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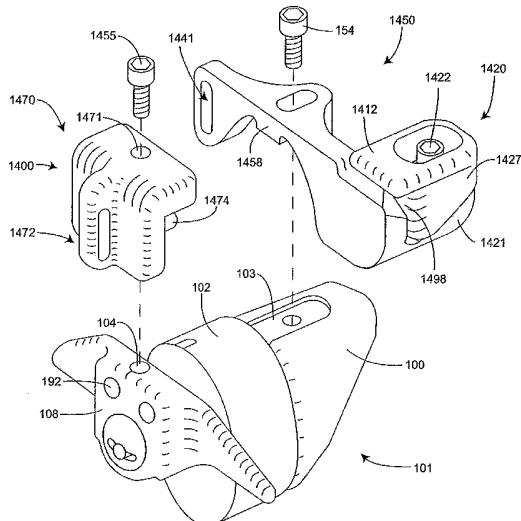
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(54) Title: INTERSPINOUS PROCESS IMPLANT INCLUDING A BINDER AND METHOD OF IMPLANTATION



(57) Abstract: Systems in accordance with embodiments of the present invention can include an implant comprising a spacer for defining a minimum space between adjacent spinous processes, a distraction guide for piercing and distracting an interspinous ligament during implantation, and a binder for limiting or preventing flexion motion of the targeted motion segment. The binder can be secured to a brace associated with the implant during implantation by a capture device. In one embodiment, the capture device includes a fixed piece extending from the brace and a slidably associated piece. A fastener can be rotated to pinch the binder between the slidably associated piece and a wall of the brace, securing the binder. A physician need not know the length of the binder prior to implantation, reducing the time required to perform a procedure.

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**INTERSPINOUS PROCESS IMPLANT INCLUDING A BINDER
AND METHOD OF IMPLANTATION**

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CLAIM OF PRIORITY

This application claims priority to the following co-pending applications, which are herein incorporated in their entirety:

U.S. Provisional Patent Application No. 60/612,465 entitled, "Interspinous Process Implant Including a Binder and Method of Implantation," by Zucherman *et al.*, filed

10 September 23, 2004 (Attorney Docket No. KLYC-01109US0);

U.S. Patent Application No. 11/095,680 entitled, "Interspinous Process Implant Including a Binder and Method of Implantation," by Zucherman *et al.*, filed March 31, 2005 (Attorney Docket No. KLYC-01109US1); and

U.S. Patent Application No. 11/095,440 entitled, "Interspinous Process Implant Including a Binder and Method of Implantation," by Zucherman *et al.*, filed March 31, 2005 (Attorney Docket No. KLYC-01109US2).

TECHNICAL FIELD

This invention relates to interspinous process implants.

20

BACKGROUND OF THE INVENTION

As the present society ages, it is anticipated that there will be an increase in adverse spinal conditions which are characteristic of older people. Certain biochemical changes can occur with aging, affecting tissue found throughout the body. In the spine, the structure of the 25 intervertebral disks can be compromised, in part as the structure of the annulus fibrosus of the intervertebral disk weakens due to degenerative effects. Spondylosis (also referred to as spinal osteoarthritis) is one example of a degenerative disorder that can cause loss of normal spinal structure and function. The degenerative process can impact the cervical, thoracic, and/or lumbar regions of the spine, affecting the intervertebral disks and the facet joints. Pain 30 associated with degenerative disorders is often triggered by one or both of forward flexion and hyperextension. Spondylosis in the thoracic region of the spine can cause disk pain during

flexion and facet pain during hyperextension. Spondylosis can affect the lumbar region of the spine, which carries most of the body's weight, and movement can stimulate pain fibers in the annulus fibrosus and facet joints.

Over time, loss of disk height can result in a degenerative cascade with deterioration of 5 all components of the motion segment resulting in segment instability and ultimately in spinal stenosis (including, but not limited to, central canal and lateral stenosis). Spinal stenosis results in a reduction in foraminal area (*i.e.*, the available space for the passage of nerves and blood vessels) which compresses the nerve roots and causes radicular pain. Another symptom 10 of spinal stenosis is myelopathy. Extension and ipsilateral rotation further reduces the foraminal area and contributes to pain, nerve root compression and neural injury. 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 15 (facets and foramen) structures, patients cannot tolerate positions of extension or flexion.

A common procedure for handling pain associated with degenerative spinal disk 15 disease is the use of devices for fusing together two or more adjacent vertebral bodies. The procedure is known by a number of terms, one of which is interbody fusion. Interbody fusion can be accomplished through the use of a number of devices and methods known in the art. These include screw arrangements, solid bone implant methodologies, and fusion devices 20 which include a cage or other mechanism which is packed with bone and/or bone growth inducing substances. All of the above are implanted between adjacent vertebral bodies in order to fuse the vertebral bodies together, alleviating associated pain.

Depending on the degree of slip and other factors, a physician may fuse the vertebra "as 25 is," or fuse the vertebrae and also use a supplemental device. Supplemental devices are often associated with primary fusion devices and methods, and assist in the fusion process. Supplemental devices assist during the several month period when bone from the adjacent vertebral bodies is growing together through the primary fusion device in order to fuse the adjacent vertebral bodies. During this period it is advantageous to have the vertebral bodies held immobile with respect to each other so that sufficient bone growth can be established. 30 Supplemental devices can include hook and rod arrangements, screw arrangements, and a number of other devices which include straps, wires, and bands, all of which are used to immobilize one portion of the spine relative to another. Supplemental devices have the disadvantage that they generally require extensive surgical procedures in addition to the

extensive procedure surrounding the primary fusion implant. Such extensive surgical procedures include additional risks, including risk of causing damage to the spinal nerves during implantation. Spinal fusion can include highly invasive surgery requiring use of a general anesthetic, which itself includes additional risks. Risks further include the possibility 5 of infection, and extensive trauma and damage to the bone of the vertebrae caused either by anchoring of the primary fusion device or the supplemental device. Finally, spinal fusion can result in an absolute loss of relative movement between vertebral bodies.

U.S. Pat. No. 5,496,318 to *Howland*, et al. teaches supplemental devices for the stabilization of the spine for use with surgical procedures to implant a primary fusion device. 10 *Howland* '318 teaches an H-shaped spacer having two pieces held together by a belt, steel cable, or polytetrafluoroethylene web material, one or both ends of which includes an attachment device fixedly connected with the respective end. *Howland* '318 teaches that the vertebra are preferably surgically modified to include a square notch to locate the fixation device in a preferred location. *Howland* '318 has the further disadvantage that the belt, cable or web material must be sized before implantation, increasing the procedure time to include sizing 15 time and reducing the precision of the fit where both ends of the belt, cable or web material include attachment devices (and as such are incrementally sized).

U.S. Pat. No. 5,609,634 to *Voydeville* teaches a prosthesis including a semi-flexible interspinous block positioned between adjacent spinous processes and a ligament made from 20 the same material. A physician must lace the ligament through the interspinous block and around the spinous processes in a figure of eight, through the interspinous block and around the spinous processes in an oval, and suture the ligament to itself to fix the interspinous block in place. *Voydeville* has the disadvantage of requiring significant displacement and/or removal 25 of tissue associated with the spinous processes, potentially resulting in significant trauma and damage. *Voydeville* has the further disadvantage of requiring the physician to lace the interspinous ligament through the interspinous block. Such a procedure can require care and time, particularly because a physician's ability to view the area of interest is complicated by suffusion of blood in the area of interest.

It would be advantageous if a device and procedure for limiting flexion and extension 30 of adjacent vertebral bodies were as simple and easy to perform as possible, and would preferably (though not necessarily) leave intact all bone, ligament, and other tissue which comprise and surround the spine. Accordingly, there is a need for procedures and implants

which are minimally invasive and which can supplement or substitute for primary fusion devices and methods, or other spine fixation devices and methods. 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 5 (increase) or maintain the space between the vertebrae to increase the foraminal area and reduce pressure on the nerves and blood vessels of the spine, and limit or block flexion to reduce pain resulting from spondylosis and other such degenerative conditions.

A further need exists for development of a minimally invasive surgical implantation method for spine implants that preserves the physiology of the spine. A still further need 10 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 and flexion.

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BRIEF DESCRIPTION OF THE DRAWINGS

Further details of embodiments of the present invention are explained with the help of the attached drawings in which:

FIG. 1 is a perspective view of an interspinous implant capable of limiting or blocking relative movement of adjacent spinous processes during extension of the spine.

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FIG. 2A is a posterior view of the implant of **FIG. 1** positioned between adjacent spinous processes.

FIG. 2B is a cross-sectional side view of a spacer of the interspinous implant of **FIGS. 1 and 2A** positioned between spinous processes.

FIG. 2C is a cross-sectional view of the spacer of **FIG. 2B** during flexion of the spine.

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FIG. 3A is a side view of an embodiment of an implant in accordance with the present invention having a distraction guide, a spacer, a brace, and a binder associated with the brace and fixable in position by a capture device.

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FIG. 3B is a side view of an alternative embodiment of an implant in accordance with the present invention including a brace wall having recesses for receiving lobes of a capture device.

FIG. 3C is a side view of still another embodiment of an implant in accordance with the present invention including a capture device having a spring-loaded cam for securing a

binder against a brace wall.

FIG. 3D is a side view of a still further embodiment of an implant in accordance with the present invention including a capture device having dual spring-loaded cams for securing a binder in position.

5 **FIG. 4A** is an end view of the implant of **FIG. 3A** positioned between adjacent spinous processes.

FIG. 4B is an end view of the implant of **FIG. 3A** positioned between adjacent spinous processes.

10 **FIG. 4C** is an end view of the implant of **FIG. 3A** positioned between adjacent spinous processes wherein the spinous processes are surgically modified to receive a binder.

FIG. 5 is an end view of an alternative embodiment of an implant in accordance with the present invention having a binder that varies in shape along the binder's length.

FIG. 6A is an end view of the implant of **FIG. 5** positioned between adjacent spinous processes.

15 **FIG. 6B** is an opposite end view of the implant of **FIG. 6A**.

FIG. 6C is an end view of still another embodiment of an implant in accordance with the present invention having a cord for a binder.

20 **FIG. 7A** is a side view of an embodiment of an implant in accordance with the present invention including a wing associated with the distraction guide to further limit or block movement of the implant.

FIG. 7B is a partial cross-sectional side view of an alternative embodiment of an implant in accordance with the present invention include an extendable wing associated with the distraction guide, the extendable wing being in a retracted position.

25 **FIG. 7C** is a partial cross-sectional side view of the implant of **FIG. 7B** wherein the extendable wing is in an extended position.

FIG. 7D is a partial cross-sectional side view of still another embodiment of an implant in accordance with the present invention including a spring-loaded wing associated with the distraction guide, the wing being in an extended position.

30 **FIG. 7E** is a partial cross-sectional side view of the implant of **FIG. 7D** wherein the spring-loaded wing is in a collapsed position.

FIG. 8 is a top view of two implants in accordance with an embodiment of the present invention positioned between the spinous processes of adjacent vertebrae, one of the implants

having a binder arranged around the adjacent spinous processes.

FIG. 9A is a perspective view of a further embodiment of an implant in accordance with the present invention having a distraction guide, a spacer, a brace, and a binder associated with the brace and fixable in position by a capture device.

5 **FIG. 9B** is a perspective view the implant of **FIG. 9A** wherein the capture device is arranged to secure a binder between the capture device and the brace.

FIG. 9C is a side view of the implant of **FIGs. 9A and 9B**.

FIG. 10A is a cross-sectional top view of a binder loosely positioned within the capture device of the implant of **FIGs. 9A and 9B**.

10 **FIG. 10B** is a cross-sectional top view of the binder secured to the brace by the capture device of the implant of **FIGs. 9A and 9B**.

FIG. 10C is a cross-sectional top view of a binder loosely positioned within an alternative embodiment of a capture device of the implant of **FIGs. 9A and 9B**.

15 **FIG. 10D** is a cross-sectional top view of the binder and capture device of **FIG. 10C** wherein the binder is secured to the brace.

FIG. 11 is an end view of the implant of **FIGs. 9A and 9B** positioned between adjacent spinous processes.

FIG. 12 is a block diagram illustrating a method of positioning the implant of **FIGs. 9A-11** between adjacent spinous processes.

20 **FIG. 13A** is a perspective view of an still another embodiment of an implant in accordance with the present invention having a distraction guide, a spacer, a first wing, and a second wing including a capture device.

25 **FIG. 13B** is a perspective view of the implant of **FIG. 13A** in accordance with the present invention having a distraction guide, a spacer, a first wing, and a second wing including a capture device.

FIG. 14 is a perspective view of an still another embodiment of an implant in accordance with the present invention having a distraction guide, a spacer, a first wing, and a second wing including a capture device.

30 **FIG. 15** is a perspective view of an still another embodiment of an implant in accordance with the present invention having a distraction guide, a spacer, a first wing, and a second wing including a capture device.

FIG. 16 is a block diagram illustrating a method of positioning the implant of **FIGs.**

13A-15 between adjacent spinous processes.

DETAILED DESCRIPTION

FIG. 1 is a perspective view of an implant as described in U.S. Pat. 6,695,842 to Zucherman, et al. and U.S. Pat. 6,712,819 to Zucherman et al., both incorporated herein by reference. The implant **100** has a main body **101**. The main body **101** includes a spacer **102**, a first wing **108**, a lead-in tissue expander **106** (also referred to herein as a distraction guide) and an alignment track **103**. The main body **101** is inserted between adjacent spinous processes. Preferably, the main body **101** remains (where desired) in place without attachment to the bone or ligaments.

The distraction guide **106** includes a tip from which the distraction guide **106** 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 **106** then gradually increases until it is substantially similar to the diameter of the main body **101** and spacer **102**. The tapered front end eases the ability of a physician to urge the implant **100** between adjacent spinous processes. When urging the main body **101** between adjacent spinous processes, the front end of the distraction guide **106** 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 **102**.

The shape of the spacer **102** is such that for purposes of insertion between the spinous processes, the spinous processes need not be altered or cut away in order to accommodate the spacer **102**. Additionally, associated ligaments need not be cut away and there is little or no damage to the adjacent or surrounding tissues. As shown in **FIG. 1**, the spacer **102** is elliptically shaped in cross-section, and can swivel about a central body (also referred to herein as a shaft) extending from the first wing **108** so that the spacer **102** 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 **102** 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 distracts and maintains apart the spinous process. For an elliptically shaped spacer, 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 108 has a lower portion 113 and an upper portion 112. As shown in **FIG. 1**, the upper portion 112 is shaped to accommodate the anatomical form or contour of spinous processes (and/or laminae) of 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. The lower portion 113 can also be rounded to accommodate the spinous processes. The lower portion 113 and upper portion 112 of the first wing 108 act as a stop mechanism when the implant 100 is inserted between adjacent spinous processes. The implant 100 cannot be inserted beyond the surfaces of the first wing 108. Additionally, once the implant 100 is inserted, the first wing 108 can prevent side-to-side, or posterior-to-anterior movement of the implant 100. The first wing 108 can further include one or more alignment holes 103 and one or more locking pin holes 104 for receiving pins of a main body insertion instrument (not shown).

The implant 100 further includes an adjustable wing 150 (also referred to herein as a second wing). The adjustable wing 150 has a lower portion 152 and an upper portion 153. Similar to the first wing 108, the adjustable wing 150 is designed to accommodate the anatomical form or contour of the spinous processes and/or lamina. The adjustable wing 150 is secured to the main body 101 with a fastener 154. The adjustable wing 150 also has an alignment tab 158. When the adjustable wing 150 is initially placed on the main body 101, the alignment tab 158 engages the alignment track 103. The alignment tab 158 slides within the alignment track 103 and helps to maintain the adjustable wing 150 substantially parallel with the first wing 108. When the main body 101 is inserted into the patient and the adjustable wing 150 has been attached, the adjustable wing 150 also can prevent side-to-side, or posterior-to-anterior movement.

FIG. 2A illustrates an implant 100 positioned between adjacent spinous processes extending from vertebrae of the lumbar region. The implant 100 is positioned between inferior articular processes 10 associated with the upper vertebrae and superior articular processes 12 associated with the lower vertebrae. The superspinous ligament 6 connects the upper and lower spinous processes 2,4. The implant 100 can be positioned without severing or otherwise destructively disturbing the superspinous ligament 6.

Referring to **FIG. 2B**, the spacer 102 of the implant 100 of **FIG. 2A** is shown in cross-section. The spacer 102 defines a minimum space between adjacent spinous processes 2,4.

During extension the spacer **102** limits or blocks relative movement between the adjacent spinous processes **2,4**, limiting or blocking the collapse of the space between the spinous processes **2,4**. Such support can alleviate symptoms of degenerative disorders by preventing a reduction of the foraminal area and compression of the nerve roots, or by avoiding aggravation of a herniated disk, or by relieving other problems. However, as shown in **FIG. 2C**, the implant **100** permits flexion, which in some degenerative disorders (for example in cases of spinal stenosis) can relieve some symptoms. As can be seen, during flexion the spacer **102** can float between the spinous processes, held in position by the interspinous ligament **8**, and/or other tissues and structures associated with the spine. The ability to float between the spinous processes **2,4** also permits varying degrees of rotation, as well as flexion. Implants as described in Zucherman '842 thus have the advantage that they permit a greater degree of movement when compared with primary and supplementary spinal fusion devices.

In some circumstances, for example where a patient develops spondylosis or other degenerative disorder that makes both flexion and extension painful and uncomfortable, it can be desired that the spinous processes be further immobilized, while providing the same ease of implantation as provided with implants described above. Referring to **FIG. 3A**, an embodiment of an implant **300** in accordance with the present invention is shown. The implant **300** includes a distraction guide **306**, a spacer **302**, and a brace **308**. As shown, the spacer **302** is rotatable about a central body **301** extending from the brace **302**, although in other embodiments the spacer **302** can be fixed in position. A binder **330** can be fixedly connected with the brace **308** at a proximal end **332** of the binder **330**. The binder **330** is flexible, or semi-flexible, and can be positioned around adjacent spinous processes so that the binder **308** engages the spinous processes during flexion of the spine. Once positioned around adjacent spinous processes, tension of the binder **330** can be set when the binder **330** is secured to the brace **308** so that relative movement of the adjacent spinous processes during flexion is limited or prevented, as desired.

As can be seen in **FIG. 3A**, in an embodiment the brace **308** can include a first end having a slot **341** through which the proximal end **332** of the binder **330** can be threaded and subsequently sutured, knotted or otherwise bound so that the proximal end **332** of the binder **330** cannot be drawn through the slot **341**. In other embodiments (not shown), the proximal end **332** can be looped or can include a connector, such as a clasp or other device, and can be fixed to the brace **308** via a fastener that engages the connector. One of ordinary skill in the art

can appreciate the myriad different ways in which the proximal end 332 of the binder 330 can be associated with the brace 308 so that tension can be applied to the binder 330, and implants in accordance with the present invention are not intended to be limited to those schemes described in detail herein.

5 The brace 308 can include a height along the spine greater than a height of the spacer 302 so that movement along a longitudinal axis L in the direction of insertion is limited or blocked by the brace 308 when the brace 308 contacts the lateral surfaces of the spinous processes. In this way, the brace 308 can function similarly to the wing 108 of the above described implant 100. In other embodiments, the brace 308 can have a height greater or
10 smaller than as shown. Once the binder 330 is positioned around the spinous processes and secured, movement of the implant 300 relative to the spinous processes is limited by the binder 330 along the longitudinal axis as well as along the spinous processes (i.e., anterior-to-posterior movement).

15 A free end of the binder 330 can be secured to the brace 308 by a capture device 320 associated with the brace 308. The brace 308 can include a flange 310 from which the capture device 320 can extend. In the embodiment shown in FIG. 3A, the capture device 320 comprises a rotatable cam 321 having a fastener 322 and one or more cut-outs 324. A tool can be mated with the cut-outs 324 and rotated to pivot the rotatable cam 321. When the cam 321 is rotated, the eccentric shape of the cam 321 causes a gap to close between the cam 321 and a
20 wall 314 of the brace 330 from which the flange 310 extends. When the binder 330 is positioned between the cam 321 and the wall 314, the rotation of the cam 321 can pinch the binder 330 between the cam 321 and the wall 314, defining a secured end 336 of the binder 330. Optionally, the fastener 322 can be screwed (i.e., rotated) so that the fastener 322 is further seated, tightening against the cam 321 to fix the cam 321 in position. Further,
25 optionally, one or both of the wall 314 and the rotatable cam 321 can include knurls, or some other texture (e.g., teeth) to prevent slippage (i.e., the slipping of the binder 330 between the cam 321 and the wall 314). The brace 308 can further include a guide 312, such as a channel or slot (a slot as shown) at a second end of the brace 308 to align the binder 330 with the capture device 320.

30 The binder 330 can comprise a strap, ribbon, tether, cord, or some other flexible (or semi-flexible), and preferably threadable structure. The binder 330 can be made from a biocompatible material. In an embodiment, the binder 330 can be made from a braided

polyester suture material. Braided polyester suture materials include, for example, Ethibond, Ethiflex, Mersilene, and Dacron, and are nonabsorbable, having high tensile strength, low tissue reactivity and improved handling. In other embodiments, the binder 330 can be made from stainless steel (i.e., surgical steel), which can be braided into a tether or woven into a strap, for example. In still other embodiments, the binder 330 can be made from some other material (or combination of materials) having similar properties.

The distraction guide 306 can optionally include a slot, bore, cut-out or other cavity 309 formed in the distraction guide 306 through which the binder 330 can be threaded or positioned. Such a cavity can allow on-axis positioning of the binder 330 (i.e., the binder can 10 be substantially aligned with the longitudinal axis L of the implant 300). Further, capturing the binder 330 within a slot or bore can prevent or limit shifting of the distraction guide 306 relative to the binder 330 to further secure the implant 300 between the spinous processes.

As will be readily apparent to one of skill in the art, implants in accordance with the present invention provide significant benefits to a physician by simplifying an implantation 15 procedure and reducing procedure time, while providing an implant that can limit or block flexion and extension of the spine. A physician can position an implant between adjacent spinous processes and can position a binder 330 connected with the brace 308 around the spinous processes without requiring the physician to measure an appropriate length of the binder 330 prior to implantation. The capture device 320 allows the binder 330 to be secured 20 to the brace 308 anywhere along a portion of the binder 330, the portion being between a distal end 334 of the binder 330 and the proximal end 332. The physician can secure the binder 330 to the brace 308 to achieve the desired range of movement (if any) of the spinous processes during flexion.

The capture device 320 and brace 308 can have alternative designs to that shown in 25 **FIG. 3A**. A side view of an implant 400 in accordance with an alternative embodiment of the present invention is shown in **FIG. 3B**, the implant 400 including a capture device 420 comprising a cam 421 positioned within a ring 426 having one or more lobes 423 corresponding with one or more recesses 413 in a wall 414 of the brace 408. The binder 330 is positioned between the capture device 420 and the brace 408. Once the binder 330 is 30 positioned as desired, the fastener 422 and cam 421 can be rotated using an appropriate tool, with the cam 421 forcing the lobes 423 of the ring 426 to mate with the recesses 413 of the brace 408, preventing the ring 426 from shifting in position and defining a secure end 336 of

the binder 330. Rotating the fastener 422 rotates and optionally tightens down the cam 421. Such a capture device 420 can provide a physician a visual indication that the binder 330 is properly secured to the brace 408, as well as preventing slippage.

Referring to FIGs. 3C and 3D, in still other embodiments, the implant can include a capture device comprising a spring-loaded mechanism. FIG. 3C illustrates an implant 500 including a capture device 520 comprising a single spring-loaded cam 521 pivotally connected with the flange 310 and biased to rotate in one direction. The distance between the pivot point of the cam 510 and the wall 314 is sufficiently narrow that the rotation of the cam 521 in the direction of bias is blocked (or nearly blocked) by the wall 314. The eccentricity of the cam 521 is large enough that a maximum gap between the wall 314 and the cam 521 is sufficiently wide as to allow the binder 330 to be threaded between the cam 521 and the wall 314. A physician can position the binder 330 between the cam 521 and the wall 514 by overcoming the spring-force of the spring-loaded cam 521. Once the binder 330 is position as desired, the physician need only allow the bias force of the spring-loaded cam 520 to force the cam 521 against the wall 314, so that the cam 521 pinches and secures the binder 330 between the cam 521 and the wall 314. Optionally, one or both of the cam 521 and the wall 314 can be knurled or otherwise textured to limit or prevent slippage. Further, the wall 314 can optionally include a recess (not shown) to receive the cam 521 so that the binder 330 is pinched within the recess (similar to the lobe and recess arrangement of FIG. 3B), thereby further limiting slippage.

FIG. 3D illustrates an implant 600 including a capture device 620 comprising dual spring-loaded cams 621, the dual spring-loaded cams 621 being pivotally connected with the flange 310. The dual spring-loaded cams 621 are biased in opposition to one another so that the cams 621 abut one another, similar to cam cleats commonly used for securing rope lines on boats. During surgery, the binder 330 can be loosely positioned around the adjacent spinous processes and threaded between the cams 621. Tension can be applied to the binder 330, as desired, by drawing the binder 330 through the cams 621. The force of the binder 330 being pulled through the cams 621 can overcome the bias force to allow the binder 330 to be tightened, while releasing the binder 330 can define a secure end 336 of the binder 330 as the cams 621 swivel together. As above, one or both of the cams 621 can be knurled or otherwise textured to limit or prevent slippage.

Embodiments of implants have been described in FIGs. 3A-3D with some level of specificity; however, implants in accordance with the present invention should not be

construed as being limited to such embodiments. Any number of different capture devices can be employed to fix a binder to a brace by defining a secure end of the binder, and such capture devices should not be construed as being limited to capture devices including cams, as described above. The capture device need only be a device that allows a physician to fit a binder having a generic size, or estimated size, around adjacent spinous processes with a desired level of precision in tension.

5 **FIG. 4A** and **4B** are an opposite end views of the implant of **FIG. 3A** positioned between adjacent spinous processes extending from vertebrae of the lumbar region. The contours of a space between adjacent spinous processes can vary between patients, and
10 between motion segments. A rotatable spacer 302 can rotate to best accommodate the shape of the space so that the implant 300 can be positioned as desired along the spinous processes. For example, it can be desirable to position the spacer 302 as close to the vertebral bodies as possible (or as close to the vertebral bodies as practicable) to provide improved support. Once the implant 300 is positioned as desired, the binder 330 can be threaded through interspinous
15 ligaments associated with motion segments (i.e., pairs of adjacent vertebrae and associated structures and tissues) above and below the targeted motion segment so that the binder 330 is arranged around the upper and lower spinous processes 2,4. The binder 330 can then be threaded through the slot 312 of the brace 308 and positioned between the capture device 320 and the brace wall 314. A first tool (not shown) can be inserted into the incision formed to
20 insert the implant 300 between the spinous processes 2,4. Though not shown, the spacer 302 can include a notch, similar to a notch 190 of the spacer 102 of **FIG. 1**, and the brace 308 can include recesses, similar to recesses 103,104 of the first wing 108 of **FIG. 1**, that can be engaged by the first tool for grasping and releasing the implant 300 during insertion. (See U.S. Patent 6,712,819, which is incorporated herein by reference.) Alternatively, some other
25 technique for grasping and releasing the implant 300 can be employed. Once the implant 300 is positioned and the binder 330 is arranged as desired, a second tool (not shown), such as a forked tool having spaced apart tines, can engage the cam 321 of the capture device 320 to rotate the cam 321, thereby securing the binder 330 to the brace 308. A hex wrench can tighten down the fastener 322 if desired. Alternatively, a single tool can be employed to
30 perform both the function of insertion of the implant 300 and rotation of the cam 321, as depicted in the above referenced patent. Optionally, the binder 330 can then be trimmed so that the distal end 334 of the binder 330 does not extend undesirably away from the brace 308.

As can be seen, the spacer 302 is rotated relative to the distraction guide 306 and the brace 308. Because the spacer 302 can rotate relative to the distraction guide 306 and the brace 308, the brace 308 can be positioned so that the binder 330 can be arranged around the upper and lower spinous processes 2,4 without twisting the binder 330. The binder 330 is positioned 5 around the lower spinous process 4, threaded or positioned at least partially within a slot 309 of the distraction guide 306, and positioned around the upper spinous process 2 so that the binder 330 can be secured to the brace 308, as described above.

Implants in accordance with the present invention can enable a physician to limit or 10 block flexion and extension in a targeted motion segment while minimizing invasiveness of an implantation procedure (relative to implantation procedures of the prior art). However, such implants can also be used where more extensive implantation procedures are desired. For 15 example, as shown in **FIG. 4C**, it can be desired that the adjacent spinous processes 2,4 be surgically modified to receive the binder 330, thereby insuring that the binder 330 does not shift or slide relative to the spinous processes 2,4. The binder 330 is threaded directly through 20 the respective spinous processes 2,4 rather than through the interspinous ligaments of adjacent motion segments. The amount of bone removed from the spinous processes 2,4 can be reduced where a cord or tether is used as a binder 330 rather than a strap. While such applications fall within the contemplated scope of implants and methods of implantation of the present invention, such application may not realize the full benefit that can be achieved using such implants due to the modification of the bone.

Still another embodiment of an implant 700 in accordance with the present invention is shown in the end view of **FIG. 5**. In such an embodiment the binder 430 can comprise a first portion 431 formed as a strap for arrangement around one of the upper and lower spinous processes 2,4, and that tapers to a second portion 433 formed as a cord. The distraction guide 25 406 can include a bore 409 or other cavity for receiving the second portion 433. As can be seen in **FIG. 6A**, once the binder 430 is threaded through the distraction guide 406, a pad 436 of biocompatible material can be associated with the binder 430, for example by slidably threading the binder 430 through a portion of the pad 436, and the pad 436 can be arranged 30 between the binder 430 and the respective spinous process 2 so that a load applied by the binder 430 is distributed across a portion of the surface of the spinous process 2. Referring to **FIG. 6B**, once the binder 430 is arranged as desired relative to the adjacent spinous processes 2,4, the binder 330 can be secured by the brace 708. The brace 708 as shown is still another

embodiment of a brace for use with implants of the present invention. In such an embodiment, the brace 708 includes a capture device 720 comprising a clip including a spring-loaded button 721 having a first hole therethrough and a shell 723 in which the button 721 is disposed, the shell 723 having a second hole. A physician depresses the button 721 so that the first and 5 second holes align. The binder 430 can then be threaded through the holes, and the button 721 can be released so that the spring forces the holes to misalign, pinching the binder 430 and defining a secure end of the binder 430.

FIG. 6C is an end view of a still further embodiment of an implant 800 in accordance with the present invention. In such an embodiment the binder 530 can comprise a cord. An 10 upper pad 536 and a lower pad 538 can be slidably associated with the binder 530 and arranged so that a load applied by the binder 530 is distributed across a portion of the upper and lower spinous processes 2,4. As can be seen, such an embodiment can include a brace 808 having a substantially different shape than braces previously described. It should be noted that the brace 808 of FIG. 6C is shown, in part, to impress upon one of ordinary skill in the art that 15 a brace and capture device for use with implants of the present invention can include myriad different shapes, mechanisms and arrangements, and that the present invention is meant to include all such variations. As shown, the footprint of the brace 808 is reduced by shaping the wall 814 of the brace 808 to taper at an upper end to form a guide 812 for aligning the binder 530 and to taper at a lower end to an eyelet 841 for capturing a proximal end 532 of the binder 20 530. The brace 808 includes a height from eyelet 841 to guide 812 such that movement of the implant 800 in the direction of insertion is blocked or limited by the brace 808.

Use of a binder to limit or prevent flexion can provide an additional benefit of limiting movement along the longitudinal axis L (shown in FIG. 3A). However, implants in accordance with the present invention can optionally further include a second wing for limiting 25 or blocking movement in the direction opposite insertion. Inclusion of such a structure can ensure that the implant remains in position, for example where the binder slips out of a slot of the distraction guide, or where the binder becomes unsecured.

Referring to FIG.7A, an implant in accordance with an embodiment can include a second wing 450 connected with the distraction guide 406 of the implant 900 by a fastener 30 454. The second wing 450 is similar to the second wing 150 described above in reference to FIG. 1. The second wing 450 can include an alignment tab 458 allowing a position of the second wing 450 to be adjusted along a longitudinal axis L of the implant 900, and a fastener

454 (for example a hex headed bolt) for affixing the second wing 450 to the implant 900 in the position along the longitudinal axis L desired. The distraction guide 406 can include an alignment groove (not shown) corresponding to the alignment tab 458. The alignment tab 458 fits within, and is movable along, the alignment groove so that a contact surface 455 of the second wing 450 can be arranged as desired. As shown, the second wing 450 includes a substantially planar contact surface arranged so that the contact surface 455 of the second wing 450 is perpendicular to the longitudinal axis L. However, in other embodiments, the contact surface 455 need not be planar, and can be shaped and oriented to roughly correspond with a contact surface of the upper and lower spinous processes. Likewise, a contact surface 315 of the binder 308 can be shaped and oriented to roughly correspond with a contact surface of the upper and lower spinous processes. As shown, the upper portion 453 and the lower portion 452 of the second wing 450 do not extend from the distraction guide 406 as substantially as the upper portion 153 and lower portion 152 of the second wing 150 of **FIG. 1**. As such, the second wing 450 includes a height H along the spine smaller than that of the second wing 150 of **FIG. 1**. It has been observed that benefits can be gained by including a wing 450, though the wing 450 does not extend from the distraction guide 406 as significantly as shown in **FIG. 1** (i.e., the wing 450 includes “nubs” extending above and/or below the height of the spacer 302). Such wings 450 will also be referred to herein as winglets. Including a second wing 450 having an overall height along the spine smaller than that of **FIG. 1** can limit movement along the longitudinal axis without interfering with (or being interfered by) the arrangement of the binder 330.

In other embodiments, implants in accordance with the present invention can include a second wing (or an upper portion and/or lower portion) extendable from the distraction guide. In this way an implant and a device for limiting or blocking movement along a longitudinal axis of the implant can be included in a single piece, possibly simplifying implantation. Referring to **FIGs. 7B** and **7C**, implants 1000 in accordance with the present invention can include a distraction guide 506 having a selectively extendable upper portion 553 and lower portion 552 disposed within a cavity of the distraction guide 506. The upper and lower portions 553,552 can be extended by actuating a nut, knob or other mechanism operably associated with a gear 556 so that the gear 556 rotates. The teeth of the gear 556 engage teeth of the upper and lower portions 553,552, causing the upper and lower portions 553,552 to extend sufficiently that the upper and lower portions 553,552 form winglets for preventing

motion of the implant **1000** in a direction opposite insertion (shown in **FIG. 7C**). Rotating the gear **556** in an opposite direction can retract the upper and lower portions **553,552**.

In an alternative embodiment, implants **1100** in accordance with the present invention can include spring-loaded upper and/or lower portions **653,652** such as shown in **FIGs. 7D** and **7E**.

5 In such an embodiment the upper and lower portions **653,652** can be fin-shaped, having sloping forward surfaces **655,654** and being spring-biased to an extended position, as shown in **FIG. 7D**. As the implant **1100** is positioned between adjacent spinous processes, the spinous processes and/or related tissues can contact the forward surface **655,654** of the upper and lower portions **653,652**, causing the upper and lower portions **653,652** to pivot about respective

10 hinge points **657,656** and collapse into cavities disposed within the distraction guide **606**, as shown in **FIG. 7E**. Once the implant **1100** clears the obstruction, the upper and lower portions **653,652** re-extend out of the distraction guide **650**. A slot and pin mechanism **660,661** or other mechanism can lock the upper and lower portion **653,652** in place once extended, disallowing over-extension of the upper and lower portion **653,652** in the direction of bias.

15 The extended upper and lower portions **653,652** limit or block movement of the implant **1100** in an a direction opposite insertion.

In still further embodiments, implants in accordance with the present invention can optionally employ some other additional mechanism for limiting or blocking motion along the longitudinal axis of the implant. Mechanisms shown and described in **FIGs. 7A-7E** are 20 merely provided as examples of possible mechanisms for use with such implants, and are not intended to be limiting.

FIG. 8 is a top-down view of still another embodiment of an implant in accordance with the present invention including a brace **708** arranged at an angle along the spinous process relative to the longitudinal axis **L** of the implant **1200**. The brace **708** is arranged at such an 25 angle to roughly correspond to a general shape of the adjacent spinous processes. Such a general shape can commonly be found in spinous processes extending from vertebrae of the cervical and thoracic region, for example. The implant **1200** further includes a second wing

752 extending from distraction guide **706** at an angle roughly corresponding to a general shape of the adjacent spinous processes. Identical implants **1200**, one above the other, are shown. The lower implant **1200** includes a binder **330** arranged around the adjacent spinous processes (only the upper spinous process is shown) and positioned in a slot **309** of the distraction guide **706**. The binder **330** includes a capture device **320** for securing the binder **330** to the brace

708, and a channel formed by guides 712 on the brace 708 for aligning the binder 330 with the capture device 320. Unlike previously illustrated embodiments, the brace wall includes a recess 717 to accommodate rotation of the rotatable spacer 302. Alternatively, the implants can include fixed spacers, for example integrally formed with the brace 708 and the distraction guide 706.

5 **FIGs. 9A** and **9B** are perspective views, and **FIG. 9C** is a side view of a still further embodiment of an implant in accordance with the present invention. The implant 1300 includes a distraction guide 806, a rotatable spacer 302, and a brace 908. As above, a binder 330 can be fixedly connected with the brace 908 at a proximal end 332 of the binder 330.

10 Once positioned around adjacent spinous processes, tension of the binder 330 can be set when the binder 330 is secured to the brace 908 so that relative movement of the adjacent spinous processes during flexion is limited or prevented, as desired.

15 As can be seen in **FIG. 9A**, the brace 908 can include a first end having an eyelet 941 through which the proximal end 332 of the binder 330 can be threaded and subsequently sutured, knotted or otherwise bound, or alternatively looped through the eyelet 941 and secured to itself (e.g., using a clasp) so that the proximal end 332 of the binder 330 cannot be drawn through the eyelet 941. One of ordinary skill in the art can appreciate the myriad different ways in which the proximal end 332 of the binder 330 can be associated with the brace 908 so that tension can be applied to the binder 330. As in previous embodiments, a free 20 end of the binder 330 can be secured to the brace 908 by a capture device 820 associated with the brace 908. The capture device 820 of **FIGs. 9A-11** is arranged at a second end of the brace 908 opposite the eyelet 941, rather than approximately centered along the brace wall 914. The brace 908 can optionally include a locking pin hole 915 that can be engaged by a locking pin of an insertion instrument (not shown), for example as described in U.S. Pat. No. 6,712,819 to 25 Zucherman, et al., incorporated herein by reference. Further, similar to implants described in Zucherman '819, the brace wall 914 can optionally include one or more holes 916 (shown in **FIG. 11**) adapted to receive alignment pins of such an insertion instrument, and the spacer 402 can include a spacer engagement hole 403 adapted to receive a spacer engagement pin of such an insertion instrument. When a spacer engagement pin engages the spacer engagement hole 30 403, rotation of the spacer 402 can be limited or blocked. Once the spacer engagement pin is released from the spacer engagement hole 403, the spacer 402 can rotate and/or swivel about a central body 917 without impedance from the spacer engagement pin. Such an arrangement

can provide a physician additional control over the positioning of the implant 1300, although in other embodiments the spacer 402 need not include an engagement hole 403. Arranging the captured device 820 at a second end of the brace 908 can allow an insertion instrument, having a configuration as described in Zucherman '819 or having some other configuration, to 5 releasably engage the implant 1300 to assist in implantation without interference from the capture device 820.

The distraction guide 806 of the implant 1300 can be wedge-shaped, as described above, or approximately conical, as shown in FIGs. 9A-9C, and can include a slot 809 disposed through the distraction guide 806 and adapted to receive the binder 330 during 10 implantation. Also as described above, the rotatable spacer 402 can be elliptical in cross-section, or otherwise shaped, and can rotate relative to the distraction guide 806 to roughly conform with a contour of a space between the targeted adjacent spinous processes.

The capture device 820 is shown in cross-section in FIGs. 10A and 10B. The capture device 820 can comprise, for example, two pieces slidably associated with one another by an 15 adjustable fastener 822 (as shown, the adjustable fastener is a hex screw). A fixed piece 821 of the capture device can extend from the brace wall 914. The fixed piece 821 can include a beveled surface 823 that can function as a ramp. A slidable piece 827 of the capture device can be slidably associated with the fixed piece 821, and can likewise include a beveled 20 surface 829 positioned in opposition to the beveled surface 823 of the fixed piece 821. As shown, the slidable piece 827 is associated with the fixed piece 821 via an adjustable fastener 822. The fastener 822 can be positioned within slots 890,892 of the fixed piece 821 and the slidable piece 827 and can include a threaded shaft 880, a head 882, and a nut 884. The head 882 of the fastener 822 can engage an anterior surface 894 of the fixed piece 821 and the nut 884 can be threaded onto the threaded shaft 880 so that the nut 884 can engage a posterior 25 surface 896 of the slidable piece 827. The slidable piece 827 is free to slide along the beveled surface 823 of the fixed piece 821 until both the nut 884 engages the posterior surface 896 and the head 882 engages the anterior surface 894, blocking further movement in one direction. The distance between the anterior surface 894 and the posterior surface 896 increases or 30 decreases as the slidable piece 827 slides along the beveled surface 823 and a distance between a capture surface 898 of the slidable piece 827 and the brace wall 914 likewise increases or decreases. The maximum distance the slidable piece 827 can travel can be defined by the distance between the nut 884 and the head 882. A physician can adjust the maximum distance

by rotating the nut 884 so that the nut 884 travels closer to, or farther from the head 882 along the threaded shaft 880, possibly urging the capture surface 898 toward the brace wall 914. Thus, when the implant 1300 is positioned between spinous processes, the physician can set the maximum distance so that the free end of the binder 330 can be threaded between the 5 capture surface 898 and the brace wall 914. As shown in FIG. 10B, the physician can then adjust the fastener 822 so that the posterior surface 896 and the anterior surface 894 are urged together, the maximum distance decreases and the distance between the capture surface 898 and the brace wall 914 decreases, thereby pinching the binder 330 between the capture surface 898 and the brace wall 914 and defining a secure end of the binder 330. In some 10 embodiments, one or both of the capture surface 898 and the brace wall 914 can include texture so that the binder 330 is further prevented from sliding when the binder 330 is placed under increasing tension (e.g., during flexion).

The slidable piece 827 can optionally further include a guide 912 extending from the slidable piece 827 so that the guide 912 overlaps a portion of the brace 908. The guide 912 can extend, for example, a distance roughly similar to the maximum distance between the capture surface 898 and the brace wall 914, and can help ensure that the binder 330 is captured between the capture surface 898 and the brace wall 914. In other embodiments, the capture device 820 of FIGS. 9A-10B can include some other shape or configuration and still fall within the contemplated scope of the invention. For example, the fastener need not include a 15 nut. In one embodiment, shown in FIGS. 10C and 10D, the fastener 922 can include a threaded shaft 980 associated with a sleeve 984. As one of the threaded shaft 980 and the sleeve 984 is rotated, the distance between a head 982 of the threaded shaft 980 and the head 985 of the sleeve 984 can decrease or increase. In still other embodiments, the fastener need not include a threaded shaft, but rather can include a smooth shaft having a retaining clip 20 frictionally associated with the smooth shaft. One of ordinary skill in the art will appreciate the myriad different devices that can be employed to selectively close a gap between a capture surface 898 and the brace wall 914.

FIG. 11 is an end view of the implant 1300 of FIGS. 9A-10D positioned between adjacent spinous processes. As shown, the binder 530 is a cord, but in other embodiments can 30 have some other geometry. As described above in reference to previous embodiments, where a cord, a tether, or the like is used as a binder, a pad 536 can be arranged along a contact surface of the respective spinous process so that a load applied to the contact surface by the tension in

the binder 530 can be distributed across a portion of the contact surface wider than the binder 530, thereby reducing stress on the portion. The capture device 820 is arranged so that the **slid**able piece 827 is posteriorly located relative to the fixed piece 821. A fastener 822 can be accessed by the physician using a substantially posterior approach.

5 A method of surgically implanting an implant 1300 in accordance with an embodiment as described above in **FIGs. 9A-11** of the present invention is shown as a block diagram in **FIG. 12**. The method can include forming an incision at the target motion segment, and enlarging the incision to access the target motion segment (Step 100). The interspinous ligament between targeted adjacent spinous processes can then be distracted by piercing or
10 displacing the interspinous ligament with the distraction guide 106 (Step 102) and urging the implant 1300 between the adjacent spinous processes (Step 104). As the interspinous ligament is displaced, the spacer 302 can be positioned between the spinous processes such that the spacer 302 can rotate to assume a preferred position between the spinous processes (Step 106).

Once the implant 1300 is positioned, the binder 330 can be threaded between interspinous
15 ligaments of adjacent motion segments so that the targeted adjacent spinous processes are disposed within a loop formed by the binder 330 (Step 108). The physician can then thread the binder 330 between the capture surface 898 of the capture device 820 and the brace wall 914 (Step 110). Once a desired tension of the binder 330 is applied (Step 112), the physician can adjust the fastener 822 of the capture device 820 so that the binder 330 is secured between the
20 captured surface 898 and the brace wall 914 (Step 114). The incision can subsequently be closed (Step 116).

FIG. 13A and **13B** are perspective views of still another embodiment of an implant 1400 in accordance with the present invention. In such an embodiment, the implant 1400 can include a main body 101 similar to the main body 101 described above in reference to **FIG. 1**.
25 As above, the main body 101 (also referred to herein as a first unit) includes a spacer 102, a first wing 108, a distraction guide 106 and an alignment track 103. The main body 101 is inserted between adjacent spinous processes. Preferably, the main body 101 remains (where desired) in place without attachment to the bone or ligaments.

The alignment track 103 includes a threaded hole for receiving a fastener. The
30 alignment track 103 need not include a threaded hole, but rather alternatively can include some other mechanism for fixedly connecting an additional piece (such as a second wing for limiting or blocking movement of an implant along the longitudinal axis). For example, in an

alternative embodiment, the alignment track 1403 can include a flange so that the second wing 1450 can be slidably received, as shown in **FIG. 15**.

As further shown in **FIGS. 13A** and **13B**, the implant 1400 includes a second wing 1450 removably connectable with the implant 1400. The second wing 1450 includes an alignment tab 1458 adapted to be received in the alignment track 103 of the main body 101, the alignment tab 1458 optionally including a slot for receiving the fastener so that the alignment tab 1458 is disposed between the fastener and the alignment track 103. In alternative embodiments, the alignment tab 1458 need not include a slot but rather can include some other mechanism for mating with the main body 101.

The second wing 1450 can include a first end having a slot (or eyelet) 1441 through which the proximal end (also referred to herein as an anchored end) 332 of a binder 330 can be threaded and subsequently sutured, knotted or otherwise bound, or alternatively looped through the slot 1441 and secured to itself (e.g., using a clasp) so that the proximal end 332 of the binder 330 cannot be withdrawn through the slot 1441. One of ordinary skill in the art can appreciate the myriad different ways in which the proximal end 332 of the binder 330 can be associated with the second wing 1450 so that tension can be applied to the binder 330. The binder 330 can be disposed around adjacent spinous processes and a portion of the length of the binder 330 (the length of the binder being that portion of the binder extending from the proximal end of the binder) can be secured to the second wing 1450 by a capture device 1420 associated with the second wing 1450.

The capture device 820 of **FIGS. 13A** and **13B** is arranged at a second end of the second wing 1450 opposite the slot 1441. The capture device 1420 can be substantially similar to capture devices 1420 as described above in reference to **FIGS. 10A** and **10B**, and can comprise, for example, two pieces slidably associated with one another by an adjustable fastener. As above, a fixed piece 1421 of the capture device can extend from the second wing 1450. The fixed piece 1421 can include a beveled surface that can function as a ramp. A slid able piece 1427 of the capture device can be slidably associated with the fixed piece 1421 (for example, via the adjustable fastener) and can likewise include a beveled surface positioned in opposition to the beveled surface of the fixed piece 1421. As the slid able piece 1427 slides along the beveled surface of the fixed piece 1421, a distance between a capture surface 1498 of the slid able piece 1427 and the second wing 1450 increases or decreases. As above, the slid able piece 1427 can optionally further include a guide 1412 extending from the

slidable piece 1427 so that the guide 1412 overlaps a portion of the second wing 1450. The guide 1412 can extend, for example, a distance roughly similar to the maximum distance between the capture surface 1498 and the second wing 1450, and can help ensure that the binder 330 is arranged between the capture surface 1498 and the second wing 1450.

5 A physician can position the binder 330 so that the binder 330 is disposed between adjacent spinous processes, threading the binder 330 between the slidable piece 1427 and the second wing 1450. The physician can then adjust the fastener 1422 so that the distance between the capture surface 1498 and the second wing 1450 decreases, thereby pinching the binder 330 between the capture surface 1498 and the second wing 1450 and defining a secure
10 end of the binder 330. In some embodiments, one or both of the capture surface 1498 and the second wing 1450 can include texture so that the binder 330 is further prevented from sliding when the binder 330 is placed under increasing tension (e.g., during flexion).

15 The implant 1400 can further include a binder aligner 1470 selectively connectable with the first wing 108 of the main body 101. The binder aligner 1470 can be connected with the first wing 108 by fastening the binder aligner 1470 to the locking pin hole 104 of the first wing 108. In such embodiments where a fastener 1455 is used to connect the binder aligner 1470 with the first wing 108 through a hole 1471 in the binder aligner 1470, it is desirable that the locking pin hole 104 be threaded, or otherwise adapted to receive the fastener 1455. The locking pin hole 104 can thus be adapted to function as a hole to slidably (and temporarily)
20 receive a locking pin of an insertion tool (not shown), thereby facilitating insertion and positioning of the main body 101, and can also be adapted to function to fixedly receive a fastener 1455 for positioning the binder aligner 1470. The binder aligner 1470 can optionally include pins 1474 corresponding to the alignment holes 192 of the main body 101 to further secure the binder aligner 1470 to the main body 101 and limit undesired movement of the
25 binder aligner 1470 relative to the main body 101.

30 The binder aligner 1470 includes a guide 1472 extending from the binder aligner 1470 to limit or block shifting of the binder 330 in a posterior-anterior direction. The guide 1472 can include a loop, as shown in FIG. 13A, or alternatively some other structure, closed or unclosed, for limiting or blocking shifting of the binder 330. Such a structure can prevent undesired relative movement between the binder 330 and the main body 101, and can additionally ease arrangement of the binder 330 during an implantation procedure, by helping to aid proper positioning of the binder 330.

In other embodiments, the capture device of FIGs. 13A and 13B can include some other shape, configuration, and mechanism and still fall within the contemplated scope of the invention. For example, referring to FIG. 14, in other embodiments, a flange 1514 can extend from the second wing 1550, from which a rotatable cam 1521 extends so that the binder 330 can be captured between the second wing 1550 and the cam 1521. Such a capture device can resemble capture devices 1520 as described above in FIGs. 3C and 3B. Referring to FIG. 15, in still other embodiments, a spring-loaded cam 1621 extends from the flange 1514 so that the binder 330 can be captured between the second wing 1514 and the spring-loaded cam 1621. Such a capture device can resemble capture devices 1520 as described above in FIGs. 3C and 3D. In still further embodiments in accordance with the present invention, some other mechanism can be employed as a capture device associated with the second wing 1550 for securing the length of the binder 330, for example as otherwise described in herein, and other obvious variations. One of ordinary skill in the art will appreciate the myriad different mechanisms for securing the binder 330 to the second wing 1450.

A system in accordance with the present invention can comprise a second wing 1450 including a capture device 1420 as described above and optionally a binder aligner 1470. The system can be used with a main body 101 in substitution for a second wing 150 as described above in FIG. 1. Alternatively, the system can optionally be used to modify a main body 101 previously implanted in a patient, for example by removing an existing second wing 150 and replacing the second wing 150 with the system, to additionally limit flexion as well as extension. Such a system can provide flexibility to a physician by allowing the physician to configure or reconfigure an implant according to the needs of a patient. Further, such a system can reduce costs by reducing the variety of components that need be manufactured to accommodate different procedures and different treatment goals.

A method of surgically implanting an implant 1400 in accordance with an embodiment as described above in FIGs. 13A-15 of the present invention is shown as a block diagram in FIG. 16. The method can include forming an incision at the target motion segment, and enlarging the incision to access the target motion segment (Step 200). The interspinous ligament between targeted adjacent spinous processes can then be distracted by piercing or displacing the interspinous ligament with the distraction guide 106 (Step 202) and urging the implant 1400 between the adjacent spinous processes (Step 204). As the interspinous ligament is displaced, the spacer 102 can be positioned between the spinous processes such that the

spacer 102 can rotate to assume a preferred position between the spinous processes (Step 206). Once the implant 1400 is positioned, the second wing 1450 can be fixedly connected with the distraction guide 106 (Step 208). A binder 330 associated with the second wing 1450 can be threaded between interspinous ligaments of adjacent motion segments so that the targeted adjacent spinous processes are disposed within a loop formed by the binder 330 (Step 210). The physician can then thread the binder 330 between the capture surface 1498 of the capture device 1420 and the second wing 1450 (Step 212). Once a desired tension of the binder 330 is applied (Step 214), the physician can adjust the fastener 1422 of the capture device 1420 so that the binder 330 is secured between the captured surface 1498 and the second wing 1450 (Step 216). The incision can subsequently be closed (Step 218).

MATERIAL FOR USE IN IMPLANTS OF THE PRESENT INVENTION

In some embodiments, the implant 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:

10

Property	Value
Density	1.3 g/cc
Rockwell M	99
Rockwell R	126
15 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 20 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. 25 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 30 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 (PEEK), 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.

As described above, the binder can be made from a biocompatible material. In an embodiment, the binder can be made from a braided polyester suture material. Braided polyester suture materials include, for example, Ethibond, Ethiflex, Mersilene, and Dacron, and are nonabsorbable, having high tensile strength, low tissue reactivity and improved handling. In other embodiments, the binder can be made from stainless steel (i.e., surgical steel), which can be braided into a tether or woven into a strap, for example. In still other embodiments, the binder can be made from some other material (or combination of materials) having similar properties.

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
5 defined by the following claims and their equivalents.

WHAT IS CLAIMED:

1. An implant for relieving pain associated with at least one of the spine and surrounding tissues and structures, which implant is positionable between spinous processes of the spine, the implant comprising:

5 a first unit including a body, a distraction guide extending from said body, and a first wing;

a second wing selectively connectable with the first unit;

a binder adapted to be disposed around the spinous processes, the binder

10 having an anchor end and a length extending from the anchor end; and

wherein:

the anchor end is connected with the second wing;

15 a capture device extends from the second wing and wherein the capture device can secure the binder along the length.

2. The implant of claim 1, further comprising:

a binder aligner selectively connectable with the first wing and wherein the binder aligner can receive the binder so that the binder is approximately aligned along a longitudinal axis of the body.

20 3. An interspinous implant, comprising:

a first wing;

25 a central body extending from the first wing, said central body having a longitudinal axis;

a spacer positioned over said central body with said spacer being able to rotate about said longitudinal axis of said central body so as to be positionable relative to said central body in order to aid in positioning said implant between spinous processes;

30 a distraction guide extending from the central body;

a second wing selectively connectable with the distraction guide, the second wing including a capture device extending therefrom;

a binder adapted to be disposed around the spinous processes, the binder having an anchor end connected with the second wing and a length extending from the

anchor end to be secured by the capture device.

4. The implant of claim 3, wherein the first wing is adapted to be positionable along first sides of the adjacent spinous processes and the second wing is adapted to be

5 positionable along second sides of the spinous processes and opposite to the first wing.

5. The implant of claim 3, further comprising:

10 a binder aligner selectively connectable with the first wing and wherein the binder aligner can receive the binder so that the binder is approximately aligned along a longitudinal axis of the body.

6. The implant of claim 3, wherein said distraction guide includes a groove that can receive said second wing.

15 7. The implant of claim 3, wherein:

the capture device includes a first portion extending from the second wing, a second portion movably associated with the first portion, and a fastener; and

the binder is fixedly associated with the brace by adjusting the fastener so that the second portion is urged toward the second wing.

20

8. The implant of claim 3, wherein:

the capture device includes a spring-loaded cam biased against the second wing so that the second wing limits the rotation of the spring-loaded cam; and

the binder is disposed between the spring-loaded cam and the second wing.

25

9. A system selectively connectable with an implant adapted to be positioned between spinous processes and including a first wing and a body extending from the first wing, the system comprising:

a second wing;

30

a capture device extending from the second wing;

a binder adapted to be disposed around the spinous processes, the binder having an anchor end connected with the second wing and a length extending from the

anchor end;

wherein the capture device can secure the binder along the length; and
wherein the second wing can be connected with the body.

5 10. The system of claim 9, further comprising:

a binder aligner adapted to receive the binder so that the binder is
approximately aligned along a longitudinal axis of the body;
wherein the binder is adapted to be connected with the first wing.

10 11. The system of claim 9, wherein:

the body includes a spacer and a distraction guide; and
the second wing is adapted to be connected with one of the spacer and the
distraction guide.

15 12. The system of claim 9, wherein:

the body includes a central body extending from the first wing, a distraction
guide extending from the central body, and a spacer pivotably disposed over at least a
portion of the central body; and

wherein the second wing can be connected with the distraction guide.

20

13. The system of claim 12, wherein:

the second wing includes an alignment tab; and
the distraction guide includes an alignment groove for receiving the
alignment tab.

25

14. A method to immobilize vertebral bodies by immobilizing respective spinous
processes extending therefrom, the method comprising:

using an implant including a spacer, a brace, and a first wing;

positioning the spacer between adjacent spinous processes;

30 connecting a second wing to the implant, wherein the second wing includes
a capture device extending from the second wing,

positioning a binder connected with the second wing around adjacent

spinous processes;

positioning the binder between the second wing and the capture device; and
adjusting the capture device to secure the binder between the capture device
and the second wing.

5

15. The method of claim 14, wherein the capture device includes at least one cam
adapted to secure the binder against the second wing.

10 16. The method of claim 15, wherein one or both of a surface of the at least one cam
and the second wing is textured to resist slippage of the binder when secured.

17. The method of claim 15, wherein:

the at least one cam includes one or more cam lobes corresponding to one or more
lobes disposed within the second wing; and

15 when the at least one cam is rotated, the binder is disposed between the one or more
cam lobes and the one or more lobes of the second wing.

18. The method of claim 14, wherein:

20 the capture device includes a first spring-loaded cam and a second spring-loaded
cam, the first and second spring-loaded cams being biased in opposition to one another and
being positioned so that rotational motion of the first spring-loaded cam in a first direction
is limited by the second spring-loaded cam and the rotational motion of the second spring-
loaded cam in a second direction is limited by the first spring-loaded cam; and

25 the binder is secured by threading the binder between the first spring-loaded cam
and the second spring-loaded cam.

19. The method of claim 18, wherein the first and second spring-loaded cams include
texture to grip the binder.

30 20. The method of claim 14, wherein:

the capture device includes a spring-loaded cam biased against the second wing so
that the second wing blocks the rotation of the spring-loaded cam in a first direction; and

the binder is secured by threading the binder between the spring-loaded cam and the second wing.

21. An interspinous implant comprising:

5 a spacer adapted to be inserted between spinous processes;
a brace;
a capture device associated with the brace;
a binder adapted to be disposed around the spinous processes, the binder
having a first end connected with the brace and a second end extending from the first end;

10 wherein the capture device includes a fastener, a first portion extending
from the brace, and a second portion movably associated with the first portion such that a
gap between the second portion and the brace is adjustable; and

15 wherein the binder is secured by positioning the binder within the gap and
actuating the fastener so that the first portion and the second portion move relative to one
another, thereby reducing the gap.

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

20 a brace;
a central body extending from the brace, said central body having a
longitudinal axis;

25 a spacer positioned over said central body with said spacer being able to
rotate about said longitudinal axis of said central body so as to be positionable relative to
said central body in order to aid in positioning said implant between spinous processes;

30 a binder having a first end connected with the brace and a second end
extending from the first end, the binder being adapted to engage the spinous processes; and
a capture device associated with the brace;

 wherein the capture device includes a first portion extending from the brace,
a second portion movably associated with the first portion, and a fastener; and

 wherein the binder is fixedly associated with the brace by adjusting the
fastener so that the second portion is urged toward the brace.

23. The implant of claim 22, further comprising a distraction guide connected with the central body, and said distraction guide including a slot that receives a portion of the binder located between the first and second ends of the binder.

5 24. The implant of claim 23, wherein the distraction guide includes a cavity for receiving the binder so that the binder passes through the distraction guide.

25. The implant of claim 22, further comprising:

a wing; and

10 a fastener to secure the wing to the central body with the spacer disposed between the wing and the brace.

26. The implant of claim 23, further comprising:

a wing; and

15 a wing fastener to secure the wing to the distraction guide so that the spacer is disposed between the wing and the brace.

27. The implant of claim 23, wherein:

20 the distraction guide includes one or more winglets having a leading edge and a trailing edge, the one or more winglets being biased so that the winglets are urged to a position extending from the distraction guide; and

wherein when the implant is positioned between adjacent spinous processes, the winglets collapse as a result of contact with a leading edge of the winglets and resist collapse as a result of contact with a trailing edge of the winglets.

25

28. The implant of claim 23, further comprising:

one or more extendable winglets associated with the distraction guide; and
a shaft accessible from the distraction guide:

wherein the extendable winglets are extended by rotating the shaft.

30

29. The implant of claim 22, wherein the binder comprises a braided polyester suture material.

30. An interspinous implant adapted to be inserted between spinous processes and adapted to immobilize vertebral bodies by immobilizing respective spinous processes extending therefrom, the implant comprising:

a brace having a proximal end and a distal end;

a capture device associated with the brace, the capture device including a first portion extending from the distal end of the brace, a second portion slidably associated with the first portion and a fastener;

a central body extending from the proximal end of the brace, said central body having a longitudinal axis;

a spacer positioned over said central body with said spacer being able to rotate about said longitudinal axis of said central body so as to be positionable relative to said central body in order to aid in positioning said implant between spinous processes;

a distraction guide extending from the central body;

a binder having a first end connected with the brace, the binder being adapted to engage the adjacent spinous processes; and

wherein a second end of the binder is fixedly associated with the brace by arranging the binder between the brace and the second portion and adjusting the fastener so that the second portion is urged toward the brace.

31. The implant of claim 30, wherein the distraction guide is wedge-shaped.

32. The implant of claim 30, wherein the distraction guide is conical.

33. The implant of claim 30, wherein the distraction guide includes a cavity for receiving the binder so that the binder passes through the distraction guide.

34. The implant of claim 33, wherein the cavity is one of a slot and a bore.

35. The implant of claim 30, wherein the spacer is substantially elliptical in shape.

36. The implant of claim 30, wherein the spacer is substantially cylindrical in shape.

37. The implant of claim 36, wherein the spacer is adapted to be positioned close to the spine and adjacent to portions of the spinous processes to spread the load placed upon the spacer by the adjacent spinous processes.

5

38. The implant of claim 30, wherein the binder has biologically acceptable material placed on a portion thereof so that the material contacts the spinous process when the binder is secured to the spinous process, thus preventing any sharp edges of the binder from cutting into the spinous process.

10

39. The implant of claim 30, wherein the implant can be adjusted so that the binder is positioned about the adjacent spinous processes, ensuring that the spacer remains positioned between adjacent spinous processes.

15

40. The implant of claim 30, wherein the binder maintains constant tension on the spinous process.

41. The implant of claim 30, further comprising:

a wing; and

20

a wing fastener to secure the wing to the distraction guide so that the spacer is disposed between the wing and the brace.

42. The implant of claim 30, wherein the second portion includes a guide extending from the second portion, the guide partially overlapping a portion of the brace.

25

43. The implant of claim 30, wherein:

the brace includes a cavity formed through the brace; and
the first end of the binder is disposed through the cavity.

30

44. The implant of claim 43, wherein the cavity is one of a slot and a bore.

45. The implant of claim 30, wherein the binder includes one of strap, ribbon, tether, and cord.

5 46. The implant of claim 45, wherein

the binder includes:

a first portion comprising one of a strap and a ribbon; and

a second portion comprising one of a tether and a cord

the implant further comprises:

10 a pad slidably associated with the second portion.

47. The implant of claim 45, wherein the binder comprises a braided polyester suture material.

15 48. The implant of claim 47, wherein the binder comprises one of Ethibond, Ethiflex, Mersilene, and Dacron.

49. The implant of claim 45, wherein the binder comprises stainless steel.

20 50. A method to immobilize adjacent vertebral bodies by immobilizing respective spinous processes extending therefrom, the method comprising:

using an implant including a spacer, a brace, a binder connected with the brace, and a capture device associated with the brace;

25 wherein the capture device includes a first portion extending from the brace and a second portion slidably associated with the first portion;

positioning the spacer between the adjacent spinous processes;

positioning the binder around the adjacent spinous processes;

threading the binder between the brace and the second portion; and

urging the second portion toward the brace, thereby fixedly associating the binder with the brace.

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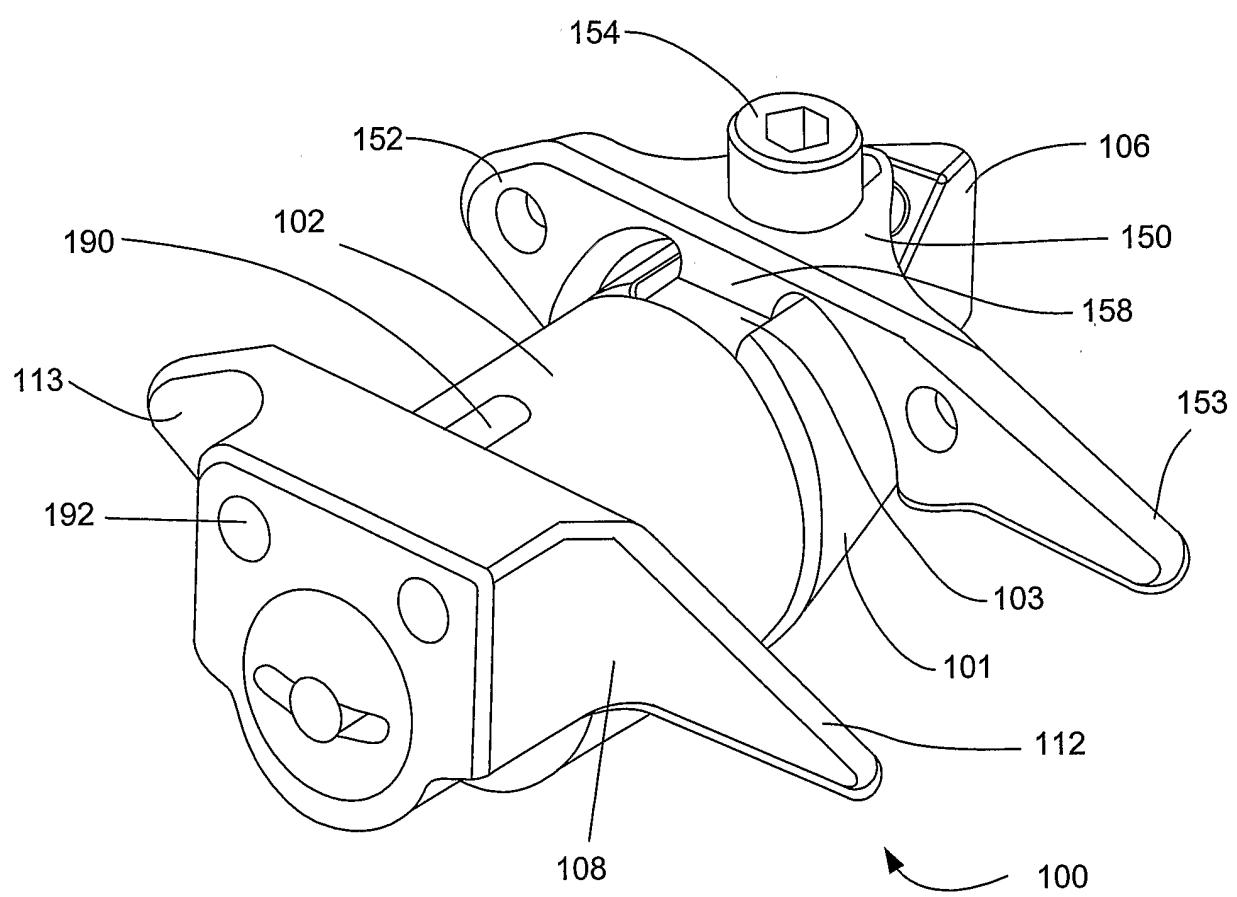


Fig. 1

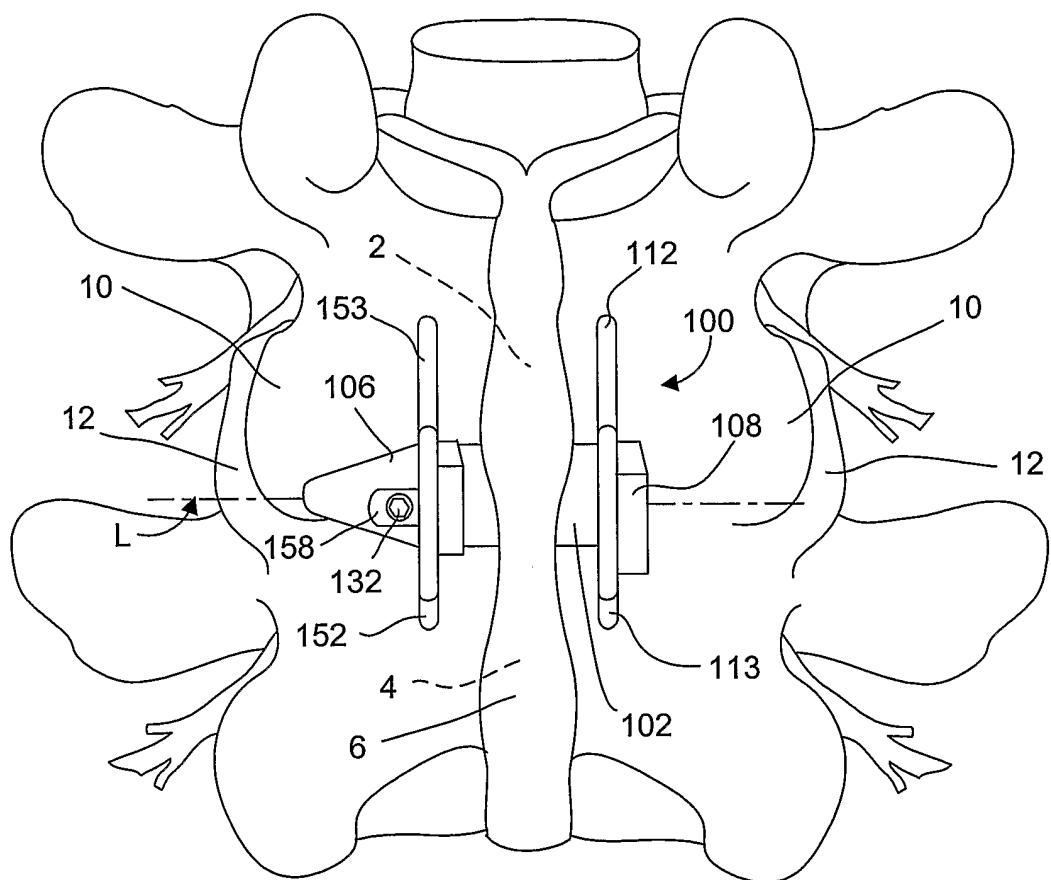


Fig. 2A

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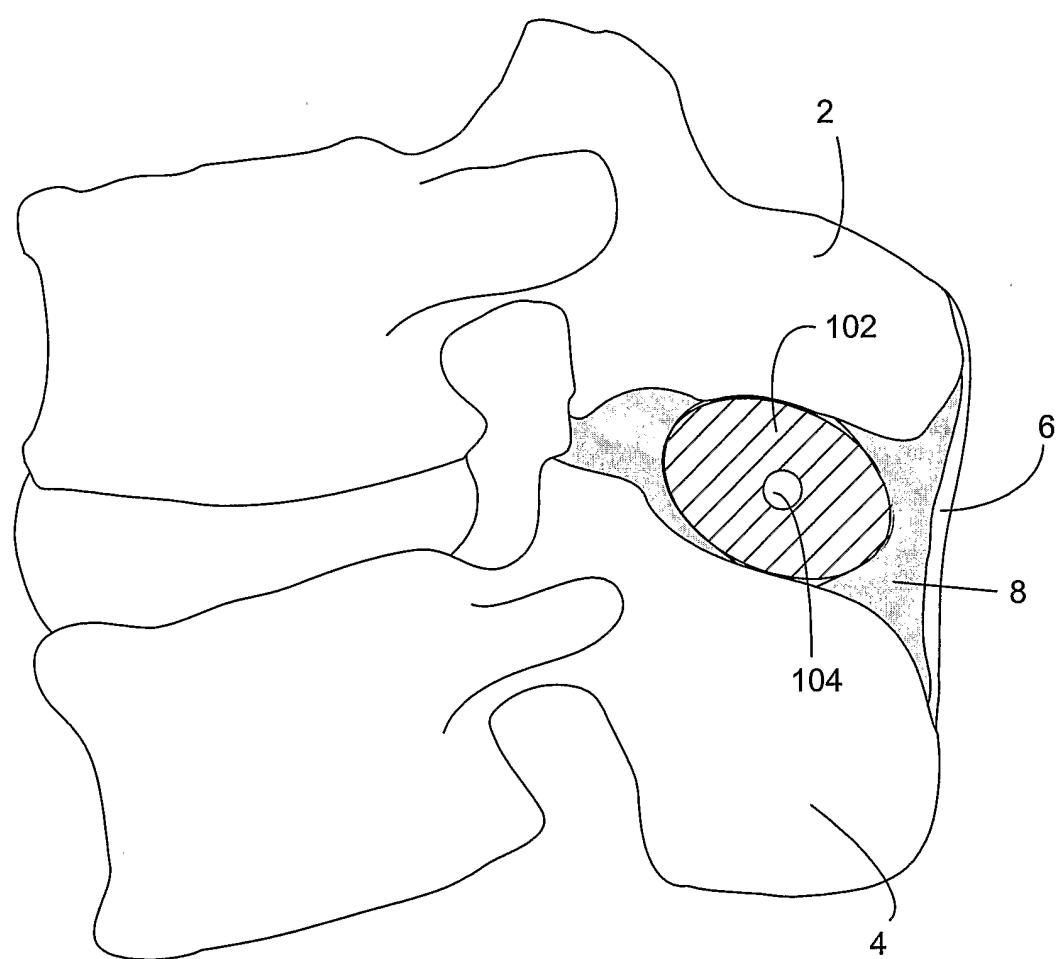


Fig. 2B

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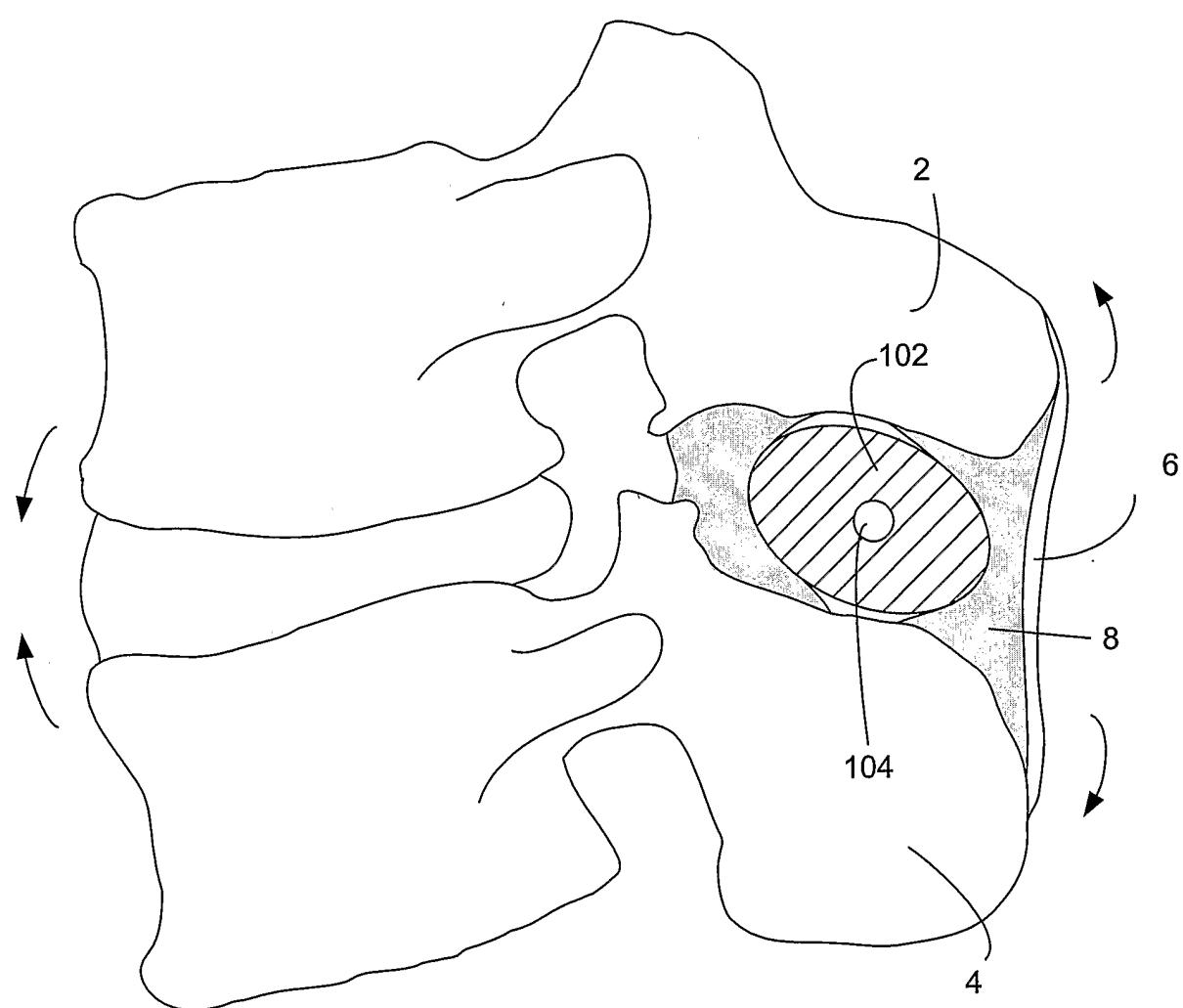


Fig. 2C

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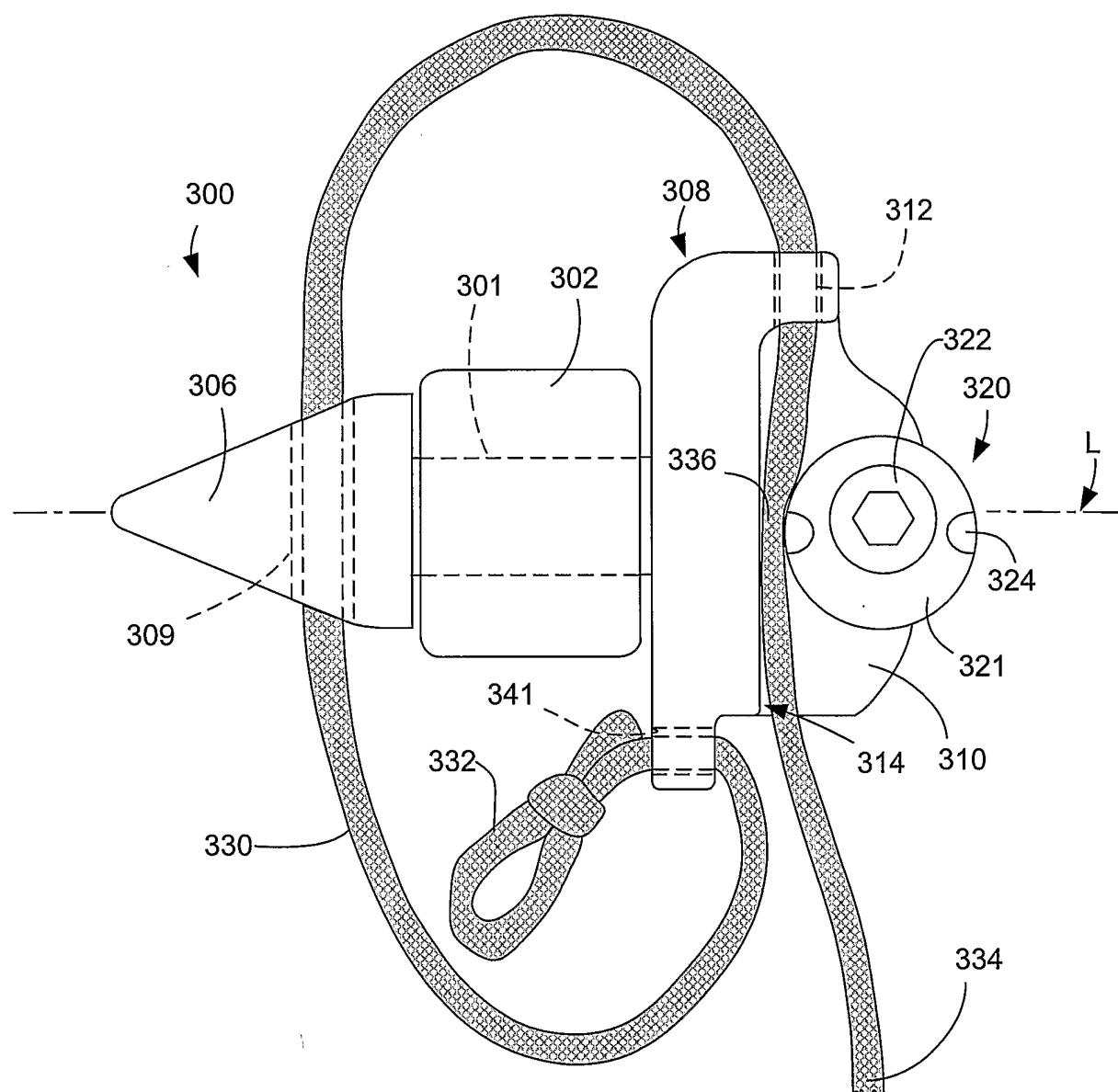


Fig. 3A

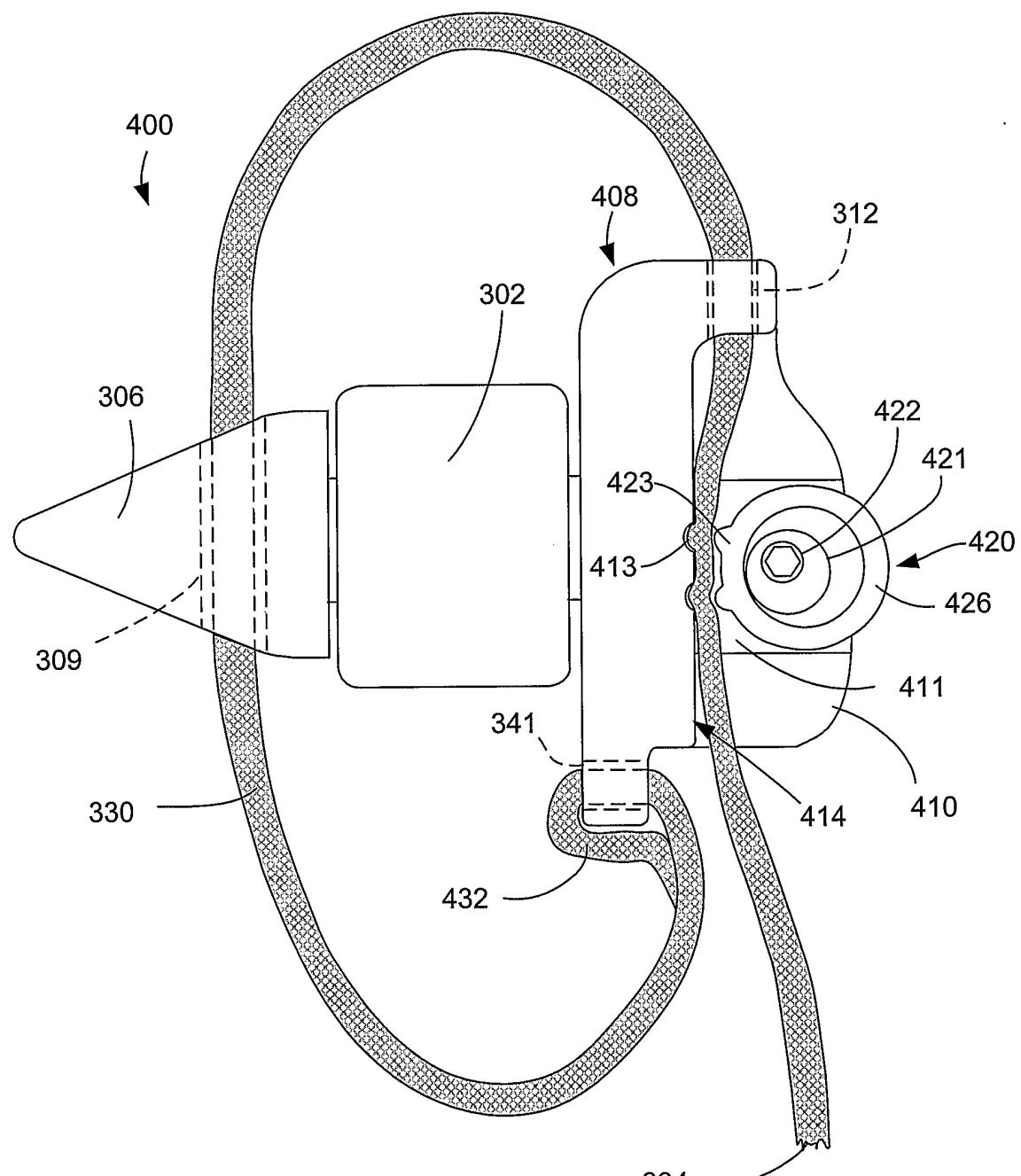


Fig. 3B

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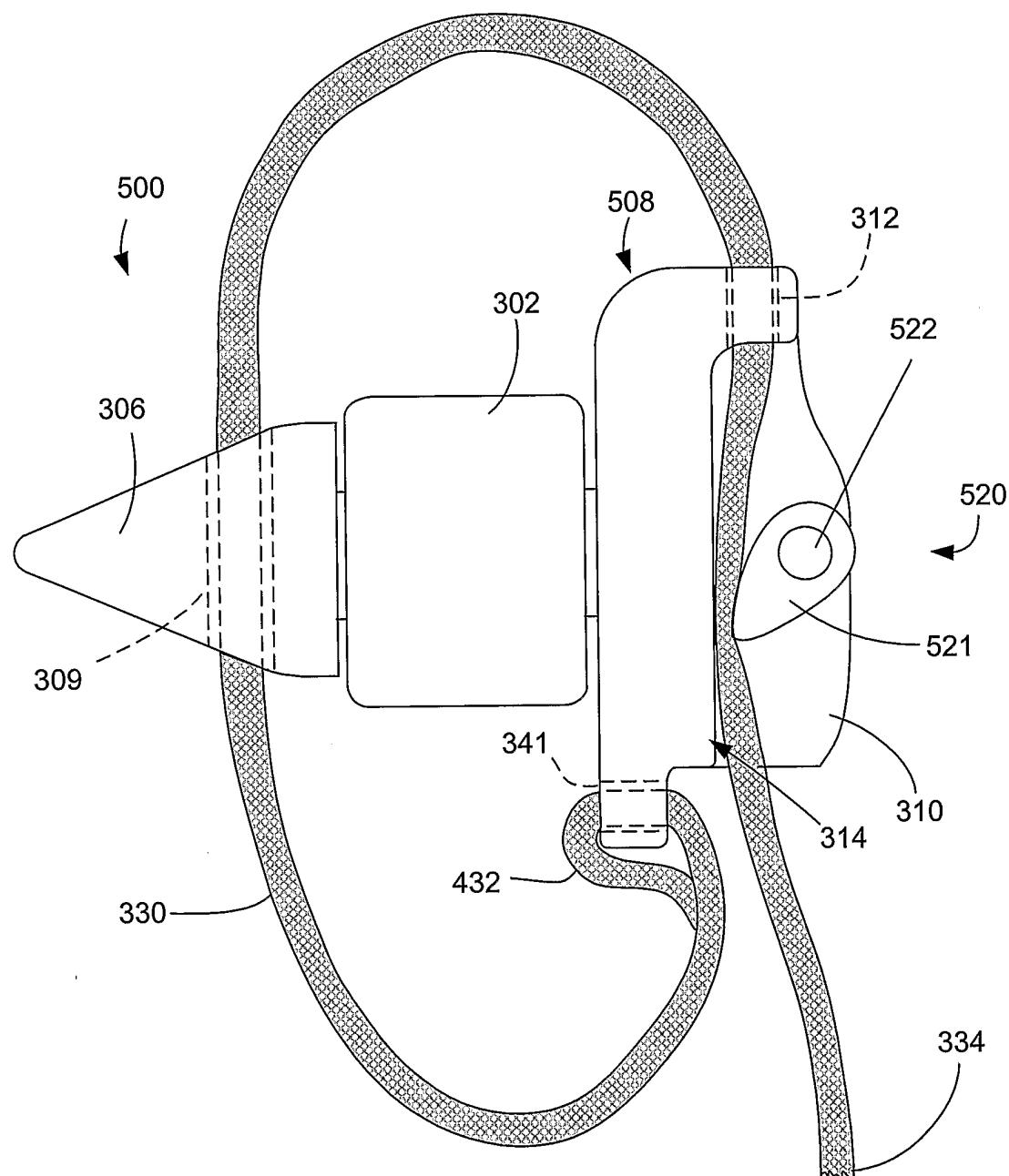


Fig. 3C

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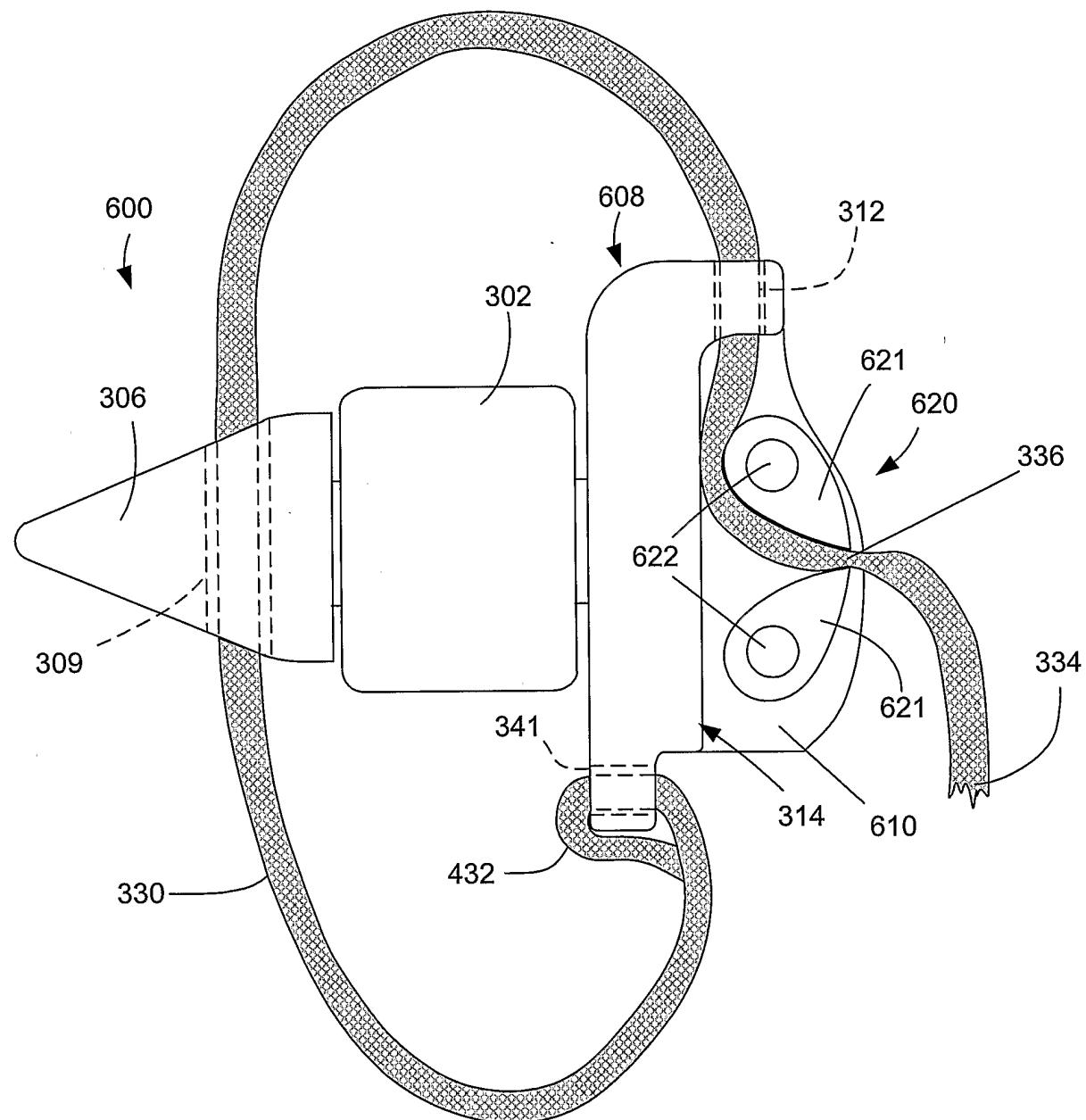


Fig. 3D

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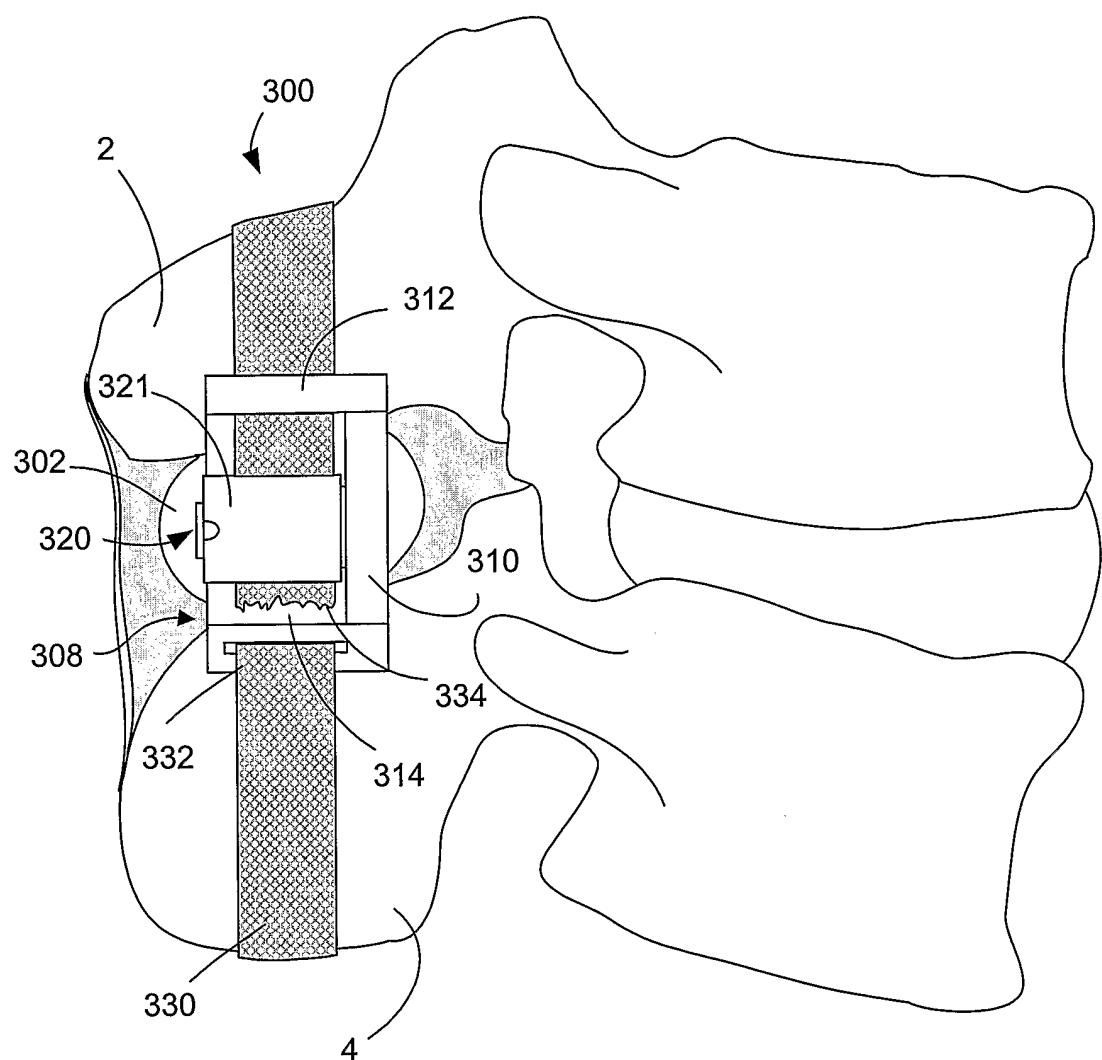


Fig. 4A

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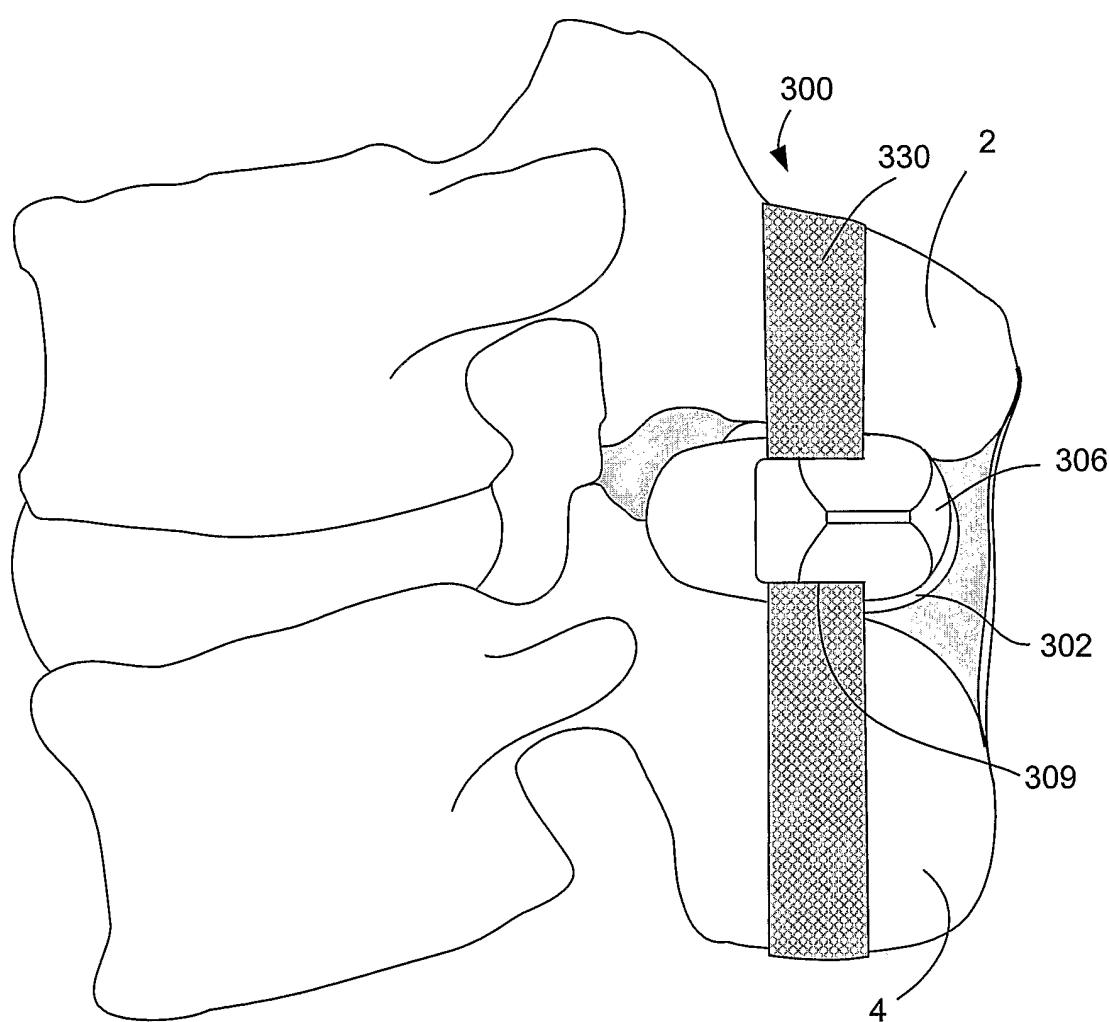


Fig. 4B

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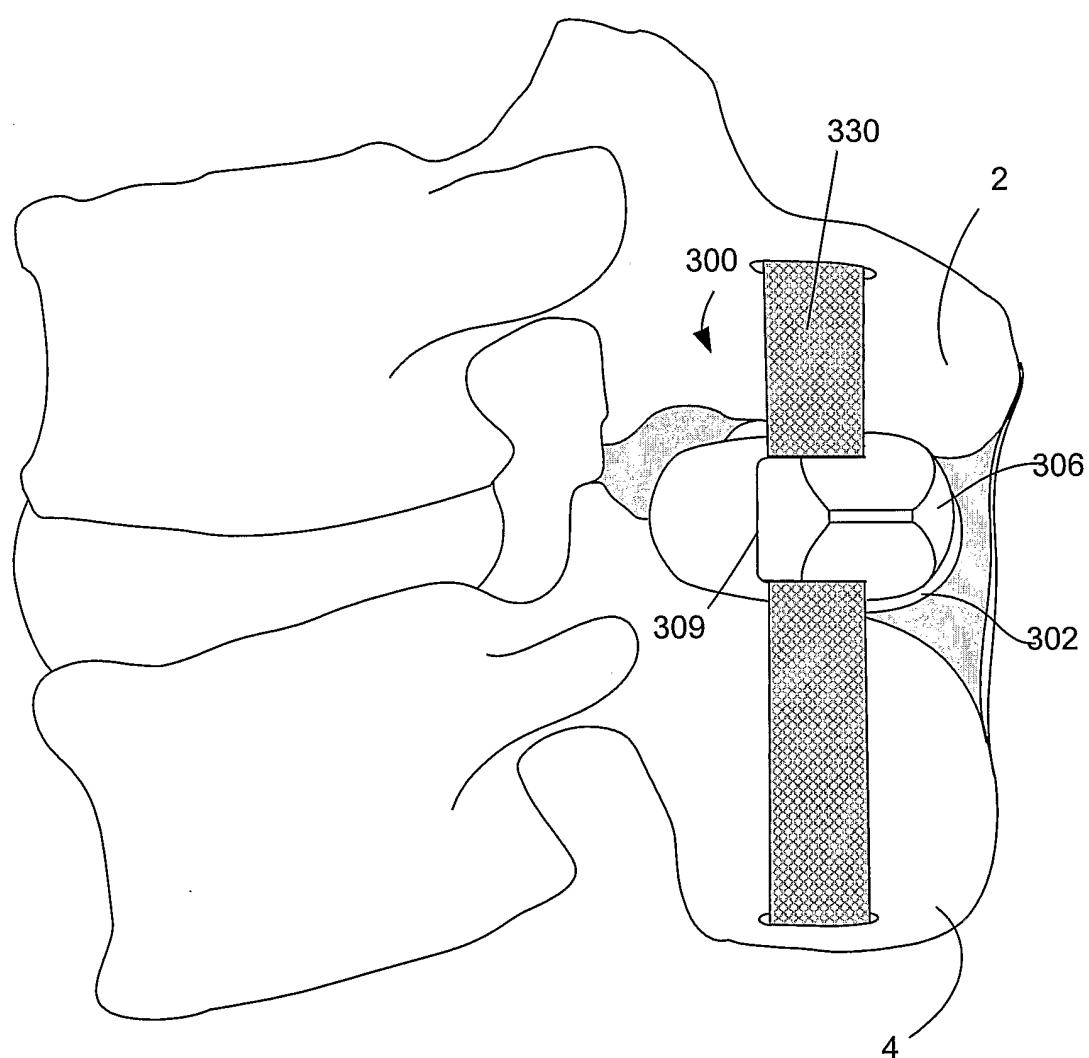
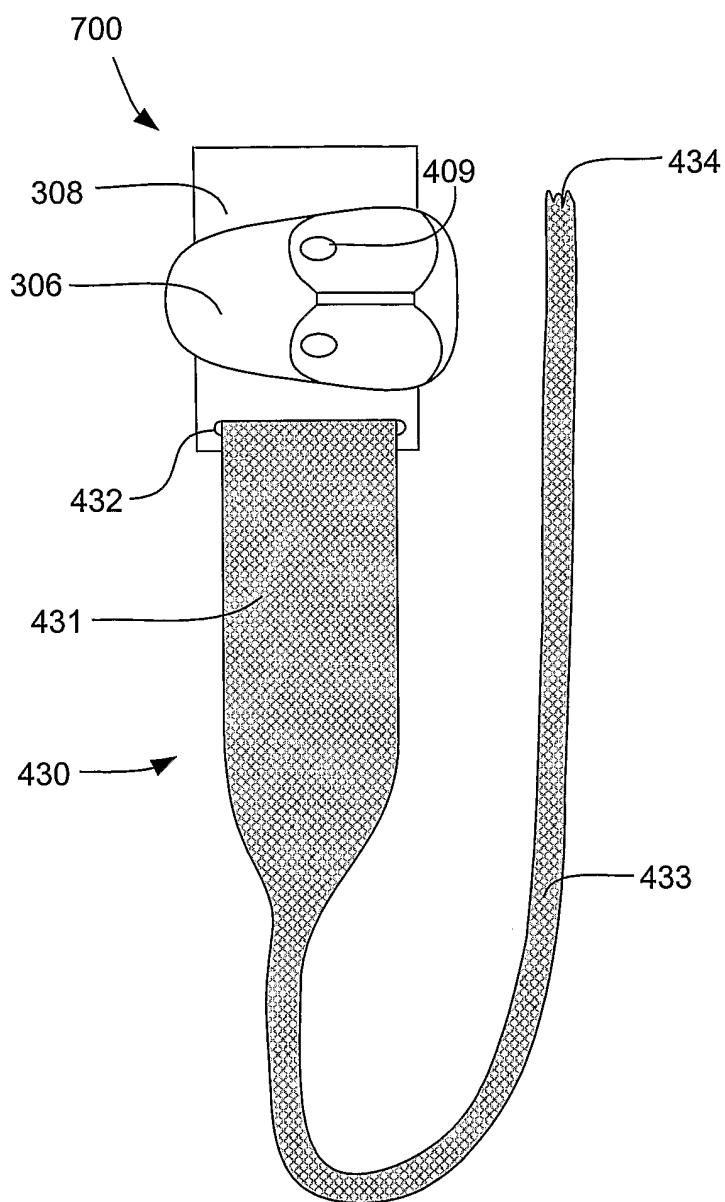


Fig. 4C

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*Fig. 5*

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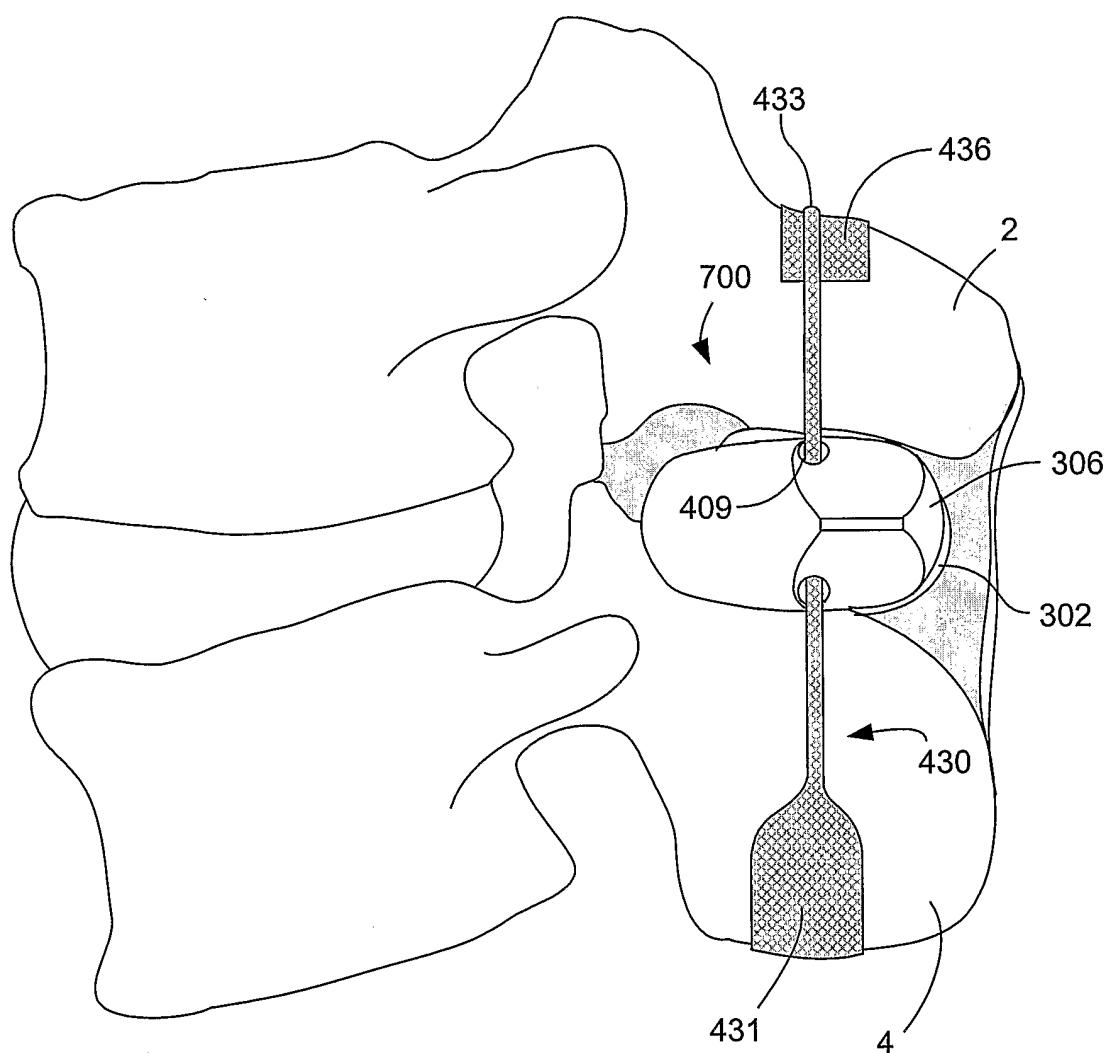


Fig. 6A

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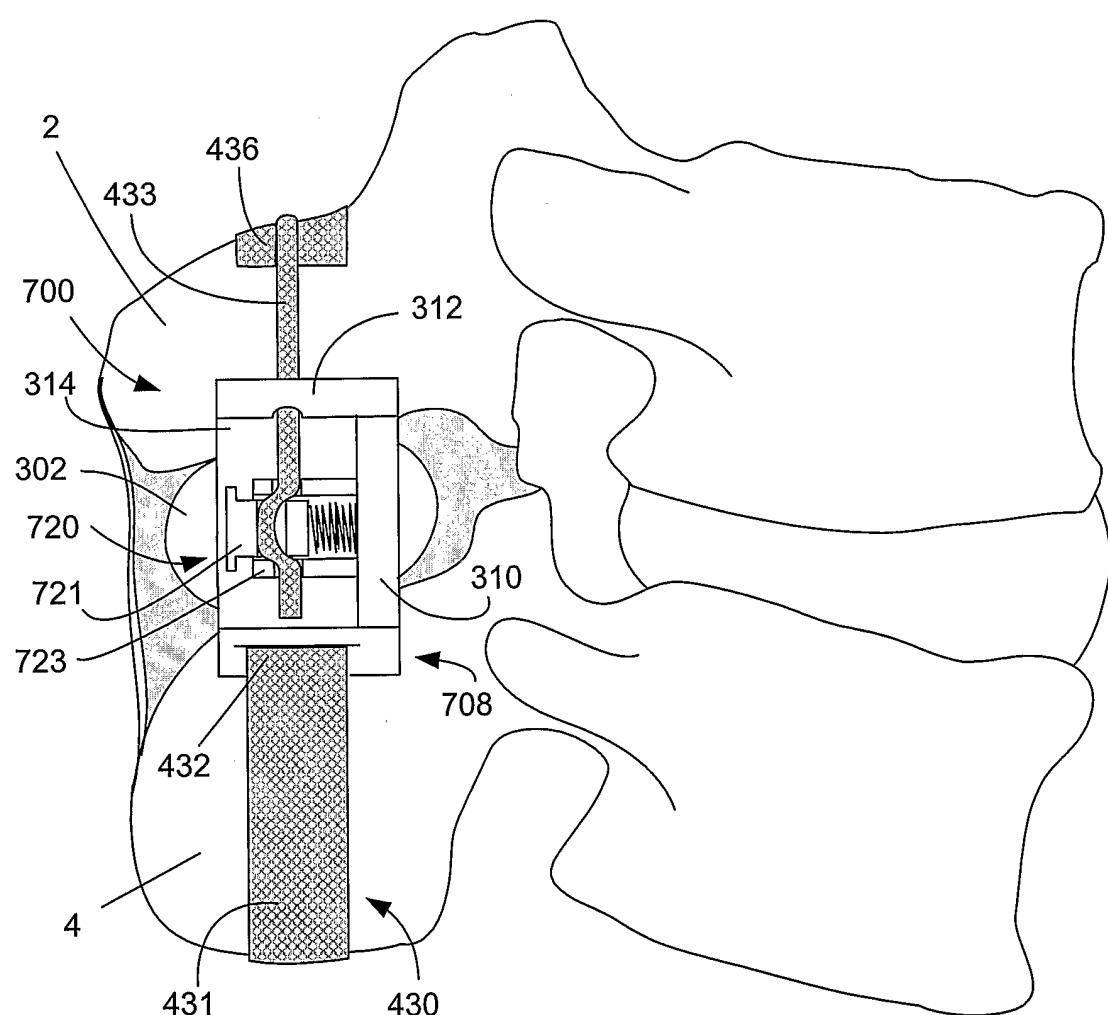


Fig. 6B

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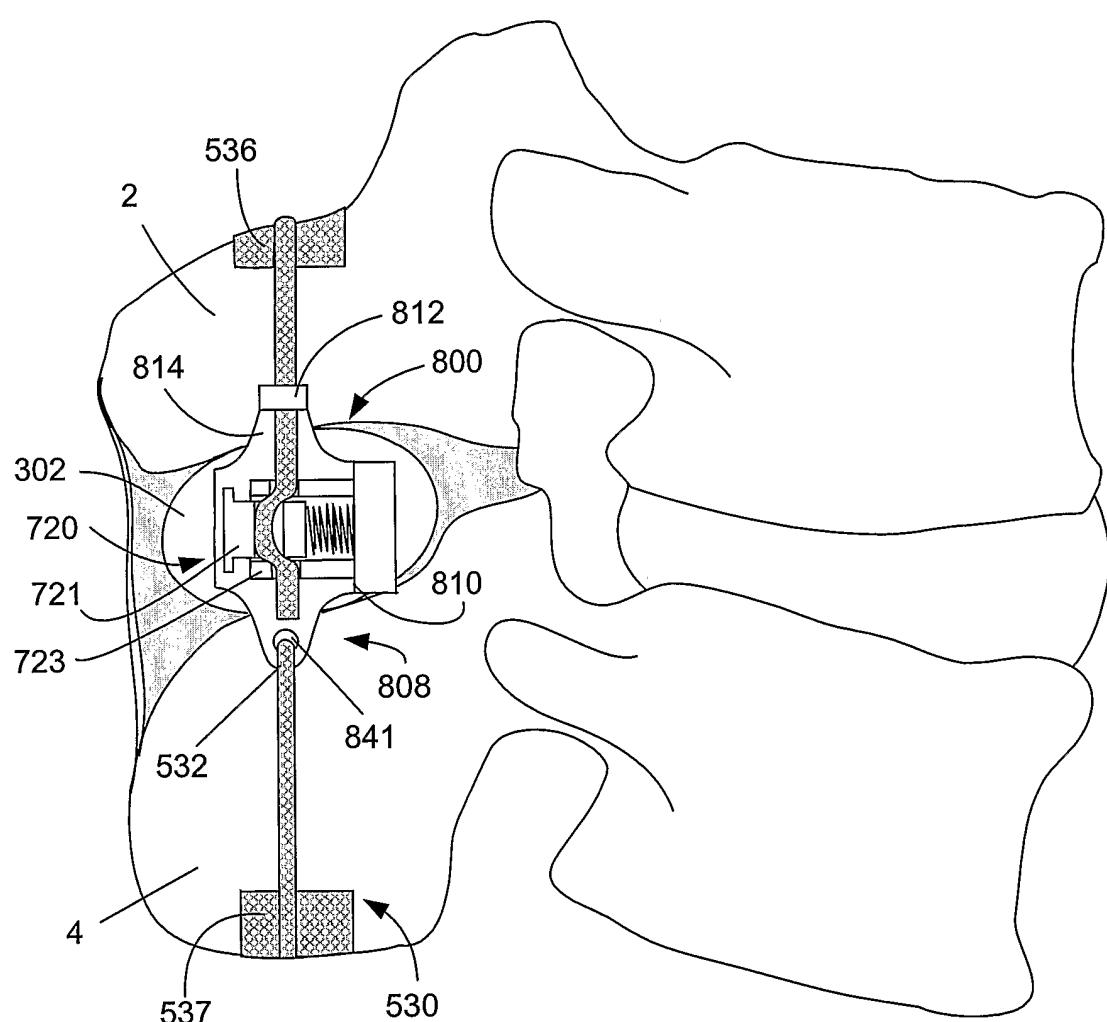


Fig. 6C

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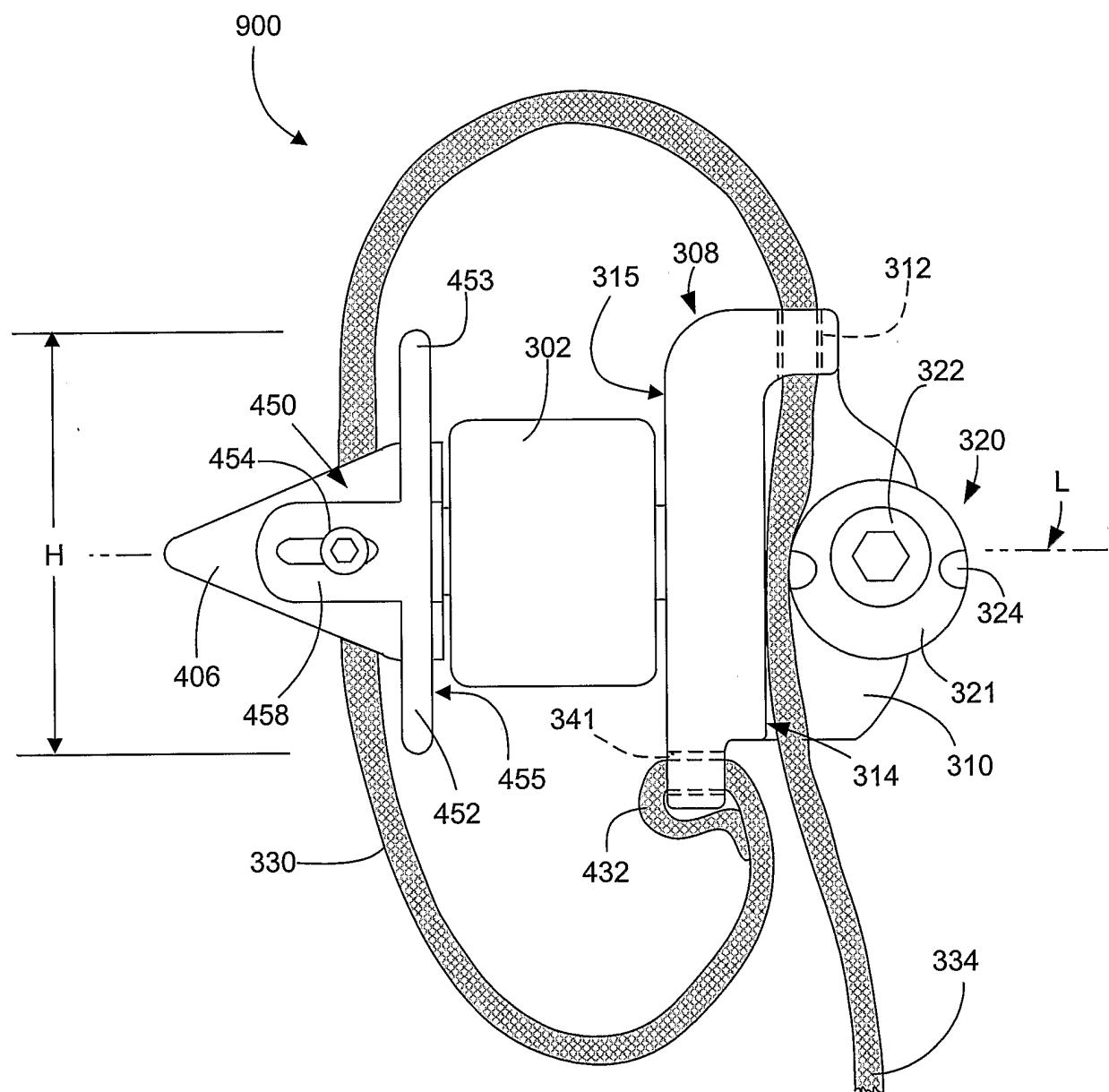


Fig. 7A

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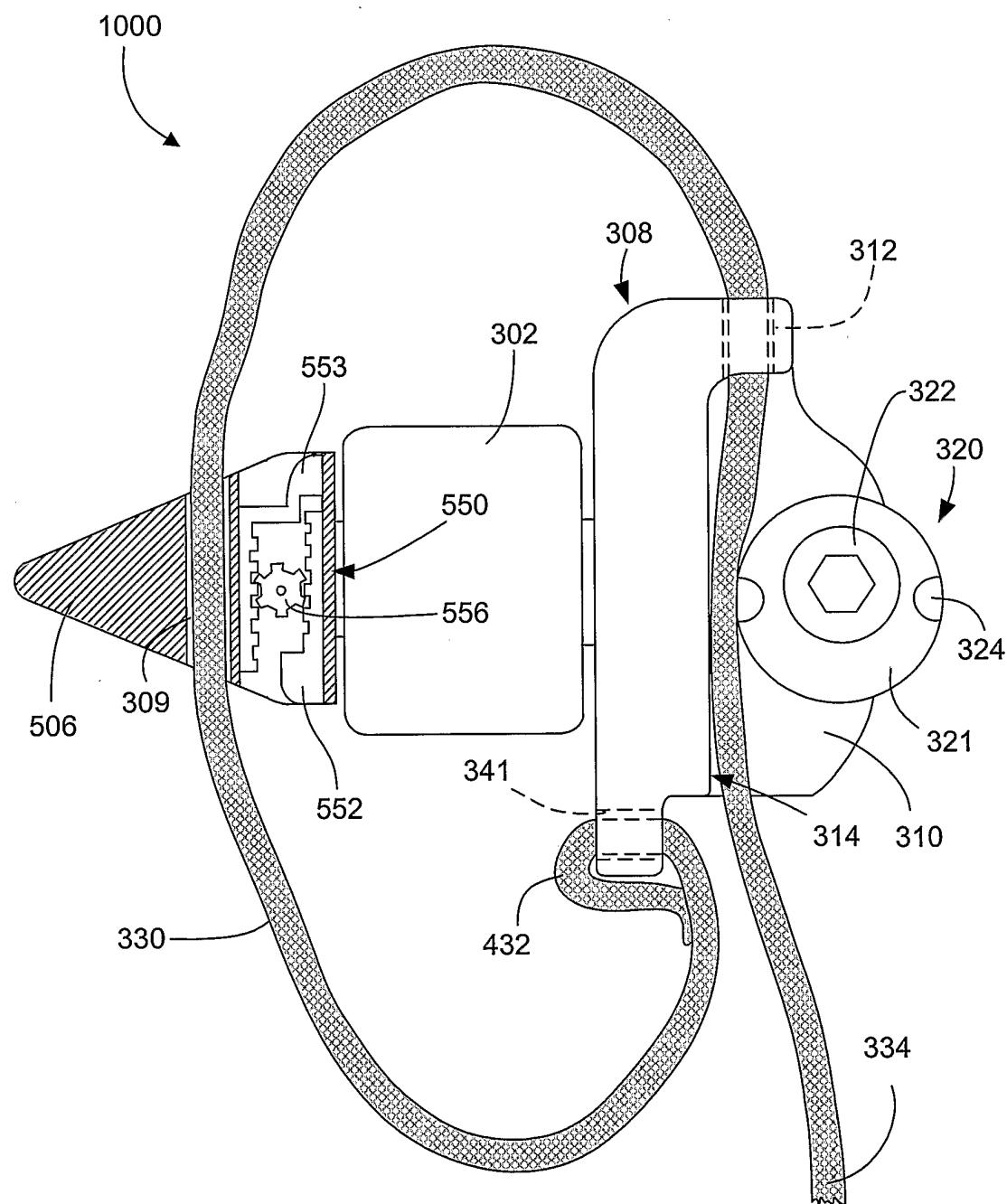


Fig. 7B

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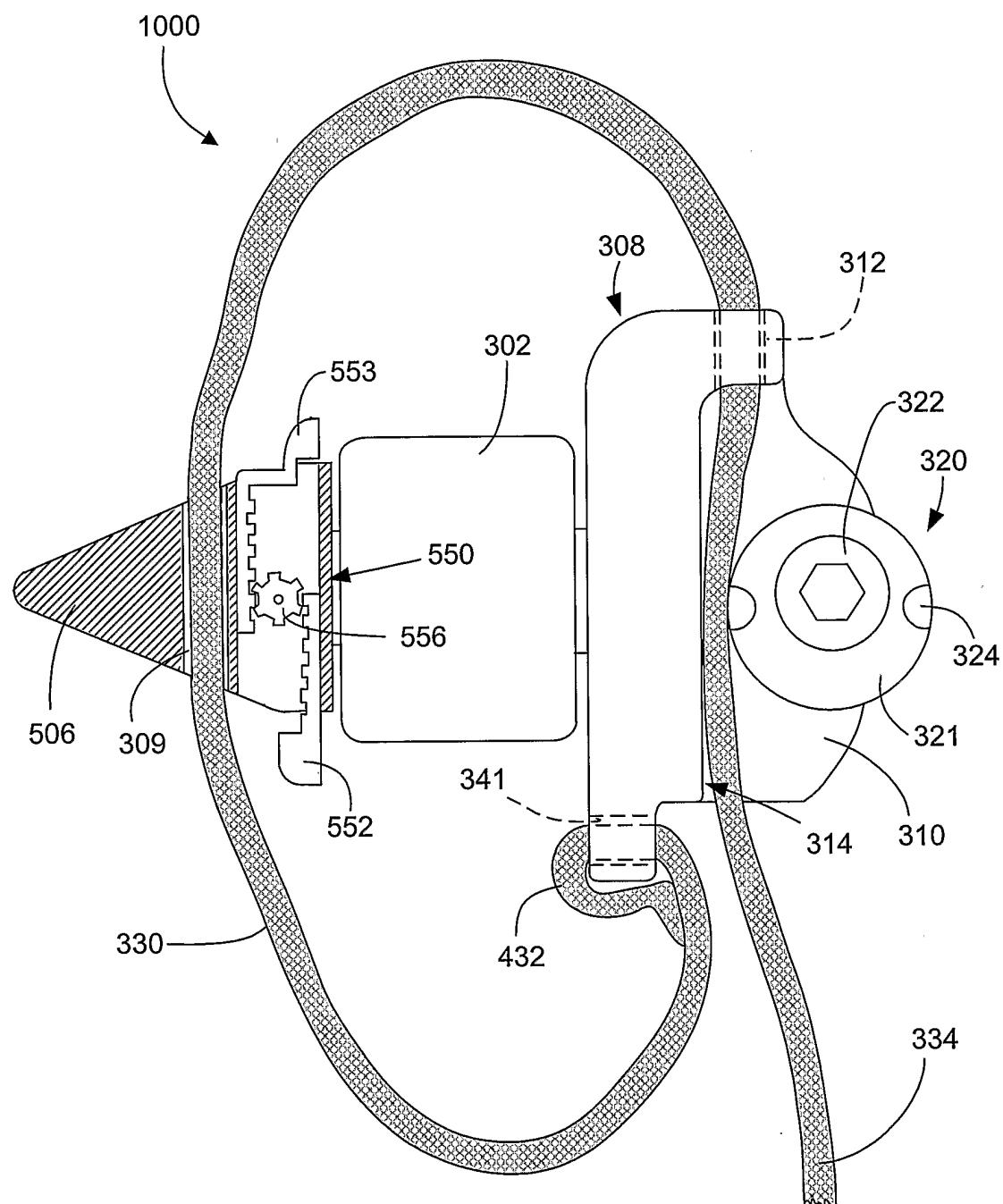


Fig. 7C

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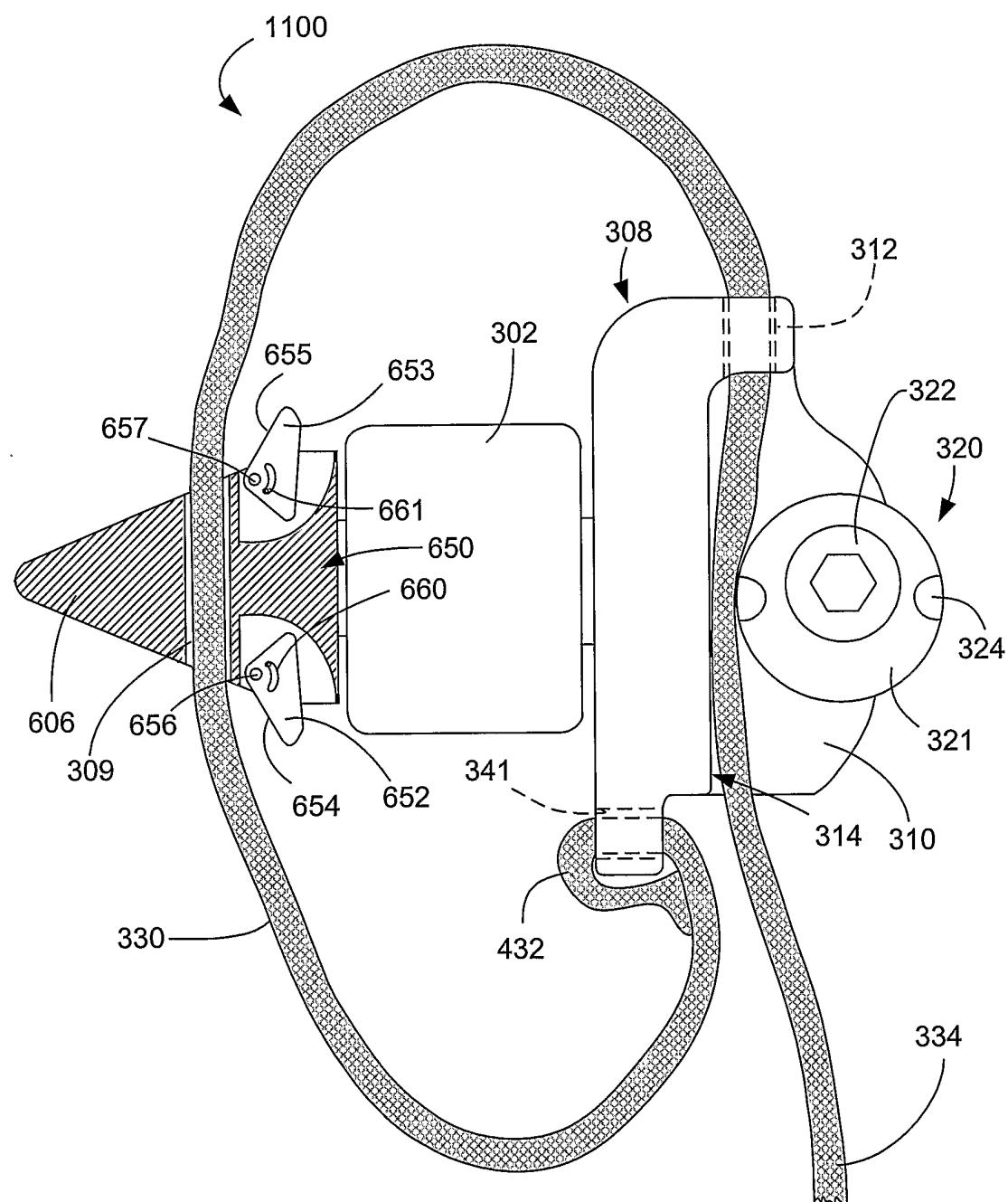


Fig. 7D

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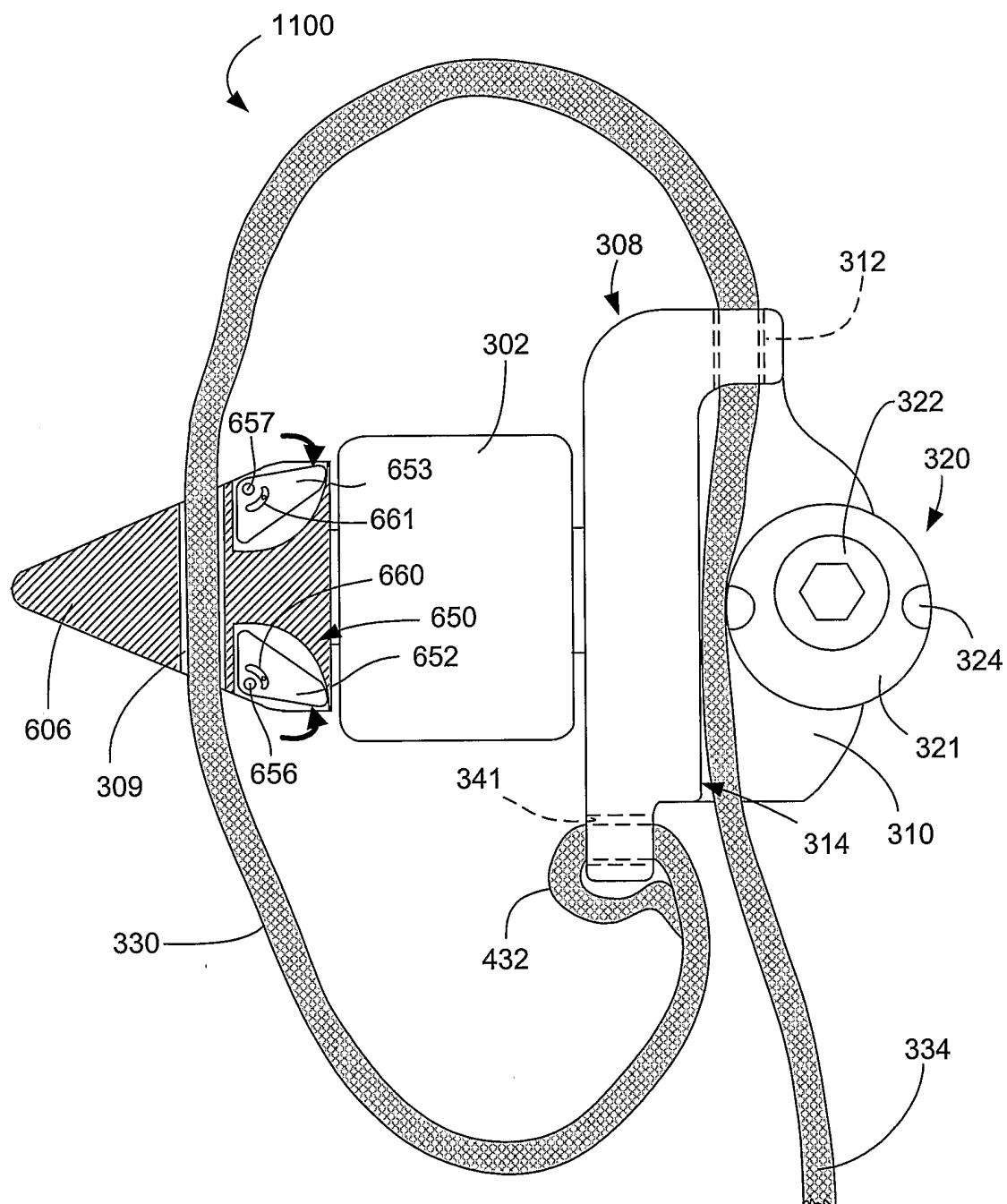


Fig. 7E

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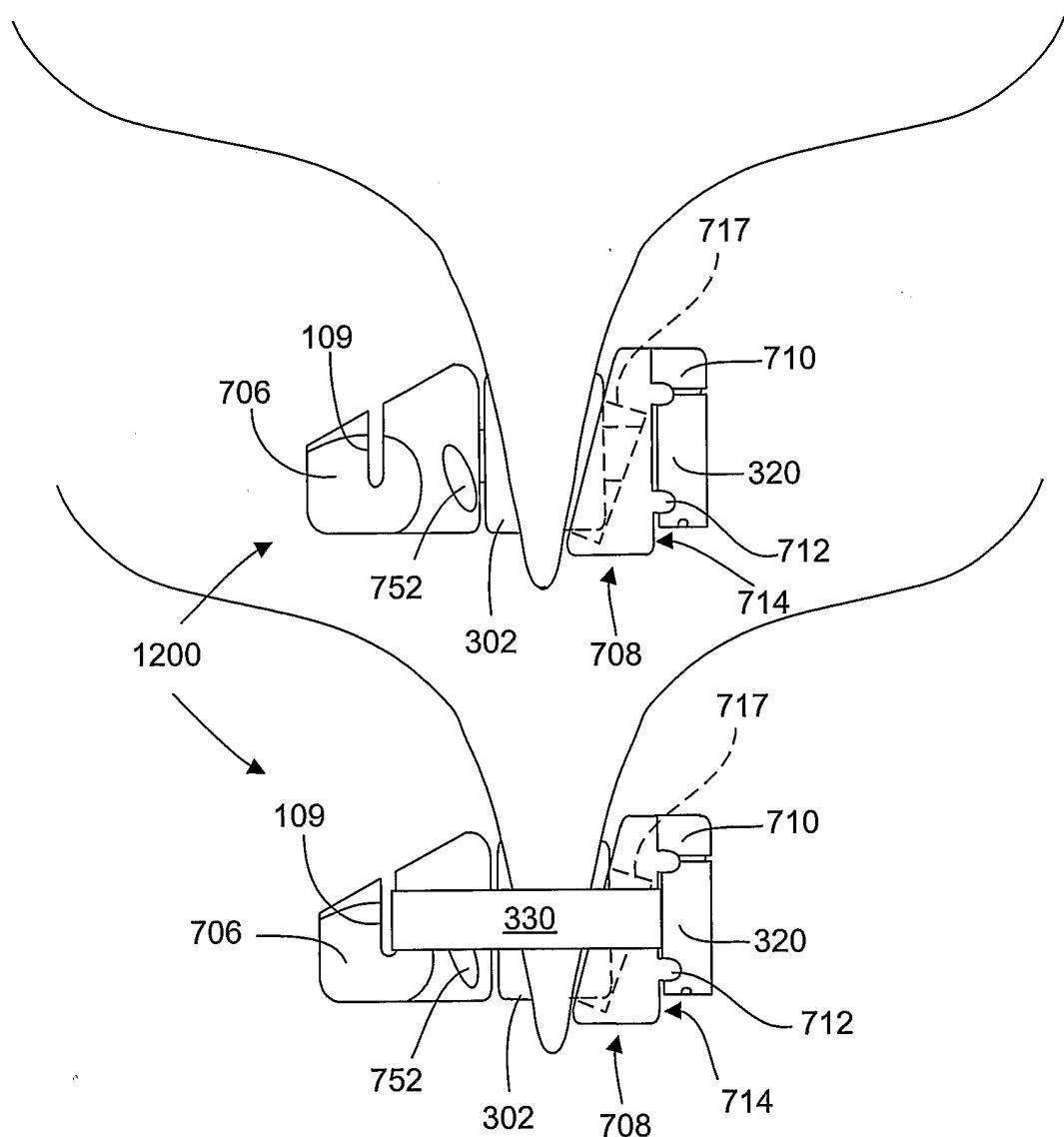


Fig. 8

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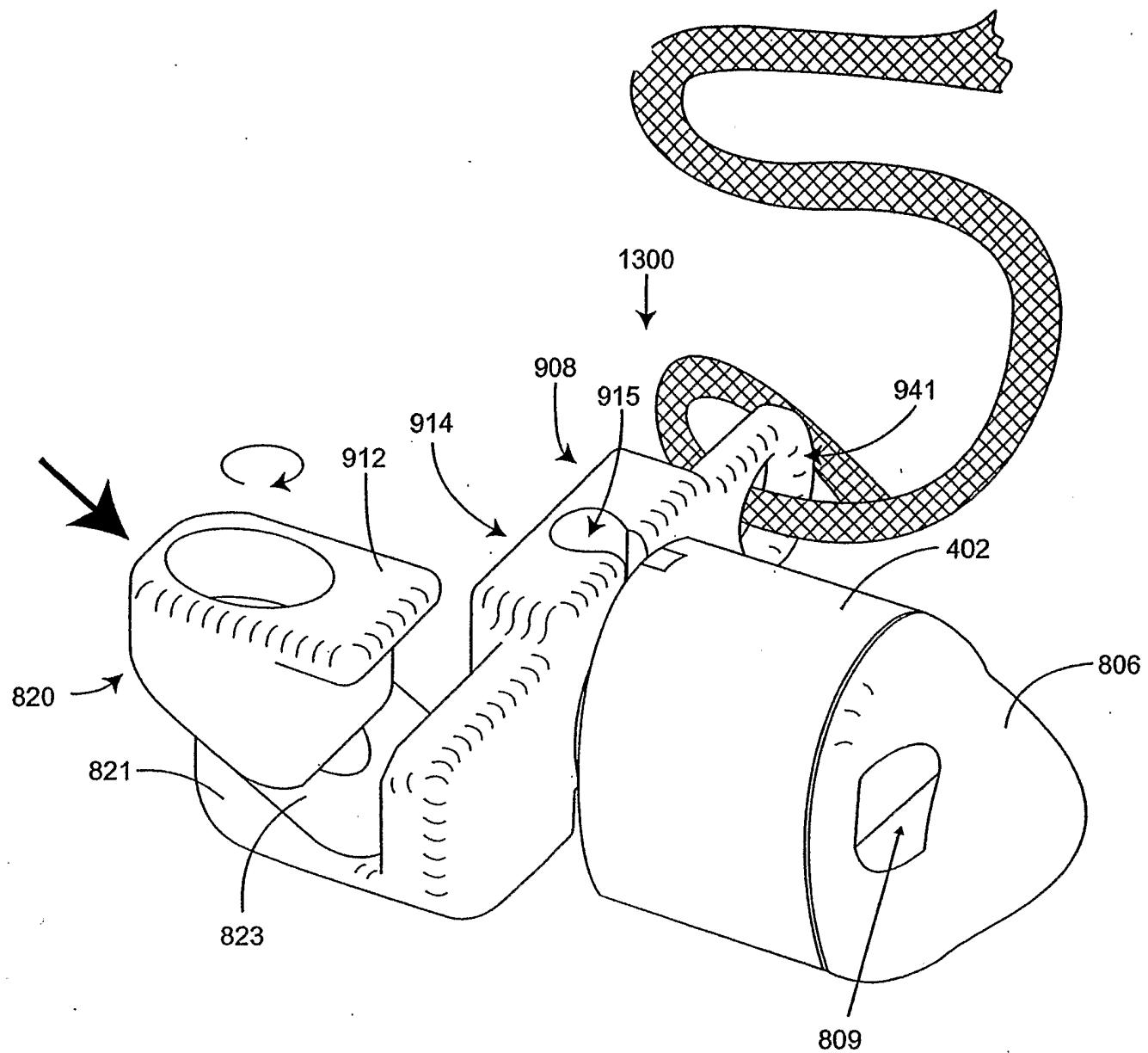


Fig. 9A

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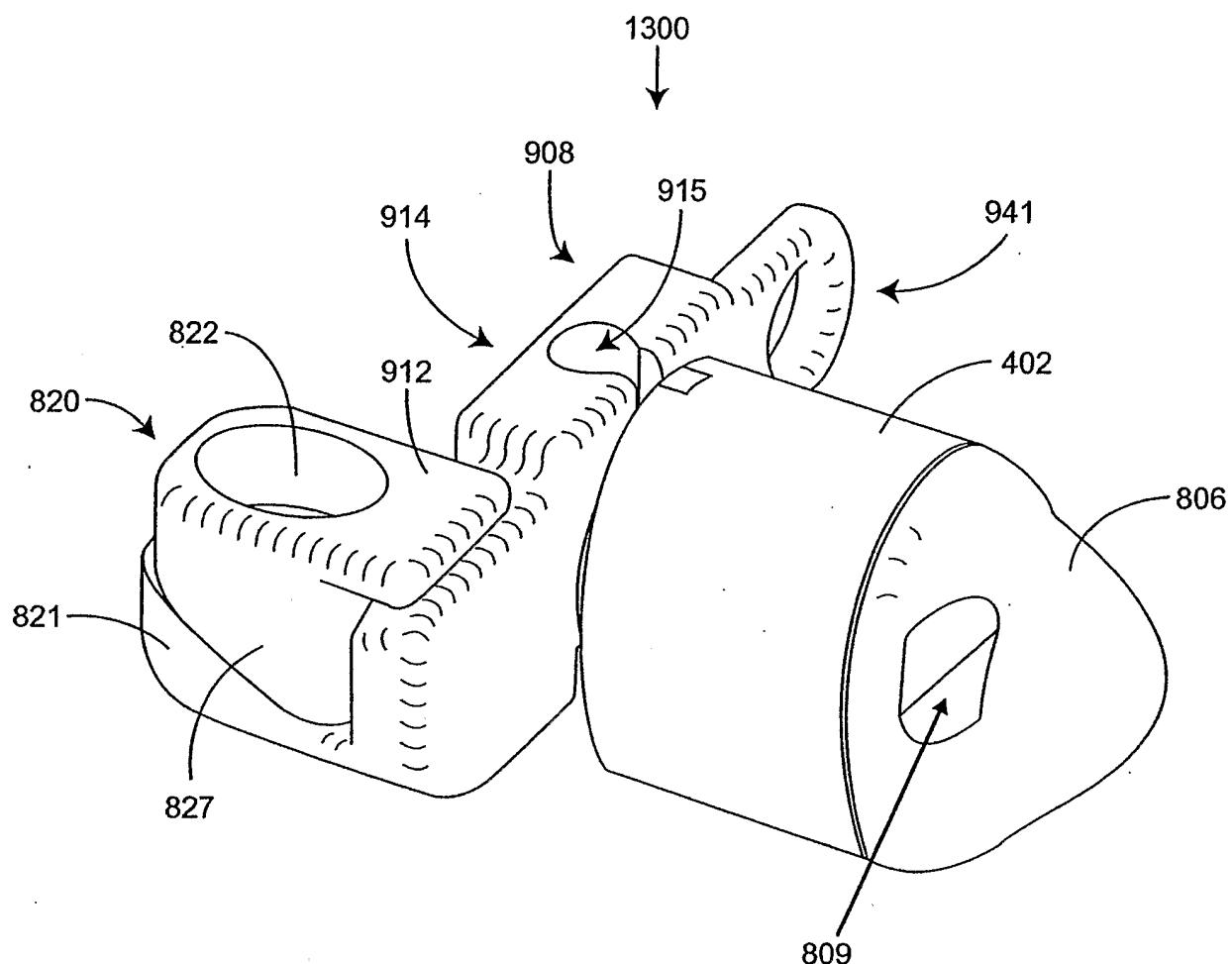


Fig. 9B

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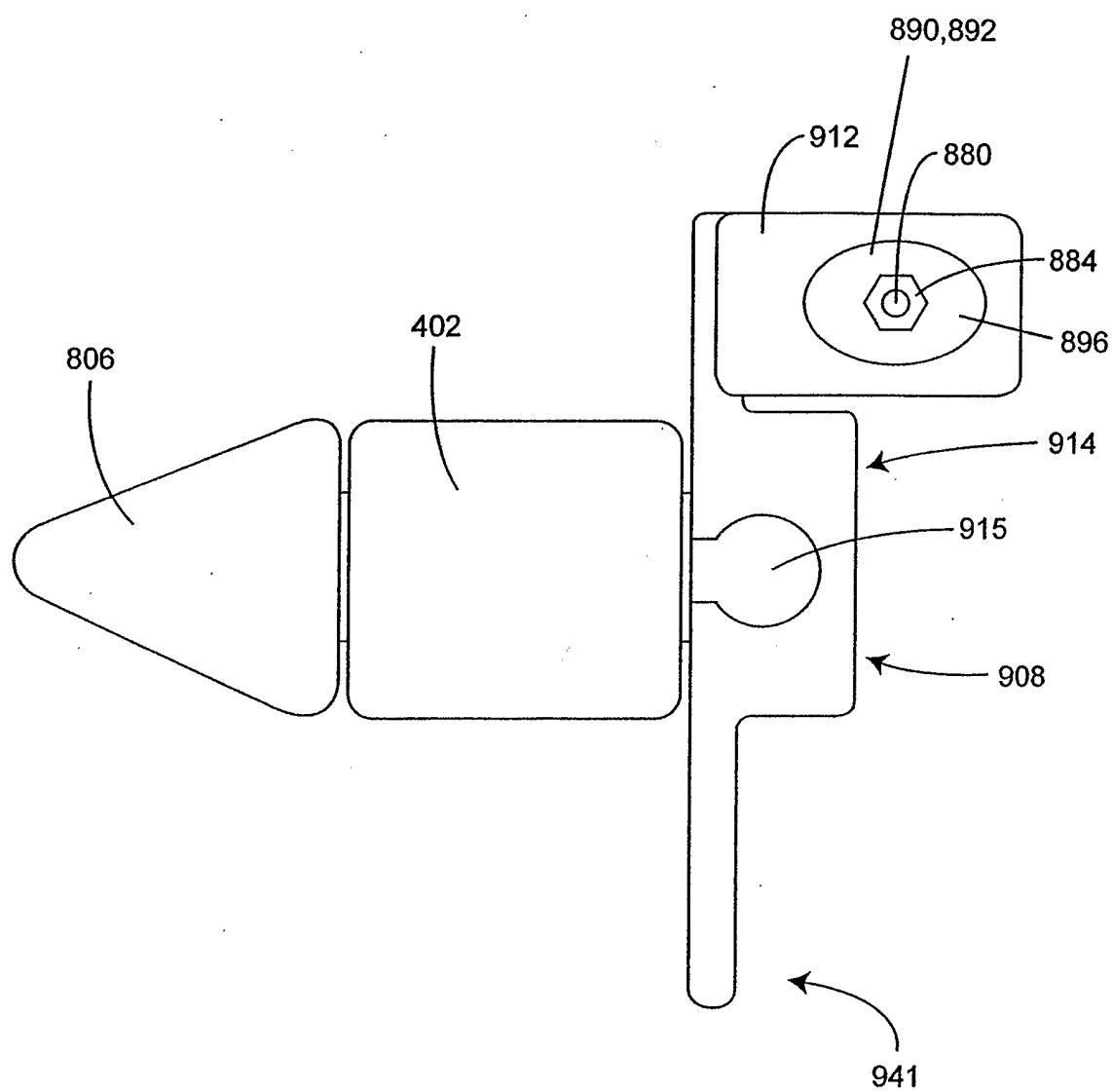
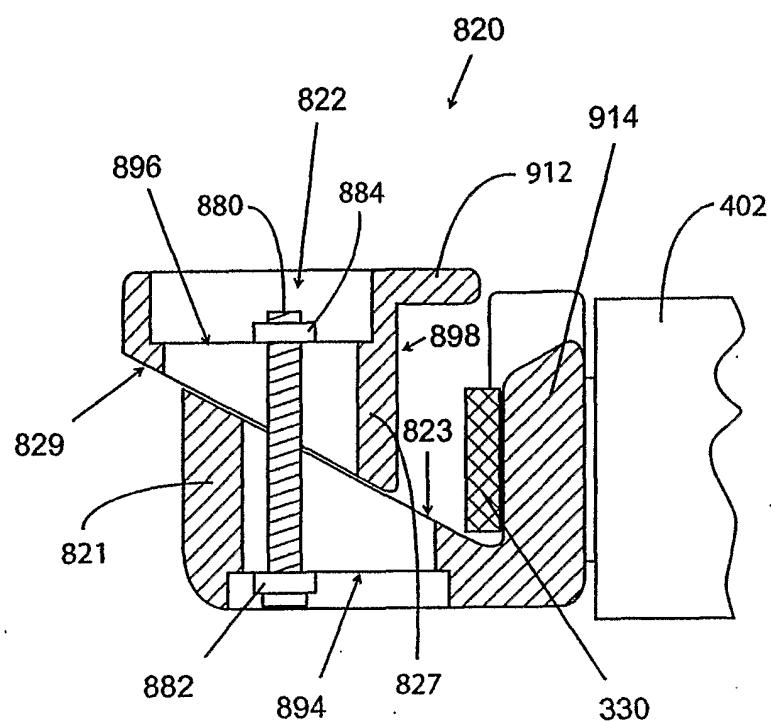
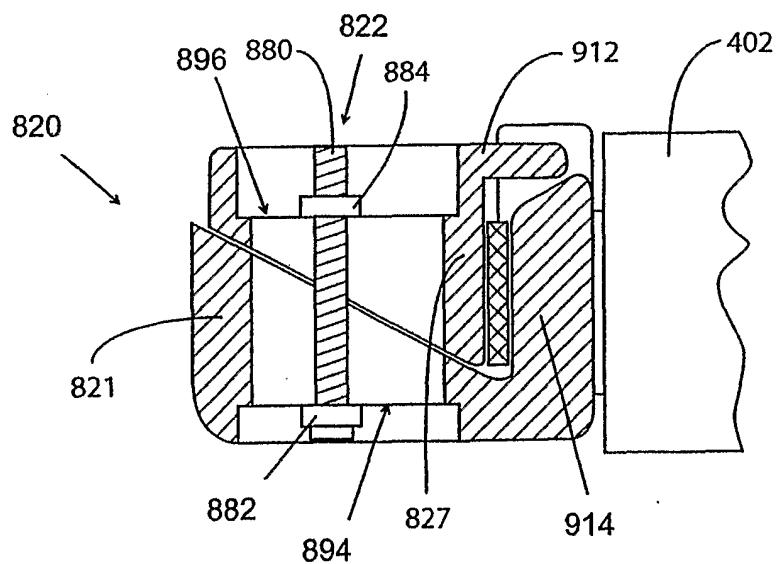
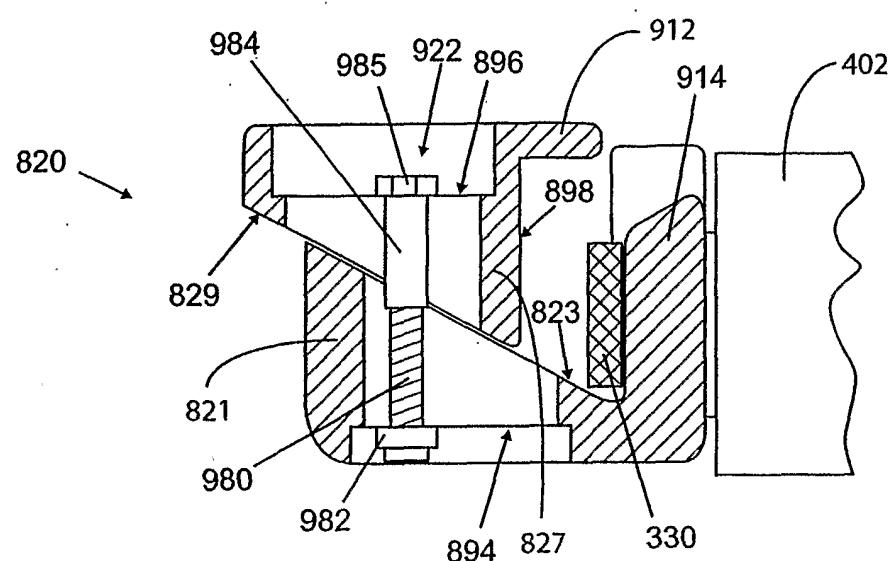
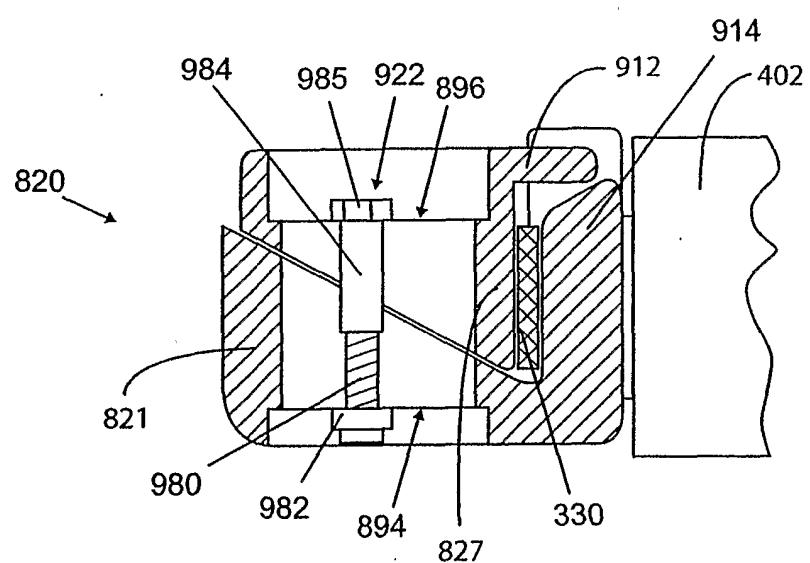


Fig. 9C

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*Fig. 10A**Fig. 10B*

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*Fig. 10C**Fig. 10D*

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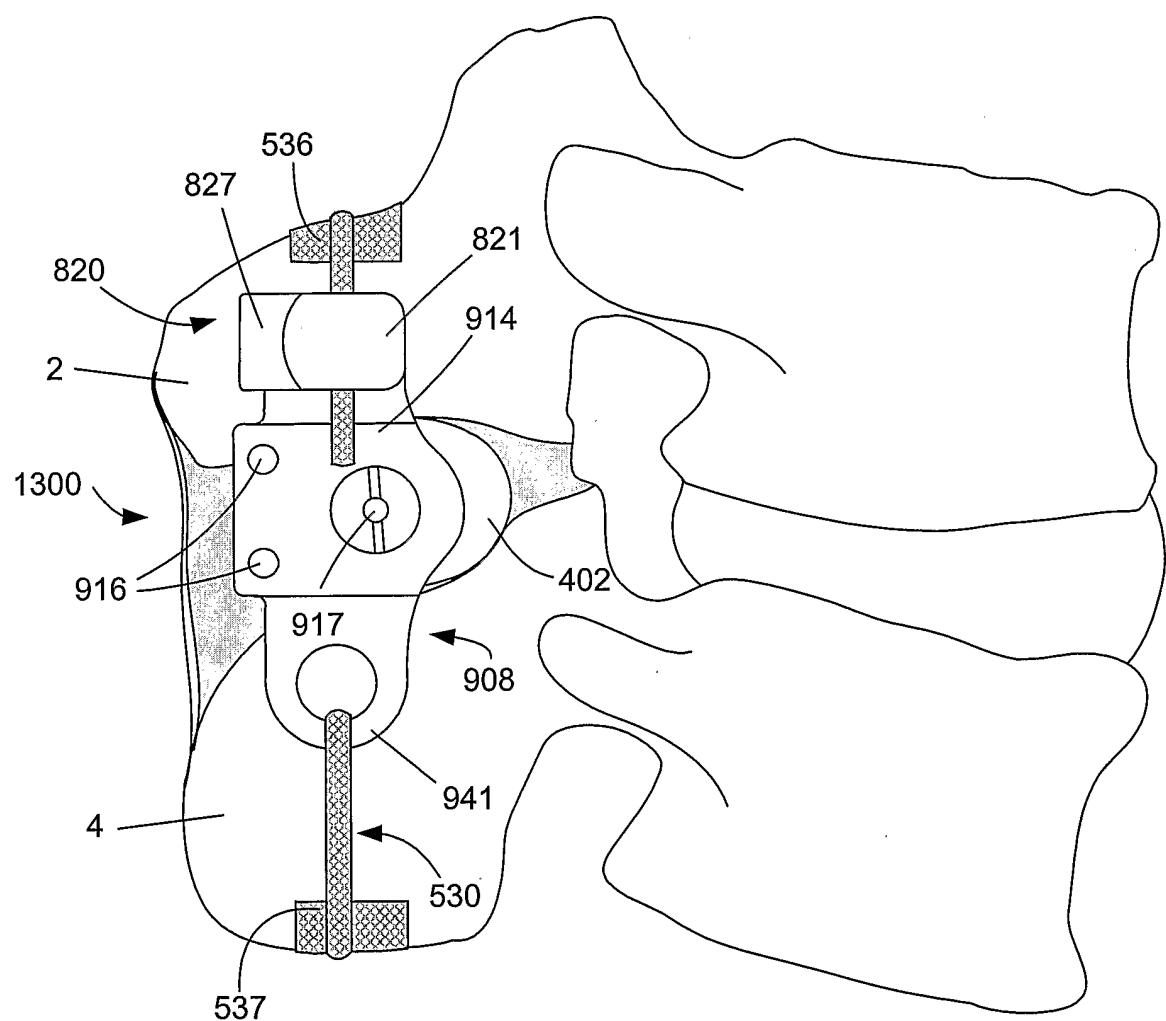


Fig. 11

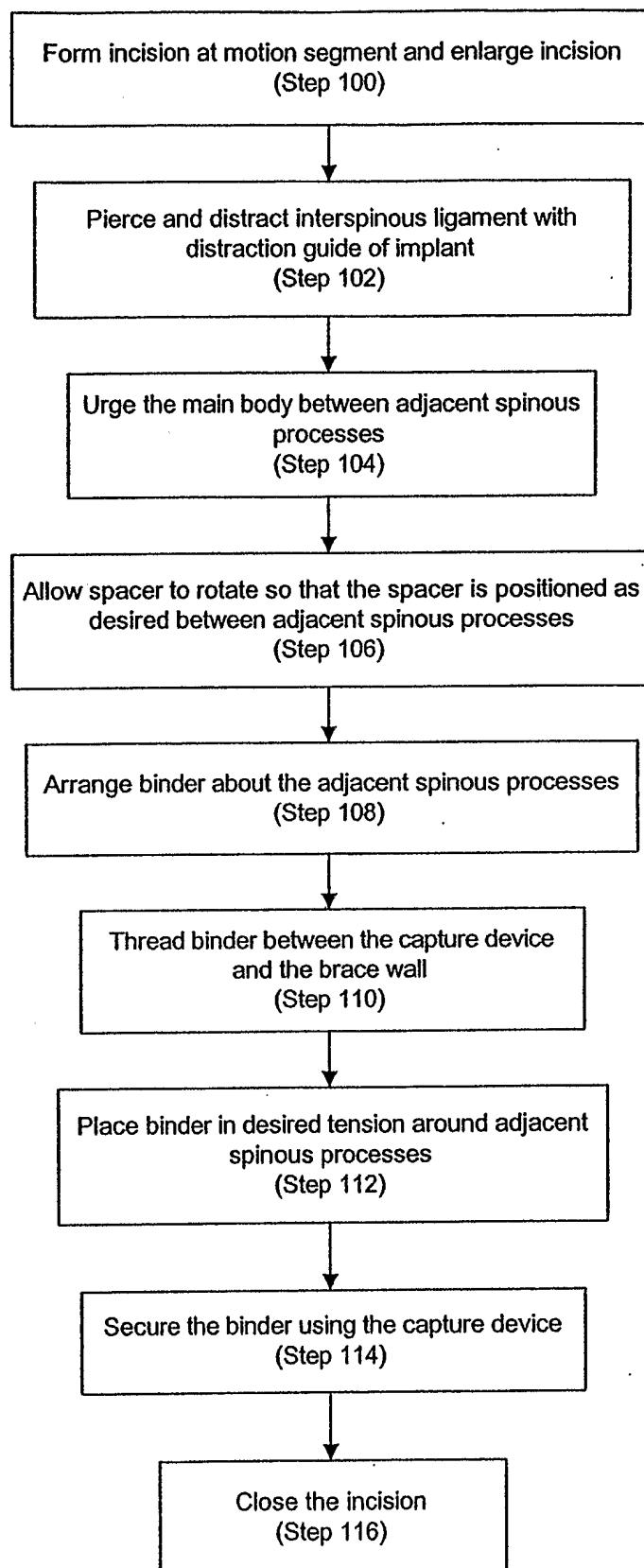


Fig. 12

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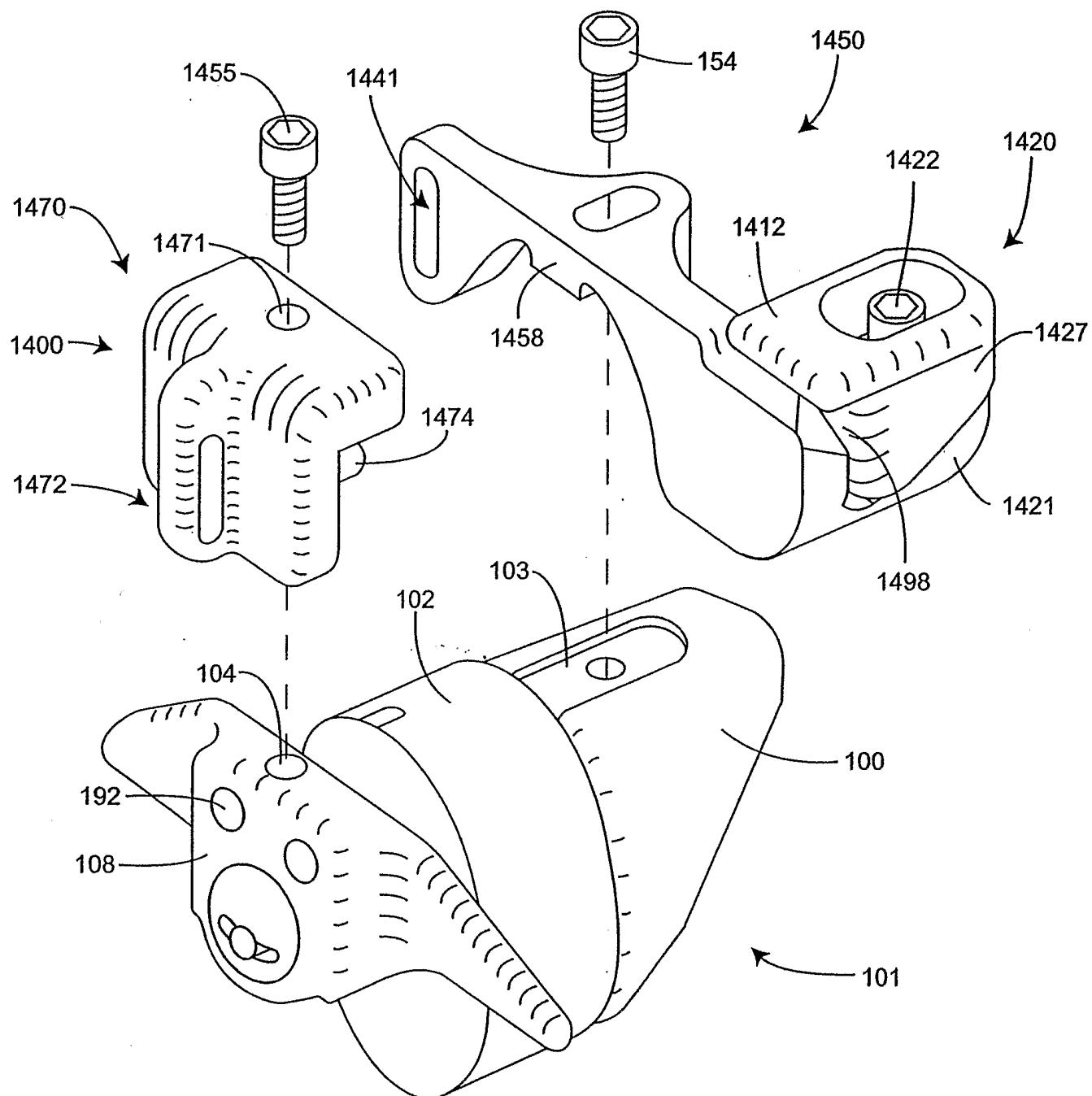


Fig. 13A

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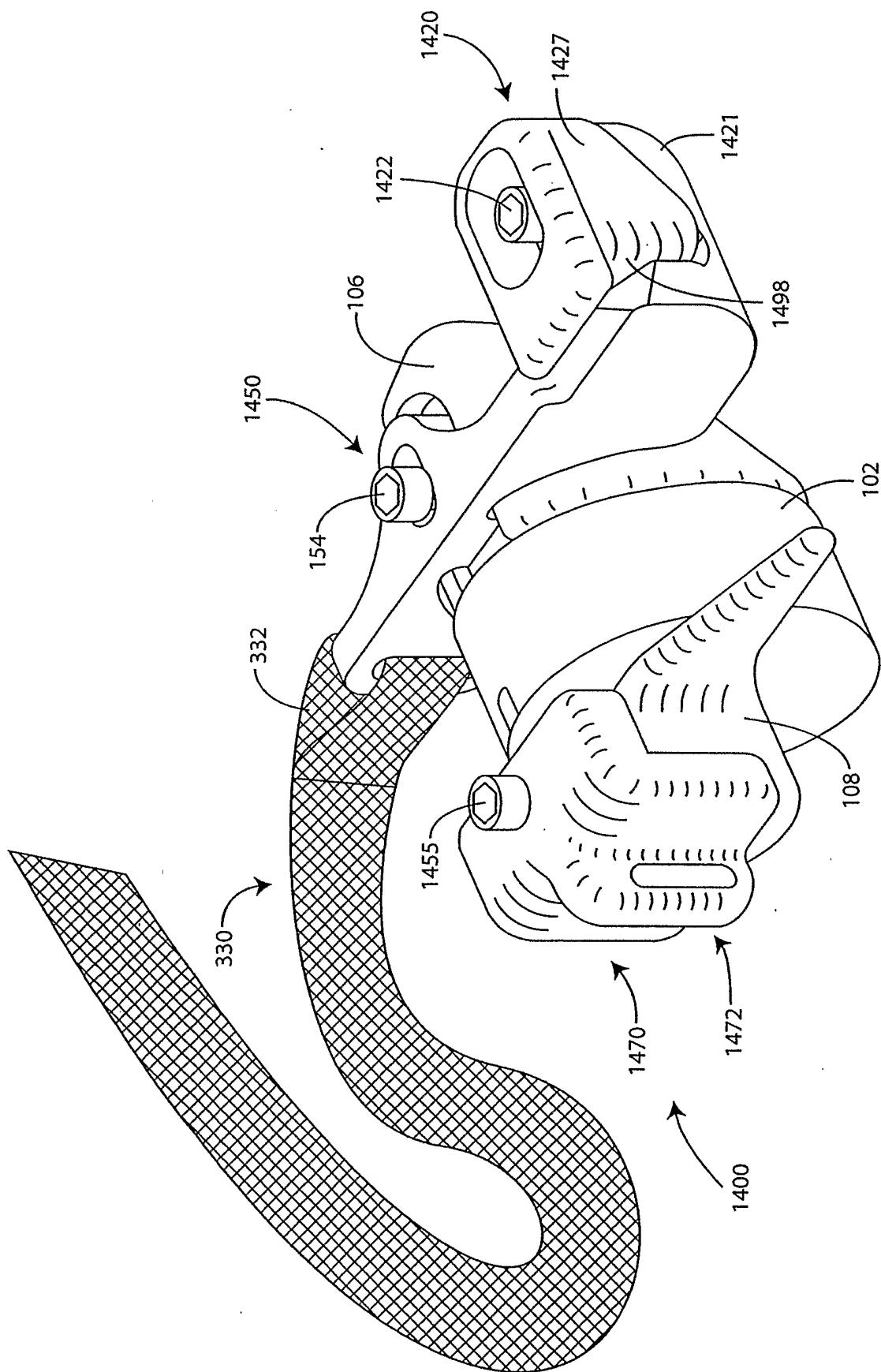


Fig. 13B

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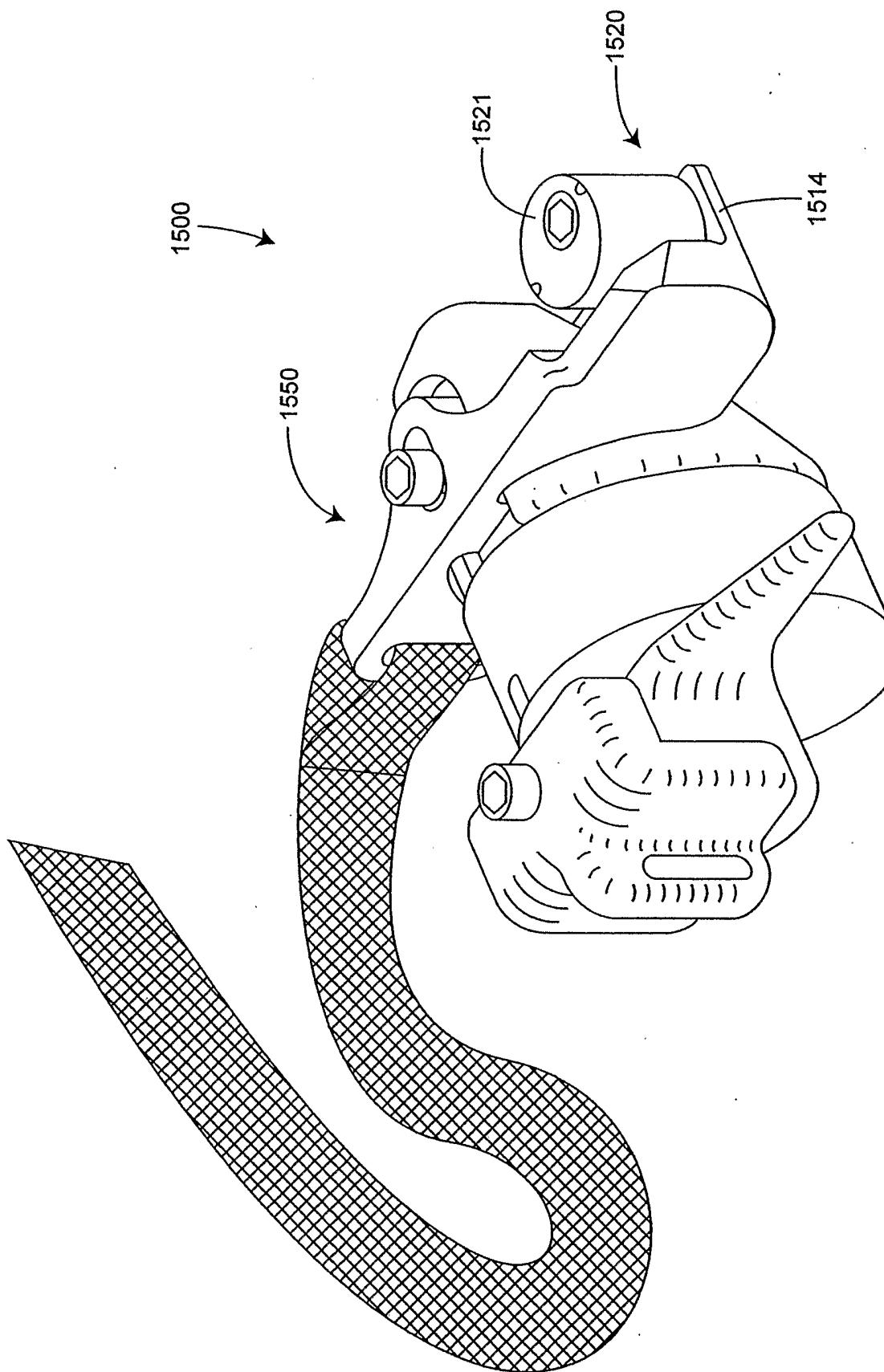


Fig. 14

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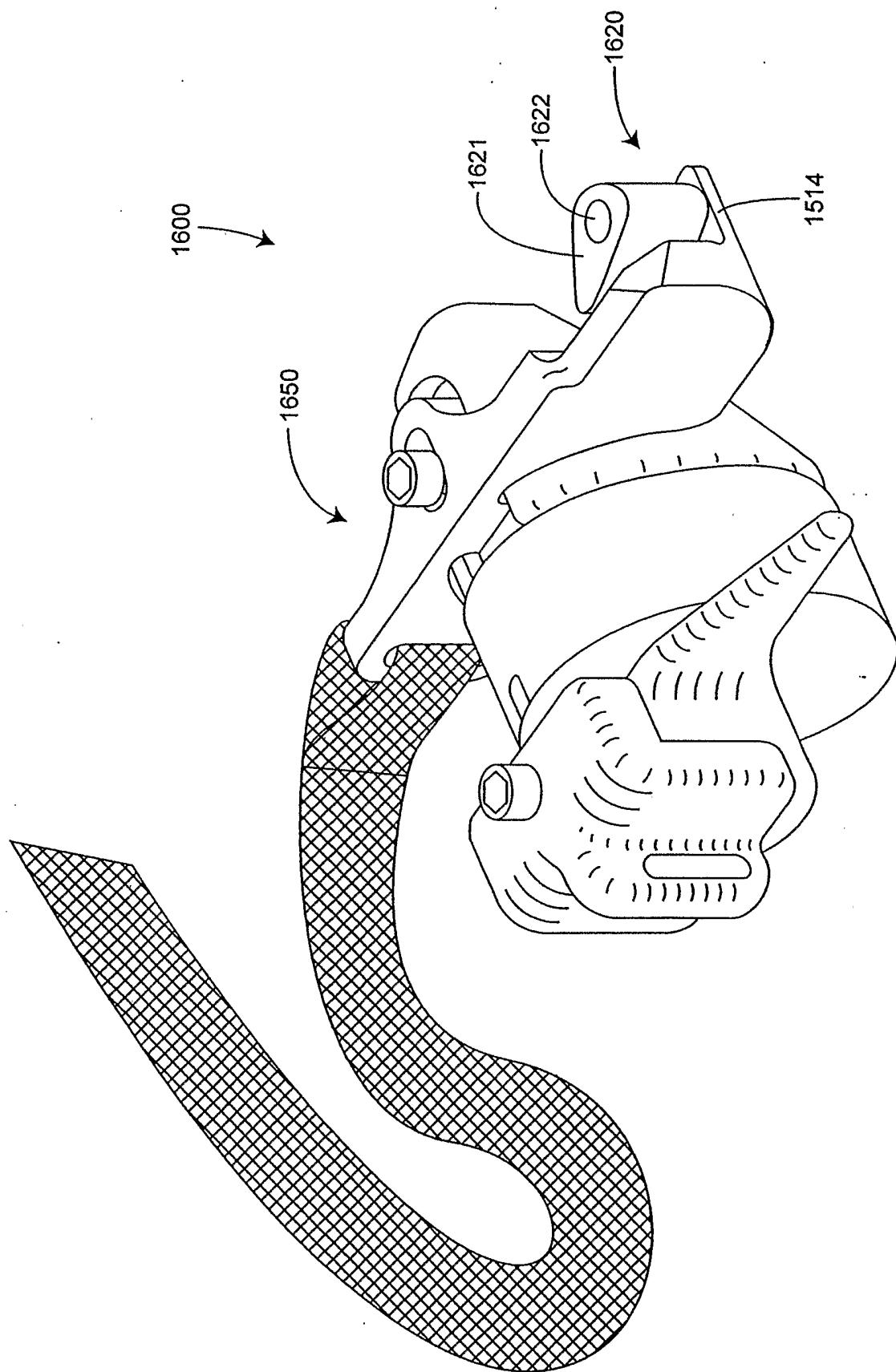


Fig. 15

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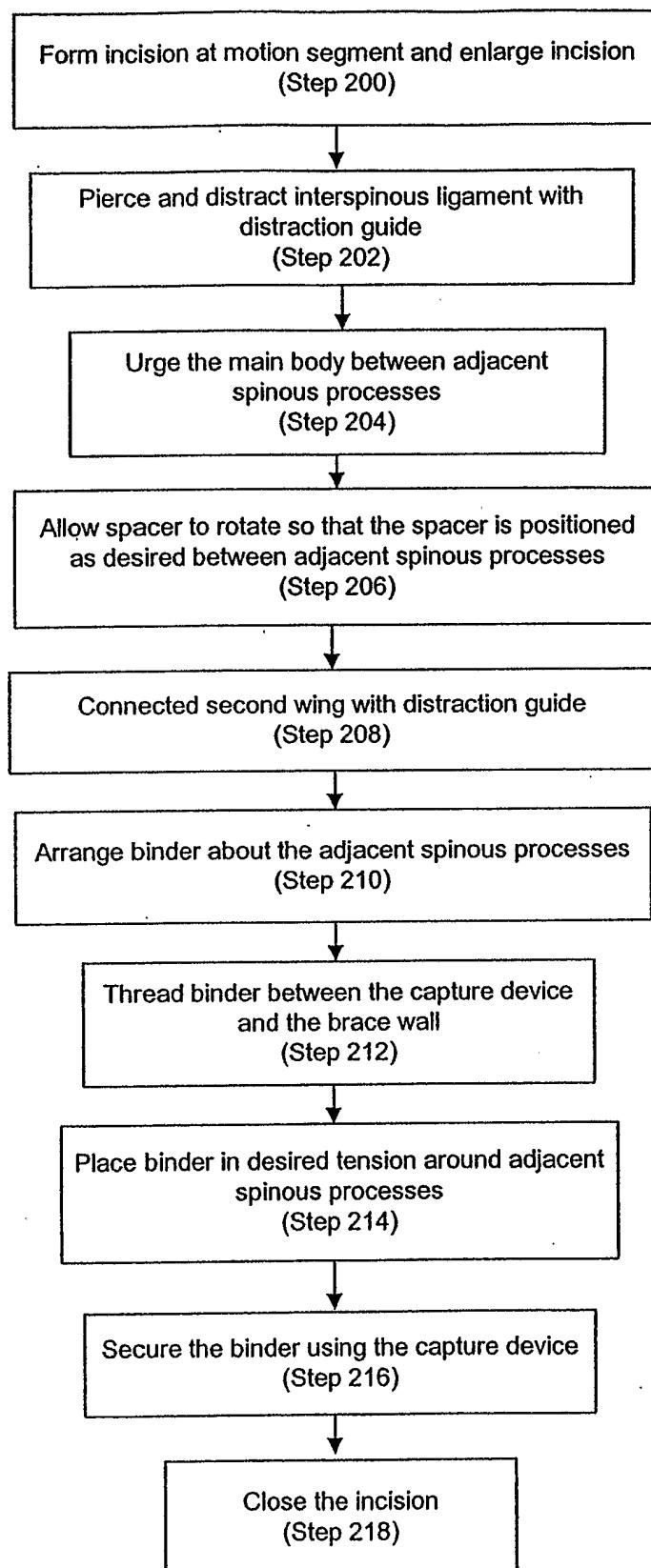


Fig. 16