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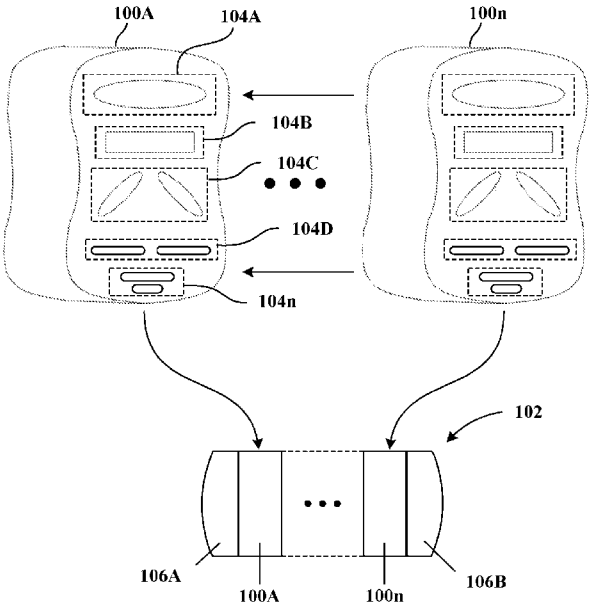

FIG. 1

(57) **Abstract:** Systems, apparatuses and methods for preserving motion in an intervertebral disc. Modular disc implant segments can be constructed from a relatively solid material configured to assume certain characteristics of a compressible solid, such as an elastomer. The material may be configured to include one or more structural voids, such as a leaf spring design, to facilitate the modular disc implant segment's ability to compress, thereby enabling an entire intervertebral disc constructed from multiple modular disc implant segments to compress with the implant recipient's movement.

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MOTION PRESERVING SYSTEM AND APPARATUS

RELATED APPLICATIONS

[00001] This application claims the benefit of Provisional Patent Application No. 63/521,495, filed on June 16, 2023, to which priority is claimed pursuant to 35 U.S.C. §119(e) and which is incorporated herein by reference in its entirety.

FIELD

[00002] This disclosure relates generally to medical motion preserving systems, devices, and methods, including disc nucleus replacement systems and apparatuses such as implantable prostheses for repairing intervertebral discs.

BACKGROUND

[00003] The spinal motion segment consists of a unit of spinal anatomy including the two vertebral bodies, the interposed intervertebral disc, as well as the attached ligaments, muscles, and the facet joints. The disc consists of the end plates at the top and bottom of the vertebral bones, the soft inner core called the nucleus pulposus, and the annulus fibrosus running circumferentially around the nucleus. In normal discs, the nucleus pulposus cushions applied loads, thus protecting the other elements of the spinal motion segment. A normal disc nucleus responds to compression forces by transferring these forces against the vertebral end plates and the annulus fibrosus. The annulus consists of collagen fibers and a smaller number of elastic fibers, both of which are effective in resisting tension forces. However, the annulus on its own is not very effective in withstanding compression shear forces, and in the absence of a functioning nucleus it loses its ability to maintain physiologic vertebral body separation. The result is compression and irritation of exiting nerve roots and development of back pain.

[00004] As people age, the intervertebral discs often degenerate naturally. Degenerative disc disease of the spine is one of the most common conditions causing pain and disability in our population. Disc degeneration occurs when the nucleus dehydrates. When a nucleus dehydrates, its ability to act as a cushion is reduced. Because the dehydrated nucleus is no longer able to bear loads, the loads are transferred to the annulus and to the facet joints. The annulus and facet joints are not capable of withstanding their increased share of the applied compression and torsional loads, and as such, they gradually deteriorate. As the annulus and facets deteriorate, many other effects ensue, including the narrowing of the interspace, bony spur formation, fragmentation of the annulus, fracture and deterioration of the cartilaginous end plates, and deterioration of the cartilage of the facet joints. The annulus and facet joints lose their structural stability, subtle but pathologic motions occur between the spinal bones.

[00005] Breakdown products of the disc, including macroscopic debris, microscopic particles, and noxious biochemical substances build up. The particles and debris may produce nerve compression and sciatica, and the noxious biochemical substances can irritate sensitive nerve endings in and around the disc and produce low back pain. Affected individuals experience muscle spasms, reduced flexibility of the low back and pain when ordinary movements of the trunk are attempted.

[00006] Degeneration of a disc is irreversible. In some cases, the body will eventually stiffen the joints of the motion segment, effectively re-stabilizing the discs. Even in the cases where re-stabilization occurs, the process can take many years and patients often continue to experience disabling pain. Extended painful episodes of longer than three months often lead patients to seek a surgical solution for pain.

[00007] Several methods have been devised to attempt to stabilize the spinal motion segment. Some of the methods include:

1) Heating the annular region to destroy nerve endings and strengthen the annulus.

2) Applying rigid or semi-rigid support members on the sides of the motion segment or within the disc space.

3) Removing and replacing the entire disc with a generally rigid plastic, articulating artificial device; removing permanently and fusing the vertebrae adjacent to the affected disc.

[00008] Until recently, spinal fusion has generally been regarded as the most effective surgical treatment to alleviate back pain due to degeneration of a disc. While this treatment is often effective at relieving back pain, all discal motion is lost in the fused spinal motion segment.

[00009] The loss of motion in the affected spinal segment necessarily limits the overall spinal mobility of the patient. Ultimately, the spinal fusion places greater stress on the disc adjacent to the fused segment as these segments attempt to compensate for lack of motion in the fused segment, often leading to early degeneration of these adjacent spinal segments.

[00010] Current developments are focusing on treatments that can preserve some or all of the motion of the affected spinal segment. One of these methods to stabilize the spinal motion segment without the disadvantages of spinal fusion is total disc replacement. Total disc replacement is a highly invasive and technically demanding procedure which accesses the disc from anterior or frontal approach and includes dividing the anterior longitudinal ligament, removing the cartilaginous end plates between the vertebral bone and the disc, large portions of the outer annulus and the complete inner nucleus. Then an artificial total disc prosthesis is placed in the evacuated disc space. Many of the artificial total disc replacements currently available consist of a generally rigid plastic such as ultra-high molecular weight polyethylene ("UHMWPE") as the nucleus that is interposed between two metal plates that are anchored or attached to the vertebral endplates.

[00011] A summary of the history of early development and designs of artificial discs is set forth in "Ray, The Artificial Disc: Introduction, history and Socioeconomics", Chpt. 21, ***Clinical Efficacy and Outcome in the Diagnosis of Low Back Pain, pgs. 205-225, Raven Press (1992).***

[00012] These types of artificial total discs have several disadvantages. First, because the artificial disc replacements are relatively large, they require relatively large surgical exposures to accommodate their insertion. The larger the surgical exposure, the higher the chance of infection, hemorrhage or even morbidity. Also, to implant the prosthetic, removal of a large portion of the annulus reduces the stability of the motion segment, at least until healing occurs around the artificial disc. Further, because the devices are constructed from rigid

materials, they can cause serious damage if they were to displace from the disc space and contact local nerve or vascular tissues. Another disadvantage is the rigid artificial disc replacements do not reproduce normal disc biomechanics.

[00013] An alternative to total disc replacement is nucleus replacement which, like an artificial disc prosthesis, are inert, non-rigid, non-biological replacements. Some prior art nucleus replacements utilize hydrogels because of their water imbibing properties that enable these replacements to expand in situ to permit a more complete filling of the evacuated nucleus cavity. However, there is usually a trade-off in that the more expansion the hydrogel achieves, the less structural support the implant can provide. As a result, many hydrogel nucleus disc replacements have generally adopted the use of some form of a jacket or fabric to constrain the hydrogel material. Without the jacket or other form of constraint, the hydrogel is susceptible to displacement because of the slippery nature of hydrogel. Unfortunately, the jacket or fabric shell will be subject to long term abrasive wear issues that could result in failure of the jacket or shell's ability to constrain the hydrogel and thus the hydrogel may be subject to displacement.

[00014] Another less desirable approach to nucleus replacement involves implantation of a balloon or other container into the nucleus, which is then filled with a biocompatible material that hardens in-situ. Among the problems with this approach is that the chemical hardening process is exothermic and can generate significant amounts of heat that may cause tissue damage. In addition, if there is a leakage of material into the disc cavity and surrounding tissues, this may cause undesirable complications. Also, in-situ cured polymers often require very toxic monomers that could leak into the patients' tissue and even into their blood stream causing serious harm. Many of the monomers are known carcinogens.

[00015] Another technique for nucleus replacement involves implanting a multiplicity of individual support members, such as beads, one at a time in the evacuated disc nucleus cavity until the cavity is full, such as described in U.S. Pat. Nos. 5,702,454 and 5,755,797. Because they are small, there is a possibility that one or more of the beads may extrude out of the evacuated disc nucleus cavity. From a mechanical perspective, this technique is limited in the ability to produce consistent and reproducible results because the location and interaction of the multiplicity of beads or support members can shift during and after implantation.

[00016] More recent attempts for a nucleus prosthesis involve using multiple elastomer pieces that results in an all-elastomeric composition, such as in U.S. Pat. No. 8,100,977. However, the polymer-polymer interface produced significant difficulties with implantation because the friction at the polymer-polymer interlock made implantation very difficult for the surgeons and secure locking of the modules was often unattainable. Additionally, the elastomeric material experiences contraction over time and loses some of its distraction capability. This undesirable behavior of many elastomers is called compression set. Such prior art further describes other solutions, one involving an elastomeric outer shell and inner hard material to allow sliding and locking of the modules, where the problems of modulus mismatch made this approach unstable biomechanically. A second approach with soft inner (hydrogel) and stiff outer shell would separate and dislocate.

[00017] Accordingly, there is a need, among other things, for a nucleus prosthesis that may be inserted using a minimally invasive procedure and that mimics the characteristics of a natural disc. The present disclosure describes systems, apparatuses and methods to address these and other shortcomings of the prior art.

SUMMARY

[00018] The present disclosure is directed to medical motion-preserving systems, apparatuses and methods. Embodiments include implantable spinal prostheses for repairing intervertebral discs. In some embodiments, such implantable prostheses include interconnected modular disc nucleus implants.

[00019] In one embodiment, one or more modular disc implant segments includes a relatively solid material(s) configured in a manner to cause it to act like or otherwise assume certain characteristics of a solid substance exhibiting at least compressibility and resiliency, such as an elastomer. For example, the material may be configured to include one or more structural voids, with can be occupied by air, liquid, gel, foam, a material having a higher compressibility, etc.

[00020] In one particular embodiment, any one or more of the modular disc implant segments includes a solid material, such as a biocompatible polymer, metal, etc., where that solid material includes one or more structural voids to enable the solid material to be compressed into the respective structural void when pressure is applied thereto. The solid material may be configured to exhibit elastic recovery characteristics to enable the respective modular disc implant segment to recover from the compression in order to partially or fully return to the original shape of the structural void(s), and therefore return the compressed modular disc implant segment(s) to its original geometric profile. In this manner, such modular disc implant segments can mimic or otherwise simulate the natural elastic properties of a healthy nucleus pulposus, and thereby serve as an implantable prosthesis for repairing damaged intervertebral discs.

[00021] While a single or multiple modular disc implant segments may be used as the implantable prosthesis for repairing damaged intervertebral discs, one embodiment involves assembling a plurality of modular disc implant segments into a unitary compressible and resilient replacement of an extracted nucleus pulposus within the annulus fibrosus. The modular implant segments may be inserted through an access orifice created in the intervertebral disc, such as through the annulus fibrosus. Each of the modular implant segments may be sequentially inserted into the disc space created by an extracted nucleus

pulposus, by way of an access orifice(s) to the disc space, with each of the second through last inserted modular implant segments respectively connecting (or substantially locking) to the adjacent modular implant segment whose insertion immediately preceded it.

[00022] In such an example, the end result is a unitary prosthesis that replaces the extracted nucleus pulposus and has compressibility and resiliency characteristics resembling a healthy nucleus pulposus, due at least to the appropriately configured modular disc implant segments utilizing the one or more structural voids.

[00023] Therefore, embodiments described herein include representative examples of connectable (and in some cases interlockable) modular disc implant segments capable of being formed *in situ* into a mimetic nucleus pulposus device that exhibits certain elastomeric properties substantially commensurate with that of a healthy nucleus pulposus, to restore an intervertebral disc to a simulated pre-impaired state.

[00024] One embodiment is directed to a modular connectable segment that can be assembled *in situ* with one or more other such modular connectable segments to ultimately provide an implanted intervertebral disc prosthesis, where the modular connectable segment is constructed from a generally non-elastic material that is compressible into one or more integrated spaces or voids. In one particular embodiment, a modular disc implant segment is provided that includes one or more structural gaps, openings, slits, or other structural voids to facilitate compression of the implant segment in response to an external force, where the implant segment is configured to return towards its original geometric shape in response to diminution of the external force.

[00025] In accordance with one embodiment, a disc nucleus replacement apparatus is provided that includes a plurality of modular disc implant segments, where at least one of the implant segments includes one or more structural voids to facilitate compression of the implant segment(s) in response to an external force, and where the implant segment(s) is configured to return towards its original geometric shape in response to diminution of the external force. An attachment mechanism is provided on each of the implant segments to facilitate connection of each of the implant segments to at least one other implant segment. The disc nucleus replacement apparatus comprises a unitary structure of connected implant segments.

[00026] In another embodiment of such a disc nucleus replacement apparatus, at least one of the structural voids is configured as a leaf-spring having one or more open-ended gaps.

[00027] In another embodiment, at least one of the structural voids is configured as a leaf-spring having one or more enclosed internal spaces.

[00028] Embodiments of such a disc nucleus replacement apparatus may involve constructing each of the modular disc implant segments from polyether ether ketone (PEEK). In still other embodiments, the modular disc implant segments are constructed from a titanium alloy.

[00029] Such a disc nucleus replacement apparatus may further include an implant segment connection mechanism configured to couple to the implant segment connection mechanism of at least one adjacent one of the modular disc implant segments. In a more particular example of such a disc nucleus replacement apparatus, the implant segment connection mechanism includes both a tongue element and groove, where the groove is configured to facilitate a slip fit connection by receiving the tongue element from an adjacent modular disc implant segment. In yet another particular example of such a disc nucleus replacement apparatus, the implant segment connection mechanism includes either a tongue element or groove, where the tongue element or groove on one modular disc implant segment is configured to facilitate a slip fit connection by connecting to the mating tongue element or groove in an adjacent modular disc implant segment.

[00030] The nucleus replacement apparatus may include modular disc implant segments that respectively include a tool connection mechanism capable of releasably connecting to an installation instrument.

[00031] In another embodiment of such a disc nucleus replacement apparatus, the structural voids are arranged in a symmetrical manner within at least one of the modular disc implant segments, where in other embodiments the structural voids are arranged in an asymmetrical manner within at least one of the modular disc implant segments. In one embodiment, the structural voids include a top set of structural voids and a bottom set of structural voids separated by a less compressible central portion.

[00032] Yet another embodiment of such a disc nucleus replacement apparatus further includes termination modular disc implant segments, having a different arrangement of structural voids than the other implant segments.

[00033] Another embodiment involves a method for implanting an intervertebral disc prosthesis in a patient. The method includes implementing a plurality of modular disc implant segments, each having a plurality of structural voids to facilitate compression of the modular disc implant segments in response to an external force, and each constructed of a material configured to return towards its original geometric shape in response to diminution of the external force. The method includes implanting a first modular disc implant segment. In connection with implanting a second modular disc implant segment, the second modular disc implant segment is connected to the first modular disc implant segment using a connection mechanism provided on each of the first and second modular disc implant segments. The method further includes implanting a last modular disc implant segment to form an aggregate intervertebral disc prosthesis in situ in the patient.

[00034] Another embodiment of such a method further includes implanting one or more additional ones of the modular disc implant segments between the first and last ones of the modular disc implant segments by way of their respective connection mechanisms.

[00035] In another embodiment, each of the modular disc implant segments is constructed from polyether ether ketone (PEEK).

[00036] Another embodiment of such a method further includes connecting an insertion tool to a connection receptacle on the second modular disc implant segment to facilitate its insertion into a disc space within the annulus fibrosus, and disconnecting the insertion tool from the connection receptable on the second modular disc implant segment when the second modular disc implant segment has been connected to the first modular disc implant segment via their respective connection mechanisms.

[00037] In another embodiment, a disc nucleus replacement implant is provided that includes a leaf spring arrangement to provide the necessary compressibility to mimic the native nucleus pulposus to allow motion between adjacent vertebrae.

[00038] In another embodiment of the disc nucleus replacement implant, the spring leaf elements of the implant's leaf spring arrangement remain connected to a main body of the implant to form the open channel, but through a series of arch spring constructs provide compressibility in flexion, extension, and lateral bending of the vertebral motion segment.

[00039] In one embodiment, the leaf spring arrangement includes a combination of open and closed leaf spring elements configured to optimize the flexibility of the implant in all vertebral motions.

[00040] Embodiments of such a disc nucleus replacement implant involve utilizing a material of the disc nucleus replacement implant that has a hardness or compression modulus similar to bone.

[00041] In still another embodiment of such a disc nucleus replacement implant, the disc nucleus replacement implant comprises two or more modules to allow separate insertion of each of the two or more modules through a pathway in the annulus fibrosus.

[00042] In a more particular embodiment of such a disc nucleus replacement implant, a non-elastomeric material is configured with one or more movable leaf springs that are connected to, but separated from, the body of the implant by an open channel such that the implant, as a whole, is compressible. In yet another particular embodiment of such a disc nucleus replacement implant an open anterior channel ends posteriorly in an enlarged, generally circular space to improve the compressibility of the leaf spring arrangement. In an alternative particular embodiment, an open posterior channel ends anteriorly in an enlarged, generally circular space to improve the compressibility of the leaf spring arrangement.

[00043] In another embodiment of such a disc nucleus replacement implant utilizing the movable leaf springs, each of the modules have channels in a Z configuration with a first open end on the upper channel facing posterior, and a second open end of the lower channel facing anterior. In an alternative embodiment, each of the modules have channels in a Z configuration with a first open end on the lower channel facing posterior, and a second open end of the upper channel facing anterior.

[00044] In another embodiment of such a disc nucleus replacement implant utilizing the movable leaf springs, two or more leaf springs are configured in each of a plurality of modules connected to form the disc nucleus replacement implant.

[00045] In other embodiments of such a disc nucleus replacement implant utilizing the movable leaf springs, the material of the disc nucleus replacement implant is PEEK, (polyether ether ketone). In another embodiment, the material of the disc nucleus replacement implant comprises a thermoplastic, where in still other embodiments the material comprises a composite of elastomer and thermoplastic. In another embodiment, the material of the disc nucleus replacement implant comprises an elastomer, where in still another embodiment the material of the disc nucleus replacement implant comprises metal. In yet another embodiment, the material of the disc nucleus replacement implant comprises a composite of metal and polymer (elastomeric or thermoplastic). The implant may be configured for insertion through Posterior Lumbar Interbody Fusion (PLIF), Transforaminal Lumbar Interbody Fusion (TLIF), and for lateral approaches. In still another embodiment, modules forming the disc nucleus replacement implant are inserted using a sequential dilator and distraction instrument.

[00046] In yet another embodiment, a device is provided for creating space between two adjacent vertebral bodies, comprising several progressively larger members placed coaxially to distend the annulus fibrosis and put force on the vertebral endplates to affect increased separation, wherein a final member in the sequence is sized to provide the desired endplate separation and have an internal dimension through which to pass instruments and an interbody implant module.

[00047] In still another embodiment, a vertebral disc nucleus replacement apparatus is provided that includes one or more structural voids within a substantially non-elastomeric component, where the structural voids facilitate compressibility of the substantially non-elastomeric component proximate the one or more structural voids when arranged within the vertebral disc as a replacement to an original nucleus pulposus.

[00048] This summary serves as an abbreviated, selective introduction of a representative subset of various concepts and embodiments that are further described or taught to those skilled in the art in the disclosure herein. This summary is not intended to refer to all

embodiments, scopes, or breadths of claims otherwise supported by the Specification, nor to identify essential features of the claimed subject matter, nor to limit the scope of the claimed subject matter.

BRIEF DESCRIPTION OF THE DRAWINGS

[00049] FIG. 1 depicts a first representative embodiment of a modular disc implant system utilizing a plurality of modular disc implant segments configured to interconnect to form an intervertebral disc prosthesis.

[00050] FIG. 2A depicts a representative embodiment of a modular disc implant segment that can form part of a intervertebral disc prosthesis that includes a plurality of modular disc implant segments.

[00051] FIG. 2B depicts the faces of the representative isometric modular disc implant segment.

[00052] FIG. 2C depicts a number of cross-sectional views of the isometric modular disc implant segment 200.

[00053] FIG. 2D depicts a number of cross-sectional views of the opposite side of the isometric modular disc implant segment 200.

[00054] FIG. 2E depicts a representative manner of connecting two (or more) of the modular disc implant segments together.

[00055] FIG. 2F is an example of a constructed intervertebral disc nucleus prosthesis formed by a plurality of connected modular disc implant segments.

[00056] FIG. 2G depicts some of the faces of the representative intervertebral disc nucleus prosthesis 210.

[00057] FIG. 2H depicts an exploded view of the termination and internal modular disc implant segments of a representative five-component intervertebral disc nucleus prosthesis.

[00058] FIG. 2I depicts another embodiment of a constructed intervertebral disc nucleus prosthesis formed by a plurality of connected modular disc implant segments.

[00059] FIG. 2J depicts a representative termination modular disc implant segment that may be used as an endcap of the intervertebral disc nucleus prosthesis.

[00060] FIGs. 3A-3E depict another embodiment of an intervertebral disc nucleus prosthesis utilizing a leaf spring design in accordance with the principles of the disclosure.

[00061] FIG. 4 depicts a representative manner in which the modular disc implant segments may be implanted into the annulus fibrosus.

[00062] FIG. 5 depicts a representative process in which a surgeon can implement the teachings herein to implant a unitary intervertebral disc nucleus prosthesis.

DETAILED DESCRIPTION

[00064] In the following description of various exemplary embodiments, reference is made to the accompanying drawings which form a part hereof, and in which is shown by way of illustration representative embodiments in which the features described herein may be practiced. It is to be understood that other embodiments may be utilized, as structural and operational changes may be made without departing from the scope of the disclosure.

[00065] Generally, systems, apparatuses and methods are disclosed for providing an implantable prosthesis for repairing damaged intervertebral discs, including but not limited to an interlocked modular disc nucleus implant device. Embodiments include modular disc implant segments that are constructed to include one or more internal portions that have a greater compressibility than the encompassing structure, thereby facilitating compression/deflection of the encompassing structure into the one or more internal portions of greater compressibility. In one embodiment, at least one of the portions having greater compressibility is a structural void that is filled with whatever surrounds the encompassing structure, such as air or fluid when surgically positioned in the human body. Such modular disc implant segments can then be sequentially inserted into a disc space and connected to one another to form a unitary structure capable of serving as a replacement nucleus pulposus in a damaged intervertebral disc.

[00066] Embodiments of the medical apparatus include a vertebral disc nucleus replacement apparatus comprising one or more structural voids within a substantially non-elastomeric component, where the structural voids facilitate compressibility of the substantially non-elastomeric component proximate the one or more structural voids when arranged within the vertebral disc as a replacement to an original nucleus pulposus. For example, some embodiments involve a leaf spring-type structure, where the structure is compressible due to the gap(s) created by the leaf spring(s) relative to another part(s) of the disc implant segment.

[00067] In one embodiment, a connectable or interlockable modular disc nucleus implant system and apparatus is provided, where the connectable/interlockable modular implants are made from a material that has compressibility, yet can withstand rigorous manipulation in the body. One such material is polyether ether ketone, or "PEEK." PEEK materials used in

embodiments herein may exhibit high temperature and chemical resistances, mechanical strength, resistance to abrasion, and biocompatibility. Such materials may also exhibit a compression modulus similar to that of human bone.

[00068] As noted above, one embodiment involves providing at least some, or all, of a plurality of modular disc implant segments with one or more structural voids to facilitate compression of the respective modular disc implant segments into the structural voids. For example, FIG. 1 depicts a first representative modular disc implant segment 100A that is configured to be interlockable or otherwise connectable with at least one adjacently-positioned modular disc implant segment 100n, where any number of connectable implant segments 100A-100n may be implemented.

[00069] The example of FIG. 1 includes at least one structural void 104A to facilitate compression of a modular disc implant segment, such as a PEEK-constructed modular disc implant segment. Any number or configuration of structural voids may be implemented to provide the proper compressibility and elastic recovery, which is depicted by the representative structural voids 104A, 104B, 104C, 104D and/or any other such constructs through 104n. It should be recognized that the representative structural voids 104A, 104B, 104C, 104D, 104n are merely illustrative, as other arrangements and implementations will be readily understood by those skilled in the art by way of the teachings herein.

[00070] When a plurality of such adjacently-positioned modular disc implant segments 100A-100n are connected to form a unitary compressible structure 102, it serves as a motion-preserving device to replace an extracted, impaired nucleus pulposus. In some embodiments, one or more end modular disc implant segments 106A, 106B may have the same, or different, internal configuration as the intermediary modular disc implant segments. As represented by FIG. 1, there may be any total number of modular disc implant segments utilized (with or without end segments). In some embodiments, the plurality of modular disc implant segments may be as low as two and up to as many as can be reasonably inserted and connected within the given disc space, although sizing preferences may involve more practical implementations from about three to five total implant segments.

[00071] Embodiments include implementation of any number of structural voids 104A-104n (collectively referred to as structural void 104) to provide the desired compressibility and required durability/safety profile. In one embodiment, there may be only one such structural void 104 that can be symmetrically or asymmetrically (e.g., offset to one side) positioned within the modular disc implant segment, or alternatively may be configured into a symmetric or asymmetric geometric shape. Other embodiments involve a plurality of such structural voids 104, which again may be incorporated into modular disc implant segments in a symmetric or asymmetric manner, where the plurality of voids 104 within the same (or even adjacent) modular disc implant segments may utilize the same or different void 104 shapes.

[00072] Alternative embodiments to a structural void(s) (*e.g.*, an open space(s)) include using a first material (e.g., PEEK) proximate one or more adjacent portions of greater compressibility, so that the first material can be compressed into, bend into, or otherwise be flexed into the receiving area(s) having a higher coefficient of compressibility. For example, in some embodiments the structural voids 104A, 104B, 104C, 104D, 104n may not simply represent carved out portions from the first material, but instead may comprise a substance(s) having a greater compressibility than the material from which the implant segments 100A-100n are otherwise constructed.

[00073] Thus, the overall compressibility is impacted by at least the material used in the portions having greater compressibility, which could be a pure void (e.g., air), fluid, gel, foam, and/or other material being more compressible than the first material (e.g., PEEK). The first material can be substantially incompressible (or at least inconsequentially compressible), or may itself have some level of compressibility. In some embodiments the first material and/or the second greater compressibility material may respectively be made from a homogeneous material, or alternatively one or both may be made from a heterogeneous material.

[00074] In a particular example of the FIG. 1 embodiment, a PEEK modular disc implant segment structure is implemented, where one or more structural voids 104A, 104B, 104C, 104D, 104n are incorporated into each of the modular disc implant segments 100A-100n, and include structural means to facilitate the interconnection thereof during the surgical implant procedure. The modular disc implant segments may be constructed in known manners,

including but not limited to extrusion, molding (e.g., injection molding, compression molding, blow molding, etc.) 3-dimensional (3D) printing, casting, and the like.

[00075] The structure of exemplary modular disc implant segments therefore provides struts, arms, support tiers, trusses, "leaf spring" designs, and/or other design that incorporates structural support where necessary while facilitating compression in targeted areas of the modular disc implant segments.

[00076] FIG. 2A represents a particular embodiment of such a modular disc implant segment. While the embodiment of FIG. 2A can be constructed from polymers, metals, and/or other biocompatible material, the embodiment of FIG. 2A is described in terms of using PEEK. PEEK has a compression modulus analogous to human bone, so provides a somewhat natural structure for building a nucleus pulposus prosthetic. PEEK also exhibits characteristics that facilitate smooth or otherwise relatively unhindered movement or sliding between adjacent modular disc implant segments as they are successively implanted into the target disc space. PEEK also exhibits a very robust longevity, thereby enabling long term benefit from the intervertebral disc prosthesis. The principles described herein are also equally applicable to other materials and compounds exhibiting some or all of these characteristics, such as metal, other polymers, etc. For example, one embodiment utilizes a titanium alloy for the body of the modular disc implant segments.

[00077] FIG. 2A depicts a representative embodiment of a modular disc implant segment 200 that can form part of a intervertebral disc prosthesis that includes a plurality of such modular disc implant segments 200. The representative embodiment of FIG. 2A includes a plurality of structural voids having some symmetry therein, including compression-absorbing spaces 202A, 202B, 202C, 202D, 202E, and 202F. These spaces or voids are strategically positioned, shaped, contoured, and otherwise arranged to properly equilibrate the absorption of, and resistance to, compression that will eventually be provided by a human recipient's spinal movement.

[00078] The representative modular disc implant segment 200 further includes an insertion-facilitating mechanism 204 to assist in the insertion of the implant segment 200 into the target disc space. In the illustrated embodiment, the insertion-facilitating mechanism 204

comprises a female-threaded hole to receive a threaded instrument that can be used to guide, and in some embodiments lock, the modular disc implant segments into the target disc space. It should be recognized that the modular disc implant segments may be equipped with any connection mechanism to facilitate its surgical positioning in the intervertebral disc within the annulus fibrosus.

[00079] The representative modular disc implant segment 200 of FIG. 2A also includes a connection mechanism 206, which in the present example comprises slip fit components including male connector 206A and female connector 206B. In this manner, a tool coupled to the modular disc implant segment 200 via the female-threaded hole 204 can facilitate the coupling of the male connector 206A onto the female connector 206B of an adjacently positioned modular disc implant segment to connect two neighboring implant segments 200. The male and female connectors 206A, 206B also facilitate proper alignment of the adjoining implant segments while connecting. In some embodiments, the "connection" is an interface or mating of physical elements, where in other embodiments the connection is made stronger in that it serves as an interlocked coupling. In some embodiments, the interface, mating, or interlocking mechanisms may be provided by intersecting physical components (e.g., tongue and groove), interlocking physical components (e.g., a slip fit), etc. In one interlocking embodiment, the mating physical components are configured to create an interference fit to provide a retention force and thereby prevent unintended separation of the adjoining parts.

[00080] In still other embodiments, magnetics can be used to mate neighboring modular disc implant segments. For example, some or all of the top half of a modular disc implant segment 200 could include magnetic material that is magnetized with a first polarity (e.g., north), and some or all of the bottom half of the implant segment 200 could include magnetic material that is magnetized with a second polarity (e.g., south) to facilitate a magnetic snap fit (with or without additional physical mating or connecting items) between the two neighboring modular disc implant segments. In such an embodiment, magnetic material in the modular disc implant segment can also serve as a radiopaque marker for visualization during the surgical procedure.

[00081] FIG. 2B depicts the faces of the representative isometric modular disc implant segment 200 of FIG. 2A. The depicted faces include the left, front, right, back, top and bottom views, where reference numbers used in connection with FIG. 2A are reproduced in FIG. 2B.

[00082] FIG. 2C depicts a number of cross-sectional views of the isometric modular disc implant segment 200 of FIG. 2A. In the illustrated embodiment, the cross sections are depicted along the X-Y PLANE, the Y-Z PLANE, and the X-Z PLANEs.

[00083] FIG. 2D depicts a number of cross-sectional views of the opposite side of the isometric modular disc implant segment 200 of FIG. 2A. From this view, one embodiment of the mail connector 206A of the connection mechanism 206 is visible.

[00084] FIG. 2E depicts a representative manner of connecting two (or more) of the modular disc implant segments 200A, 200B together. In one embodiment, these segments 200A, 200B are connected after the segment 200A has been inserted into the disc space created by evacuating the existing nucleus pulposus, and during insertion of the adjacent segment 200B into the disc space. In the illustrated embodiment, an insertion part 206A of a first modular disc implant segment 200A is slid over and along a groove 206B of the adjacent modular disc implant segment 200B, such as in a slip fit configuration. In one embodiment, the shape of the male connector 206A within the female connector 206B holds the two modular disc implant segments 200A, 200B together. In other embodiments, a friction or interference fit may instead, or additionally, be implemented to maintain the two modular disc implant segments 200A, 200B in their desired relative positions.

[00085] FIG. 2F is an example of a constructed intervertebral disc nucleus prosthesis 210 formed by a plurality of connected modular disc implant segments 200. In this embodiment, there are five modular disc implant segments, including 3 internal modular disc implant segments 200, and first and second termination modular disc implant segments 201A, 201B. In one embodiment, the termination modular disc implant segments 201A, 201B differ in structural arrangement from the internal modular disc implant segments 200, as they have only one open side in the illustrated embodiment. The cross-sectional view 211 of the representative intervertebral disc nucleus prosthesis 210 reveals the internal portions of the aggregation of modular disc implant segments, including the insertion-facilitating mechanism male connector

206A and female connector 206B of the connection mechanism 206. As previously noted, the male connector 206A and female connector 206B of the connection mechanism 206 hold the modular disc implant segments together to form a unitary intervertebral disc nucleus prosthesis 210, thereby serving as a motion-preserving device.

[00086] In one embodiment, the intervertebral disc nucleus prosthesis 210 is sized, relative to the receiving target disc space of the extracted nucleus pulposus, to eliminate or limit migration. For example, in one embodiment, the intervertebral disc nucleus prosthesis 210 is sized to as large or larger (at least in some dimensions) than the target disc space. In other embodiments, the size of the intervertebral disc nucleus prosthesis 210 may be smaller than the target disc space, but preferably held substantially in place with minimal ability to internally migrate.

[00087] FIG. 2G depicts some of the faces of the representative intervertebral disc nucleus prosthesis 210 of FIG. 2F. FIG. 2G depicts an isometric view, a side view of each termination modular disc implant segments 201A, 201B, a top view, a front view, and a back view. The representative intervertebral disc nucleus prosthesis 210 of FIG. 2G. When external pressure is exerted on such an intervertebral disc nucleus prosthesis 210 (e.g., from lateral, anterior and/or posterior movement of the prosthesis-receiving patient), the pressure-experiencing portion(s) of the intervertebral disc nucleus prosthesis 210 will deflect inward to absorb and respond to the exerted pressure.

[00088] FIG. 2H depicts an exploded view of the modular disc implant segments 200, 201A, 201B of a five-component intervertebral disc nucleus prosthesis 210. Among other things, this depiction indicates a representative manner to connect the modular disc implant segments, such as by way of the male connector 206A of the connection mechanism 206 (receiving/female connector 206B not visible in FIG. 2H). In one embodiment, the mail connector 206A is slid over a receiving groove (not shown) on an adjacent modular disc implant segment. In one particular embodiment, the abutting modular disc implant segments can then be locked together using, for example, a set screw in the insertion-facilitating 204 may bolster the connection therebetween, where in other embodiments such set screw or other

additional connection means is not used in addition to the physical mating of the connection elements.

[00089] FIG. 2I depicts another embodiment of a constructed intervertebral disc nucleus prosthesis 210B formed by a plurality of connected modular disc implant segments 200. In the illustrated embodiment, the intervertebral disc nucleus prosthesis 210B includes fewer modular disc implant segments than the example of FIGs. 2F and 2G. This illustrates that the intervertebral disc nucleus prostheses described herein may be of any number of sizes, with any number of disc implant segments (including or exclusive of termination modular disc implant segments), where in this illustrated embodiment the total number of modular disc implant segments is three. Particularly, this illustrative intervertebral disc nucleus prosthesis 210B includes one modular disc implant segments 200, and two termination modular disc implant segments 201A, 201B.

[00090] FIG. 2J depicts a representative termination modular disc implant segment 201A. In this embodiment, the insertion-facilitating mechanism 204 (e.g., female-threaded hole) can be accessed through an access space 212A in the termination modular disc implant segment 201A. In the illustration, the female connector 206B of the connection mechanism 206 is visible, and in a state where it can receive a mail connector 206A from an adjacently placed modular disc implant segment in order to interconnect the segments. Additionally, pivot hinges 212A and 212B may further facilitate deflection, in addition to the structure of the termination modular disc implant segment 201A into the structural void created thereby.

[00091] The examples of FIGs. 2A-2J depict a representative modular connectable segment that can be assembled *in situ* with one or more other such modular connectable segments to ultimately provide an implanted intervertebral disc prosthesis, where the modular connectable segment may be constructed from a generally non-elastic material that is compressible into one or more integrated spaces or voids. For example, in one embodiment, a modular disc implant segment is provided that includes one or more structural gaps, openings, slits, or other structural voids to facilitate compression of the implant segment in response to an external force, where the implant segment is configured to return towards its original geometric shape in response to diminution of the external force.

[00092] FIG. 3A depicts another embodiment of an intervertebral disc nucleus prosthesis 310 in accordance with the principles of the disclosure. This embodiment includes first and second termination modular disc implant segments 301A, 301B, and 3 intermediary modular disc implant segments 300. Set screw 303 depicts a representative manner in which the modular disc implant segments can be locked together. When interconnected, the modular disc implant segments 300, 301A, 301B collectively form the intervertebral disc nucleus prosthesis 310 depicted in FIG. 3B.

[00093] FIG. 3C depicts another representative configuration of structural voids in the modular disc implant segments. In this embodiment, the structural voids are represented by slits or open channels terminating at opposite ends of the modular disc implant segments 300. These structural voids enable bending/flexing of the arms 314A, 314B to facilitate the compression of the aggregate intervertebral disc nucleus prosthesis 310. As in other embodiments, this "leaf spring" arrangement properly equilibrates the absorption of, and resistance to, compression that will eventually be exerted due to a human recipient's spinal movement.

[00094] FIG. 3D depicts four faces of the representative modular disc implant segment 300 of FIGs. 3A-3C. FIG. 3D depicts locations of the gaps 302A, 302B (structural voids) between the arms 314A, 314B relative to the internal body of the modular disc implant segment 300 itself. FIG. 3D also displays a connection mechanism including a male connector 306 which can be used to align and connect to another, adjacent implant segment 300. Further, FIG. 3D depicts another embodiment of an insertion-facilitating mechanism 404 to assist in the insertion of the implant segment 300 into the target disc space. In the illustrated embodiment, the insertion-facilitating mechanism 304 comprises a female-threaded hole to receive a threaded instrument that can be used to guide, and in some embodiments lock, the modular disc implant segments into the target disc space. FIG. 3E depicts additional details on the embodiment described in connection with FIGs. 3A-3D.

[00095] FIG. 4 depicts a representative manner in which the modular disc implant segments may be implanted into the annulus fibrosus 401. The representative implant tool 400 can couple to the modular disc implant segments 402 to guide them through an access orifice

404 created in the annulus fibrosus 401, and facilitate interconnection and/or interlocking an adjacent modular disc implant segment. In such a manner, the target disc space 406 can be equipped with a unitary intervertebral disc nucleus prosthesis as described herein.

[00096] FIG. 5 depicts a representative process in which a surgeon can implement the teachings herein to implant a unitary intervertebral disc nucleus prosthesis. In such an embodiment, the surgeon can utilize modular disc implant segments, each having structural voids to enable compression of the modular disc implant segments in response to an external force, and where each are constructed of a material configured to return towards its original geometric shape in response to diminution of the external force. The process includes implanting a first modular disc implant segments, and in connection with implanting a second modular disc implant segment, the surgeon can connect the second modular disc implant segment to the first modular disc implant using a connection mechanism provided on each of the first and second modular disc implant segments. The last of the modular disc implant segments is then implanted to form an aggregate intervertebral disc prosthesis in situ in the patient.

[00097] The present disclosure solves numerous problems of the prior art, including insertion and biomaterial problems. In one embodiment, a solution is provided by using a single well known, biocompatible, thermoplastic material with a unique design that takes advantage of this material's excellent flexion fatigue characteristic to provide a compression modulus for the motion segment similar to the native nucleus pulposus in all ranges of motion, while also having a compression modulus of the material similar to bone.

[00098] Such an embodiment will allow the surgeon to reestablish the normal disc height and re-tense the annulus fibrosus fibers to establish a physiologic load sharing between the annulus and the nucleus pulposus.

[00099] Embodiments set forth herein include a simple yet robust attachment system to make implantation for the modules fast, reproducible, easily learned and secure.

[00100] As noted herein, the inventive information includes the various representative embodiments disclosed herein, which those skilled in the art can appreciate other embodiments

from the teachings provided herein. Other representative/exemplary embodiments are set forth herein.

[00101] In one representative embodiment, a disc nucleus replacement apparatus is provided that implements a leaf spring arrangement to provide the necessary compressibility to mimic the native nucleus pulposus to allow motion between adjacent vertebrae.

[00102] In another particular embodiment, such a disc nucleus replacement apparatus (also referred to herein as an "implant") includes a non-elastomeric material configured with one or more moveable leaves, (connected but separated from the body of the implant by an open channel) such that the implant as a whole is compressible. In a more specific representative embodiment, two or more leaf springs are configured in each module. In another more specific embodiment, the material comprises polyether ether ketone (PEEK), and in some embodiments the material is made entirely of PEEK.

[00103] In yet another embodiment of such a disc nucleus replacement apparatus, the material comprises a thermoplastic material, where in other embodiments the material comprises an elastomer, where in still other embodiments the material comprises a composite of elastomer and thermoplastic. In still other embodiments the material comprises a metal, where in yet other embodiments the material comprises a composite of metal and polymer (e.g., elastomeric or thermoplastic).

[00104] In another particular embodiment of such a disc nucleus replacement apparatus, the material has a hardness or compression modulus similar to bone.

[00105] In another particular embodiment, the implant includes two or more modules to allow insertion through a pathway in the annulus fibrosus. In a more specific embodiment, the modules include channels configured in a Z configuration with the open end on the upper channel facing posterior, and the open end of the lower channel facing anterior. In an alternative specific embodiment, the modules include channels configured in a Z configuration with the open end on the upper channel facing anterior, and the open end of the lower channel facing posterior. In yet other embodiments, the implant is inserted through a sequential dilator and distraction instrument(s), while in other embodiments the open anterior channel ends

posteriorly in an enlarged, generally circular space to improve the compressibility of the leaf element. In another embodiment, the open posterior channel ends posteriorly in an enlarged, generally circular space to improve the compressibility of the leaf element.

[00106] In another embodiment, such a disc nucleus replacement apparatus is configured for insertion through Posterior Lumbar Interbody Fusion (PLIF), Transforaminal Lumbar Interbody Fusion (TLIF), and for lateral approaches.

[00107] Another embodiment includes a vertebral disc nucleus replacement apparatus comprising one or more structural voids within a substantially non-elastomeric component, where the structural voids facilitate compressibility of the substantially non-elastomeric component proximate the one or more structural voids when arranged within the vertebral disc as a replacement to an original nucleus pulposus.

[00108] The foregoing description of representative embodiments has been presented for the purposes of illustration and description. It is not intended to be exhaustive or to limit the disclosure to the precise forms disclosed. Many modifications and variations are possible in light of the above teaching without departing from the broader scope and spirit of the disclosure. Teachings in the specification and drawings are therefore regarded as illustrative, and not restrictive. The invention covers alternatives, modifications, and equivalents that come within the scope and spirit of the principles set out herein and/or in the appended claims.

[00109] The accompanying drawings forming a part of the disclosure show, by way of illustration and not of limitation, particular representative embodiments in which the disclosed concepts may be practiced. Therefore, this Detailed Description is not to be taken in a limiting sense, and the scope of various embodiments is defined only by the appended claims, along with the full range of equivalents to which such claims are entitled.

[00110] The embodiments of the innovative subject matter may be collectively or individually referred to herein as the "invention" for convenience, without intending to restrict the scope of this application to any single invention or inventive concept if multiple concepts are disclosed. Therefore, while specific embodiments have been illustrated and described herein, it should be understood that any arrangement designed to achieve the same purpose may

be substituted for the specific embodiments shown. This disclosure intends to encompass all adaptations or variations of various embodiments. Those skilled in the art will recognize combinations of the above embodiments and other embodiments not explicitly described herein upon reviewing the foregoing description.

WHAT IS CLAIMED IS:

1. A disc nucleus replacement apparatus comprising:

a plurality of modular disc implant segments, wherein at least one of the plurality of implant segments comprises one or more structural voids to facilitate compression of the at least one implant segment in response to an external force, and wherein the at least one implant segment is configured to return towards its original geometric shape in response to diminution of the external force;

an attachment mechanism on each of the plurality of implant segments to facilitate connection of each of the implant segments to at least one other one of the implant segments; and

wherein the disc nucleus replacement apparatus comprises a unitary structure of connected ones of the plurality of implant segments.

2. The disc nucleus replacement apparatus as in Claim 1, wherein at least one of the structural voids is configured as a leaf-spring having one or more open-ended gaps.

3. The disc nucleus replacement apparatus as in Claim 1, wherein at least one of the structural voids is configured as a leaf-spring having one or more enclosed internal spaces.

4. The disc nucleus replacement apparatus as in Claim 1, wherein each of the plurality of modular disc implant segments is constructed from polyether ether ketone.

5. The disc nucleus replacement apparatus as in Claim 1, wherein each of the plurality of modular disc implant segments is constructed from a titanium alloy.

6. The disc nucleus replacement apparatus as in Claim 1, further comprising an implant segment connection mechanism configured to couple to the implant segment connection mechanism of at least one adjacent one of the modular disc implant segments.

7. The disc nucleus replacement apparatus as in Claim 6, wherein the implant segment connection mechanism comprises both a tongue element and groove, and wherein the groove is

configured to facilitate a slip fit connection by receiving the tongue element from an adjacent one of the modular disc implant segments.

8. The disc nucleus replacement apparatus as in Claim 6, wherein the implant segment connection mechanism comprises one of a tongue element or groove, and wherein the tongue element or groove on a first of the modular disc implant segments is configured to facilitate a slip fit connection by connecting to the mating one of the tongue element or groove in an adjacent one of the modular disc implant segments.

9. The disc nucleus replacement apparatus as in Claim 1, wherein each of the plurality of modular disc implant segments comprises a tool connection mechanism capable of releasably connecting to an installation instrument.

10. The disc nucleus replacement apparatus as in Claim 1, wherein the one or more structural voids are arranged in a symmetrical manner within at least one of the modular disc implant segments.

11. The disc nucleus replacement apparatus as in Claim 1, wherein the one or more structural voids are arranged in an asymmetrical manner within at least one of the modular disc implant segments.

12. The disc nucleus replacement apparatus as in Claim 1, wherein the one or more structural voids comprise a top set of structural voids and a bottom set of structural voids separated by a less compressible central portion.

13. The disc nucleus replacement apparatus as in Claim 1, further comprising termination modular disc implant segments, having a different arrangement of the one or more structural voids than the at least one of the plurality of implant segments.

14. A method for implanting an intervertebral disc prosthesis in a patient, comprising:

implementing a plurality of modular disc implant segments, each comprising a plurality of structural voids to facilitate compression of the modular disc implant segments in response

to an external force, and each constructed of a material configured to return towards its original geometric shape in response to diminution of the external force;

implanting a first one of the modular disc implant segments;

in connection with implanting a second one of the modular disc implant segments, connecting the second one of the modular disc implant segments to the first one of the modular disc implant segments using a connection mechanism provided on each of the first and second modular disc implant segments; and

implanting a last one of the modular disc implant segments to form an aggregate intervertebral disc prosthesis in situ in the patient.

15. The method of Claim 14, further comprising implanting one or more additional ones of the modular disc implant segments between the first and last ones of the modular disc implant segments by way of their respective connection mechanisms.

16. The method of Claim 14, wherein each of the modular disc implant segments comprises polyether ether ketone.

17. The method of Claim 14, further comprising connecting an insertion tool to a connection receptacle on the second modular disc implant segment to facilitate its insertion into a disc space within the annulus fibrosus, and disconnecting the insertion tool from the connection receptable on the second modular disc implant segment when the second modular disc implant segment has been connected to the first modular disc implant segment via their respective connection mechanisms.

18. A disc nucleus replacement implant comprising a leaf-spring arrangement to provide the necessary compressibility to mimic the native nucleus pulposus to allow motion between adjacent vertebrae.

19. A disc nucleus replacement implant as in Claim 18, comprising a non-elastomeric material configured with one or more movable leaf springs that are connected to, but separated

from, the body of the implant by an open channel such that the implant, as a whole, is compressible.

20. A disc nucleus replacement implant as in Claim 19, wherein an open anterior channel ends posteriorly in an enlarged, generally circular space to improve the compressibility of the leaf spring arrangement.

21. A disc nucleus replacement implant as in Claim 19, wherein an open posterior channel ends posteriorly in an enlarged, generally circular space to improve the compressibility of the leaf spring arrangement.

22. A disc nucleus replacement implant as in Claim 18, where spring leaf elements of the implant's leaf spring arrangement remain connected to a main body of the implant to form the open channel, but through a series of arch spring constructs provide compressibility in flexion, extension, and lateral bending of the vertebral motion segment.

23. A disc nucleus replacement implant as in Claim 18, wherein the leaf spring arrangement comprises a combination of open and closed leaf spring elements configured to optimize the flexibility of the implant in all vertebral motions.

24. A disc nucleus replacement implant as in Claim 18, wherein a material of the disc nucleus replacement implant has a hardness or compression modulus similar to bone.

25. A disc nucleus replacement implant as in Claim 18, wherein the disc nucleus replacement implant is composed of two or more modules to allow separate insertion of each of the two or more modules through a pathway in the annulus fibrosus.

26. A disc nucleus replacement implant as in Claim 19, wherein each of the modules have channels in a Z configuration with a first open end on the upper channel facing posterior, and a second open end of the lower channel facing anterior.

27. A disc nucleus replacement implant as in Claim 19, wherein each of the modules have channels in a Z configuration with a first open end on the lower channel facing posterior, and a second open end of the upper channel facing anterior.

28. A disc nucleus replacement implant as in Claim 19, where two or more leaf springs are configured in each of a plurality of modules connected to form the disc nucleus replacement implant.

29. A disc nucleus replacement implant as in Claim 19, wherein the material of the disc nucleus replacement implant is PEEK, (polyether ether ketone).

30. A disc nucleus replacement implant as in Claim 19, wherein the material of the disc nucleus replacement implant comprises a thermoplastic.

31. A disc nucleus replacement implant as in Claim 19, wherein the material of the disc nucleus replacement implant comprises a composite of metal and a polymer, wherein the polymer comprises an elastomer or thermoplastic.

32. A disc nucleus replacement implant as in Claim 19, wherein the material of the disc nucleus replacement implant comprises an elastomer.

33. A disc nucleus replacement implant as in Claim 19, wherein the material of the disc nucleus replacement implant comprises metal.

34. A disc nucleus replacement implant as in Claim 19, wherein the material of the disc nucleus replacement implant comprises a composite of metal and an elastomeric or thermoplastic polymer.

35. A disc nucleus replacement implant as in Claim 19, wherein the implant is configured for insertion through Posterior Lumbar Interbody Fusion (PLIF), Transforaminal Lumbar Interbody Fusion (TLIF), and for lateral approaches.

36. A disc nucleus replacement implant as in Claim 19, wherein modules forming the disc nucleus replacement implant are inserted using a sequential dilator and distraction instrument.

37. A device for creating space between two adjacent vertebral bodies, comprising several progressively larger members placed coaxially to distend the annulus fibrosis and put force on the vertebral endplates to affect increased separation, wherein a final member in the sequence is sized to provide the desired endplate separation and have an internal dimension through which to pass instruments and an interbody implant module.

38. A vertebral disc nucleus replacement apparatus comprising one or more structural voids within a substantially non-elastomeric component, where the structural voids facilitate compressibility of the substantially non-elastomeric component proximate the one or more structural voids when arranged within the vertebral disc as a replacement to an original nucleus pulposus.

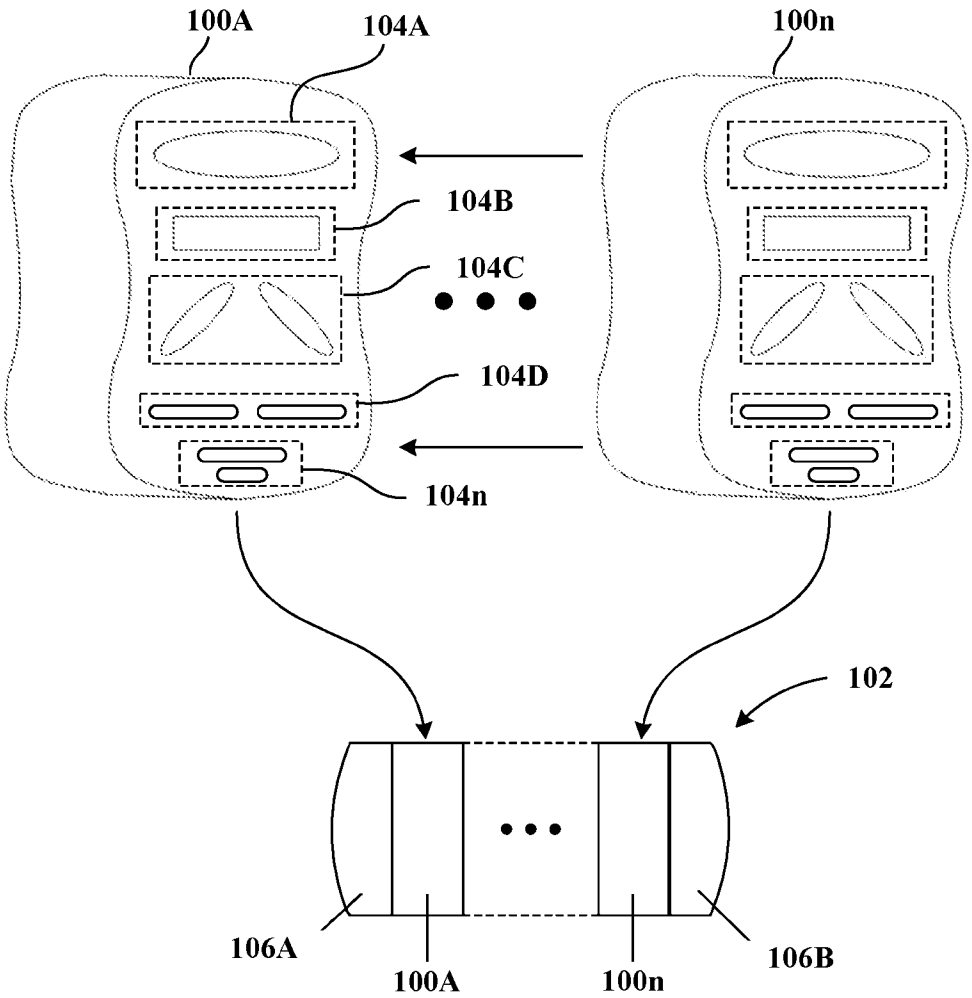


FIG. 1

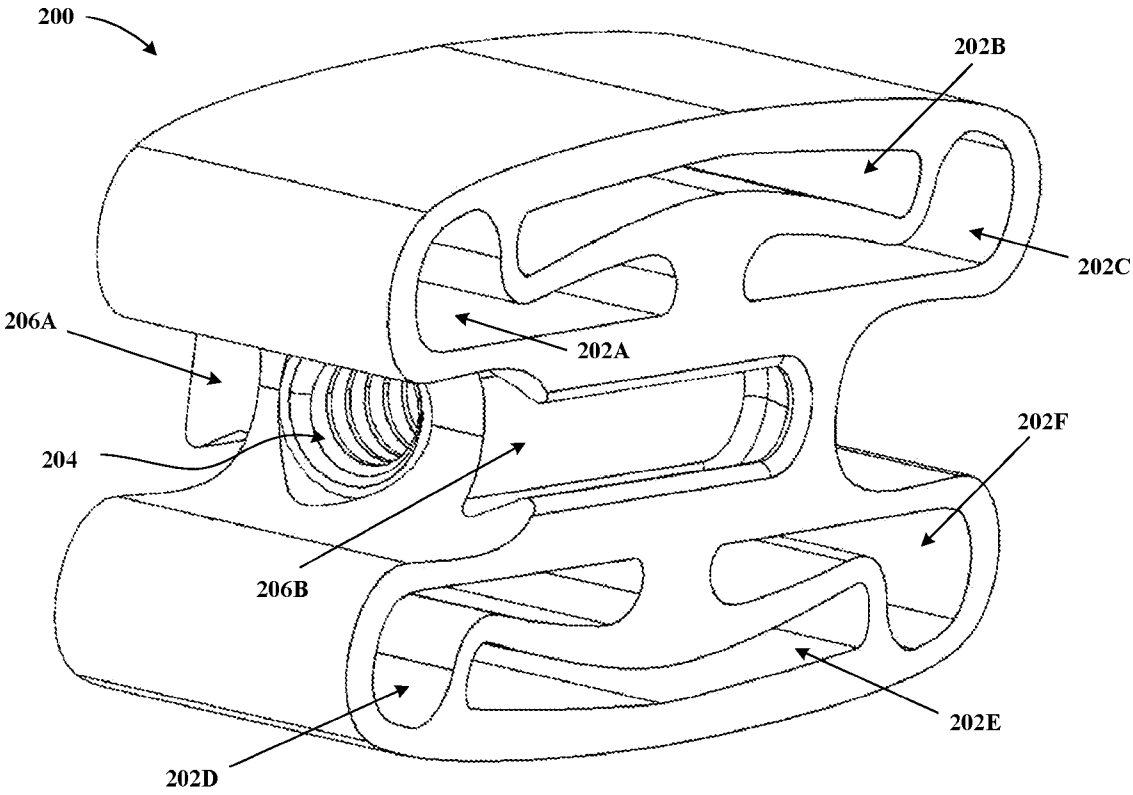
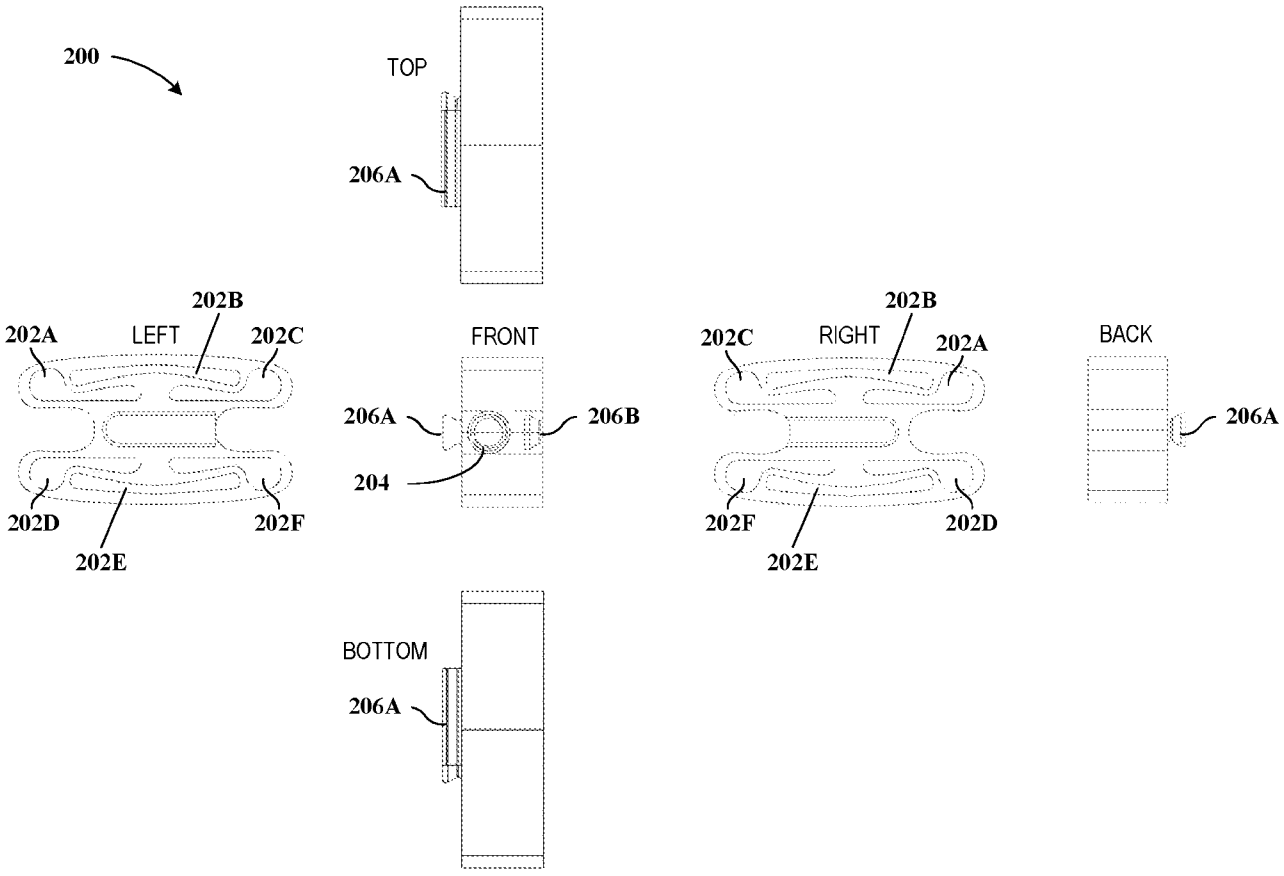


FIG. 2A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206A
202B
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202C
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BACK
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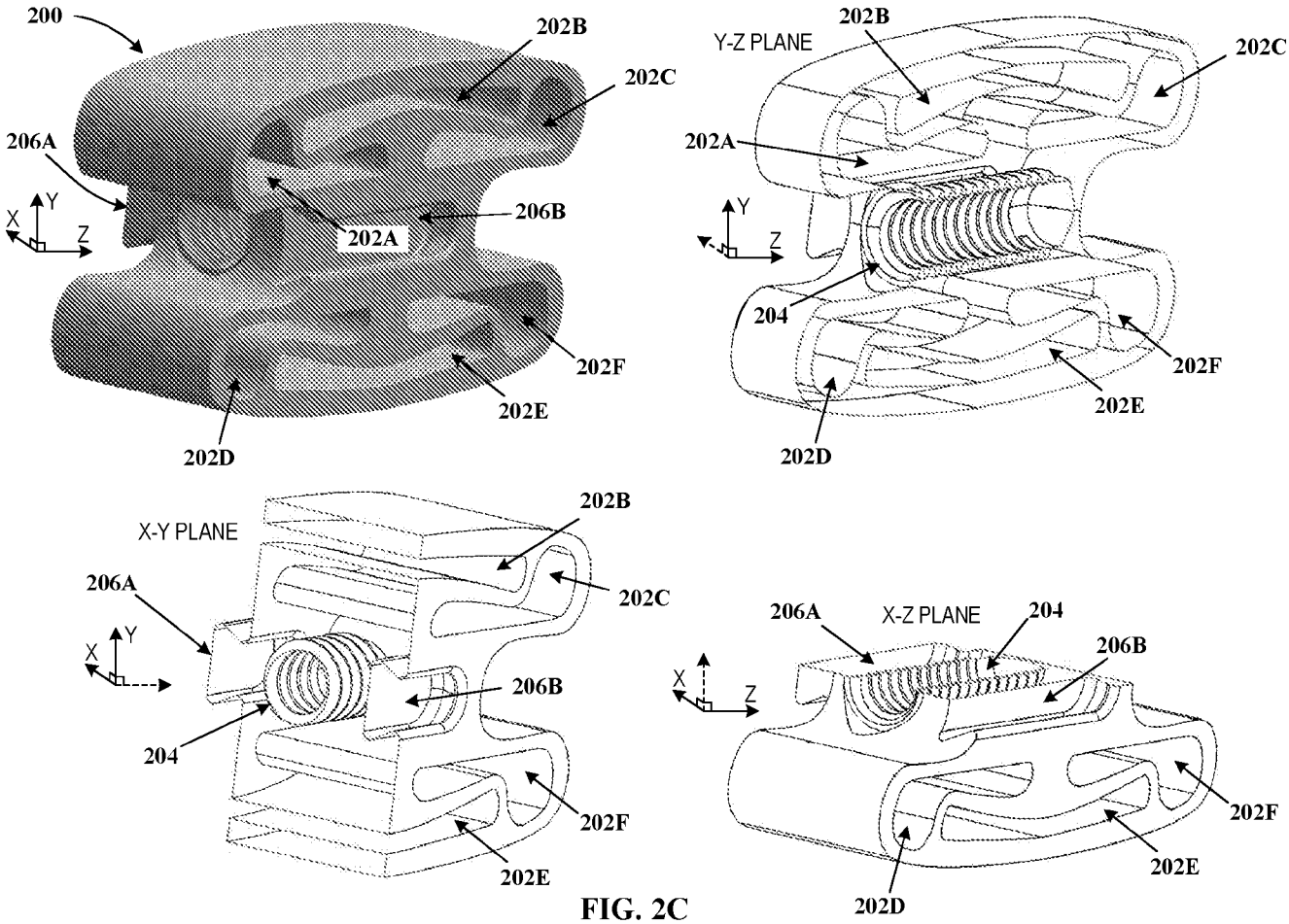
BOTTOM
206A

FIG. 2B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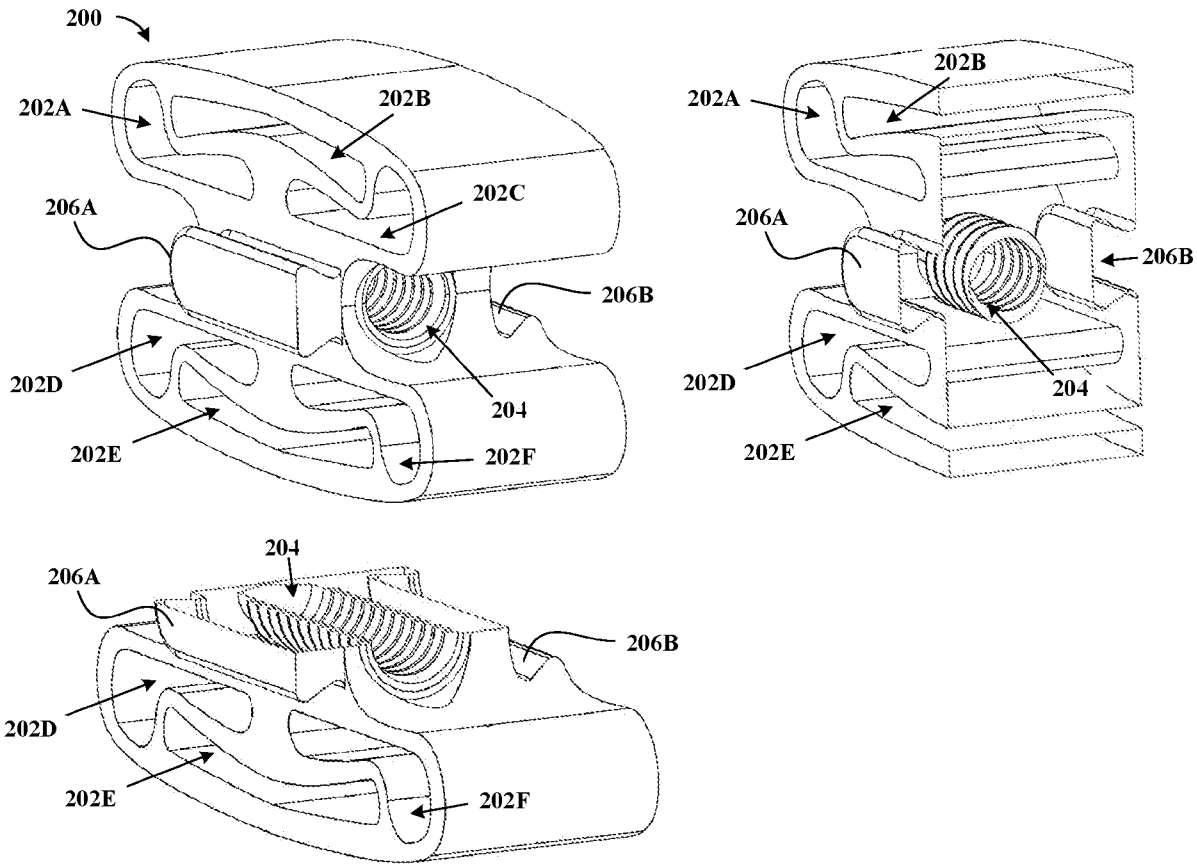
X
Y
Z

FIG. 2C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202F

FIG. 2D

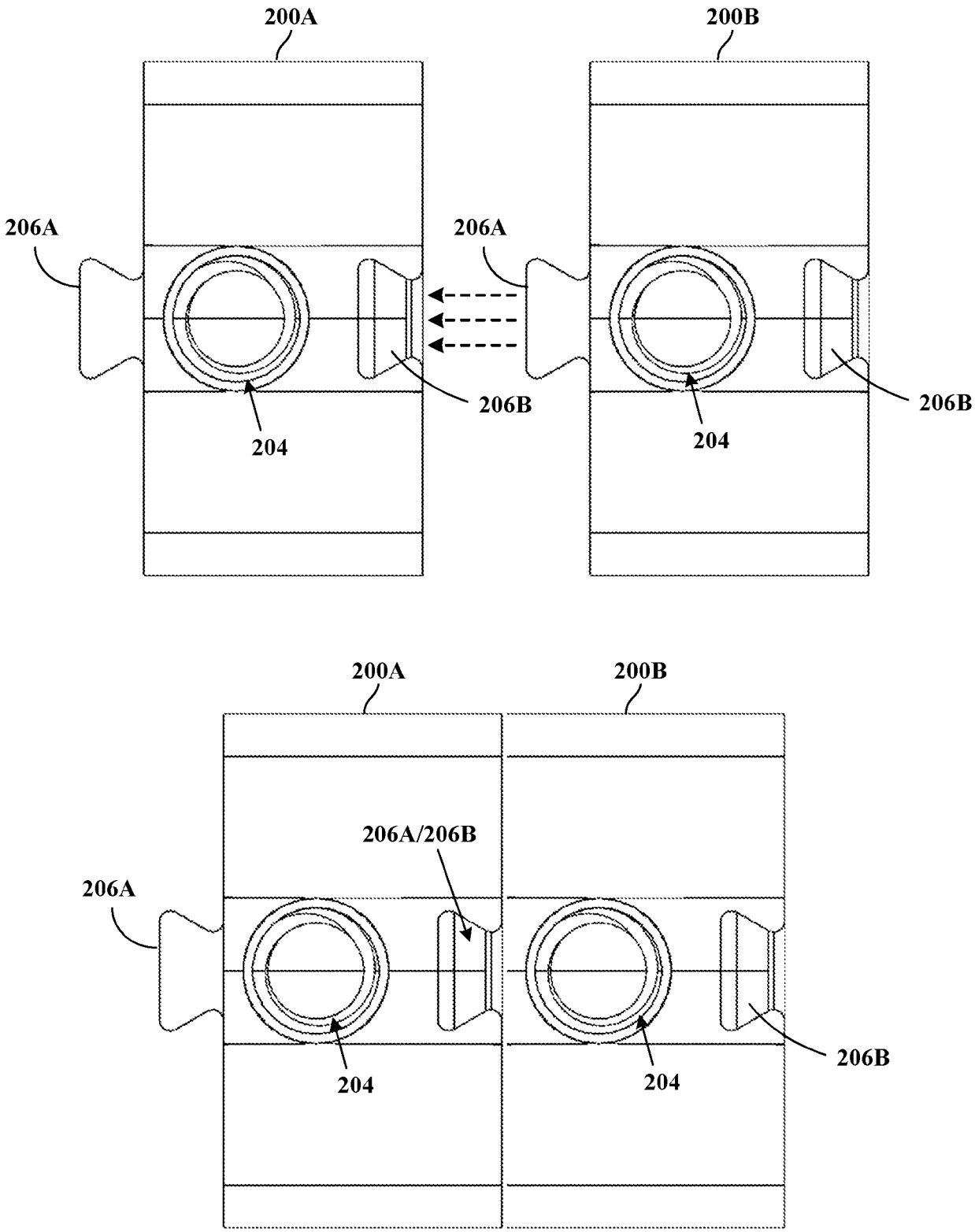
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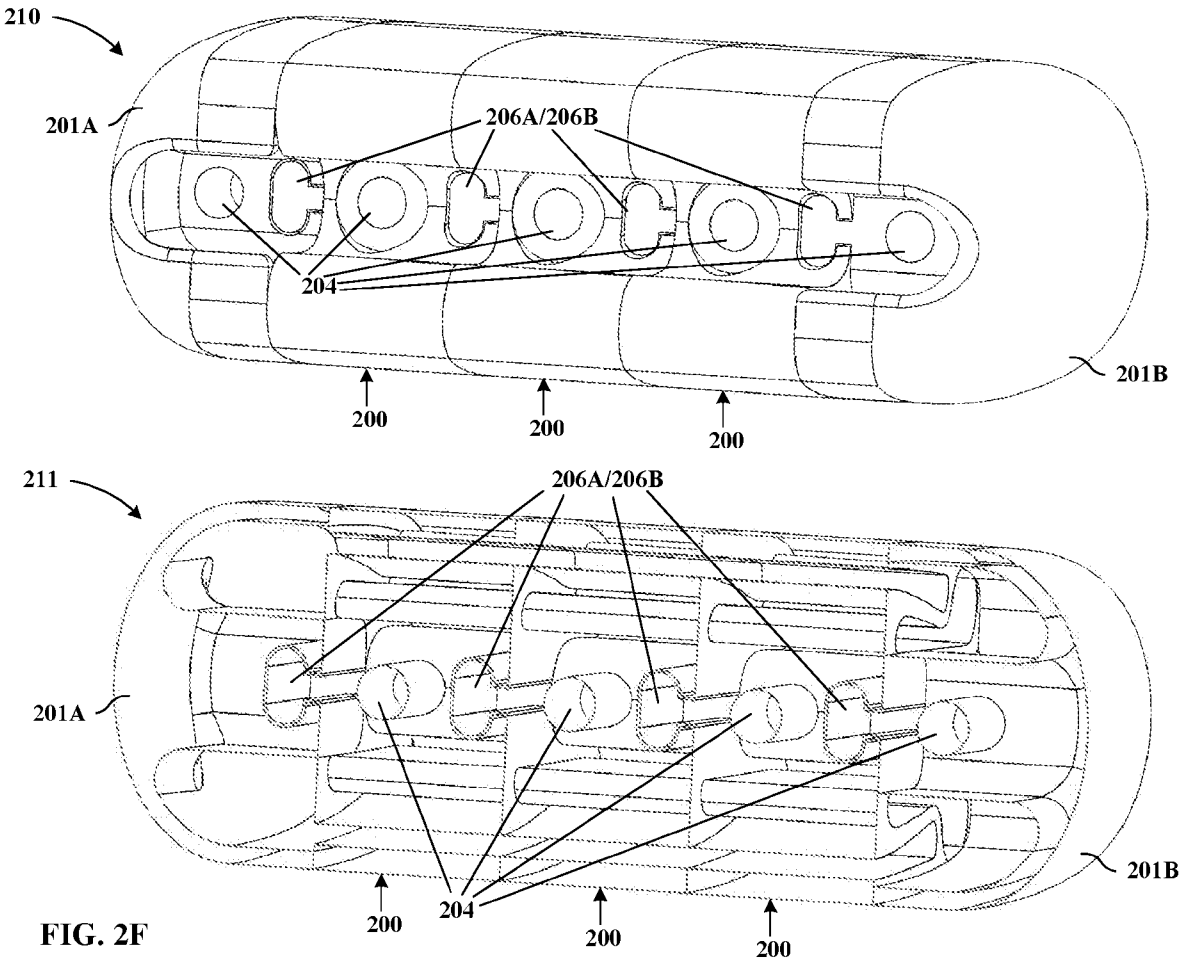
FIG. 2E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201A
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201B
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211
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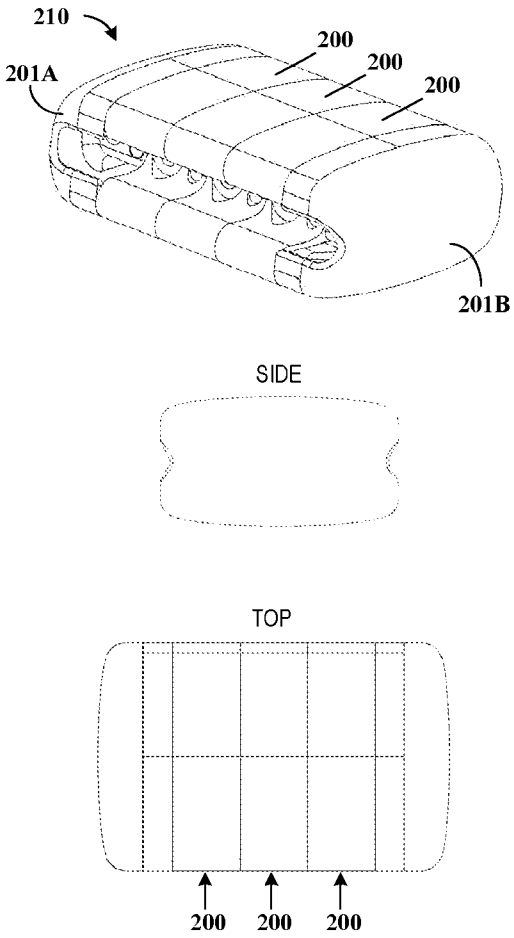
200
200
200

FIG. 2F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201A
201B
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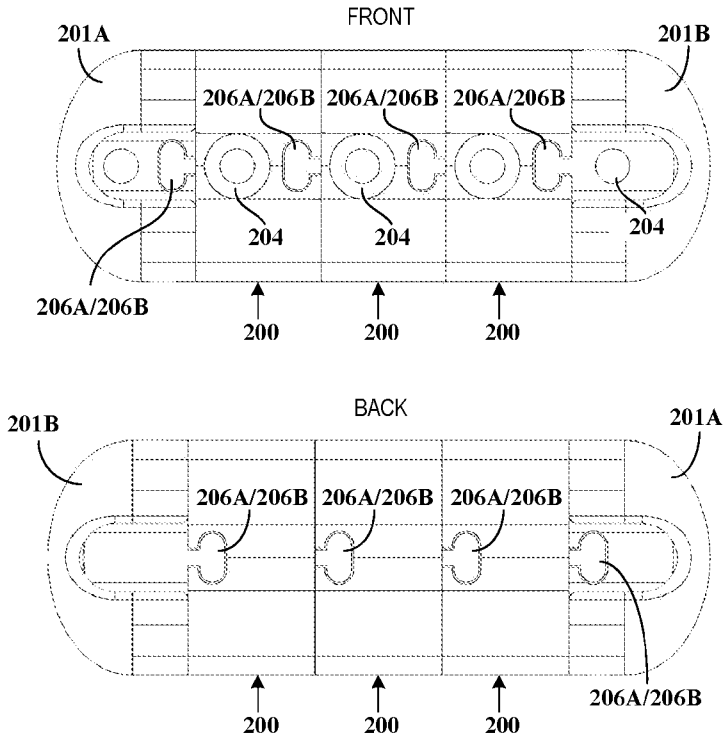
TOP
200
200
200


FRONT
201A
201B
206A/206B
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206A/206B
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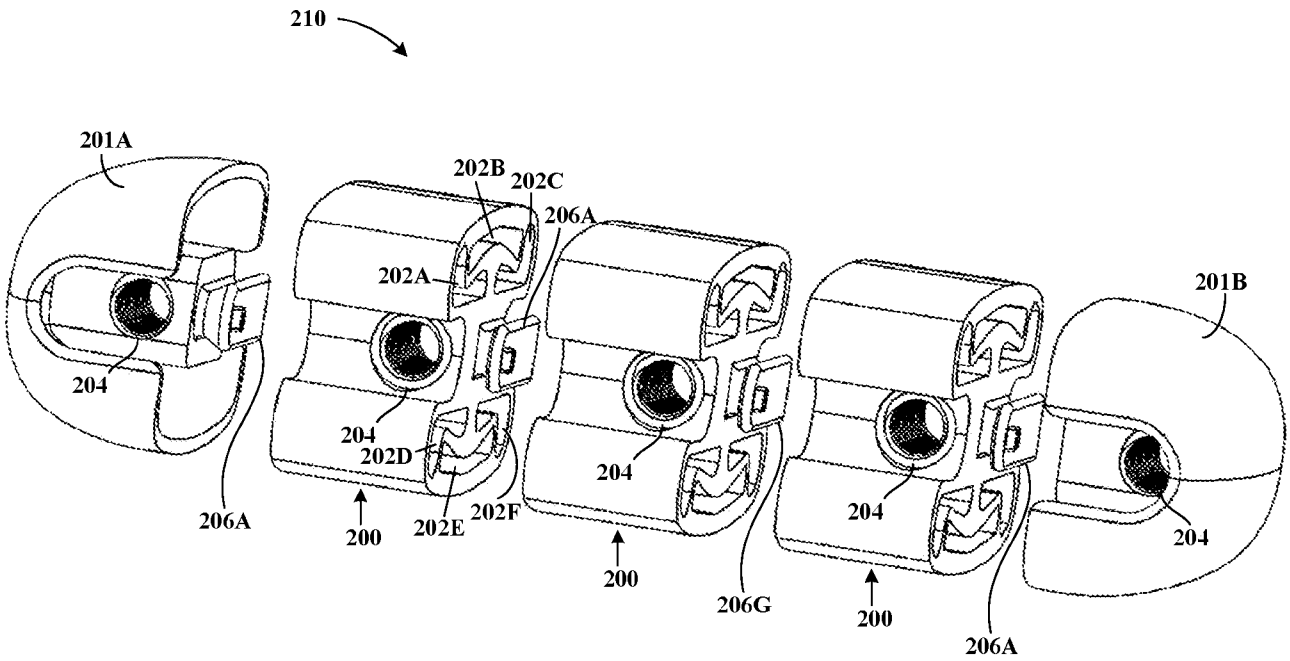
200
200

FIG. 2G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206G
200
206A

FIG. 2H

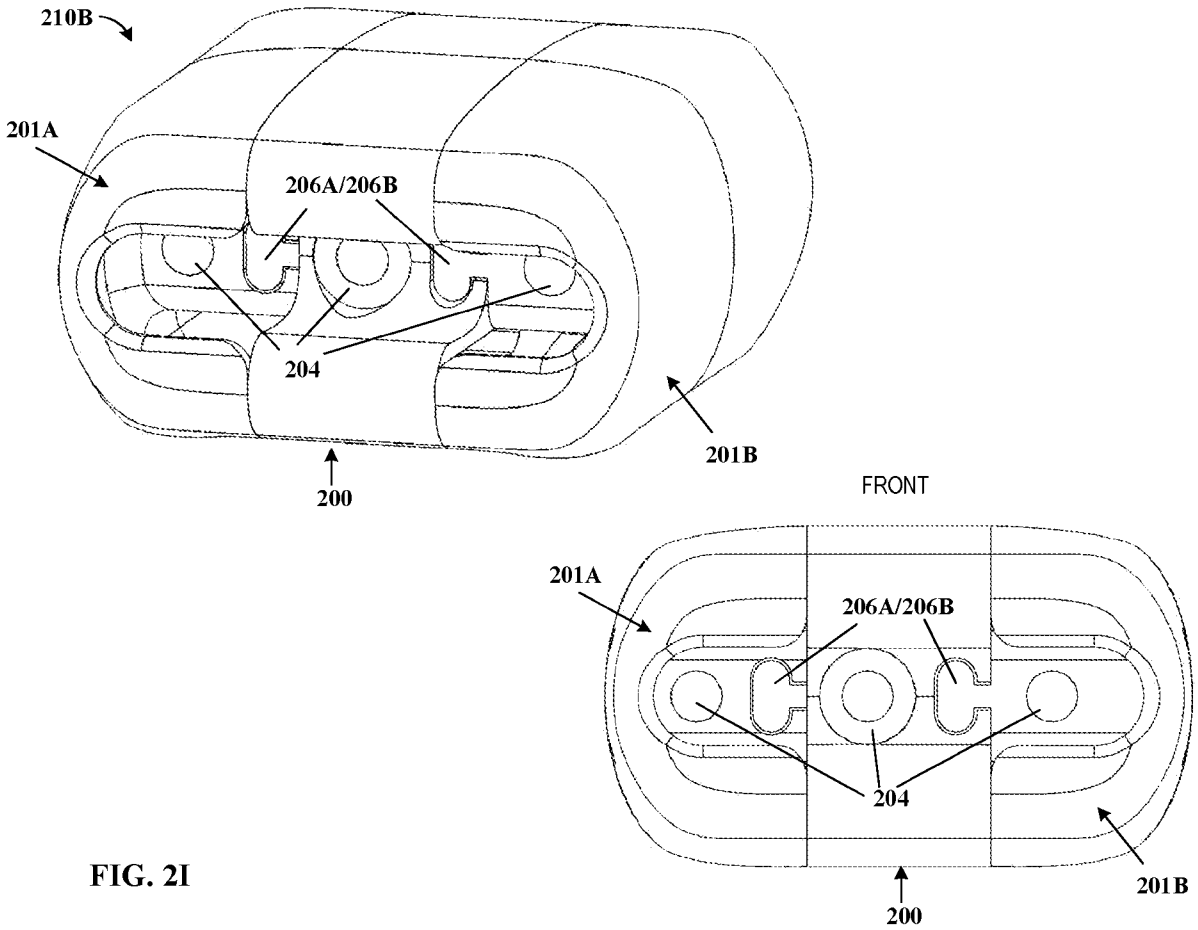
210B
201A
206A/206B
204
201B
200
FRONT
201A
206A/206B
204
201B
200

FIG. 2I

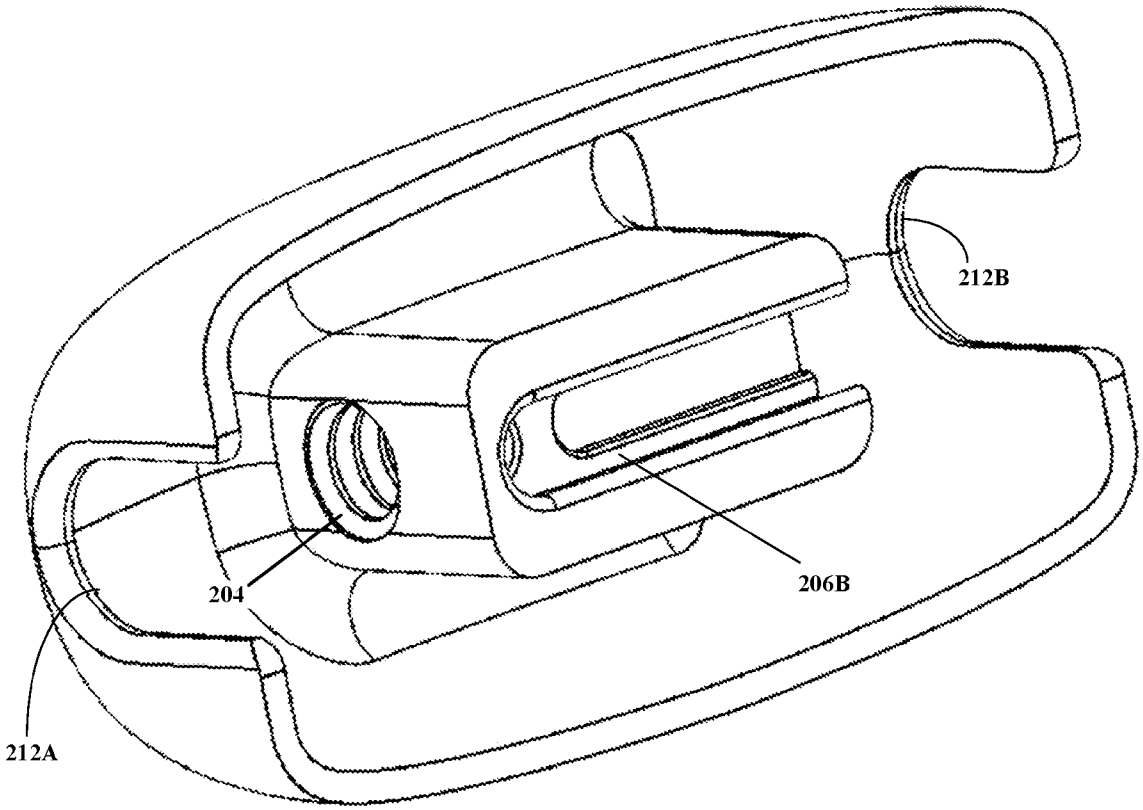

FIG. 2J

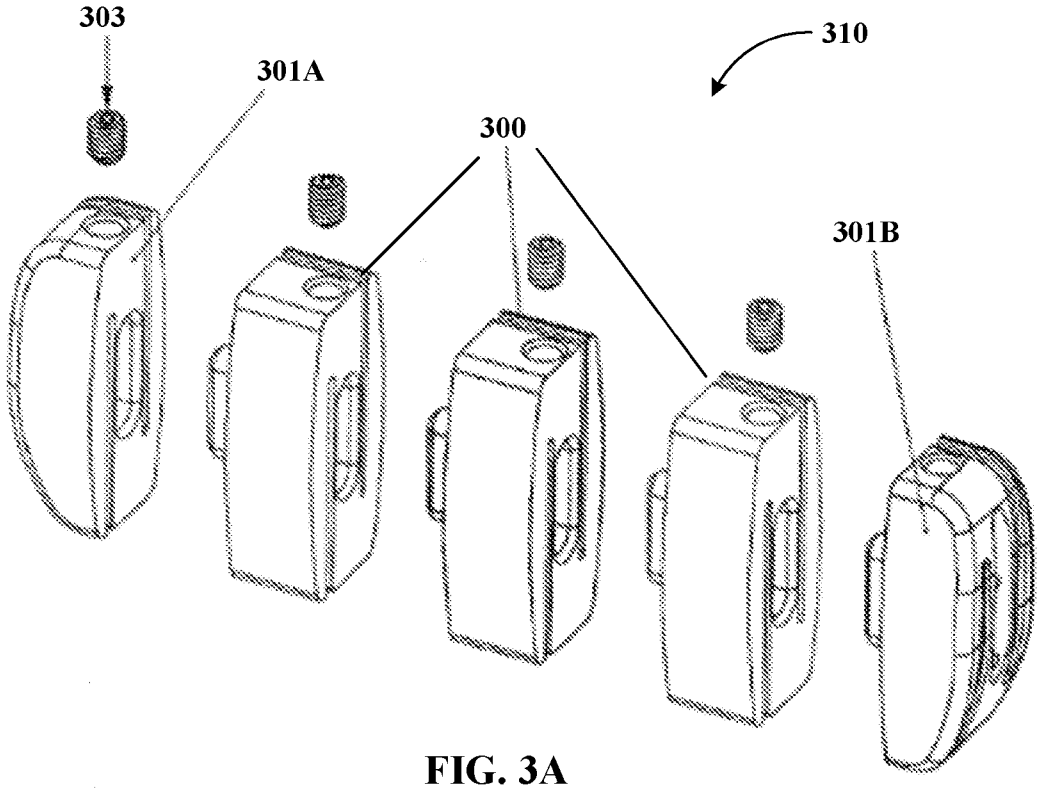

FIG. 3A

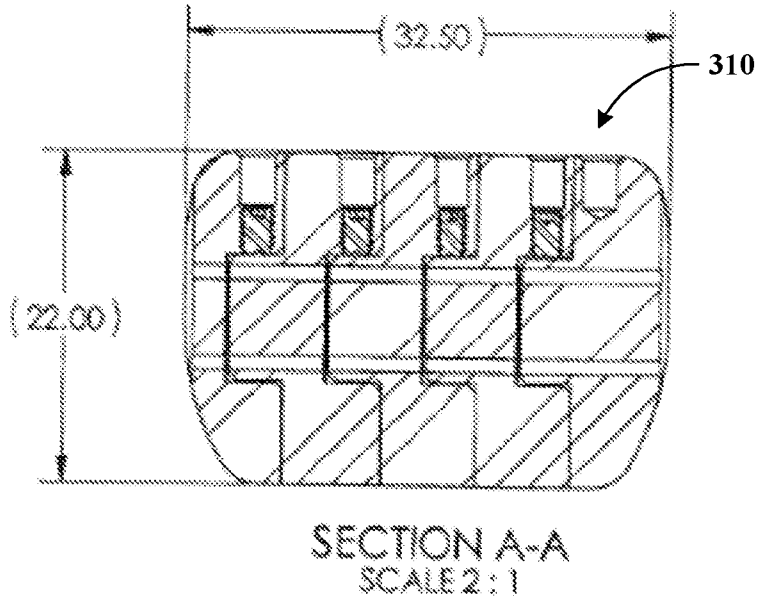

FIG. 3B

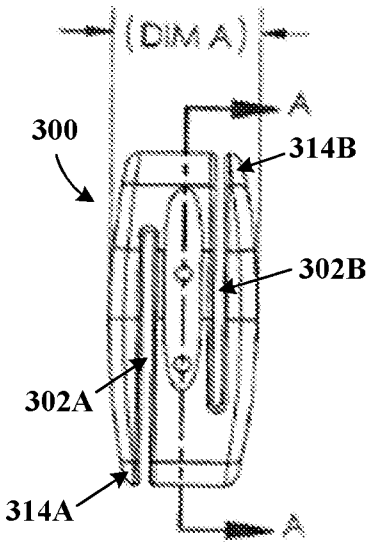

FIG. 3C

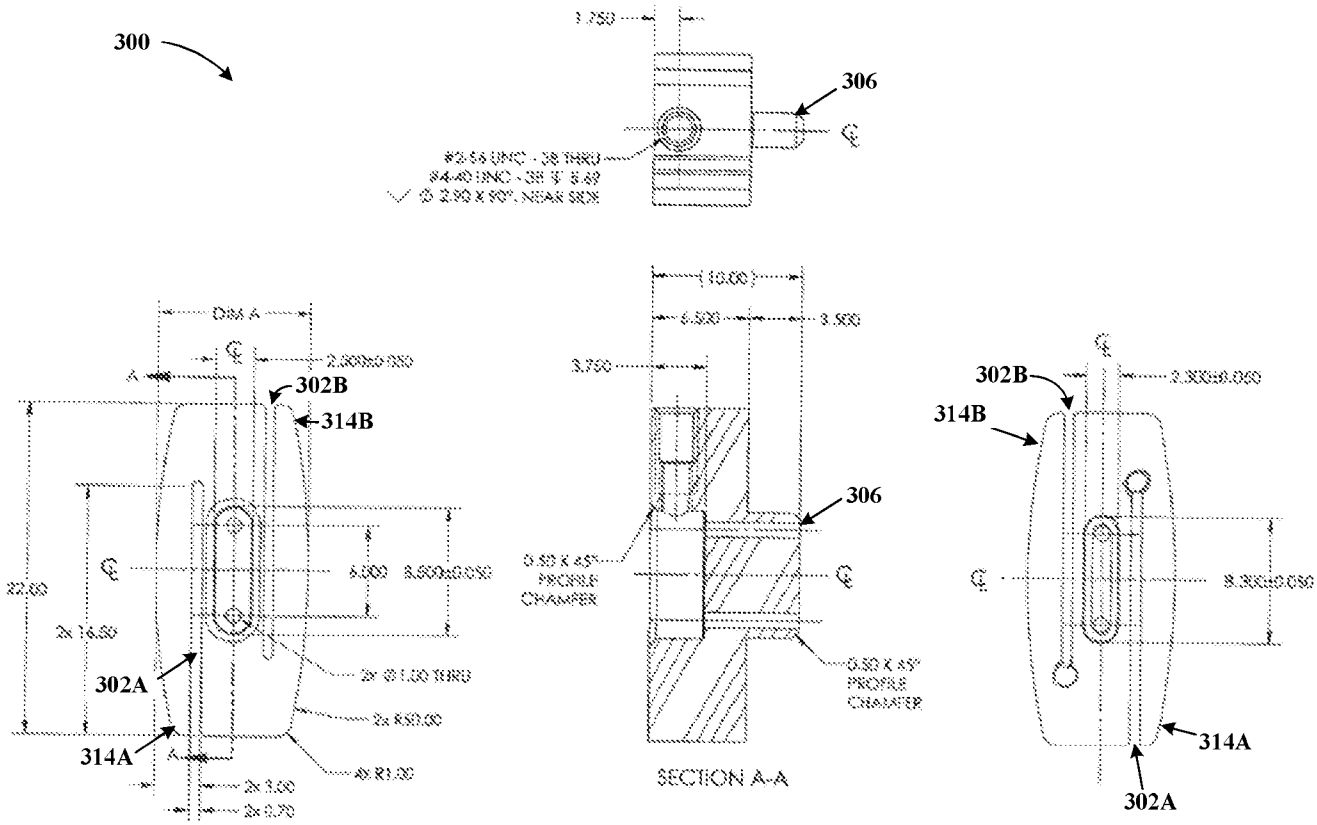

FIG. 3D

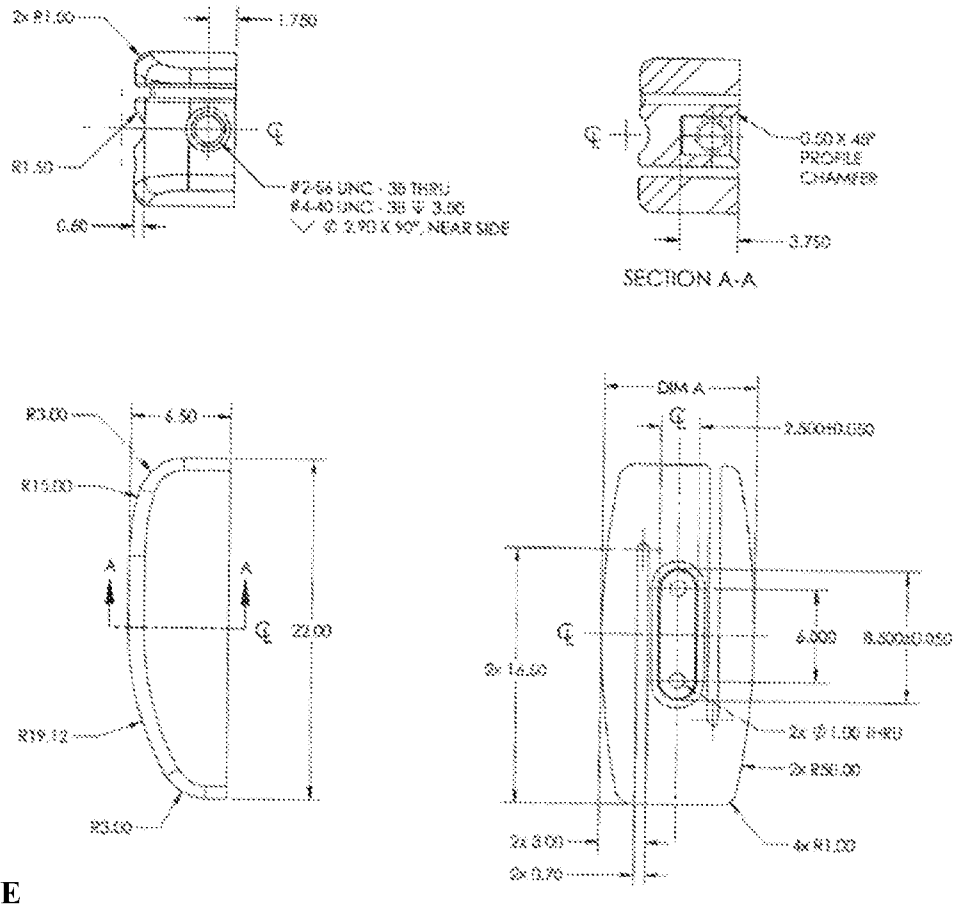

FIG. 3E

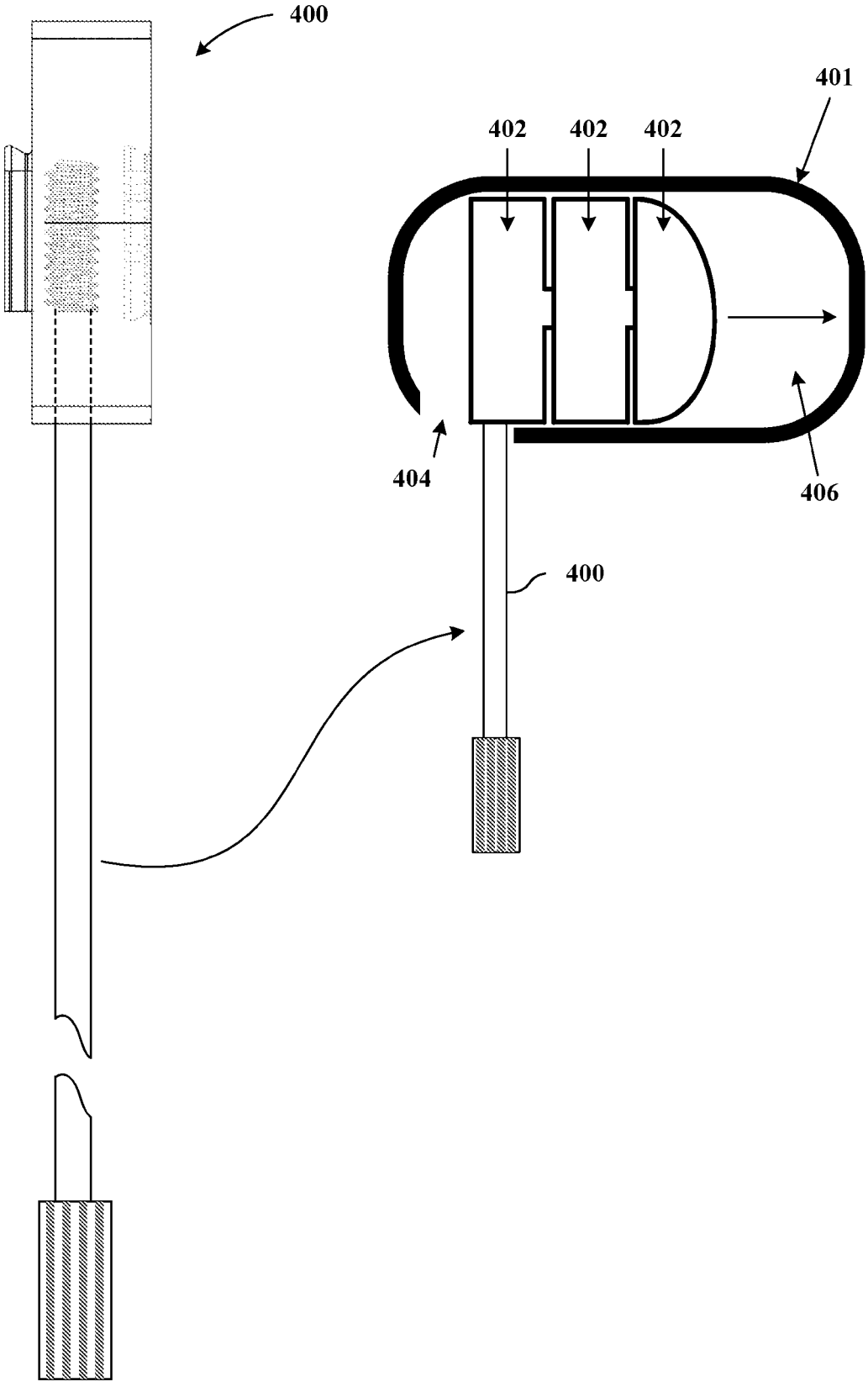

FIG. 4

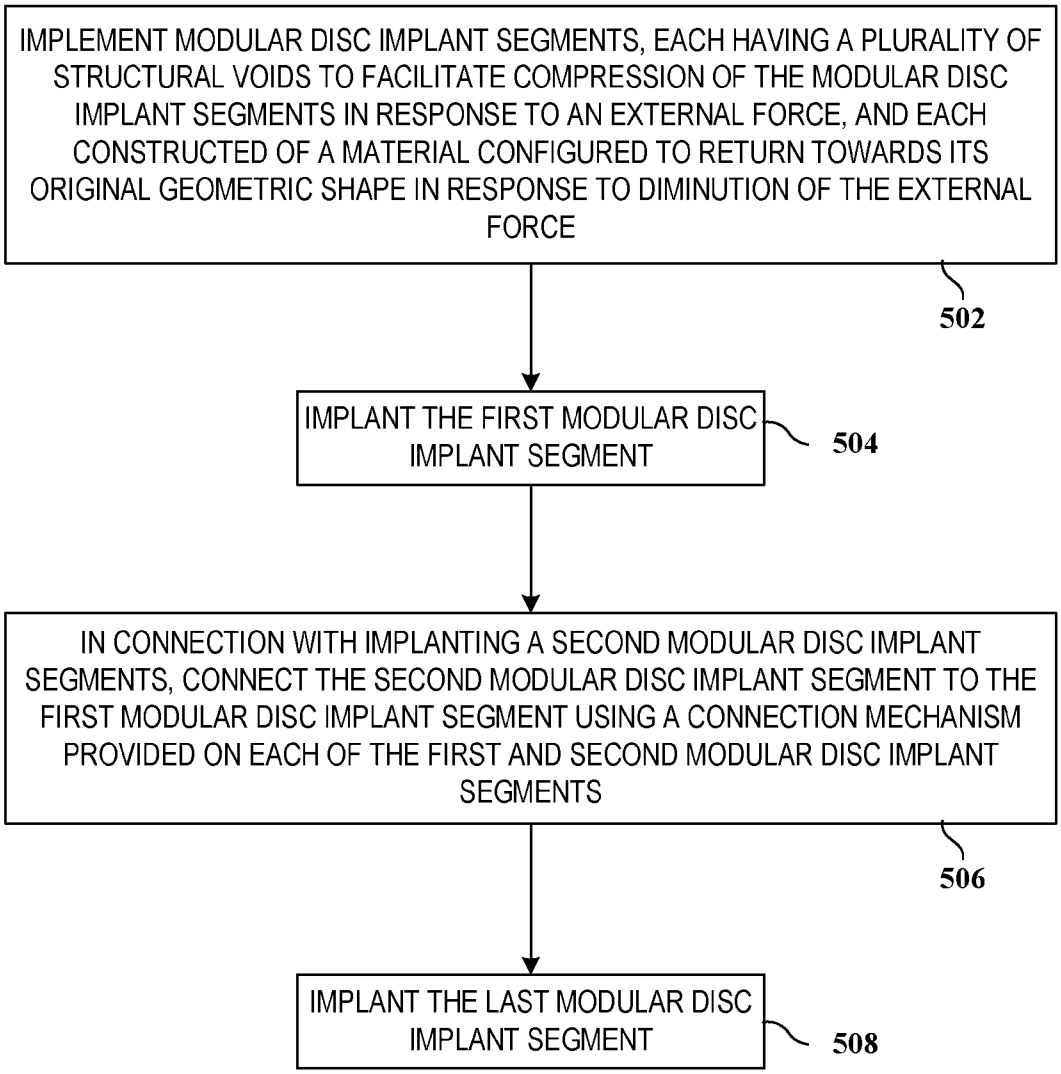
IMPLEMENT MODULAR DISC IMPLANT SEGMENTS, EACH HAVING A PLURALITY OF STRUCTURAL VOIDS TO FACILITATE COMPRESSION OF THE MODULAR DISC IMPLANT SEGMENTS IN RESPONSE TO AN EXTERNAL FORCE, AND EACH CONSTRUCTED OF A MATERIAL CONFIGURED TO RETURN TOWARDS ITS ORIGINAL GEOMETRIC SHAPE IN RESPONSE TO DIMINUTION OF THE EXTERNAL FORCE
502
IMPLANT THE FIRST MODULAR DISC IMPLANT SEGMENT
504
IN CONNECTION WITH IMPLANTING A SECOND MODULAR DISC IMPLANT SEGMENTS, CONNECT THE SECOND MODULAR DISC IMPLANT SEGMENT TO THE FIRST MODULAR DISC IMPLANT SEGMENT USING A CONNECTION MECHANISM PROVIDED ON EACH OF THE FIRST AND SECOND MODULAR DISC IMPLANT SEGMENTS
506
IMPLANT THE LAST MODULAR DISC IMPLANT SEGMENT
508

FIG. 5

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2024/034344

A. CLASSIFICATION OF SUBJECT MATTER

IPC: ***A61F 2/44*** (2023.01)

CPC: ***A61F 2/442;*** *A61F 2002/444; A61F 2002/4485; A61F 2002/30331; A61F 2002/30571*

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

See Search History Document

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

See Search History Document

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

See Search History Document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
	US 2021/0186707 A1 (HSIEH) 24 June 2021 (24.06.2021)	
X	Entire document.	1-11, 13-17, 38
Y	Entire document.	12
	US 2005/0165485 A1 (TRIEU) 28 July 2005 (28.07.2005)	
Y	entire document	12
	US 6,595,998 B2 (JOHNSON et al.) 22 July 2003 (22.07.2003)	
A	entire document	1-17, 38
	US 2003/0171812 A1 (GRUNBERG et al.) 11 September 2003 (11.09.2003)	
A	entire document	1-17, 38
	US 2009/0138086 A1 (DEWEY) 28 May 2009 (28.05.2009)	
A	entire document	1-17, 38

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"D" document cited by the applicant in the international application

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
18 September 2024 (18.09.2024)	**21 November 2024 (21.11.2024)**

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2024/034344

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Group I: Claims 1-17, 38, directed to a plurality of modular disc implant segments comprising one or more structural voids.

Group II: Claims 18-36, directed to a leaf-spring arrangement to mimic the native nucleus pulposus to allow motion between adjacent vertebrae.

Group III: Claim 37, directed to a device to create space for implantation.

The groups of inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Special Technical Features:

Group I includes the special technical feature a plurality of modular disc implant segments, wherein at least one of the plurality of implant segments comprises one or more structural voids; an attachment mechanism on each of the plurality of implant segments to facilitate connection of each of the implant segments to at least one other one of the implant segments; and the apparatus comprises a unitary structure of connected ones of the plurality of implant segments, not required in any other group.

Group II includes the special technical feature comprising a leaf-spring arrangement to mimic the native nucleus pulposus to allow motion between adjacent vertebrae, note required in any other group.

Group III includes the special technical feature a device for creating space between two adjacent vertebral bodies, comprising several progressively larger members placed coaxially to distend the annulus fibrosis and put force on the vertebral endplates to affect increased separation, wherein a final member in the sequence is sized to provide the desired endplate separation and have an internal dimension through which to pass instruments and an interbody implant module, not required in any other group.

Common Technical Features:

Group III shares not features with any other Group.

Group I-III share the common technical features of a disc nucleus replacement implant: comprising compressibility. However these features are known in the art to US 2021/0186707 A1 (HSIEH). Hsieh describes a disc nucleus replacement implant (Abstract, FIGS. 11-14; supporting member 100, FIGS. 2): comprising compressibility (para[0055]: " the material of the supporting member … elastomers"; para[0053]: "after the positioning portions are fastened together, the U-shaped groove structures 151 will return to their original shapes elastically to ensure that the positioning bump is securely fastened to the positioning hole to prevent the supporting members from separating from each other").

Accordingly, the inventions listed as Groups above lack unity of invention under PCT Rule 13 because they do not share a same or corresponding special technical feature providing contribution over prior art.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2024/034344

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☑ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.: **1-17, 38**

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.