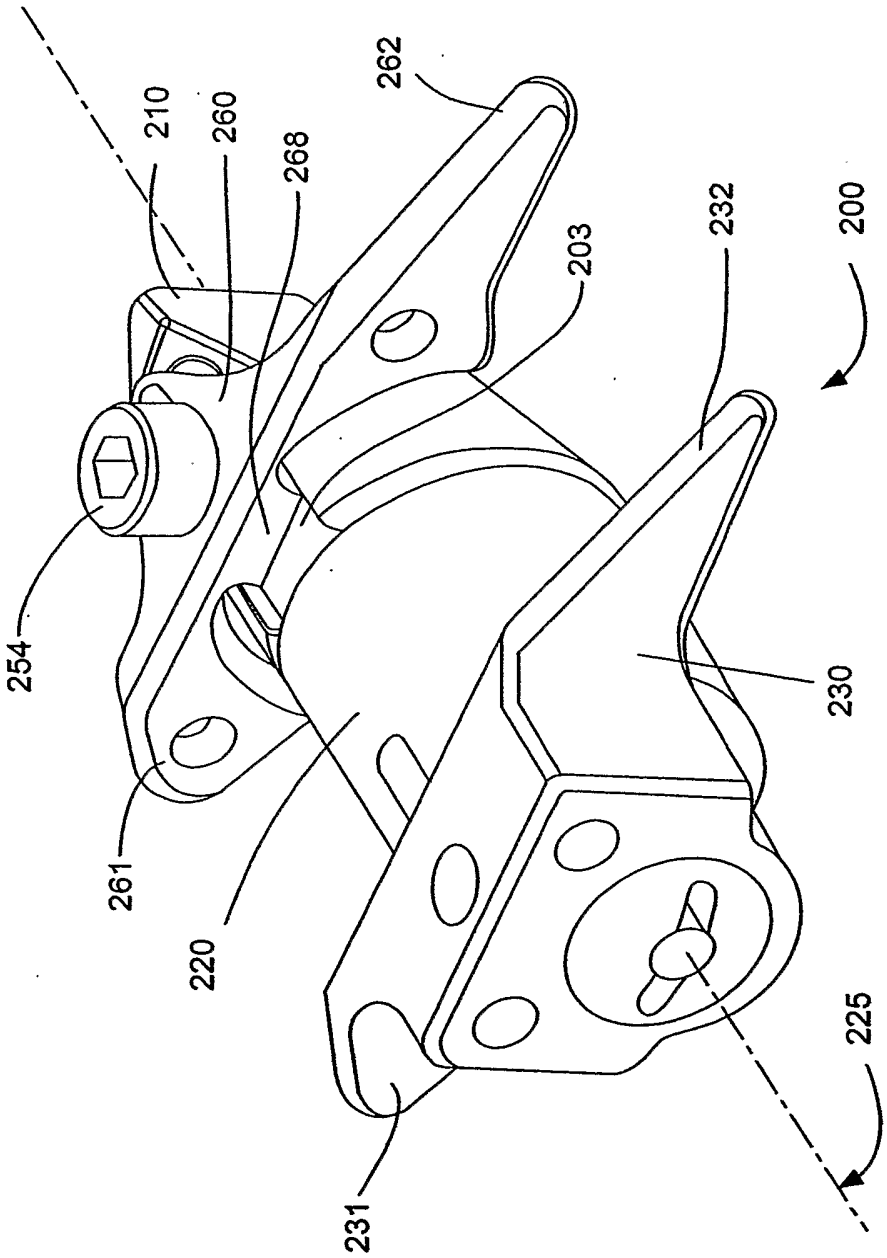


Fig. 1B

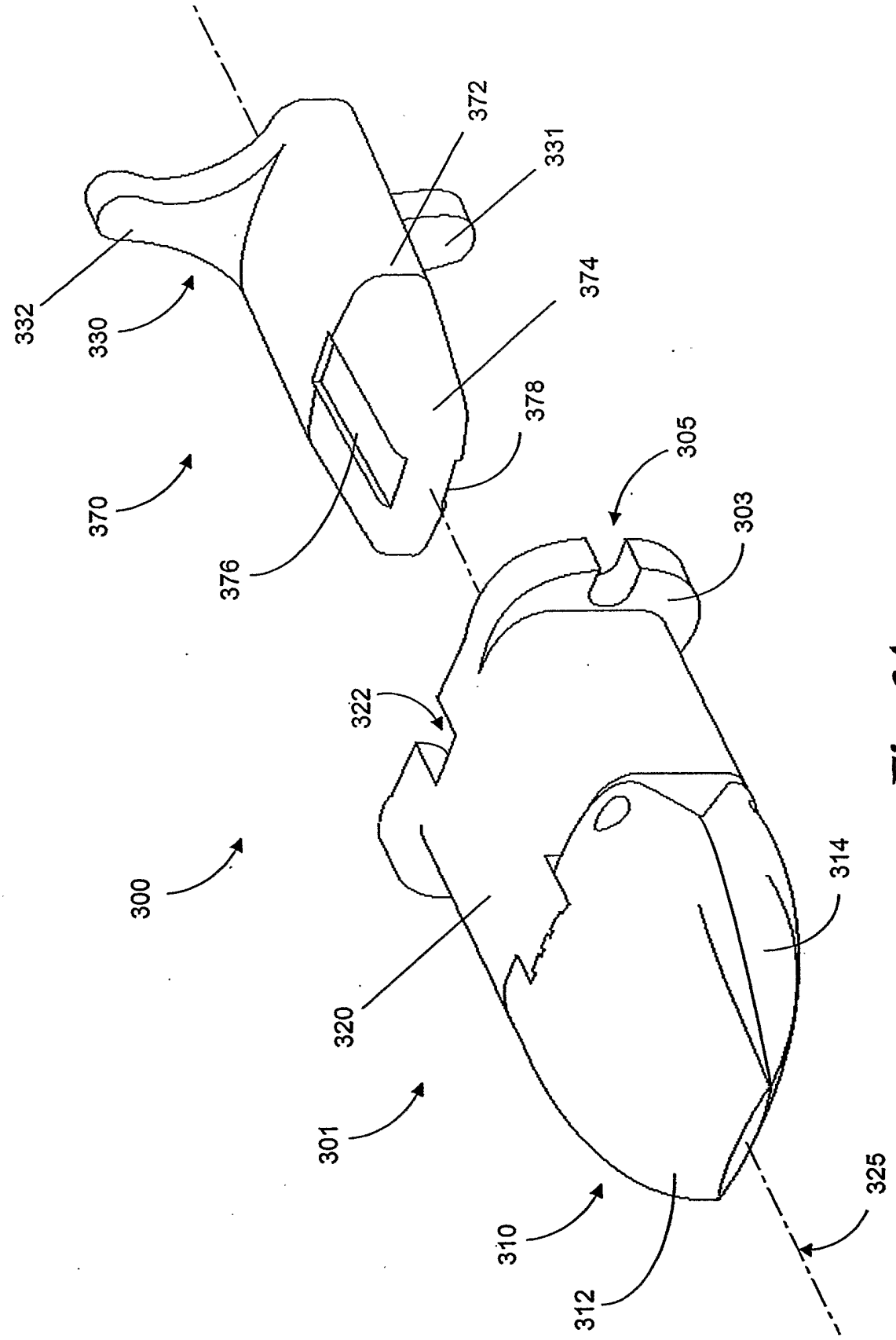

372
331
332
330
374
378
305
370
376
303
322
300
314
320
301
325
310
312

Fig. 2A

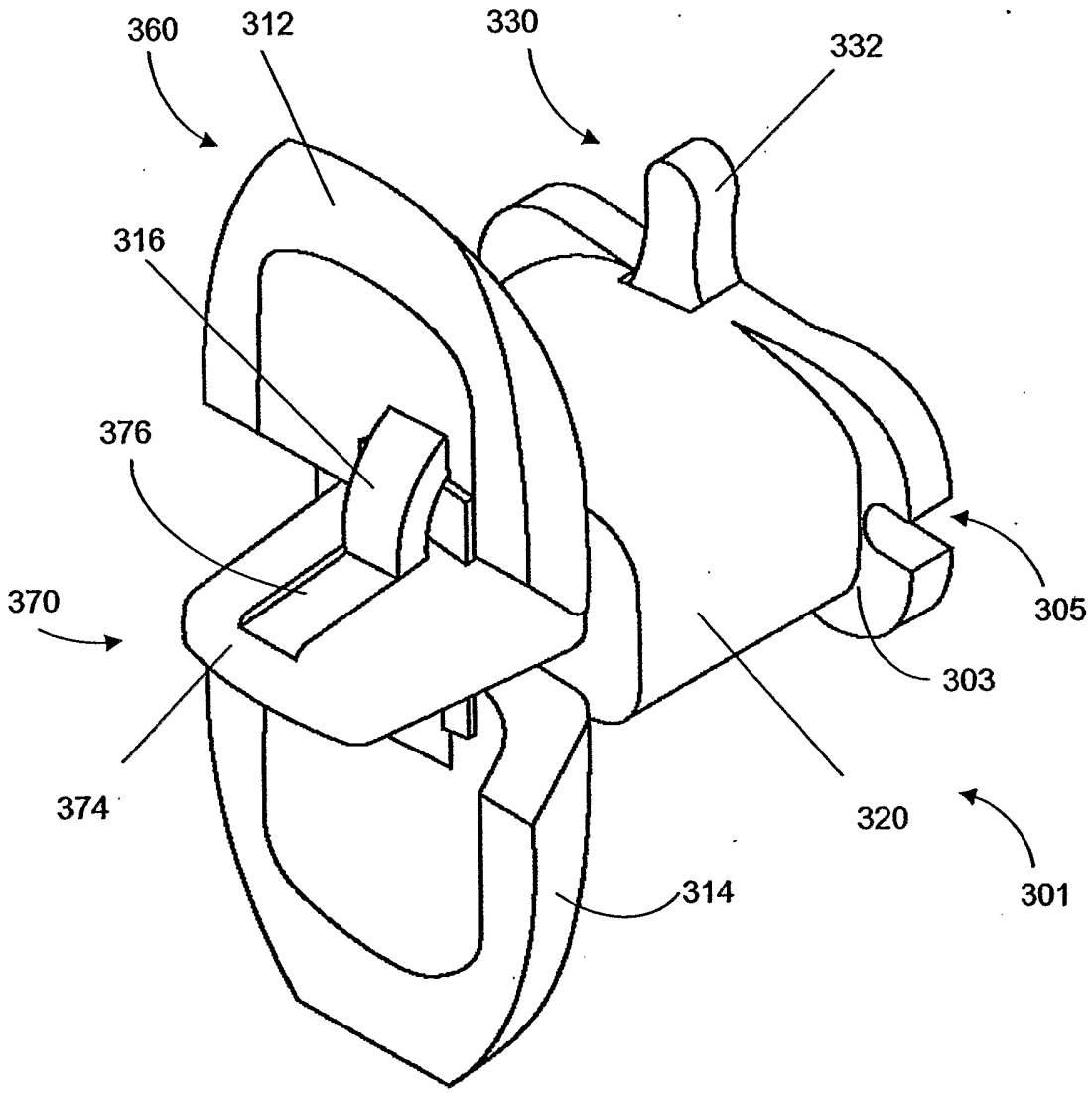


Fig. 2B

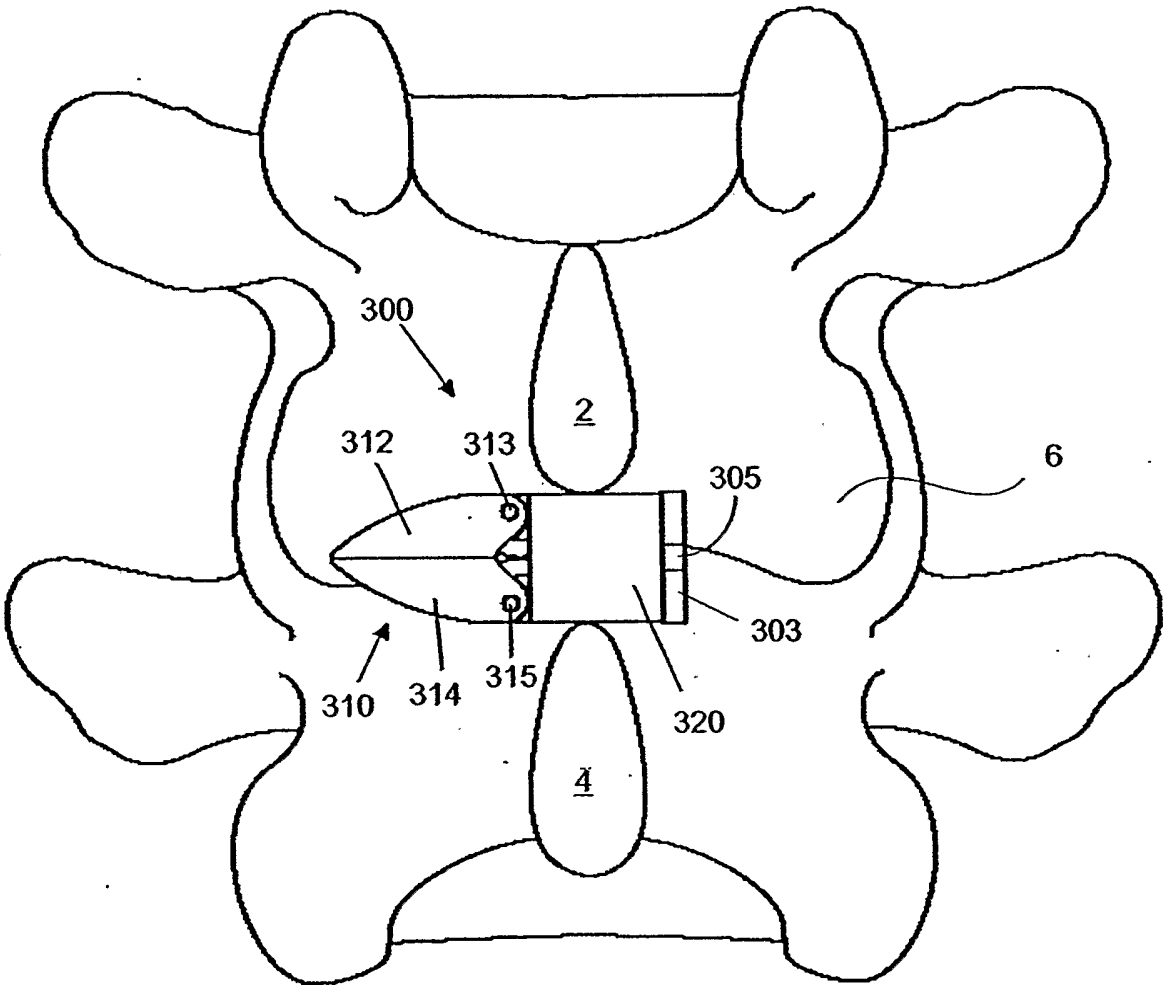


Fig. 3A

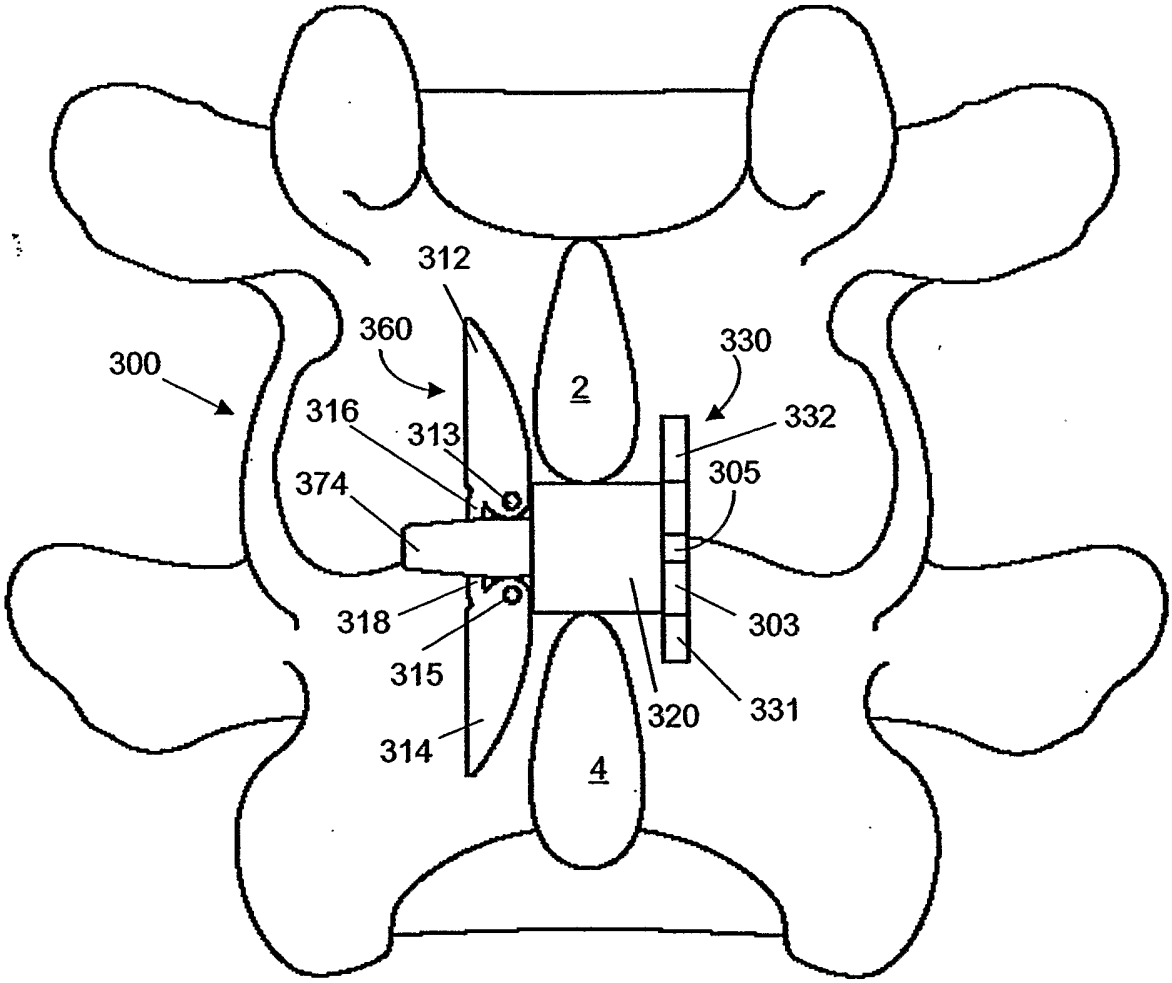


Fig. 3B

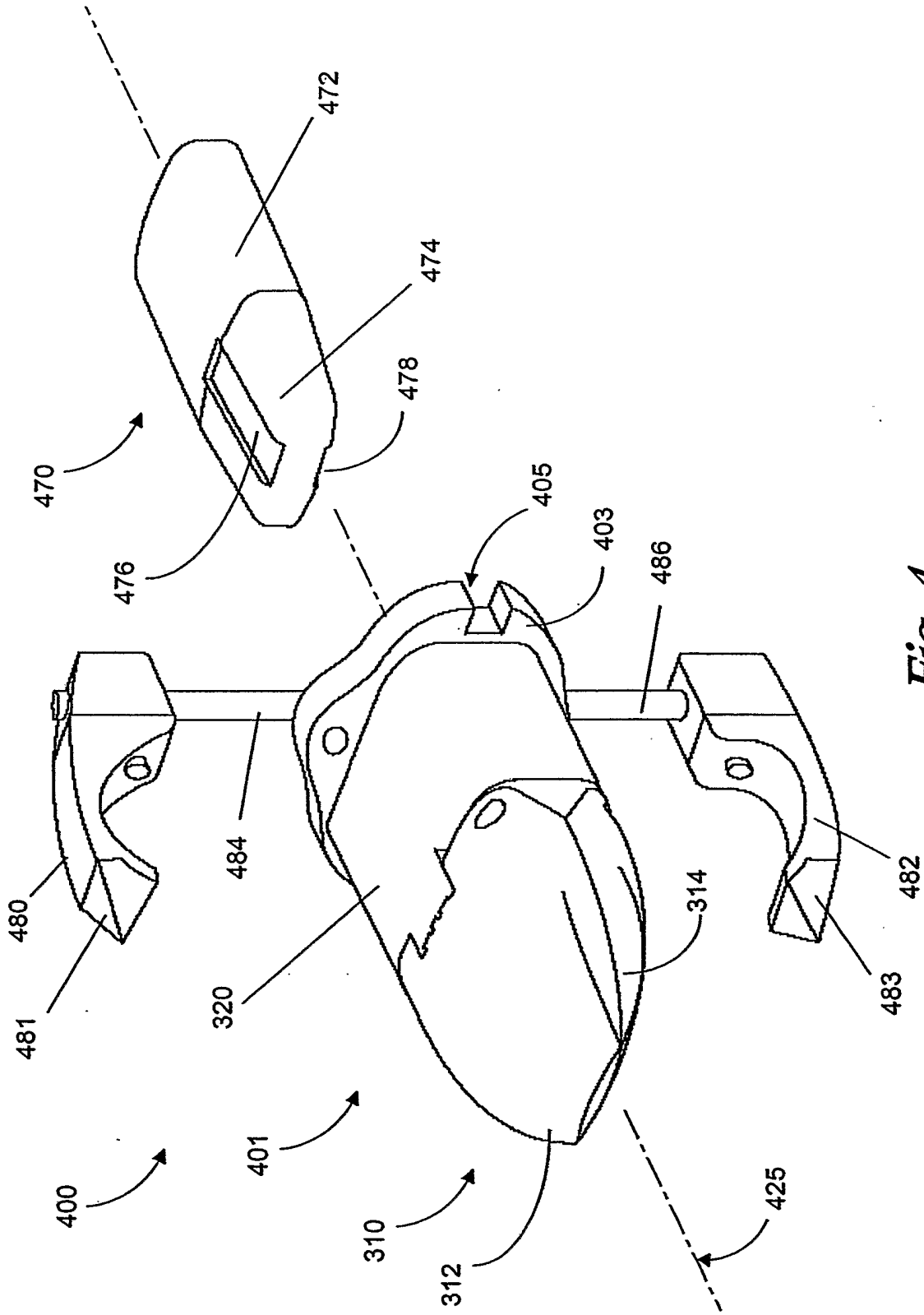

472
474
478
470
476
405
403
486
484
480
481
320
314
482
483
400
401
310
312
425

Fig. 4

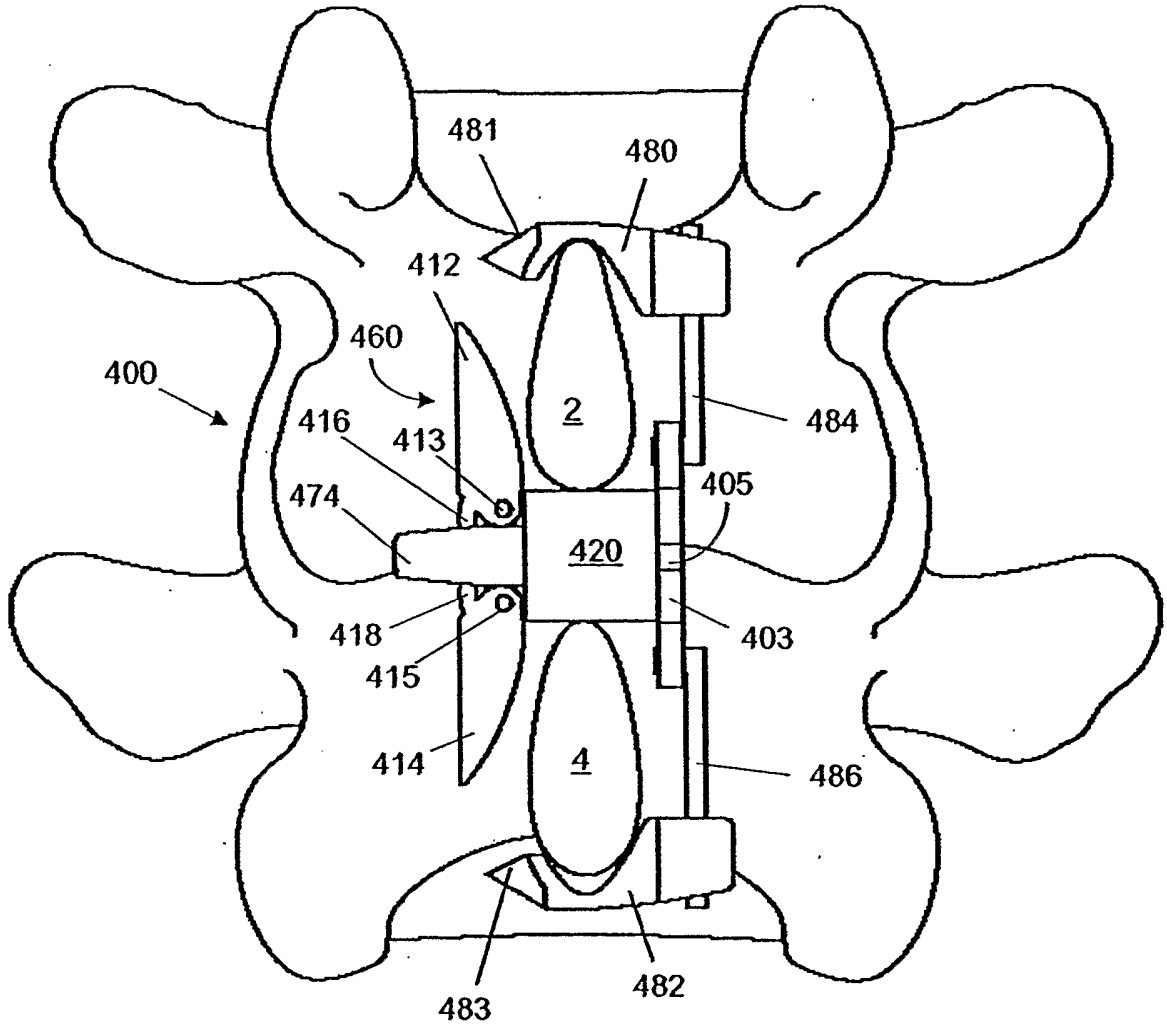

481
480
412
460
400
2
484
416
413
405
474
420
418
403
415
414
4
486
483
482

Fig. 5

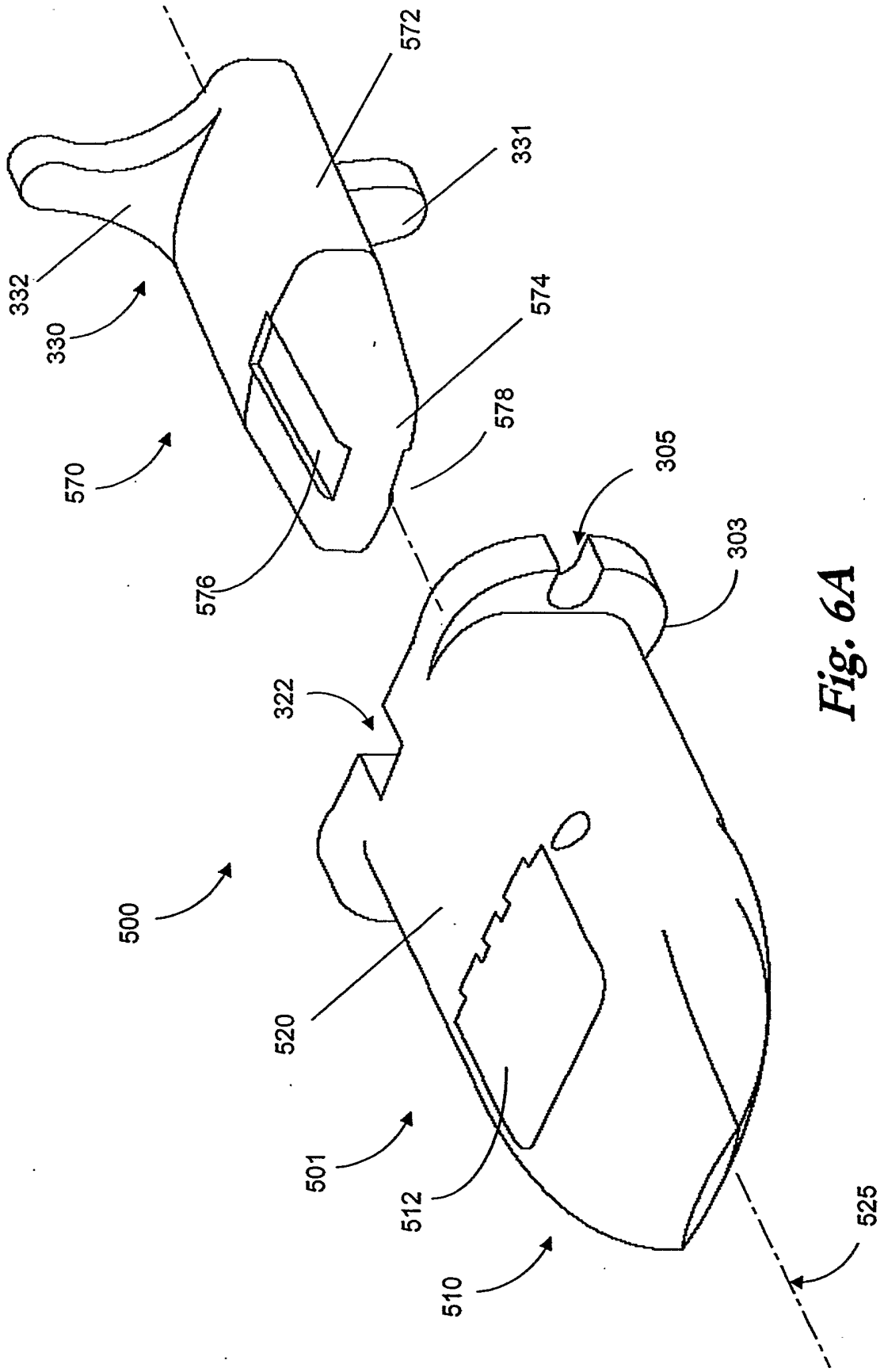

572
331
332
330
574
578
570
305
576
303
322
500
520
501
512
510
525

Fig. 6A

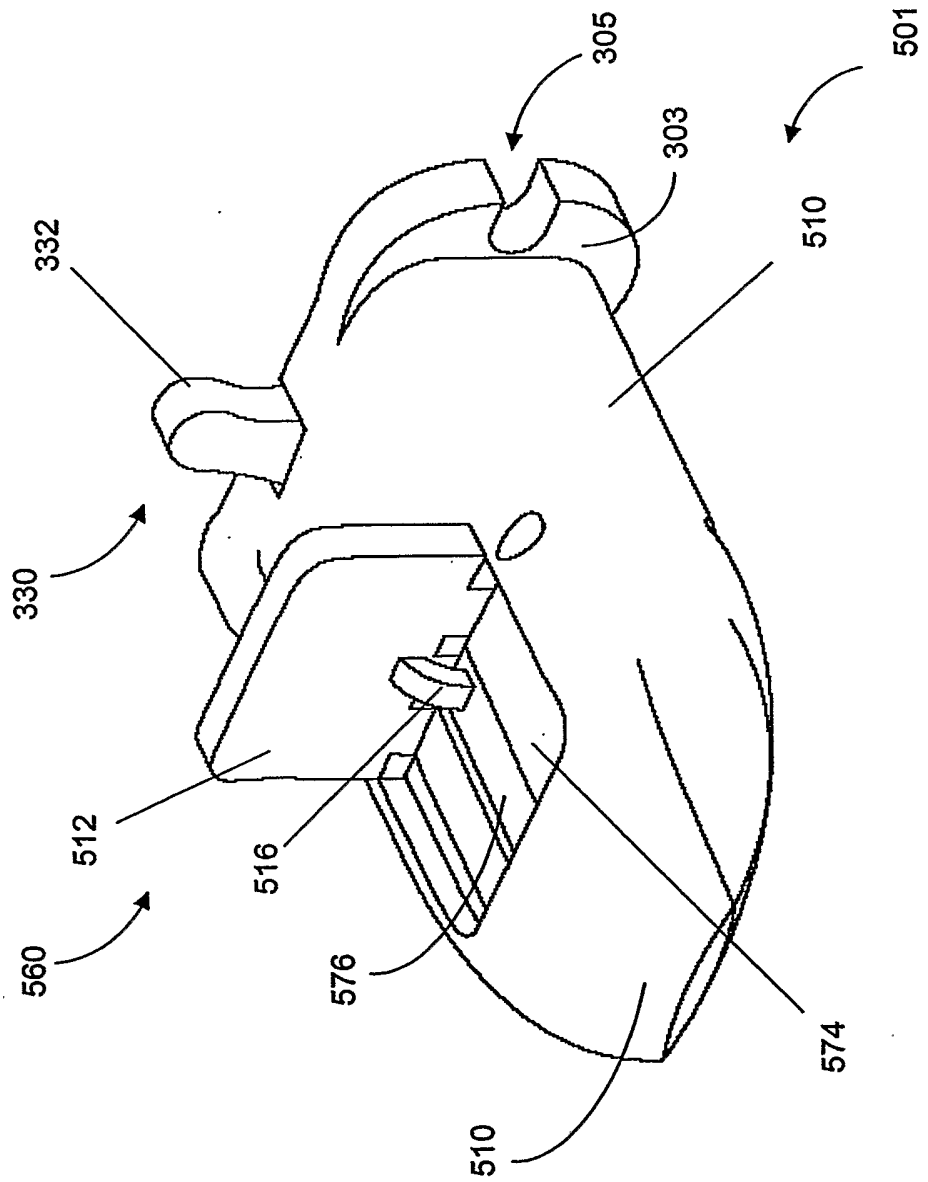


Fig. 6B

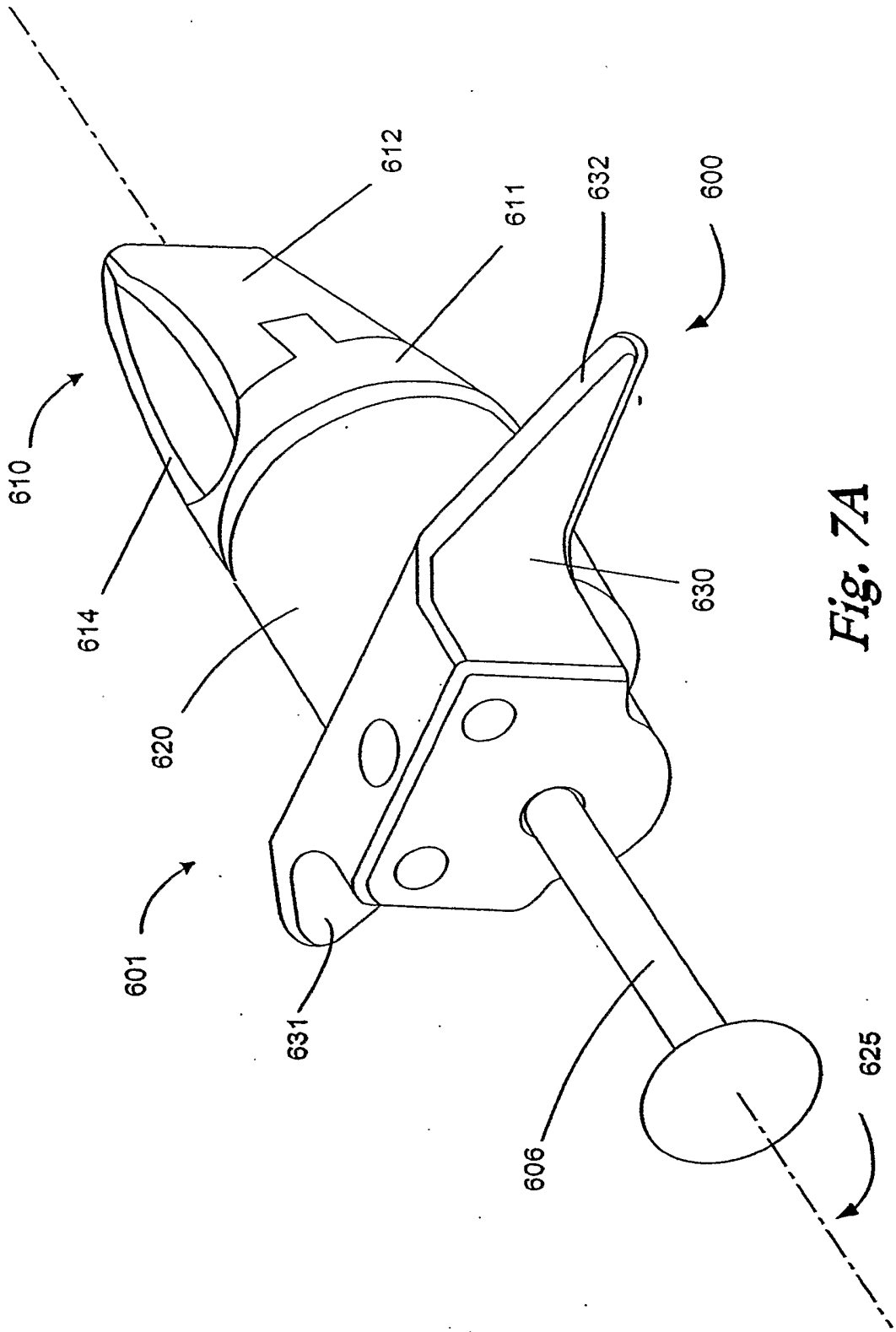


Fig. 7A

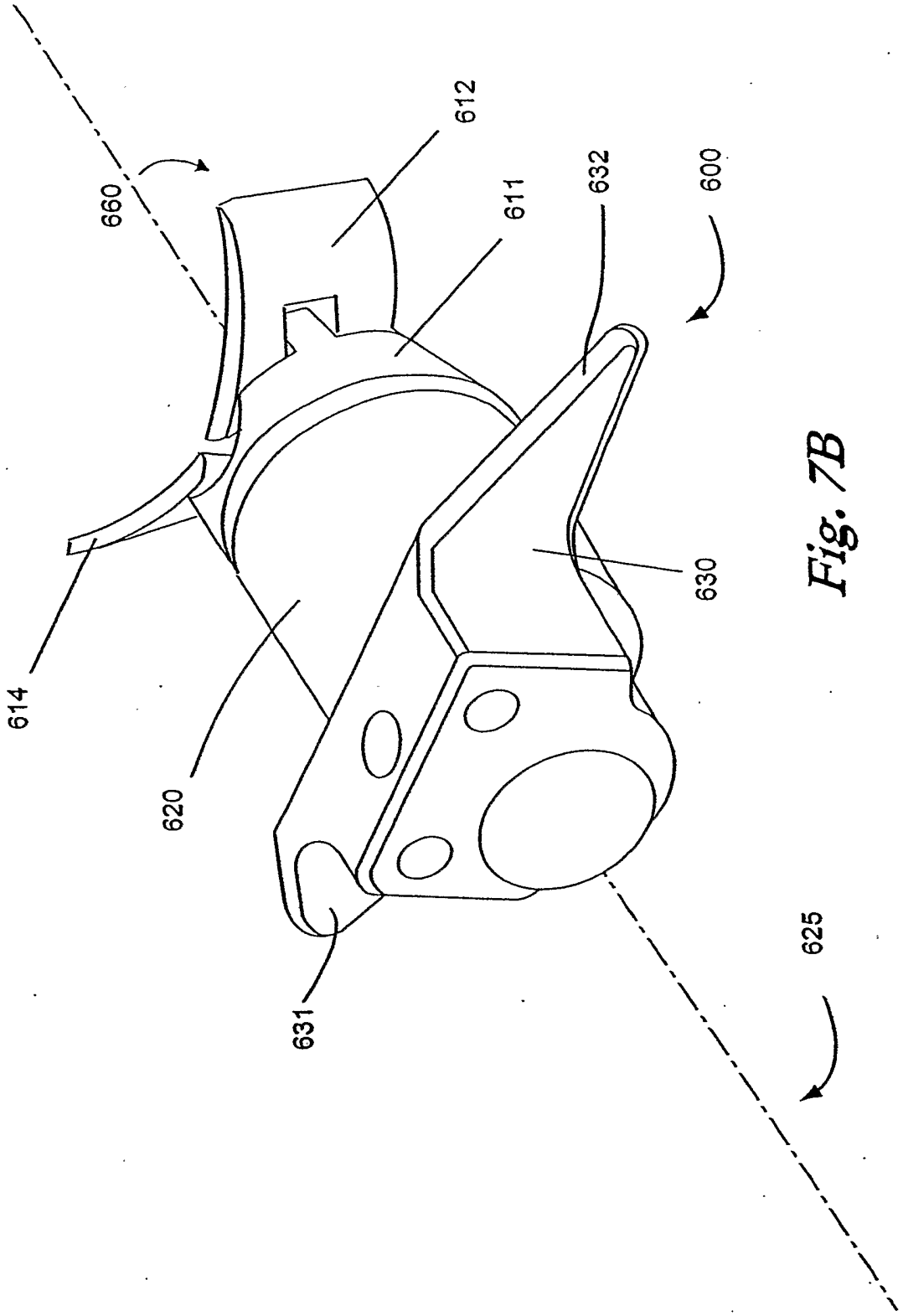


Fig. 7B

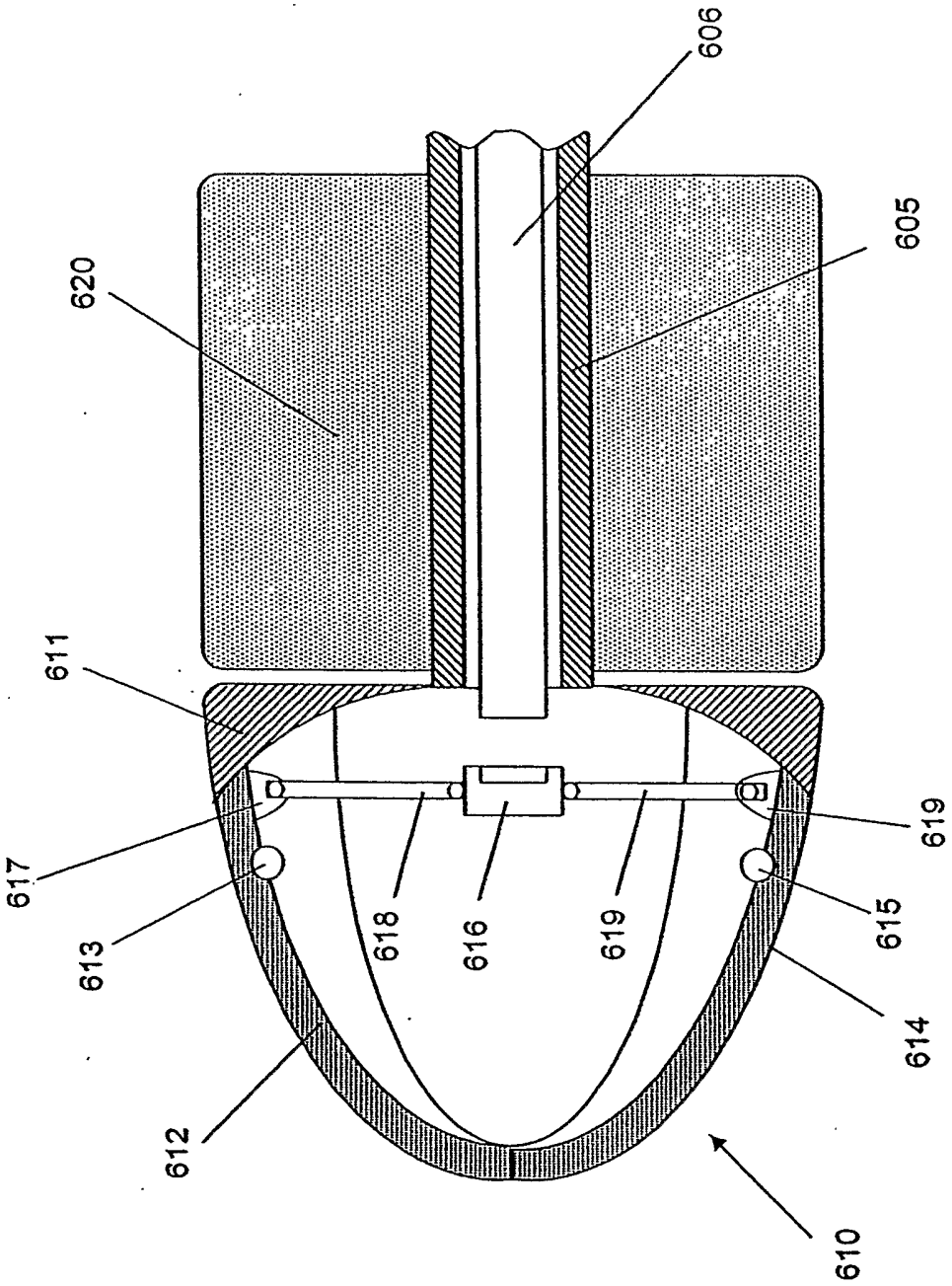


Fig. 7C

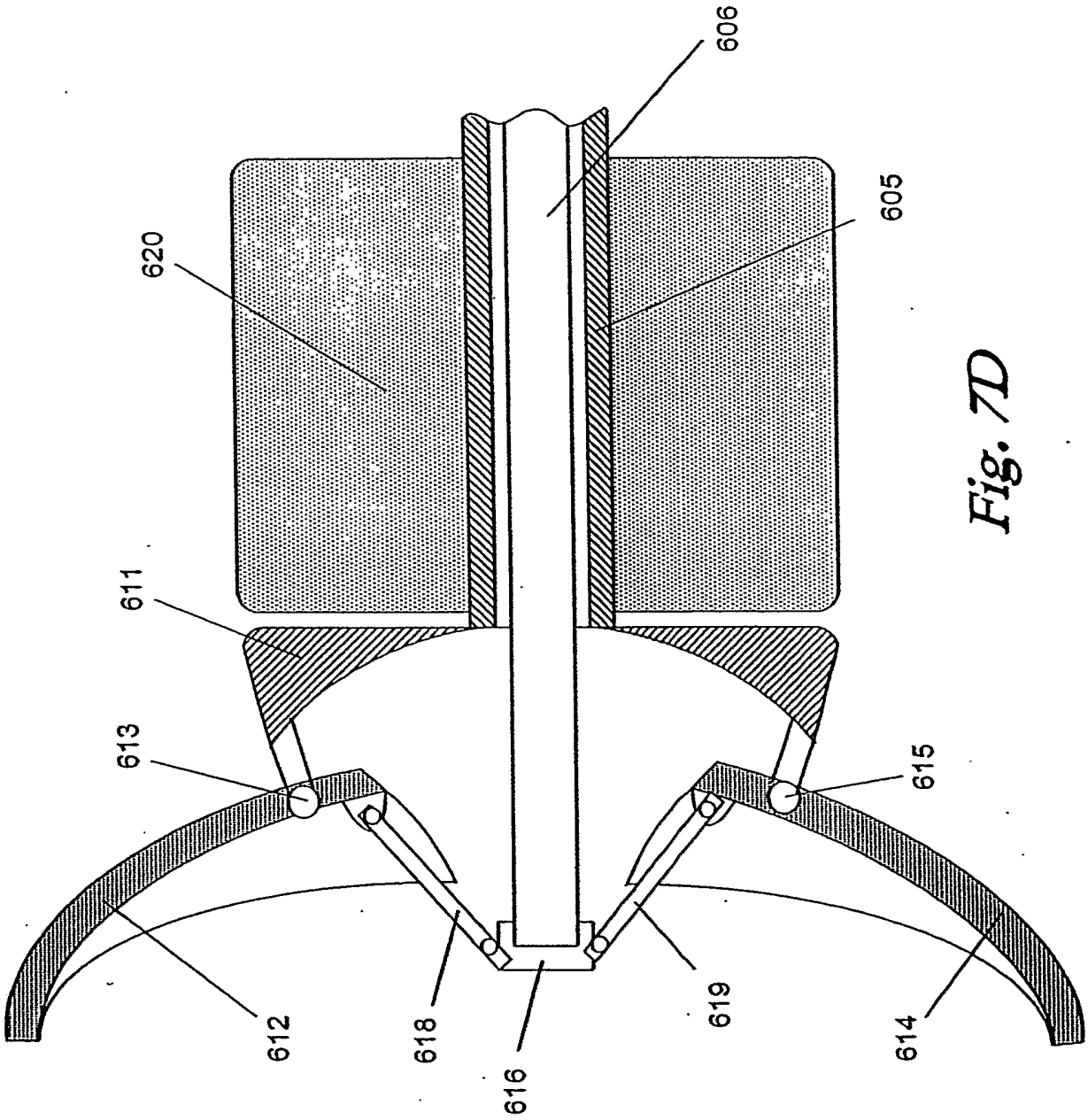


Fig. 7D

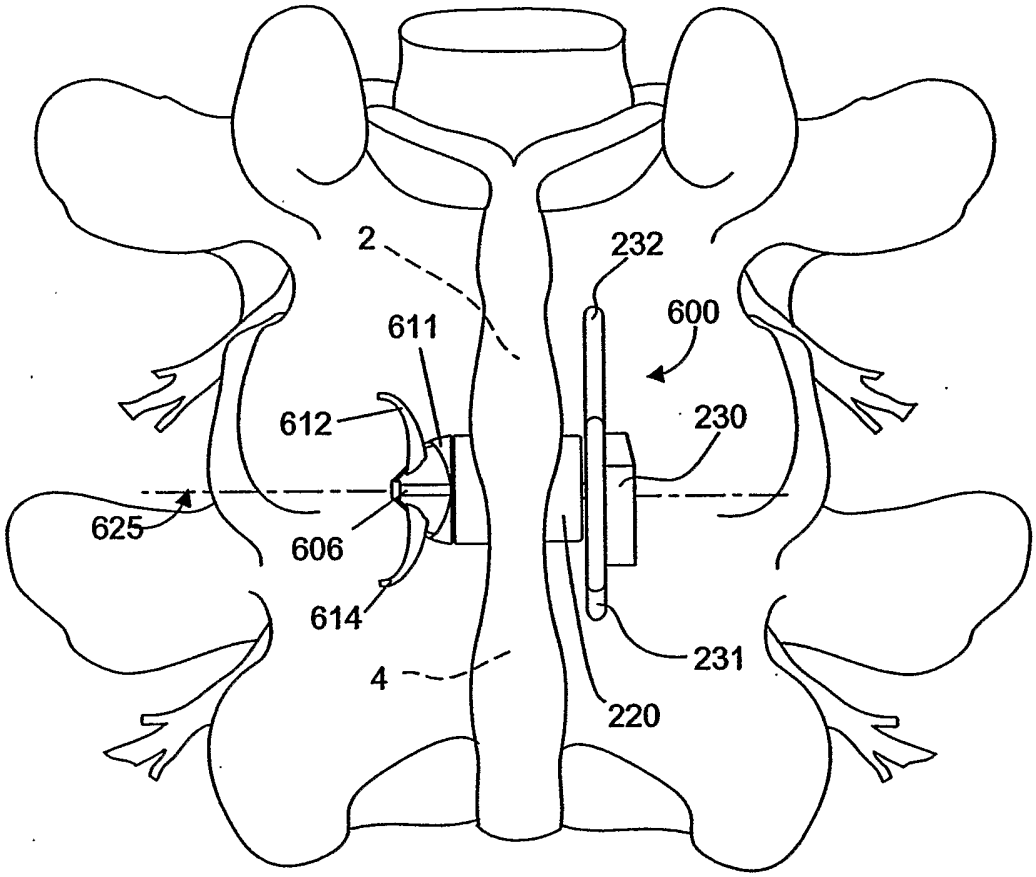


Fig. 8

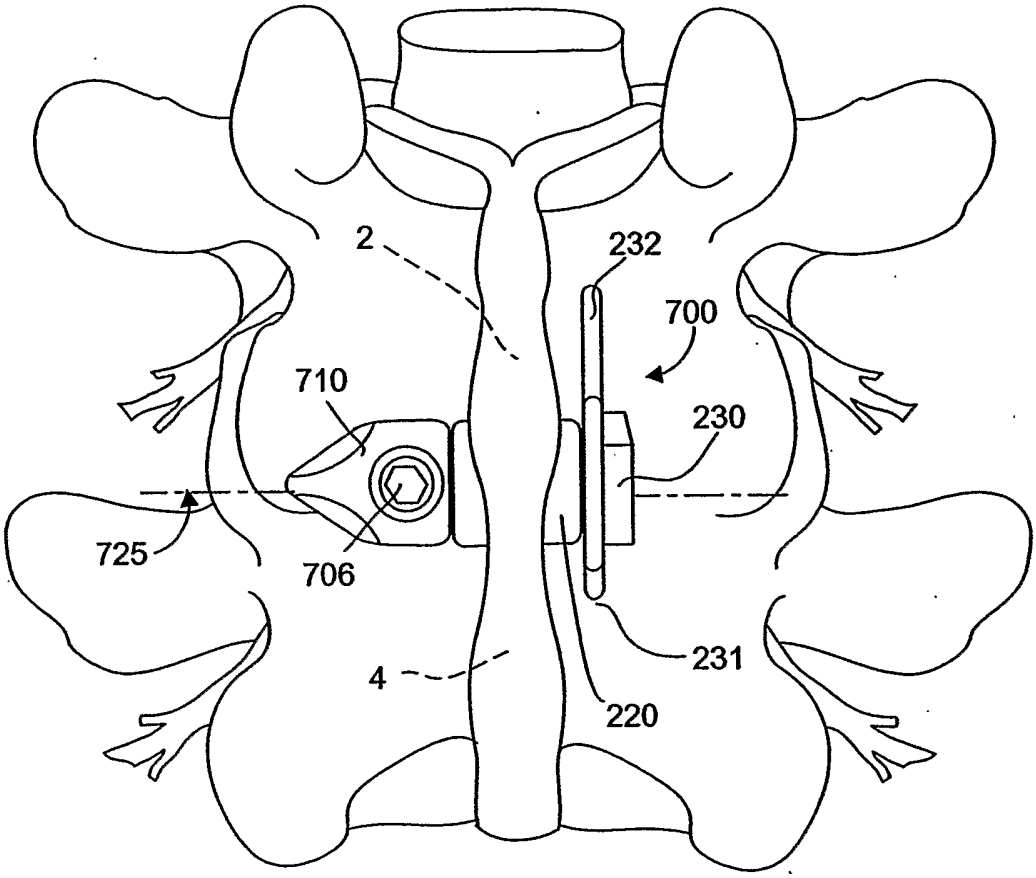


Fig. 9A

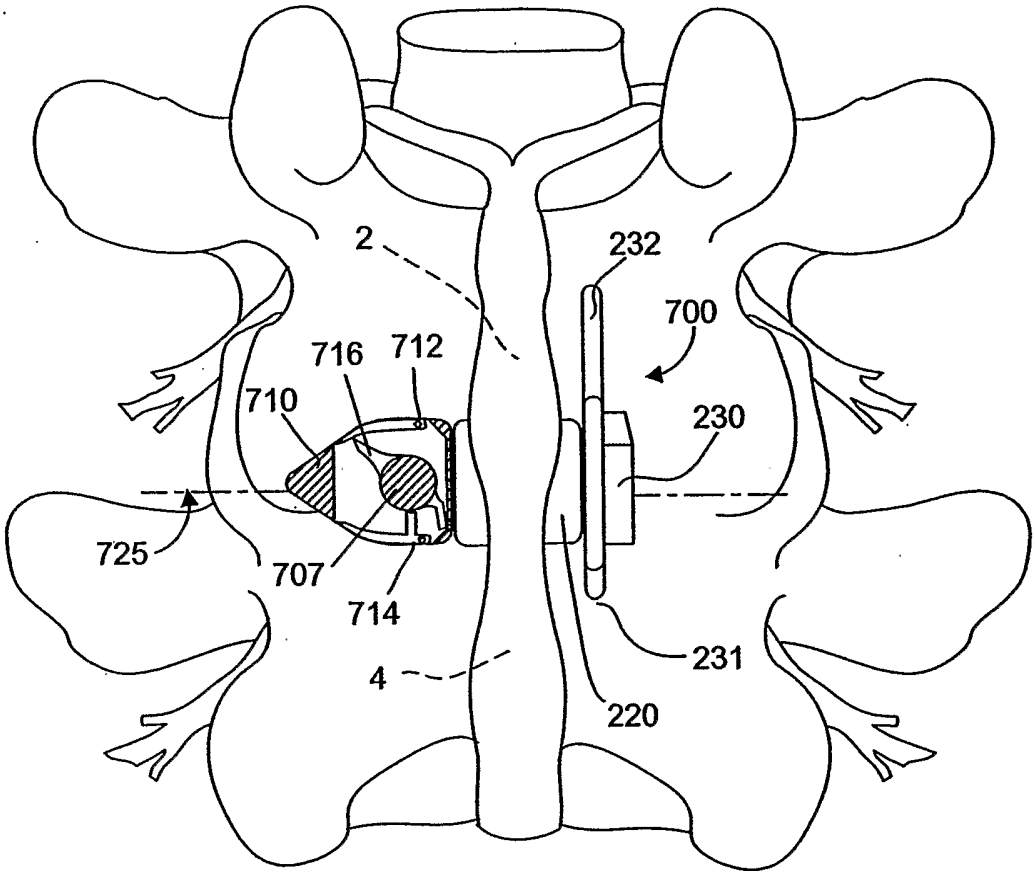


Fig. 9B

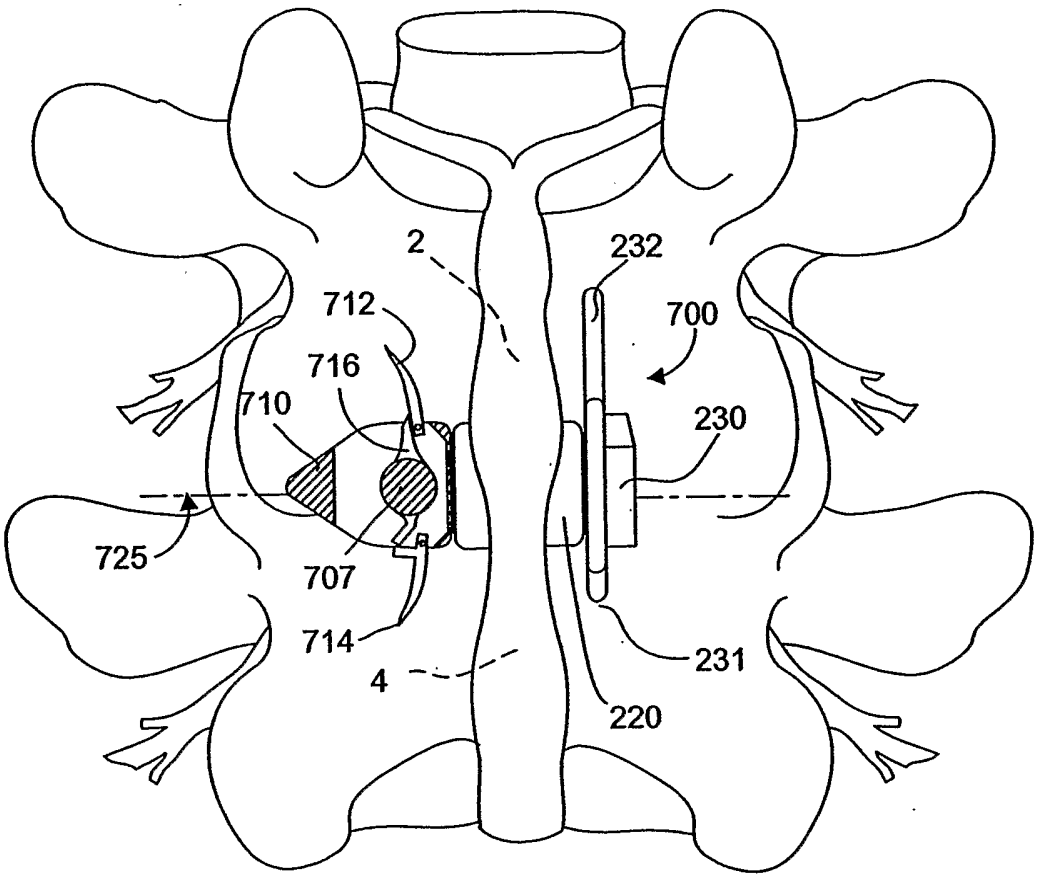


Fig. 9C

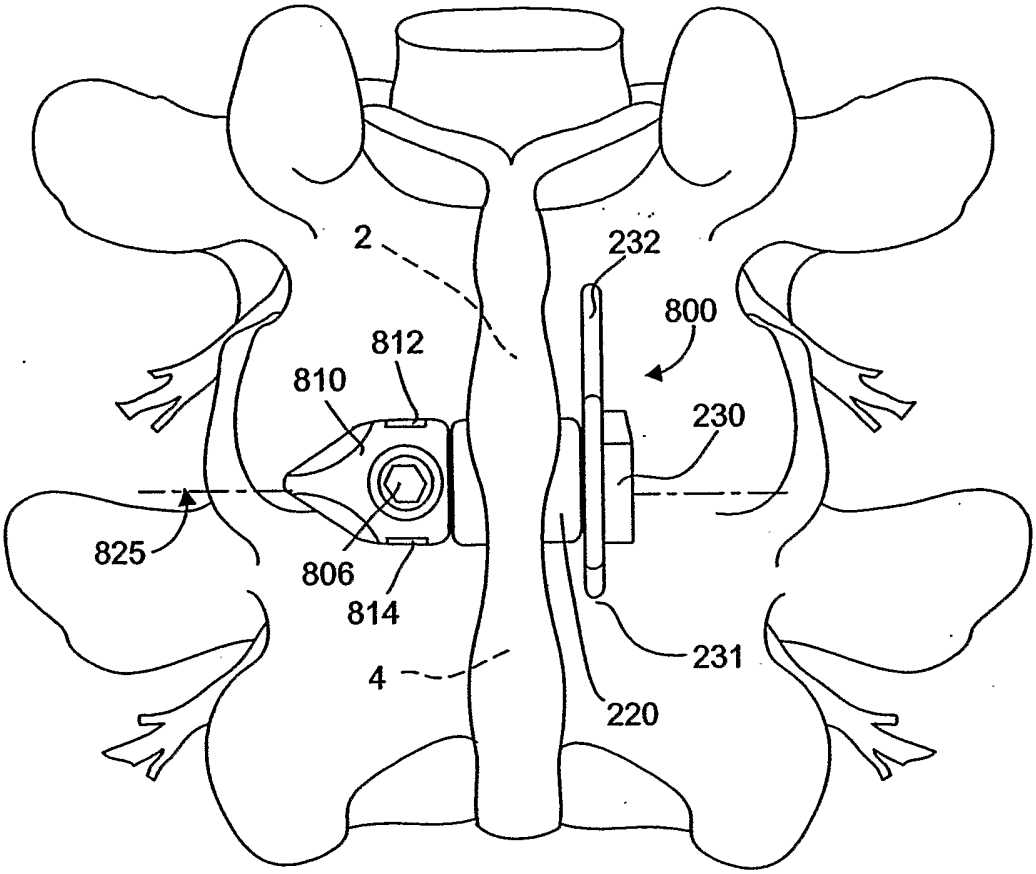


Fig. 10A

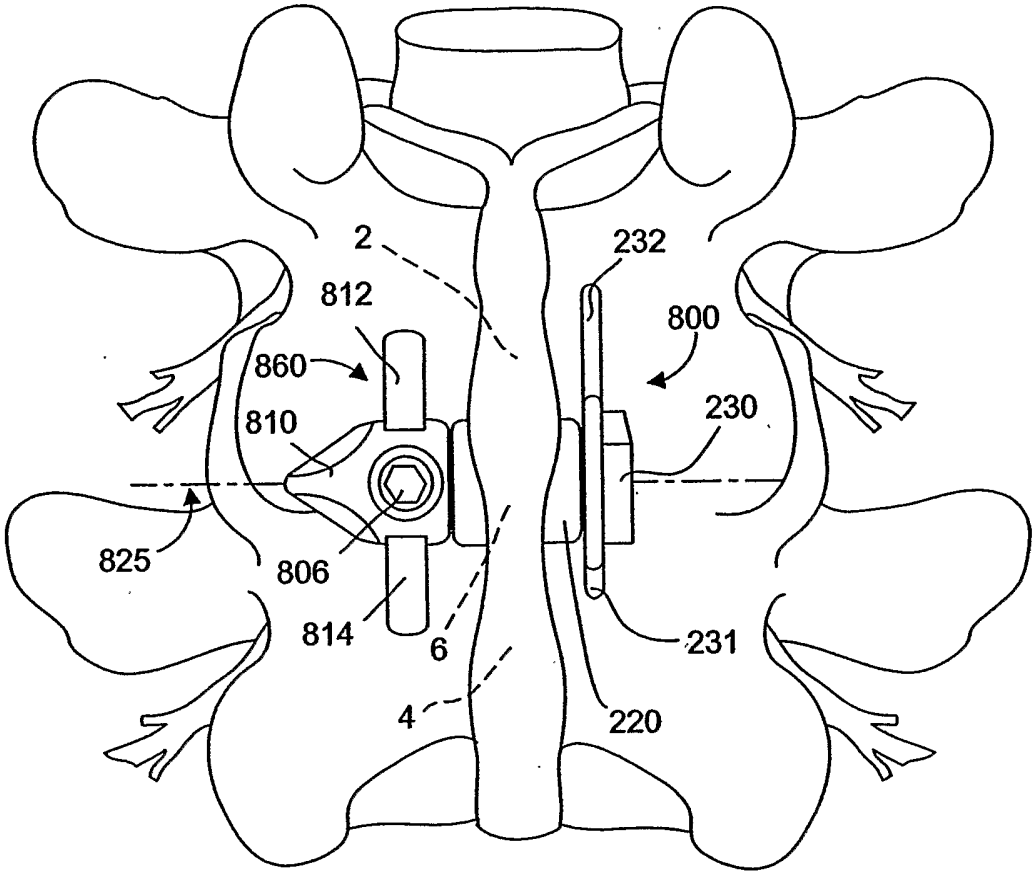


Fig. 10B

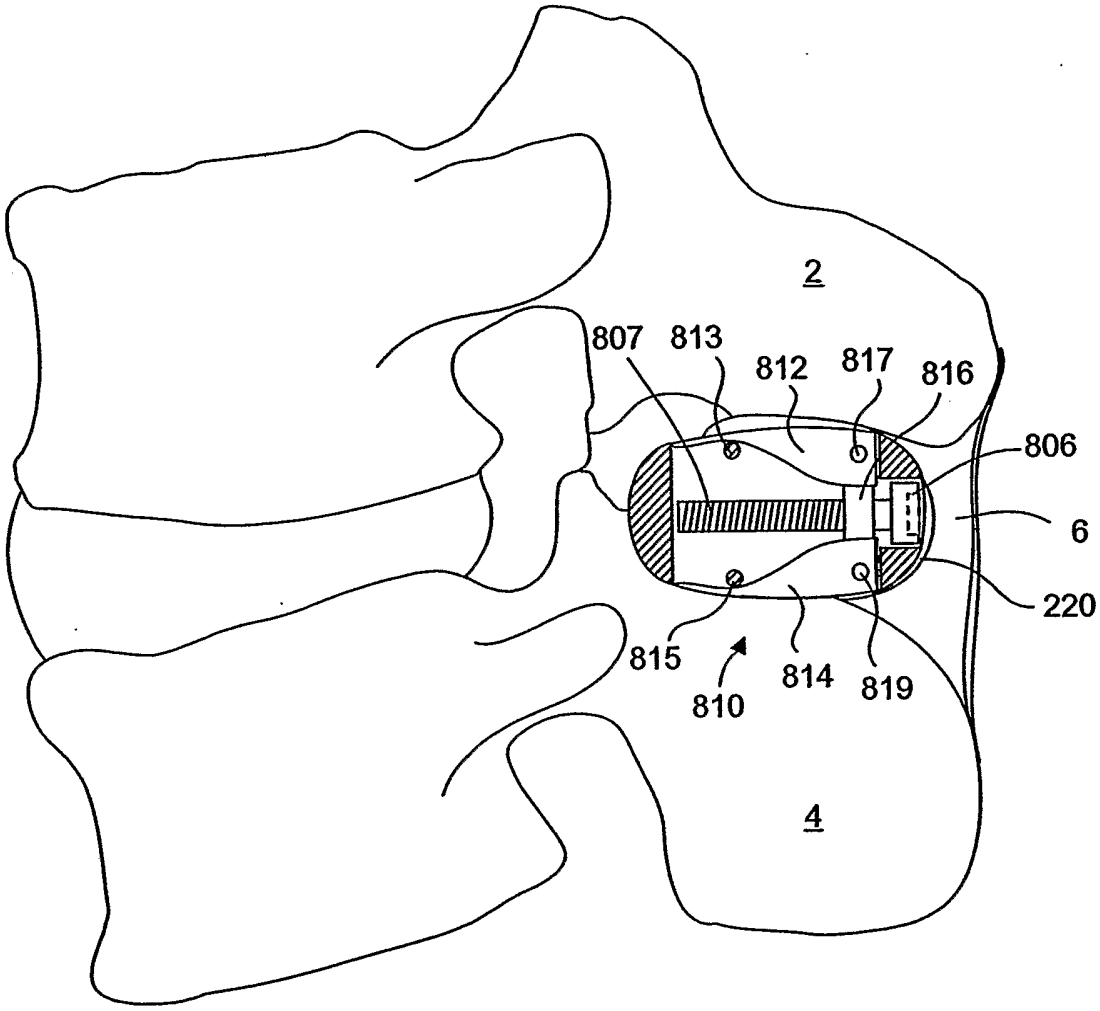


Fig. 10C

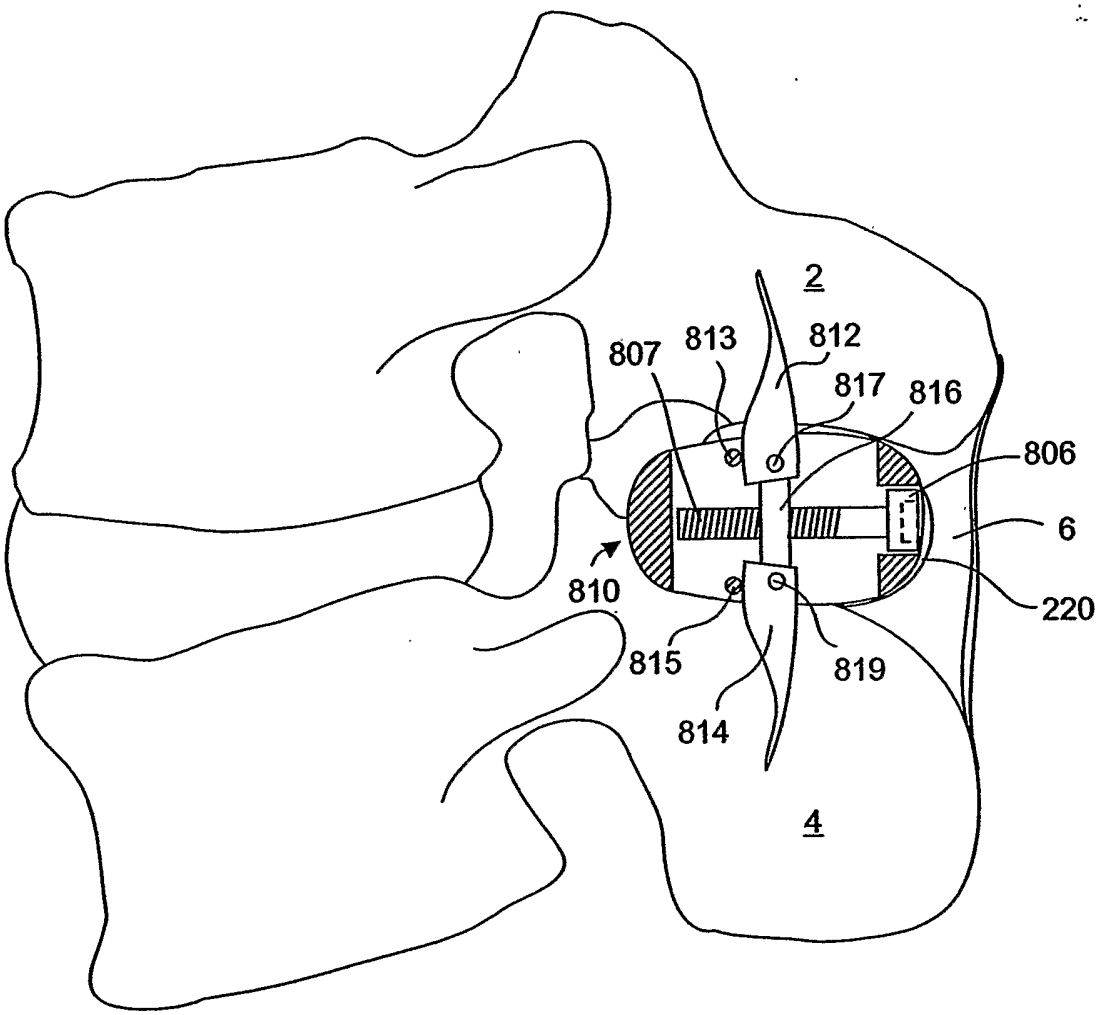


Fig. 10D

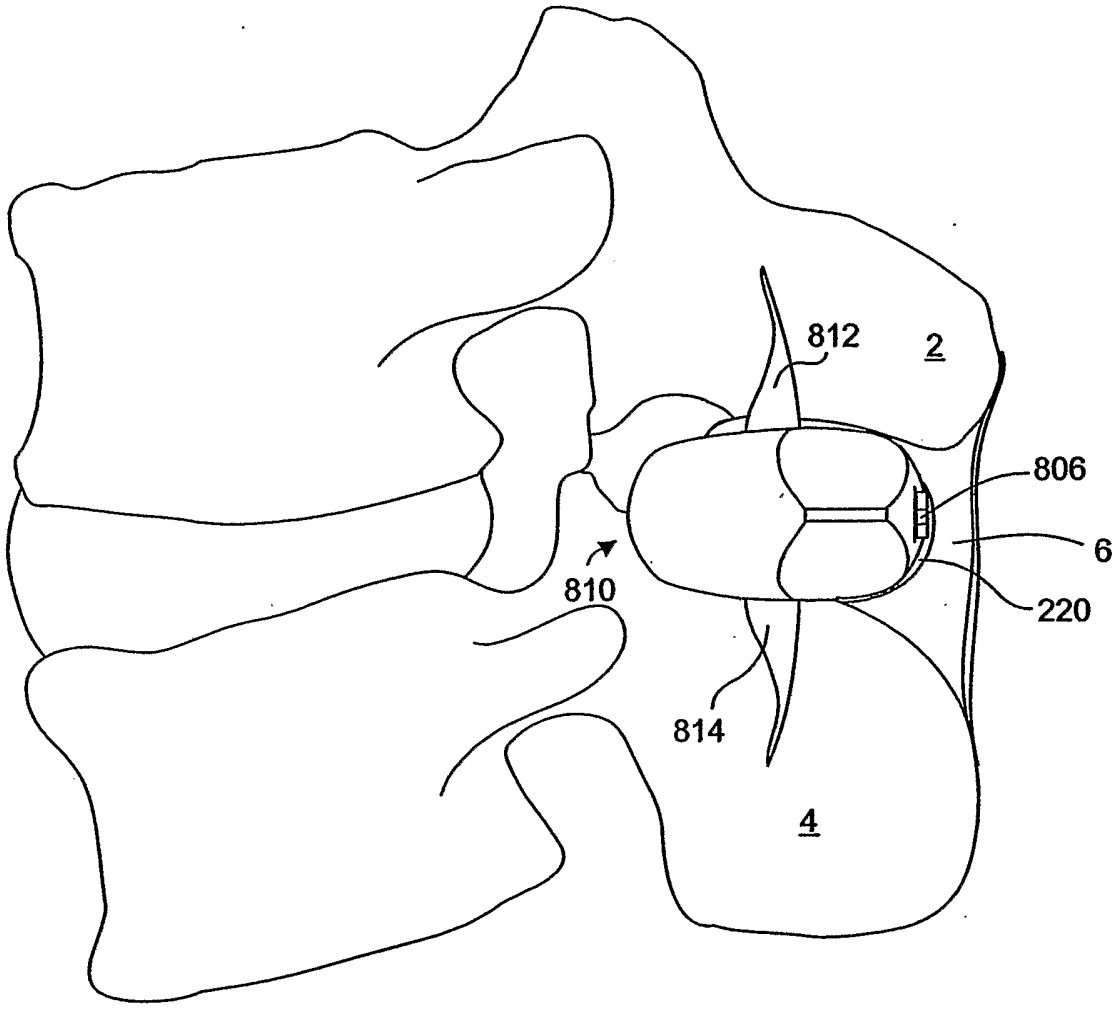


Fig. 10E

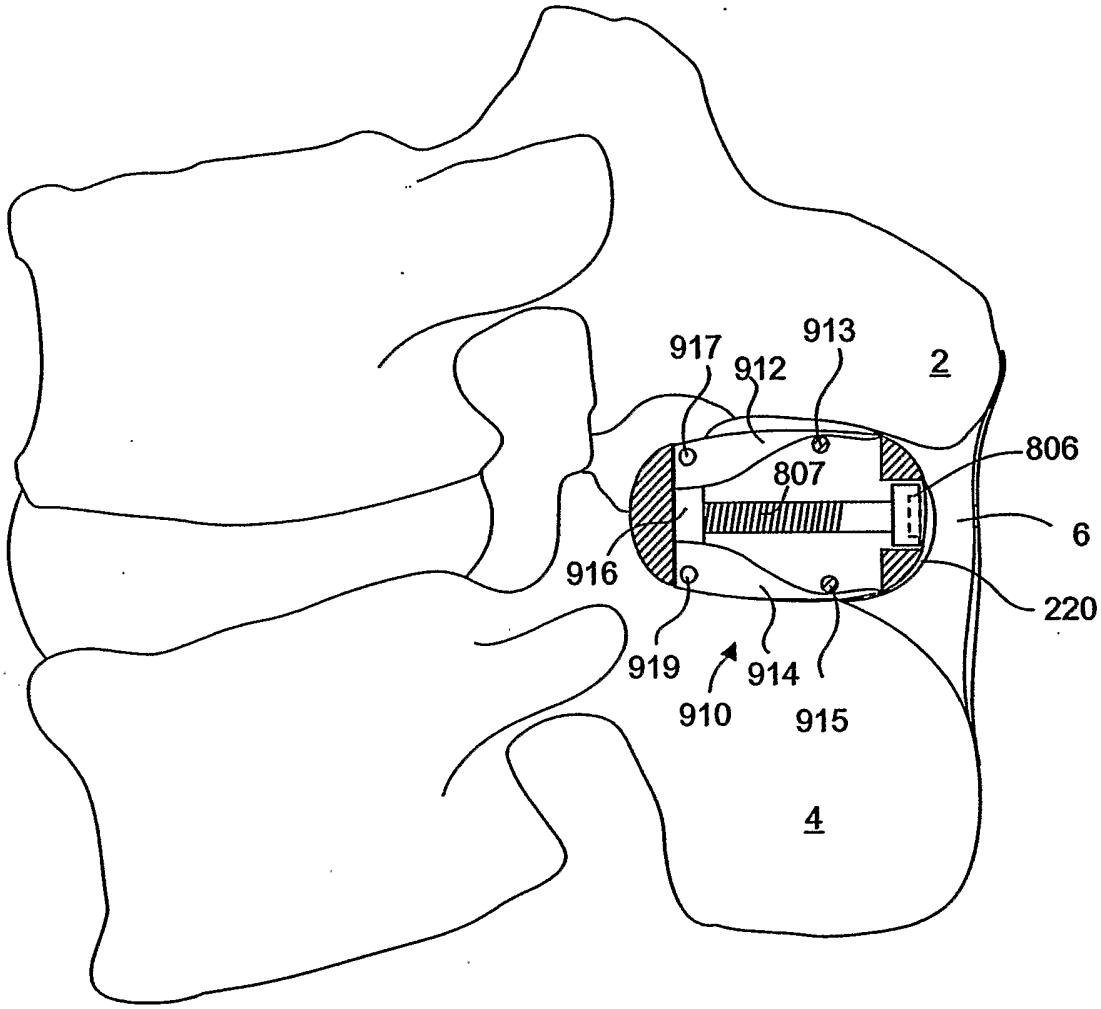


Fig. 11A

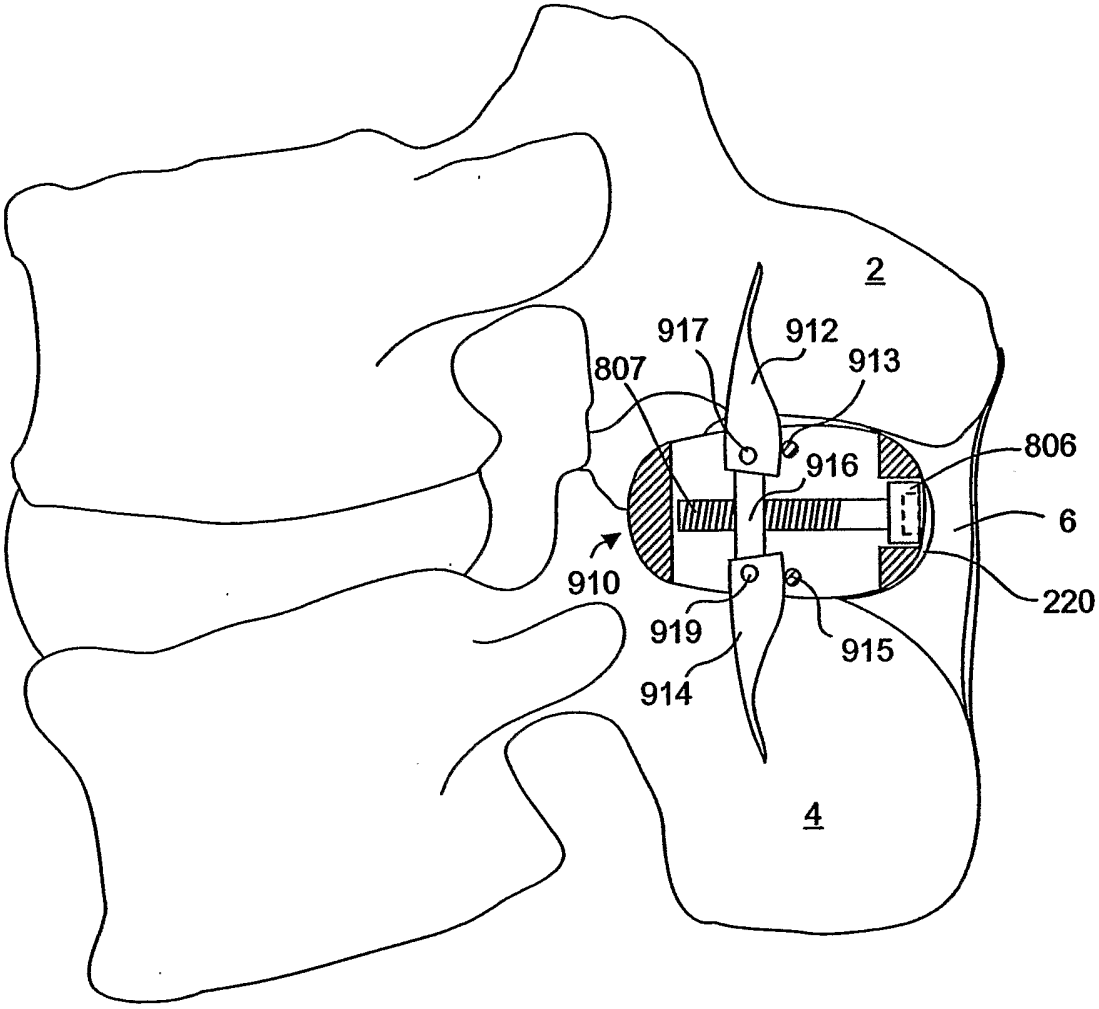


Fig. 11B

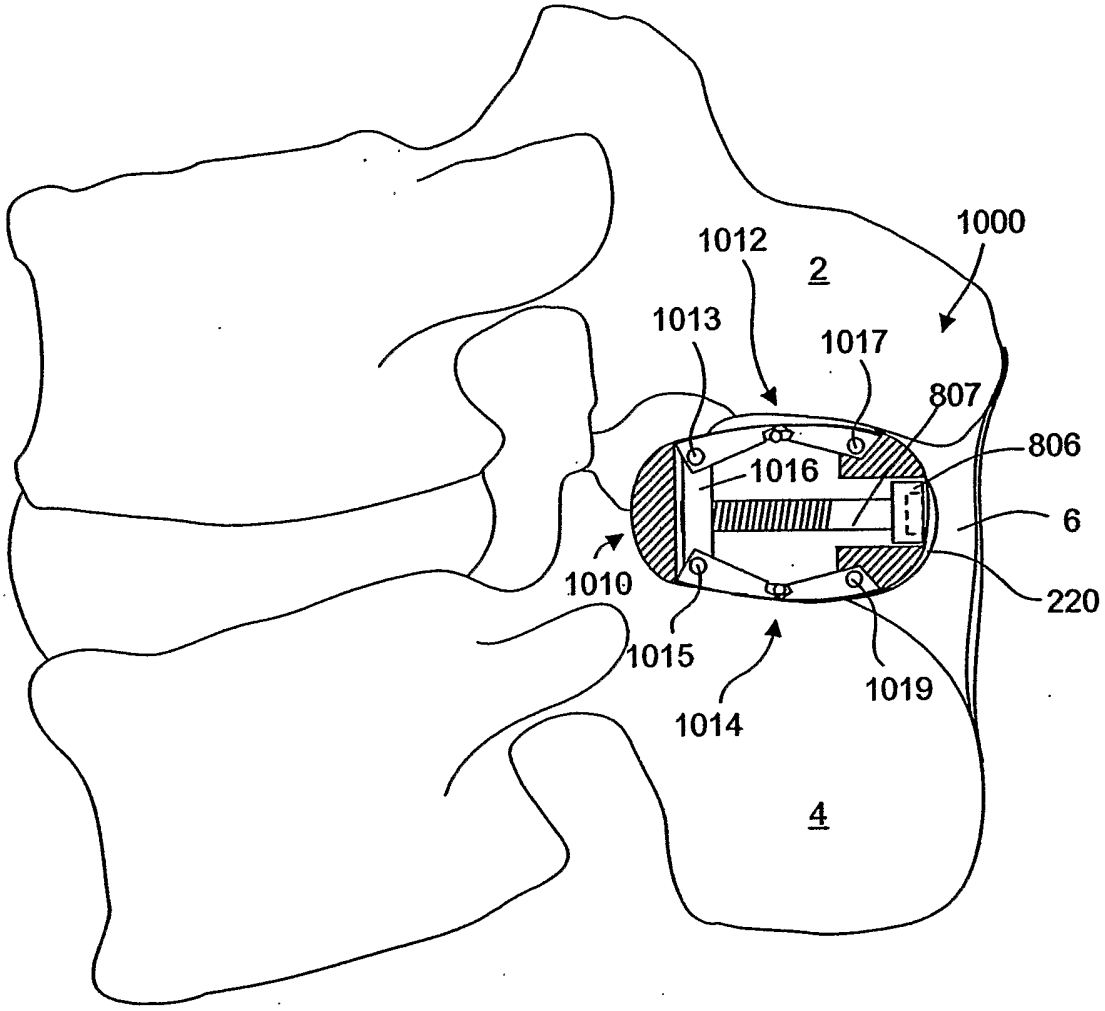


Fig. 12A

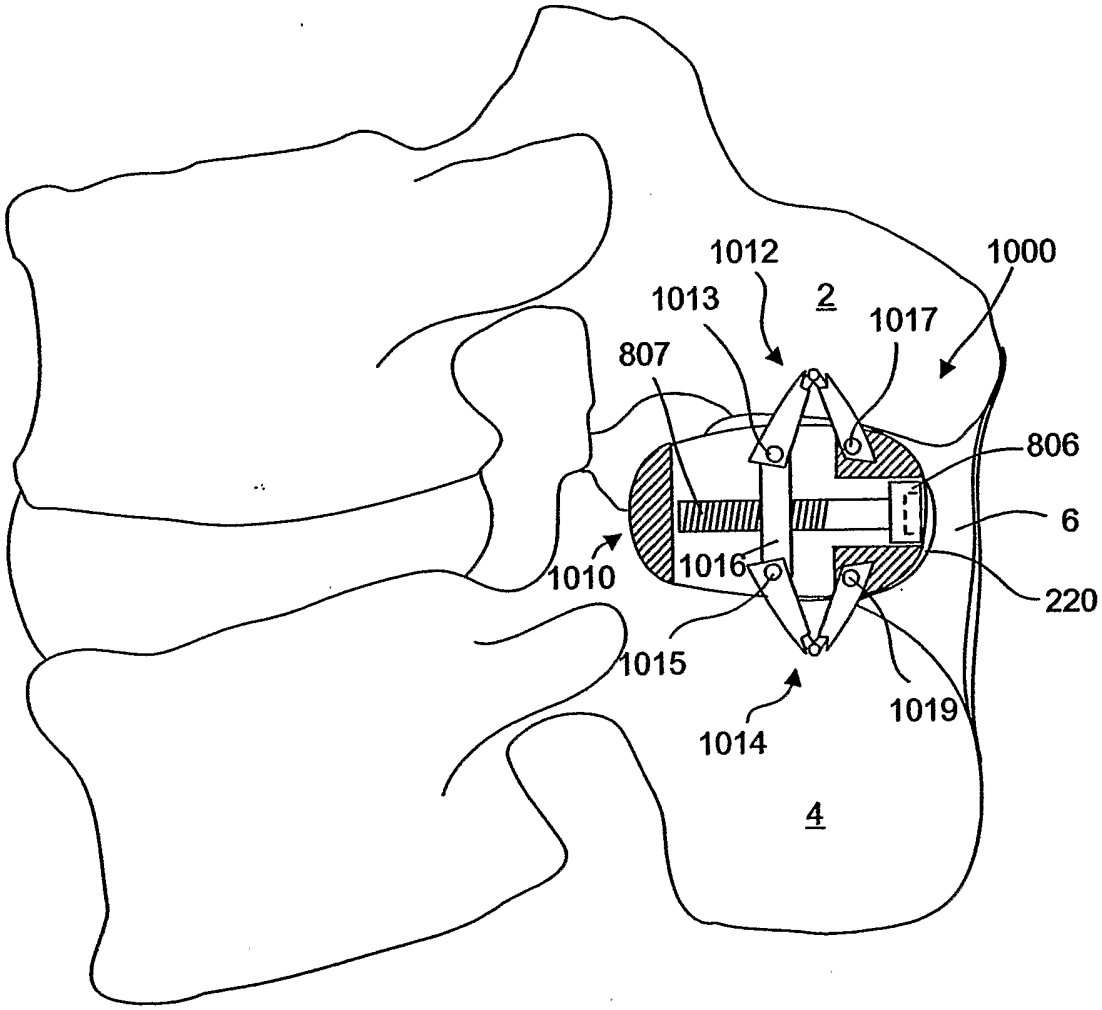


Fig. 12B

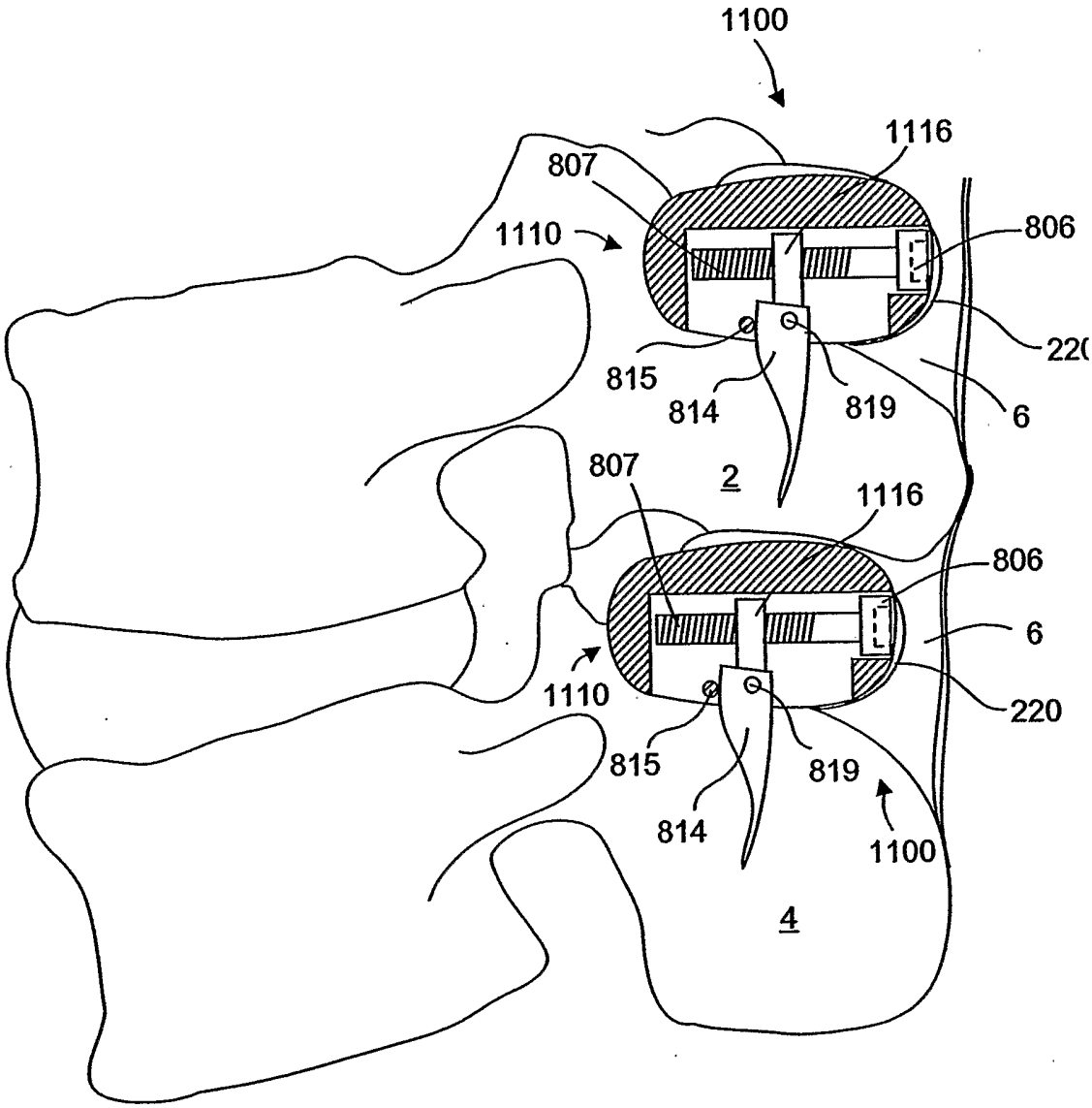

1100
1116
807
1110
806
220
815
814
819
6
807
2
1116
806
6
1110
220
815
819
814
1100
4

Fig. 13

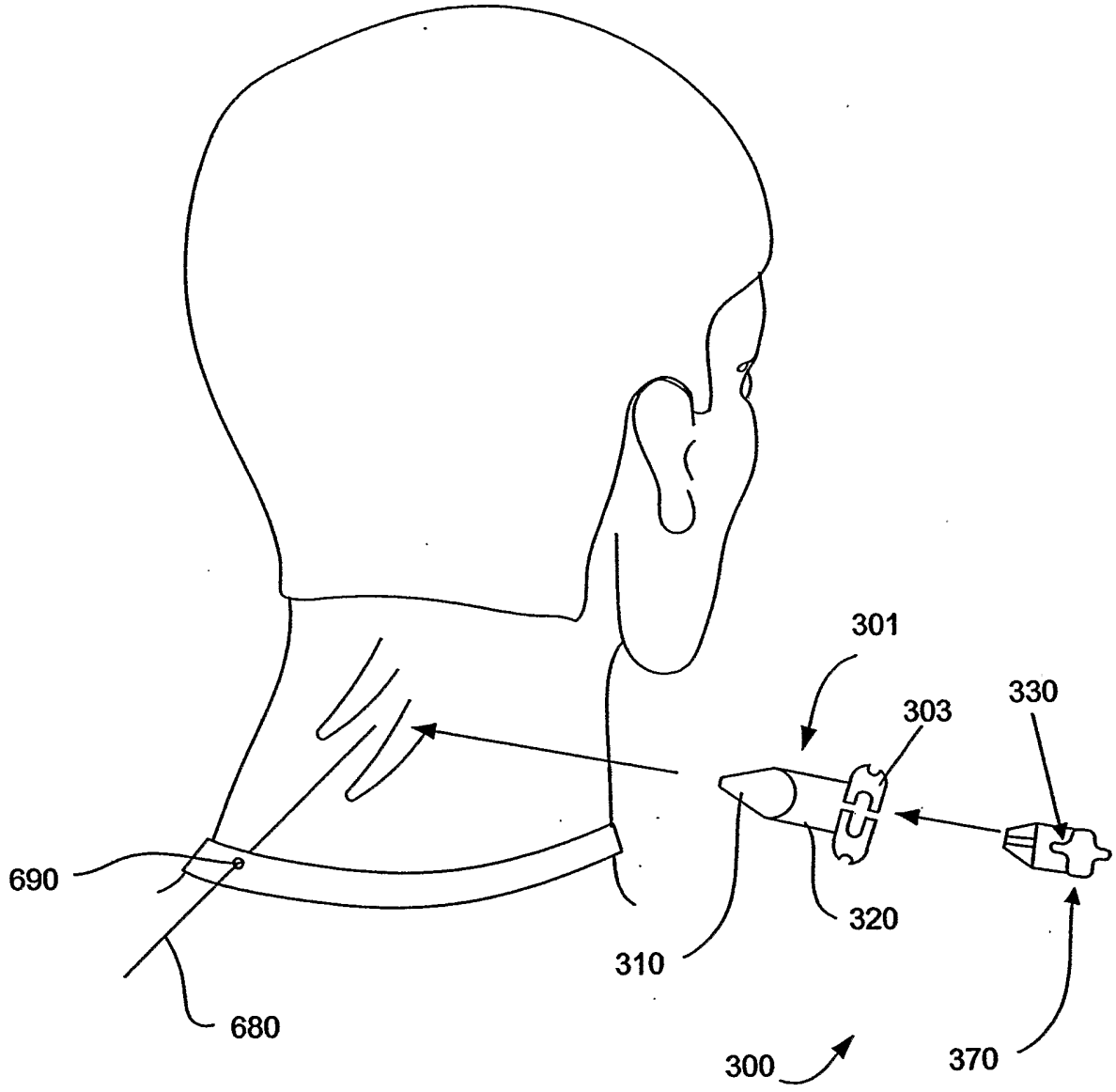


Fig. 14

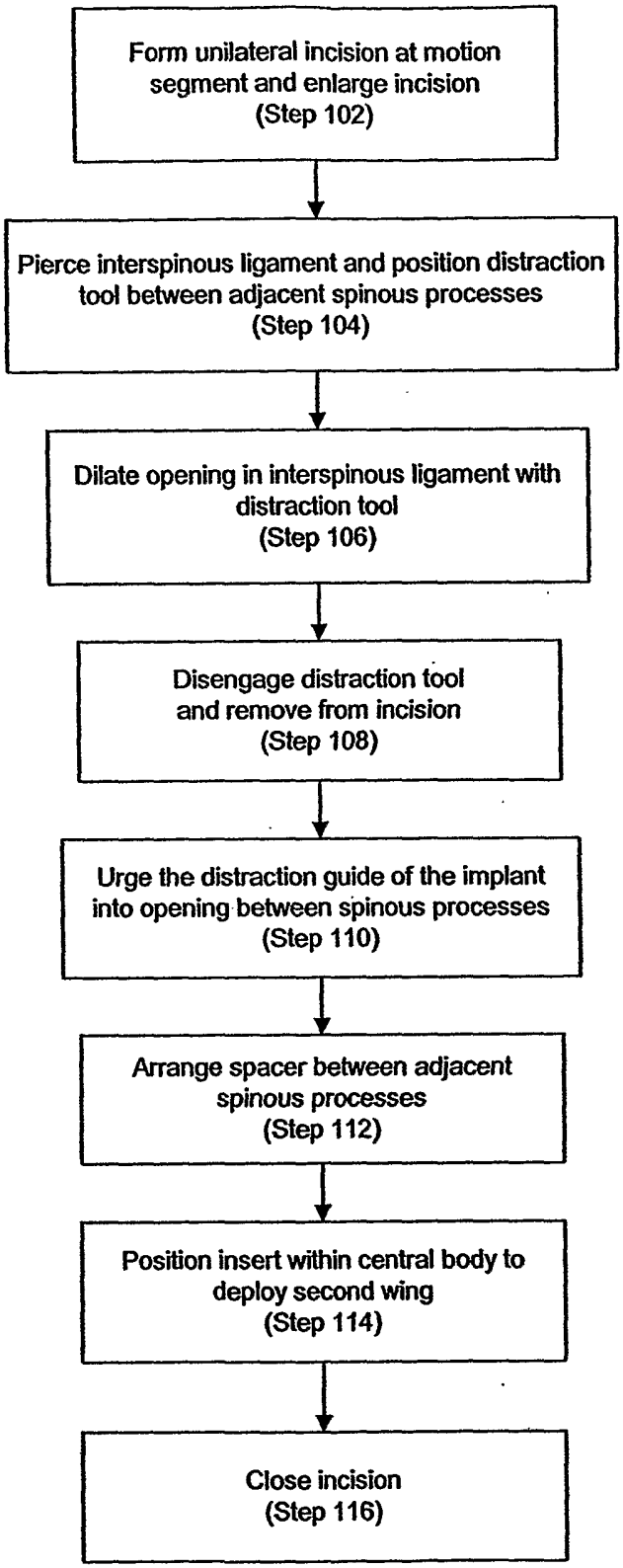

Form unilateral incision at motion segment and enlarge incision (Step 102)
Pierce interspinous ligament and position distraction tool between adjacent spinous processes (Step 104)
Dilate opening in interspinous ligament with distraction tool (Step 106)
Disengage distraction tool and remove from incision (Step 108)
Urge the distraction guide of the implant into opening between spinous processes (Step 110)
Arrange spacer between adjacent spinous processes (Step 112)
Position insert within central body to deploy second wing (Step 114)
Close incision (Step 116)

Fig. 15A

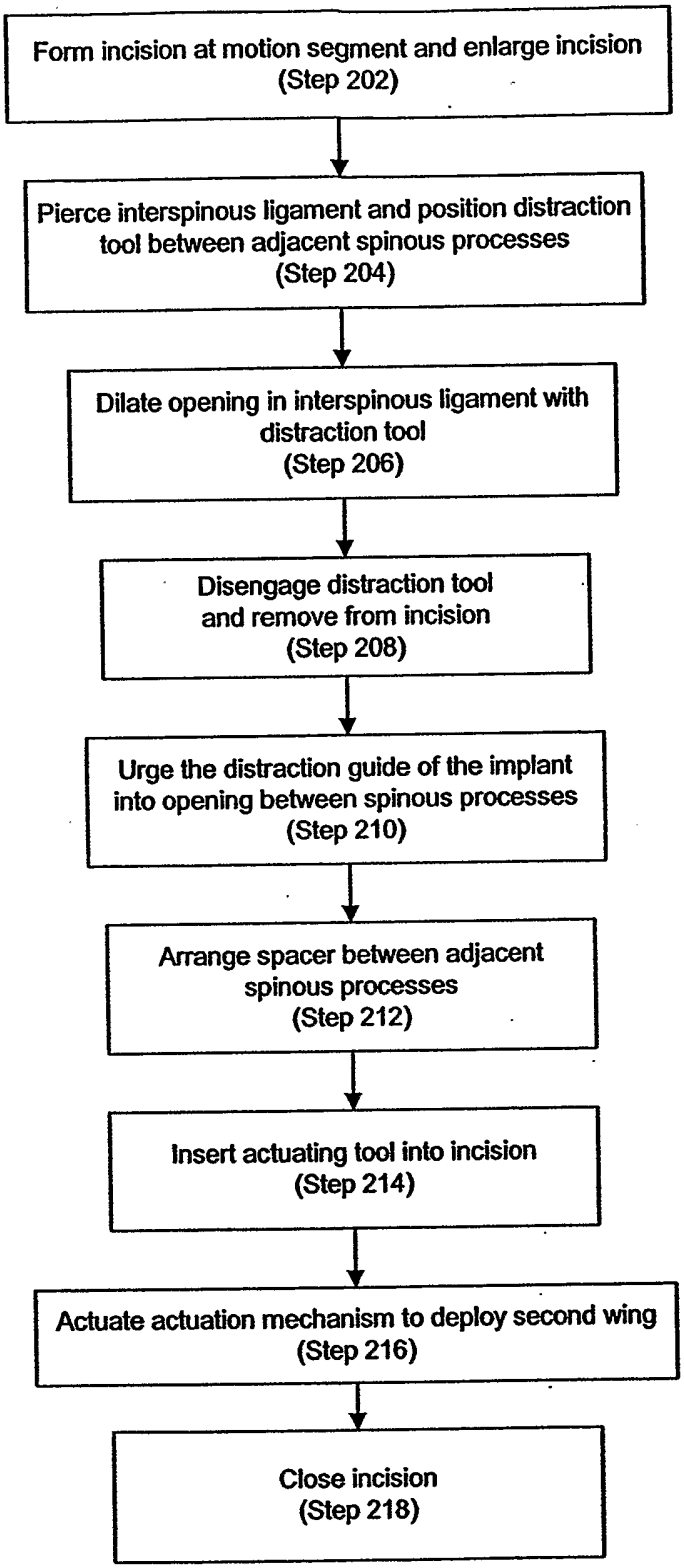

Form incision at motion segment and enlarge incision
(Step 202)
Pierce interspinous ligament and position distraction tool between adjacent spinous processes
(Step 204)
Dilate opening in interspinous ligament with distraction tool
(Step 206)
Disengage distraction tool and remove from incision
(Step 208)
Urge the distraction guide of the implant into opening between spinous processes
(Step 210)
Arrange spacer between adjacent spinous processes
(Step 212)
Insert actuating tool into incision
(Step 214)
Actuate actuation mechanism to deploy second wing
(Step 216)
Close incision
(Step 218)

Fig. 15B