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Suddaby

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(54) **EXPANDABLE TOTAL DISC REPLACEMENT IMPLANT**

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See application file for complete search history.

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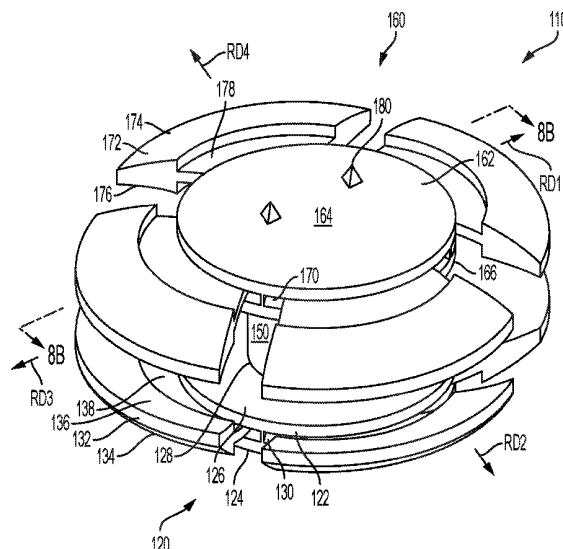
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(57) **ABSTRACT**

An expandable intervertebral total disc replacement implant, including an inferior component, including a first core including a first outer surface and a first inner surface, and a first plurality of arms telescopingly engaged with the first core, a superior component, including a second core including a second outer surface and a second inner surface, and a second plurality of arms telescopingly engaged with the second core, and an expansion mechanism connected to the first inner surface and the second inner surface, the expansion mechanism operatively arranged to displace the superior component with respect to the inferior component.

19 Claims, 13 Drawing Sheets



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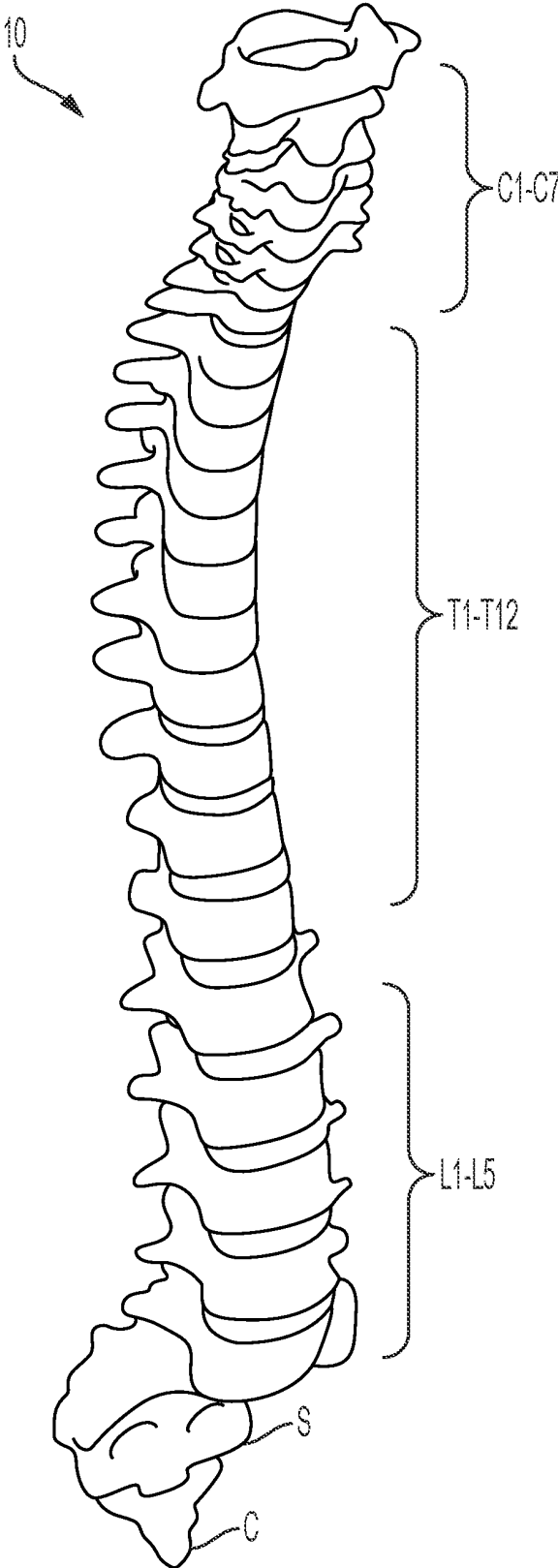


FIG. 1

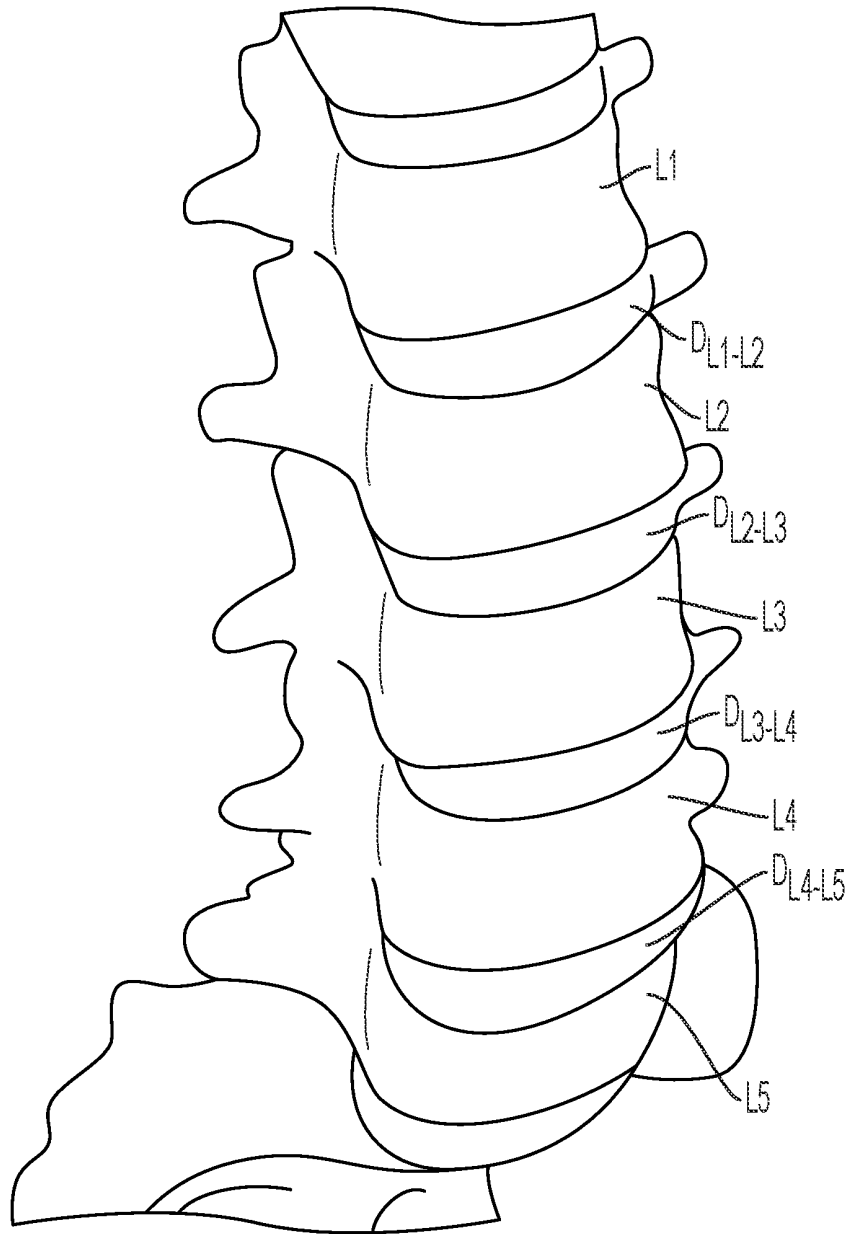


FIG. 2

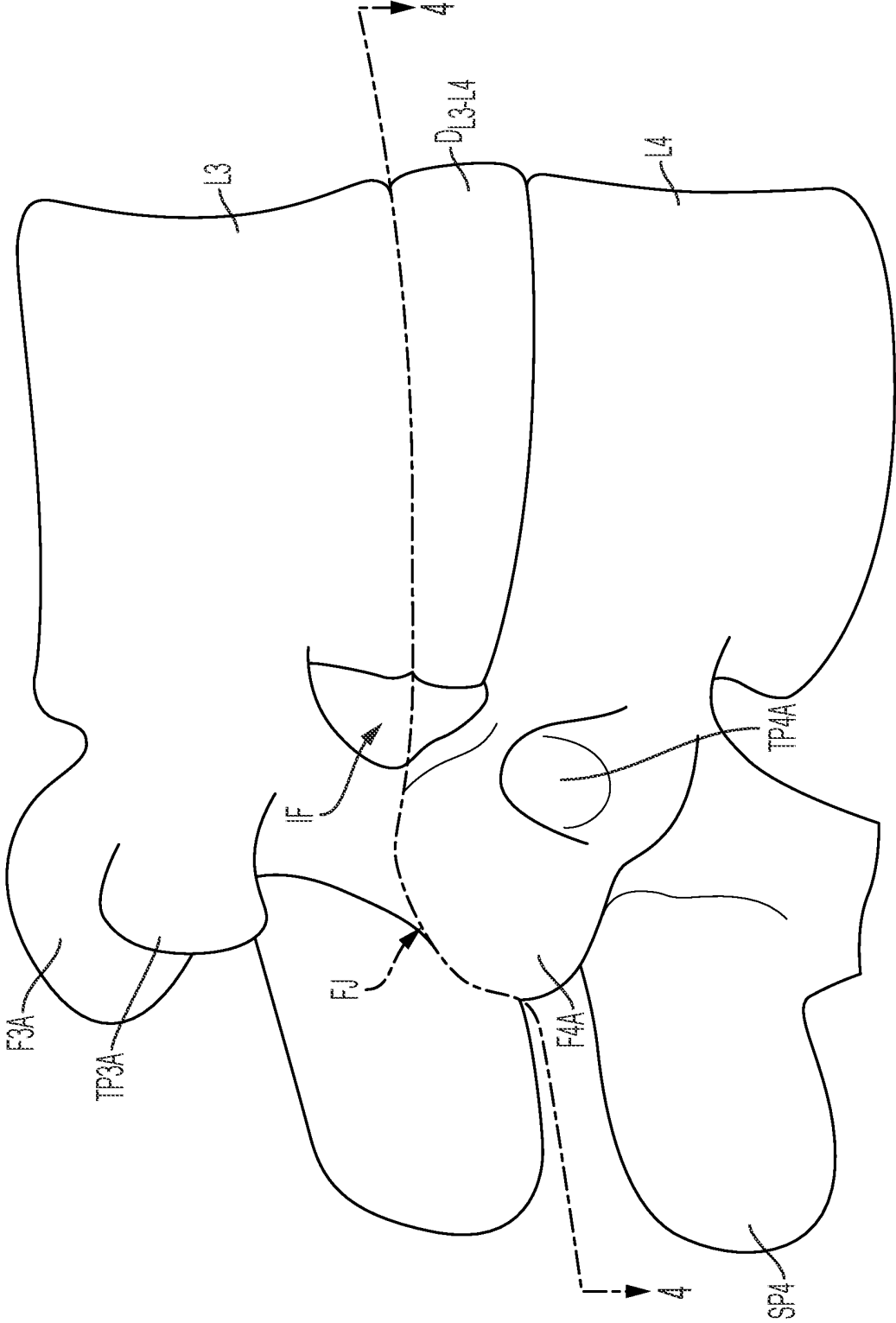
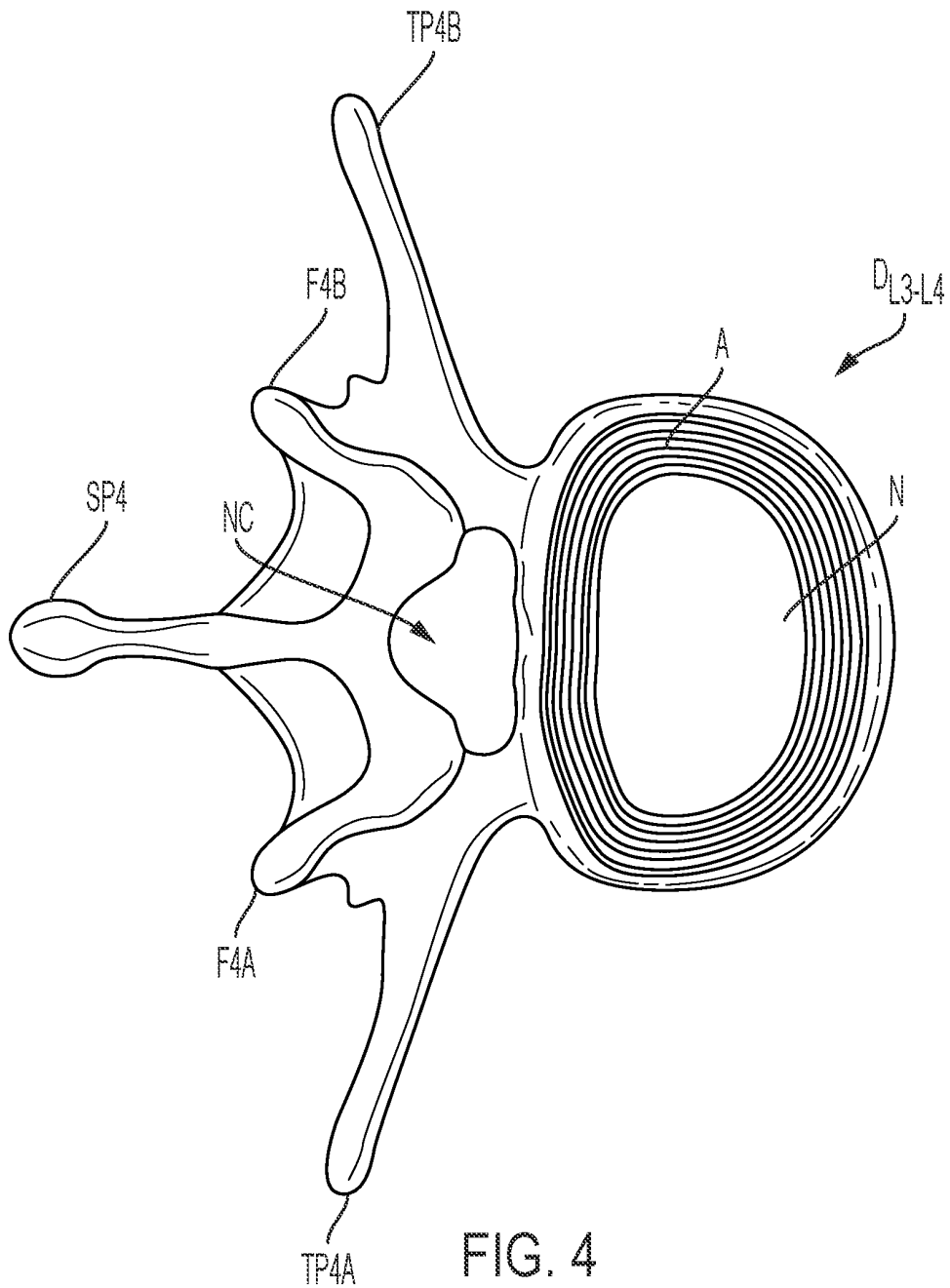


FIG. 3



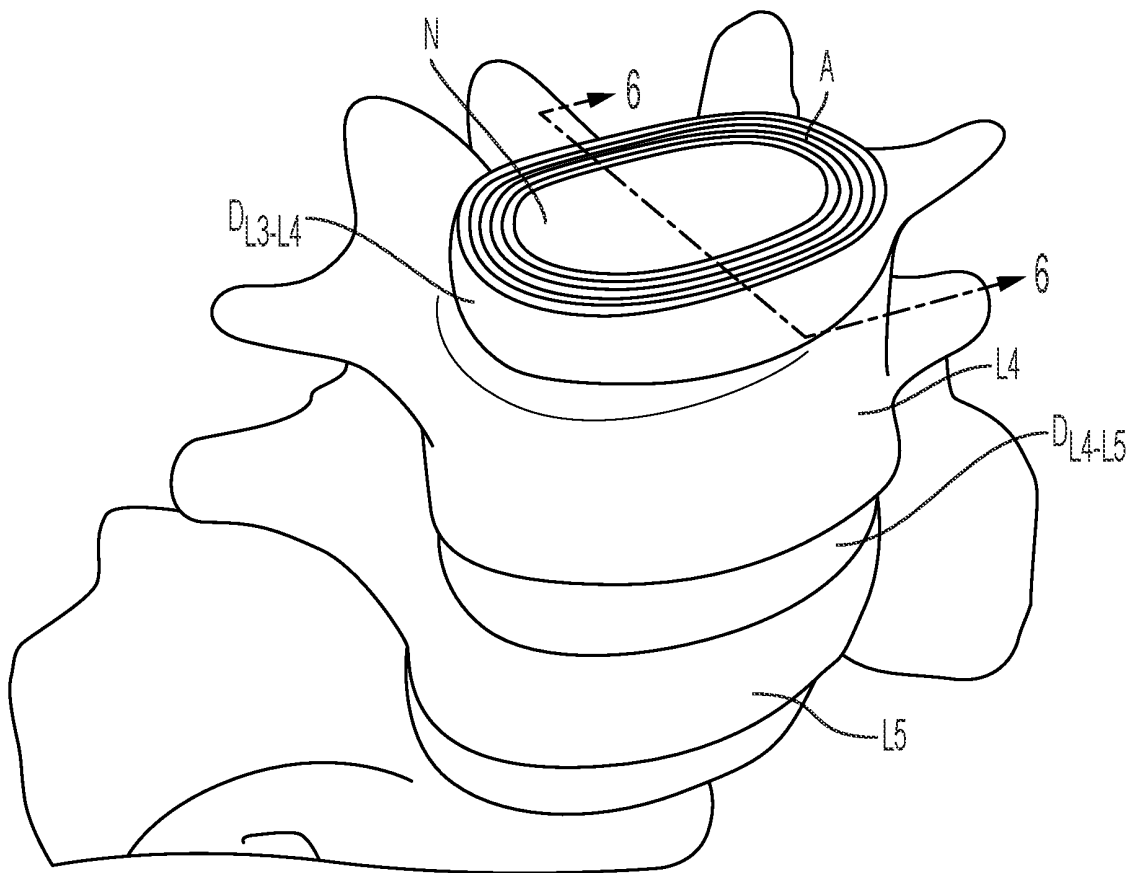


FIG. 5

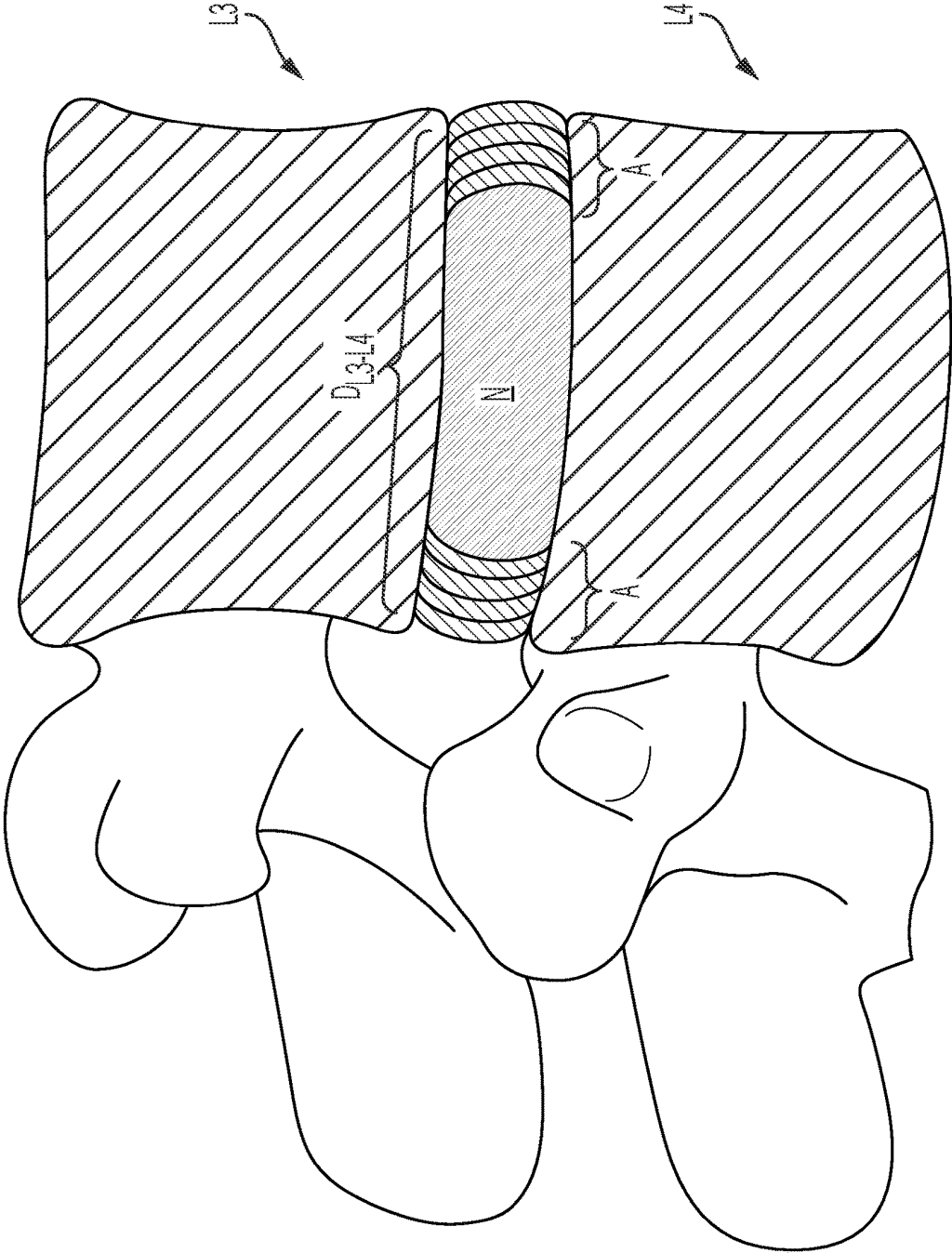


FIG. 6

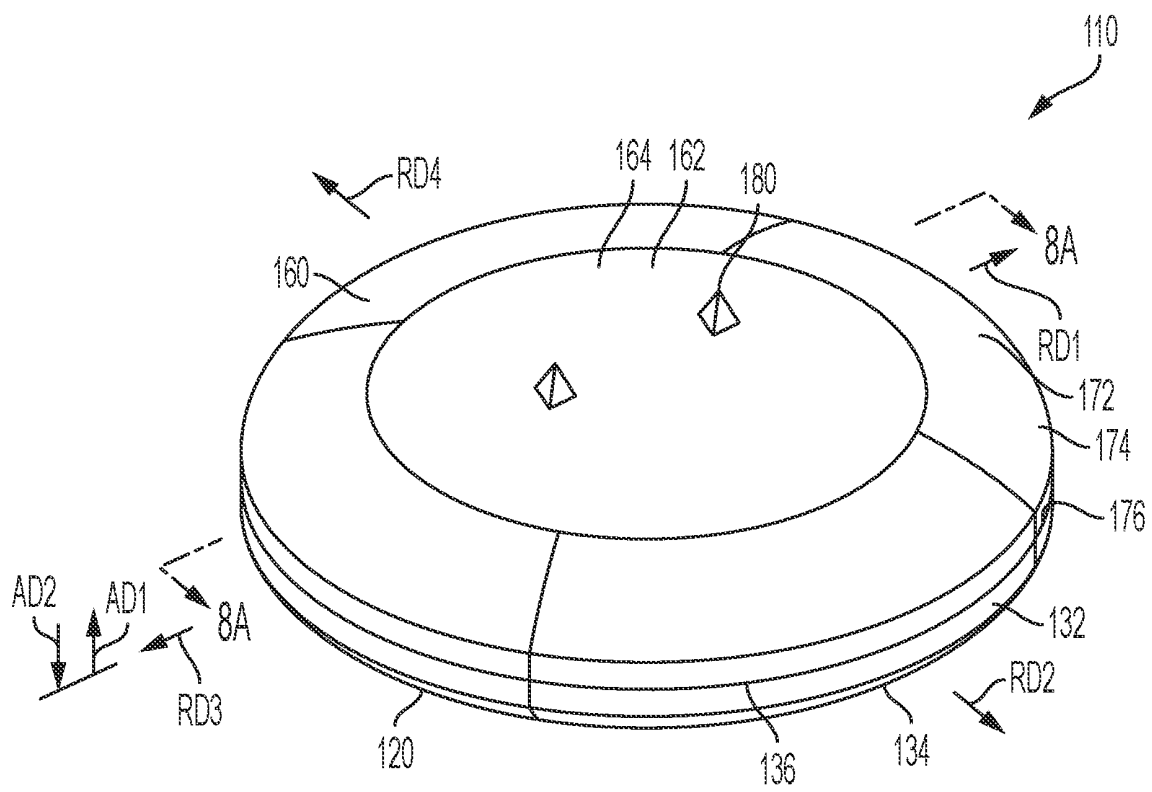


FIG. 7A

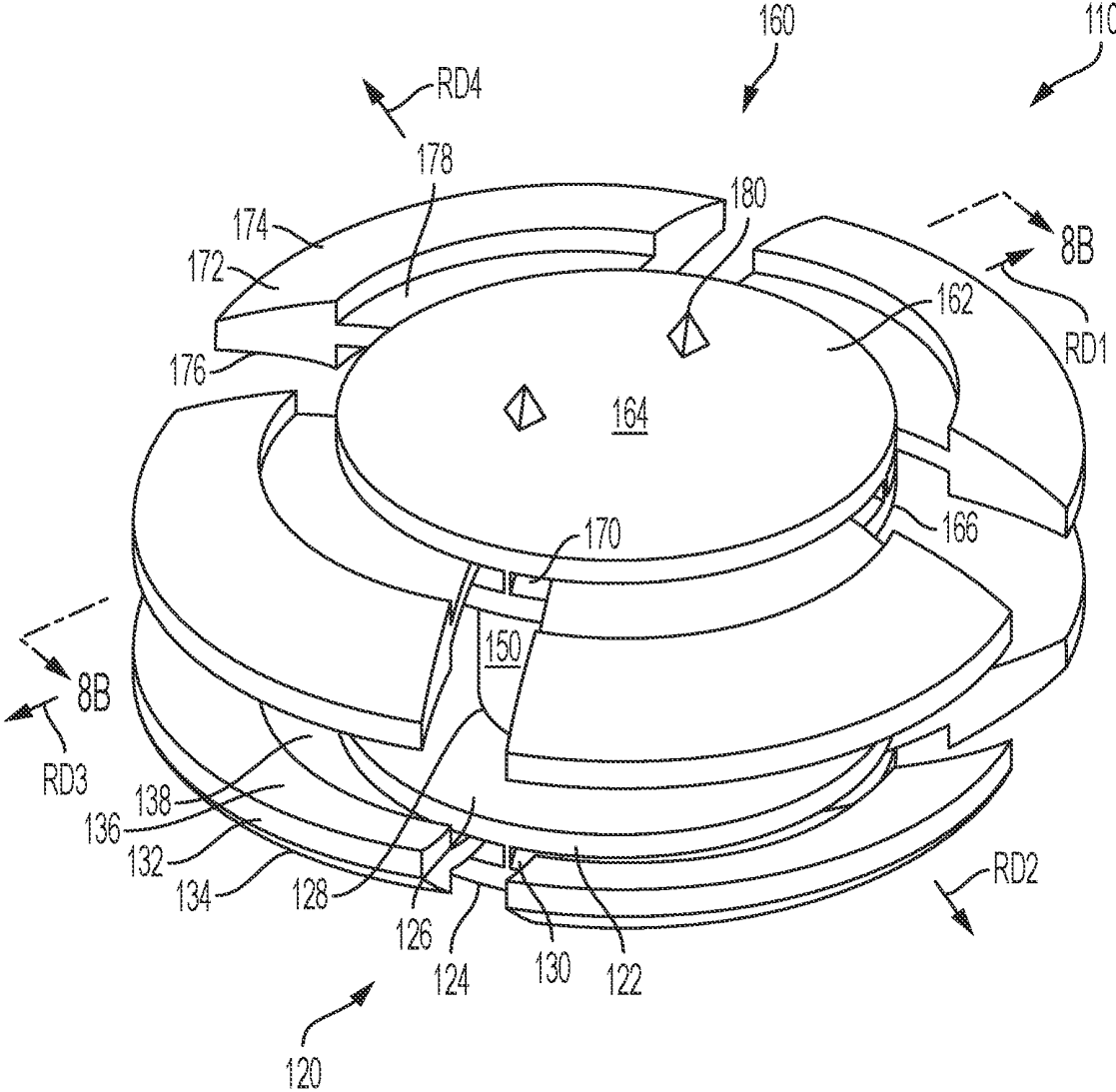


FIG. 7B

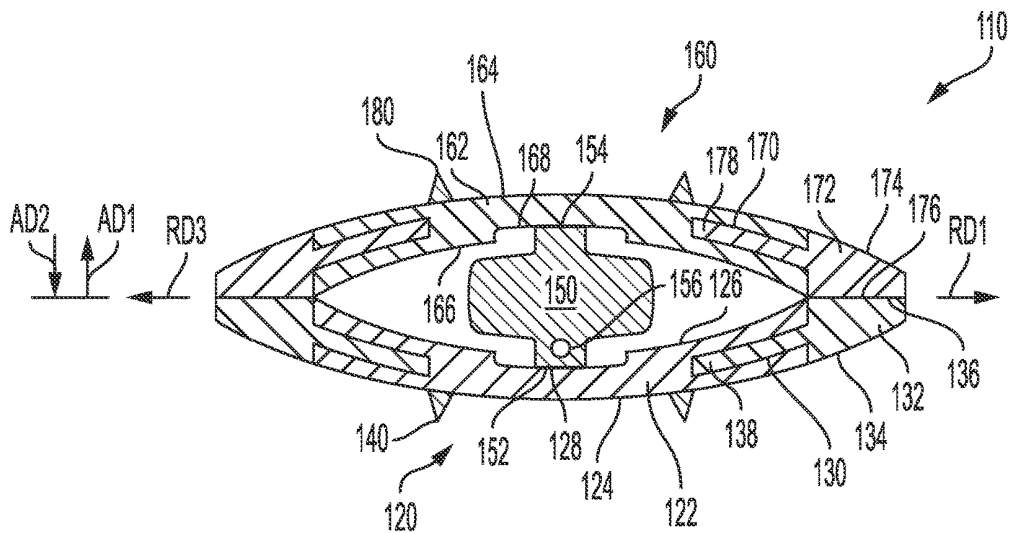


FIG. 8A

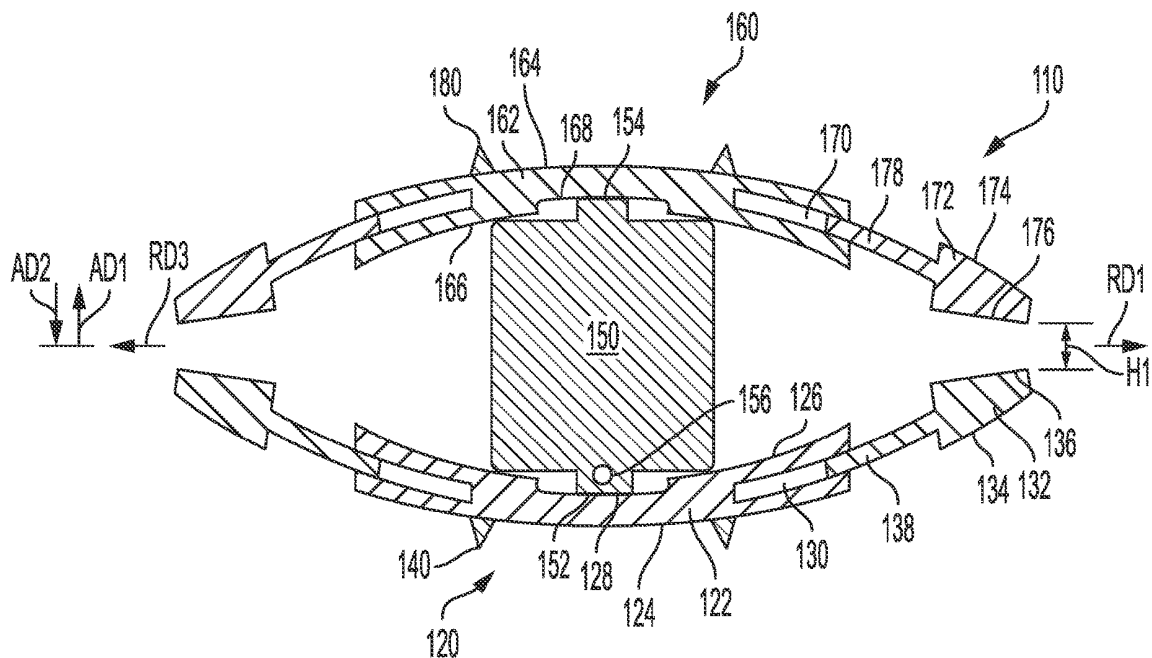


FIG. 8B

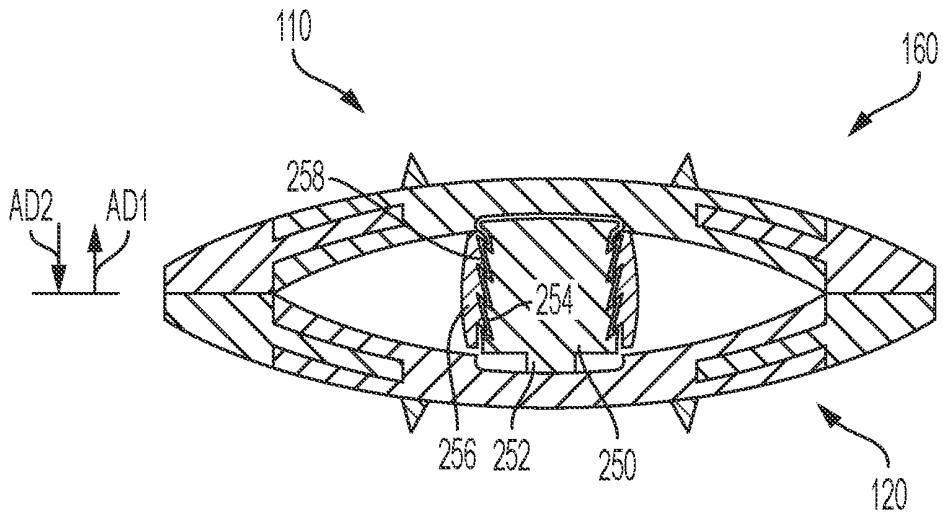


FIG. 9

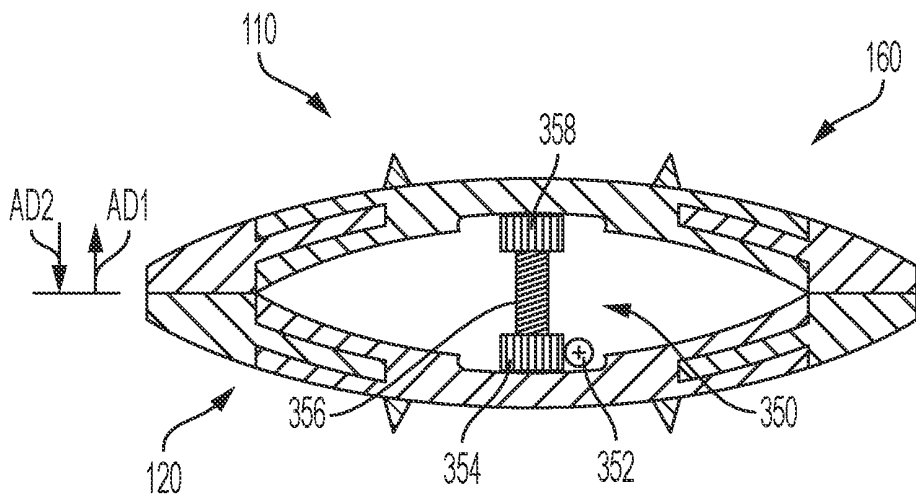


FIG. 10

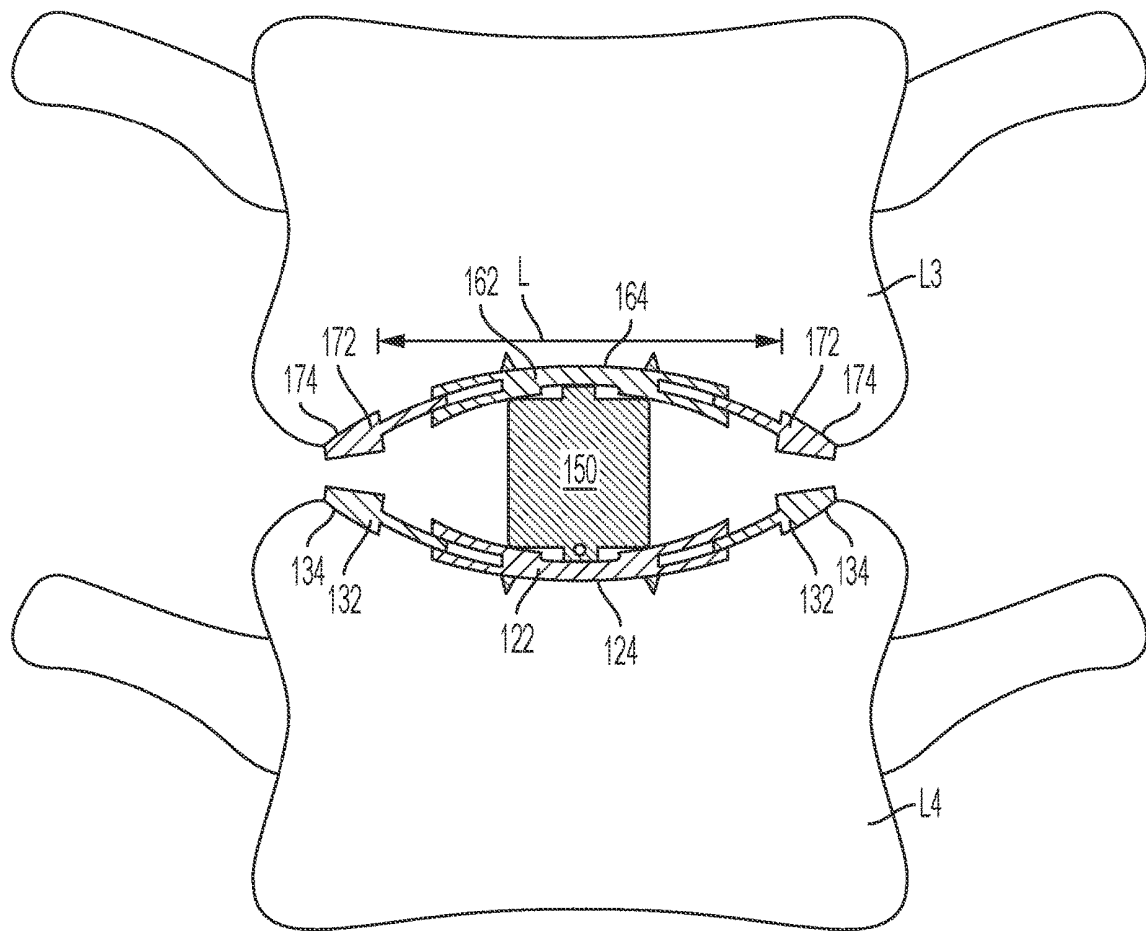


FIG. 11

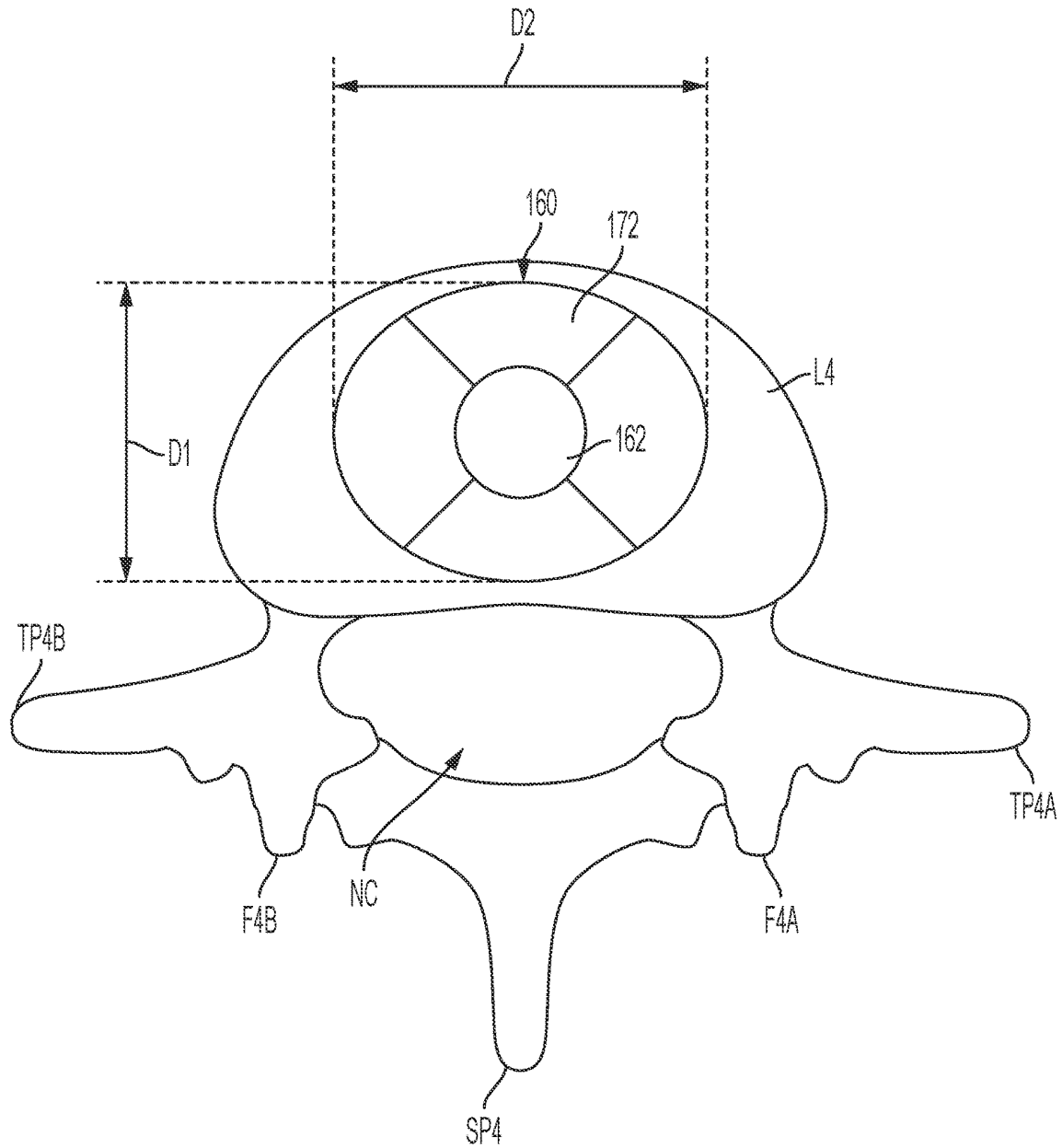


FIG. 12A

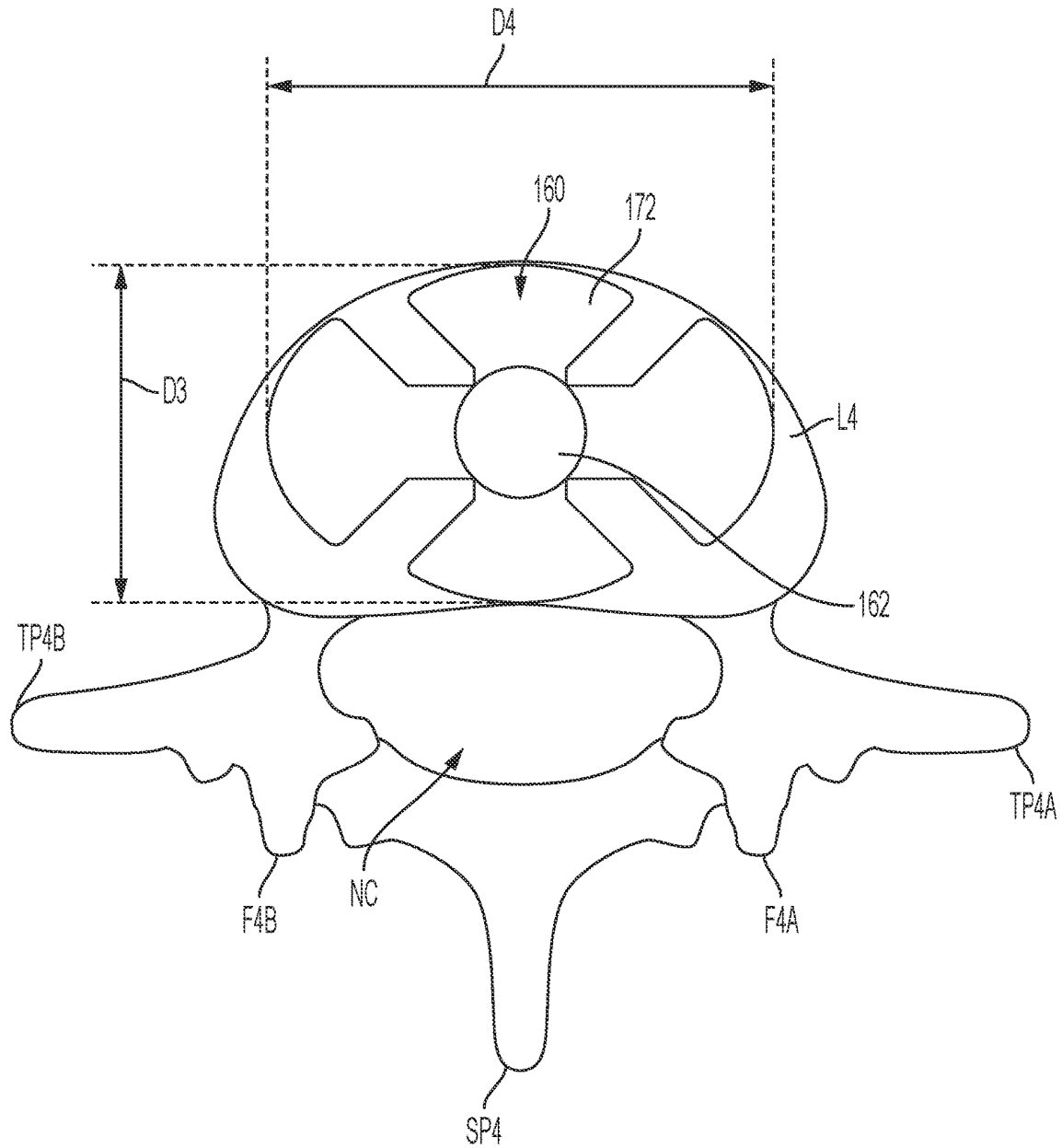


FIG. 12B

1

EXPANDABLE TOTAL DISC REPLACEMENT
IMPLANT

FIELD

The present disclosure relates to orthopedic surgery, and more particularly to an expandable and deployable intervertebral or total disc replacement implant capable of being placed within an intervertebral disc space and expanded.

BACKGROUND

The spinal column, or backbone, is one of the most important parts of the body. It provides the main support, allowing us to stand upright, bend, and twist. As shown in FIG. 1, thirty three (33) individual bones interlock with each other to form the spinal column. The vertebrae are numbered and divided into regions. The cervical vertebrae C1-C7 form the neck, support the head and neck, and allow nodding and shaking of the head. The thoracic vertebrae T1-T12 join with the ribs to form the rib cage. The five lumbar vertebrae L1-L5 carry most of the weight of the upper body and provide a stable center of gravity when a person moves. Five vertebrae of the sacrum S and four of the coccyx C are fused. This comprises the back wall of the pelvis. Intervertebral discs are located between each of the mobile vertebra. Intervertebral discs comprise a thick outer layer with a crisscrossing fibrous structure annulus A that surrounds a soft gel-like center, the nucleus N. Discs function like shock-absorbing springs. The annulus pulls the vertebral bodies together against the elastic resistance of the gel-filled nucleus. When we bend, the nucleus acts like a ball bearing, allowing the vertebral bodies to roll over the incompressible gel. Each disc works in concert with two facet joints, forming a spinal motion segment. The biomechanical function of each pair of facet joints is to guide and limit the movement of the spinal motion segment. The surfaces of the joint are coated with cartilage that helps each joint move smoothly. Directly behind the discs, the ring-like vertebral bodies create a vertical tunnel called the spinal canal or neuro canal. The spinal cord and spinal nerves pass through the spinal canal, which protects them from injury. The spinal cord is the major column of nerve tissue that is connected to the brain and serves as an information super-highway between the brain and the body. The nerves in the spinal cord branch off to form pairs of nerve roots that travel through the small openings between the vertebrae and the intervertebral foramens.

Various medical conditions require a surgeon to repair, remove and/or replace the aforementioned discs. For example, in one surgical procedure, known as a discectomy (or diskectomy) with interbody fusion, the surgeon removes the nucleus of the disc and replaces it with an implant. As shown in FIG. 2, it may be necessary, for example, for the surgeon to remove the nucleus of the disc between the L3 and L4 vertebrae. Disc D_{L3-L4} is shown in an enlarged view in FIG. 3. This figure also shows various anatomical structures of the spine, including facets F3A and F4A, facet joint FJ, spinous processes SP3 (not shown) and SP4, transverse processes TP3A and TP4A, and intervertebral foramen IF. FIG. 4 is a top view of the section of the spinal column shown in FIG. 3, with the L3 vertebra removed to expose annulus A and nucleus N of disc D_{L3-L4} . Neural canal NC is also shown. FIG. 5 is an anterior perspective view of the section of the spinal column shown in FIG. 4. FIG. 6 is a partial cross-sectional view of the section of the spinal

2

column shown in FIG. 5, taken generally along line 6-6, but with vertebra L3 in place atop disc D_{L3-L4} .

Of all animals possessing a backbone, human beings are the only creatures who remain upright for significant periods of time. From an evolutionary standpoint, this erect posture has conferred a number of strategic benefits, not the least of which is freeing the upper limbs for purposes other than locomotion. From an anthropologic standpoint, it is also evident that this unique evolutionary adaptation is a relatively recent change, and as such has not benefitted from natural selection as much as have backbones held in a horizontal attitude. As a result, the stresses acting upon the human backbone (or "vertebral column"), are unique in many senses, and result in a variety of problems or disease states that are peculiar to the human species.

The human vertebral column is essentially a tower of bones held upright by fibrous bands called ligaments and contractile elements called muscles. There are seven bones in the neck or cervical region, twelve in the chest or thoracic region, five in the lower back or lumbar region, and five in the pelvic or sacral region, which are normally fused together to form the back part of the pelvis. This column of bones is critical for providing structural support for the entire body.

Between the vertebral bones themselves exist soft tissue structures, i.e., discs, composed of fibrous tissue and cartilage that are compressible and act as shock absorbers for sudden downward forces on the upright column. The discs allow the bones to move independently of each other, as well. The repetitive forces which act on these intervertebral discs during repetitive activities of bending, lifting, and twisting cause them to break down or degenerate over time.

Presumably, because of humans' upright posture their intervertebral discs have a high propensity to degenerate. Overt trauma or covert trauma, occurring in the course of repetitive activities, disproportionately affects the more highly mobile areas of the spine. Disruption of a disc's internal architecture leads to bulging, herniation, or protrusion of pieces of the disc and eventual disc space collapse. Resulting mechanical and even chemical irritation of surrounding neural elements (spinal cord and nerves) cause pain, attended by varying degrees of disability. In addition, loss of disc space height relaxes tension on the longitudinal spinal ligaments, thereby contributing to varying degrees of spinal movement.

The time-honored method of addressing the issues of neural irritation and instability resulting from severe disc damage has largely focused on removal of the damaged disc and fusing the adjacent vertebral elements together. Removal of the disc relieves the mechanical and chemical irritation of neural elements, while osseous union (i.e., bone knitting) solves the problem of stability.

While cancellous bone appears ideal to provide the biologic components necessary for osseous union to occur, it does not initially have the strength to resist the tremendous forces that may occur in the intervertebral disc space, nor does it have the capacity to adequately stabilize the spine until long term bony union occurs. For these reasons, many spinal surgeons have found that interbody fusion using bone alone has an unacceptably high rate of bone graft migration or even expulsion or nonunion due to structural failure of the bone or residual degrees of motion that retard or prohibit bony union. Intervertebral prosthesis in various forms has therefore been used to provide immediate stability and to protect and preserve an environment that fosters growth of the grafted bone such that a structurally significant bony fusion can occur.

Limitations of most present-day intervertebral implants are significant and revolve largely around the marked variation in the disc space height and shape that result from either biologic variability or pathologic change. For example, if a disc space is 20 mm in height, a circular implant bridging this gap requires a minimum diameter of 20 mm just to contact the end plate of the vertebral bone. Generally, end plate disruption must occur to allow a generous bony union, meaning that an additional 2-3 mm must be added on either side resulting in a final implant size of 24-26 mm. During implantation from an anterior approach (i.e., from the front of the body), excessive retraction (or pulling) is often required on the great blood vessels, which greatly enhances the risk of devastating complications such as vascular tears or thrombosis. On the other hand, during a posterior approach, large implant diameters may require excessive traction on neural elements for adequate placement, even if all posterior bony elements are removed. In some instances, an adequate implant size cannot be inserted posteriorly, particularly if there is a significant degree of distraction to obtain stability by tightening the annular ligamentous tension band. Compromising on implant size risks sub-optimal stability or a loose implant, which has a greater risk of migration within, or expulsion from, the disc space. The alternative of excessively retracting neural elements to facilitate a posterior implant application results in a neuropraxia at best and permanent neural damage at worst.

Thus, there is a long-felt need for an expandable and deployable intervertebral disc replacement implant capable of being placed within an intervertebral disc space and expanded.

SUMMARY

According to aspects illustrated herein, there is provided an expandable intervertebral total disc replacement implant, comprising an inferior component, including a first core comprising a first outer surface and a first inner surface, and a first plurality of arms telescopingly engaged with the first core, a superior component, including a second core comprising a second outer surface and a second inner surface, and a second plurality of arms telescopingly engaged with the second core, and an expansion mechanism connected to the first inner surface and the second inner surface, the expansion mechanism operatively arranged to displace the superior component with respect to the inferior component.

In some embodiments, the expansion mechanism is an inflatable sac. In some embodiments, the expansion mechanism comprises a first component including first plurality of teeth, and a second component including a second plurality of teeth, wherein the second plurality of teeth engage the first plurality of teeth to prevent the superior component from displacing toward the inferior component. In some embodiments, the expansion mechanism is a screw jack. In some embodiments, the first core comprises a first plurality of radial extending apertures and the first plurality of arms are engaged with the first plurality of radial extending apertures. In some embodiments, each of the first plurality of radial extending apertures is arranged between and spaced apart from the first outer surface and the first inner surface. In some embodiments, at least one of the first inner surface and the second inner surface comprises a recess, and the expansion mechanism is engaged with the recess.

In some embodiments, each arm of the first plurality of arms comprises a first protrusion telescopingly engaged with the first core, a third outer surface, and a third inner surface, wherein in a fully collapsed state the third outer surface is

aligned with the first outer surface to form a first continuous outer surface. In some embodiments, each arm of the second plurality of arms comprises a second protrusion telescopingly engaged with the second core, a fourth outer surface, and a fourth inner surface, wherein in the fully collapsed state the fourth outer surface is aligned with the second outer surface to form a second continuous outer surface.

In some embodiments, in the fully collapsed state the fourth inner surface abuts against the third inner surface. In some embodiments, the superior component is axially displaceable relative to the inferior component, the first plurality of arms are radially displaceable with respect to the first core, and the second plurality of arms are radially displaceable with respect to the second core. In some embodiments, at least one of the inferior component and the superior component are pivotable with respect to the expansion mechanism. In some embodiments, the first plurality of arms are displaceable with respect to each other and the second plurality of arms are displaceable with respect to each other.

According to aspects illustrated herein, there is provided an expandable intervertebral total disc replacement implant, comprising an inferior component, including a first core comprising a first outer surface, a first inner surface, and a first plurality of apertures arranged between the first outer surface and the first inner surface, and a first plurality of arms slidingly engaged with the first plurality of apertures, a superior component, including a second core comprising a second outer surface, a second inner surface, and a second plurality of apertures arranged between the second outer surface and the second inner surface, and a second plurality of arms slidingly engaged with the second plurality of apertures, and an expansion mechanism connected to the first inner surface and the second inner surface, the expansion mechanism operatively arranged to axially displace the superior component with respect to the inferior component.

In some embodiments, the expansion mechanism is an inflatable balloon. In some embodiments, the first plurality of arms are radially displaceable with respect to the first core, and the second plurality of arms are radially displaceable with respect to the second core. In some embodiments, at least one of the inferior component and the superior component are pivotable with respect to the expansion mechanism. In some embodiments, the first plurality of arms are displaceable with respect to each other and the second plurality of arms are displaceable with respect to each other. In some embodiments, each of the first plurality of radial extending apertures is spaced apart from the first outer surface and the first inner surface. In some embodiments, the first inner surface comprises a first recess, the second inner surface comprises a second recess, and the expansion mechanism is engaged with the first recess and the second recess.

According to aspects illustrated herein, there is provided a system relating to orthopedic surgery, and more particularly, to a prosthetic intervertebral disc replacement system which can be implanted into a suitably prepared intervertebral disc space via minimally invasive surgical techniques to provide for and restore substantial normalcy of movement.

According to aspects illustrated herein, there is provided a system including adjustable endplates and an adjustable mobile core such that anatomic variants can be more precisely accommodated and so ligaments can be restored to normal tensions that occurred prior to the onset of degeneration.

The system comprises artificial endplates having slidably arms extending from a center axis cup. These arms are

mechanically deployable and adjustable such that they can be positioned well under the cortical rim of the vertebrae to mitigate the tendency of the prosthesis to subside in the softer central vertebral bone. Adjustment of the arms situated in an anterior posterior attitude also permits optimization of the center of rotation of the device which generally lies a third of the distance anterior to the posterior cortical limit.

Because the arms are mechanically deployable after implantation of the endplates, a much smaller disc opening can be made to enucleate the disc nucleus so that surrounding ligaments can be maximally preserved. Since it is largely the ligaments and facet joints that determine normal disc motion, preserving as much of the surrounding ligaments as possible would seem prudent.

At the center of the endplates is a cup or depression that can accommodate the central core of the device in a constrained, unconstrained, semi-constrained, or other fashion. This can be varied as well whereby the superior end plate constrains the core and the inferior endplate does not, and so forth.

The wear surfaces between the endplates and the core can be metal, ceramic, plastic, or combinations thereof.

In some embodiments, the system has an adjustable core which can permit incremental changes in height to optimally restore ligamentous tautness and consequentially normal ranges of motion. While the core can be adjusted mechanically (ratcheting member, screw jack, etc.), in some embodiments the core is expanded hydraulically such that pressure can be monitored while expansion occurs. By measuring pressure and observing facet distraction under fluoroscopy, excessive forces that might damage ligaments or encourage endplate fracture and subsidence are avoided.

In some embodiments, therefore, the system comprises a distensible sac or chamber which can first be inflated with saline or contrast to observe placement of the in situ configured device, observe disc height restoration and facet distraction prior to permanent implantation. Once the pressure and volume of the injectable core material is known it is removed and a similar volume of hardenable liquid polymer is injected to form a long-term stable construct with optimally placed endplates, a customized center of rotation, and a patient specific height pertaining to the disc being replaced. In some embodiments, the hardenable material comprises polymethyl methacrylate (PMMA) or polyurethane if a degree of compressibility is desired to mitigate against axial shock loads. In the case of polyurethane or other viscoelastic polymers, a prefabricated central core could be inserted with the disc complex applied to the disc space in a compressed state allowed to expand in situ. In some embodiments, the adjustable endplates comprise metal such as titanium or nitinol, polyether ether ketone (PEEK) or similar plastics or ceramic. The corresponding and mating wear surface of the core and the endplates could be ultra-high-molecular-weight polyethylene (UHMWPE), metal, ceramic, or other biocompatible materials.

Ultimately, what is achieved by the system is an infinitely adjustable endplate/core prosthetic total disc replacement device that can be inserted via minimally invasive techniques and optimized dimensionally in situ to provide a customized patient specific disc replacement.

In some embodiments, the endplate arms comprise nitinol or plastic polymers capable of slight but sufficient flex to better conform to variations in endplate curvature. These endplate surfaces abutting the bony surfaces shall be coated, contain, or manufactured with porous materials that favor and allow bone ingrowth to assist in anchoring the

device. Spikes or small ridges could also be employed on or at the interface with the bone when the endplate is pushed against the bone upon expansion of the core.

The implant of the present disclosure allows for an insertion opening that is significantly smaller than other implants thus preserving more of the support ligaments. In some embodiments, the expansion mechanism of the implant comprises a ratcheting mechanism expandable core. In some embodiments, the expansion mechanism of the implant comprises an inflatable core including an inflation port. The inflatable core can be inflated using hardenable polymers like acrylic (PMMA) or other suitable viscoelastic polymers (e.g., polyurethane). In some embodiments, the expansion mechanism of the implant comprises a screw jack and/or a worm drive. In some embodiments, the expansion mechanism of the implant comprises a scissor jack and a screw that engages the scissor jack. As is known in the art of scissor jacks, as the screw is turned in a first direction, the scissor jack increases in height, and as the screw is turned in a second direction, opposite the first direction, the scissor jack decreases in height.

The implant comprises extendable arms or endplate wings which slidingly and/or telescopingly engage a central core of the implant. In some embodiments, the central core of the implant is 6-7 mm in diameter. In some embodiments, in a fully collapsed state, the diameter of the entire implant is between 10 and 14 mm. In some embodiments, in a fully collapsed state, the diameter of the implant in a first direction is 10 mm and the diameter of the implant in a second direction is 14 mm. In some embodiments, in a fully expanded state, the diameter of the entire implant is 16 mm.

These and other objects, features, and advantages of the present disclosure will become readily apparent upon a review of the following detailed description of the disclosure, in view of the drawings and appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

Various embodiments are disclosed, by way of example only, with reference to the accompanying schematic drawings in which corresponding reference symbols indicate corresponding parts, in which:

FIG. 1 is an anterior perspective view of a spinal column;

FIG. 2 is an anterior perspective view of the lumbar section of the spinal column shown in FIG. 1;

FIG. 3 is a lateral perspective view of two vertebrae, a disc, and related spinal anatomy;

FIG. 4 is a top view of a section of the spinal column, taken generally along line 4-4 in FIG. 3;

FIG. 5 is an enlarged anterior perspective view of the spinal column shown in FIG. 2, except with the top vertebra and all other structure above the top vertebra removed;

FIG. 6 is a partial cross-sectional view of the top and bottom vertebrae and disc, taken generally along line 6-6 in FIG. 5;

FIG. 7A is a front perspective view of an expandable total disc replacement implant, in a collapsed state;

FIG. 7B is a front perspective view of the expandable total disc replacement implant shown in FIG. 7A, in an expanded state;

FIG. 8A is a cross-sectional view of the expandable total disc replacement implant taken generally along line 8A-8A in FIG. 7A;

FIG. 8B is a cross-sectional view of the expandable total disc replacement implant taken generally along line 8B-8B in FIG. 7B;

FIG. 9 is a cross-sectional view of the expandable total disc replacement implant taken generally along line 8A-8A in FIG. 7A;

FIG. 10 is a cross-sectional view of the expandable total disc replacement implant taken generally along line 8A-8A in FIG. 7A;

FIG. 11 is a cross-sectional view of the expandable total disc replacement implant shown in FIG. 7B, engaged with vertebrae;

FIG. 12A is a top elevational view of the expandable total disc replacement implant engaged with vertebrae, in a collapsed state; and,

FIG. 12B is a top elevational view of the expandable total disc replacement implant engaged with vertebrae, in an expanded state.

DETAILED DESCRIPTION

At the outset, it should be appreciated that like drawing numbers on different drawing views identify identical, or functionally similar, structural elements. It is to be understood that the claims are not limited to the disclosed aspects.

Furthermore, it is understood that this disclosure is not limited to the particular methodology, materials and modifications described and as such may, of course, vary. It is also understood that the terminology used herein is for the purpose of describing particular aspects only, and is not intended to limit the scope of the claims.

Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood to one of ordinary skill in the art to which this disclosure pertains. It should be understood that any methods, devices or materials similar or equivalent to those described herein can be used in the practice or testing of the example embodiments. The assembly of the present disclosure could be driven by hydraulics, electronics, pneumatics, and/or springs.

It should be appreciated that the term “substantially” is synonymous with terms such as “nearly,” “very nearly,” “about,” “approximately,” “around,” “bordering on,” “close to,” “essentially,” “in the neighborhood of,” “in the vicinity of,” etc., and such terms may be used interchangeably as appearing in the specification and claims. It should be appreciated that the term “proximate” is synonymous with terms such as “nearby,” “close,” “adjacent,” “neighboring,” “immediate,” “adjoining,” etc., and such terms may be used interchangeably as appearing in the specification and claims. The term “approximately” is intended to mean values within ten percent of the specified value.

It should be understood that use of “or” in the present application is with respect to a “non-exclusive” arrangement, unless stated otherwise. For example, when saying that “item x is A or B,” it is understood that this can mean one of the following: (1) item x is only one or the other of A and B; (2) item x is both A and B. Alternately stated, the word “or” is not used to define an “exclusive or” arrangement. For example, an “exclusive or” arrangement for the statement “item x is A or B” would require that x can be only one of A and B. Furthermore, as used herein, “and/or” is intended to mean a grammatical conjunction used to indicate that one or more of the elements or conditions recited may be included or occur. For example, a device comprising a first element, a second element and/or a third element, is intended to be construed as any one of the following structural arrangements: a device comprising a first element; a device comprising a second element; a device comprising a third element; a device comprising a first element and a

second element; a device comprising a first element and a third element; a device comprising a first element, a second element and a third element; or, a device comprising a second element and a third element.

Moreover, as used herein, the phrases “comprises at least one of” and “comprising at least one of” in combination with a system or element is intended to mean that the system or element includes one or more of the elements listed after the phrase. For example, a device comprising at least one of: a first element; a second element; and, a third element, is intended to be construed as any one of the following structural arrangements: a device comprising a first element; a device comprising a second element; a device comprising a third element; a device comprising a first element and a second element; a device comprising a first element and a third element; a device comprising a first element, a second element and a third element; or, a device comprising a second element and a third element. A similar interpretation is intended when the phrase “used in at least one of:” is used herein. Furthermore, as used herein, “and/or” is intended to mean a grammatical conjunction used to indicate that one or more of the elements or conditions recited may be included or occur. For example, a device comprising a first element, a second element and/or a third element, is intended to be construed as any one of the following structural arrangements: a device comprising a first element; a device comprising a second element; a device comprising a third element; a device comprising a first element and a second element; a device comprising a first element and a third element; a device comprising a first element, a second element and a third element; or, a device comprising a second element and a third element.

By “non-rotatably connected” elements, we mean that: the elements are connected so that whenever one of the elements rotate, all the elements rotate; and, relative rotation between the elements is not possible. Radial and/or axial movement of non-rotatably connected elements with respect to each other is possible, but not required. By “rotatably connected” elements, we mean that: the elements are rotatable with respect to each other; and, whenever one element is displaced radially and/or axially, all the elements are displaced radially and/or axially.

Adverting now to the figures, and as described previously, FIGS. 1-6 depict various parts and sections of spinal anatomy.

FIG. 7A is a front perspective view of expandable total disc replacement implant 110, in a collapsed state. FIG. 7B is a front perspective view of expandable total disc replacement implant 110, in an expanded state. FIG. 8A is a cross-sectional view of expandable total disc replacement implant 110 taken generally along line 8A-8A in FIG. 7A. FIG. 8B is a cross-sectional view of expandable total disc replacement 100 implant taken generally along line 8B-8B in FIG. 7B. Expandable total disc replacement implant 110, or implant 110, generally comprises inferior component 120, superior component 160, and an expansion mechanism, for example, expansion mechanism 150, 250, 350. The following description should be read in view of FIGS. 7A-8B.

Inferior component 120 comprises core 122 and one or more arms 132 slidingly and/or telescopingly engaged with core 122. In some embodiments, and as best shown in FIGS. 7A-B, inferior component 120 comprises four arms 132. Core 122 comprises outer surface 124, inner surface 126, recess 128, and one or more apertures 130. Outer surface 124 generally faces radially outward and is operatively arranged to engage an adjacent vertebra (see FIG. 11). Inner surface 126 generally faces radially inward, or toward

superior component 160. Inner surface 126 comprises recess 128 operatively arranged to engage expansion mechanism 150. The engagement of expansion mechanism 150 with recess 128 limits radial displacement of expansion mechanism 150 with respect to inferior component 120. In some embodiments, expansion mechanism 150 is translationally connected to inferior component 120 such that it slides within recess 128. Such arrangement allows translational movement between inferior component 120 and superior component 160. Apertures 130 are arranged radially within core 122. Specifically, apertures 130 extend from an outermost perimeter of core 122 radially inward. In some embodiments, and as shown, apertures 130 reside between and spaced apart from outer surface 124 and inner surface 126. Apertures 130 allow arms 132 to be telescopingly and/or slidingly engaged with core 122. In some embodiments, core 122 comprises four apertures 130 to engage with four arms 132.

Each of arms 132 comprises outer surface 134, inner surface 136, and protrusion 138. Outer surface 134 generally faces radially outward and is operatively arranged to engage with an adjacent vertebra (see FIG. 11). In some embodiments, and as shown in FIG. 8A, in the fully collapsed state outer surface 134 is aligned with outer surface 124 so as to create a smooth continuous outer surface of inferior component 120. Inner surface 136 generally faces radially inward or toward superior component 160. In some embodiments, and as shown in FIG. 8A, in the fully collapsed state, inner surface 136 engages and/or abuts against inner surface 176 of arms 172 (of superior component 160). The engagement of surfaces 136 and 176 and the alignment of surfaces 134 and 124, in the fully collapsed state, prevent ingress of material into implant 110 during insertion and also creates facilitates easier implantation by providing a smooth and continuous outer implant surface. Protrusion 138 is a generally radially extending element that engages aperture 130. In some embodiments, and as shown, protrusion is arranged between and spaced apart from outer surface 134 and inner surface 136. The engagement of protrusion 138 and aperture 130 creates the telescoping and/or sliding connection between arm 132 and core 122, which allows inferior component 120 to be expanded radially in a plurality of directions, as will be described in greater detail below.

In some embodiments, core 122 and/or arms 132 are flexible or elastically deformable which allows inferior component to form to the adjacent vertebra for optimal engagement therewith. In some embodiments, outer surface 124 and/or outer surface 134 comprises one or more projections, for example projections 140, operatively arranged to fixedly secure inferior component 120 to the adjacent vertebra.

Superior component 160 comprises core 162 and one or more arms 172 slidingly and/or telescopingly engaged with core 162. In some embodiments, and as best shown in FIGS. 7A-B, superior component 160 comprises four arms 172. Core 162 comprises outer surface 164, inner surface 166, recess 168, and one or more apertures 170. Outer surface 164 generally faces radially outward and is operatively arranged to engage an adjacent vertebra (see FIG. 11). Inner surface 166 generally faces radially inward, or toward inferior component 120. Inner surface 166 comprises recess 168 operatively arranged to engage expansion mechanism 150. The engagement of expansion mechanism 150 with recess 168 limits radial displacement of expansion mechanism 150 with respect to superior component 160. In some embodiments, expansion mechanism 150 is translationally connected to superior component 160 such that it slides

within recess 168. Such arrangement allows translational movement between superior component 160 and inferior component 120. Apertures 170 are arranged radially within core 162. Specifically, apertures 170 extend from an outermost perimeter of core 162 radially inward. In some embodiments, and as shown, apertures 170 reside between and spaced apart from outer surface 164 and inner surface 166. Apertures 170 allow arms 172 to be telescopingly and/or slidingly engaged with core 162. In some embodiments, core 162 comprises four apertures 170 to engage with four arms 172.

Each of arms 172 comprises outer surface 174, inner surface 176, and protrusion 178. Outer surface 174 generally faces radially outward and is operatively arranged to engage with an adjacent vertebra (see FIG. 11). In some embodiments, and as shown in FIG. 8A, in the fully collapsed state outer surface 174 is aligned with outer surface 164 so as to create a smooth continuous outer surface of superior component 160. Inner surface 176 generally faces radially inward or toward inferior component 120. In some embodiments, and as shown in FIG. 8A, in the fully collapsed state, inner surface 176 engages and/or abuts against inner surface 136 of arms 132 (of inferior component 120). The engagement of surfaces 176 and 166 and the alignment of surfaces 174 and 164, in the fully collapsed state, prevent ingress of material into implant 110 during insertion and also creates facilitates easier implantation by providing a smooth and continuous outer implant surface. Protrusion 178 is a generally radially extending element that engages aperture 170. In some embodiments, and as shown, protrusion is arranged between and spaced apart from outer surface 174 and inner surface 176. The engagement of protrusion 178 and aperture 170 creates the telescoping and/or sliding connection between arm 172 and core 162, which allows superior component 160 to be expanded radially in a plurality of directions, as will be described in greater detail below.

In some embodiments, core 162 and/or arms 172 are flexible or elastically deformable which allows inferior component to form to the adjacent vertebra for optimal engagement therewith. In some embodiments, outer surface 164 and/or outer surface 174 comprises one or more projections, for example projections 180, operatively arranged to fixedly secure superior component 160 to the adjacent vertebra.

Expansion mechanism or inflatable balloon or inflatable sac 150 is generally an inflatable device operatively arranged to be filled with material to displace superior component 160 with respect to inferior component 120, or vice versa. In some embodiments, inflatable sac 150 comprises an elastomer, such as rubber. In some embodiments, inflatable sac 150 comprises a nonelastic material. Inflatable sac 150 comprises first end 152, second end 154, and port 154. First end 152 is operatively arranged to engage inner surface 126, specifically recess 128, of inferior component 120 and end 154 is operatively arranged to engage inner surface 166, specifically recess 168, of superior component 160. In some embodiments, end 152 is pivotably connected to inferior component 120 and/or end 154 is pivotably connected to superior component. Such pivotable connection allows general movement and flexion between inferior component 120 and superior component 160, mimicking the normal movement between vertebrae via a disc. Additionally, the elastic properties of cores 122 and 162 and arms 132 and 172 allow further natural movement between vertebrae. In some embodiments, end 152 is fixedly secured to inferior component 120 and/or end 154 is fixedly secured to superior component 160. Material, such as a hardenable polymer,

11

acrylic, PMMA, a viscoelastic polymer, polyurethane, or any other suitable material, is injected into inflatable sac 150 through port 156. As material is injected into inflatable sac 150, inflatable sac 150 expands and superior component 160 is displaced away from inferior component 120. As material is removed from inflatable sac 150, inflatable sac 150 contracts and superior component 160 is capable of displacing toward inferior component 120.

As previously described, in the fully collapsed state, as best shown in FIG. 8A, surfaces 176 engage and/or abut against surfaces 136. It should be appreciated, that in some embodiments, a gap or aperture is arranged in implant 110 such that the expansion mechanism therein is accessible in the fully collapsed state. For example, port 156 would be accessible in the fully collapsed state such that implant 110 can be expanded. In the expanded state, wherein superior component 160 is displaced in axial direction AD1 with respect to inferior component 120, as best shown in FIG. 8B, surfaces 176 are separated from surfaces 136 by height H. This expansion (i.e., in axial direction AD1) is referred to herein as axial expansion.

Implant 110 is also capable of radial expansion, for example, in radial directions RD1-4. As best shown in FIGS. 7B and 8B, arms 132 and arms 172 can be displaced radially with respect to cores 122 and 162, respectively. For example, one of arms 132 and one of arms 172 can be displaced in radial direction RD1 with respect to cores 122 and 162, respectively, one of arms 132 and one of arms 172 can be displaced in radial direction RD3, opposite radial direction RD1, with respect to cores 122 and 162, respectively, one of arms 132 and one of arms 172 can be displaced in radial direction RD2 with respect to cores 122 and 162, respectively, and one of arms 132 and one of arms 172 can be displaced in radial direction RD4, opposite radial direction RD2, with respect to cores 122 and 162, respectively. In some embodiments, radial direction RD2 is arranged perpendicular to radial direction RD1. It should be appreciated that each of arms 132 and 172 are displaceable with respect to each other, allowing for a completely customizable radial expansion. Such customizable radial expansion allows implant 110 to be formed to the exact shape of the patient's vertebra. For example, a patient may have vertebra L4 that is larger than vertebra L3, and thus arms 172 of superior component 160 should be radially expanded less than arms 132 of inferior component 120.

FIG. 9 is a cross-sectional view of implant 110 taken generally along line 8A-8A in FIG. 7A. FIG. 9 shows expansion mechanism or ratcheting expansion mechanism 250. Ratcheting expansion mechanism 250 comprises first section 252 engaged with inferior component 120 and second section 256 engaged with superior component 160. In some embodiments, first section 252 is translationally connected to inferior component 120 such that it slides within recess 128. Such arrangement allows translational movement between inferior component 120 and superior component 160. First section 252 comprises plurality of teeth 254 and second section 256 comprises plurality of teeth 258 operatively arranged to engage plurality of teeth 254. The engagement of teeth 258 with teeth 254 allows superior component 160 to be displaced away from inferior component 120 (i.e., in axial direction AD1) but prevents superior component 160 from being displaced toward inferior component 120 (i.e., in axial direction AD2). Thus, ratcheting expansion mechanism 250 provides a locking feature. It should be appreciated that ratcheting expansion mechanism 250 can be used in place of or in addition to inflatable sac 150.

12

FIG. 10 is a cross-sectional view of implant 110 taken generally along line 8A-8A in FIG. 7A. FIG. 10 shows expansion mechanism or screw jack or worm drive 350. Screw jack 350 comprises worm screw 352, worm wheel 354 engaged with worm screw 352, shaft 356 non-rotatably connected to worm wheel 354, and translating nut 358 engaged with shaft 356 and connected to superior component 162. Worm screw 352 comprises threading that engages gear teeth on worm wheel 354. Rotating worm screw 352 causes worm wheel 354 and shaft 356 to rotate. Shaft 356 comprises threading that threadably engages translating nut 358. As shaft 356 rotates in a first direction translating nut 358 and thus superior component 160 displaces in axial direction AD1. As shaft 356 rotates in a second direction, opposite the first direction, translating nut 358 and thus superior component 160 displaces in axial direction AD2. In some embodiments, translating nut 358 is non-rotatably connected to superior component 160. It should be appreciated that screw jack 350 can be used in place of or in addition to ratcheting expansion mechanism 250 and/or inflatable sac 150. In some embodiments, the expansion mechanism of implant 110 comprises a scissor jack.

FIG. 11 is a cross-sectional view of implant 110 engaged with vertebrae L3 and L4. FIG. 12A is a top elevational view of implant 110 engaged with vertebra L4, in a collapsed state. FIG. 12B is a top elevational view of implant 110 engaged with vertebra L4, in an expanded state.

To insert implant 110 into a patient, implant 110 should be arranged in the fully collapsed position, as shown in FIGS. 7A and 8A. Implant 110 is then implanted in the disc space between vertebrae, for example, vertebra L3 and vertebra L4, or where disc D_{L3-L4} should be. In some embodiments, and as shown in FIG. 12A, in the collapsed position, implant 110 may be ovalar and comprise diameter D1 along the short axis and diameter D2 along the long axis, wherein D2 is greater than D1. In some embodiments, implant 110 comprises a circular geometry. It should be appreciated that implant 110 may comprise any suitable geometry, for example, square, rectangular, ellipsoidal, triangular, trapezoidal, etc.

Once positioned between vertebrae L3 and L4, implant 110 can then be radially expanded as desired. For example, arms 132 and arms 172 are expanded radially outward with respect to core 122 and core 162, respectively, to the desired diameter. For example, implant 110 may be radially expanded such that it comprises diameter D3 along the short axis and diameter D4 along the long axis, wherein D4 is greater than D3. As previously described, the radial expansion of superior component 160 and inferior component 120 is customizable in a plurality of radial directions, for example, radial directions RD1-4.

Once arms 132 and 172 are arranged in their desired positions, expansion mechanism 150, 250, 350 is vertically expanded to displace superior component 160 away from inferior component 120, or vice versa. Expansion mechanism 150, 250, 350 is expanded until the desired height is reached, for example such that implant 110 comprises the height of the original disc for which it is replacing, and left in situ. It should be appreciated that implant 110 may be expanded prior to insertion, or after insertion. In some embodiments, implant 110 is then filled with fusion material, for example, between superior component 160 and inferior component 120.

It will be appreciated that various aspects of the disclosure above and other features and functions, or alternatives thereof, may be desirably combined into many other different systems or applications. Various presently unforeseen or

unanticipated alternatives, modifications, variations, or improvements therein may be subsequently made by those skilled in the art which are also intended to be encompassed by the following claims.

REFERENCE NUMERALS

- A Annulus
- C Coccyx
- C1-C7 Cervical vertebrae
- D_{L1-L2} Disc
- D_{L2-L3} Disc
- D_{L3-L4} Disc
- D_{L4-L5} Disc
- F Facet
- FJ Facet joint
- IF Intervertebral foramen
- L1-L5 Lumbar vertebrae
- N Nucleus
- NC Neural canal
- S Sacrum
- SP Spinous process
- TP Transverse process
- T1-T12 Thoracic vertebrae
- 10 Spinal column
- 110 Expandable intervertebral total disc replacement implant
- 120 Inferior component
- 122 Core
- 124 Outer surface
- 126 Inner surface
- 128 Recess
- 130 Aperture
- 132 Arm
- 134 Outer surface
- 136 Inner surface
- 138 Protrusion
- 140 Projections
- 150 Expansion mechanism or inflatable sac or balloon
- 152 End
- 154 End
- 156 Port
- 160 Superior component
- 162 Core
- 164 Outer surface
- 166 Inner surface
- 168 Recess
- 170 Aperture
- 172 Arm
- 174 Outer surface
- 176 Inner surface
- 178 Protrusion
- 180 Projections
- 250 Expansion mechanism or ratchet device
- 252 Section
- 254 Teeth
- 256 Section
- 258 Teeth
- 350 Expansion mechanism or screw jack or worm drive
- 352 Worm screw
- 354 Worm wheel
- 356 Shaft
- 358 Translating nut
- AD1 Axial direction
- AD2 Axial direction
- D1 Diameter
- D2 Diameter

- D3 Diameter
- D4 Diameter
- H Height
- L Length
- 5 RIM Radial direction
- RD2 Radial direction
- RD3 Radial direction
- RD4 Radial direction
- 10 What is claimed is:
- 1. An expandable intervertebral total disc replacement implant, comprising:
 - an inferior component, including:
 - a first core comprising a first outer surface and a first inner surface; and
 - a first plurality of arms;
 - a superior component, including:
 - a second core comprising a second outer surface and a second inner surface; and
 - a second plurality of arms telescopingly engaged with the second core; and
 - an expansion mechanism connected to the first inner surface and the second inner surface, the expansion mechanism operatively arranged to displace the superior component with respect to the inferior component;
 - wherein each arm of the first plurality of arms comprises:
 - a first protrusion telescopingly engaged with the first core;
 - a third outer surface; and
 - a third inner surface, wherein in a fully collapsed state the third outer surface is aligned with the first outer surface to form a continuous outer surface.
- 2. The expandable intervertebral total disc replacement implant as recited in claim 1, wherein the expansion mechanism is an inflatable sac.
- 3. The expandable intervertebral total disc replacement implant as recited in claim 1, wherein the expansion mechanism comprises:
 - a first component including first plurality of teeth; and
 - a second component including a second plurality of teeth, wherein the second plurality of teeth engage the first plurality of teeth to prevent the superior component from displacing toward the inferior component.
- 4. The expandable intervertebral total disc replacement implant as recited in claim 1, wherein the expansion mechanism is a screw jack.
- 5. The expandable intervertebral total disc replacement implant as recited in claim 1, wherein the first core comprises a first plurality of radially extending apertures and the first plurality of arms are engaged with the first plurality of radially extending apertures.
- 6. The expandable intervertebral total disc replacement implant as recited in claim 5, wherein each of the first plurality of radially extending apertures is arranged between and spaced apart from the first outer surface and the first inner surface.
- 7. The expandable intervertebral total disc replacement implant as recited in claim 1, wherein at least one of the first inner surface and the second inner surface comprises a recess, and the expansion mechanism is engaged with the recess.
- 8. The expandable intervertebral total disc replacement implant as recited in claim 1, wherein each arm of the second plurality of arms comprises:
 - a second protrusion telescopingly engaged with the second core;
 - a fourth outer surface; and

15

a fourth inner surface, wherein in the fully collapsed state the fourth outer surface is aligned with the second outer surface to form a second continuous outer surface.

9. The expandable intervertebral total disc replacement implant as recited in claim 8, wherein in the fully collapsed state the fourth inner surface abuts against the third inner surface.

10. The expandable intervertebral total disc replacement implant as recited in claim 1, wherein:

the superior component is axially displaceable relative to the inferior component;

the first plurality of arms are radially displaceable with respect to the first core; and

the second plurality of arms are radially displaceable with respect to the second core.

11. The expandable intervertebral total disc replacement implant as recited in claim 1, wherein at least one of the inferior component and the superior component are pivotable with respect to the expansion mechanism.

12. The expandable intervertebral total disc replacement implant as recited in claim 1, wherein the first plurality of arms are displaceable with respect to each other and the second plurality of arms are displaceable with respect to each other.

13. An expandable intervertebral total disc replacement implant, comprising:

an inferior component, including:

a first core comprising a first outer surface, a first inner surface, and a first plurality of apertures arranged between the first outer surface and the first inner surface; and

a first plurality of arms slidingly engaged with the first plurality of apertures;

a superior component, including:

a second core comprising a second outer surface, a second inner surface, and a second plurality of apertures arranged between the second outer surface and the second inner surface; and

16

a second plurality of arms slidingly engaged with the second plurality of apertures and comprising a third outer surface, wherein in a fully collapsed state the third outer surface is aligned with the second outer surface to form a continuous outer surface; and

an expansion mechanism connected to the first inner surface and the second inner surface, the expansion mechanism operatively arranged to axially displace the superior component with respect to the inferior component.

14. The expandable intervertebral total disc replacement implant as recited in claim 13, wherein the expansion mechanism is an inflatable balloon.

15. The expandable intervertebral total disc replacement implant as recited in claim 13, wherein:

the first plurality of arms are radially displaceable with respect to the first core; and

the second plurality of arms are radially displaceable with respect to the second core.

16. The expandable intervertebral total disc replacement implant as recited in claim 13, wherein at least one of the inferior component and the superior component are pivotable with respect to the expansion mechanism.

17. The expandable intervertebral total disc replacement implant as recited in claim 13, wherein the first plurality of arms are displaceable with respect to each other and the second plurality of arms are displaceable with respect to each other.

18. The expandable intervertebral total disc replacement implant as recited in claim 13, wherein each of the first plurality of apertures is spaced apart from the first outer surface and the first inner surface.

19. The expandable intervertebral total disc replacement implant as recited in claim 13, wherein:

the first inner surface comprises a first recess;

the second inner surface comprises a second recess; and the expansion mechanism is engaged with the first recess and the second recess.

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