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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
9 December 2010 (09.12.2010)

PCT

(10) International Publication Number
WO 2010/141910 A2

(51) International Patent Classification:
A61F 2/44 (2006.01) *A61L 27/34* (2006.01)
A61L 27/14 (2006.01) *A61B 17/70* (2006.01)
A61L 27/04 (2006.01)

(21) International Application Number:
PCT/US2010/037532

(22) International Filing Date:
4 June 2010 (04.06.2010)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/184,568 5 June 2009 (05.06.2009) US

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

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

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(54) Title: SPINAL IMPLANTS AND METHODS

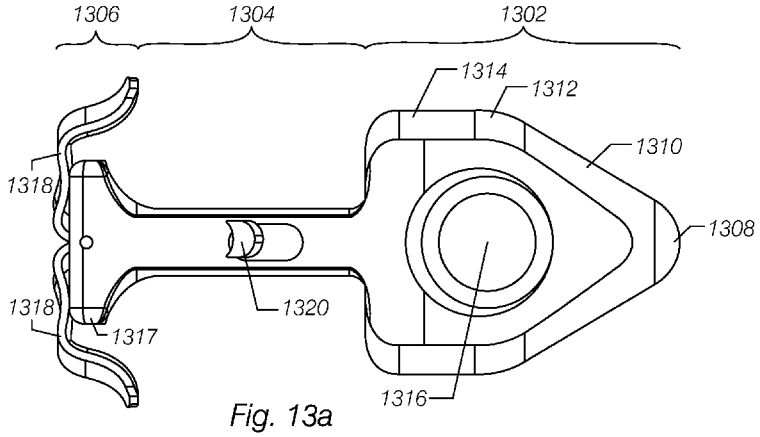

Fig. 13a

(57) Abstract: Spinal implants are disclosed that can be used for annular repair, facet unloading, disc height preservation, disc decompression, or for sealing a portal through which a nucleus implant was placed. In some embodiments, an implant is placed within the intervertebral disc space, primarily within the region of the annulus fibrosus. In some embodiments, the implant comprises a base structure onto which resilient anchor structures are affixed. In some embodiments, the implant comprises a base structure onto which resilient or elastomeric materials are affixed to provide an outer covering for at least a portion of the base structure. In some embodiments, the implant has a sealing tail structure comprising a tail flange and a connector. In some embodiments, the sealing tail structure limits the extrusion or expulsion of disc material, either annulus fibrosus or nucleus, into the posterior region of the spine where it could impinge on nerves. In some embodiments, the tail structure is retained in place within the annulus fibrosus by means of the anchor. In some embodiments, the implant is provided in a plurality of sizes to provide an optimal fit to an individual patient's anatomy. In some embodiments, the implant is delivered using a delivery system that comprises a hand manipulated instrument that is releasably affixed to the implant by a specialized coupler.

WO 2010/141910 A2

Published:

— *without international search report and to be republished upon receipt of that report (Rule 48.2(g))*

SPINAL IMPLANTS AND METHODS

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority to United States Provisional Patent Application No. 61/184,568 entitled SPINAL IMPLANTS AND METHODS filed June 5, 2009, the entire disclosure of which is expressly incorporated herein by reference. Additionally, this application is a continuation-in-part of U.S. Patent application Ser. No. 11/732,360, filed April 2, 2007, which in turn is a continuation-in-part of a U.S. patent application Ser. No. 11/726,664 entitled, "SPINAL IMPLANTS AND METHODS OF PROVIDING DYNAMIC STABILITY TO THE SPINE", filed March 21, 2007, which is a continuation in part of U.S. application Ser. No. 11/398,434, entitled "SPINAL IMPLANTS AND METHODS OF PROVIDING DYNAMIC STABILITY TO THE SPINE", filed April 5, 2006, which claims priority from U.S. Provisional Application No. 60/711,714, filed on August 26, 2005; this application also claims priority to U.S. Provisional Patent App. No. 61/032,921, filed on February 29, 2008, which in turn claims priority to U.S. Provisional Patent App. No. 61/016,417, filed on December 21, 2007, which in turn claims priority to U.S. Provisional Patent App. No. 60/989,100, filed on November 19, 2007, the entire contents of all of these applications being hereby incorporated herein by reference.

BACKGROUND

Field of the Invention

[0002] The present disclosure relates to devices and methods for treating intervertebral discs using implants.

Description of the Related Art

[0003] The vertebral spine is the axis of the skeleton upon which all of the body parts "hang, or are supported. In humans, the normal spine has seven cervical, twelve thoracic, and five lumbar segments. Functionally each segment can be thought of as comprising an intervertebral disc, sandwiched between two vertebral bodies. The lumbar segments sit upon a sacrum, which then attaches to a pelvis, in turn supported by hip and leg bones. The bony vertebral bodies of the spine are separated by intervertebral discs, which

act as joints, but allow known degrees of flexion, extension, lateral bending, axial rotation and resist axial compression.

[0004] Each intervertebral disc serves as a mechanical cushion, or hydraulic damper, between the vertebral bones, permitting controlled motions within vertebral segments of the axial skeleton. The main spinal nerve, the spinal cord, extends along the spine posteriorly thereof.

[0005] The normal disc is a unique, mixed structure, comprised of three component tissues: The nucleus pulposus (nucleus), the annulus fibrosus (annulus), and two opposing vertebral end plates. The two vertebral end plates are each composed of thin cartilage overlying a thin layer of hard, cortical bone which attaches to the spongy, richly vascular, cancellous bone of the vertebral body. The end plates thus serve to attach adjacent vertebrae to the disc and transfer nutrients between the vertebrae and nucleus pulposus. In other words, a transitional zone is created by the end plates between the malleable disc and the bony vertebrae.

[0006] The annulus of the disc is a tough, outer fibrous ring that binds together adjacent vertebrae and confines the nucleus pulposus. This fibrous portion is generally about 10 to 15 millimeters (mm) in height and about 15 to 20-mm in thickness, although in diseased discs these height dimensions may be diminished while the thickness of the annulus may increase. The fibers of the annulus consist of 15 to 20 overlapping multiple plies, and are inserted into the superior and inferior vertebral bodies at roughly a 30-degree angle in both directions. This configuration particularly resists torsion, as about half of the angulated fibers will tighten when the vertebrae rotate in either direction, relative to each other. The laminated plies are less firmly attached to each other.

[0007] Immersed within the annulus, within the intervertebral disc space, is the nucleus pulposus. The annulus and opposing end plates maintain a relative position of the nucleus in what can be defined as a nucleus cavity. The healthy nucleus is largely a gel-like substance, comprising poly-mucosaccharides having high water content, and similar to air in a tire, serves to keep the annulus tight yet flexible. The nucleus-gel moves slightly within

the annulus when force is exerted on the adjacent vertebrae with bending, lifting, etc. The nucleus is capable of absorbing water and generating varying amounts of pressure within the intervertebral disc. As a person ages, intervertebral discs, especially those of the lumbar spine, tend to increasingly lose the distinction between annulus and nucleus. The annulus tissue, comprising circumferentially disposed fibrous tissue, tends to migrate inward taking up space formerly occupied by nucleus. The demarcation between annulus and nucleus becomes progressively undefined. Previously nuclear tissue becomes annulus tissue with the decreasing amount of nucleus tissue being constrained increasingly radially inward within the intervertebral disc. The ability of an aged lumbar intervertebral disc to retain water is diminished relative to the disc of a younger person.

[0008] Under certain circumstances, an annulus defect (or annulotomy) can arise that requires surgical attention. These annulus defects can be naturally occurring, the result of injury, surgically created, or a combination thereof. A naturally occurring annulus defect is typically the result of trauma or a disease process, and may lead to a disc herniation. A disc herniation occurs when the annulus fibers are weakened or torn and the inner tissue of the nucleus becomes permanently bulged, distended, or extruded out of its normal, internal annular confines. It is also possible that the annular wall contributes to the disc herniation. A disc herniation may also occur when the structural integrity of the disc is weakened resulting in a permanently bulged disc that causes the annulus to distend beyond its original boundaries. The mass of a herniated or slipped nucleus, annulus, or a combination thereof, can compress a spinal nerve, resulting in leg pain, back pain, sciatica, radiculopathy, neuropathy, loss of muscle control, or even paralysis.

[0009] Where the naturally occurring annulus defect is relatively minor and/or little or no nucleus tissue has escaped from the nucleus cavity, satisfactory healing of the annulus may be achieved by immobilizing the patient for an extended period of time. However, many patients require surgery, such as microdiscectomy or discectomy to remove the herniated portion of the disc or nerve decompression may be attempted. After the traditional microdiscectomy, loss of disc space height may also occur because

degenerated disc nucleus is removed as part of the surgical procedure. Loss of disc space height can also be a source of continued or new lumbar spine generated pain.

[0010] In other cases, annulotomies may be used to gain access to the intervertebral disc as part of a surgical procedure performed within the disc space. Alternatively, with discal degeneration, the nucleus loses its water binding ability and deflates, as though the air had been let out of a tire. Subsequently, the height of the nucleus decreases, causing the annulus to buckle or collapse in areas where the laminated plies are loosely bonded. As these overlapping laminated plies of the annulus begin to buckle and separate, either circumferential or radial annular tears can occur, which may contribute to persistent and disabling pain. Adjacent, ancillary spinal facet joints can also be forced into an overriding position or overloaded condition, which can create additional back pain. Alternatively, a reduced disc height can result in spinal stenosis and be a progenitor for further degenerative disc disease.

[0011] In many cases, to alleviate pain from degenerated or herniated discs, the nucleus is removed and the two adjacent vertebrae surgically fused together. While this treatment can alleviate the pain, all discal motion is lost in the fused segment. Ultimately, this procedure places greater stress on the discs adjacent the fused segment as they compensate for the lack of motion, perhaps leading to premature degeneration of those adjacent discs.

[0012] Regardless of whether the annulus defect occurs naturally or as part of a surgical procedure, an effective device and method for repairing such defects, while at the same time providing for dynamic stability of the motion segment, would be of great benefit to sufferers of herniated discs, annulus defects, and nucleus pulposus degeneration.

SUMMARY OF THE INVENTIONS

[0013] A more desirable surgical solution entails replacing, in part or as a whole, the damaged annulus or other damaged part (e.g. nucleus pulposus) of an intervertebral disc, with a suitable, sterile prosthesis having the ability to complement the normal height and motion of the disc while stimulating, at

least in part, natural disc physiology. Disclosed embodiments of the present spinal implants and methods of providing dynamic stability to the spine have several features, no single one of which is solely responsible for their desirable attributes. Without limiting the scope of these spinal implants and methods as expressed by the claims that follow, their more prominent features will now be discussed briefly. After considering this discussion, and particularly after reading the section entitled Detailed Description, one will understand how the features of the disclosed embodiments provide advantages, which include, *inter alia,* the capability to repair annular defects and stabilize adjacent motion segments of the spine without substantially diminishing the range of motion of the spine, simplicity of structure and implantation, and a low likelihood that the implant will migrate from the implantation site. Other embodiments disclose methods and apparatus for nuclear replacement, annulus seal for nucleus injections or material delivery, height distraction and preservation, spinal stenosis, innerbody fusion, autograft containment, spondylolisthesis stabilization or correction, dynamic stabilization of the spine, and the like.

[0014] The implant can be fabricated from materials including, but not limited to, biocompatible metals such as titanium, nickel titanium alloys (nitinol), stainless steel, strontium, or cobalt nickel alloys, or it can comprise biocompatible polymers such as, but not limited to, polyetheretherketone (PEEK), carbon fiber, polyester (PET), polyethylene, polytetrafluoroethylene (PTFE), expanded PTFE, polycarbonate urethane, polyurethane, silicone elastomer, polysulfone and ceramics. The implant can further comprise biodegradable or bioerodable materials such as polylactic acid, polyglycolic acid, sugar, collagen, and the like. The implant can include layers consisting of adhesives, binding materials, hydrophilic coatings, hydrophobic coatings, stem cells, growth factors, fibrin sealant, pharmaceutical agents, chondrocytes, artificial tissues, autologous tissues or other seeding or dose delivery material media. The axially elongate structure can comprise rigid materials, it can be compressible, or it can comprise a combination of rigid and compressible materials to assist with the maintenance of spine repair and mobility.

[0015] In some embodiments, the implant can be suited for a population of patients who have pain from an unruptured hernia (bulge) that can be decompressed by implanting a distraction device separating the vertebrae enough to pull the bulge in and relieving the disc of axial compression, and perhaps allowing the disc to re-hydrate. The decompression feature of the device can assist in preventing future herniation. In some embodiments, the implant can further serve as a stabilizer for the spine since it can offset, or compensate for, asymmetrical loading or it can be configured to apply support uniformly from left to right. Further, the implant can preserve some motion in the spine since the implant is generally located at the center of rotation of the spine, which can still hinge forward or backward about the device to at least some extent. The implant can serve as this distraction device. The location of the implant can be at the center of flexion-extension and the implant can serve as a barrier against re-herniation along the entire length of the internal posterior wall of the annulus. In some embodiments, a single implant can be placed to separate, or distract, the vertebrae. In some embodiments, the implant can be placed to block extrusion of material from the annulus. In some embodiments, a plurality of implants can be placed to separate the vertebrae at multiple levels of the spine. In certain embodiments, two implants can be placed, one on each side of the posterior portion of the spine, to stabilize the spine laterally and to provide one or more of the functions of decompression, vertebral distraction, facet unloading, nerve decompression, to facilitate vertebral fusion, and disc height preservation or restoration. In some embodiments, the implants can have their longitudinal axes oriented generally laterally with regard to the anatomic axis of the spine. In some embodiments, the implants can have their longitudinal axes oriented generally in the approximate anterior or posterior direction. In certain embodiments, the implants can have their longitudinal axes oriented radially with respect to the geometric center of the intervertebral disc. In some embodiments, these devices can provide for motion preservation of the spine segment within which the devices are implanted. In certain embodiments, the implants can partially or totally restrict motion within that segment. In certain embodiments the implant can be adjusted after implantation. In some embodiments, the implants can be used in conjunction with spinal fusion procedures to maintain

early postoperative stability of spinal support. In certain embodiments, the implant can reside totally within the outer boundary of the annulus of the intervertebral disc. In some embodiments, the implant can reside with a portion of its structure external to the outer boundary of the intervertebral disc annulus. In some embodiments, the implant includes features for retention that can include anchors, screws, pins, or the like that can further comprise complex geometries for insertion into the posterior vertebrae, the end plates, or both. In some embodiments, the implant can have surface features that promote fixation to the posterior vertebrae, the endplates, or both. In some embodiments, the decompression devices are placed using a posterior access. In some embodiments, the decompression devices are placed using posteriolateral access. In some embodiments, the decompression devices are placed using anterior or anteriolateral access. In some embodiments the disc space is approached minimally invasively, using fluoroscopy to monitor and guide the procedure. In some embodiments the disc space is approached percutaneously or endoscopically, using fluoroscopy to monitor and guide the procedure.

[0016] In some embodiments, the implant comprises a main body, a tail flange, and an anchor. In some embodiments, the anchor comprises spring-structures that are outwardly biased to maintain contact with the end plates or vertebrae, even when the vertebrae move apart or move closer together. The anchor comprising the spring-structures follows the motion of the bone within which it is embedded and maintains contact to prevent expulsion of the implant from the spine even under conditions of spinal flexion or torsion. The anchor comprising the spring-structures can project out the superior side of the main body, the inferior side of the main body, or both. The anchor comprising the spring-structures can project out the superior and inferiors sides of the body while also projecting out the lateral sides of the body. The anchor comprising the spring-structures can project out the lateral sides of the body while also projecting out the anterior or posterior sides of the body. The anchor can be affixed to the main body at one or more locations at one or both ends. The anchor can be configured to be fixed to the main body at the distal end of the implant while the anchor is slidably constrained along the

longitudinal axis of the implant at its proximal end. The anchor can be configured as a curved leaf spring. The anchor can comprise, at its proximal end, a feature or features that engage with structures on a coupler to permit the coupler to grasp the implant, to retract the lateral extent of the spring-structures, and to release the spring-structures as well as the implant under control of the user. The anchor can comprise spring materials such as, but not limited to, cobalt nickel alloys, nickel titanium alloys, titanium, stainless steel, and the like. The anchor can be produced from tubing, sheet or strip, wire, strand, cable, and novel extrusions and drawing techniques. Furthermore materials may be combined during ingot formation, drawing techniques, welding, deposition, dipping, or mechanical bonding, and the like. The anchor can comprise spring materials that are embedded, enclosed, surrounded, flowed, coated or deposited on the surface forming at a minimum a secondary surface layer.

[0017] In some embodiments, the vertebral following anchor can comprise a single structure projecting laterally away from the main body of the implant. In other embodiments, the vertebral following anchor can comprise a plurality of structures projecting laterally away from the main body of the implant. In some embodiments, the vertebral following anchor can comprise a leaf spring curved in its central portion and having a convex surface that engages the vertebrae. In some embodiments, the vertebral following anchor can comprise a single leaf spring without any perforations, fenestrations, or separations. In other embodiments, the vertebral following anchor can comprise a plurality of leaf springs. In yet other embodiments, the vertebral following anchor can comprise a single leaf spring with perforations, fenestrations, or separations running substantially parallel to the longitudinal axis of the implant. In other embodiments, the vertebral following anchor can comprise a plurality of leaf springs that are affixed to each other substantially near the ends of the leaf springs. In some embodiments, the vertebral following anchor can comprise an arcuate shape projecting laterally away from the implant main body and further comprising a reverse arcuate shape near the ends of the anchor such that the vertebral following anchor can be

aligned substantially parallel to the longitudinal axis of the implant near its proximal end, distal end, or both.

[0018] In certain embodiments, an implant is provided for maintaining a height between adjacent vertebrae. The implant includes an anchor member comprising a shape memory material, the expandable member changing from an initial configuration to a secondary, compressed configuration in response to an activation energy. When implanted in the patient the anchor member can be compressed so as to fit between adjacent vertebrae in response to the activation energy. The anchor member can next be restored to its fully deflected configuration. The anchor member fills a portion of the intervertebral disc space between the adjacent vertebrae and maintains a height between the vertebrae.

[0019] In some embodiments, an implant is provided that, upon insertion, has a pre-load applied by the adjacent vertebrae. In other embodiments, an implant is provided which is configured to subside into the vertebral end plates. In other embodiments, an implant is provided which is configured to minimize subsidence into the vertebral end plates. In other embodiments, an implant is provided that has a pre-load by the adjacent vertebrae and subsides into the vertebral endplates.

[0020] In certain embodiments, an implant is provided for maintaining a height between adjacent vertebrae. The implant includes an anchor member, sized and shaped to be positioned between the adjacent vertebrae. Superior or inferior expansion of the anchor member is effective to anchor the implant between the adjacent vertebrae. In certain embodiments, the anchor member and an expander member are sized and shaped to be inserted through a defect in the annulus fibrosus of an intervertebral disc between the adjacent vertebrae. In certain embodiments, the anchor member can have a lumen within it, and the expander member moves axially within the lumen. In certain embodiments, the anchor member includes a screw thread, and the expander member moves axially within the lumen when the expander member is rotated. In certain embodiments, the anchor member includes a screw configured to foreshorten at least a portion of the implant, while effecting radial expansion of the anchor member. In certain embodiments, the anchor

member includes a wedge, located within a lumen of the implant, the wedge configured to expand radially the anchor member as the wedge is moved within the lumen.

[0021] In certain embodiments, an implant is provided for maintaining a height between adjacent vertebrae. The implant includes a head, comprising a central portion and a compressible, member, wherein the compressible member is radially disposed around at least part of the central portion. When implanted in the patient, the compressible member resides within the intervertebral disc space and exerts an outward bias force on the adjacent vertebrae, resulting in anchoring of the implant within the intervertebral disc space. The central portion is configured to move axially with respect to the compressible member.

[0022] In certain embodiments, the compressible member is deflected by the internal annulus wall resulting in a self-tensioning of the implant between the internal annulus wall and the posterior annulus wall approximated by the tail flange.

[0023] In certain embodiments, when the compressible member is compressed by the adjacent vertebrae, the central portion moves axially with respect to the compressible member. In certain embodiments, the at least one compressible member is self-expanding. In certain embodiments, the central portion includes a groove or lumen, configured to receive a portion of the compressible member. In certain embodiments, the compressible member is sized and shaped to be inserted through a defect in an intervertebral disc between the adjacent vertebrae. The sizing step is generally performed while the anchor or compressible member is in its compressed configuration.

[0024] In certain embodiments, a method is provided for maintaining a height between the adjacent vertebrae. The method includes providing an implant having a head in an unexpanded state, inserting the head into the intervertebral disc space of the patient, and, after the inserting, expanding the head from the unexpanded state to an expanded state until the head substantially engages tissue in the intervertebral disc space. The implant also

includes elements or components which, after the expanding, the elements or components maintain a height between the adjacent vertebrae. The expansion or compression occurs primarily in the superior-inferior direction.

[0025] In certain embodiments of the method, the placing includes inserting the implant through a defect in the annulus fibrosus of an intervertebral disc between the adjacent vertebrae. In certain embodiments of the method, the placing includes positioning the implant entirely within the annulus fibrosus of an intervertebral disc between the adjacent vertebrae.

[0026] In certain embodiments, at least a portion of the expandable member is compressible by the adjacent vertebrae. In certain embodiments, when implanted in the patient and expanded, the expandable anchor exerts a bias force on the adjacent vertebrae. In certain embodiments, the expandable anchor is sized and shaped to be inserted through the annular defect. In certain embodiments, the expandable anchor includes a swellable polymer. In certain embodiments the expandable anchor has solid members permanently affixed. In certain embodiments, the tail portion includes a tail connector or tail shelf that supports and maintains a minimum intradiscal lip height. In certain embodiments, the tail portion includes a flange that is expandable laterally away from the longitudinal axis of the implant. In certain embodiments, the tail portion includes a flange that is expandable radially away from the anterior to posterior axis of the implant. In certain embodiments, the anchor portion is coupled to the tail section to apply tension to the annulus wall or adjacent vertebrae. In certain embodiments, the tail portion includes a swellable polymer. In certain embodiments, the tail portion includes a coating of resilient or elastomeric material. In certain embodiments, the tail portion includes a covering of porous material such as cloth such as can be woven, knitted, braided, or the like. In certain embodiments, the tail flange is configured to promote fibrous ingrowth. In certain embodiments, a vertebral motion following anchor includes a shape memory material that changes from a first, compressed configuration to a second, expanded configuration in response to an activation energy.

[0027] In certain embodiments, the implant can be delivered into the defect in the intervertebral disc using a coupler, which can be releasably affixed to

the implant. In certain embodiments, the coupler can be permanently or removably affixed to a delivery instrument, tool, catheter, or introducer. In certain embodiments, the introducer or delivery system can comprise an axially elongate shaft onto which the coupler is affixed. In certain embodiments, the introducer or delivery system can comprise a gun-like handle. In certain embodiments, the introducer can comprise a trigger configured to activate the coupler such that activation of the coupler causes release of the implant from the coupler. In certain embodiments, the introducer and trigger are configured to have multiple activation limits such that the user has to release locks or withdraw pins for activation or release of the implant. In some embodiments, the coupler is affixed to the implant prior to packaging and sterilization. In some embodiments, the coupler is affixed to the implant following being separately packaged and sterilized and the coupler is affixed to the implant by the user at the site of patient therapy. In one non-limiting embodiment, the implant may comprise an implant body having a distal head portion, a mid portion, a proximal tail flange, at least one lateral engagement member (e.g., collapsible outwardly-biased spring member(s) on the mid-portion of the device and at least one proximal engagement member (e.g., collapsible outwardly-biased strut members configured to engage adjacent anatomical structures). The shape of and particular direction(s) in which the lateral engagement member(s) extend may vary depending on the intended implantations site and surrounding anatomy. The lateral and proximal engagement member(s) are deployable in a collapsed configurations to facilitate insertion or delivery of the device into the desired implantation position and subsequently moveable (e.g., upon removal of a constraining tube or sheath or delivery activation source) to an extended position whereby they frictionally engages or extends into adjacent anatomical structures. In some embodiments, the device may be of variable length (e.g., telescoping) thus enabling the distance between the distal head portion and proximal tail flange and/or proximal engagement member(s) to be determined by the compression of the lateral and proximal engagement members on the adjacent anatomical structures. One such variable length embodiment of the device may be constructed by coupling the distal head portion to a separate tail flange through the lateral and proximal engagement member(s) this

[0028] For purposes of summarizing the disclosure, certain aspects, advantages and novel features are described herein. It is to be understood that not necessarily all such advantages may be achieved in accordance with any particular embodiment of the disclosure. Thus, for example, the disclosure can be embodied or carried out in a manner that achieves one advantage or group of advantages as taught herein without necessarily achieving other advantages as may be taught or suggested herein.

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BRIEF DESCRIPTION OF THE DRAWINGS

[0029] A general architecture that implements the various features of the invention will now be described with reference to the drawings. The drawings and the associated descriptions are provided to illustrate embodiments of the invention and not to limit the scope of the invention. Throughout the

drawings, reference numbers are re-used to indicate correspondence between referenced elements.

[0030] Fig. 1a is an oblique view, looking from the proximal end, of a small size spinal implant comprising a body, a tail flange, and a plurality of resilient anchors configured to follow the motion of adjacent vertebrae and resist expulsion from the interdiscal space, according to an embodiment of the invention;

[0031] Fig. 1b is an oblique view, looking from the distal end, of a small size spinal implant comprising a body, a tail flange, and a resilient anchor configured to follow the motion of adjacent vertebrae and resist expulsion from the interdiscal space, according to an embodiment of the invention;

[0032] Fig. 1c is a side view of a small size spinal implant comprising a body, a tail flange, and a resilient anchor configured to follow the motion of adjacent vertebrae and resist expulsion from the interdiscal space, according to an embodiment of the invention;

[0033] Fig. 2a illustrates an oblique view of a resilient anchor, in a small size, which can be movably affixed within a spinal implant body, according to an embodiment of the invention;

[0034] Fig. 2b illustrates a side view of a resilient anchor, in a small size, which can be movably affixed within a spinal implant body, according to an embodiment of the invention;

[0035] Fig. 2c illustrates a top view of a resilient anchor, in a small size, which can be movably affixed within a spinal implant body, according to an embodiment of the invention;

[0036] Fig. 3 illustrates an oblique view of a coupler configured to releasably grasp a spinal implant of the type illustrated in FIG. 1 and further configured to be releasably affixed to an implantation tool or delivery instrument, wherein the grasping arms have been moved inward by an external force, according to an embodiment of the invention;

[0037] Fig. 4 illustrates an oblique view of the coupler of FIG. 3 releasably affixed to the proximal side of a small size spinal implant, according to an embodiment of the invention;

[0038] Fig. 5a illustrates an oblique view of an introducer or delivery instrument affixed to the proximal end of the coupler of FIG. 3, which is releasably affixed to the small spinal implant as illustrated in Fig. 1, according to an embodiment of the invention;

[0039] Fig. 5b illustrates a side view of the introducer, coupler, and small spinal implant, according to an embodiment of the invention;

[0040] Fig. 6 illustrates an oblique view of the coupler of Fig. 3, wherein the engagement detents have sprung outward to their neutral position upon removal of the external force, according to an embodiment of the invention;

[0041] Fig. 7a illustrates an oblique view, looking from the distal end, of a large size spinal implant comprising a body, a tail flange, and a plurality of resilient anchors configured to follow the motion of adjacent vertebrae, according to an embodiment of the invention;

[0042] Fig. 7b illustrates a medium sized spinal implant comprising a medium sized anchor portion and a central connector bar, according to an embodiment of the invention;

[0043] Fig. 8 is an oblique view of a spring anchor member in a large size, according to an embodiment of the invention;

[0044] Fig. 9 illustrates a delivery instrument for a spinal implant, according to an embodiment of the invention;

[0045] Fig. 10 illustrates a cowling adapted to cover a coupler as illustrated in Fig 3, according to an embodiment of the invention;

[0046] Fig. 11a illustrates a front view, looking from the distal end toward the proximal end, of the spinal implant of Fig. 7a having anchor portions that are disposed in an arcuate shape only in the inferior and superior directions, lateral to the longitudinal axis of the spinal implant, according to an embodiment of the invention;

[0047] Fig. 11b illustrates a front view of a spinal implant having anchor portions, some of which are disposed in a complex arcuate shape that project laterally, left to right, as well as in the superior and inferior directions, according to an embodiment of the invention;

[0048] Fig. 11c illustrates a front view of a spinal implant having anchor portions, some of which project superiorly and inferiorly while some anchor portions project laterally left and right, according to an embodiment of the invention;

[0049] Fig. 11d illustrates a front view of a spinal implant having anchor portions which project superiorly and inferiorly while further comprising a plurality of circumferentially disposed bands, according to an embodiment of the invention;

[0050] Fig. 12a illustrates an oblique view of a main body frame or base structure for a spinal implant, prior to the frame being covered with a resilient, soft, or elastomeric material, according to an embodiment of the invention;

[0051] Fig. 12b illustrates the main body frame of Fig. 12a after being covered or coated with a soft, resilient, or elastomeric material, according to an embodiment of the invention; and

[0052] Fig. 12c illustrates an oblique view of the coated main body frame after installation of anchor means projecting both superiorly and inferiorly from the partially-covered main body frame, according to an embodiment of the invention.

[0053] Figure 13A is a side view of another embodiment of a spinal implant device of the present invention.

[0054] Figure 13B is a top perspective view of the device of Figure 13A.

[0055] Figure 13C is a distal end view of the device of Figure 13A.

[0056] Figure 13D is a right side view of a portion of the spinal column of a human subject with a portion of an intervertebral disc cut away showing the device of Figure 13A implanted therein.

[0057] Figure 13E is a left-posterior perspective view of a portion of the spinal column of a human subject having the device of Figure 13A implanted therein.

[0058] Figure 13F is a posterior-right perspective view of a portion of the spinal column of a human subject having the device of Figure 13A implanted therein.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0059] The inventions may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive. The scope of the invention is therefore indicated by the appended claims rather than the foregoing description. All changes that come within the meaning and range of equivalency of the claims are to be embraced within their scope.

[0060] The inventions can be generally termed an implant, delivery instrument, tool, coupler, reamer, sizer, system, catheter, or sheath. As is commonly used in the art of medical devices, the proximal end of the device is that end that is closest to the user, typically a neurosurgeon or orthopedic surgeon. The distal end of the device is that end closest to the patient or that is first inserted into the patient. A direction being described as being proximal to a certain landmark will be closer to the user, along the longitudinal axis, and further from the patient than the specified landmark.

[0061] With regard to anatomical directions, superiorly refers to a direction toward the head of the patient. Inferiorly refers to a direction toward the feet of the patient. Anteriorly refers to a direction toward the front of the patient. Posteriorly refers to a direction toward the back of the patient. Laterally refers to a direction, either to the anatomical right or anatomical left of the patient. The anatomical right side of the patient is the right side of the patient as if viewed from the rear, or posterior, direction.

[0062] Fig. 1a illustrates a spinal implant 100 in a small size adapted for placement between the vertebrae of a mammalian spine, as viewed obliquely toward the proximal end. The implant 100 is configured for use within the

lumbar spine, but can also be adapted for use within the cervical or thoracic spine. The implant 100 comprises a main body portion 102, a tail portion 104, two resilient anchor portions 106, an anchor connector 108, a tail connector 116, a plurality of main body windows 118, and an anchor engagement access port 114.

[0063] The resilient anchor portions 106 are affixed within a lumen 110 (not shown) within the main body portion 102 such that the distal end of the resilient anchor portions 106 is affixed to the main body portion 102 by the anchor connector 108, and the central bulge of the resilient anchor portions 106 project superiorly and inferiorly through the main body windows 118. The proximal end of the resilient anchor portions 106 is slidably disposed within the lumen 110 (not shown) such that the resilient anchor portions 106 are constrained to move only along the longitudinal axis of the main body portion 102 and the tail connector 116. When the proximal end of the resilient anchor portions 106 is withdrawn proximally, the central outward bulge, or projection, of the resilient anchor portions 106 are reduced such that they do not project through the windows 118. The tail connector 116 can be affixed, or integral to, the main body portion 102.

[0064] Referring to Fig. 1a, the main body portion 102 can comprise materials such as, but not limited to, titanium, cobalt nickel alloy, polyetheretherketone, stainless steel, nickel titanium alloy, and the like. The resilient anchor portions 106 can comprise spring metals such as, but not limited to, superelastic nitinol, shape memory nitinol, stainless steel, cobalt nickel alloy, titanium, and the like. The resilient anchor portions 106 can have overall widths substantially equal to, or less than, the width of the main body portion 102 less the thickness of the material making up the main body portion 102. The resilient anchor portions 106 can have thicknesses ranging between 0.005 inches and 0.100 inches. The length of the main body portion 102 can range between 0.25 inches and 3.0 inches. The width of the main body portion 102 can range between 0.1 inches and 1.0 inches. The height of the main body portion 102 in the region of the tail connector 116 can range between 2.0mm and 20.0mm. The maximum projection of the two resilient anchor portions 106, combined, away from the longitudinal axis of the main

body portion 102 can range between 3.0mm and 30.0mm. The anchor height, or maximum distance between the superior projection and the inferior projection of the anchor portion, is generally greater than the inferior to superior height of the tail flange. The anchor height, as described herein, generally ranges between 1.2 to 3.0 times the thickness of the main body portion 102 or the tail connector 116.

[0065] The tail connector 116 is configured with substantial strength such that it can accommodate the force of the lips of the vertebrae when the vertebrae are fully loaded in compression or when the spine is bent backward in extension at that location. Thus, the structure under the tail connector 116 is configured to support loads up to about 3,000 Newtons or higher. This region can comprise PEEK, PET, polysulfone, or other polymers, and can further be reinforced with metals. In other embodiments, the tail connector 116 can be comprised only of metallic materials such as, but not limited to, stainless steel, titanium, nitinol, cobalt nickel alloy, and the like.

[0066] Fig. 1b illustrates the spinal implant 100, as viewed obliquely toward the distal end. The implant 100 comprises the main body portion 102, the tail portion 104, two resilient anchor portions 106, the anchor connector 108, the main body windows 118, and the main body interior space 110. The lumen or main body interior space 110 is visible as it can open to the distal end of the main body portion 102.

[0067] Referring to Fig. 1b, the tail portion 104 is configured to flare outward, away from the longitudinal axis of the spinal implant 100. The tail portion 104 is flared outward for the purpose of sealing an annular defect from the outside, providing an indexing function such that the spinal implant 100 is not advanced too far into the annulus of an intervertebral disc, or both. The tail portion 104 can be disposed laterally with no curvature, or it can comprise a small amount of curvature configured to substantially match the curvature of the exterior of an intervertebral disc. The radius of curvature of the tail portion 104 can range from about 2-cm to about 15-cm and preferably between about 3-cm and 10-cm. Curvature of the flange of the tail portion 104 in the superior or inferior direction is generally not needed, although it could be provided if specific spinal geometries so dictate.

[0068] Fig. 1c illustrates the spinal implant 100, as viewed from the side. The implant 100 comprises the main body portion 102, the tail portion 104, the two resilient anchor portions 106, and the tail connector 116.

[0069] Referring to Fig. 1a, the anchor portions 106 can be controlled by an anchor, jack screw, or other mechanism comprising a mechanical advantage and optionally comprising controllable or lockable positioning or motion limits. The proximal end 212 of the anchor portions 106 can comprise a female threaded structure configured to mate with a male threaded structure such that the proximal end 212 can be moved along the axis of the implant along the longitudinal axis while the distal 210 of the anchor portion 106.

[0070] Fig. 2a illustrates an oblique view of an anchor portion 106 adapted for use with the spinal implant 100 as illustrated in Fig. 1a. The anchor portion 106 comprises two arcuate leaf strands 214 separated by a gap 208, a distal end 210, a fastener hole 202, a proximal end 212, a plurality of engagement detents 206, and the proximal grasping end 204.

[0071] The two arcuate leaf strands 214 can be separate structures affixed together at the proximal end, distal end, or both, or the two arcuate leaf strands 214 can be comprised by a single integral structure. The fastener hole 202 is a complete perforation of the thickness of the distal end 210. The engagement detents 206 are cut from the material of the proximal end 212 with a remaining, substantially full width proximal grasping end 204 remaining proximal to the detents 206. The engagement detents 206 can be integral to, or separate and affixed to, the proximal end 212. The grasping detents 206 can also comprise undercuts, perforations, holes, or thickness increases at various other locations on the proximal end 212, although the preferred embodiment is as illustrated in Fig. 2a.

[0072] Fig. 2b illustrates a side view of the anchor portion 106. The anchor portion 106 comprises the arcuate leaf strands 214, the distal end 210, and the proximal end 212.

[0073] Fig. 2c illustrates a top view of the anchor portion 106. The anchor portion 106 comprises the two arcuate leaf strands 214 separated by the gap

[0074] Fig. 3 illustrates an oblique view of an implant coupler 300 as viewed looking from the distal end toward the proximal end. The coupler 300 comprises a proximal end 314, a grasping detent 316, an axially elongate body 302, a plurality of fasteners 304, an internal lumen 318, a spring main body 306, an indexing projection 322, a plurality of spring catches 320 separated from the indexing projection 322 by the gaps 312, the implant grasping projections 308, and the distal opening 310. The spring catches 320 are illustrated inwardly displaced by an external force such that the grasping projections 308 can engage complimentary features on a spinal implant.

[0075] Referring to Fig. 3, the implant coupler 300 forms a structure with no relative motion between an of the components, with the exception that the spring catches 320 can bend outward and inward, away from and toward, respectively, the indexing projection 322. The spring main body 306 comprises the indexing projection 322, the spring catches 320, the grasping projections 308, and the distal opening 310. The spring main body 320 is affixed to the axially elongate body 302 by the fasteners 304 such that no relative motion can occur between the spring main body 320 and the axially elongate body 302. The axially elongate body 302 comprises the internal lumen 318, which is sized and configured to slidably accept the spring main body 306. The axially elongate body 302 comprises the proximal end 314, further comprising the grasping detent 316, which is affixed, or integral to, the proximal end 314. The fasteners 304 can comprise crimps, adhesive bonds, welds, set screws, solder joints, and the like.

[0076] The spring main body 320 can comprise materials such as, but not limited to, stainless steel, cobalt nickel alloy, titanium, nitinol, and the like. The spring main body 320 is constructed such that it retains a high spring constant. The axially elongate body 302 can comprise stainless steel, cobalt nickel alloy, titanium, nitinol, tantalum, and the like. The axially elongate body 302 comprises materials that can be fully annealed or retain full spring hardness. The grasping detent 316 can comprise one or more undercuts or cutaways in the proximal end 314 and is configured to slidably engage with a

[0077] Fig. 4 illustrates an oblique view of the implant coupler 300, which has been releasably affixed to the spinal implant 100. The cowling 402 encloses the spring main body 306, the indexing projection 322, and the axially elongate body 302, as illustrated in Fig. 3. The cowling 402, at its distal end, abuts the tail 104 of the spinal implant 100.

[0078] Referring to Fig. 4, the cowling 402 is hollow and comprises an internal lumen (not shown) that permits the implant coupler 300 to slidably move along its longitudinal axis relative to the cowling 402. The distal end of the cowling 402 can exert a compressive force on the proximal end of the tail 104 of the spinal implant 100 while the coupler 300 can exert a tensile force on components of the spinal implant 100, to which it is releasably affixed. The cowling 402 can be forced toward the spinal implant 100 by an axially elongate tubular structure comprised by a delivery system (not shown). The cowling can comprise metals such as, but not limited to, titanium, stainless steel, cobalt nickel alloy, nitinol, tantalum, or it can comprise polymers such as, but not limited to, polysulfone, polycarbonate, polyetheretherketone, or the like. The coupler 300, cowling 402, and spinal implant 100 are illustrated in their unstressed configuration. The grasping projections 308 grip the engagement detents 206 on the proximal end of the anchor portion 106 due to inwardly directed force on the spring catches 320 caused by a narrow width of the engagement access port 114 in the spinal implant 100. The spring catches 320 are biased outwardly and would move outwardly except for the restraining force of the width of the engagement access port 114.

[0079] Fig. 5a illustrates an oblique view of a delivery system 500 affixed to a coupler 300, which is, in turn, affixed to a spinal implant 100. The delivery system 500 further comprises a handle body 520, an axially elongate shaft 502 further comprising an internal lumen (not shown), a handle 504, a trigger 506, which rotatably constrained about the hinge 512, a trigger shroud 514, a trigger release 508, a trigger limiter 528, a trigger release hinge 522, a trigger catch window 530, and a control rod 524 further comprising a coupler grip 526.

[0080] Referring to Fig. 5a, the control rod 524 is slidably restrained within the axially elongate shaft 502 such that it can move axially relative thereto. The distal end of the control rod 524 comprises the coupler grip 526, which can be affixed, or fabricated integrally, thereto. The distal end of the axially elongate shaft abuts the proximal end of the cowling 402 and can exert compressive force on the cowling 402 to move the cowling 404 distally, relative to the control rod 524. The coupler grip 526 is illustrated engaged with the grasping detent 316 on the proximal end of the coupler 300. An optional coupler stop or limit (not shown) prevents over positioning of the coupler grip 526 with the grasping detent 316.

[0081] The main handle body 520 is affixed to the axially elongate shaft 502. The handle 504 is affixed to the main handle body 520 and projects laterally therefrom to permit a palm grip by a human hand. The trigger 506 is rotatably constrained to move about its hinge, which is affixed to the main handle body 520. The trigger 506 is configured to be engaged by the fingers of the human hand and force the trigger 506 toward the handle 504. The trigger 506 further comprises the trigger shroud 514, which permits the fingers of the hand to force the trigger 506 away from the handle 504. The proximal end of the control rod 524 is affixed, and operably connected to the trigger 506, either directly or by an articulating linkage, such that pulling the trigger 506 toward the handle 504 causes the control rod 524 to move proximally, relative to the axially elongate shaft 502.

[0082] The trigger release 508 is rotatably affixed to the handle 504 by the trigger release hinge 522 and projects through the trigger release window 530. The travel limiter 528, affixed to the trigger release 508 at a position that upon full trigger 506 withdrawal toward the handle 504, prevents the grasping projections 308 from being pulled out of the constraining engagement access port 114 of the spinal implant 100 and thus prevents the coupler 300 from disengaging from the spinal implant 100. The trigger release window 530 is large enough that the trigger release 508 can be grasped by the user and moved such that the travel limiter 528 passes through the trigger release window 530 and allows the trigger 506 to move sufficiently close to the handle 504 that the grasping projections 308 can pull outside the constraining

engagement access port 114, spring open, and release the grip on the spinal implant 100, thus releasing or disengaging the delivery system 500 and coupler 300 from the spinal implant 100. The trigger release 508 can be biased downward to ensure that the travel limiter 528 engages with the trigger release window 530 bottom edge by means such as, but not limited to, a spring, gravity, magnetic attraction or repulsion, or the like. Other travel limit devices can also be used as a substitute for the hinged bar with a projection that only passes through a window if controllably chosen to do so.

[0083] Fig. 5b illustrates a side view of another embodiment of the delivery system 500, the coupler 300, the cowling 402, and the spinal implant 100. The delivery system 500 further comprises the axially elongate shaft 502, the handle body 520, the hinge 512, the handle 504, the grip stabilizer 518, the trigger 506, the trigger shroud 514, the finger hole 516, the trigger release 508, a plurality of ratchet teeth 510, the travel limiter 528, the trigger release window 530, the complimentary teeth 532, and the trigger release hinge 522.

[0084] In the embodiment shown in Fig. 5b, the trigger release 508 comprises, on its bottom side, the plurality of ratchet teeth 510 that engage with complimentary teeth 532 projecting upward on the bottom edge of the trigger release window 530. A pull of the trigger 506 toward the handle 504 to any position, before the travel limiter 528 interferes with the trigger 506, withdraws the grasping projections 308 on the coupler 300 to retract the anchor portions 106, causing their arcuate shape to collapse toward the implant main body portion 102, but not release the spinal implant 100 from the coupler 300. The ratchet teeth 510 engage with the complimentary teeth 532 such that the trigger 506 can be advanced to various distances from the handle 504 and maintain their position without slipping. Moving the trigger release 508 upward allows the travel limiter to not engage the window 520, thus the trigger 506 can be withdrawn toward the handle 504 to the extent necessary to completely pull the grasping projections 308, on the coupler 300, from the constraining engagement access port 114 in the tail of the spinal implant 100 such that the spinal implant 100 is released or disengaged from the coupler 300.

[0085] Fig. 6 illustrates an oblique view of an implant coupler 300 as viewed looking from the proximal end toward the distal end. The coupler 300 comprises the proximal end 314, the grasping detent 316, the axially elongate body 302, the plurality of fasteners 304, the internal lumen 318 (not shown), the spring main body 306, the indexing projection 322, the plurality of spring catches 320 separated from the indexing projection 322 by the gaps 312, the implant grasping projections 308, and the distal opening 310.

[0086] Referring to Fig. 6, the spring catches 320, further comprising the implant grasping projections 308 have been restored to their neutral, unstressed position. The spring catches 320 are spring biased to assume the position as illustrated in Fig. 6 and are moved from this position only under the influence of an external force or constraint. The gap 312 between the indexing projection 322 and the spring catches 320 is wider than that of the configuration of the coupler 300 as illustrated in Fig. 3. The indexing projection 322 serves to help align the coupler 300 with an implant during installation onto the implant and to prevent overly inwardly forcing the spring catches 320.

[0087] Fig. 7a illustrates an oblique view, looking from the distal end toward the proximal end, of a spinal implant 700 configured in a large size. The spinal implant 700 is adapted for placement between the vertebrae of a mammalian spine. The implant 700 is configured for use within the lumbar spine, but can also be adapted for use within the cervical or thoracic spine. The implant 700 comprises a main body portion 702, a tail portion 706, two resilient anchor portions 704, a tail connector 708, a plurality of main body windows 712, the anchor engagement access port 714 (not shown), and a main body interior void 710.

[0088] Referring to Figs. 7a and 1a, the spinal implant 700 comprises the same materials as the spinal implant 100 but comprises a four leaf anchor portion 704. The width of the spinal implant 700 as well as the thickness in the superior to inferior direction in the region of the tail coupler 708 can be greater than that of the smaller spinal implant 100.

[0089] Figs. 1a, 1b, 1c, and 7a describe spinal implants. Generally speaking, coupled to the head portion of the spinal implant 100 or 700 is a barrier portion 104 or 706, herein described as a tail portion or tail flange. The barrier portions 104, 706 have widths that are greater than the width of the annular defect. The barrier portion is configured to prevent substantial extrusion of nucleus pulposus from the intervertebral disc when the barrier portion is positioned to contact an out surface of the annulus fibrosis, and spans the width of the annular defect. The barrier portions 104, 706 can be further comprise a tail connector portion 116, 708. As discussed herein, in certain embodiments, a tail portion 104, 706 comprises a tail flange portion.

[0090] Fig. 7b illustrates an oblique view of a medium sized spinal implant 720 comprising a main body 722 and an anchor portion 724 further comprising a central connector 726. The distal portion of the anchor portion 724 is affixed to the main body 722 with the connectors 728.

[0091] Fig. 8a illustrates an oblique view of an anchor portion, or spring, 704 adapted for use with the spinal implant 700 as illustrated in Fig. 7a. The anchor portion 704 comprises four arcuate leaf strands 814 separated by a plurality of gaps 808, a distal end 810, a fastener hole 802, a proximal end 804, and a plurality of engagement detents 806.

[0092] Referring to Fig. 8a, the anchor portion 704 is affixed to the main body portion 702 in the same way as that the spinal implant 100. The four arcuate leaf strands 814 can further comprise interconnection bars (not shown) disposed at positions intermediate the proximal end 804 and the distal end 810. These interconnection bars (not shown) can connect each of the arcuate leaf strands 814 at one or more points along the curve and different pairs of bars can be interconnected at different locations.

[0093] Fig. 8b illustrates a side view of the heavy duty anchor portion 704 comprising the leaf strands 814, the proximal end 804, and the distal end 810. The arcuate shape of the leaf strands 814 is clearly shown as is the bend back to alignment of the proximal end 804 and the distal end 810 along the same axis such that they are parallel to each other and to the longitudinal axis

of an implant main body portion within which they are configured for placement.

[0094] Fig. 9 illustrates an oblique view of the delivery system 500 for a spinal implant 100, 700. The delivery system 500 comprises the handle main body 520, the handle 504, the trigger 506, the axially elongate tube 502 further comprising a proximal end, a distal end, an internal lumen 904, the control rod 524, and the coupler grasper 526.

[0095] Referring to Fig. 9, the control rod 524 is slidably retained within the internal lumen 904 such that it is constrained from movement in the radial direction but free to move in the longitudinal direction under control of the trigger 506 and any intermediate operable linkages (not shown). Referring to Figs. 9 and 3, the coupler grasper 526 comprises complimentary structures that mate with the grasping detents 316 on the proximal end 314 of the coupler 300. The grasping detents 316 are configured to slide, either freely or with some friction, into the coupler grasper 526 from a direction lateral to the longitudinal axis of the control rod 524. The coupler grasper 526, the grasping detents 316, or both, can further comprise travel limiters (not shown) that prevent over-engagement of the two components such that they are misaligned and non-concentric. Further, the coupler grasper 526, the grasping detents 316, or both can comprise a latch (not shown) that permits positive locking of the two components 526 and 316, when substantially, concentrically aligned. The latch can be permanent or releasable.

[0096] Fig. 10 illustrates a cowling 402 configured to shield couplers such as those illustrated in Figs. 3 and 6. The cowling 402 is further configured to transmit compressive force from the axially elongate tubular shaft 502, comprised by the delivery system 500, onto the tail flange or tail portion 104 of the spinal implant 100. The cowling 402 comprises the axially elongate main body 1002 further comprising the internal lumen 1004 and the flare adapter 1006.

[0097] Referring to Fig. 10, the flare adapter 1006 and the axially elongate main body 1002 can be affixed to each other or they can be integral to each other. The proximal end of the axially elongate main body 1002 is sized to

match the diameter of the axially elongate tubular structure 502 on the delivery system 500. The inner lumen 1004 is sized to accept the coupler 300 such that the coupler 300 freely moves within the cowling 402 or moves with a small amount of controlling friction. The distal end of the flare adapter 1006 is sized to substantially match, and engage, the tail portion 104 of the spinal implant 100. The distal end of the flare adapter 1006 can also be sized to match the tail portion 706 of a large sized spinal implant 700, or other intermediate sizes. Thus, the axially elongate main body is generally the same size for all sizes of cowlings, however, the distal end of the flare adapter 1006 can vary substantially, depending on the size of spinal implant to which it is mated.

[0098] Fig. 11a illustrates a front view of the spinal implant 700 comprising anchor portions 704 that project superiorly and inferiorly away from the main axis of the main body portion 702. The main body portion 702 is affixed to the tail portion 706 by the tail connector 708, not shown.

[0099] The anchor portions 704, or other anchor portions described herein, in certain embodiments, can comprise shape memory, superelastic, or pseudoelastic nitinol. The desired configuration or shape of the anchor portions 704 can be generated by shape setting the nitinol or other shape memory material for a preferential shape to interact with the endplates. The shape setting typically is performed in a vacuum oven, sand bath aerated with nitrogen, argon, or other inert gas, salt bath, or other heating chamber between temperatures of about 475°C and 550°C. The anchor portions 704 are placed within a form that and locked in place to achieve the desired shape. The anchor portions 704, in their form, are lowered into the sand bath or salt bath, or placed in the vacuum oven and heated for the desired amount of time, following which they are removed and quenched in water. The austenite finish temperature (A_f) is typically maintained around 15°C to 22°C. In other embodiments the A_f can be adjusted to higher temperatures such that the nitinol comprises shape memory properties. Following shape setting, the anchors comprising the nitinol are cooled, generally to around –60°C and are deformed into a delivery shape. The shape memory anchor portions 704 can be inserted such that they are cooled below their austenite start temperature

(A_s) and then inserted into the spine. Afterward, body temperature raises the temperature of the nitinol to above A_f such that the stress within the shape memory anchor portions 704 rises to cause a reversion to a pre-set shape. The austenite start temperature can, in other embodiments, be set to even higher values, above body temperature, such that following implantation the anchor portion 704 equilibrates to body temperature, about 37°C. Application of electrical, resistive, electromagnetic, or Ohmic heating, can raise the temperature of the anchor portion 704 sufficiently to cause a shape memory change to a yet different shape and maintain the shape through hysteresis, even after the energy has been removed to cause the temporary increase in anchor portion 704 temperature.

[00100] Fig. 11b illustrates another embodiment of a spinal implant 1118 comprising the main body portion 702, the tail portion 706, two arcuate leaf strands 1104 that project outwardly in a complex curve that extends laterally left and right, as well as superiorly and inferiorly. The two central members or arcuate leaf strands 1102 remain projecting only in the superior and inferior directions relative to the main body portion 702. The arcuate leaf strands 1104 and 1102 can be affixed to each other at the proximal and distal ends, or they can be integral to each other. The main body portion 702 is substantially unchanged from that of Fig. 7a and 11a.

[00101] Fig. 11c illustrates another embodiment of a spinal implant 1120 comprising not only a plurality of primary anchor portions 1106 which project superiorly and inferiorly only, but also secondary anchor portions 1110 that project laterally left and right away from the main body portion 1108. The secondary anchor portions 1110 are affixed to the main body portion 1108 near their distal end and are constrained such that they project through side windows (not shown) in the main body portion 1108. The primary anchor portions 1106 project through windows (not shown) in the main body portion 1108 similarly to the anchor portions 704 projecting through the windows 712 in the main body portion 702. Inward deflection, or retraction, of the secondary anchor portions 1110 is caused by proximal retraction of their proximal ends by engagement with the coupler 300, or a variant thereof. The primary and secondary anchor portions 1106 and 1110, respectively, can be

fabricated from the same materials as those used to fabricate the anchor portions 704 of the spinal implant 700.

[00102] Fig. 11d illustrates another embodiment of a spinal implant 1122 viewed from the distal end and looking proximally. The spinal implant 1122 comprises the main body portion 702, the tail portion 706, a plurality of central anchor portions 1112, a plurality of complex external anchor portions 1114, and a plurality of orbital or circumferential anchor portions 1116. The main body portion 702 is substantially the same as the main body portion 702 of the spinal implant 700. The orbital or circumferential anchor portions 1116 area affixed to the complex external anchor portions 1114 by welding, crimping, or placement through gaps, openings, windows, holes, or the like. Upon proximal retraction of the proximal end of the anchor portions 1114 and 1112, which are affixed to each other at the proximal and distal ends and which are further affixed to the main body portion 702 at the distal end, the anchor portions 1114 and 1112 compress laterally and cause the orbital or circumferential anchor portions 1116 to be withdrawn inward in the superior or inferior directions, thus reducing their projection or cross-sectional binding area. Referring to Figs 1a and 7, the circumferential or orbital anchor portions 1116, as well as the anchor portions 1114 and 1112 comprise the same materials used to fabricate the anchor portions 704 and 106.

[00103] Fig. 12a illustrates a main body frame portion 1202 of a spinal implant comprising a tail connector 1216, a plurality of main body windows 1212, and an internal lumen 1214. The main body frame portion 1202 can comprise the same materials as those used for the main body portions 102 and 702 of Figs. 1a and 7. These materials are generally rigid or semi-rigid and comprise significant strength in compression and tension. The tail connector 1216 steps down from the more central region comprising the main body windows 1212 so that the tail connector 1216 can be coated with an extra thick layer of soft, elastomeric or resilient, coating. The tail connector region 1216 is necessarily very strong and able to resist high compressive loading imposed in the superior or inferior direction.

[00104] Fig. 12b illustrates the main body frame portion 1202 covered with a soft overlayer 1220. The connector attachment port 1210 is visible on the

proximal side of the tail flange 1206. The soft overlayer 1220 is bonded, adhesively affixed, welded, inserted molded, overmolded, cast, or otherwise affixed to the outside of the main body frame portion 1202. The region immediate around the windows 1212 is not covered with the soft overlayer 1220, as is the region near the distal end of the main body frame portion 1202.

[00105] Referring to Fig. 12b, the elastomeric surround or soft overlayer 1220 ranges between 0.010 and 0.10 inches thick and covers the main body portion 1202 from at least the distal end of the window 1212 to the point where the tail portion 1206 flares outward. In the illustrated embodiment, the soft surround layer 1220 also covers the outwardly flared portion of the tail portion 1206. The elastomeric surround layer 1220 can comprise materials such as, but not limited to, polycarbonate urethane, polyurethane, silicone elastomer, PTFE, polyethylene, polyimide, polyamide, thermoplastic elastomer, and the like. The elastomeric surround layer 1220 preferably is highly resilient and provides a soft landing over the tail connector 1216 onto which the vertebral lips can rest when the spine is placed in compression. The elastomeric surround layer can further comprise a highly porous or rough outer surface. The elastomeric surround layer can be further covered by a layer of fabric (not shown) fabricated from PTFE, PET, and the like. The fabric layer (not shown) can be woven, knitted, braided, or the like. The elastomeric surround layer can further be coated with bone growth factors, thrombogenic materials, stem cells, fibrin sealant, anti-inflammatory materials, antimicrobial materials, tissue forming materials, tissue resistant materials, or the like.

[00106] Fig. 12c illustrates a spinal implant 1200 comprising comprises the main body frame portion 1202, a tail portion 1204, two resilient anchor portions 704, a tail connector 1216, one or more main body windows 1212, the main body interior space 1206, a connector attachment port 1210 (not shown), and a soft overlayer 1220. The lumen or main body interior space 1214 is visible and open to the distal end of the main body frame portion 1202.

[00107] Referring to Fig. 12c, the anchor portions 704 are inserted within the interior lumen 1214 and then secured or affixed to the main body structural portion 1202 by a pin, weld, or other type of fastener proximate the distal end of the main body structural portion 1202. The proximal end of the anchor portions 704 are generally affixed together and are free to slide along the longitudinal axis of the main body structural portion 1202. Proximal withdrawal of the proximal end of the anchor portions 704 results in lateral compression or collapse of the arcuate central portions of the anchor portions 704, thus minimizing or eliminating any projection superiorly or inferiorly beyond the boundaries of the coated main body structural portion 1202.

[00108] Figures 13A-13F show another embodiment of a spinal implant device 1300. This device 1300 comprises a distal main body that includes a head portion 1302, a mid-portion 1304 and a proximal portion 1306 that comprises a tail flange 1317. This device 1300 further comprises an anchor system that includes one or more lateral engagement members 1320 and one or more proximal engagement members 1318. The lateral engagement member(s) act to frictionally engage or abut against adjacent portions of a spinal disc or other anatomical structure in which the device 1300 is implanted and stabilize rotational forces. The proximal engagement member(s) 1318 extending from the proximal portion 1306 to engage adjacent bony structures (e.g., processes of vertebrae) or other adjacent anatomical structures to deter unwanted migration of the implanted device 1300 in a distal direction. In the non-limiting example shown, the lateral engagement member(s) 1320 comprise two outwardly biased springs on the mid-portion 1304, that are initially deployable (e.g., compressed and constrained) in collapsed positions during insertion of the device 1300 and subsequently transitionable (e.g., released and allowed to self-extend) to extended positions as shown in Figures 13A-13B. When the device 1300 is implanted in the spinal column of a subject, as seen in Figures 13D-13F, these lateral engagement member(s) 1320 will abut against, insert into or otherwise frictionally engage the annular portion of an intervertebral disc IVD in which the mid-portion 1304 resides. This will stabilize the implanted device 1300 and deter unwanted migration in either the distal or proximal or rotational directions. Also, in the non-limiting

example shown, the proximal engagement member(s) 1318 comprise four elastic or superelastic strut members that are initially deployable (e.g., compressed and constrained) in collapsed positions during insertion of the device 1300 and subsequently transitionable (e.g., released and allowed to self-extend) to extended positions as shown in Figures 13A-13B. When the device 1300 is implanted in the spinal column of a subject, as seen in Figures 13D-13F, these proximal engagement member(s) 1318 will abut against bony portions of adjacent vertebrae V1 and V2 or other tissue to further stabilize the device 1300 in a manner that deters unwanted post-implantation migration of the device in at least the distal direction. Following implantation, in at least some subjects, body tissue such as a fibrous tissue capsule may overgrow these proximal engagement member(s) 1318, thereby further stabilizing the implanted device 1300. In view of this, in some embodiments of the device 1300, holes, apertures, perforations, surface disruptions, serrations, grooves, channels, depressions, protrusions, bumps, cavities, or other tissue ingrowth or engagement area(s) (not shown) may be formed on or in the proximal engagement member(s) 1318 or elsewhere on the device 1300 to facilitate an interlocking, union, coupling, connections, adhesion or other engagement between the proximal engagement member(s) 1318 and the body tissue that develops after implantation of the device 1300.

[00109] The main body 1302, 1304 and proximal flange 1317 may be constructed in the same manner, and of the same materials, as described in the parent United States Patent Applications Ser. No. 11/732,360, filed April 2, 2007; Ser. No. 11/726,664 filed March 21, 2007 and Ser. No. 11/398,434 filed April 5, 2006, which are referred to above and expressly incorporated herein by reference. In general, it will be appreciated that the device 1300 has a height greater than its width such that it may be initially inserted into a previously-bored, undercut cavity while in a first rotational orientation and subsequently rotated 90 degrees to cause the distal head portion 1302 to extend into undercut areas of the cavity, thereby deterring unwanted proximal and/or distal movement of the device 1300. In this non-limiting example, the distal head portion 1302 has a blunt tip 1308, a tapered region 1310, a transitional region 1312 and a proximal head region 1314. The proximal head

region 1314 is the tallest part of the head portion 1302. Optionally, one or more tissue ingrowth areas such as apertures or cavities 1316 may be formed in the head portion 1300 so that the annular tissue of the intervertebral disc IVD or other tissue adjacent to that region of the head portion 1302 may invade or grow into the head portion 1302 thereby further securing and deterring unwanted migration of the device 1300.

[00110] In some embodiments, the lateral engagement member(s) 1320 and proximal engagement member(s) 1318 may be formed as a unitary assembly by laser cutting or otherwise cutting wings or projections from the wall of a tube (e.g., a Nitinol tube) and subsequently forming and heat setting those wings or projections to create the final geometry of the lateral engagement member(s) 1320 and proximal engagement member(s) 1318. This assembly may then be inserted into a cavity or bore in the body of the implant (e.g., a body made of PEEK) or in some embodiments the polymeric body of the implant may be molded around or onto the assembly. In some embodiments, a retention pin or other member may be inserted through the body of the implant and assembly to hold the assembly in place. In some embodiments, the lateral engagement member(s) 1320 may, when in their expanded configuration, have a height that is greater than the thickness of the tail flange 1317 but when in their collapsed configuration they may nest or be compressed adjacent to the body of the implanted device such that they do not protrude outboard of or beyond the outer edges of the tail flange 1317, thereby facilitating insertion or delivery of the device. Also, in some embodiments, proximal engagement member(s) 1318 may be designed to eliminate and replace the tail flange 1317.

[00111] Other aspects of the inventions described herein include methods of use. With each embodiment, an implant procedure can be provided. The implant procedure can comprise preparation steps including, but not limited to, magnetic resonance imaging of the affected region, computer aided tomography imaging of the affected region, placement of a trocar at the correct location under fluoroscopy, placement of one or more guidewires, advancement of nested, staged, or expanding access sheaths into the target location, monitoring the procedure under fluoroscopy, and monitoring the

procedure under direct vision such as through a surgical operating microscope that comprises direct visualization, video capture using a camera, or a combination thereof.

[00112] The implant procedure can include steps including tunneling through the facets using burrs, Rongeurs, or other cutting instruments to carefully remove the minimum material necessary for access. The implant procedure can include the steps of moving nerves aside and protecting nerves from damage. The implant procedure can include the steps of removing herniated disc material using grasping, scraping, cutting, grinding, or scooping instruments placed through the sheath. The implant procedure can include, without limitation, the use of lip sizers, the use of lip reamers, the use of implant reamers, the use of trial units to determine appropriate implant fit, the use of distracting instrumentation, the use of annulus coring tools, the use of implant delivery tools, and the like. Furthermore, the procedure can include measuring the features of the anatomy including the Mean distraction distance (MMDD), disc height, intradiscal pressure, variations in disc height measured in prone and supine positions, and the like. The procedure can include the use of specialized instruments configured to obtain the measurements described herein, said instruments comprising specialized pressure sensors, disc height measuring tools, distraction distance measuring instruments, and the like.

[00113] In some embodiments, the devices and procedures described herein are configured to secure a plug or seal to a defect in the annulus of an intervertebral disc. Those intervertebral discs exhibiting herniation and requiring repair may have non-discreet delineation between the nucleus and the annulus tissue. There may be little or no clearly defined nucleus. There may be no inner boundary of the annulus against which an implant can be secured. The annulus may be highly degenerated and incapable of supporting sutures or other attachments which could otherwise be able to provide some fixation for an implant. These conditions are more likely than not to occur in patients requiring an augmentation of an annular defect, or a plug placed therein. The devices described herein are configured to be constrained by the vertebrae, the end plates of the vertebrae, or by an intact

annulus. These devices do not require that any nucleus be present within the intervertebral disc.

[00114] In other embodiments, the devices described herein are configured for support or treatment of scoliosis. The scoliosis-targeted implants can be asymmetric lordotic implants. In other embodiments, the devices described herein are configured for disc decompression, facet unloading, height preservation, or height restoration. The devices described herein can be used in embodiments that preserve spinal motion along at least one axis. The motion preserving devices can be configured to provide dynamic stability to the spine along one or more axes.

[00115] In some embodiments, the devices described herein can be configured for placement using posterior approaches. In other embodiments, the devices described herein can be configured for lateral approaches. In some embodiments, the devices described herein can be configured for percutaneous or minimally invasive approaches. In some embodiments, the devices described herein can be configured for trans-foramenal approaches.

[00116] In some embodiments, reamers can be utilized for use in removing or modifying tissue within the annulus or adjacent vertebrae. In some embodiments, the reamers are expandable.

[00117] The implants described herein can be placed through posterior, lateral, or posterior-lateral approaches. These implants can comprise a plurality of components. These implants, which comprise axially elongate structures, can be configured to comprise a first, unexpanded state and a second expanded state, wherein the expansion occurs in a direction generally normal, or lateral, to the longitudinal axis of the implant.

[00118] In some embodiments, the implants can be configured to comprise a first, natural state and a second, compressed or tensioned state, wherein the compression or tension occurs in a direction generally normal, or lateral to, the longitudinal axis of the implant. In some embodiments, implants are self-tensioning on the annulus with one component positioned on the internal annulus wall and a second component positioned on the annulus posterior wall.

[00119] In some embodiments, implants can be guided into place using a delivery system. The delivery system can comprise a catheter, trocar, port, guidewire, or the like. The delivery system can comprise a pre-curved or adjustable curve configuration. Adjustability, shape change, or curving can be accomplished using shape memory means, spring-loaded means, or steering means, wherein the steering means are controlled from the proximal end of the delivery system.

[00120] The implants described herein are fabricated from materials suitable for long-term implantable use and are biocompatible in nature. The implants are provided in aseptic packaging and are sterilized prior to use using methodology such as, but not limited to, ethylene oxide exposure, gamma irradiation at 25 to 40 kGray, electron beam irradiation, steam sterilization, and the like. The delivery systems, couplers, and surgical preparation tools and instruments are fabricated from materials that are biocompatible for short-term surgical use and are sterilized using the same methods described for the implants.

[00121] In exemplary embodiments, the procedure for placement of the spinal implant comprises locating the surgical target site and advancing a needle through the back or side of the patient to the target site under fluoroscopy. A surgical port access system is next advanced to the target site under fluoroscopy. Rongeurs, burrs, and other surgical instruments are used to dissect downward through tissue and bone until the herniated disc is visualized. The herniation site is accessed through the port access system, following careful avoidance, and sideways distraction and shielding, of the nerve root that generally lies obstructing the target site. The herniation is removed using graspers, forceps, pituitary rongeurs, or the like, placed through the port access system while carefully avoiding the nerve root. Disc material is next removed using a surgical scalpel and then a tissue reamer system placed through the scalpel incision, or annulus defect, to remove soft tissue as well as bone just inside the vertebral lips. The correct size of implant is next determined using MRI, ultrasound, fluoroscopy, sizers, and any other appropriate methodology. The correct size implant and its pre-attached coupler are next removed from its sterile packaging. The delivery

system is removed from its sterile packaging. The coupler is attached to the coupler engagement features on the distal end of the delivery system and the outside sleeve of the delivery system is advanced over the coupler so that the coupler cannot become disengaged from the delivery system. The trigger is next pulled proximally on the delivery system to retract the anchor portions so that they are lower than the height of the tail flanges or substantially flush with the main body portion of the spinal implant. The spinal implant is next inserted through the surgical port access system and routed to the target site by the delivery system. The spinal implant is advanced into the target region until the tail flange portion of the tail portion abuts and is located against the outermost aspect of the intervertebral disc. The trigger release is next disengaged and the trigger pulled fully toward the handle to release the implant from the delivery system and permit the anchor portions to fully expand in the superior and inferior directions. The delivery system and coupler are removed from the patient. The surgical site is carefully inspected for remaining debris and then the port access system is removed from the patient. The patient's minimally invasive access is surgically closed according to standard hospital procedure.

[00122] The procedure can further comprise processes that can be performed during manufacturing or during use. Such processes include attachment of the coupler to the spinal implant. First, the cowling 402 is installed over the coupler 300 and pulled proximally relative to the coupler 300 to expose the distal grasping projections 308 at the distal end of the cowling 402. Releasable, reversible, or detachable affixing of the coupler 300 to the spinal implant, 100 or 700, comprises withdrawing the proximal end of the anchor portion 106 or 704 out the anchor engagement access port 114, 714 at the proximal end of the implant and engaging the grasping projections 308 on the coupler with the engagement detents 206, 806, which are comprised by the proximal ends of the anchor portions 106, 704 of the spinal implants 100 or 700, respectively. The spring loaded anchor portions 106, 704 are allowed to revert to its unconstrained unstressed configuration while maintaining the spring catches 320 of the coupler in their inwardly biased, implant engaging, configuration until the grasping projections 308 are within

[00123] In some embodiments, instruments are disclosed for distracting the vertebrae, vertebral lips, intervertebral disc opening, or the like. The distraction instruments can be applied through an open surgical incision, or they can be applied through a minimally invasive approach such as port access. The distraction instruments generally comprise an axially elongate shaft, a handle, and distraction components that distract using approaches such as reverse pliers, a rotating cam, an expandable collet, or the like. In some embodiments, the force to cause distraction is applied by squeezing opposing grips or pulling a trigger or lever at the proximal end of the device with the force being delivered along the length of the axially elongate instrument by means of linkages, shafts, or the like. In other embodiments, the distraction force can be applied by rotating an element at the proximal end of the instrument which causes the entire instrument, or a part thereof, to rotate at the distal end. In yet other embodiments, the distraction at the distal end can be generated with mechanical advantage by operably connecting the distracting jaws or elements to a jackscrew, lever, threaded rod, or the like.

[00124] In general, embodiments of the present spinal implant comprise a head portion and a barrier, or tail portion. The head portion is configured for placement between adjacent vertebrae at the site of an annular defect. The head portion includes a buttress portion that when positioned in the intervertebral space, spans a distance between, and contacts, adjacent vertebrae or endplates. The head portion is effective as a spacer to maintain a desired separation distance between the adjacent vertebrae.

[00125] The skilled artisan will recognize the interchangeability of various features from different embodiments. Similarly, the various features and steps discussed above, as well as other known equivalents for each such feature or step, can be mixed and matched by one of ordinary skill in this art

to perform compositions or methods in accordance with principles described herein. Although the disclosure has been provided in the context of certain embodiments and examples, it will be understood by those skilled in the art that the disclosure extends beyond the specifically described embodiments to other alternative embodiments and/or uses and obvious modifications and equivalents thereof. Accordingly, the disclosure is not intended to be limited by the specific disclosures of embodiments herein.

CLAIMS

What is claimed is:

1. An implant, for at least one of (i) treating an annular defect in an intervertebral disc between adjacent vertebrae of a patient, (ii) maintaining a height between the adjacent vertebrae, (iii) nuclear replacement, (iv) height distraction and preservation, (v) innerbody fusion, (vi) autograft containment, (vii) spondylolisthesis stabilization or correction, (viii) treating spinal stenosis, (ix) providing an annulus seal for nucleus injection, (x) dynamic stabilization of the spine or (xi) forming an artificial tensioning band on the annulus fibrosus wall comprising:

a main body portion, sized and shaped to be positioned within the intervertebral disc space between the adjacent vertebrae;

a tail portion, wherein the tail portion is affixed to the proximal end of the main body portion, further wherein the tail portion comprises a projection that extends laterally of the main body in at least one direction; and

an anchor portion, wherein the anchor portion is affixed to the main body portion, further wherein the anchor portion is configured to interact with at least one vertebral endplate;

wherein, the tail portion is configured for placement substantially in contact with an outer aspect of the intervertebral disc; and

further wherein the anchor portion is configured to at least one of the vertebra and follow the vertebra with which it is engaged independent of the spacing or alignment between adjacent vertebrae surrounding the implant.

2. The implant of Claim 1, wherein the main body portion further comprises a tail connector configured to support a lip portion of the vertebrae under physiological compression loads.

3. The implant of Claim 1, wherein the tail portion comprises a substantially flat proximal surface.

4. The implant of Claim 1, wherein the tail portion comprises a substantially concave proximal surface moving from left to right.

5. The implant of Claim 4, wherein the concave proximal surface of the tail portion is adapted to substantially conform to the curvature of the intervertebral disc.

6. The implant of Claim 1, wherein the main body portion and the tail portion comprise materials with substantially rigid structure.

7. The implant of Claim 6, wherein the materials with substantially rigid structure are chosen from a group of materials including polyetheretherketone, stainless steel, titanium, cobalt nickel alloy, and polysulfone.

8. The implant of Claim 1, wherein at least a part of the main body portion is covered by a layer of resilient material.

9. The implant of Claim 8, wherein the resilient material is chosen from a group of materials including polyurethane, polycarbonate urethane, polyethylene, hydrogels and silicone elastomer.

10. The implant of Claim 8, wherein at least a part of the tail portion is covered by a layer of resilient material.

11. The implant of Claim 1, wherein the main body portion comprises an opening on its superior surface, its inferior surface, or both, wherein the opening is configured to allow projection of the anchor portion from an interior portion of the main body portion through to a position extending beyond the exterior geometry of the main body portion.

12. The implant of Claim 1, wherein the main body portion comprises features to permanently affix the anchor portion thereto.

13. The implant of Claim 1, wherein the anchor portion is affixed to the main body portion at least one axial location within the main body portion.

14. The implant of Claim 1, wherein the anchor portion is affixed to the main body portion proximate the distal end of the main body portion.

15. The implant of Claim 1, wherein the anchor portion is slidably affixed within the main body portion such that the proximal end of the anchor portion is constrained to move only in the axial direction but is otherwise constrained from substantial motion.

16. The implant of Claim 1, wherein the anchor portion comprises a coupling feature disposed proximate the proximal end of the anchor portion, wherein the coupling feature is configured to engage with a delivery system coupler.

17. The implant of Claim 1, wherein proximal movement of the proximal end of the anchor portion causes the anchor portion to extend longitudinally and contract laterally such that projection of the anchor portion in the inferior direction, the superior direction, or both is reduced.

18. The implant of Claim 1, wherein the anchor portion comprises a thin wall, arcuate shape projecting away from the main body portion.

19. The implant of Claim 1, wherein the anchor portion comprises a thin wall, arcuate shape with ends that run substantially parallel to the longitudinal axis of the main body portion.

20. The implant of Claim 1, wherein the anchor portion comprises a spring metal structure.

21. The implant of Claim 1, wherein the anchor portion comprises materials selected from the group including shape memory nitinol, titanium, superelastic nitinol, stainless steel, and cobalt nickel alloy.

22. The implant of Claim 1, wherein the anchor portion is configured to follow, and remain spring biased against the vertebra with which it is engaged.

23. The implant of Claim 1, wherein the anchor portion comprises a single strand.

24. The implant of Claim 1, wherein the anchor portion comprises a plurality of strands, separated by gaps, wherein the gaps run at least a portion of the distance from the proximal end to the distal end of the anchor portion.

25. The implant of Claim 1, wherein the anchor portion comprises a plurality of strands, further wherein the strands are disposed to project superiorly, inferiorly, or both from the main body portion.

26. The implant of Claim 1, wherein the anchor portion comprises a plurality of strands, further wherein the strands are disposed to project laterally as well as superiorly, inferiorly, or both.

27. The implant of Claim 1, wherein the main body portion is configured to fit between the vertebrae.

28. The implant of Claim 1, wherein the main body portion is configured to fit between the vertebrae following distraction of the vertebrae.

29. The implant of Claim 1, wherein the main body portion comprises a tail connector portion configured to fit between the vertebrae under conditions of no distraction.

30. The implant of Claim 1, wherein the main body portion comprises a tail connector with a lateral width greater than its height in the inferior/superior direction.

31. A delivery system, adapted for introducing a spinal implant into an intervertebral disc of a patient, comprising:

a handle configured to fit into the hand of a user;

an axially elongate tubular delivery shaft having a proximal end, a distal end, and a lumen extending therethrough;

a trigger configured to fit into the fingers of the user and be advanced or retracted by the fingers, further wherein the trigger is affixed to a linkage that travels the length of the lumen within the axially elongate shaft; and

a distal adapter configured to be releasably affixed to a coupler, wherein the linkage from the trigger is operably connected to the distal adapter and is capable of causing the distal adapter to open and close a grasping mechanism.

32. A coupler, adapted for use with a delivery system for a spinal implant, comprising:

an axially elongate shaft having a proximal end and a distal end;

a plurality of outwardly biased spring elements, wherein the spring elements are disposed at the distal end of the axially elongate shaft, further wherein the spring elements comprise inwardly directed grasping projections proximate their distal ends;

an indexing projection extending distally from the axially elongate shaft and positioned between the spring elements;

a proximal delivery system adapter configured to engage a grasping mechanism on a separate delivery system; and

a cowling configured to surround the coupler and transmit compressive force from an axially elongate tube, comprised by the separate delivery system, onto the spinal implant;

wherein axial motion of the coupler in the proximal direction, forced by proximal motion of the grasping mechanism on the delivery system, causes proximal withdrawal of the outwardly biased spring elements relative to the cowling, which maintains the spinal implant substantially immobile relative to the axially elongate tube of the delivery system;

further wherein the outwardly biased spring elements are maintained inwardly forced by a restricted lumen within the spinal implant and within which the proximal end of a vertebral following anchor portion is slidably constrained, wherein the spring elements grasp the anchor portion causing proximal withdrawal of the proximal end of the anchor portion causing the anchor portion to collapse in directions out of the longitudinal axis of the spinal implant; and

wherein maximum proximal withdrawal of the outwardly biased spring elements by the coupler pulls the proximal end of the anchor portion out of the spinal implant restricted lumen, allowing the outwardly biased spring elements to open and release their grip on the proximal portion of the anchor portion, resulting in the spring biased anchor portion to be restored to its maximum possible projection away from the longitudinal axis of the implant, following which the delivery system, cowling, and coupler can be removed from the patient.

33. The implant of Claim 8, wherein the resilient layer modulus of elasticity ranges between that of nucleus pulposus and cortical bone.

34. The implant of Claim 1, wherein the anchor portion has projections to penetrate the vertebrae for fixation.

35. The implant of Claim 1, wherein the anchor portion is larger in a lateral dimension than the annular defect.

36. The implant of Claim 1, wherein the anchor portion is configured to resist expulsion from the interdiscal space.

37. The implant of Claim 1, wherein the anchor portions comprise a spring component with a surrounding member that circumferentially attaches to the spring.

38. The implant of Claim 1, wherein the surrounding member comprises materials selected from a group including shape memory nitinol, superelastic nitinol, polyurethane, polycarbonate urethane, polyetheretherketone, polyethylene, and silicone.

39. The implant of Claim 1, wherein the anchor portion comprises a tube, sheet, film, wire, cable, or strip disposed to project superiorly, inferiorly, or both from the main body portion.

40. The implant of Claim 1, wherein the main body portion comprises a tail connector portion configured with a resilient layer to be compressed between the vertebrae during loading conditions.

41. The implant of Claim 8, wherein the tail portion comprises a resilient structure chosen from a group of materials including polyurethane, polycarbonate urethane, polyethylene, and silicone elastomer.

42. The implant of Claim 1, wherein the main body portion distracts the resting height of the adjacent vertebrae.

43. An implant according to Claim 1 wherein the main body portion is sized to be positioned within the annulus of the vertebral disc without extending inwardly beyond the innermost lamella of the annulus.

44. A method for performing at least one of; (i) treating an annular defect in an intervertebral disc between adjacent vertebrae of a patient, (ii) maintaining a height between the adjacent vertebrae, (iii) nuclear replacement, (iv) height distraction and preservation, (v) innerbody fusion, (vi) autograft containment, (vii) spondylolisthesis stabilization or correction, (viii) treating spinal stenosis, (ix) providing an annulus seal for nucleus injection, or (x) dynamic stabilization of the spine, in a human or animal subject, said method comprising the steps of:

(A) obtaining or providing an implantable device that comprises a main body portion, a tail portion and an anchor portion; and

(B) implanting the implantable device in the subject's body such that the main body portion is positioned within an intervertebral disc space between adjacent vertebrae, the tail portion is substantially in contact or engagement with an outer aspect of the intervertebral disc and the anchor portion engages or extends through an endplate of at least one vertebra.

45. A method according to claim 44 wherein the anchor follows the vertebra with which it is engaged independent of the spacing or alignment between adjacent vertebrae surrounding the implant.

46. A method according to claim 44 wherein the tail connector supports a lip portion of a vertebrae under physiological compression loads.

47. A method according to claim 44 wherein the tail portion has a proximal surface that substantially conforms to a curvature of the intervertebral disc.

48. A method according to claim 44 wherein main body portion comprises an opening on its superior surface, its inferior surface, or both, and wherein the anchor portion extends from an interior portion of the main body portion through said opening to a position extending beyond the exterior geometry of the main body portion.

49. A method according to claim 48 wherein the main body portion is configured to fit between the vertebrae following distraction of the vertebrae and wherein the method further comprises the step of causing distraction of the vertebrae.

50. A method according to claims 49 wherein the main body portion comprises a tail connector portion that is configured to fit between the vertebrae and wherein Step B comprises inserting said tail connector portion between vertebrae without concurrent distraction.

51. A method according to any of claims 44-50 wherein the intervertebral disc comprises an annulus having a plurality of lamellae including an innermost lammela and a nucleus pulposis and wherein Step B comprises positioning the implantable device within the annulus such that a portion of the device frictionally engages or inserts into the annulus..

52. A method according to claim 51 wherein a defect exists in the annulus and wherein at least part of the main body portion of the implantable device is positioned within the annular defect.

53. A method according to claim 51 further comprising the step of creating a channel that extends into or through the annulus and wherein at least part of the main body portion of the implantable device is positioned within that channel.

54. A spinal implant device implantable in the body of a human or animal subject, comprising:

an implant body comprising a distal head portion, a mid portion and a proximal tail flange;

at least one lateral engagement member on the mid-portion of the device, said lateral engagement member being initially deployable in a collapsed configuration and subsequently moveable to an extended position whereby it frictionally engages or extends into an adjacent anatomical structure of the subject's body; and

at least one proximal engagement member on the proximal tail flange, said at least one proximal engagement member being initially deployable in a collapsed configuration and subsequently moveable to an extended position whereby it frictionally engages or extends into an adjacent anatomical structure of the subject's body.

55. A device according to claim 54 wherein at least the distal head portion has a height that is greater than its width.

56. A device according to claim 54 wherein the at least one lateral engagement member comprises a plurality of spring members.

57. A device according to claim 54 wherein the at least one proximal engagement member comprises a plurality of elastic or superelastic strut members.

58. A device according to claim 54 wherein the at least one proximal engagement member and proximal engagement member are produced from tubing, sheet, foil, wire, braid, strand, deposition, lithography, print or rod material.

59. A device according to claim 54 further comprising at least one tissue ingrowth or engagement area to facilitate interlocking, union, coupling, connection, adhesion or other engagement between the device body tissue that develops after implantation of the device within the subjects body.

60. A device according to claim 58 wherein the at least one tissue ingrowth or engagement area comprises a structure or surface feature selected from: holes, apertures, perforations, surface disruptions, serrations, grooves, channels, depressions, protrusions, bumps, cavities and other tissue ingrowth or engagement areas.

61. A device according to claim 54 wherein the proximal tail flange is absent and replace by at least one proximal engagement member that is connected to the implant body.

62. A device according to claim 54 having variable length.

63. A device according to claim 62 whrein the device is biased toward a shortest variable length so as to capture or compress an anatomical structure or body portion between the lateral and proximal engagement members.

64. A spinal implant device comprising a distal portion that inserts into an intervertebral disc and a proximal portion that resides outside of the

intervertebral disc, wherein the length between the distal portion and the proximal portion is variable.

65. A device according to claim 64 wherein the device is biased toward a shortened length.

66. A device according to claim 65 wherein the proximal and distal portions are configured such that the bias causes a portion of the annulus fibrosis of the intervertebral disc to be captured or compressed between the distal portion and the proximal portion.

67. A device according to claim 64 wherein the distal portion comprises a head member that is insertable into or through an opening or defect in the annulus fibrosis of the intervertebral disc and the proximal portion comprises at least one flange or other abutment member that abuts against an outer surface of the intervertebral disc and/or portions of adjacent vertebrae.

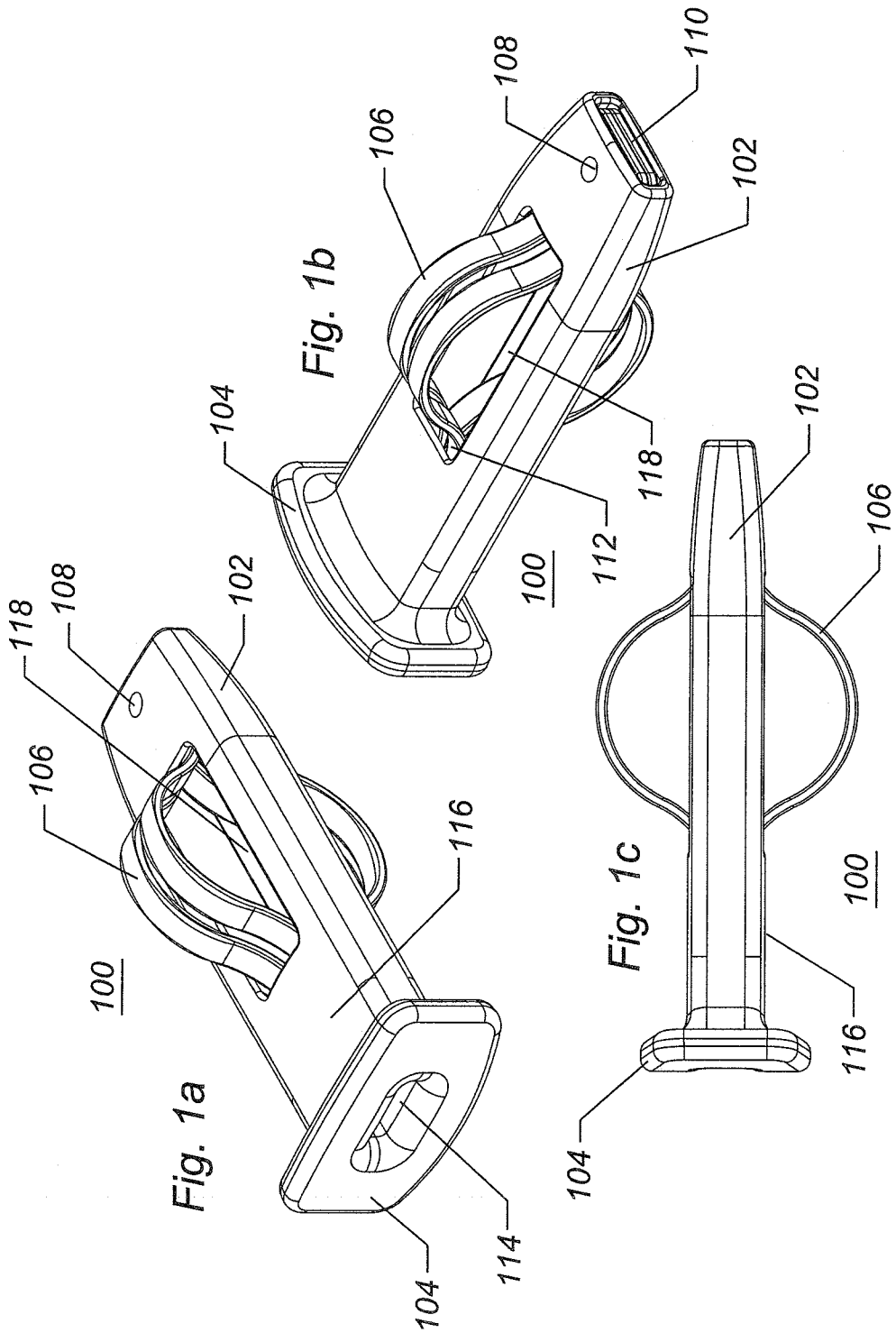
Fig. 1a
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Fig. 1b
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Fig. 1c
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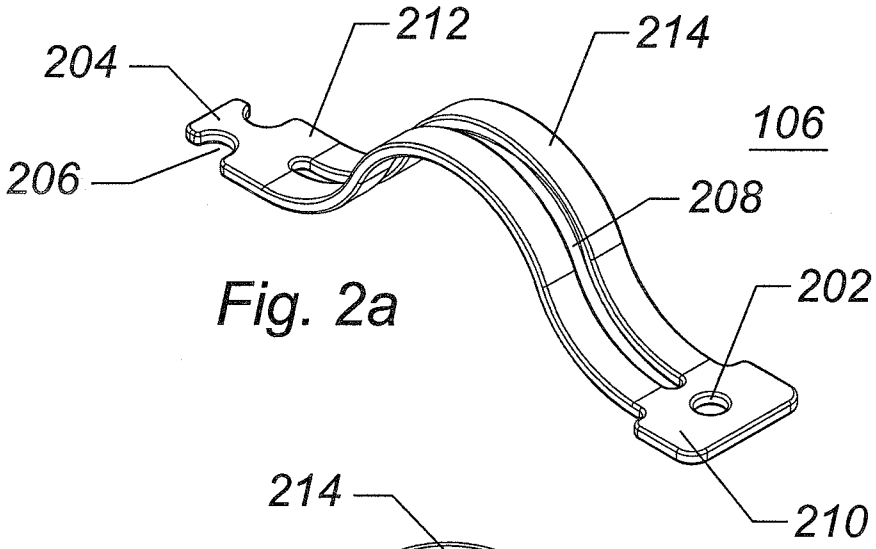

Fig. 2a

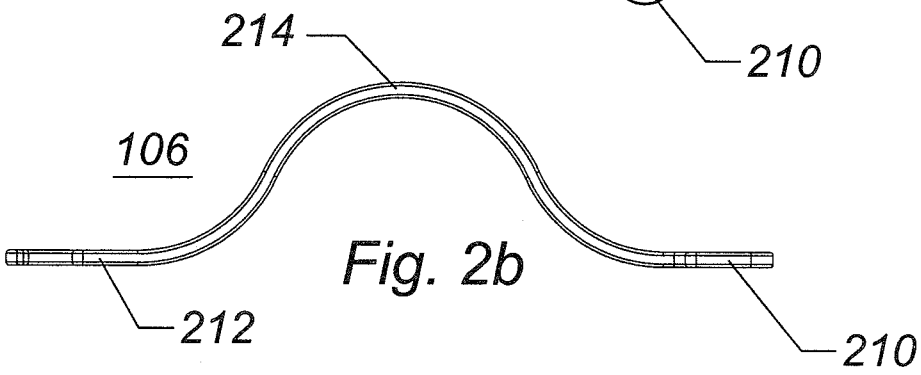

Fig. 2b

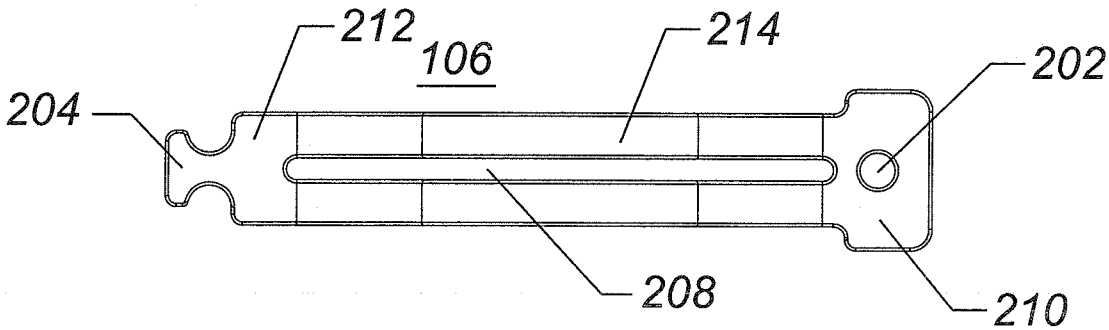

Fig. 2c

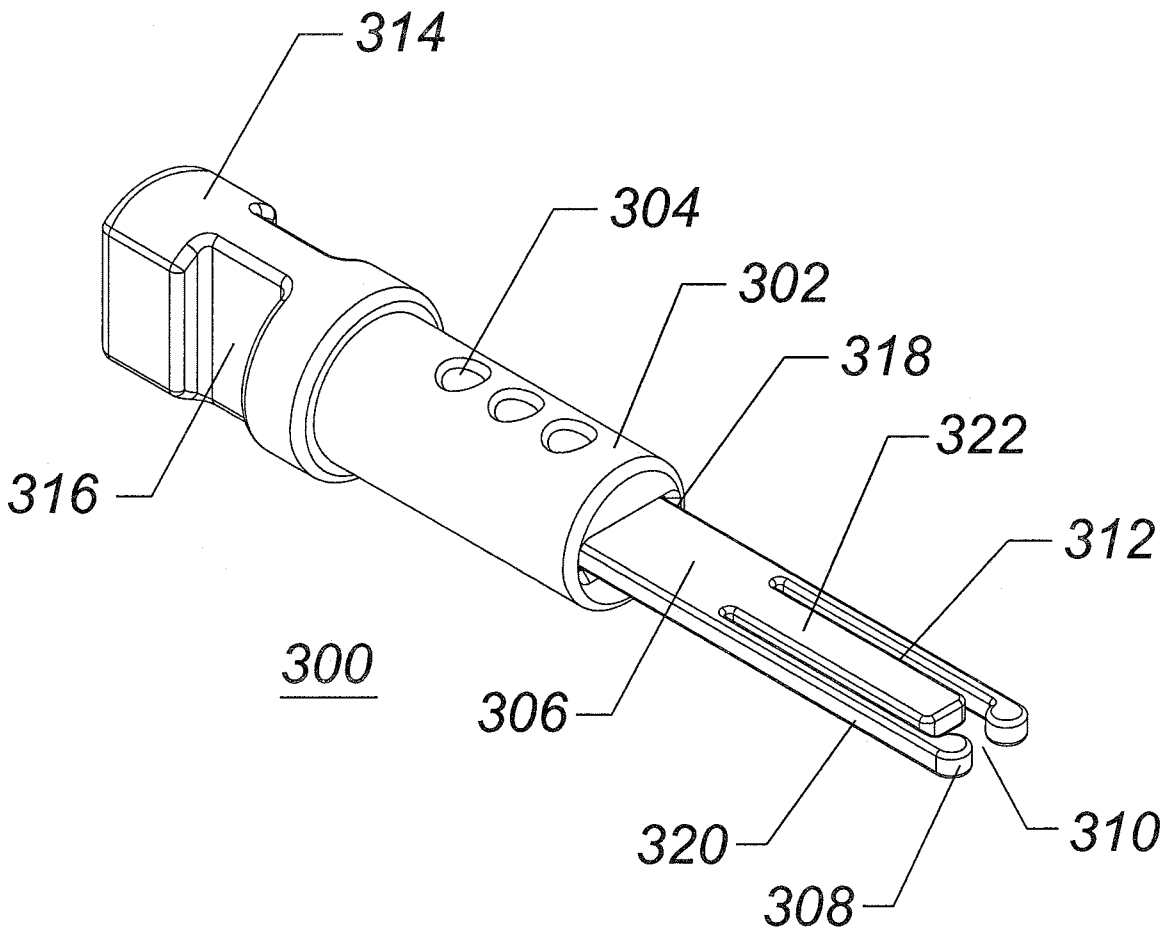

Fig. 3

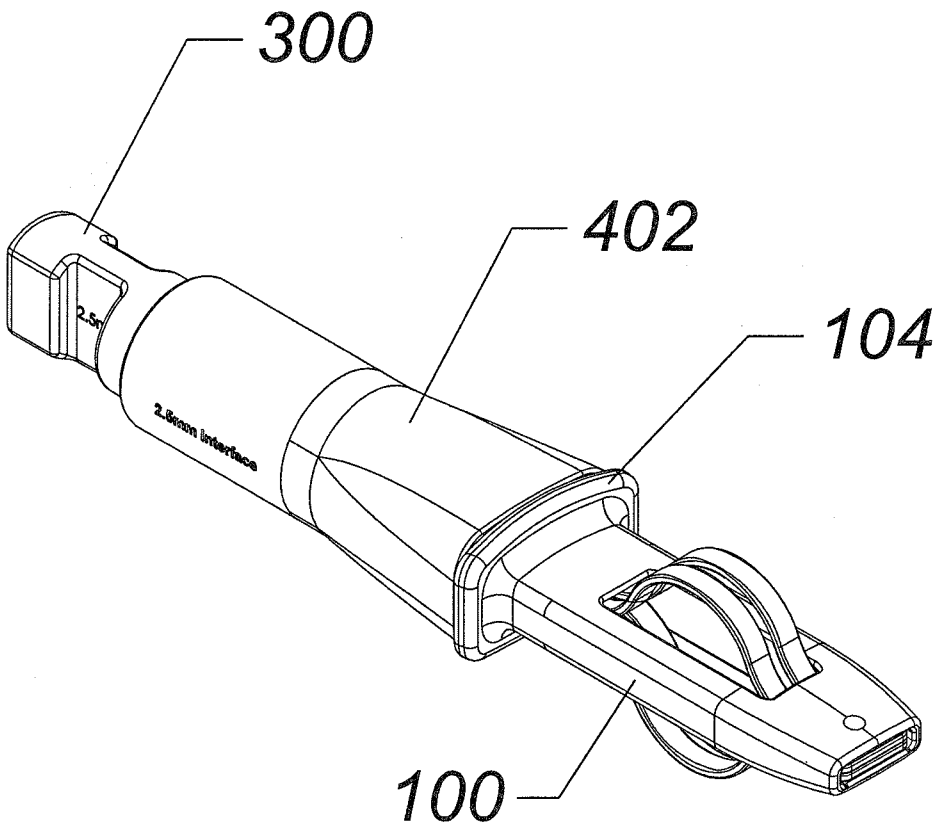

Fig. 4

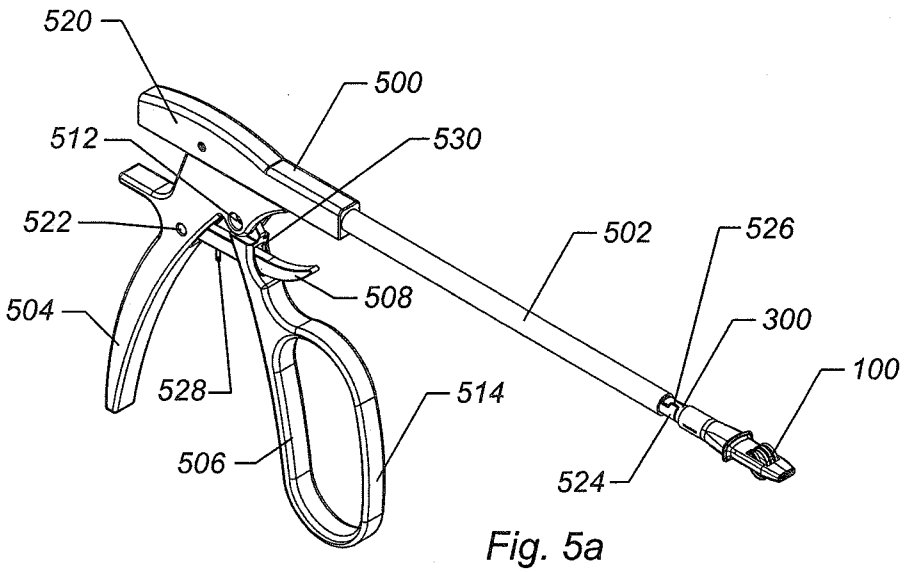
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Fig. 5a

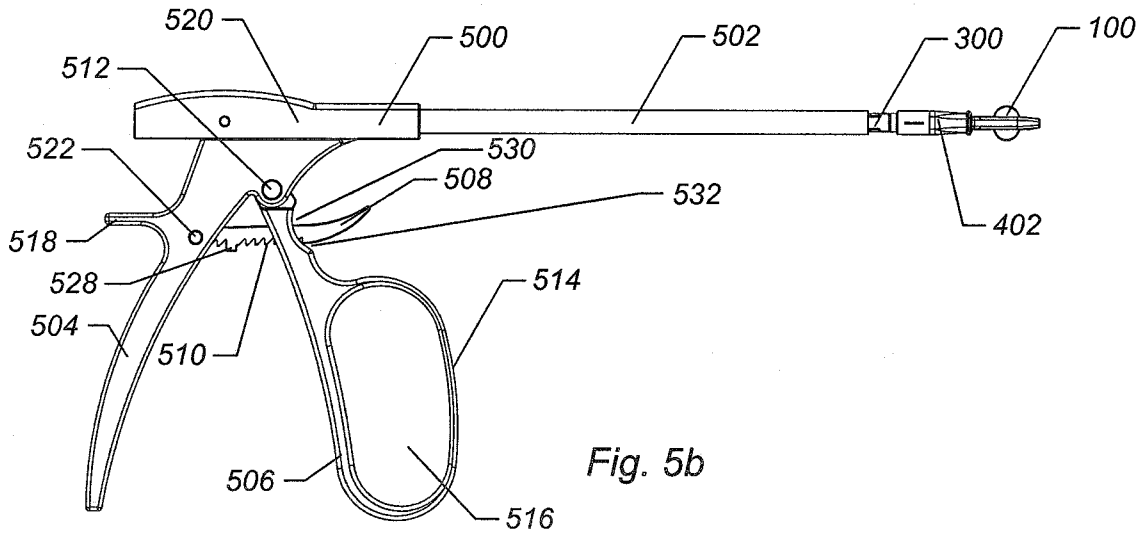
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Fig. 5b

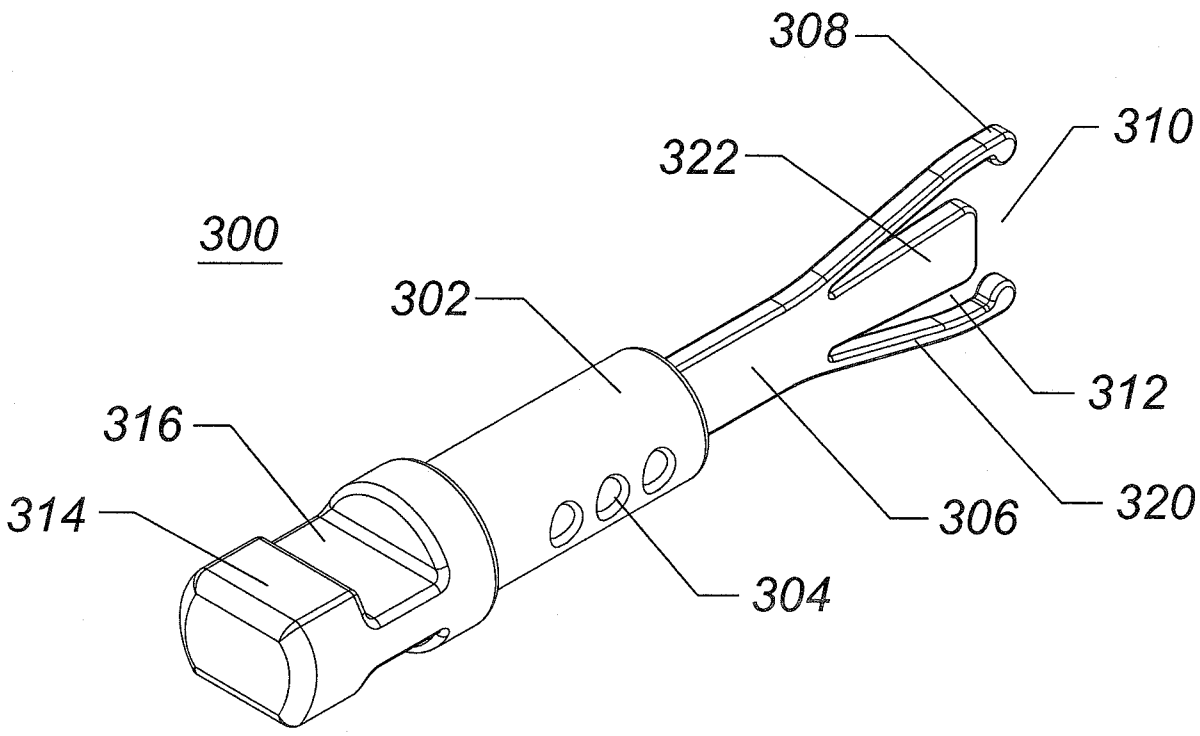

Fig. 6

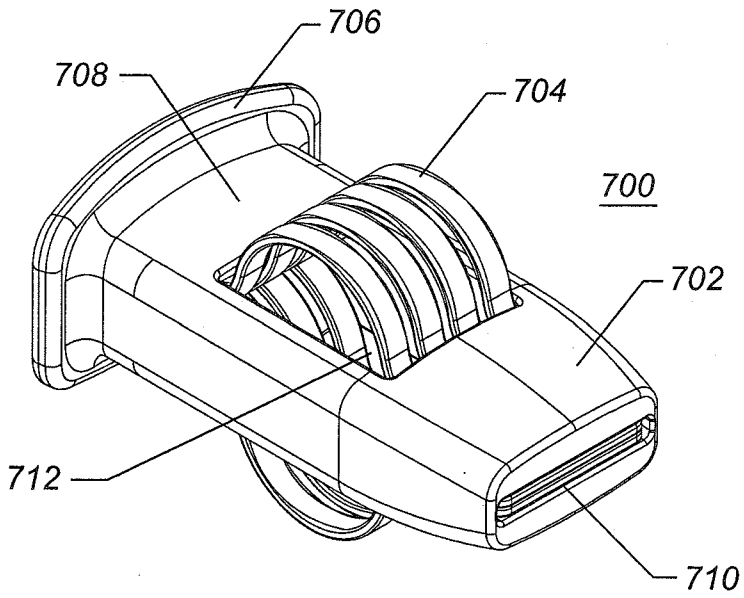

Fig. 7a

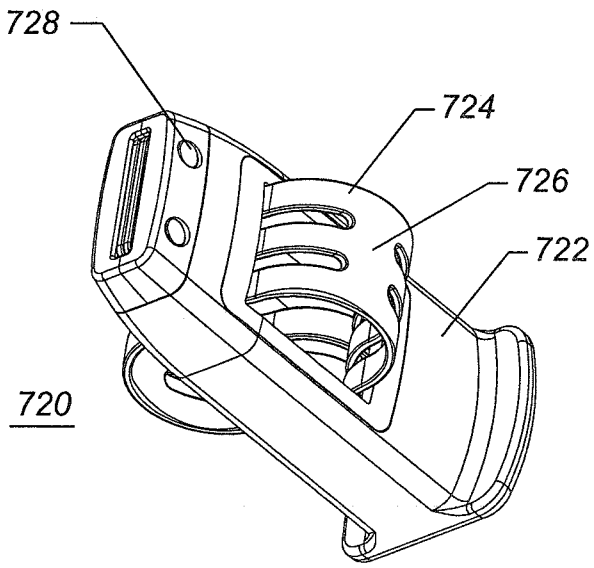

Fig. 7b

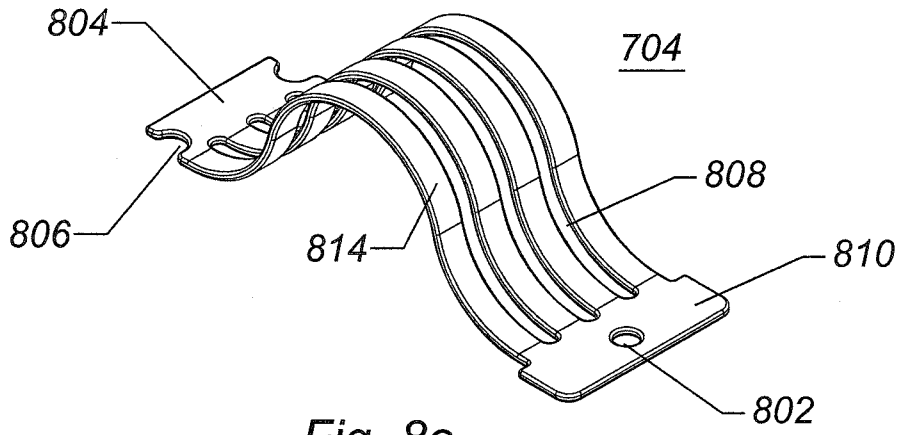

Fig. 8a

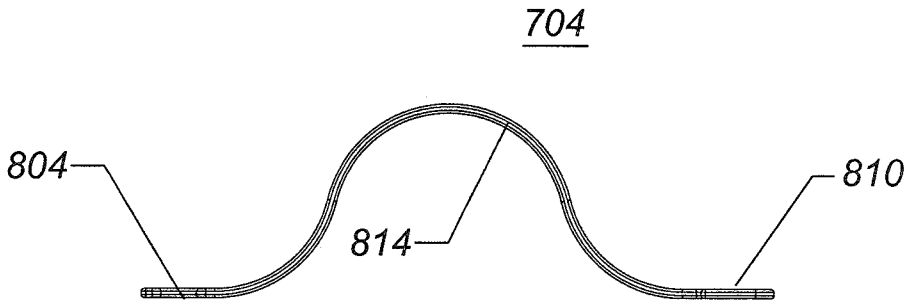

Fig. 8b

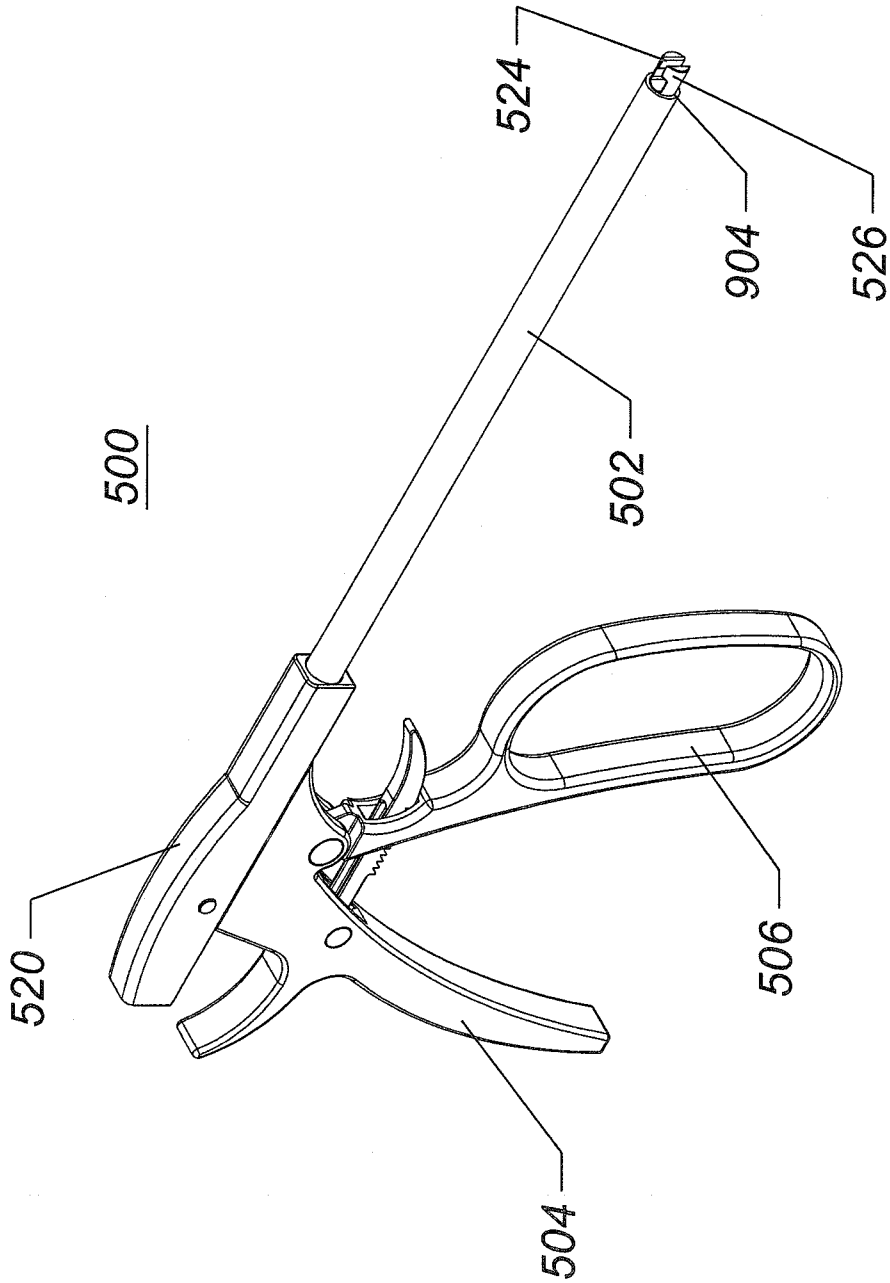

Fig. 9

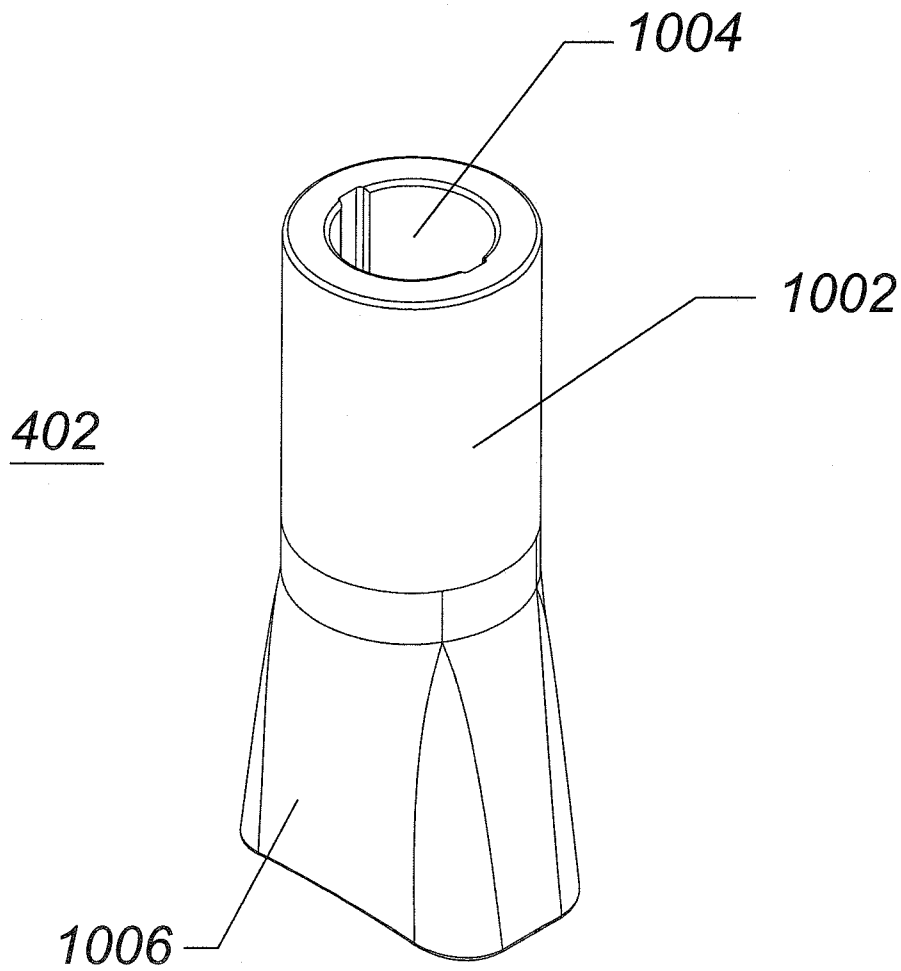

Fig. 10

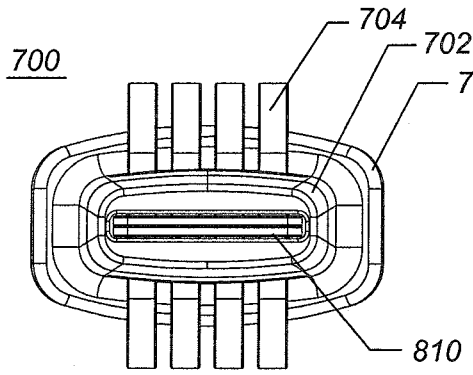

Fig. 11a

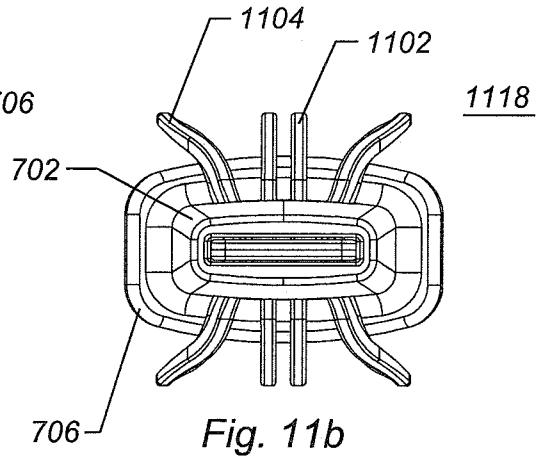

Fig. 11b

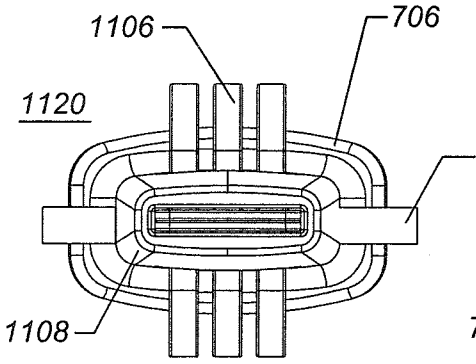

Fig. 11c

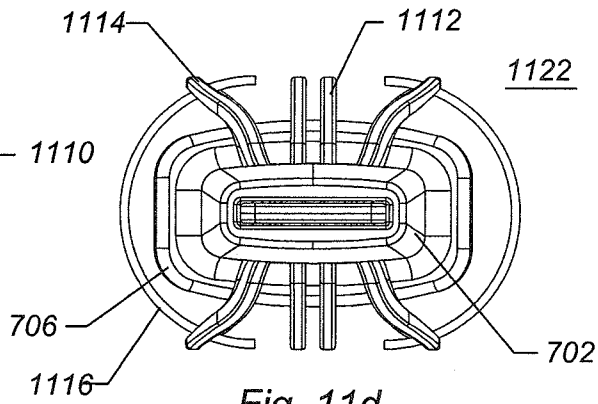

Fig. 11d

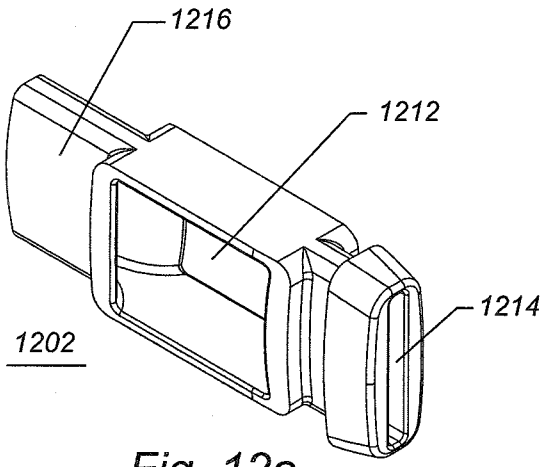

Fig. 12a

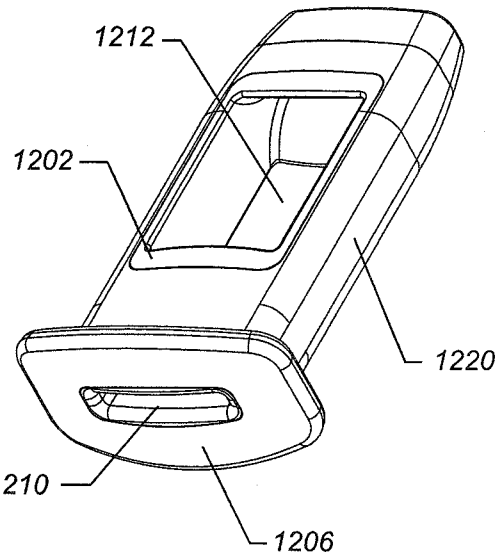

Fig. 12b

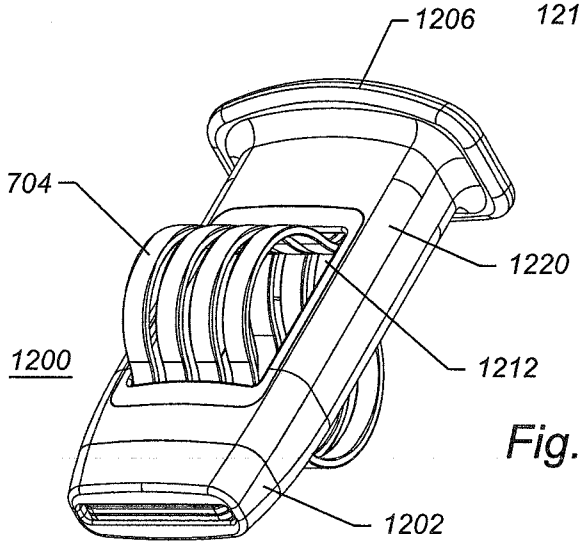

Fig. 12c

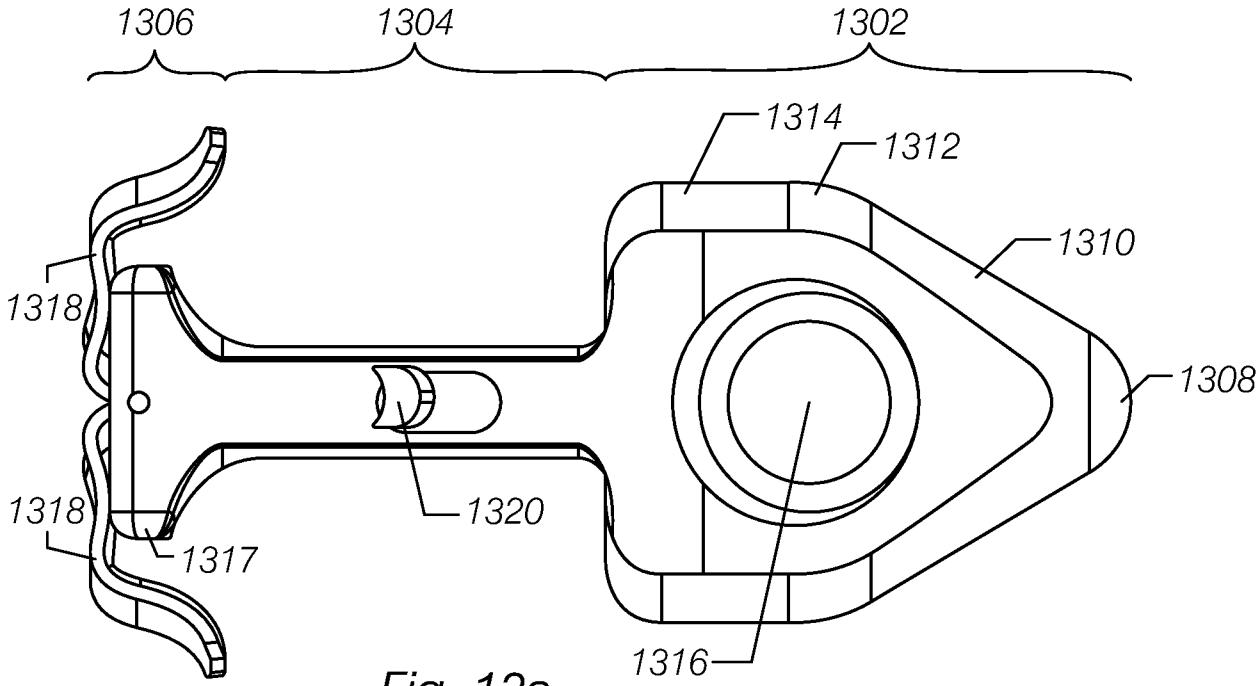

Fig. 13a

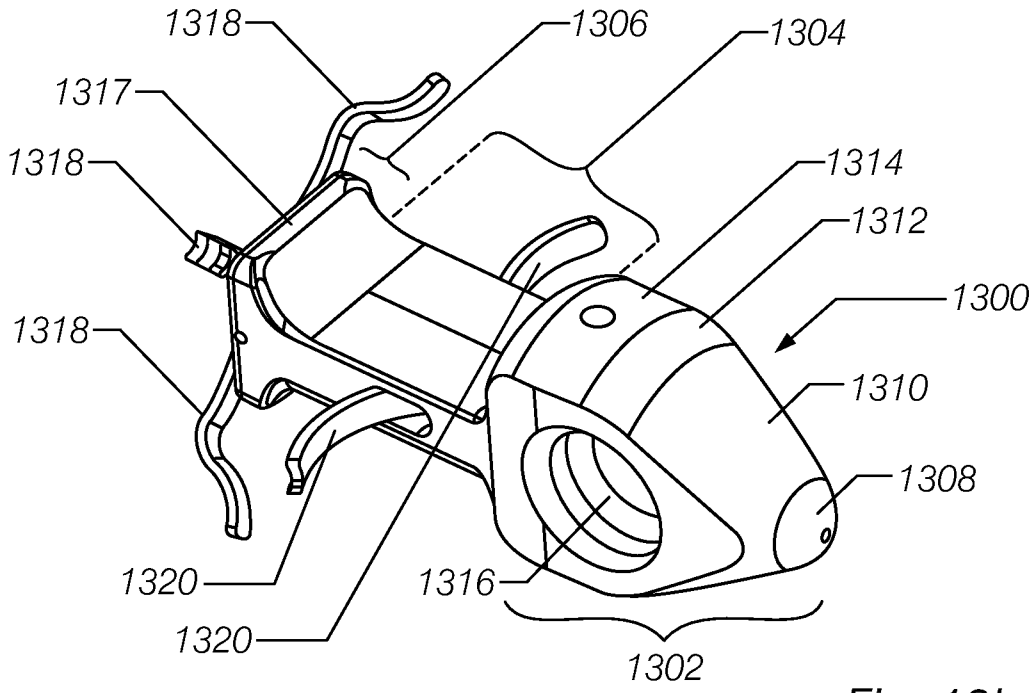

Fig. 13b

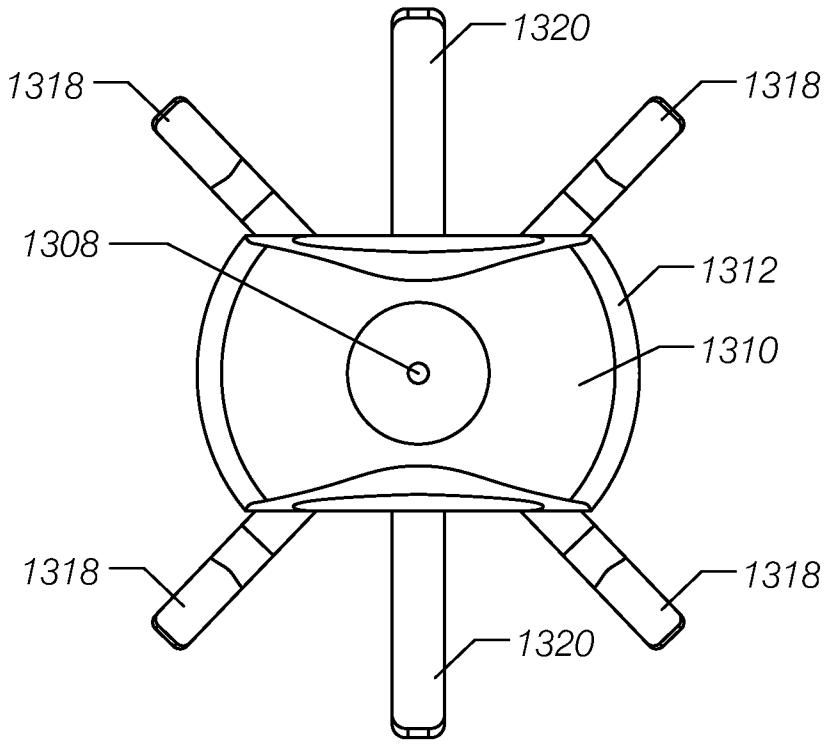

Fig. 13c

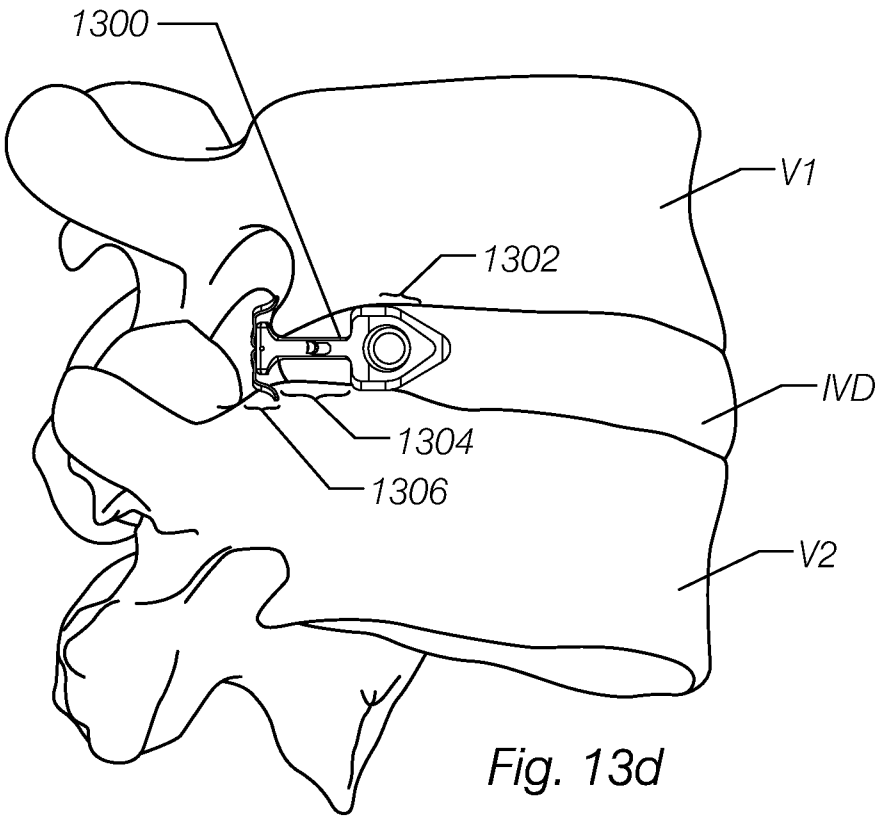

Fig. 13d

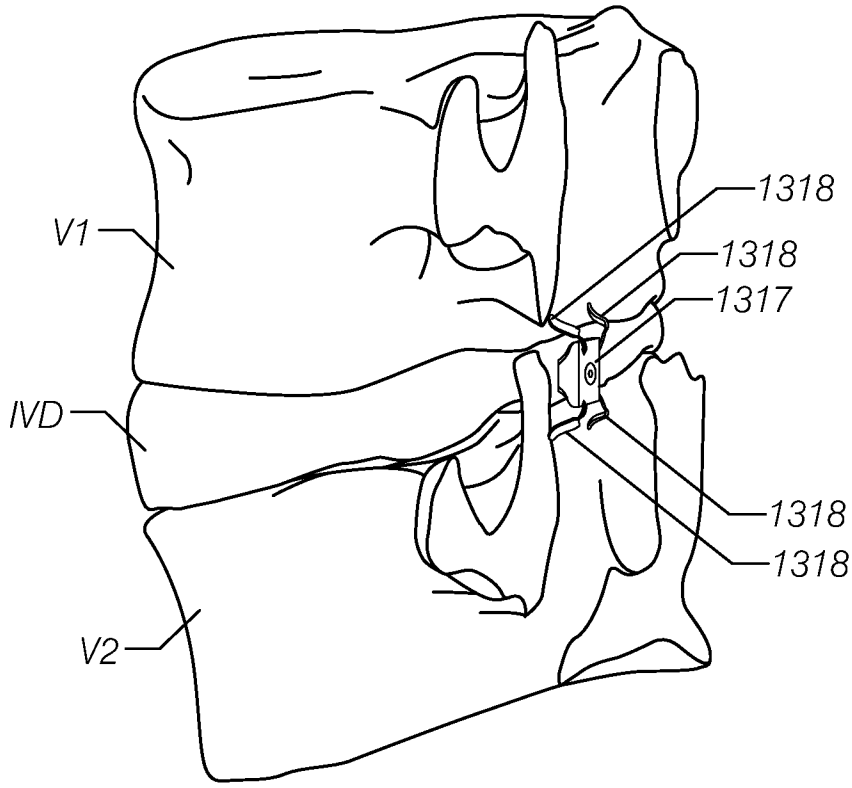

Fig. 13e

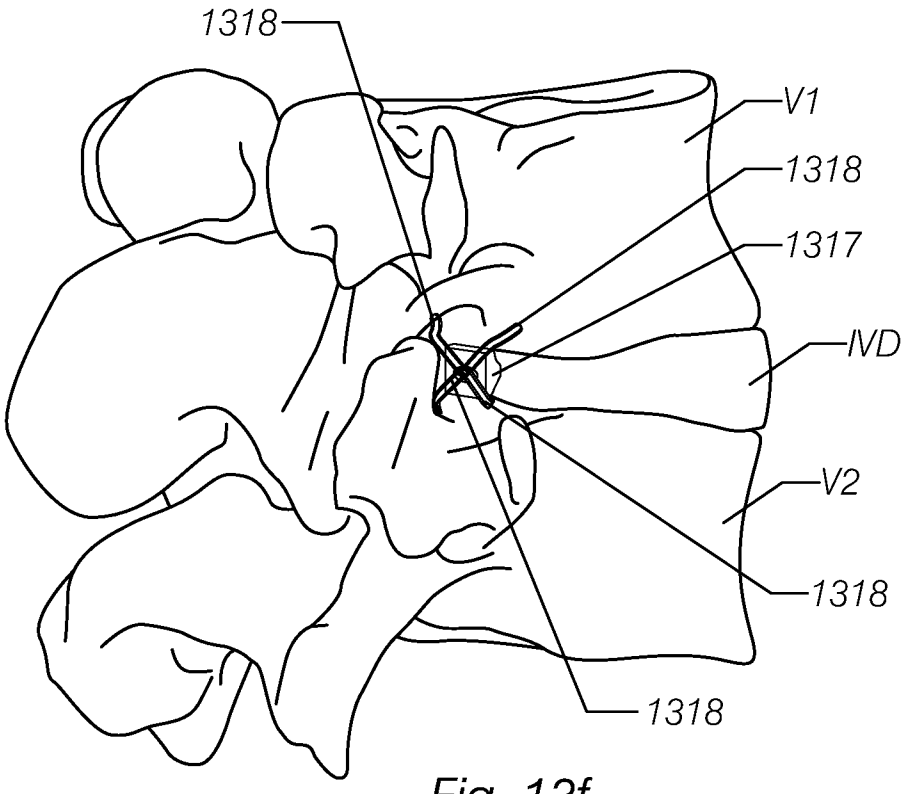

Fig. 13f