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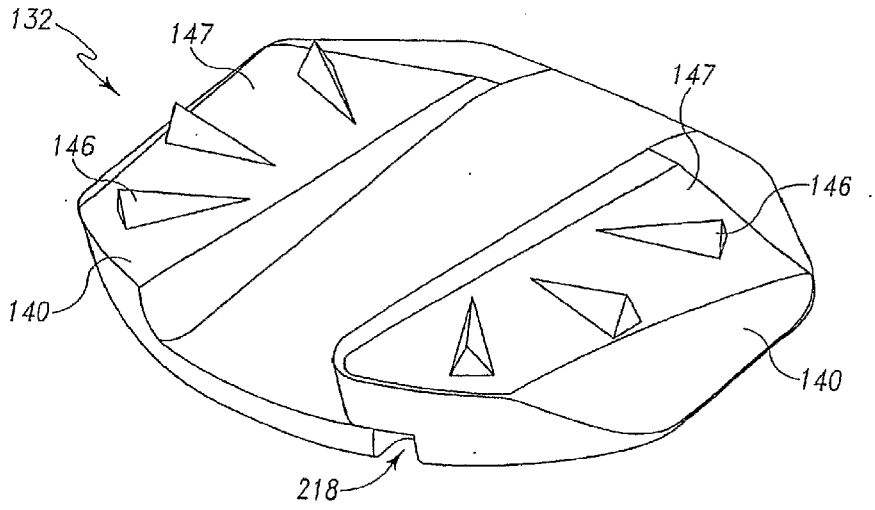
(54) Title: METHOD AND APPARATUS FOR FIXATION OF INTERVERTEBRAL DISC PROSTHESIS



(57) Abstract: An intervertebral disc prosthesis comprises a superior endplate and an inferior endplate. The superior and inferior endplates include vertebra fixation surfaces designed to engage vertebral bodies. A composite material is provided on the vertebra fixation surfaces. The composite material includes an osteoconductive component and an osteoinductive component. The osteoconductive component provides a porous matrix or base that facilitates bone growth. The osteoinductive component provides a stimulant material that encourages growth of the bone cells between the osteoconductive component of the endplate and the vertebral body facing the endplate. In one embodiment, the osteoconductive component is permeated by an osteoinductive material to provide the composite material. In another embodiment, the composite material includes a non- resorbable portion that includes osteoconductive substances and a resorbable portion that is doped with osteoinductive substances.

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METHOD AND APPARATUS FOR FIXATION OF INTERVERTEBRAL DISC PROSTHESIS

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation-in-part of U.S. patent application serial no. 11/264,471 filed October 31, 2005.

BACKGROUND

[0002] This invention relates to the field of prosthetics, and more particularly, to an intervertebral disc prosthesis designed to replace a damaged intervertebral disc.

[0003] The human spine consists of twenty-four small bones known as vertebrae, or "vertebral bodies," that protect the spinal cord and provide stability to the torso. The vertebrae are arranged in a column and stacked vertically upon each other. Between each vertebra is a fibrous bundle of tissue called an intervertebral disc. These intervertebral discs act as a cushion to the spinal column by absorbing energy and transmitting loads associated with everyday movement. They also prevent the vertebrae from rubbing against each other.

[0004] Each intervertebral disc comprises two distinct regions. A firm outer region, the annulus, maintains the shape of the intervertebral disc. An inner region, the nucleus, provides a resilient tissue that enables the disc to function as a shock absorber. Over time, the normal aging process causes the intervertebral discs to degenerate, diminishing their water content and thereby reducing their ability to properly absorb the impact associated with spinal movements. Diminished water content in the intervertebral

discs may also cause the vertebrae to move closer together. Tears and scar tissue can weaken the discs, resulting in injury. When the discs wear out or are otherwise injured, a condition known as degenerative disc disease results. With this condition, discs do not function normally and may cause pain and limit activity.

[0005] The condition of degenerative disc disease can potentially be relieved by a surgical procedure called artificial disc replacement. In this procedure, the damaged intervertebral disc is replaced by a prosthetic disc. One well known intervertebral prosthetic disc is produced by DePuy Spine, Inc. of Raynaham, MA and is sold under the trademark CHARITÉ®. This disc prosthesis is comprised of two metal endplates and a center polyethylene core. The center core includes a superior spherical bearing surface and an inferior spherical bearing surface. The superior endplate includes a concave surface that fits upon and is congruent with the superior bearing surface of the core. The inferior endplate includes a concave surface that fits under and is congruent with the inferior bearing surface of the core. During the CHARITÉ® artificial disc replacement procedure, the damaged disc is first removed via an anterior surgical approach and the end surfaces of the exposed vertebrae are cleared of debris. The vertebrae are spread apart and the metal endplates are positioned on the respective vertebra and tapped into place. The polyethylene core is then inserted between the endplates and the vertebrae are returned to their normal position. The pressure of the spinal column further seats the endplates into the vertebral bones and secures the core in place.

[0006] Although current intervertebral disc prosthetic devices have enjoyed success, it would be beneficial to add additional desirable features to the prosthetic device. For example, it would be desirable to design the prosthetic device to provide

improved fixation features to ensure attachment of the prosthetic device to the vertebral bodies. It would be particularly advantageous if such fixation features facilitated bony in-growth between the prosthetic device and the vertebral bodies, thus providing a secure and natural fixation of the prosthetic device to the vertebral bodies.

SUMMARY

[0007] An intervertebral disc prosthesis comprises a superior endplate and an inferior endplate. A bearing surface is positioned between the superior endplate and the inferior endplate such that the superior endplate is operable to pivot relative to the inferior endplate. The superior and inferior endplates include vertebra fixation surfaces designed to engage the vertebral bodies. The vertebra fixation surfaces are typically included on the faces of the endplates. For example, the vertebra fixation surfaces may be provided on a plurality of teeth found on the faces of the endplates.

[0008] A textured surface is formed on each vertebra fixation surface. The textured surface provides a substrate that will accommodate bony in-growth between the endplate and the vertebral body. The surface texture on the teeth or other endplate surfaces may take any of several forms. In one embodiment, the texture is provided by an osteoconductive coating. The textured surface may also be provided by mechanical processes such as grinding or engraving, energy beam processes such as laser beam or electron beam, lithographical processes such as chemical lithography or electrochemical lithography, or other processes known in the art. The textured surface may be patterned or random and may include pockets, slots, grooves, indentations, bumps, or other texturing.

[0009] The textured surface to provides a substrate for bone growth and attachment. An osteoinductive material is incorporated into or applied onto the substrate or the osteoconductive material to promote accumulation, attachment, and in-growth of the bone cells. Bony in-growth will result in a secure attachment between the endplate and the vertebral body.

[0010] Provision of the textured surface may also be included as a composite material applied to the fixation surface of the endplate, wherein the composite material includes an osteoconductive component and an osteoinductive component. The osteoconductive component provides a porous matrix or base that facilitates bone attachment. The osteoinductive component provides a stimulant material that encourages growth of the bone cells between the osteoconductive component of the endplate and the vertebral body facing the endplate.

[0011] In one embodiment, the osteoconductive component is soaked in or otherwise permeated by an osteoinductive material to provide the composite material. In another embodiment, the composite material includes a non-resorbable portion that includes osteoconductive substances and a resorbable portion that is doped with osteoinductive substances. The resorbable portion of the composite material is subject to dissolution in the body and essentially serves as a carrier designed to deliver a timed release of osteoinductive substances. As the resorbable component breaks down in the body, the osteoinductive substance is released and promotes bony ingrowth/attachment to the non-resorbable portion of the coating.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] FIG. 1 shows an superior perspective view of an intervertebral disc prosthesis including a superior plate and a inferior plate separated by a core;

[0013] FIG. 2 shows a side cross-sectional view of the intervertebral disc prosthesis of FIG. 1;

[0014] FIG. 3 shows a side cross-sectional view of the intervertebral disc prosthesis of FIG. 1 with the superior plate rotated to display flexion;

[0015] FIG. 4 shows a perspective view of an alternative embodiment of the intervertebral disc prosthesis of FIG. 1;

[0016] FIG. 5 shows a top plan view of the intervertebral disc prosthesis of FIG. 4 including a top plan view of a superior plate of the intervertebral disc prosthesis;

[0017] FIG. 6 shows a bottom plan view of the superior plate of the intervertebral disc prosthesis of FIG. 5, showing an articulation socket;

[0018] FIG. 7 shows a right side elevational view of the superior plate of the intervertebral disc prosthesis of FIG. 5;

[0019] FIG. 8 shows a cross-sectional view of the intervertebral disc prosthesis through line X-X of FIG. 5;

[0020] FIG. 9 shows a cross-sectional view of the intervertebral disc prosthesis through line XI-XI of FIG. 5;

[0021] FIG. 9A shows a cross-sectional view of an alternative embodiment of the intervertebral disc prosthesis of FIG. 9;

[0022] FIG. 10 shows a bottom plan view of the superior plate of FIG. 6 and its footprint in relation to a vertebral body;

[0023] FIG. 11 shows a perspective view of an alternative embodiment of an endplate of the intervertebral disc prosthesis of FIG. 4;

[0024] FIG. 11A shows a perspective view of another alternative embodiment of the endplate of FIG. 11 including a coating on the face of the endplate;

[0025] FIG. 12 shows a perspective view of an alternative embodiment of the bottom surface of an endplate of the intervertebral disc prosthesis of FIG. 4;

[0026] FIG. 12A shows a perspective view of an alternative embodiment of the intervertebral disc prosthesis of FIG. 4 including additional insertion features;

[0027] FIG. 13 shows a perspective view of an alternative embodiment of the intervertebral disc prosthesis of FIG. 4;

[0028] FIG. 14A shows a cross-sectional view of an alternative embodiment of the intervertebral disc prosthesis of FIG. 4 having a core with an extended flange configured to limit motion;

[0029] FIG. 14B shows a cross-sectional view of an alternative embodiment of the intervertebral disc prosthesis of FIG. 14A;

[0030] FIG. 15 shows a top view of an alternative embodiment of a core of the intervertebral disc prosthesis of FIG. 4;

[0031] FIG. 15A shows a cross-sectional view of the core of FIG. 15 through line A-A;

[0032] FIG. 16 shows a top view of another alternative embodiment of a core of the intervertebral disc prosthesis of FIG. 4;

[0033] FIG. 16A shows a cross-sectional view of the core of FIG. 16 through line A-A;

[0034] FIG. 17 shows a top view of yet another alternative embodiment of a core of the intervertebral disc prosthesis of FIG. 4;

[0035] FIG. 17A shows a cross-sectional view of the core of FIG. 17 through line A-A;

[0036] FIG. 17B shows a cross-sectional view of the core of FIG. 17 through line B-B;

[0037] FIG. 18 shows a perspective view of an disc insertion tool for the intervertebral disc prosthesis of FIG. 4 in a retracted position;

[0038] FIG. 19 shows a perspective view of the disc insertion tool of FIG. 18 inserting the intervertebral disc prosthesis between vertebral bodies;

[0039] FIG. 20 shows a perspective view of the disc insertion tool of FIG. 18 in an extended position;

[0040] FIG. 21 shows a top view of the intervertebral disc prosthesis of FIG. 12A engaged with a disc insertion tool; and

[0041] FIG. 22 shows a perspective view of the disc insertion tool of FIG. 21.

DESCRIPTION

General Structure

[0042] With reference to FIGs. 1-3, an intervertebral disc prosthesis 30 comprises a superior plate 32, an inferior plate 34, and a core 36. The core 36 is sandwiched between the superior plate 32 and the inferior plate 34. The superior plate 32 and the inferior plate 34 ride upon the core 36 and are operable to rotate relative to the core.

[0043] The superior plate 32 serves as a first endplate for the prosthetic device 30. In one embodiment, the superior plate 32 is comprised of metal. In particular, the superior plate 32 may be comprised of a medical grade cobalt chromium alloy. The superior plate 32 comprises an upper surface 40 on one side and a lower surface 42 on the other side. An outer perimeter edge 44 defines the "footprint" shape of the superior plate 32.

[0044] The upper surface 40 of the superior plate 32 is designed for engagement with a vertebral surface of a patient. To this end, the upper surface 40 of the superior plate may be slightly convex for close engagement with the slightly concave vertebral surface of the patient. A typical convexity of the superior plate is based on a 90-200 mm radius of curvature. The preferred convexity will vary from patient to patient, depending upon the size and vertebral surface shape of the patient.

[0045] Teeth 46 are included on the upper surface 40 of the superior plate 32. The teeth 46 are designed to penetrate into the vertebral surface, helping to secure the superior plate 32 to the vertebral surface. As explained in further detail below, certain advantages are achieved based on the positioning of the teeth on the plate 32, the size of the teeth 46, and the shape of the teeth. Screws (not shown) may also be threaded through holes (not shown) in the superior plate to provide further assistance in securing the superior plate 32 to the vertebral surface.

[0046] The inferior surface 42 of the superior plate 32 is generally flat near the outer perimeter edge 44. However, with reference to FIGs. 2-3, a donut-shaped collar portion 48 depends from the center of the inferior surface 42 of the plate 32. An inner concave surface 49 is provided at the center of the collar portion 48. As explained in

further detail below, this inner concave surface 49 serves as a bearing surface/articulating surface for engagement with the core. As explained in further detail below, the bearing surfaces of the endplates and core together provide ball and socket joint arrangements for the prosthetic device.

[0047] The inferior plate 34 is a mirror image of the superior plate 32 and is also made of a medical grade cobalt chromium alloy. The inferior plate 34 includes a slightly convex inferior surface 50 outlined by an outer perimeter edge 54. A plurality of teeth 56 extend from the inferior surface 50. The teeth 56 are designed to help secure the inferior plate 34 to a vertebral surface. The upper surface 52 of the inferior plate 34 includes a collar portion 58 with an inner concave surface 59 which provides a bearing surface/articulating surface for engagement with the core.

[0048] The prosthesis core 36 is sandwiched between the superior plate 32 and the inferior plate 34. The core 36 is arranged within an interior space of the prosthesis 30 defined between the lower surface 42 of the superior plate 32 and the upper surface 52 of the inferior plate 34. In one embodiment, the prosthesis core 36 is comprised of a plastic material having a high resistance to wear, such as ultra high molecular weight polyethylene (UHMWPE), which allows the endplates 32 and 34 to slide easily on the core. The prosthesis core 36 is generally disc shaped with an outer radial flange 60, an upper spherical surface 62, and a lower spherical surface 64. The upper spherical surface and lower spherical surface act as bearing surfaces/articulating surfaces that engage the bearing surfaces of the endplates 32 and 34. As shown in FIG. 2, a first groove 66 is formed between the flange 60 and the superior spherical surface 62. A second groove 68 is formed between the flange 60 and the inferior spherical surface 64.

[0049] When the prosthesis 30 is assembled, the concave surface 49 of the superior plate 32 and the upper spherical surface 62 of the core 36 engage one another and form articular surfaces. Likewise, the concave surface 59 of the inferior plate 34 and the lower spherical surface 64 of the core 36 engage one another and form articular surfaces.

[0050] In one preferred embodiment, the articular surfaces 49, 62, 59, 64 are substantially spherical and remain congruous during torsional rotation around the vertical axis 70. In this embodiment, the radii of the arcs in the frontal plane (i.e., the lateral bending plane) are equal to the radii of the arcs in the sagittal plane (i.e., flexion plane). This allows the plates 32 and 34 to rotate upon the core 36, including rotation in the transversal plane (i.e., torsional plane) while the articular surfaces remain in congruous contact. In this embodiment, the articular surfaces 49, 62, 59, 64 do not offer significant resistance to torsional rotation.

[0051] With reference to FIG. 3, the radial flange 60 and associated grooves 66 and 68 provide for limited movement of the endplates in the frontal (lateral bending) plane and sagittal (flexion/extension) plane. In particular, at a certain angle of rotation of the superior plate 32 relative to the inferior plate 34 in the frontal and sagittal planes, the flange 60 of the prosthesis core engages the collar portions 48 and 58 of the endplates 32, 34. This provides a defined stop against excessive rotation in the frontal (lateral bending) plane and sagittal (flexion/extension) plane of the prosthesis 30.

Further Embodiments

[0052] With reference to FIG. 4, an alternative embodiment of an intervertebral disc prosthesis 130 is shown. As shown in FIG. 4, the prosthesis 130 comprises a superior plate 132, an inferior plate 134 and a core 136 sandwiched between the superior plate 132 and the inferior plate 134. The superior plate 132 is generally symmetric to the inferior plate 134. The plates are configured to include an anterior side 180, a posterior side 182, a left side 184, and a right side 186.

[0053] The "footprint" of each endplate 132 and 134 is designed to provide a more anatomically representative endplate shape that generally conforms to the vertebral endplate anatomy, as shown in FIG. 10. With reference to FIGs. 5, 6 and 10, the left side 184 of the superior endplate 132 is generally straight/flat and parallel to the right side 186 of the plate 132. The anterior side 180 of the endplate 132 is generally arched and provides a curved edge that extends from the left side 184 to the right side 186 of the endplate 132. The anterior edge 180 of the endplate 132 provides an arch defined by a radius of curvature ranging from 10 to 40mm.

[0054] The posterior side 182 of the endplate includes three angled edges that give the endplate a trapezoidal appearance. In particular, the posterior side 182 of the endplate 132 includes a rear edge 178, a left bevel 174, and a right bevel 176. The left bevel 174 joins the rear edge 178 to the left edge 184 and the right bevel 176 joins the rear edge 178 to the right edge 186. The left bevel 174 is substantially straight and extends between the rear edge 178 and the left edge 184 at a 45° angle relative to the rear edge. Likewise, the right bevel 176 is substantially straight and extends between the rear

edge 178 and the right edge 178 at a 45° angle relative to the rear edge. The rear edge 178 is generally perpendicular to the right edge 186 and left edge 184.

[0055] As shown in FIG. 10, the above-described endplate footprint allows the endplate to substantially conform to the vertebral body 200 of the patient. In particular, the endplate footprint covers a substantial portion of the vertebral body, thus providing additional surface area for connection and bony in-growth between the endplate and the vertebral body. This in-growth may be facilitated by a porous bony in-growth coating on the endplates.

[0056] In addition to the above, each endplate 132 and 134 of the prosthesis 130 is slightly convex for close engagement with the slightly concave vertebral surface of the patient. A typical convexity of the superior plate is based on a 90-200 mm radius of curvature. The preferred convexity will vary from patient to patient, depending upon the patient's size and vertebral surface shape.

Endplate Teeth and Fixation Features

[0057] As shown in FIGs. 4 and 5, the teeth 146 of the endplates 132 and 134 are generally pyramidal in shape with a triangular base positioned on the outer surface 140 of the endplate (i.e., the upper surface of the superior endplate). The triangular base is an acute triangle with two of the triangular sides significantly longer than the triangular side opposite the vertex 190 of the triangular base. This results in pyramidal shaped teeth having two elongated faces 192, 194. The teeth are arranged radially upon the endplates 132 and 134 with the vertex 190 of each triangular base pointed toward a central portion of the endplate. The teeth 146 are also generally positioned toward the left side 184 and

right side 186 of the endplates. The radial arrangement of the teeth 146 on the left and right sides of the endplate results in the elongated faces 192 and 194 of the teeth directed generally toward the anterior or posterior sides of the endplates (i.e., anterior-posterior faces).

[0058] Each pyramidal shaped tooth 146 may be further defined by a width and a height. The width of the tooth 146 is generally defined as the distance between the vertex 190 of the triangular base and the opposing side of the triangular base on the surface of the endplate. The height of the tooth is generally defined as the perpendicular distance from the pyramidal vertex 196 of the tooth 146 to the face of the endplate. The teeth shown in FIGs. 4 and 5 are broad teeth having a width that is greater than their height. This generally short yet broad tooth structure allows the prosthesis 130 to be more easily inserted into the intervertebral space than those prosthetic devices with longer teeth. This tooth structure also results in broad antero-posterior faces. The broad antero-posterior faces provide significant resistance to migration and antero-posterior shear/expulsion once the prosthetic device is in place in the intervertebral space. The radial arrangement of the teeth provides resistance to lateral shear and rotation relative to the vertebral bodies.

[0059] Another alternative embodiment of the teeth is shown in FIG. 13. The teeth of FIG. 13 include two elongated radial teeth 246 and two elongated circumferential teeth 248. The radial teeth are wedge shaped and extend laterally from right to left near the lateral midline of the prosthesis. Each radial tooth includes an elongated anterior face 250 and an elongated posterior face (not shown). The circumferential teeth 248 bisect the radial teeth 246 as they extend circumferentially upon the face of the endplate. The

circumferential teeth 248 are also wedge shaped. Each circumferential tooth 248 includes an exterior face 254 and an interior face 256. Together, the radial teeth 246 and circumferential teeth 248 form cross-shaped teeth on the left side and the right side of each endplate face. The teeth are relatively short and broad, allowing the intervertebral prosthesis to be more easily inserted in the intervertebral space. In addition, the cross-shaped tooth arrangement is configured to provide significant resistance to migration of the endplates once the intervertebral prosthesis is positioned in a patient.

[0060] In addition to the above features, the teeth may include a textured surface that will accommodate bony in-growth between the endplate and the vertebral body. However, the use of a textured surface on the endplate is not limited to the teeth. Textured surfaces may be provided on other portions of the endplate where bony in-growth is desirable. For example, as shown in FIG. 11A, the face 140 of the endplate 132 includes a textured portion 147 designed to contact a vertebra.

[0061] The surface texture on the teeth or other endplate surfaces may take any of several forms. In one embodiment, the texture is provided by a coating of titanium, hydroxyapatite (HA), calcium phosphate, an osteoconductive matrix of cross-linked collagen fibers coated with hydroxyapatite (such as that sold under the trademark Healos®), or other osteoconductive materials as are known in the art. Such osteoconductive materials and/or coatings generally provide a porous substrate capable of accommodating bone growth and attachment. Osteoconductive coatings may be applied by a physical packing, brush, spray, chemical vapor deposition, physical vapor deposition, electrochemical deposition, or other methods as are known in the art. Alternatively, the textured surface may be provided by mechanical processes such as

grinding or engraving, energy beam processes such as laser beam or electron beam, lithographical processes such as chemical lithography or electrochemical lithography, or other processes known in the art. The textured surface may be patterned or random and may include pockets, slots, grooves, indentations, bumps, or other texturing. As used herein, the term "textured surface" generally refers to a surface where texturing is intentionally formed on a surface using an osteoconductive coating, mechanical process, lithographical process, energy beam process, or other process. However, the term "textured surface" as used herein does not refer to the microscopic texture inherent to a surface that is not otherwise intentionally formed on the surface.

[0062] The faces 192 and 194 of the teeth generally provide a good surface area where a textured surface capable of accommodating bone growth may be formed. However, as mentioned above, other surfaces on the endplate are also appropriate for a textured surface, such as textured portion 147 on the endplate 132 of FIG. 11A.

[0063] Bony in-growth will result in a secure attachment between the endplate and the vertebral body. Bone morphogenetic protein (BMP), bone marrow, stem cells or other osteoinductive material is used as the stimulant to promote bony in-growth. The osteoinductive material can be incorporated into or applied onto the endplate or the osteoconductive material. This combination of an osteoinductive material in association with an osteoconductive material on the surface of the endplate provides a desirable setting for bony in-growth. In one embodiment, an osteoconductive coating is provided as a first coating on the vertebra fixation surface of the endplate. An osteoinductive material is then applied as a second coating over the first coating of osteoconductive material. The osteoinductive material provides a stimulant material that encourages

growth of the bone cells between the osteoconductive coating of the endplate and the vertebral body facing the endplate.

[0064] In another embodiment, a coating of a composite material is applied to the vertebra fixation surface, wherein the composite material includes an osteoconductive component incorporated with an osteoinductive component. For example, a composite material including an osteoconductive component and an osteoinductive component may be provided by Healos® soaked in or otherwise permeated with BMP or bone marrow. In this example, the Healos® provides the osteoconductive material/component and the BMP or bone marrow provides the osteoinductive material/component. The Healos® is soaked in the BMP or bone marrow before application to the vertebra fixation surface of the endplate. After the Healos® is soaked in BMP (or bone marrow) the soaked material may be cut to a desired size and/or configuration for proper placement on the vertebra fixation surface. The soaked Healos® is then packed in a textured surface formed on the endplate, such as pockets or grooves on the anterior/posterior faces of the teeth or other vertebra fixation surface. While this embodiment has been described with reference to Healos® soaked in BMP or bone marrow, it should be recognized that other osteoconductive materials may soaked with the same or different osteoinductive materials to prepare the material to be packed on the vertebra fixation surface. In addition, it should be recognized that the osteoconductive material could actually be packed on the endplate before the osteoconductive material is soaked in the osteoinductive material.

[0065] In addition to the above, other coatings of composite materials having osteoinductive and osteoconductive properties may be provided. For example, in one embodiment the composite material includes a non-resorbable portion that includes

osteoconductive substances and a resorbable carrier portion that is doped with osteoinductive substances. The resorbable portion of the composite material is subject to dissolution in the body and essentially serves as a carrier designed to deliver a timed release of osteoinductive substances.

[0066] Examples of materials that may be used as the non-resorbable portion of such composite material include titanium, metal matrix composite (MMC), ceramic or combinations thereof. Such osteoconductive substances serve as a porous matrix or base to which the resorbable carrier adheres. Examples of materials that may be used as the resorbable carrier portion include calcium phosphate, hydroxyapatite, collagen, mineralized collagen, biodegradable polyglycolic acid (PGA), polylactic acid (PLA), hydrogels, or combinations thereof. As mentioned above, the resorbable carrier portion is doped or impregnated with an osteoinductive substance, such as BMP, the patient's bone marrow, stem cell concentrates, or combinations thereof. As the resorbable component breaks down in the body, the osteoinductive substance impregnated in the resorbable component is released, promoting bony ingrowth and attachment to the non-resorbable portion of the coating.

Posterior Center of Rotation

[0067] FIG. 6 shows a plan view of the lower surface 142 of the superior plate 132 of one embodiment of the intervertebral disc prosthesis 130. As shown in FIG. 6, a donut-shaped collar portion 148 is included on the lower surface 142 of the upper plate 132. The collar 148 extends outward from other portions of the lower surface 142 and surrounds a semi-spherical concave surface 149 that provides a socket for the core 136 of

the prosthesis. The concave surface 149 defines a center-of-rotation for the superior plate 132 relative to the core 136. The position of the center of rotation is shown in FIG. 6 by a "+" 120. Also shown in FIG. 6 is a lateral midline 122 extending laterally across the plate 132 from the left side 184 to the right side 186. The lateral midline 122 is a line located directly between the furthermost anterior edge and the furthermost posterior edge of the endplate 132.

[0068] As shown in FIG. 6, the radial collar 148 is centered upon the plate 132 such that it is closer to the posterior edge 182 than the anterior edge 180 of the plate. As a result, the center of rotation 120 of the superior plate 132 is positioned to the posterior of the lateral midline 122. In particular, the center of rotation 120 is located a distance "d" behind the lateral midline 122. In a preferred embodiment, the center of rotation is about 1 mm to 3 mm posterior to the lateral midline. This posterior center of rotation arrangement closely mimics the true anatomy of healthy vertebral bodies and intervertebral discs.

Insertion Features

[0069] With continued reference to FIGs. 4-7, the endplates 132 and 134 of the prosthesis are designed with several features that allow the prosthesis 130 to be more easily inserted into the intervertebral space. For example, as best seen in FIG. 7, the posterior side 182 of the endplate 132 is bulleted such that the rear edge 176, left bevel 174, and right bevel 176 are all tapered and provide a generally pointed edge. This tapered edge on the posterior side 182 of endplate allows the endplate to be more easily inserted into a collapsed intervertebral space if an anterior approach is taken when

inserting the prosthesis 130. In particular, the tapered rear edge 176 provides a bulleted surface to help wedge the prosthesis in the intervertebral space. In addition, the left edge 184 and right edge 186 are tapered. These tapered edges further allow the endplate to be more easily inserted into a collapsed intervertebral space if a lateral approach is taken when inserting the prosthesis 130.

[0070] While the posterior side 182 of the prosthesis 130 is tapered, the anterior side 180 is more flat and blunt. As explained in further detail below, this blunt side 180 provides a flat anterior surface that may be pressed upon as the endplate is forced into the intervertebral space during insertion from an anterior approach.

[0071] In addition to the above, the prosthesis 130 includes a central channel/slot 202 formed on the face of the superior plate 132, as shown in FIGs. 4 and 5. The central channel 202 is formed by a left side rail 204 and a right side rail 206 that extend above the face of the superior plate from the anterior side 180 to the posterior side 182 and define the sides of the central channel 202. As explained in further detail below, the central channel is designed to engage a distracting ramp provided by an insertion arm of on an disc insertion tool, thus facilitating insertion of the prosthesis device into the intervertebral disc space.

[0072] In one alternative embodiment, the central channel 202 may be defined by oblique rails or lateral rails that extend across the face of the superior plate 130 at 45° or 90° angles with respect to the rails 204 and 206 shown in FIGs. 4 and 5. Such oblique rails or lateral rails would facilitate oblique or lateral insertion of the intervertebral disc prosthesis 130.

[0073] In yet another alternative embodiment, the central channel may be embedded in the face of the endplate, such as that shown in FIG. 11. In this embodiment, the central channel 202 is defined by a left side rail embedded in the face of the plate to form a left side wall 205. Likewise the right side rail is embedded in the face such that it forms a right side wall 207. The central channel 202 gradually ramps deeper into the face of the endplate from the anterior to the posterior. In this embodiment, the endplate itself becomes gradually thicker from the anterior side 180 to the posterior side 182 of the endplate. This allows the endplate to incorporate a lordotic angle in the sagittal plane of the prosthesis. For example, if each endplate incorporates a 3.5° angle from anterior to posterior, the intervertebral prosthesis as a whole will incorporate a 7° lordotic angle in the sagittal plane. Endplates incorporating such a lordotic angle may desirable for certain patients.

[0074] Another feature designed to assist with insertion of the prosthesis device are retention surfaces in the form of indentations positioned on the endplates, such as grooves, notches, cavities, channels, crevices, or other recesses. As best seen in FIGs. 4, 8 and 9, in one embodiment, the retention surfaces take the form of grooves 210 formed by the collar 148 of the endplate. The grooves 210 are dimensioned to receive and engage prongs or "retaining arms" of the disc insertion tool, allowing the endplate to be retained by the instrument during insertion, as explained in further detail below. Preferably, the indentations are designed to allow the insertion/distraction instrument to hold the endplates and core of the prosthesis simultaneously to facilitate insertion of the prosthesis as a unitary assembled piece. In an alternative embodiment, such as that shown in FIG. 12, the indentations take the form of notches 212 in the anterior corners on

the left side 184 and right side 186 of the endplate 132. In this embodiment, the prongs of the insertion/distraction instrument grasp the surface of the endplate exposed by the notches 212 in order to hold the endplate and encourage the endplate toward the intervertebral space.

[0075] Another feature of the intervertebral prosthesis 130 are lateral holding features, such as notches, holes, grooves, indentations, protrusions or other structural features that provide an easy means of grasping the endplates or the intervertebral prosthesis 130 in general. Examples of lateral holding features include the hole 220 in the central channel of FIG. 13 and the notches 212 in the lower surface 142 of plate 132 in FIG. 12. These lateral holding features facilitate non-anterior insertion of the intervertebral prosthesis 130 and non-anterior revision/retrieval of the prosthesis. In particular, the lateral holding features provide structural components that may be easily grasped by instrumentation that may be used to properly orient the prosthesis 130 during implantation or help retract an implanted prosthesis. Alternatively, the groove 210 formed in the collar 148 of the endplate could be a circumferential groove, such that an instrument could attach to this groove from any direction, including anterior, lateral, or posterior surgical approaches. An example of an embodiment with the circumferential groove is shown in FIG. 12A.

[0076] With reference to FIG. 12A, an alternative embodiment of the intervertebral disc prosthesis 130 includes additional insertion features. In particular, an anti-rotation notch 218 is provided in both the superior plate 132 and the inferior plate 134. The anti-rotation notch 218 takes the form of a semi-cylindrical notch carved in the anterior edge 181 of the endplate, extending from the upper surface of the endplate to the

lower surface of the endplate. As explained in further detail below, the anti-rotation notch is designed to engage a peg on the disc insertion tool, and prevent rotation of the disc 130 during the insertion process.

[0077] As also shown in FIG. 12A, the intervertebral disc prosthesis 130 may include a spring-arm detent 222 formed in each endplate 132, 134. The spring arm detent 222 is formed in the lower surface 142 of the superior plate 132 and the upper surface 152 of the inferior plate 134. Each spring arm detent 222 extends partially into the endplate and provides a small cavity designed to receive the lip of a spring arm on a disc insertion tool. As explained in further detail below, the interaction between the detent 222 and the spring arm of the disc insertion tool provides additional stability for the intervertebral disc prosthesis during the implantation process.

Shear-Limiting Features

[0078] With reference to FIGs. 8 and 9, the intervertebral disc prosthesis 130 is configured to allow the endplates 132 and 134 to rotate/pivot from front-to-back and side-to-side. FIG. 8 shows a cross-sectional view of the prosthesis 130 with the endplates 132 and 134 pivoting toward the left side. FIG. 9 shows a cross-sectional view of the prosthesis 130 with the endplates 132 and 134 pivoting to the posterior side 182. As shown in both FIG. 8 and FIG. 9, the degree to which the endplates are allowed to pivot is restricted by the radial flange 160 of the core 136. In particular, when an endplate 132 or 134 rotates a certain degree relative to the core 136, the collar 148 or 158 of the endplate will contact the flange 160 of the core and thus prohibit further pivoting of the endplate 132 or 134 relative to the core 136.

[0079] In an alternative embodiment, the radial flange 160 of the core may be extended toward the inferior endplate or the superior endplate to further limit or prevent articulation on that side of the core. For example, with reference to FIG. 14A, the core 136 comprises a central disc portion 138 and a radial flange portion 160. The central disc portion includes an upper bearing surface 162 and a lower bearing surface 164. The convex upper bearing surface 162 engages the concave articulating surface 143 of the superior plate 132, while the convex lower bearing surface 164 engage the concave articulating surface 145 of the inferior plate 134. The flange portion 160 is positioned in a ring-like fashion about the central disc portion 138.

[0080] The flange portion 160 includes a radially extending portion 166 and a lip portion 168. The radially extending portion 166 extends outwardly from the central disc portion 138 in a radial direction (relative to a vertical axis of the prosthesis). The lip portion 168 extends in an axial direction relative to the radially extending portion 166 and forms a ring about the central disc portion 138. As explained in further detail below with reference to FIGs. 15-17, the core 136 may be formed as an integral component or a combination of materials and components.

[0081] In the embodiment of FIG. 14A, the lip portion 168 of the flange 160 extends downward and encompasses the collar 158 of the inferior plate 134 in the neutral position (i.e., with the endplate un-pivoted relative to the core in the lateral bending plane or flexion plane). However, in this embodiment, the lip portion 168 of the flange 160 does not contact the surface of the endplate 134 around the collar 158 in the neutral position. This configuration substantially limits the amount of pivoting allowed for the inferior endplate relative to the core. At the same time, the lip portion 168 of the flange

extends only slightly upward and does not encompass the collar 148 of the superior plate 132 in the neutral position. This allows normal pivoting of the superior endplate 132 relative to the core 136.

[0082] In another embodiment, such as that shown in FIG. 14B, the lip portion 168 of the flange 160 of the core 136 is configured to extend completely to the inferior endplate 134 when the inferior endplate is in the neutral position. Furthermore, the lip portion 168 of the flange 160 encases the collar 158 of the inferior endplate when the endplate is in a neutral position. In this embodiment, the lip portion 166 on the flange 160 of the core 136 substantially conforms to and engages an upper surface of the inferior endplate 134, including the collar 158. In an alternative embodiment, the lip portion 168 of the flange 160 of the core 136 is also configured to engage the groove 210 in the collar 158. Such engagement between the lip portion 168 of the core 136 and the groove 210 of the endplate 134 may be provided in a snap fit engagement to secure the core 136 to the endplate 134. When securing the core to the inferior endplate, the core may be stretched and pressed to properly engage the lip portion 168 of the flange 160 with the upper surface of the inferior endplate 134, thus properly positioning the core 136 on the inferior endplate 134. After positioning the core 136 on the inferior endplate 134, the extended flange 160 of the core, and particularly the lip portion 168 of the flange 160, prevents the inferior endplate 134 from lateral bending and flexion relative to the core 136.

[0083] In addition to the above, it will be recognized from FIG. 14B that the fit between the flange 160 and the collar 158 of the inferior endplate 134 may also prohibit or significantly restrict torsional movement of the inferior endplate relative to the core. In particular, if a relatively tight fit is provided between the flange 160 and the collar 158,

torsional movement will be prevented or restricted. However, if a relatively loose fit is provided between the flange 160 and the collar 158, torsional movement may be allowed.

[0084] In yet another embodiment, the flange 160 extends to the surface of the inferior endplate and includes protrusions that are press-fit into holes or other indentations formed in the surface of the inferior endplate 134. In this embodiment, the core 136 is fixed to the inferior plate by the protrusions that fit into the holes, intentionally preventing movement of the endplate 134 relative to the core 136. These protrusions on the core may be press-fit into the holes in the inferior plate when the physician assembles the prosthesis.

[0085] Each of the above embodiments are designed to limit the amount of articulation between the endplates 132 and 134 and the core 136 and thus provide shear resistance to help protect the facets. Although the features have been shown with respect to the inferior endplate 134, they could likewise be provided with respect to the superior endplate 132.

Alternative Materials

[0086] As discussed above, the metal endplates 132, 134 may be comprised of a cobalt chromium alloy. The core 136 may be comprised of a plastic material such as ultra high molecular weight polyethylene. Because plastic materials are typically not radio-opaque, a cobalt chromium alloy wire may be provided around the core to allow the physician to determine the location of the core when viewing an x-ray image of an installed prosthesis. The cobalt chromium alloy wire is typically inserted into a channel on the core, such as channel 37 of FIG. 1 and channel 137 of FIG. 4.

[0087] In many cases, a physician may desire an MRI image rather than an x-ray image of an implanted prosthesis. Unfortunately, cobalt chromium alloy is not MRI compatible. Thus, in an alternative embodiment of the prosthesis, the endplates 132 and 134, and the wire in the core channel 137, are all comprised of titanium. The use of titanium allows the endplates and core wire of an implanted prosthesis to be MRI compatible. Other MRI compatible materials that could be used for the endplates and core wire include ceramics, polycarbonate-polyurethane (PCPU), polyetheretherketone (PEEK), or composites thereof.

[0088] In addition to alternative materials that make the intervertebral prosthesis MRI compatible, other materials may be advantageous to the surgeon, depending upon the desired outcome for the patient. For example, a ceramic core could be used for excellent wear performance in the youngest patients. A PCPU core could be used to offer shock-absorbing capabilities for more active patients.

Composite Core

[0089] In one embodiment, the core 136 is a composite core comprised of a plurality of different portions made of different materials exhibiting different properties. For example, FIGs. 15-17 show a plurality of different embodiments for a composite core comprising at least two materials with different properties, joined to form a single component. One embodiment of the composite core is a dual durometer core having a relatively soft bearing surface and a hardened flange.

[0090] With reference to FIGs. 15 and 15A, the core 136 is formed as a three-part composite core comprising a central disc portion 163, an upper bearing portion 162, and a

lower bearing portion 164. The radial flange 160 is provided by the disc portion 163 and encompasses a convex bearing surface 161. The bearing surface 161 is provided by the upper bearing portion 162 and the lower bearing portion 164. The surface of the upper bearing portion 162 is designed to engage the socket 149 of the superior endplate 132 and the surface of the lower bearing portion 164 is designed to engage the socket of the inferior endplate 134. The upper bearing portion 162 and lower bearing portion 164 are fixed to the disc portion 163 such that the core is provided as a unitary piece. The core 136 may be configured such that the bearing portions 162, 164 attach to the disc portion 163 by any number of different methods, such as press-fit, threaded engagement, snap fit, welding, insert or two-shot injection molding, insert compression molding, brazing, bonding with adhesives, sintering, or other methods as will be recognized by those of skill in the art.

[0091] Another embodiment of a composite core is shown in FIGs. 16 and 16A. In this embodiment, the core 136 is a two-part composite core comprising a central bearing portion 262 and an outer ring portion 264 encircling the central bearing portion. The top surface 261 of the central bearing portion 262 is designed to engage the socket of the superior plate 132, and the bottom surface 263 of the central bearing portion 262 is designed to engage the socket of the inferior plate 134. The outer ring portion 264 is the flange 160 of the core 136. When the central bearing portion 262 is comprised of a relatively soft material and the outer ring portion 263 is comprised of a relatively hard material, the ring portion 263 acts as a retaining wall for the bearing portion 262, making the bearing portion creep resistant. In particular, when the soft material of the bearing portion 262 is compressed following implantation in the patient, the harder material of

the ring portion 263 prevents the soft material of the bearing portion from deforming into a flatter shape. Alternatively, the bearing portion 262 may be comprised of a relatively hard wear-resistant material while the ring portion 263 may be comprised of a relatively resilient or tough material that limits extreme motions, such as that shown in FIGs. 14 and 14A. The core 136 may be configured such that the bearing portion 262 is attached to the ring portion 163 by any number of different methods, such as press-fit, snap fit, welding, insert or two-shot injection molding, insert compression molding, brazing, bonding with adhesives, sintering, or other methods as will be recognized by those of skill in the art.

[0092] FIGs. 17, 17A and 17B show yet another embodiment of the prosthesis core 136. In this embodiment, the prosthesis core 136 is specifically designed to allow injection molding of two materials using insert or two-shot molding, where a second material is molded over a first material. As shown in FIG. 17A, the core comprises an inner skeleton 266 of a first material and an outer bearing flesh 267 of a second material. The skeleton 266 is generally disc shaped and the material of the skeleton extends continuously across the core from one point on the flange 160 to an opposite point on the flange. The skeleton also provides a ridge 269 where the bearing flesh 267 abuts the skeleton 266. However, in certain locations on the core 136, as shown in FIG. 17B, the skeleton does not extend continuously across the core, and is interrupted by portions of bearing flesh 267. This arrangement provides a cohesive part with strong mechanical interconnections. Furthermore, if the bearing flesh 267 is comprised of a relatively soft material and the skeleton 266 is comprised of a relatively hard material, the flange of the skeleton provides a retaining wall along with the ridge 269 to prevent creep of the soft

bearing material during compression. As discussed above, the arrangement shown in FIGs. 17-17B is specifically configured for insert molding of the core.

[0093] From the above examples it will be clear that a core 136 may be provided in multiple portions comprised of differing materials such that the properties of the core vary from location to location in an advantageous manner. For example, as discussed above, the core may be manufactured in a manner such that the core provides a soft bearing surface on the exterior and a rigid support skeleton on the inside. As another example, the core may be manufactured with a hard bearing surface and a relatively resilient skeleton.

[0094] Example materials for use with the core include PEEK or titanium with a wear-improving coating, PCPU, MMC, cobalt chromium alloy, ceramics, double-network hydrogels, in addition to ultra-high molecular weight polyethylene (UHMWPE). Alternate combinations of interest from a wear perspective include metal matrix composites (MMC) with cobalt chromium or MMC with ceramic. Example ceramics include synthetic ruby, zirconia, alumina, zirconia toughened alumina (ZTA), Y-TZP, silicon nitride, or combinations thereof.

[0095] Examples of core material combinations and arrangements include a ruby bearing portion brazed to a metal flange; a cobalt chromium, titanium or stainless steel flange press fit around a ceramic bearing; a MMC such as titanium with titanium carbide bearing surface over a titanium skeleton; polycarbonate-polyurethane (PCPU) or UHMWPE bearing surfaces injection or compression molded over a metal flange insert; a ceramic bearing with a PCPU or UHMWPE flange; or a PEEK bearing with PCPU or a metal flange skeleton. As another example, a PCPU core could be produced by multi-

shot or insert injection molding a relatively rigid central frame and flange with a relatively soft outer bearing surface (e.g., shore 55D frame and shore 80A bearing). In another example embodiment, layered sintering of MMC to a similar metal results in a MMC bearing surface applied to a metal frame, thus providing a bearing surface with ceramic-like properties and a retention flange with non-ceramic (i.e., non-brittle) properties.

Modular Prosthesis Components

[0096] As described above, various configurations and compositions are possible for the endplates 132, 134 and core 136. With a wide variety of differing endplates and cores available, the surgeon may desire a specific endplate and core combination based on the particular needs of a patient. Therefore, the various endplates and cores are made available to the surgeon as part of a modular prosthesis system, where differing endplates may be matched with any number of different cores to arrive at the desired prosthesis. This provides the surgeon with a method of designing an intervertebral disc prosthesis that is customized to the needs of the particular patient.

[0097] When customizing the intervertebral prosthesis, the surgeon analyzes and/or tests the patient to determine features that may be desirable for the patient based on his or her particular situation. These features may include, for example, material composition of the prosthesis, structural features, and size of the prosthesis. The surgeon then decides which features to include in the patient's intervertebral prosthesis, and places an order for the desired prosthesis with the prosthesis manufacturer. The surgeon's decision to order certain structural features, sizes, or materials for the

prosthesis will likely be made based on the patient's concerns, the patient's medical history, testing conducted on the patient, the patient's age, the patient's size, the patient's health, the patient's activity level, and the physician's general best judgment. The surgeon's order includes a description of the desired endplates as well as a description of the desired core. After the customized prosthesis is ordered, a manufacturer or other assembler puts together a prosthesis package for the physician and patient by selecting the modular endplate and core components that provide the desired prosthetic device. The components are then delivered to the physician for implantation in the patient.

[0098] As an example of the modular prosthesis system in operation, consider a particular situation where the patient is allergic to nickel. In this situation, the surgeon will not want to use a cobalt chromium endplate, since nickel is found in cobalt chromium alloy, and the patient's body is likely to have an adverse reaction to the nickel. However, because the prosthesis described herein may be assembled from various modular components, the surgeon will have the choice of selecting an endplate that contains no nickel, such as a titanium endplate. In addition, the surgeon may determine that a patient may benefit from a core having a rigid ceramic-like bearing surface with a non-brittle and more cushioned retention flange. For this core, the surgeon may use a core comprised of an MMC material applied to a metal frame using layered sintering. As another example, the surgeon may decide that movement of the inferior endplate should be restricted for a particular patient. In this case, the surgeon may order a prosthesis having a core similar to that of FIG. 14B as opposed to the core shown in FIGs. 8 and 9. In any case, the modular characteristics of the prosthesis system described herein allow

the surgeon to choose endplates and a core that together provide the prosthesis that is most appropriate for the patient.

[0099] After receiving an order for an intervertebral disc prosthesis having a specified superior plate, core, and inferior plate, the seller of the prosthetic devices obtains the appropriate modular components and sends them to the physician. After receiving the modular components, the physician assembles the components before implanting the assembled prosthesis in the patient.

[00100] It should be recognized that various alternative methods of ordering and order fulfillment of customized prosthetic devices are available. Orders for customized prosthetic devices may be placed by mail, telephone, on-line or by any other method known in the art. In addition, the orders may be received, assembled and shipped by a single entity or by different entities cooperating with each other. Furthermore, the entity receiving and/or fulfilling the order may be completely independent of the surgeon or associated with the surgeon in some way. For example, a hospital may purchase an array of modular components from a manufacturer and make custom prosthetic devices available to surgeons associated with the hospital. In this situation a surgeon would place an order for the custom prosthetic device directly with the hospital. After receiving the request for the custom prosthetic device, the hospital would assemble the requested prosthetic device and deliver it to the surgeon.

Insertion of Intervertebral Prosthesis

[00101] After selecting and receiving the proper endplates 132 and 134 and core 136 for a particular patient, the surgeon assembles the intervertebral prosthesis 130 by

sandwiching the core between the endplates. Once assembled the prosthesis may be implanted in the patient as a complete unit using an insertion/distraction instrument.

[00102] In particular, with reference to FIG. 18 an intervertebral prosthesis 130 is shown positioned within a disc insertion tool 300. The disc insertion tool 300 generally includes a handle 302 and associated lever 304. Separate insertion arms 306 extend from the handle. The insertion arms 306 end in flat fingers 308 that contact one another at a tip 310 opposite the handle 302. Holding prongs/retention arms 312 are provided between the insertion arms. The retention arms 312 are designed to retain the prosthesis 130 on the disc insertion tool 300 by engaging the insertion features, such as indentations 210, 212 positioned on the endplates 132 and 134, as discussed above. Activation of the lever 304 causes a ratcheting operation that moves the insertion arms 312 and prosthesis 300 toward the tip 310.

[00103] As shown in FIG. 19, once the old disc is removed from the intervertebral space, the tip 310 of the disc insertion tool is placed in the intervertebral space with blunt edges of the insertion arms 306 positioned against the vertebral bodies 320. As the prosthesis is gradually ratcheted toward the intervertebral space the central channel 202 of the prosthesis 130 receives the insertion arms/distracting ramp 306, and this engagement properly orients and stabilizes the prosthesis 130 as it enters the vertebral space. Furthermore, as the prosthesis is ratcheted further and further down the insertion arms 306 toward the tip 310, the prosthesis causes the insertion arms 306 to spread apart near the tip 310. As the insertion arms 306 and fingers 308 are moved apart, space is created between the vertebral bodies 320 for the prosthesis 130.

[00104] The height of the fingers 308 in the intervertebral space is greater than the height of the teeth 146 on the prosthesis 130. This allows the prosthesis 130 to slide into position between the vertebral bodies 320, moving along the insertion arms 306 and fingers 308 without contacting the vertebral bodies 320 until the fingers 308 are removed from the intervertebral space.

[00105] Stop blocks 314 are provided on the disc insertion tool toward the rear of the retention arms 312. In one embodiment, the position of the stop blocks 314 could be adjustable relative to the insertion arms 312. The stop blocks 314 are designed to prevent the prosthesis 130 from being inserted too far into the intervertebral space. In particular, when the prosthesis 130 has been moved down the insertion arms and to a position in the intervertebral space such that the disc insertion tool should be removed, the stop blocks 314 will contact the vertebral bodies 320 at the end of the insertion arms 306. FIG. 20 shows the disc insertion tool 300 near such a position. Continued ratcheting of the lever 304 at this point causes the insertion arms 306 to retract from the vertebral bodies 320, as the stop blocks 314 press against the vertebral bodies. Once the insertion fingers 308 are removed from the intervertebral space, the teeth 146 of the prosthesis 130 contact the vertebral bodies 320. Natural compression of the prosthesis 130 by the vertebral bodies 320 causes the teeth 146 to sink into the vertebral bodies, securing the prosthesis 130 in place between the vertebral bodies. Bony in-growth between the endplate and bone further secures the prosthesis in place over time.

[00106] An alternative embodiment of disc insertion tool 300 is shown in FIGs. 21 and 22. This embodiment of the disc insertion tool 300 is configured for use with the intervertebral disc prosthesis shown in FIG. 12A. In this embodiment, the disc insertion

tool 300 includes anti-rotation pegs 318 as well as spring arms 316. The anti-rotation pegs 318 are fixed to the retention arms 312 of the disc insertion tool 300. One anti-rotation peg 318 is provided on a top retention arm 312a and another anti-rotation peg is provided on a lower retention arm 312b (the lower anti-rotation peg is not shown in the figures). When the anti-rotation pegs 318 are fully inserted into the anti-rotation notches 218 of the disc prosthesis 130, as shown in FIG. 21, the prosthesis 130 is prevented from rotating relative to the disc insertion tool, thus maintaining the proper orientation of the disc prosthesis during the implantation procedure.

[00107] The spring arms 316 are provided at the central back portion of the retention arms 312. The spring arms 316 are cantilever arms having resilient qualities that allow the spring arms to bend and spring back into place. The spring arms 316 each include a lip extending from the end of the spring arm. These lips are designed to fit into the spring arm detents 222 of the disc prosthesis 130 (see FIG. 12A). When the lips of the spring arms 316 extend into the spring arm detents 222, the disc prosthesis 130 is further secured to the insertion tool 300 during the implantation process. Once the disc prosthesis 130 is properly situated in the intervertebral space, the spring arms 316 may be automatically released, allowing the lips of the spring arms to move away from the spring arm detents 222. With the spring arms 316 released, the disc insertion tool 300 may be pulled away, leaving the disc prosthesis 130 in place in the intervertebral space.

Alternative Embodiments Possible

[00108] Although the present invention has been described with respect to certain preferred embodiments, it will be appreciated by those of skill in the art that other

implementations and adaptations are possible. For example, the prosthetic disc components shown in the attached drawings are most commonly associated with artificial lumbar discs, but the features described herein could also apply to other discs such as artificial cervical discs.

[00109] Another example of a possible alternative embodiment is shown in FIG. 9A. In this embodiment, the prosthesis 130 comprises a superior endplate 132, inferior endplate 134 and an intermediate core 136. However, unlike the embodiment of FIG. 9 which included a socket and concave bearing surface on each endplate, the embodiment of FIG. 9A includes opposing concave bearing surfaces 151 and 153 on the intermediate core 136. These concave bearing surfaces 151 and 153 respectively engage convex bearing surface 165 of the superior plate 132 and convex bearing surface 167 of the inferior plate 167. In this embodiment, the core 136 essentially provides opposing sockets for the substantially spherical/ball-shaped bearing surfaces of the endplates 132 and 134. The endplates 132 and 134 are thus configured to pivot upon the core 136, as the bearing surfaces 165 and 167 of the endplates engage the bearing surfaces 151 and 153 of the core.

[00110] In addition to the above, it should be recognized that there are advantages to individual advancements described herein that may be obtained without incorporating other aspects described above. In view of the foregoing, the spirit and scope of the appended claims should not be limited to the description of the preferred embodiments contained herein.

CLAIMS

What is claimed is

1. An intervertebral disc prosthesis comprising:
   a) a first endplate including a first vertebra fixation surface;
   b) a second endplate including a second vertebra fixation surface, wherein the first endplate is operable to pivot relative to the second endplate; and
   c) a composite material provided on the first vertebra fixation surface, the composite material comprising an osteoconductive material and an osteoinductive material.
2. The intervertebral disc prosthesis of claim 1 wherein the osteoconductive material is permeated with the osteoinductive material.
3. The intervertebral disc prosthesis of claim 1 wherein the composite material includes a resorbable portion doped with the osteoinductive material and a non-resorbable portion comprising the osteoconductive material.
4. The intervertebral disc prosthesis of claim 3 wherein the resorbable portion comprises a resorbable carrier selected from the group consisting of calcium phosphate, hydroxyapatite, collagen, biodegradable polyglycolic acid, polylactic acid or a hydrogel.
5. The intervertebral disc prosthesis of claim 1 wherein the osteoconductive material is selected from the group consisting of titanium, metal matrix composite, ceramic, calcium phosphate, hydroxyapatite or a matrix of cross-linked collagen fibers coated with hydroxyapatite.

6. The intervertebral disc prosthesis of claim 1 wherein the osteoinductive material is selected from the group consisting of bone morphogenetic protein, bone marrow or stem cells.

7. A method of fixing an intervertebral disc prosthesis in an intervertebral space, the method comprising:

a) providing an intervertebral disc prosthesis including at least one vertebra fixation surface; and

b) applying a composite material to the vertebra fixation surface, the composite material comprising an osteoconductive component and an osteoinductive component.

8. The method of claim 7 further comprising the step of inserting the intervertebral disc prosthesis in an intervertebral space with the vertebra fixation surface in contact with a vertebral body.

9. The method of claim 7 wherein the at least one vertebra fixation surface includes a first vertebra fixation surface and a second vertebra fixation surface, wherein the first vertebra fixation surface is operable to pivot relative to the second vertebra fixation surface.

10. The method of claim 7 wherein the osteoconductive component comprises a first material and the osteoinductive component comprises a second material, and wherein the first material is permeated with the second material.

11. The method of claim 10 further comprising the step of soaking the first material in the second material in order to permeate the first material with the second material.

12. The method of claim 7 wherein the vertebra fixation surface comprises a textured surface.

13. The method of claim 12 wherein the step of applying the composite material to the vertebra fixation surface comprises the step of packing the composite material on the textured surface.

14. The intervertebral disc prosthesis of claim 7 wherein the osteoinductive component includes a resorbable portion and the osteoconductive component includes a non-resorbable portion.

15. The intervertebral disc prosthesis of claim 14 wherein the resorbable portion is doped with an osteoinductive material, and the osteoinductive material includes bone morphogenetic protein or bone marrow.

16. An intervertebral disc prosthesis comprising:

a) a first vertebra fixation surface; and

b) a composite material provided on the first vertebra fixation surface, the composite material comprising an osteoconductive material and an osteoinductive material.

17. The intervertebral disc prosthesis of claim 16 further comprising a second vertebra fixation surface, wherein the first vertebra fixation surface is operable to pivot relative to the second vertebra fixation surface.

18. The intervertebral disc prosthesis of claim 17 further comprising a bearing surface positioned between the first vertebra fixation surface and the second vertebra fixation surface, wherein the first vertebra fixation surface is operable to pivot upon the bearing surface.

19. The intervertebral disc prosthesis of claim 16 wherein the osteoconductive material is permeated with the osteoinductive material.

20. The intervertebral disc prosthesis of claim 19 wherein the first vertebra fixation surface comprises a textured surface, and the composite material is applied to the textured surface.

21. The intervertebral disc prosthesis of claim 16 wherein the composite material includes a resorbable portion and a non-resorbable portion.

22. The intervertebral disc prosthesis of claim 21 wherein the resorbable portion is doped with the osteoinductive material and the non-resorbable portion comprises the osteoconductive material.

23. The intervertebral disc prosthesis of claim 16 further comprising an endplate including a face, wherein the first vertebra fixation surface is provided on the face of the endplate.

24. The intervertebral disc prosthesis of claim 23 wherein at least one tooth is included on the face of the endplate and the first vertebra fixation surface is provided on the at least one tooth.

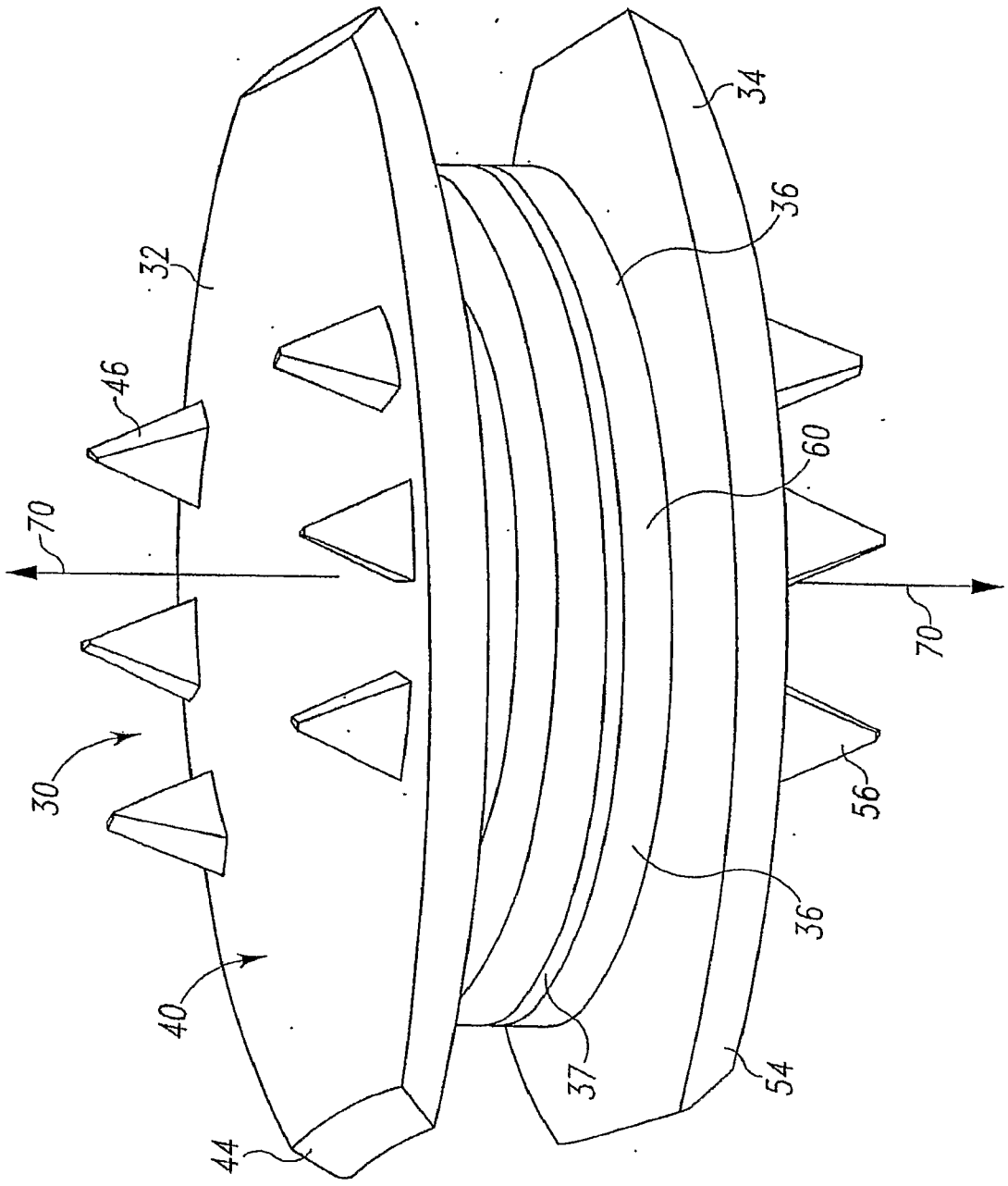

Fig. 1

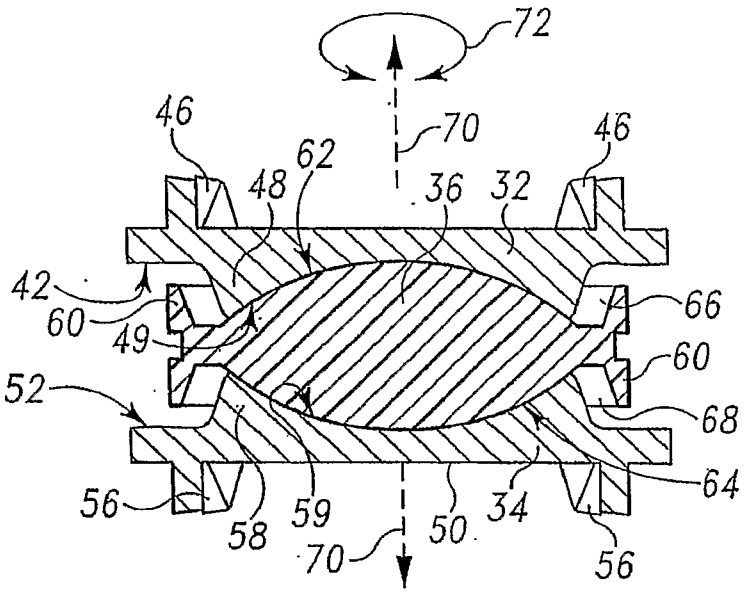
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Fig. 2

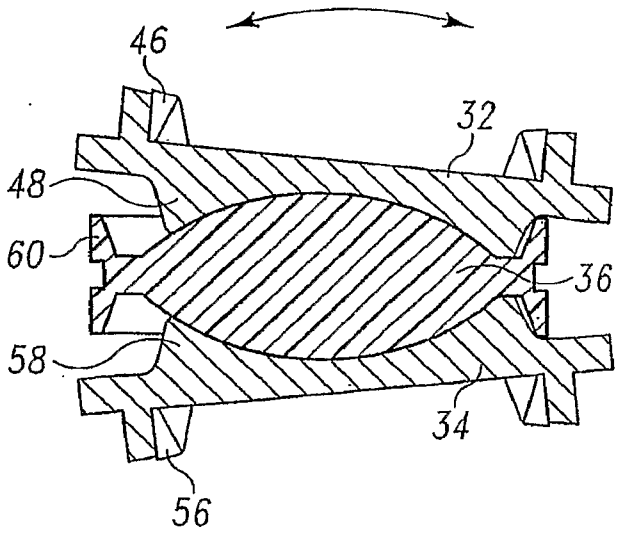
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Fig. 3

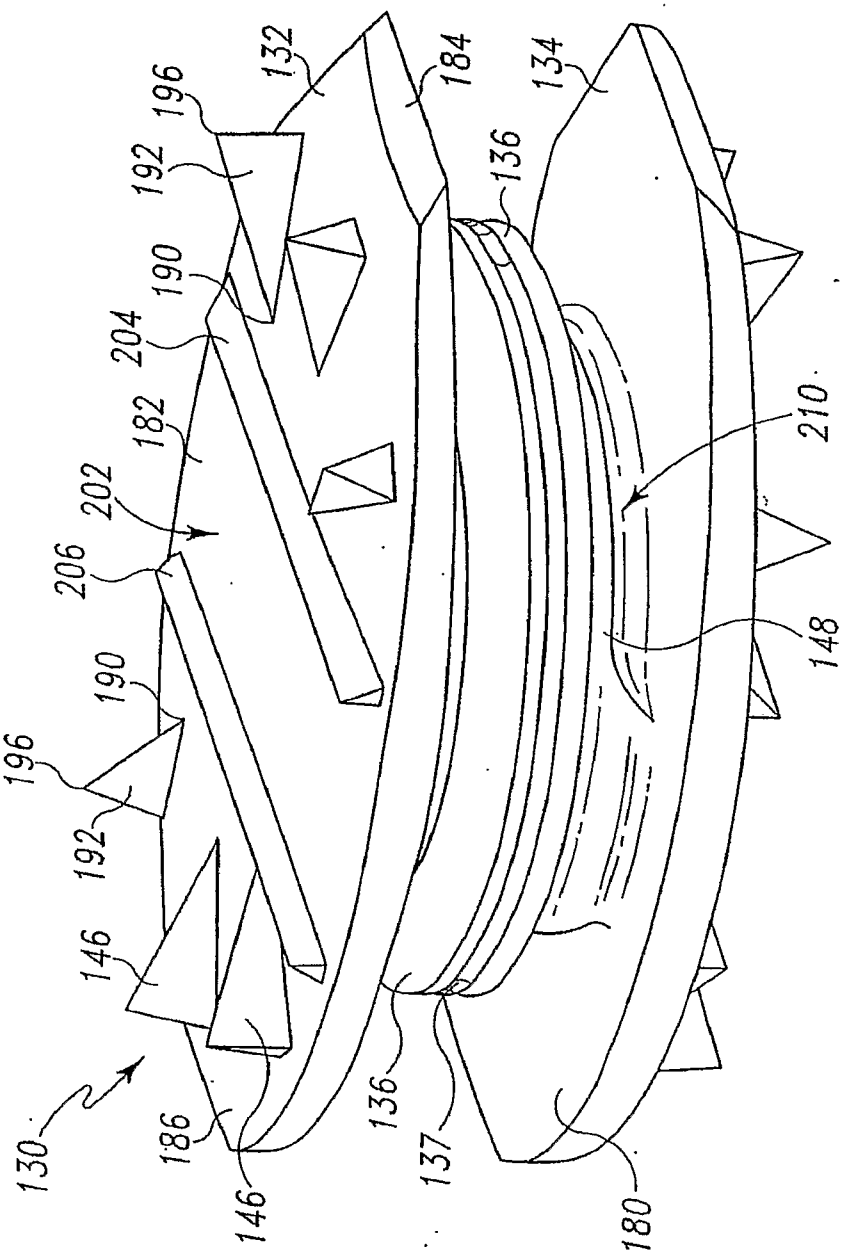
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Fig. 4

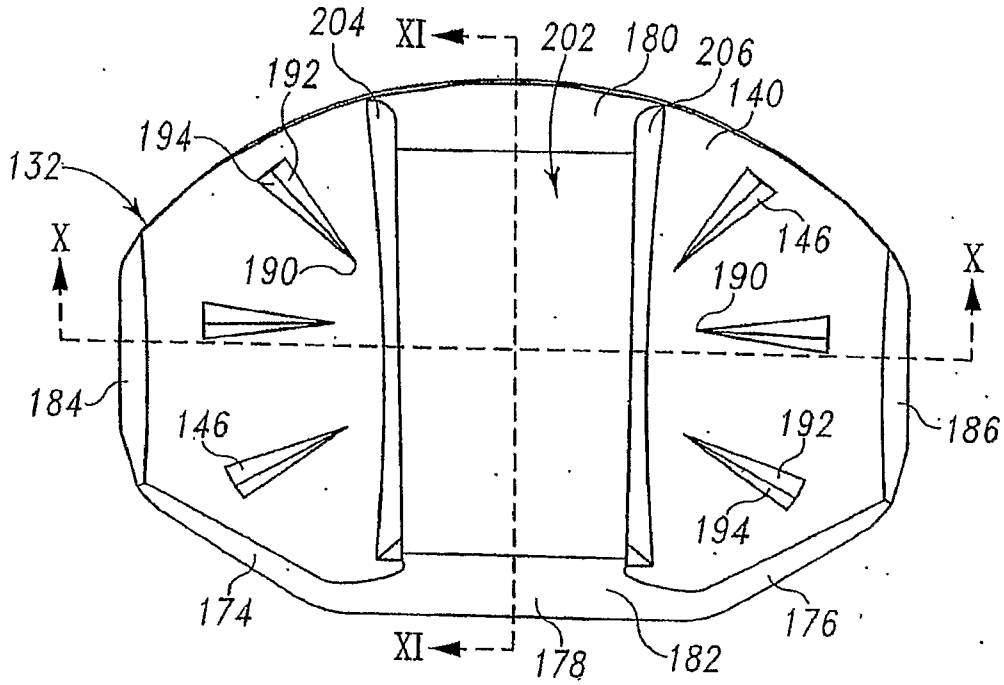
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Fig. 5

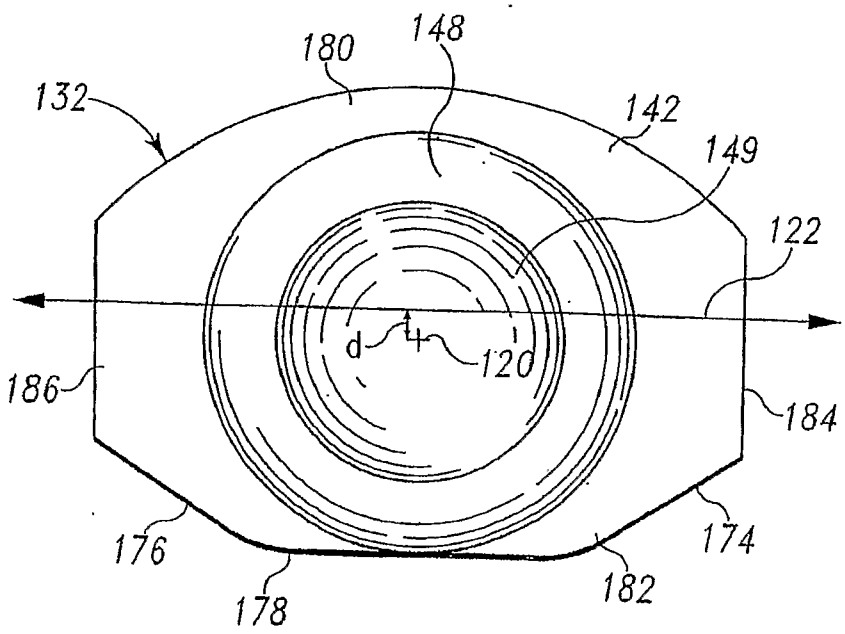
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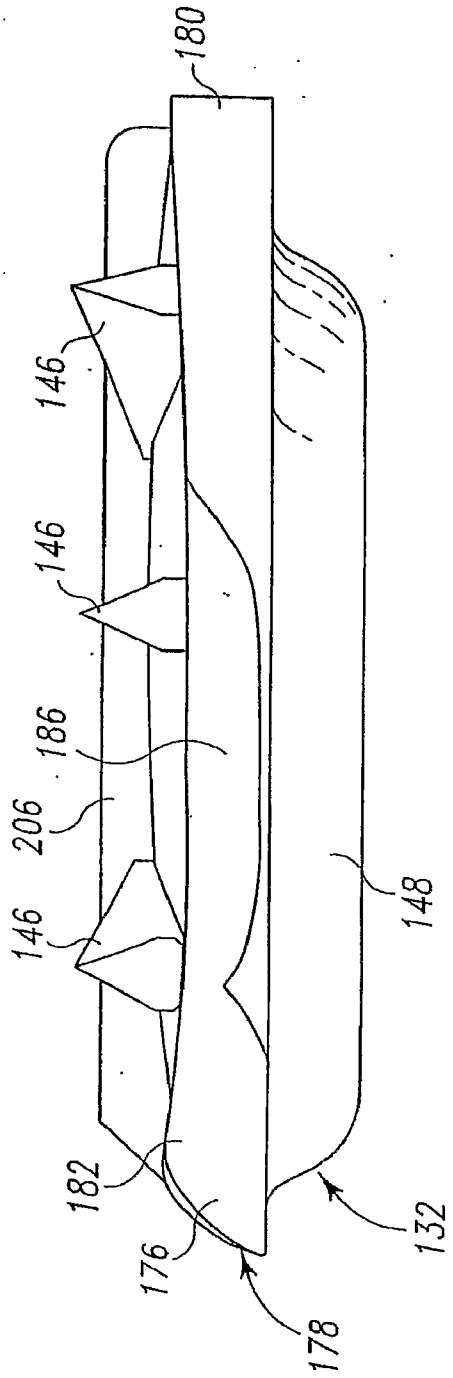
Fig. 6



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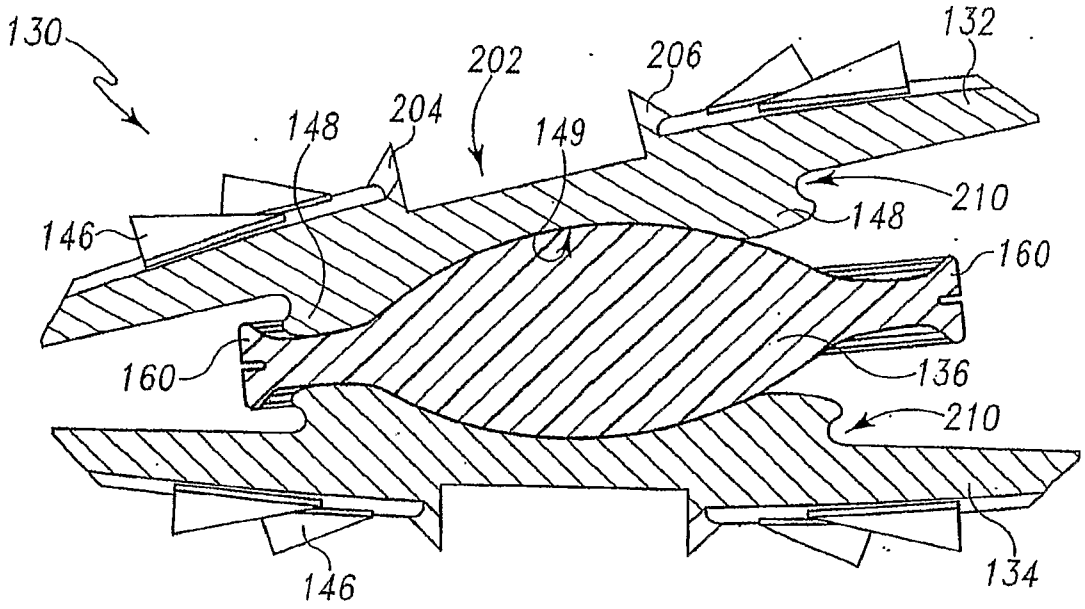
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Fig. 8

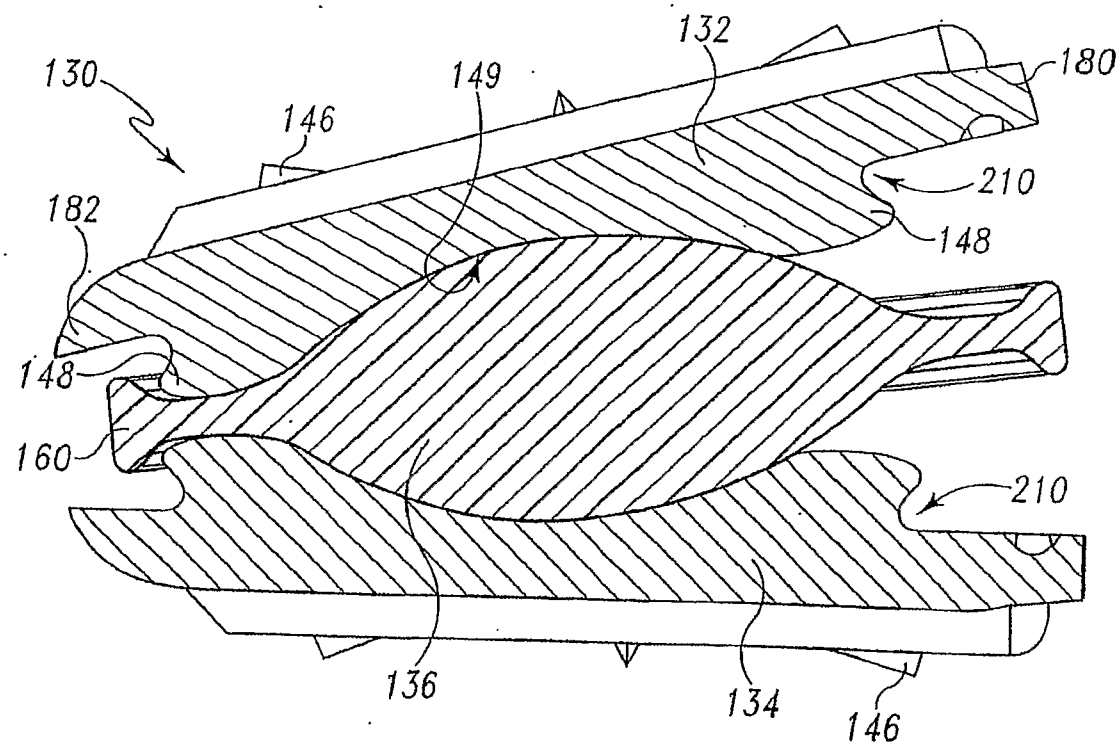
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Fig. 9

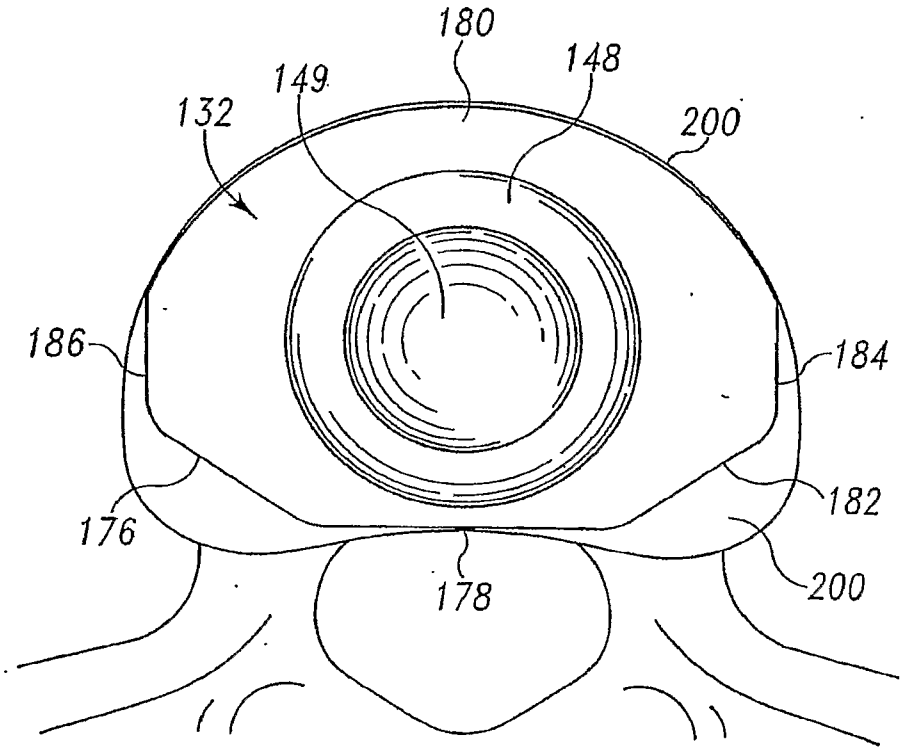

Fig. 10

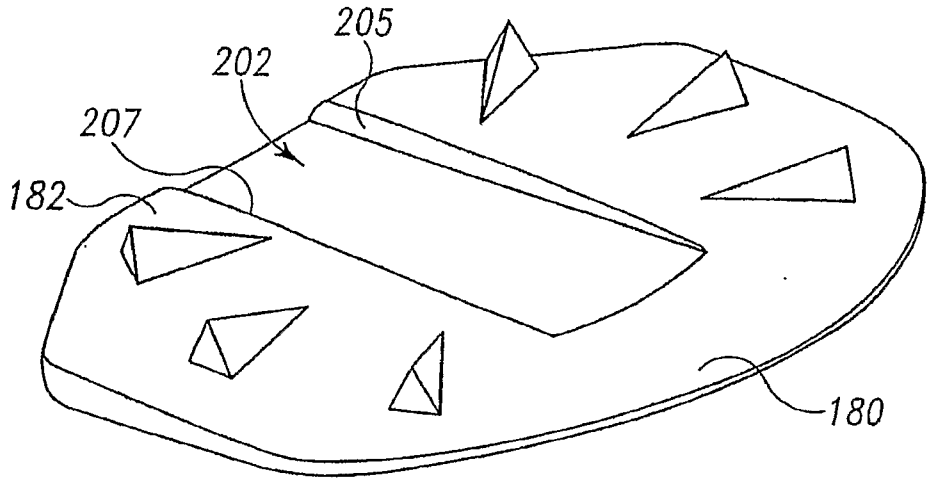

Fig. 11

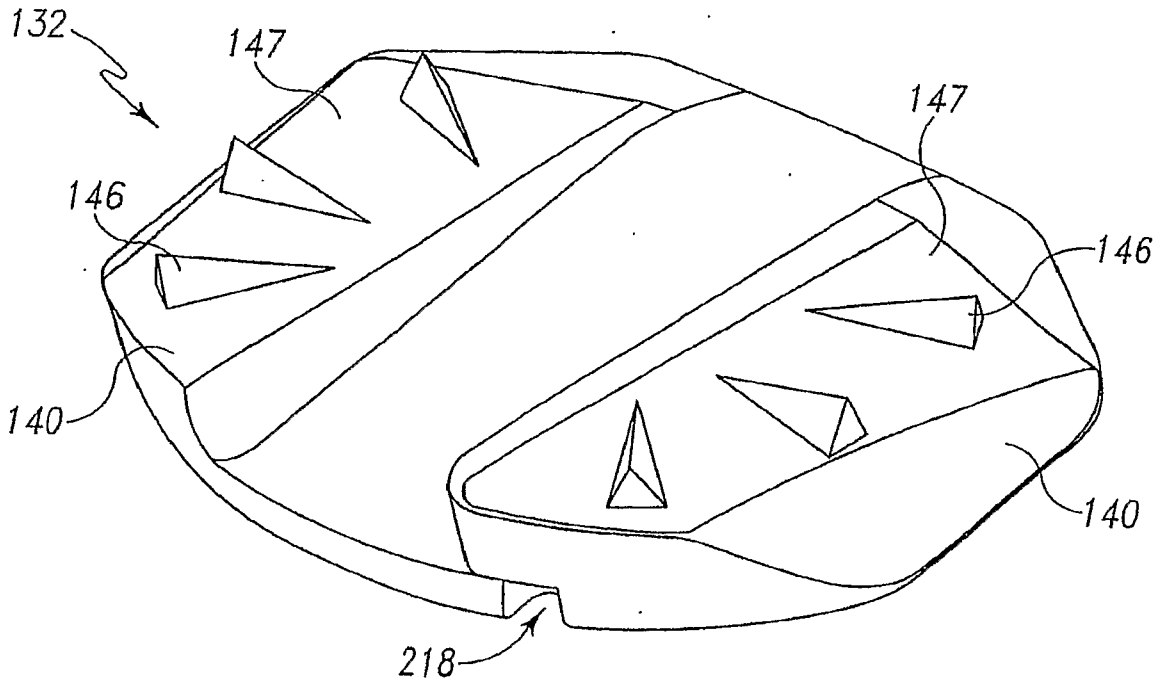

Fig. 11A

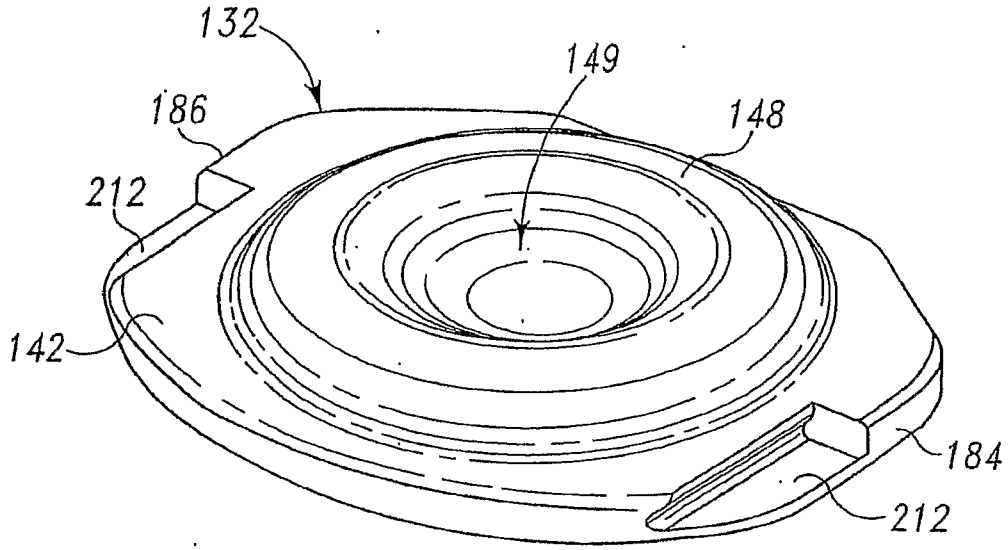

Fig. 12

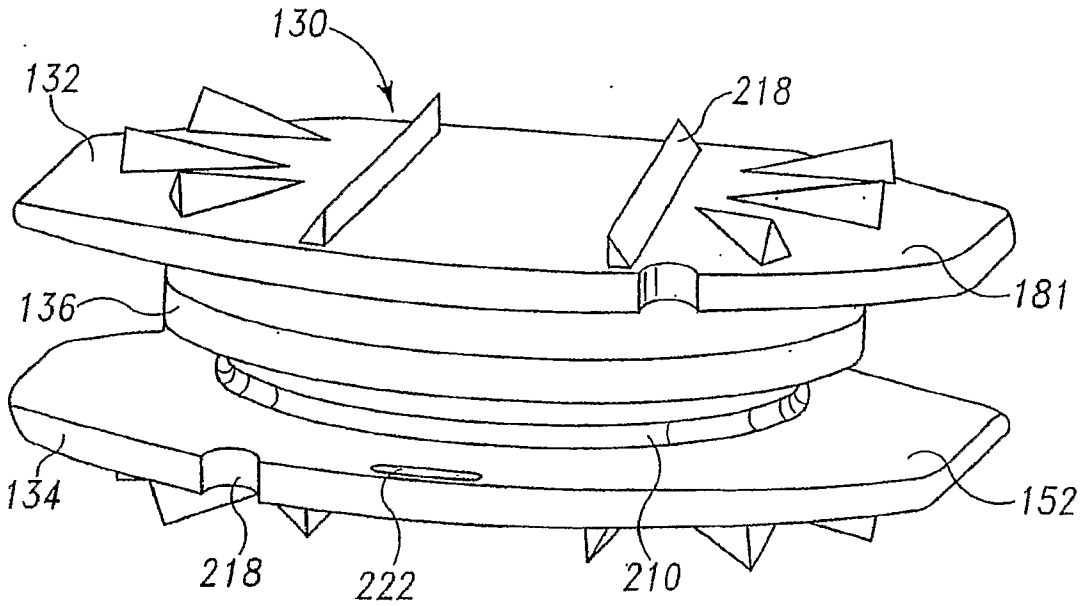

Fig. 12A

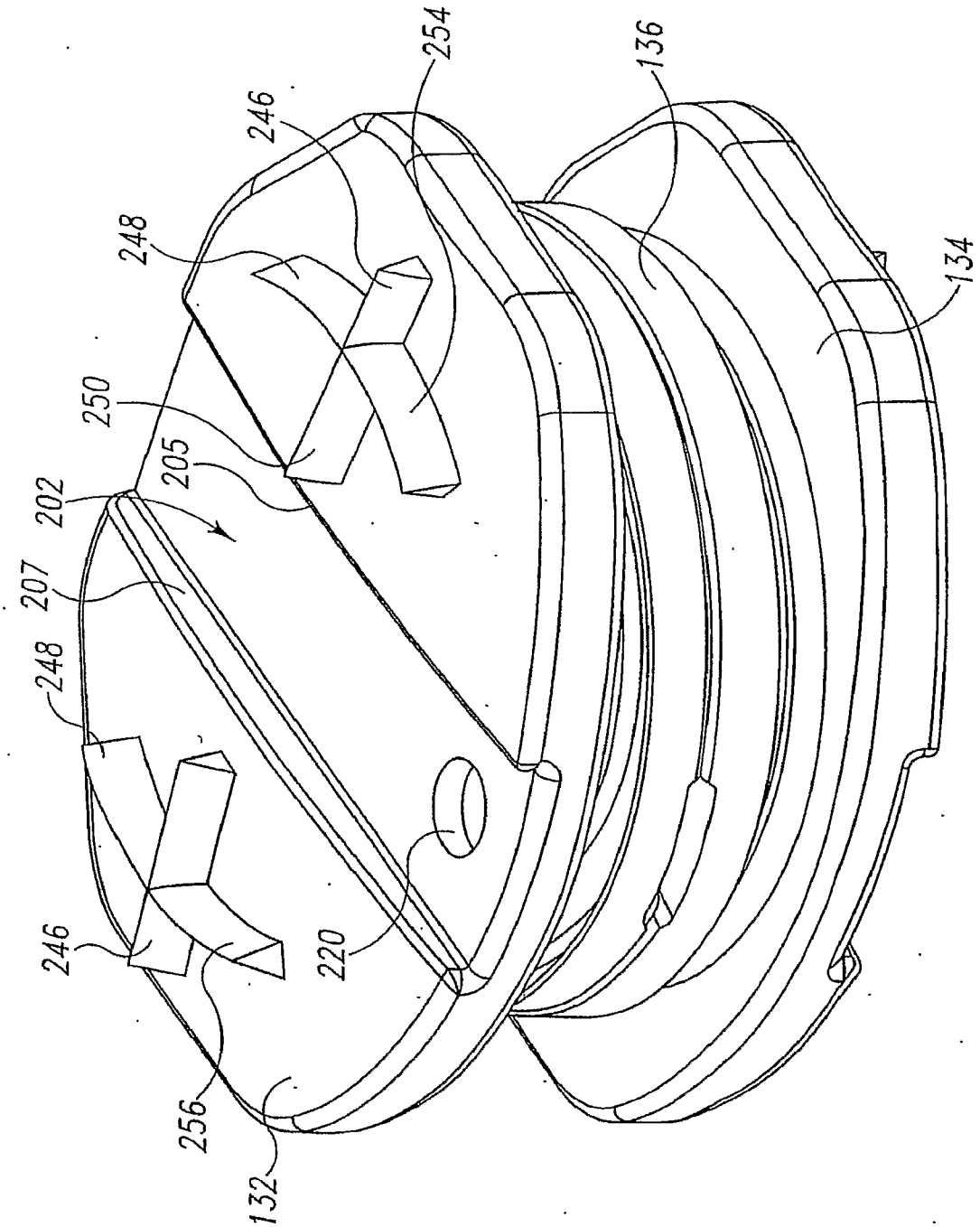

Fig 12

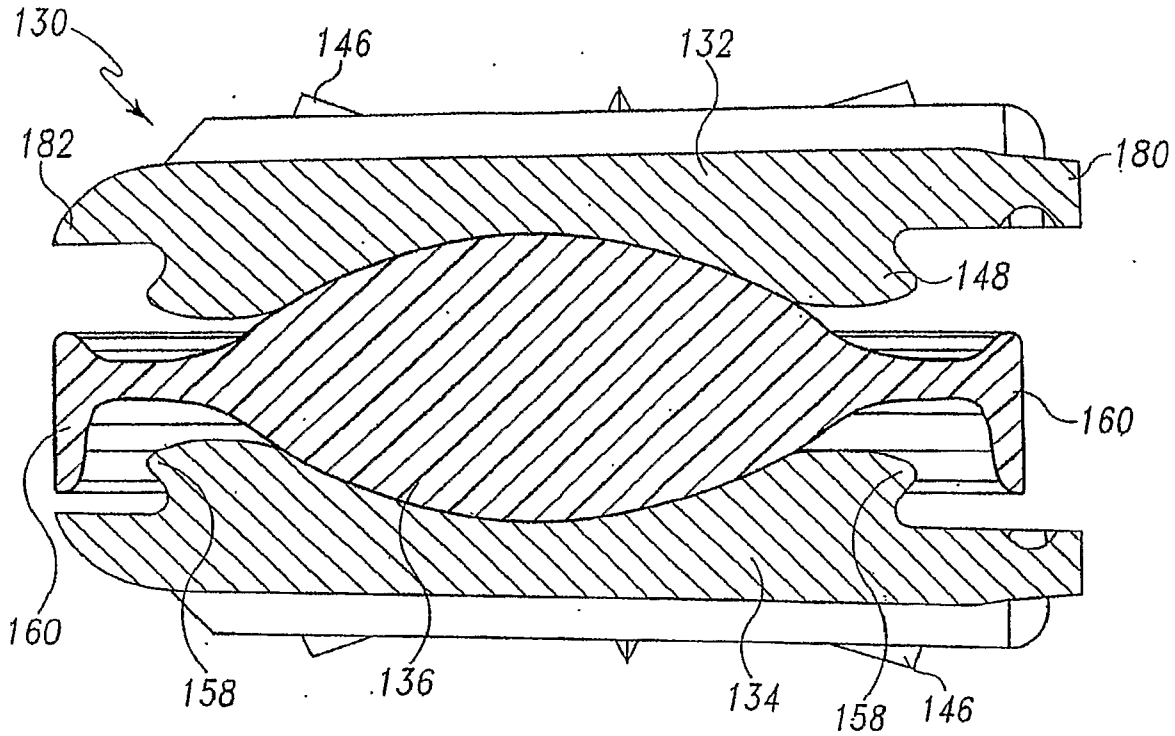

Fig. 14A

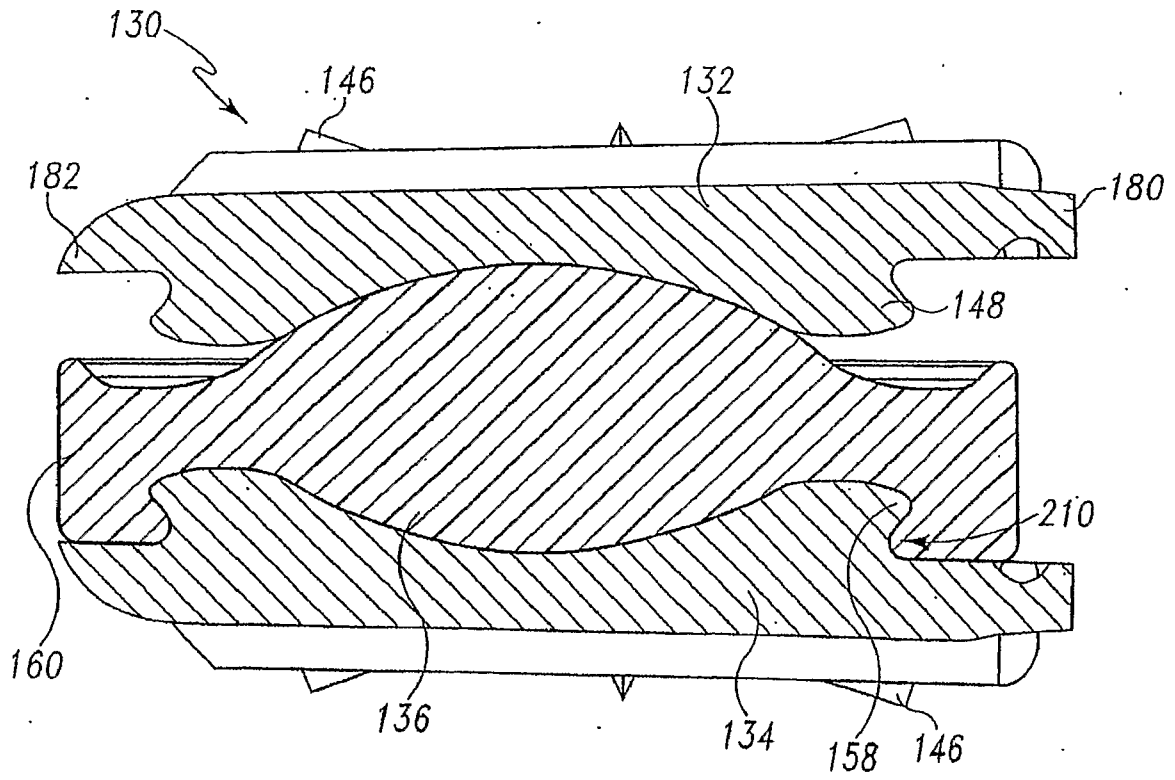

Fig. 14B

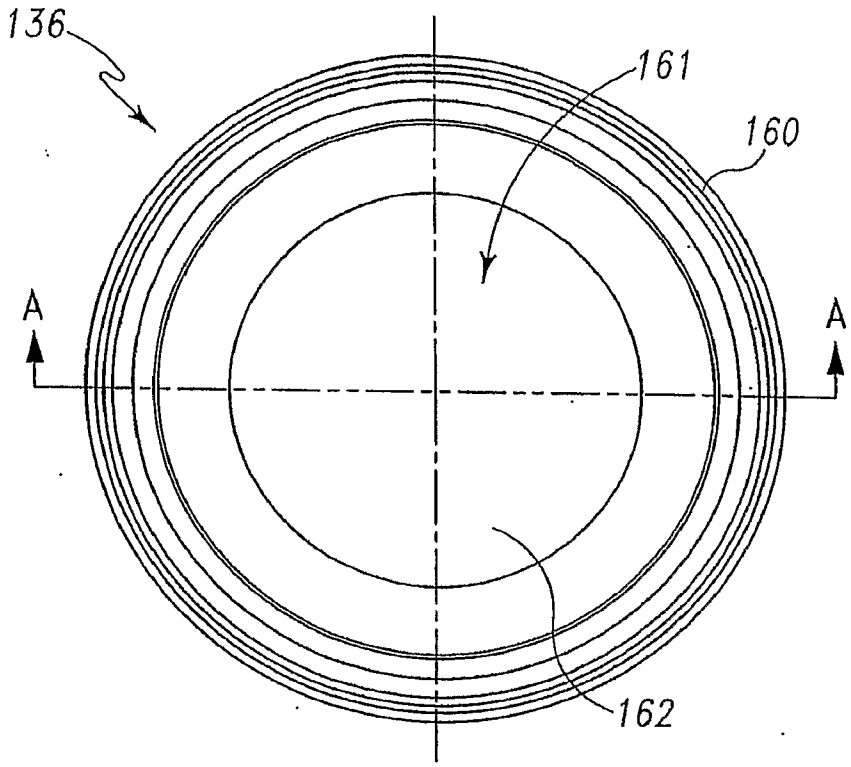

Fig. 15

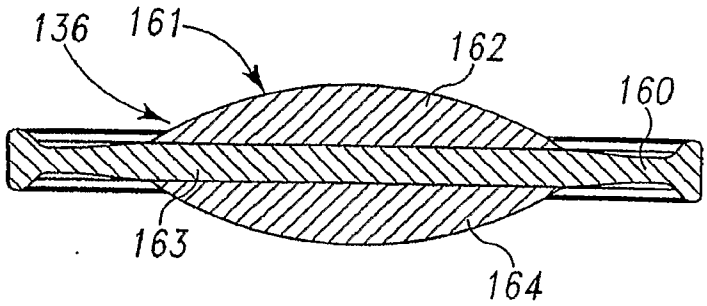

Fig. 15A

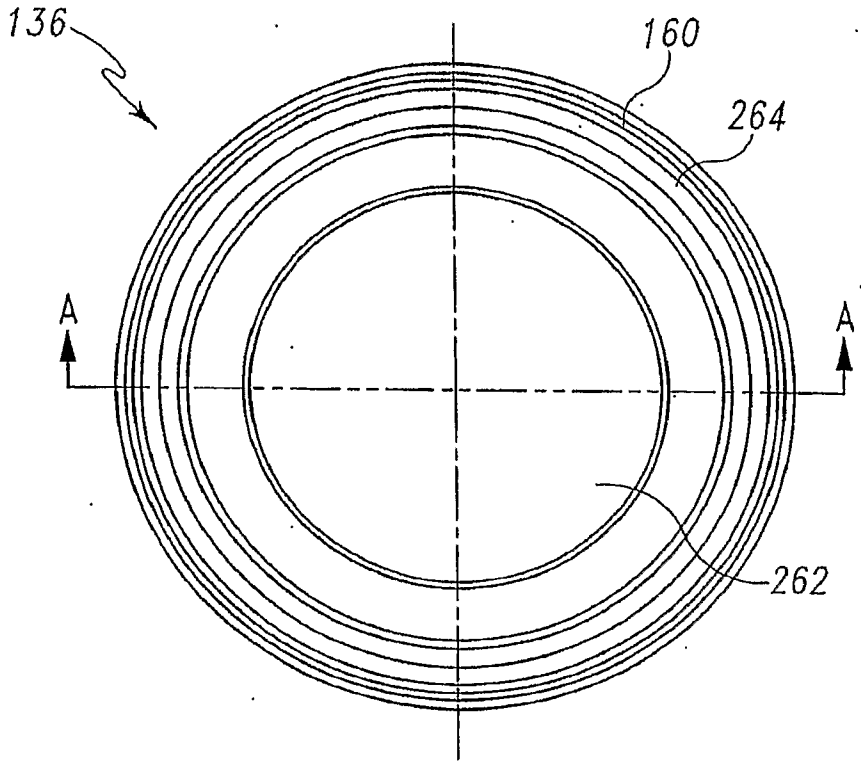

Fig. 16

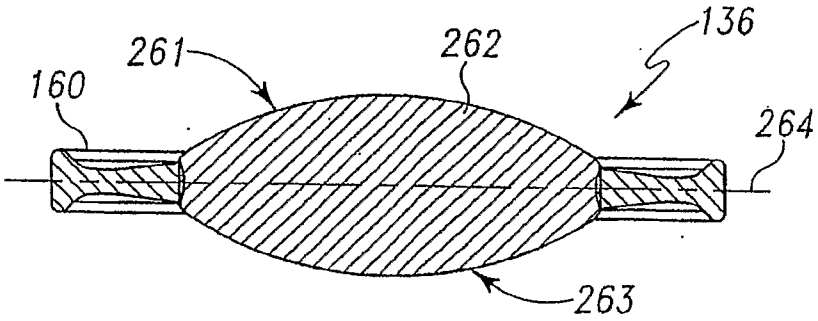

Fig. 16A

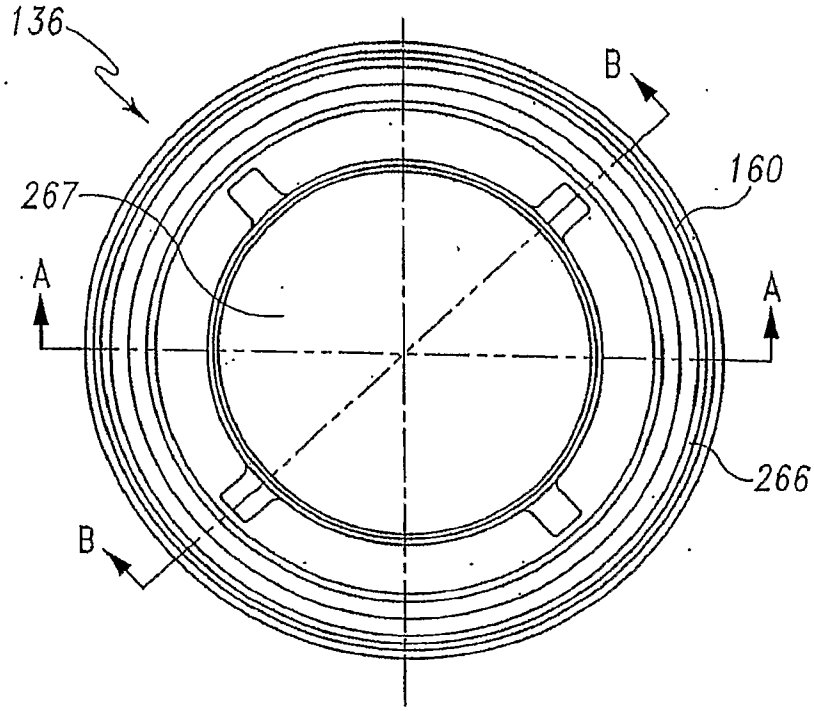

Fig. 17

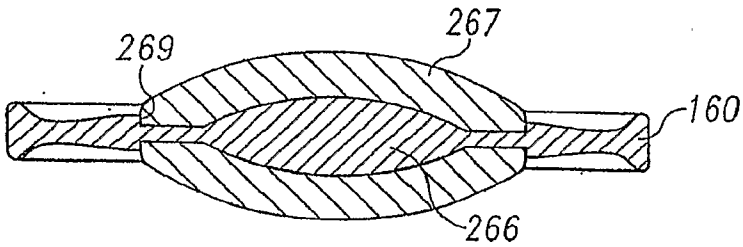

Fig. 17A

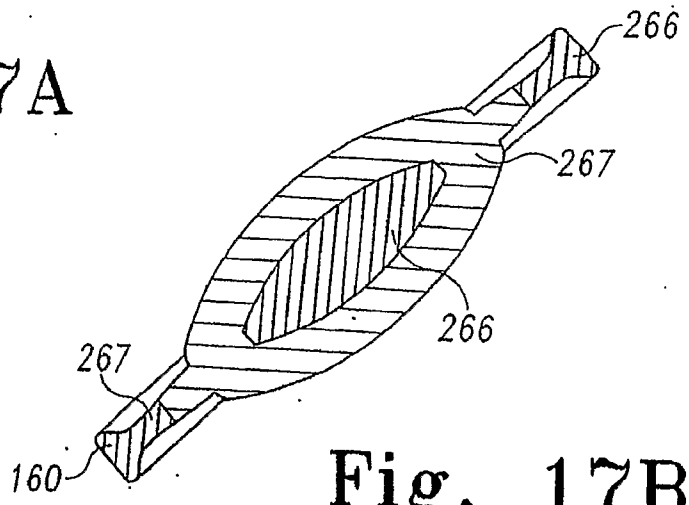

Fig. 17B

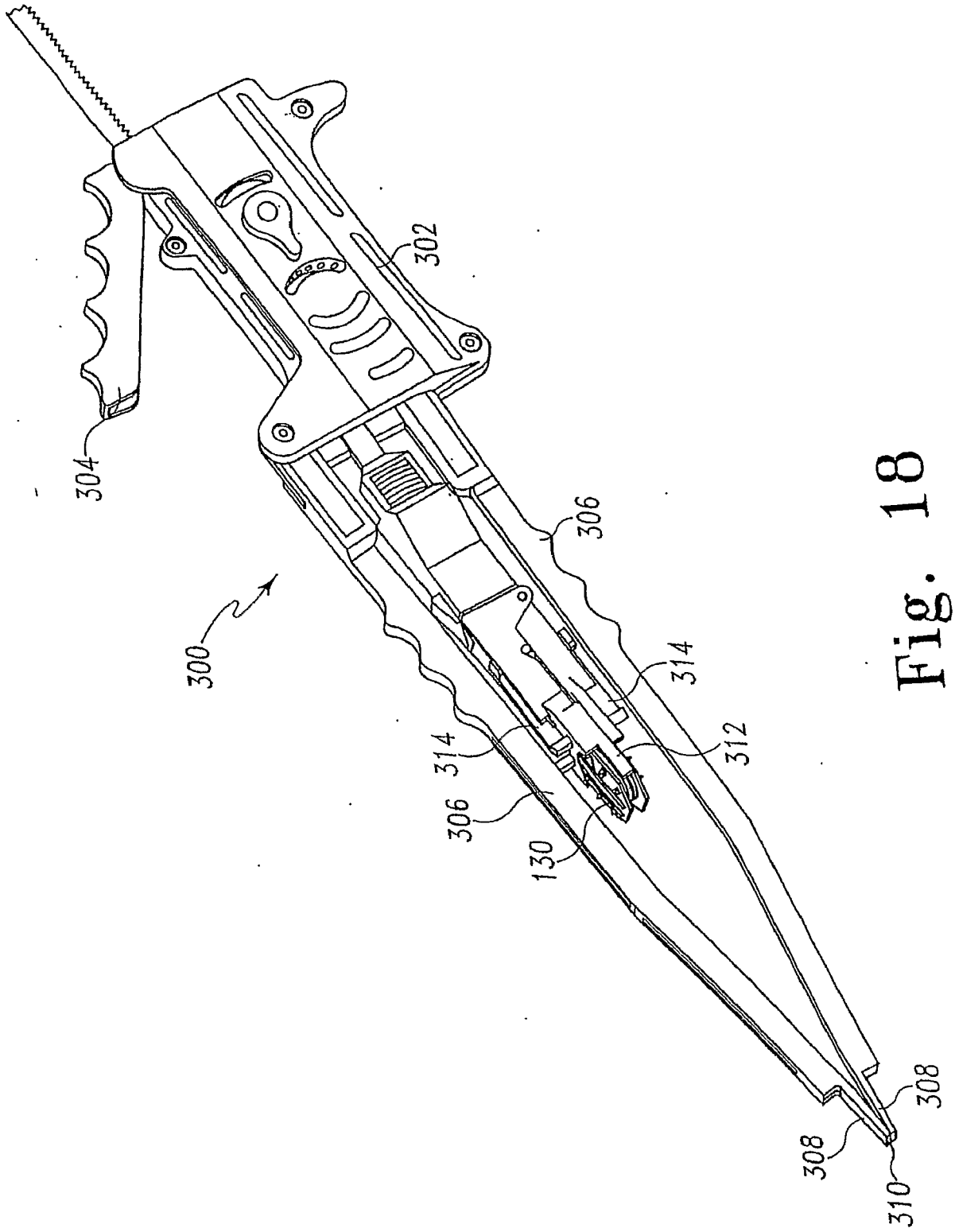

Fig. 18

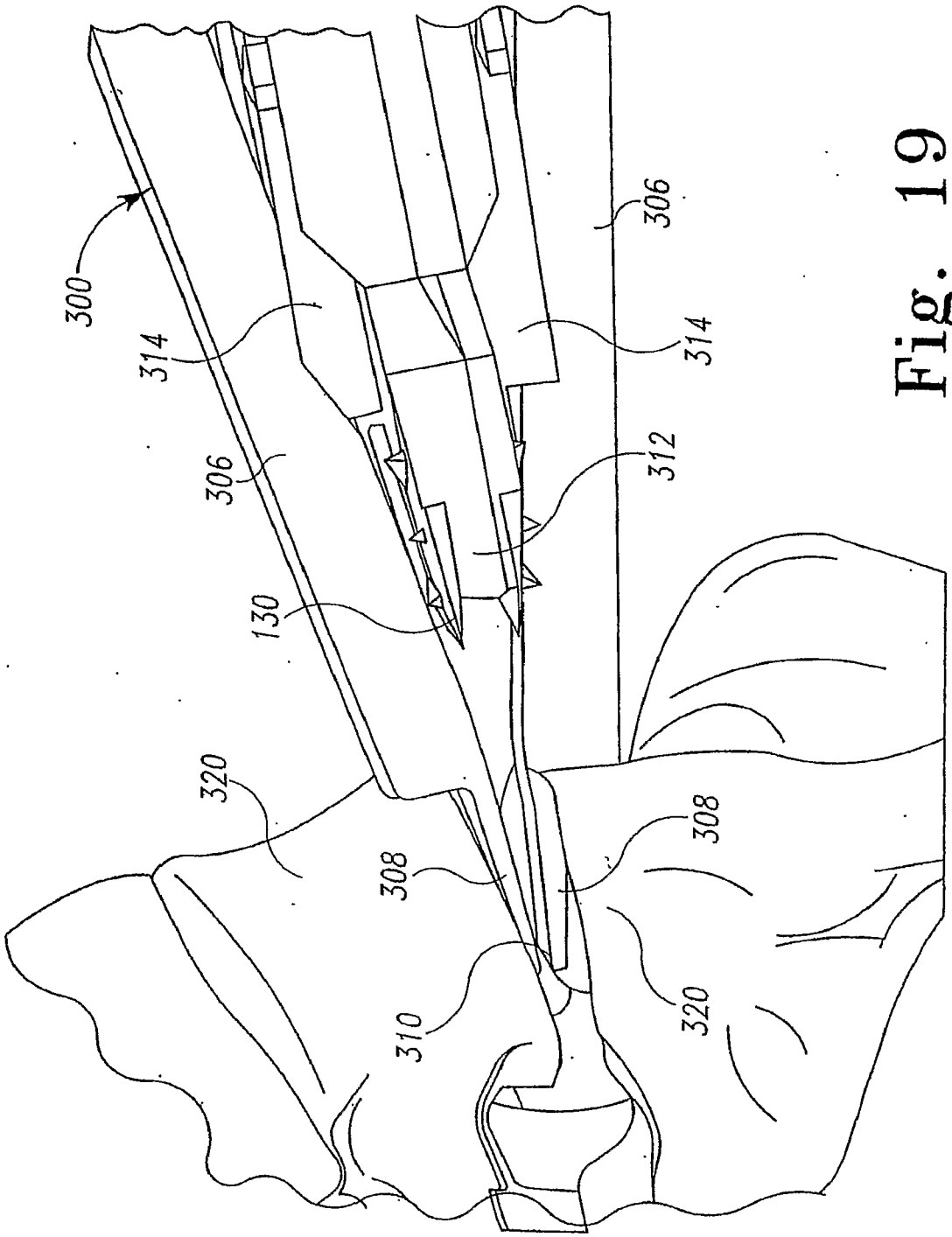

Fig. 19

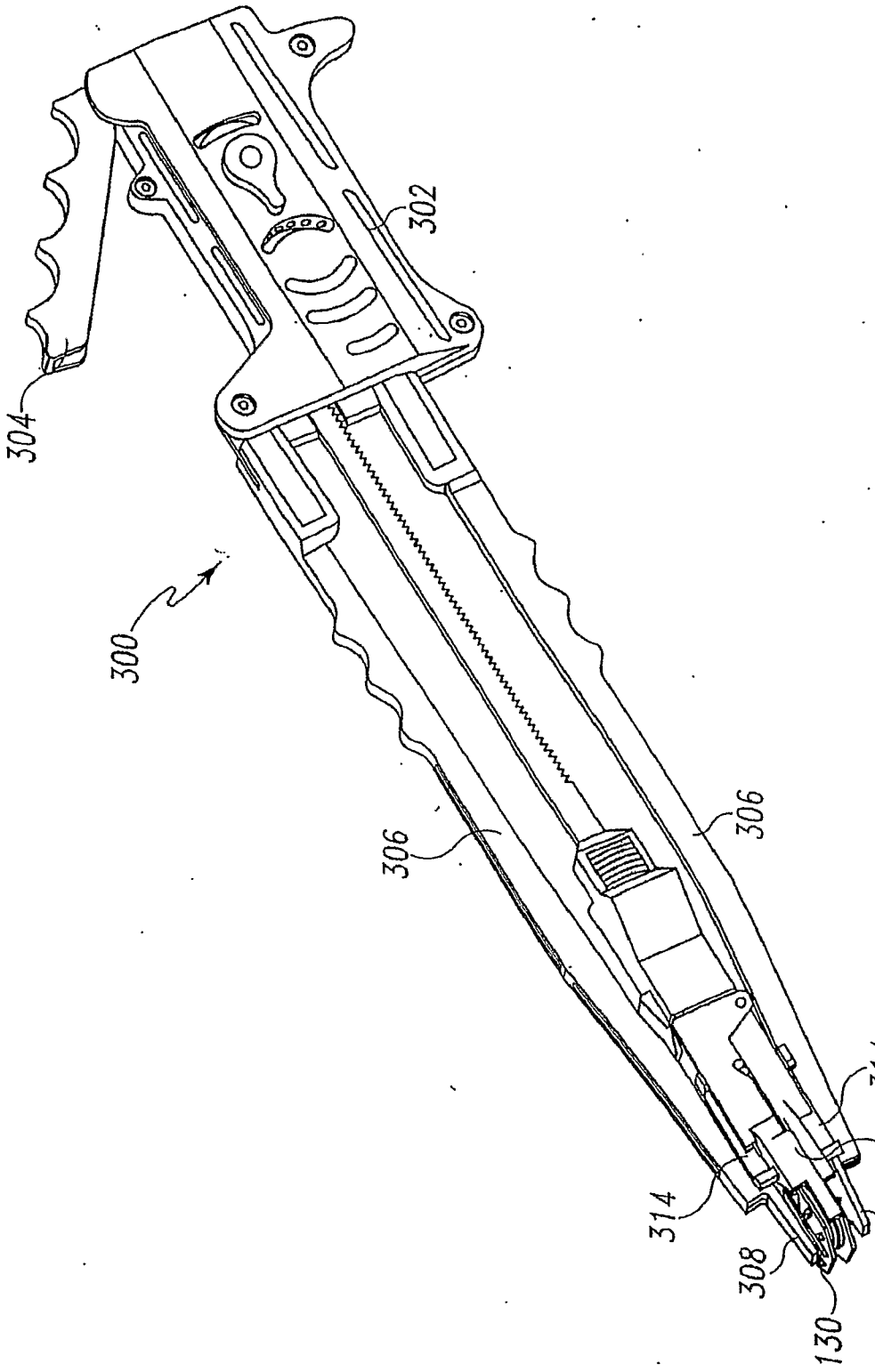

Fig. 20

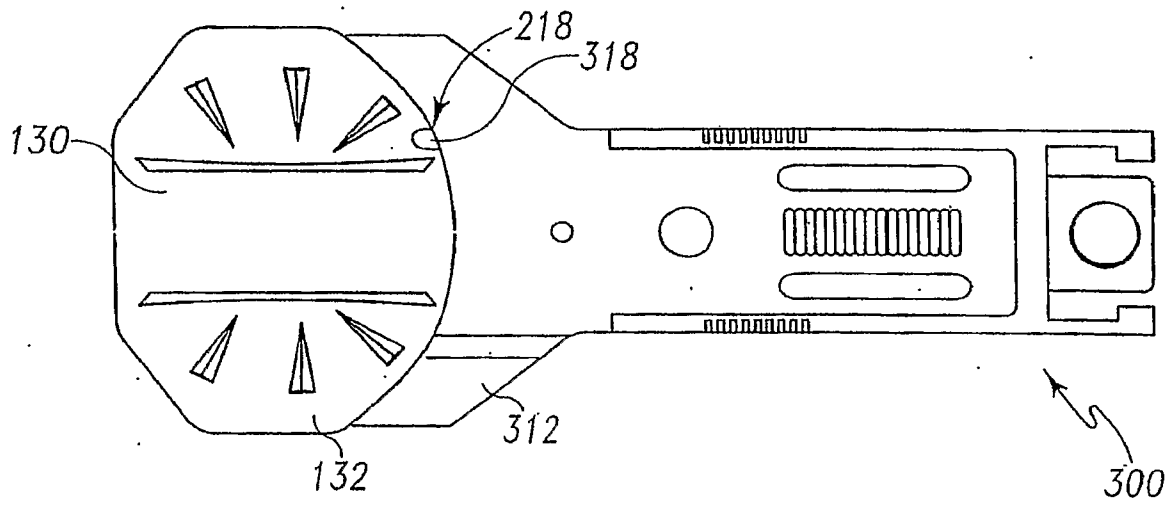

Fig. 21

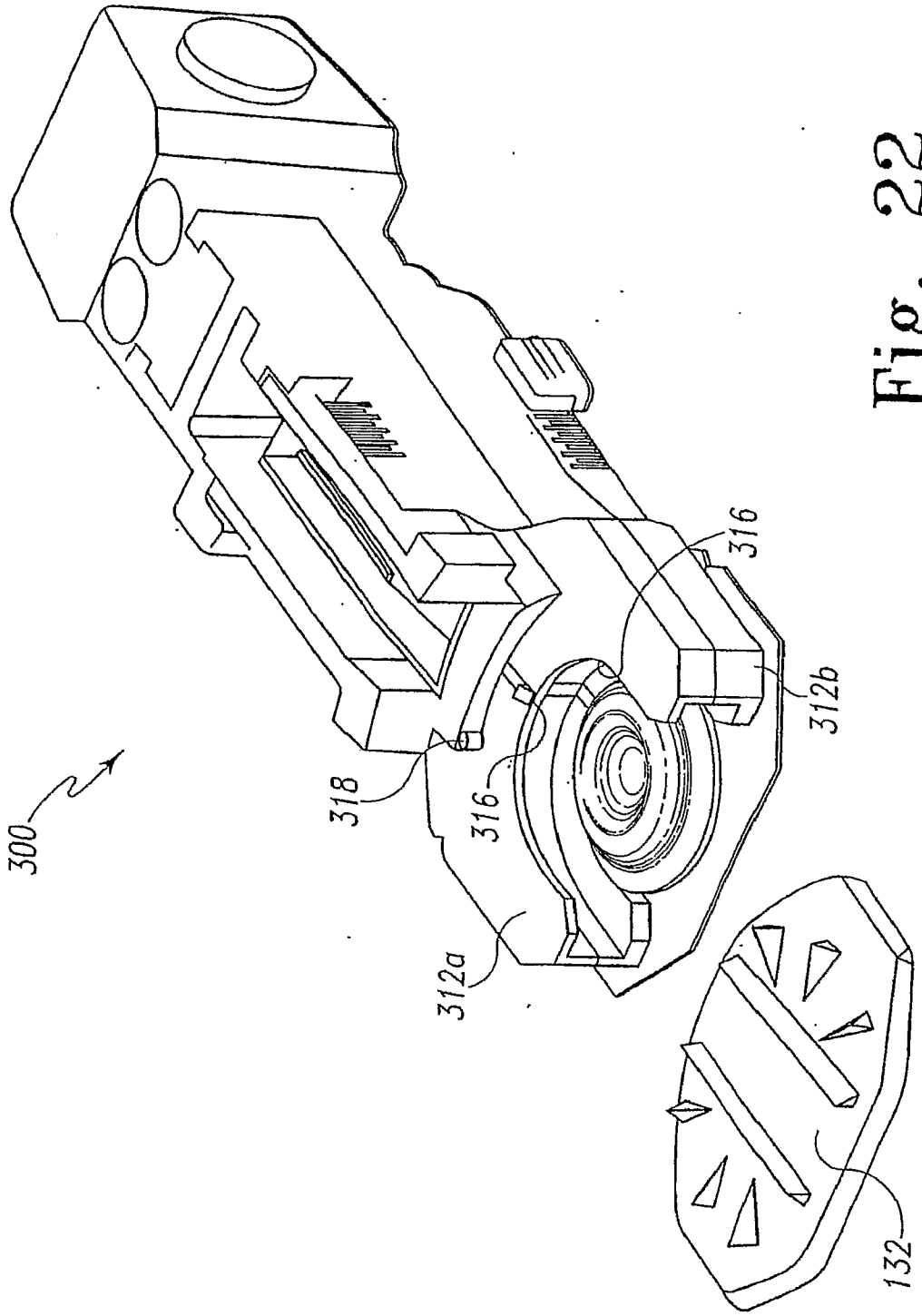

Fig. 22