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(54) **MODULAR SEGMENTED DISC NUCLEUS IMPLANT**

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(57) **ABSTRACT**

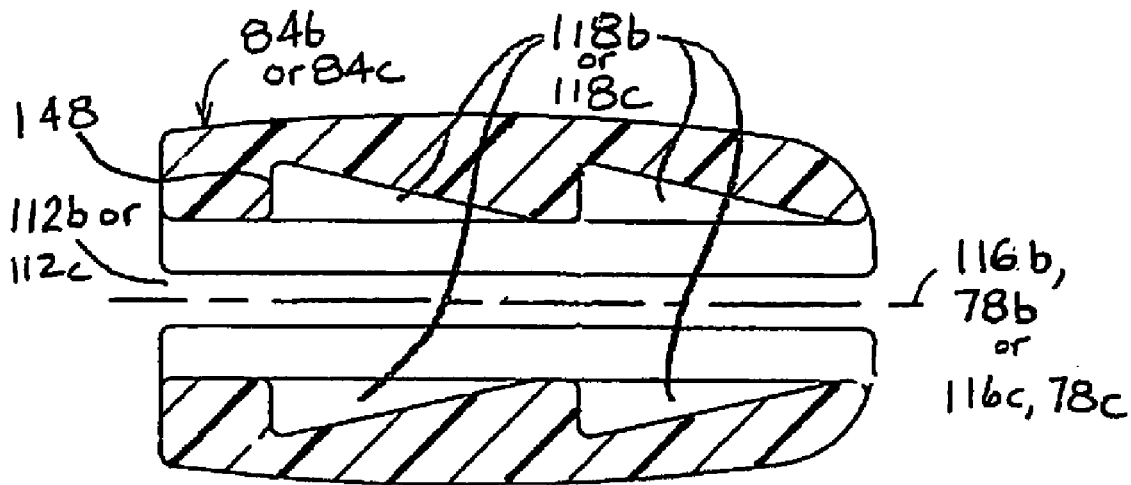
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A segmented disc nucleus replacement prosthesis and system for its implantation wherein the segments are made of a compliant, homogeneous material throughout. The prosthesis comprises a plurality of modular segments that mate together in a rail-and-slot arrangement. The rails and slots are configured to interlock and hold together under load despite being formed of compliant materials. In one embodiment, insertion tools and stabilizers are utilized for manipulation of the modular segments, the insertion tools and stabilizers being designed to accommodate for handling the compliant modular segments.

Related U.S. Application Data

(63) Continuation of application No. 13/833,998, filed on Mar. 15, 2013, now Pat. No. 9,510,953.

(60) Provisional application No. 61/685,383, filed on Mar. 16, 2012.



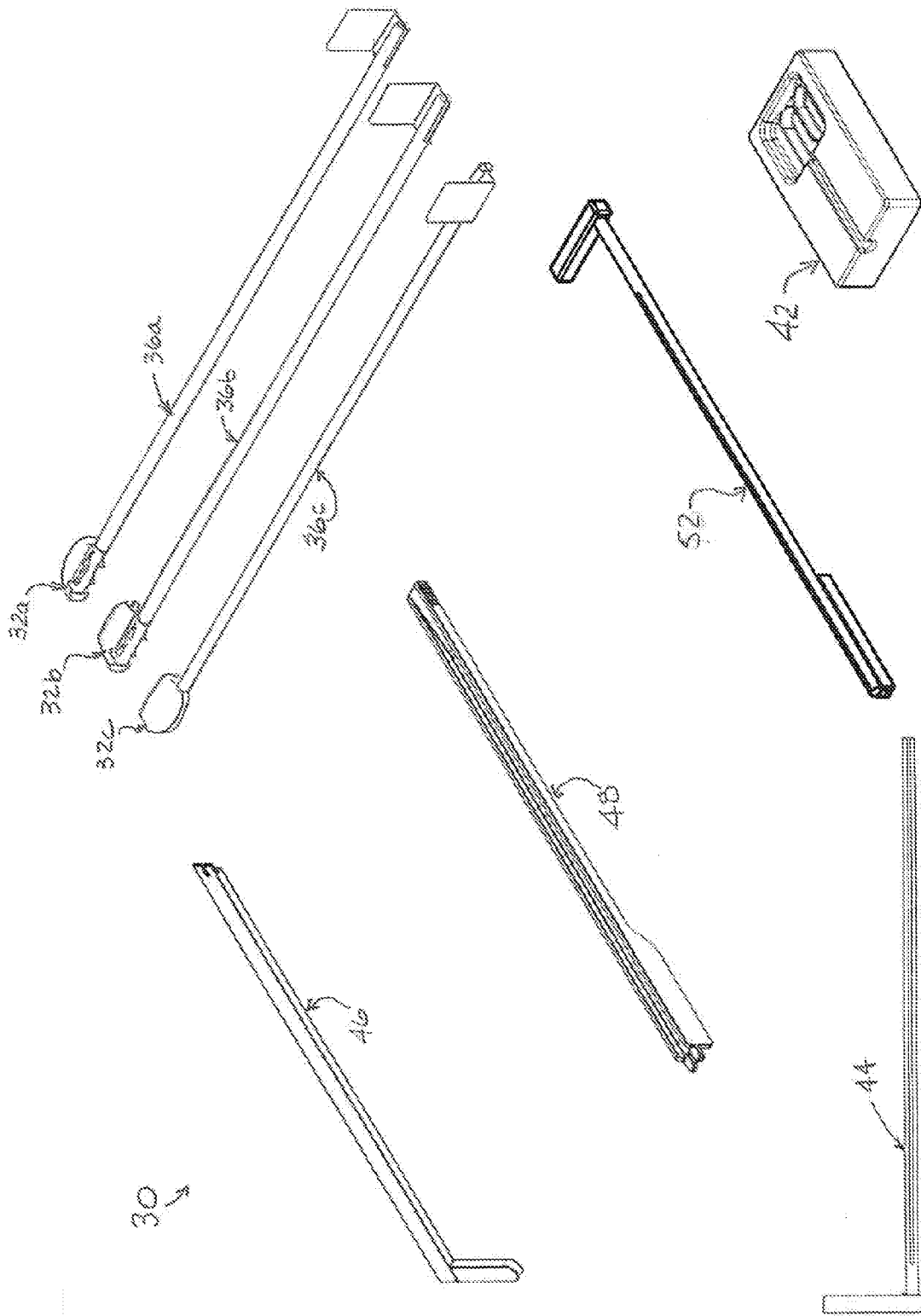


FIG. 1

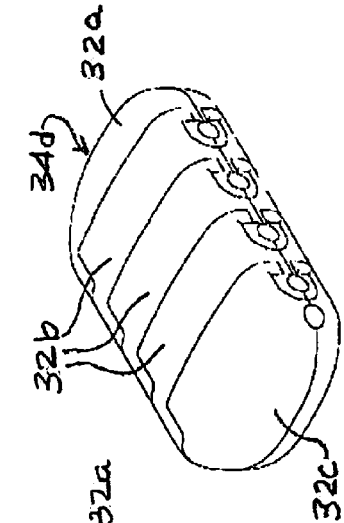


FIG. 2A

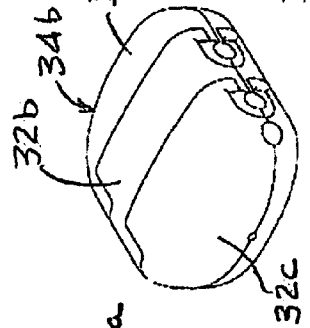


FIG. 2B

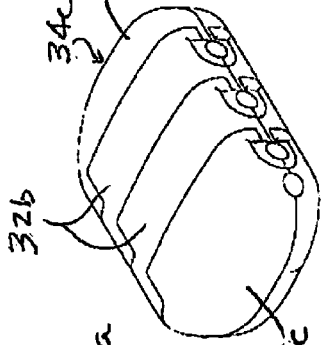


FIG. 2C

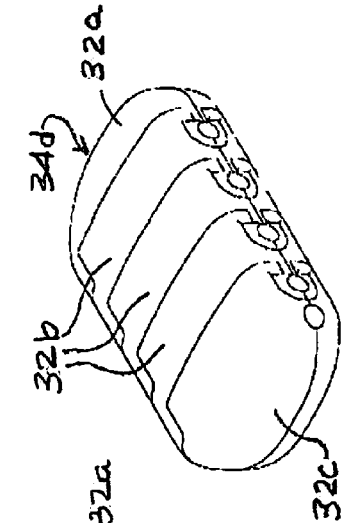


FIG. 2D

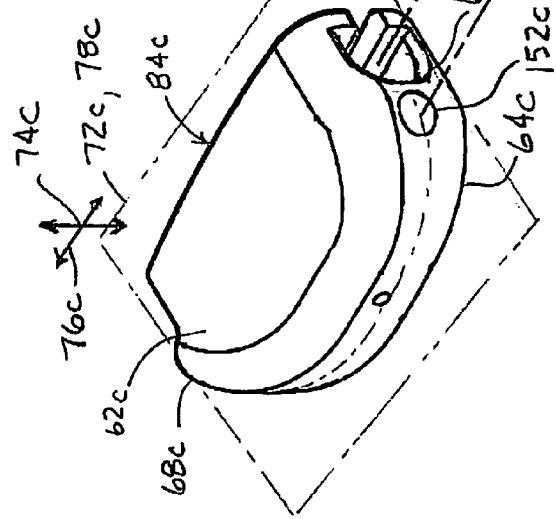


FIG. 3A

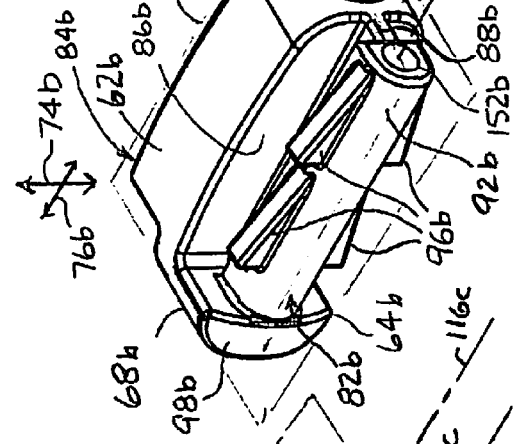


FIG. 3B

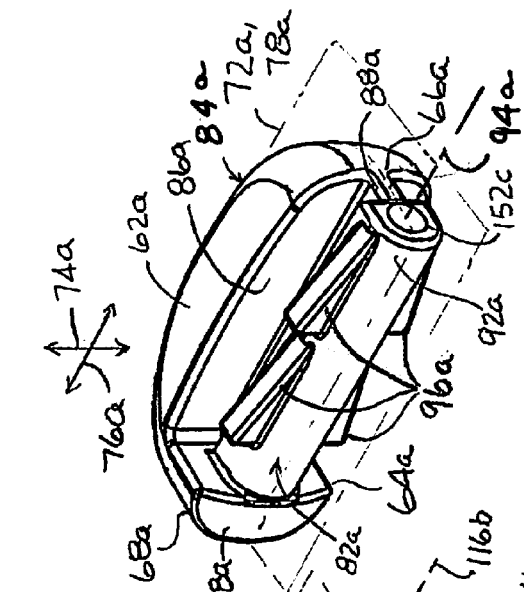


FIG. 3C

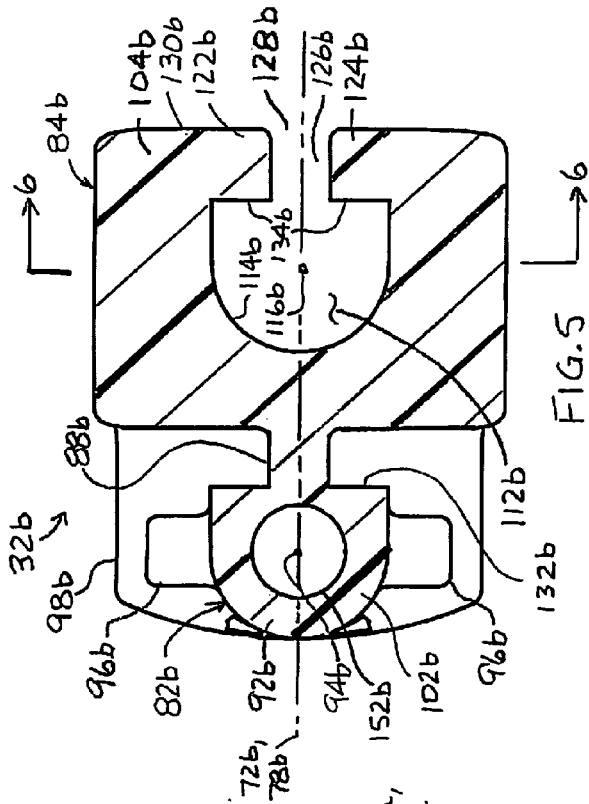


FIG. 4

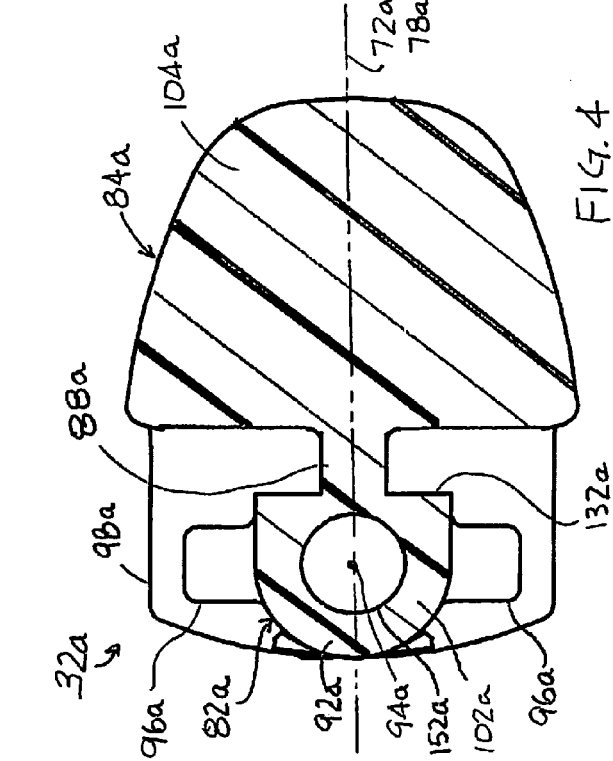


FIG. 5

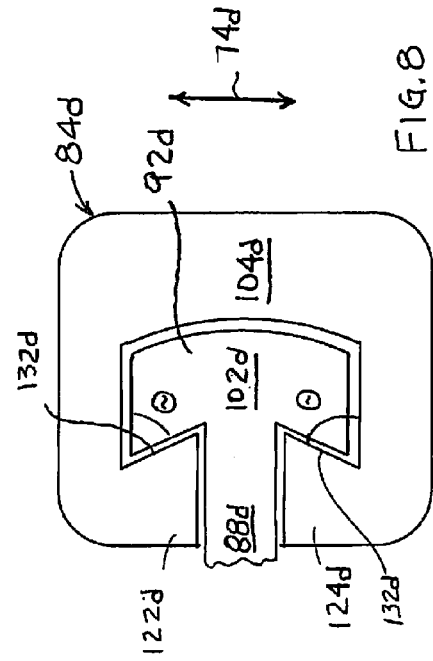


FIG. 6

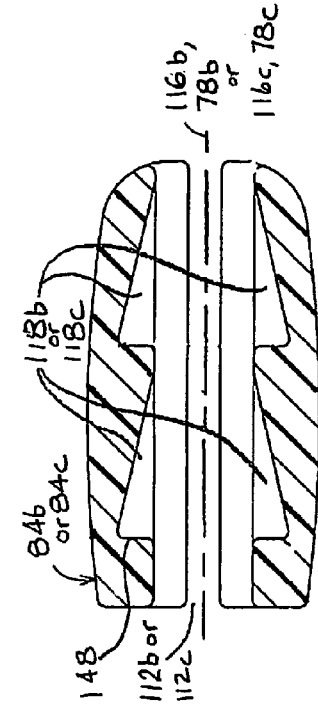


FIG. 7

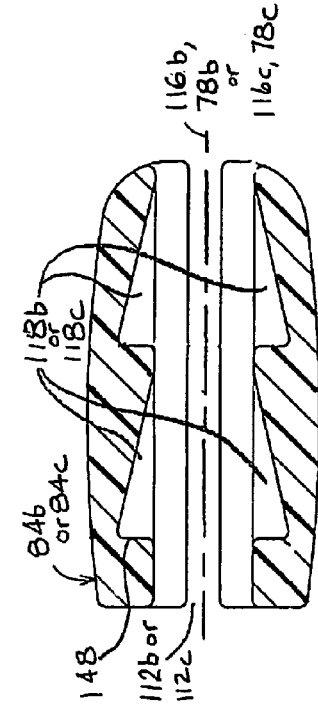


FIG. 8

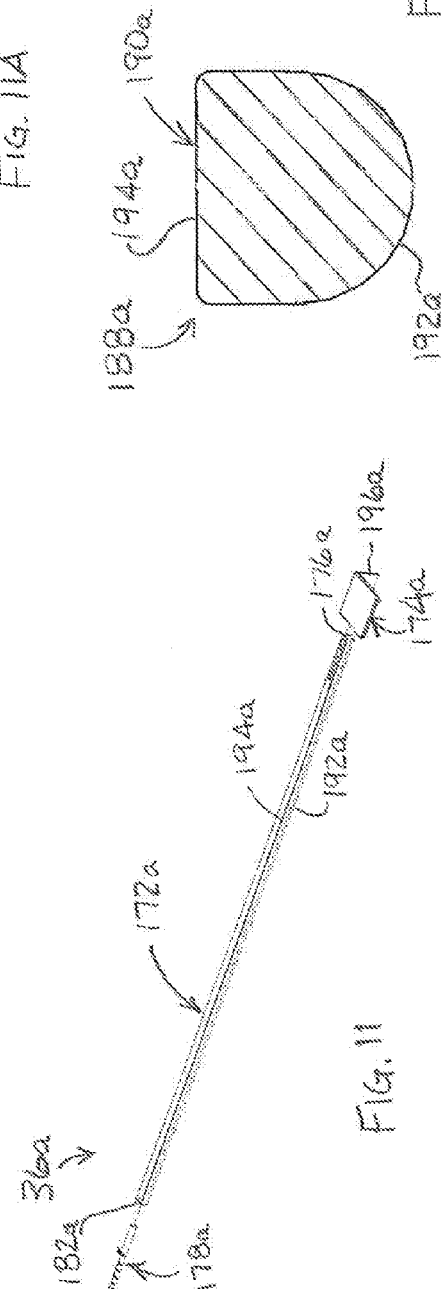
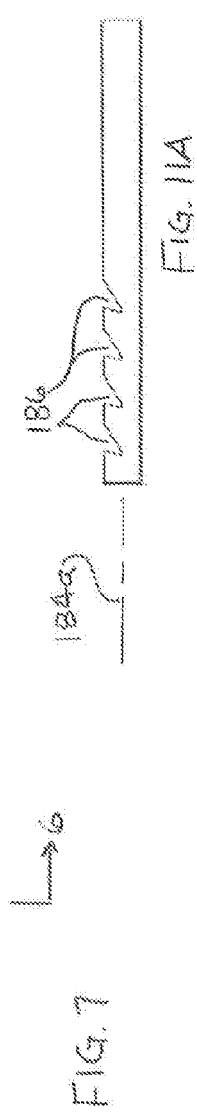
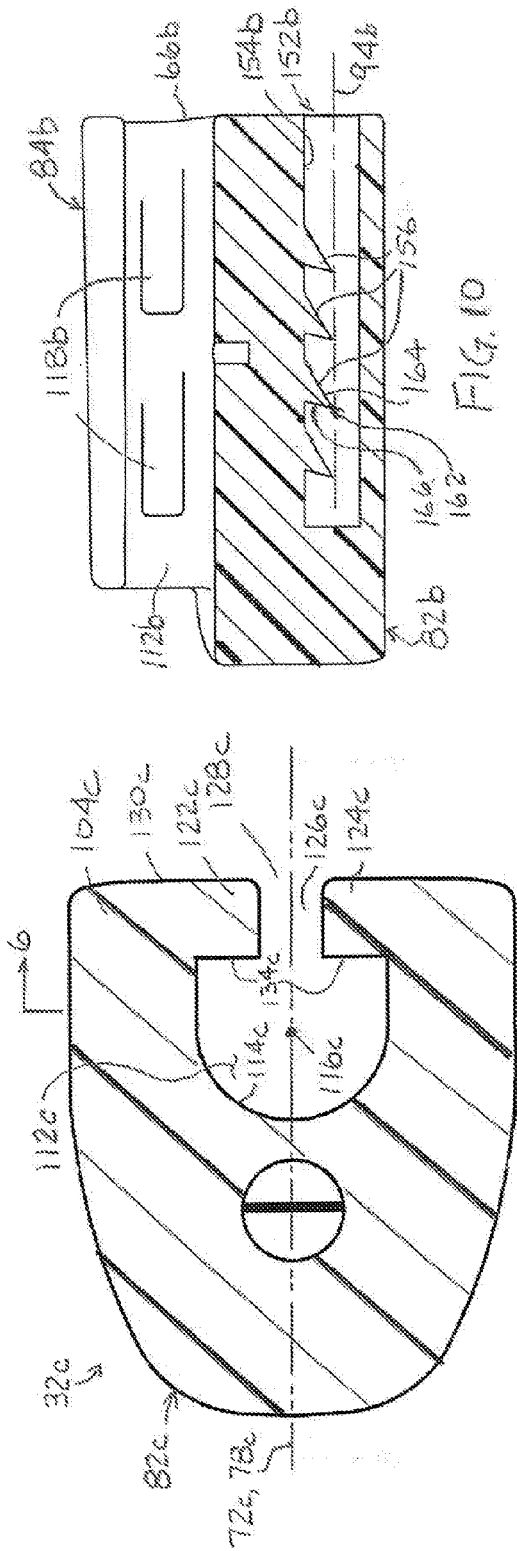


FIG. 11B

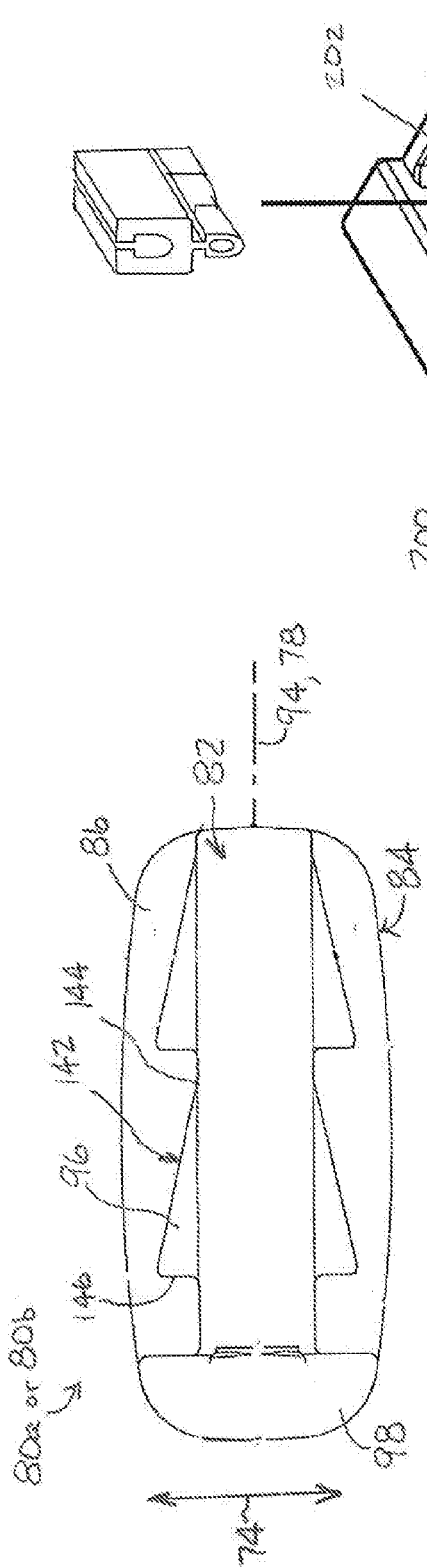


FIG. 9

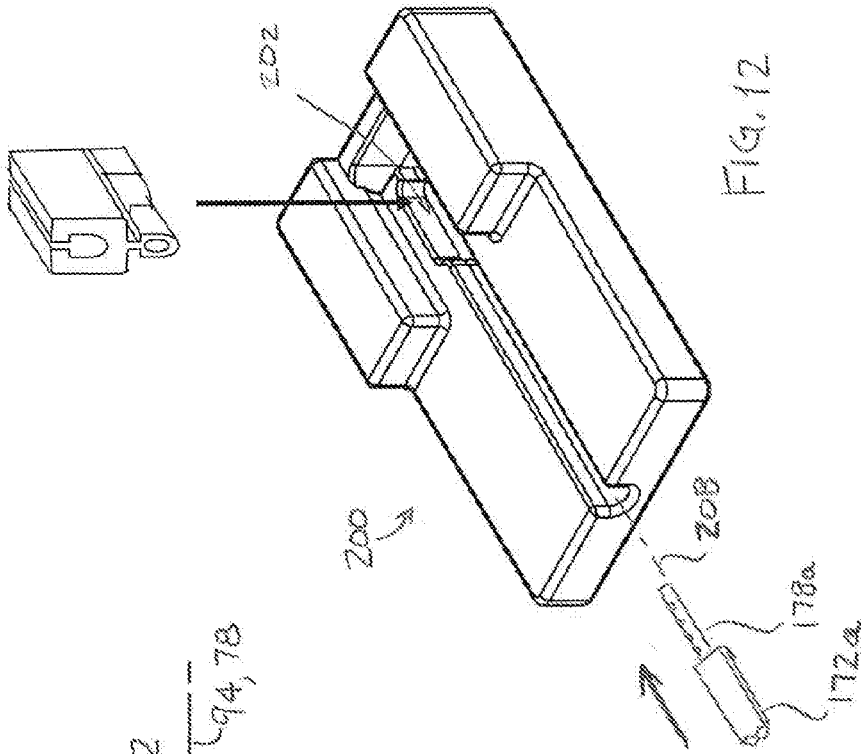


FIG. 12

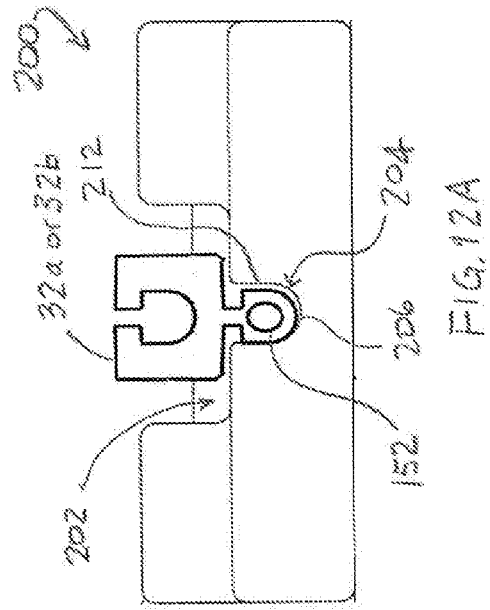
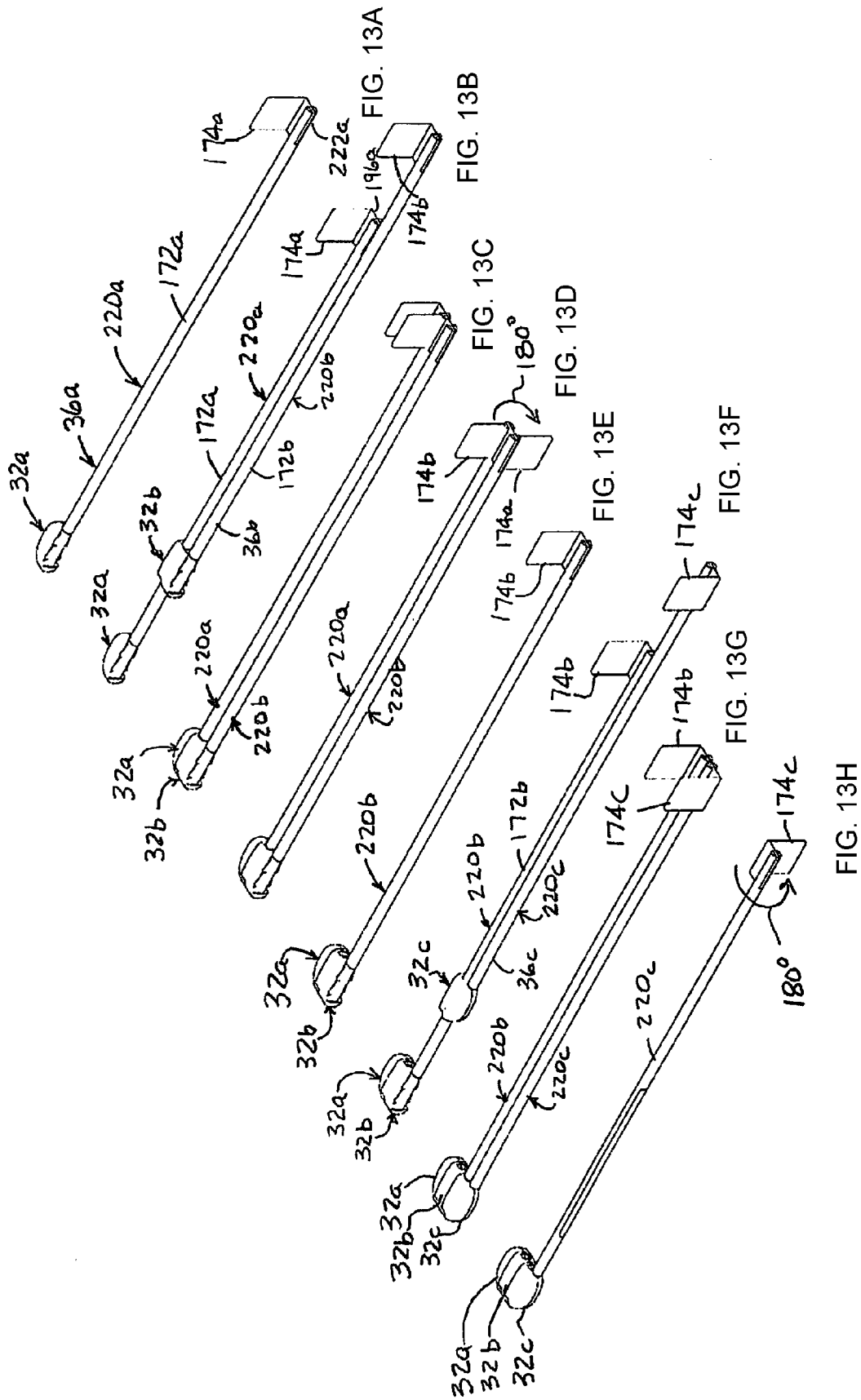
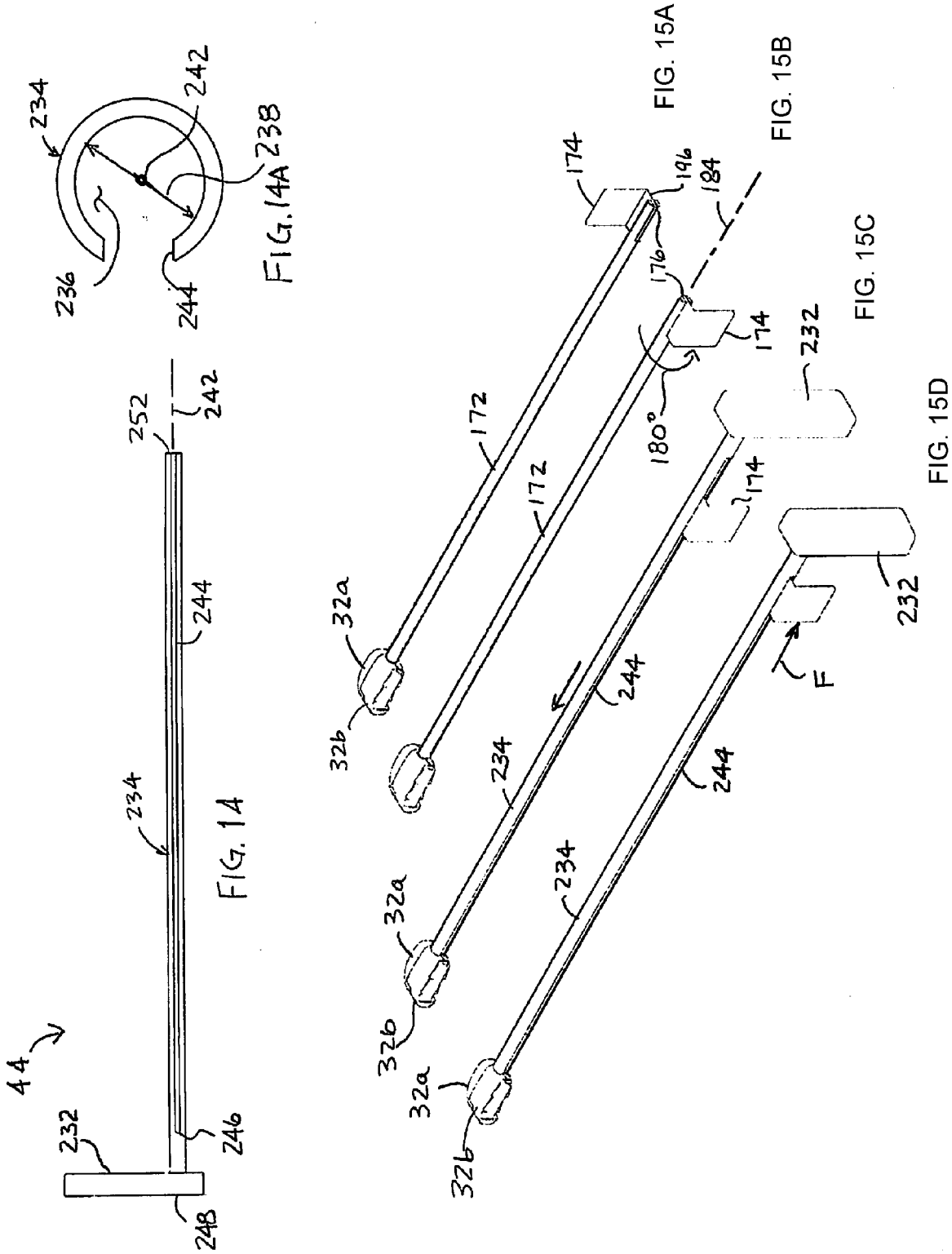
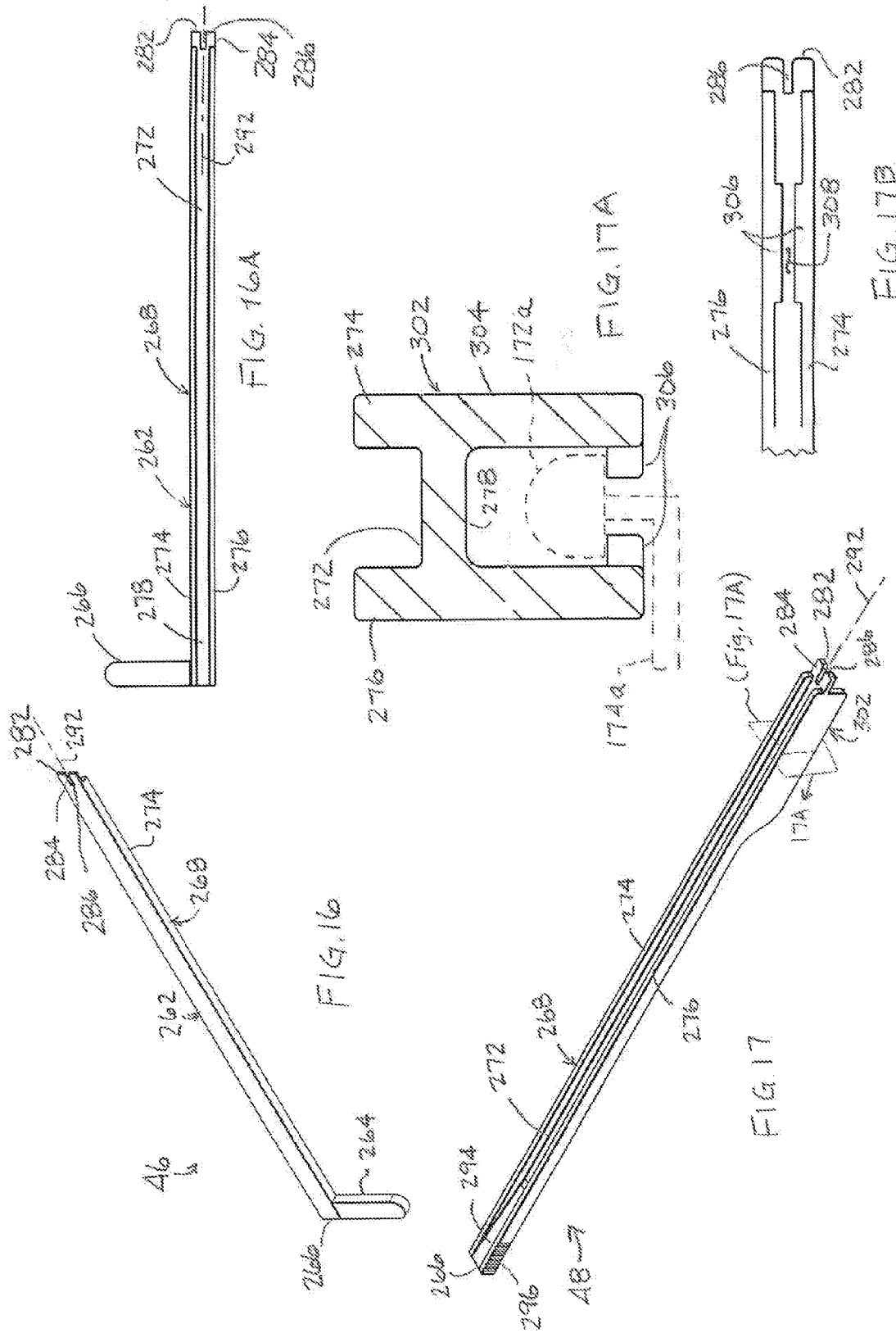


FIG. 12A







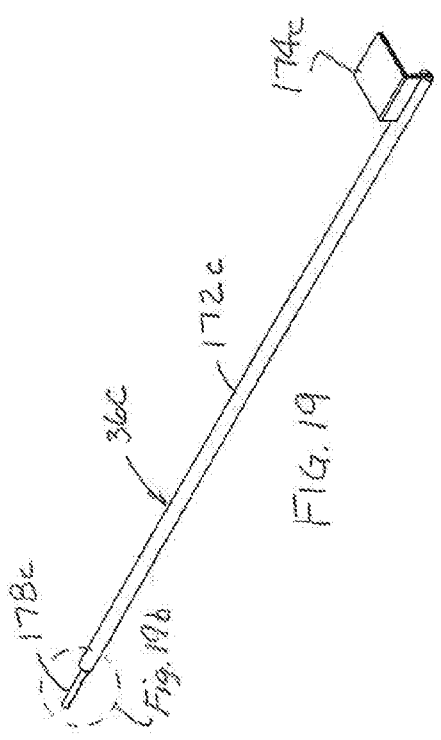


FIG. 19

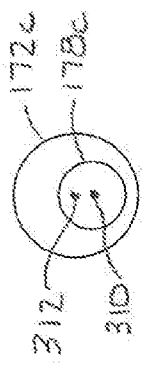


FIG. 19A

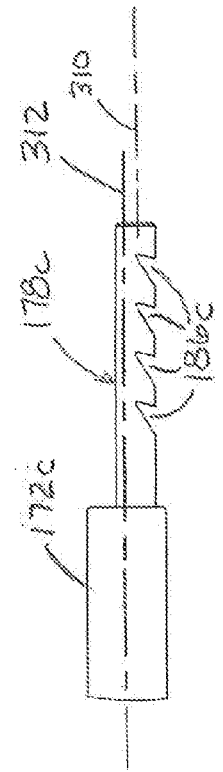


FIG. 19B

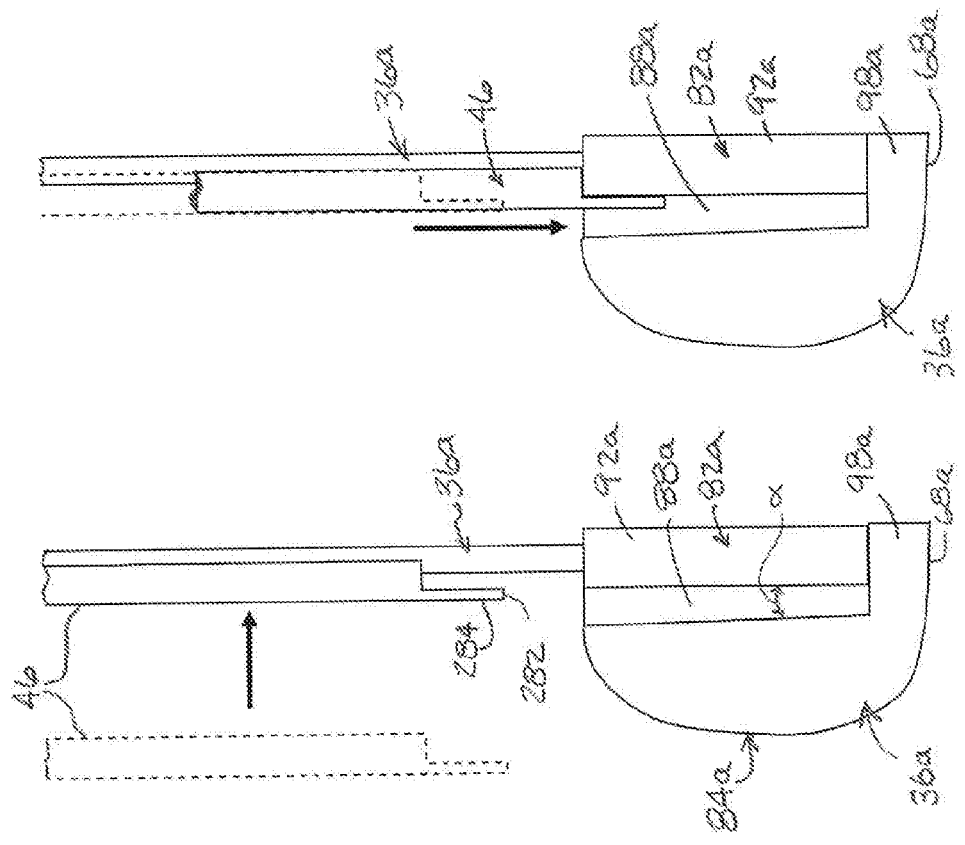


FIG. 18B

FIG. 18A

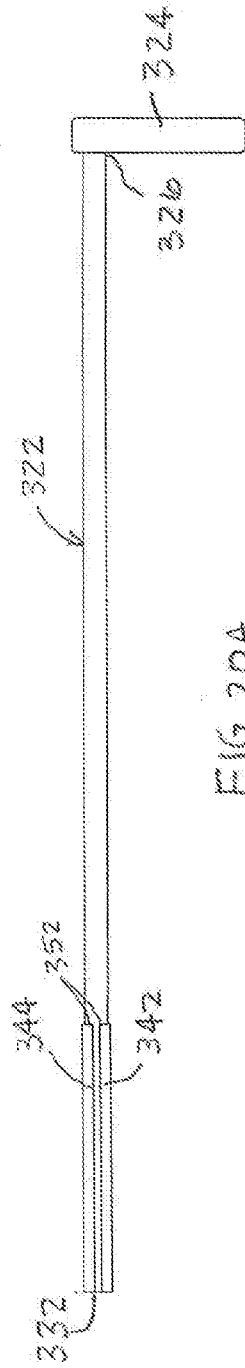
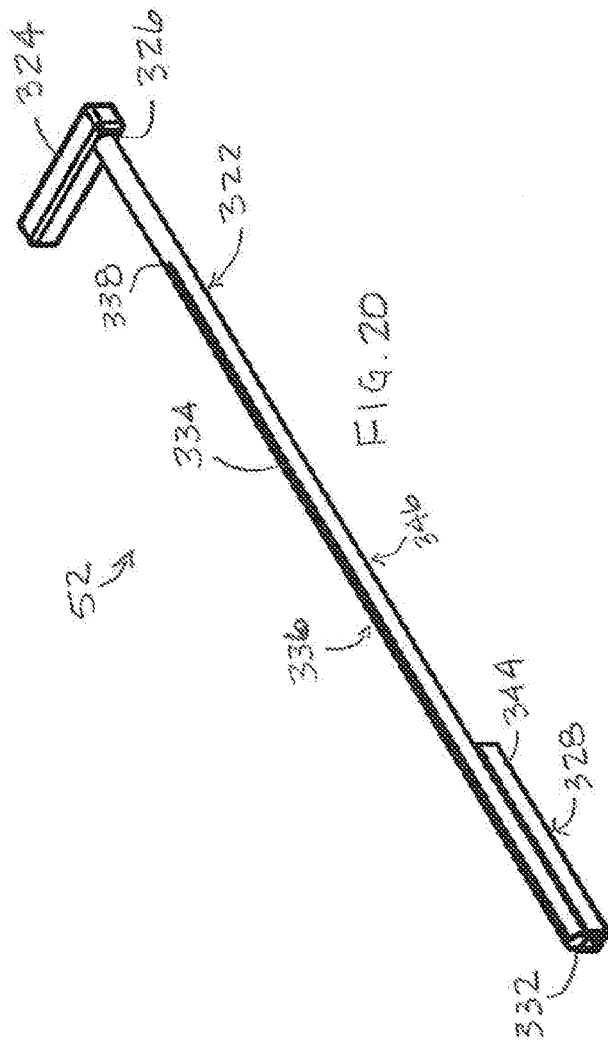
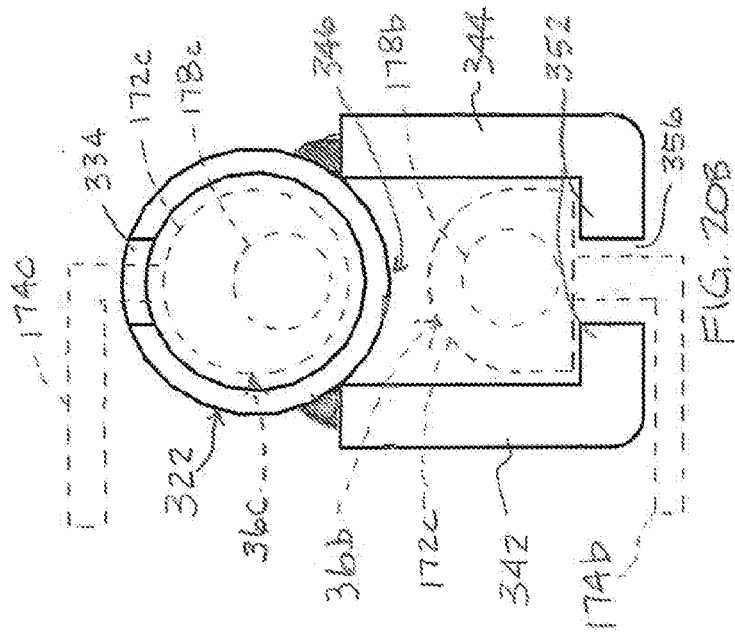


FIG. 20A

FIG. 20B

FIG. 20

MODULAR SEGMENTED DISC NUCLEUS IMPLANT

RELATED APPLICATIONS

[0001] This application is a continuation of application Ser. No. 13/833,998 filed Mar. 15, 2013, which claims the benefit of U.S. Provisional Application No. 61/685,383, filed Mar. 16, 2012, the disclosure of which is incorporated herein in its entirety except for express definitions contained therein.

BACKGROUND

[0002] The use of segmented spinal implants where the segments are implanted sequentially using insertion guides for so-called “minimally invasive” surgical techniques is known. United States Patent Application No. 2008/0133017 to Beyar, et al. (hereinafter “Beyar”) discloses a two-level, motion preserving total disc replacement system using dual-level segments, each segment comprising a top “slice” and a bottom “slice” in order to construct both levels of the motion-preserving device.

[0003] U.S. Pat. No. 7,591,853 to Felt, et al. (hereinafter “Felt”) discloses a segmented disc nucleus implant that includes a hard inner core surrounded by a compliant outer shell. While the compliant outer shell facilitates motion preserving aspects, the inner core can be constructed of harder materials such as polyetheretherketone (PEEK) to facilitate structures for reliably interlocking the segments.

[0004] A system that, like the device of Felt but unlike the device of Beyar, replaces only the disc nucleus for enhanced reduced invasiveness, and that further enhances the motion preserving aspects of the device of Felt would be welcomed.

SUMMARY

[0005] Various embodiments of the invention include a segmented nucleus disc prosthesis made of a single compliant material homogeneously throughout the prosthesis. The compliant material provides a disc nucleus implant that more closely mimics the motion of a natural disc nucleus than the other segmented motion-preserving devices available. The segmented aspect enables implantation of the device with reduced invasiveness, as well as a modular design that enables prostheses of varying dimension to be constructed from modular segment “building blocks.”

[0006] Heretofore, the presence of harder materials was thought necessary to facilitate the interlocking. Thus, the segmented implants of Beyar and Felt have included interlocking structures comprising hard materials such as metals and PEEK. The presence of these hard materials can affect the complexity of the design of motion preserving devices, or limit the motion of the spine relative to a natural disc nucleus. The disclosed invention differs from Beyar and Felt in that the interlocking modular segments do not include hard materials to facilitate the interlocking aspects. Rather, the interlocking modular segments of various embodiments of the invention are made of a single compliant material. Furthermore, Beyar teaches a total disc replacement, rather than a disc nucleus replacement, and is therefore generally more invasive than the present invention.

[0007] Structurally, various aspects of the embodiments of the invention are directed to enable affirmative interlocking of the segments despite the use of the compliant material. In certain embodiments, a plurality of modular segments is

included, each including a superior side, an inferior side, a proximal end, and a distal end opposite the proximal end. The superior and inferior sides are disposed on opposing faces of a transverse plane of the respective modular segment, the transverse plane being orthogonal to a superior/inferior coordinate of the respective modular segment when in an implanted configuration. In some embodiments, the transverse plane corresponds to a central transverse plane. Each of the plurality of modular segments are adapted to interlock with an adjacent one of the plurality of modular segments in a side-by-side arrangement on the transverse plane when in the implanted configuration. The plurality of modular segments can comprise a first end modular segment including a first end body portion and a first end rail portion, the first end rail portion extending from a flanking face of the first end body portion the first end rail portion defining a first end rail axis that passes through the proximal end and the distal end of the first end modular segment. The first end rail axis lies on the transverse plane of the first end modular segment. The first end rail portion includes a plurality of diametrically opposed barbs that extend radially outward relative to the first end rail axis and parallel to the superior/inferior coordinate of the first end modular segment, the first end rail portion having a first end rail cross-section that is normal to the first end rail axis. In one embodiment, the first end rail portion includes a web and a rail head, the web being disposed between the rail head and the flanking face and extending along the transverse plane. The rail head can include planar faces that intersect the web at one of a right angle and an acute angle.

[0008] The prosthesis can further comprise an opposing end modular segment including a body portion that defines an opposing end elongate slot having an interior surface, the opposing end elongate slot passing through the body portion of the opposing end modular segment to define an opposing end slot axis, the opposing end slot axis lying on a transverse plane that is normal to the superior/inferior coordinate of the opposing end modular segment. The body portion of the opposing end modular segment defines an opposing end body cross-section normal to the opposing end slot axis, the body portion of the opposing end modular segment further defining a plurality of recesses that are recessed from the interior surface of the opposing end elongate slot. Each of the plurality of recesses can extend radially outward relative to the opposing end slot axis and parallel to the superior/inferior coordinate of the opposing end modular segment.

[0009] The body portion of the opposing end modular segment can include a superior lip portion and an inferior lip portion, each of the lip portions being adjacent the opposing end elongate slot and extending parallel to the opposing end slot axis and each protruding toward the transverse plane of the opposing end modular segment. Each of the superior lip portion and the inferior lip portion of the opposing end modular segment can define an interior face that complements the planar faces of the rail head. In one embodiment, the first end rail portion defines a first mounting port accessible from the proximal end of the first end modular segment. The first end segment can further comprise a stop portion at the distal end of the first segment.

[0010] In one embodiment, the opposing end body cross-section can be complementary to the first end rail cross-section of the first end rail portion for sliding engagement between the first end modular segment and the opposing end modular segment along the first end rail axis. Each of the

plurality of recesses of the opposing end modular segment can be positioned and dimensioned complementary to a corresponding one of the plurality of barbs of the first end modular segment. The diametrically opposed barbs of the first end rail portion are adapted for capture within the plurality of recesses of the body portion of the opposing end modular segment when in the implanted configuration. The first end modular segment and the opposing end modular segment can be adapted to interlock with each other to define an implanted configuration presenting a generally continuous periphery that generally corresponds to the evacuated nucleus disc space.

[0011] In another embodiment the plurality of modular segments that make up the prosthesis includes an intermediate modular segment having an intermediate body portion and an intermediate rail portion. The intermediate rail portion extends from a flanking face of the intermediate body portion, the intermediate rail portion defining an intermediate rail axis that passes through the proximal end and the distal end of the intermediate modular segment. The intermediate rail portion can include a plurality of diametrically opposed barbs that extend radially outward relative to the intermediate rail axis and parallel to the superior/inferior coordinate of the intermediate modular segment. The intermediate rail portion defines an intermediate cross-section normal to the intermediate rail axis.

[0012] The intermediate body portion defines an intermediate elongate slot having an interior surface, the intermediate elongate slot passing through the intermediate body portion to define an intermediate slot axis. The intermediate rail axis and the intermediate slot axis can be substantially parallel to each other and lying on the transverse plane of the intermediate modular segment, the intermediate body portion defining an intermediate body cross-section normal to the intermediate slot axis. The body portion of the intermediate modular segment can further define a plurality of recesses that are recessed from the interior surface of the intermediate elongate slot and extend radially outward relative to the intermediate slot axis and parallel to the superior/inferior coordinate of the intermediate modular segment. In one embodiment, the intermediate body portion includes a superior lip portion and an inferior lip portion, each being adjacent the intermediate elongate slot and extending parallel to the intermediate slot axis and each protruding toward the transverse plane of the intermediate modular segment.

[0013] In one embodiment of the invention, the intermediate body cross-section is complementary to the first end rail cross-section of the first end rail portion for sliding engagement between the first end modular segment and the intermediate modular segment along the first end rail axis. Each of the plurality of recesses of the intermediate modular segment can be positioned and dimensioned complementary to a corresponding one of the plurality of diametrically opposed barbs of the first end modular segment. The diametrically opposed barbs of the first end rail portion can be configured for capture within the plurality of recesses of the intermediate modular segment when in the implanted configuration. In this embodiment, the opposing end body cross-section is complementary to the intermediate rail cross-section for sliding engagement between the opposing end modular segment and the intermediate modular segment along the intermediate rail axis. Each of the plurality of recesses of the opposing end modular segment can be positioned and dimensioned complementary to a corre-

sponding one of the plurality of diametrically opposed barbs of the intermediate modular segment. The diametrically opposed barbs of the intermediate rail portion can be adapted for capture within the plurality of recesses of the body portion of the opposing end modular segment when in the implanted configuration. The first end modular segment can be adapted to interlock with the intermediate modular segment and the intermediate modular segment being adapted to interlock with the opposing end modular segment to define an implanted configuration presenting a generally continuous periphery that generally corresponds to the evacuated nucleus disc space.

[0014] In various embodiments, each modular segment is of a homogenous material having a compressive modulus between about 2 and about 100 MPa.

[0015] In various embodiments, each of the plurality of modular segments includes structure defining a mounting port disposed on and accessible from the proximal end, the mounting port including an interior surface and a plurality of detents that extend from a first side of the interior surface, wherein a second side opposite the first side defines a cylindrical surface.

[0016] In another embodiment of the invention, a system for configuring the modular disc nucleus prosthesis includes a plurality of insertion tools, one for each of the plurality of segments and each including a tip portion having a plurality of notches formed on one side thereof, the tip portion extending along a rotation axis and being dimensioned for insertion into the mounting ports of the modular segments, the notches being configured to mate with the detents within the mounting port. The tip portion can be selectively releasable from the corresponding one of the mounting ports by rotating the insertion tool about the central axis.

[0017] Various embodiments of the invention are suitable for implantation from any direction relative to the superior/inferior coordinate (i.e., a posterior, anterior or lateral approach, or any approach in between).

BRIEF DESCRIPTION OF THE DRAWINGS

[0018] FIG. 1 depicts various components of a disc nucleus replacement system in an embodiment of the invention;

[0019] FIGS. 2A through 2D are perspective views of various modular disc nucleus prostheses embodiments of the invention;

[0020] FIGS. 3A through 3C are perspective views of individual modular segments of the prostheses of FIGS. 2A through 2D in embodiments of the invention;

[0021] FIG. 4 is a sectional view of a first end modular segment ("A-segment") in an embodiment of the invention;

[0022] FIG. 5 is a sectional view of an intermediate modular segment ("B-segment") in an embodiment of the invention;

[0023] FIG. 6 is a sectional view of an elongate slot portion of the modular segments of FIGS. 4 and 5 in an embodiment of the invention;

[0024] FIG. 7 is a sectional view of an opposing end modular segment ("C-segment") in an embodiment of the invention;

[0025] FIG. 8 is a partial sectional view of an alternative rail portion and body portion configuration in an embodiment of the invention;

[0026] FIG. 9 is a side view of an A-segment or a B-segment in an embodiment of the invention;

[0027] FIG. 10 is a sectional view of a B-segment at the transverse plane in an embodiment of the invention;

[0028] FIG. 11 is an exploded view of an A/B insertion tool in an embodiment of the invention;

[0029] FIG. 11A is an enlarged, elevation view of a tip portion of the A/B insertion tool of FIG. 11 in an embodiment of the invention;

[0030] FIG. 11B is a sectional view of the “D-shaped” shaft portion of the A/B insertion tool of FIG. 11 in an embodiment of the invention;

[0031] FIG. 12 is a perspective view of an assembly of an A- or B-segment/insertion tool assembly in an embodiment of the invention;

[0032] FIG. 12A is an elevational view of the assembly of FIG. 12;

[0033] FIGS. 13A through 13H depict the assembly of a modular nuclear disc prosthesis in an embodiment of the invention;

[0034] FIG. 14 is a side view of a removal tool in an embodiment of the invention;

[0035] FIG. 14A is a sectional view of the removal tool of FIG. 14;

[0036] FIGS. 15A through 15D depict operation of the removal tool of FIG. 14 in an embodiment of the invention;

[0037] FIG. 16 is a perspective view of an A-segment stabilizer in an embodiment of the invention;

[0038] FIG. 16A is a side view of the A-segment stabilizer of FIG. 16 in an embodiment of the invention;

[0039] FIG. 17 is a perspective view of a B-segment stabilizer in an embodiment of the invention;

[0040] FIG. 17A is a sectional view of the B-segment stabilizer of FIG. 17 in an embodiment of the invention;

[0041] FIG. 17B is a partial plan view of the B-segment stabilizer of FIG. 17 in an embodiment of the invention;

[0042] FIGS. 18A and 18B are plan views depicting the coupling of the A-segment stabilizer to an A-segment/insertion tool assembly in an embodiment of the invention;

[0043] FIG. 19 is a perspective view of a C-segment insertion tool in an embodiment of the invention;

[0044] FIG. 19A is an end view of the C-segment insertion tool in an embodiment of the invention;

[0045] FIG. 19B is a partial elevational view of the tip portion of the C-segment insertion tool of FIG. 19 in an embodiment of the invention;

[0046] FIG. 20 is a perspective view of a C-segment stabilizer C-segment insertion tool in an embodiment of the invention;

[0047] FIG. 20A is an elevational view of the C-segment stabilizer C-segment insertion tool of FIG. 20 in an embodiment of the invention; and

[0048] FIG. 20b is an end view of the C-segment stabilizer C-segment insertion tool of FIG. 20 in an embodiment of the invention.

DETAILED DESCRIPTION

[0049] Referring to FIG. 1, a disc nucleus replacement system 30 is depicted in an embodiment of the invention. The disc nucleus replacement system 30 includes modular segments 32a, 32b and 32c for assembly of modular disc nucleus prostheses 34a through 34d (FIG. 2) (hereinafter “the prosthesis” or “prostheses”), insertion tools 36a and 36c for installing the modular segments 32 of the prosthesis, and various tools to assist in the installation of the prosthe-

sis, including a loading platform 42, a removal tool 44, an A-segment stabilizer 46, a B-segment stabilizer 48 and a C-segment stabilizer 52.

[0050] Throughout this disclosure, it is noted that certain components have numerical references consisting of a number followed by a letter suffix (e.g., modular segments 32a, 32b and 32c and insertion tools 36a and 36c above). Where this numbering convention is utilized, the number refers to the item generically or collectively, and the letter to the item in particular. Following this convention, when the number is referred to alone, the reference is to the item generically or collectively (e.g., modular segment(s) 32 or insertion rod(s) 36).

[0051] Referring to FIGS. 2A through 2D (referred to collectively as FIG. 2) and FIGS. 3A through 3C (referred to collectively as FIG. 3), various prostheses and the modular segments from which they are constructed are depicted in embodiments of the invention. Each prosthesis 32a through 32d includes a plurality of modular segments 32 (i.e., at least two segments) interlocked with each other. Each modular segment 32 includes a superior side 62, an inferior side 64, a proximal end 66, and a distal end 68 opposite the proximal end 66. The superior and inferior sides 62 and 64 of each modular segment 32 are disposed on opposing faces of a transverse plane 72a, 72b and 72c of the respective modular segment 32, the transverse planes 72a, 72b and 72c being orthogonal to a superior/inferior coordinate 74a, 74b and 74c of the respective modular segment 32a, 32b and 32c when in an implanted configuration. Proximal/distal coordinates 76a, 76b and 76c are also defined as orthogonal to the superior inferior coordinates 74a, 74b and 74c and extending in a direction from the proximal ends 66 to the distal ends 68. Each of the plurality of modular segments 32 are adapted to interlock with an adjacent one of the plurality of modular segments in a side-by-side arrangement relative to the respective transverse planes 72 when in the implanted configuration.

[0052] The superior and inferior sides 62 and 64 are so named to correspond with their orientation along a respective superior/inferior coordinate 74 or superior/inferior direction when the prosthesis 34 is installed in an implanted configuration within the human body. In one embodiment, the modular segments 32 of the prosthesis 34 can be symmetric about the transverse plane 72; that is, for this embodiment, the superior side 62 of each modular segment 32 is a mirror image of the inferior side 64 about the transverse plane 72, thus establishing the transverse plane 72 as a central transverse plane 78.

[0053] The prostheses depicted in FIG. 2 include up to three modular segment types, depicted in FIG. 3: the first end modular segment 32a, alternatively referred to herein as an “A” segment (FIG. 3A); the intermediate modular segment 32b, alternatively referred to herein as a “B” segment (FIG. 3B); and the opposing end modular segment 32c, alternatively referred to herein as a “C” segment (FIG. 3C). In various embodiments of the invention, prostheses 34 can include one or more B-segments 32b, or can have no B-segments 32b (i.e., the A-segment 32a is coupled directly to the C-segment 32c, as depicted in FIG. 2A). While the length, width and thickness dimensions of individual B-segments 32b can vary, the general characteristics are the same, as described below. In some embodiments employing multiple B-segments 32b, the B-segments 32b are identical.

[0054] Referring to FIG. 4 and again to FIG. 3A, the first end modular segment 32a (A-segment) is depicted in an embodiment of the invention. The first end modular segment 32a includes a body portion 84a and a rail portion 82a, the rail portion 82a extending from a flanking face 86a of the body portion 84a. In one embodiment, the rail portion 82a includes a web 88a and a rail head 92a, the flanking face 86a and the rail head 92a being separated by the web 88a. The rail head 92a can define a rail axis 94a that passes through the proximal and distal ends 66a and 68a of the modular segment 32a. The rail portion 82a can also include a plurality of diametrically opposed barb portions 96a that extend radially outward relative to the rail axis 94a and parallel to the superior/inferior coordinate 74a of the first end modular segment 32a. In one embodiment, the first end modular segment 32a includes a stop portion 98a located at the distal end 68a. Cross-sections 102a and 104a of the rail portion 82a and the body portion 84a, respectively, of the first end modular segment 32a are depicted at FIG. 4, the cross-sections 102a, 104a being normal to the rail axis 94a.

[0055] Herein, the rail portion 82a, rail axis 94a, rail portion cross-section 102a, body portion 82a and body portion cross-section 104a of the first end modular segment 32a are alternatively referred to as the first end rail portion 82a, first end rail axis 94a, first end rail cross-section 102a, first end body portion 82a, and first end body portion cross-section 104a, respectively, to clarify association with the first end modular segment 32a.

[0056] Referring to FIGS. 5 and 6 and again to FIG. 3B, the intermediate modular segment 32b (B-segment) is depicted in an embodiment of the invention. The intermediate modular segment 32b includes a body portion 82b and a rail portion 82b, the rail portion 82b extending from a flanking face 86b of the body portion 82b. In one embodiment, the rail portion 82b includes a web 88b and a rail head 92b, the flanking face 86b and the rail head 92b being separated by the web 88b. The rail head 92b can define a rail axis 94b that passes through the proximal and distal ends 66b and 68b of the modular segment 32b. The rail portion 82b can also include a plurality of diametrically opposed barb portions 96b that extend radially outward relative to the rail axis 94b and parallel to the superior/inferior coordinate 74b of the intermediate modular segment 32b. In one embodiment, the intermediate modular segment 32b includes a stop portion 98b located at its distal end. Cross-sections 102b and 104b of the rail portion 82b and the body portion 84b, respectively, of the intermediate modular segment 32b are depicted at FIG. 5, the cross-sections 102b, 104b being normal to the rail axis 94b.

[0057] The body portion 84b of the intermediate modular segment 32b defines an elongate slot 112b that passes through the body portion 84b and includes an interior surface 114b. The elongate slot 112b further defines a slot axis 116b that is substantially parallel to the intermediate rail axis 94b of the intermediate modular segment 32b. In one embodiment, the rail axis 94b and the slot axis 116b lie on the transverse plane 72b of the intermediate modular segment 32b. In the depicted embodiment, the transverse plane 72b corresponds to the central transverse plane 78b. The body portion 84b can also include a plurality of recesses 118b that extend parallel to the superior/inferior coordinate 74b in both the superior and inferior directions relative to the slot axis 116b (FIG. 6).

[0058] Herein, the rail portion 82b, rail axis 94b, rail portion cross-section 102b, body portion 84b, elongate slot 112b, slot axis 116b and body portion cross-section 104b of the intermediate modular segment 32b are alternatively referred to as the intermediate rail portion 82b, intermediate rail axis 94b, intermediate rail portion cross-section 102b, intermediate body portion 84b, intermediate elongate slot 112b, intermediate slot axis 116b and intermediate body portion cross-section 104b, to clarify association with the intermediate modular segment 32b.

[0059] The intermediate body portion 84b can also be characterized as having a superior lip portion 122b and an inferior lip portion 124b, each being named for their location along the superior/inferior coordinate 74b relative to the transverse plane 72b. The lip portions 122b, 124b are adjacent to and partially define the intermediate elongate slot 112b, and protrude toward each other. A gap 126b is defined between the superior lip portion 122b and the inferior lip portion 124b, defining an open side 128b of the elongate slot 112b. In the depicted embodiment, each lip portion 122b, 124b protrudes toward the central transverse plane 78b. The lip portions 122b and 124b can also define an opposing flanking face 130b that faces in a direction opposite the flanking face 86b of the intermediate body portion 84b.

[0060] Referring to FIG. 7 and again to FIG. 6, the opposing end modular segment 32c (C-segment) is depicted in an embodiment of the invention. (It is noted that the cross-section depicted in FIG. 6 applies to both FIGS. 5 and 7). The opposing end modular segment 32c includes a body portion 84c that defines an elongate slot 112c, the elongate slot 112c further defining a slot axis 116c that lies on the transverse plane 72c. The elongate slot 112c includes an interior surface 114c and passes through the body portion 84c of the opposing end modular segment 32c. The body portion 84c includes a body portion cross-section 104c that is normal to the slot axis 116c. The body portion 84c of the opposing end modular segment 32c can also include a superior lip portion 122c and an inferior lip portion 124c having the same characteristics as the superior and inferior lip portions 122b and 124b of the intermediate modular segment 32b. The body portion 84c of the opposing end modular segment 32c can further define a plurality of recesses 118c that are recessed from the interior surface 114c of the elongate slot 112c of the body portion 84c. The recesses 118c can extend radially outward relative to the slot axis 116c and are parallel to the superior/inferior coordinate 74c of the opposing end modular segment 32c.

[0061] Herein, the body portion 84c, elongate slot 112c, slot axis 116c and body portion cross-section 104c of the opposing end modular segment 32c are alternatively referred to as the opposing end body portion 84c, opposing end elongate slot 112c, opposing end slot axis 116c and opposing end body portion cross-section 104c, to clarify association with the opposing end modular segment 32c.

[0062] The rail heads 92 can each include faces 132 that are substantially planar and substantially parallel to the respective superior/inferior coordinate 74, the faces 132 thereby being at a right angle relative to the respective web portion 88. The body portion 84 of the adjacent, mating modular segment 32, being complementary to the rail portion 82, can include the superior and inferior lip portions 122 and 124 that also include interior faces 134 that are substantially planar and substantially parallel to the superior/inferior coordinate 74 (e.g., FIGS. 5 and 7).

[0063] Referring to FIG. 8, an alternative rail cross-section 102d and mating body portion cross section 104d is presented in an embodiment of the invention. For these embodiments, lip portions 122d, 124d also include faces 132d that are each substantially planar, but each being oblique relative to the superior/inferior coordinate 74d so as to define a “dovetail” profile. That is, the planar faces 132d of the rail head 92d that are adjacent the web 88d for the rail portion 82d intersect web 88d at an acute angle θ . The body portion 84d of the adjacent, mating segment, being complementary, also defines an acute angle θ relative the web portion 88d.

[0064] Functionally, the right angle or acute angle configurations between the faces 132 and the web portion 88 enhance the mechanical coupling between adjacent segments in a direction that is normal to both the superior/inferior coordinate 74 and rail axis 94. These configurations rely primarily on compressive contact between the engaged segments and less on friction between the segments, thereby providing for a positive mechanical coupling therebetween. The enhanced coupling is particularly advantageous when the segments comprise a soft or compliant material having a relatively low hardness. A non-limiting example of a soft or compliant material is a polymer such as biocompatible polyurethane. A non-limiting example of a hardness of a soft or compliant material is a material with a durometer hardness ranging from about Shore 18 A to about Shore 55D. A further and non-limiting example of a soft or compliant material is a material with a compressive modulus between about 2 and about 100 MPa. In a preferred embodiment, the compressive modulus is between about 6 and about 20 MPa.

[0065] The cross-sections 102 and 104 of the various rail portions 82 and the various body portions 84 can be configured to be complementary to itself and the other modular segments 32. That is, the various rail portion cross-sections 102 can be shaped and dimensioned to mate with the various body portion cross-sections 104. Likewise, the various recesses 118 can be positioned and dimensioned to accept (i.e., to be complementary with) the barb portions 96 on the various rail portions 82 of the modular segments 32.

[0066] In this way, a given A-segment 32a can be coupled to either a given B-segment 32b or a given C-segment 32c, a given C-segment 32c can be coupled with either a given A-segment 32a or a given B-segment 32b, and a given B-segment 32b can be coupled with another B-segment 32b. The modularity of the system enables the construction of a variety of prosthesis sizes by interlocking the various segments together in a side-by-side manner, the A, B and C-segments 32a, 32b and 32c constituting the building blocks of the modular system.

[0067] In certain embodiments, the flanking faces 86 of the various segments are oblique relative to the rail axes 94 (i.e., are not parallel to the rail axes 94). Instead, the flanking faces 86 slope slightly towards the rail axes 94 at an angle α from the proximal end 66 to the distal end 68, as best seen in FIG. 18A. That is, the flanking faces 86 are spaced further from the rail axes 94 at the proximal ends 66 than at the distal ends 68. Thus, for embodiments that include this aspect, the rail axis 94 of a given modular segment 32 will intersect plane of the respective flanking face 86 at a point distal to the modular segment 32.

[0068] To accommodate the oblique flanking face configuration, the lip portions 122, 124 of the modular segments 32b and 32c can be of varying thickness from the proximal end 66 to the distal end 68 of the respective body portion

84b, 84c. While the interior face 134 of a given lip portion 122, 124 is parallel to the respective slot axis 116, the thickness of the lip portions 122, 124 (i.e., the dimension normal to the slot axis 116) can decrease from the proximal end 66 to the distal end 68, so that the lip portions 122, 124 themselves form a complementary oblique interface with the oblique flanking face 86 of the adjacent modular segment 32a or 32b. Referring to FIG. 9, a side view of a modular segment 32a or 32b is presented in an embodiment of the invention. The barb portions 96 can each define an inclined profile 142. The inclined profile 142 intersects an outer surface of the rail portion 82 at an intersection point 144 on the proximal end of the barb portion 96. From the intersection point 144, the dimension of the barb portion increases toward a distal end 146 of the barb portion 96. In the depicted embodiments, the distal ends 146 of the barb portions 96 are parallel to the superior/inferior coordinate 74 of the respective modular segment 32. Thus, in this embodiment, the barb portions 96 each define a right-triangular profile in a plane that is parallel to both the superior/inferior coordinate 74 and the rail axis 94 of a given segment 32a, 32b.

[0069] In one embodiment, the corresponding recesses 118 of the body portion 84 of the adjacent modular segment 32b or 32c can define a similar, triangular shape that is complementary to the triangular shape of the barb portion 96 (FIG. 6). In other embodiments, the recesses 118 can be, for example, rectangular, so long as a distal boundary 148 of the recesses 118 are complementary to the distal ends 146 of the barb portions 96.

[0070] For assembly of the implant of, for example, FIG. 2b, the B-segment 32b is positioned proximal to the proximal end of the A-segment 32a, so that the slot axis 116b of the body portion 84b of the B-segment 32b is substantially concentric with the rail axis 94a of the rail portion 82a of the A-segment 32a. The body portion 84b of the B-segment 32b is then slid over the rail portion 82a of the A-segment 32a in the distal direction along the rail axis 94a until the barb portions 96a of the rail portion 82a are captured within the recesses 118b of the body portion 84b of the B-segment 32b. The distal end 68b of the body portion 84b of the B-segment 32b can be substantially registered against the stop portion 98a of the A-segment 32a when the barb portions 96a of the A-segment 32a are secured within the recesses 118b of the B-segment 32b.

[0071] As the body portion 84b of the B-segment 32b is slid over the rail portion 82a of the A-segment 32a, the interior surface 114b of the elongate slot 112b of the B-segment 32b rides over the protruding barb portions 96a of the A-segment 32a. This interaction causes the barb portions 96a of the A-segment 32a to be compressed and the wall of the body portion of the B-segment 32b to deflect upwards. However, once the barb portions 96a are registered within the respective recess 118b, there is essentially no deformation of the components.

[0072] After the B-segment 32b is secured to the A-segment 32a, the C-segment 32c is positioned proximal to the proximal end of the B-segment 32b, so that the slot axis 116c of the body portion of the C-segment 32c is substantially concentric with the rail axis 94b of the B-segment 32b. The body portion 82c of the C-segment 32c is then slid over the rail portion 82b of the B-segment 32b in the distal direction along the rail axis 94b until the barb portions 96b of the rail portion 82b are captured within the recesses 118c of the

body portion **84c** of the C-segment **32c**. The distal end **68c** of the body portion **84c** of the C-segment **32c** can be substantially registered against the stop portion **98b** of the B-segment **32b** when the barb portions **96b** of the B-segment **32b** are secured within the recesses **118b** of the C-segment **32c**.

[0073] For a 2-segment implant (FIG. 2A), the C-segment **32c** is interlocked directly to the A-segment **32a** in similar fashion. Likewise, for an implant having four or more segments, additional intermediate B-segments are interlocked in similar fashion. As a non-limiting example, embodiments can have as many as 8 modular segments (one A-segment **32a**, one C-segment **32c**, and six B-segments **32b**).

[0074] Functionally, the various structural aspects of the rail and slot portions **82**, **112** of the modular segments **32** prevent relative motion between the modular segments **32** in all directions, even where a relatively soft or compliant material is utilized for the modular segments **32**. The engagement of a given rail portion **82** with an adjacent body portion **84** prevents relative motion between the engaged segments along the superior/inferior coordinates **74**. Engagement between the barb portions **96** and stop portions **98** of a given modular segment **32**, when engaged with an adjacent segment **32**, prevent relative motion between the engaged segments **32** along the proximal/distal coordinates **76**. Both the lip portions **122** and **124** and the barb portions **96** provide shear resistance to movement parallel to the transverse plane **72**. The superior and inferior lip portions **122** and **124** of a given modular segment **32**, along with the barb portions **96** of an adjacent, engaged modular segment **32**, prevent separation of the modular segments **32**.

[0075] The inclined profile **142** of the barb portions **96** enable the body portion **84** of an adjacent segment **32** to be more easily slid over the barb portions **96** as the adjacent segment **32** is moved in the distal direction relative to the given segment **32**. However, once the barb portions **96** are registered within their corresponding recesses **118**, the distal ends **146** of the barb portions **96** interact with the distal boundaries **148** of the recesses **118** to prevent the adjacent segment from moving along the proximal/distal coordinate **76**.

[0076] For embodiments utilizing oblique flanking faces **86**, there is little or no sliding interference between the flanking faces **86** and the superior and inferior lip portions **122** and **124** of adjacent segments until the adjacent segments are at or near the implanted position. This helps limit the frictional load during assembly.

[0077] Referring to FIG. 10, a cross-section of a B-segment **32b** that cuts through the transverse plane **72b** is presented depicting a mounting port **152b** in an embodiment of the invention. The modular segments **32** can each include such a mounting port **152** for mounting the respective modular segment **32** to an insertion tool. While the discussion below is directed to the mounting port **152b**, the general aspects apply to all mounting ports **152**.

[0078] In one embodiment, the mounting port **152b** defines a substantially cylindrical cavity **154b** that is concentric about the rail axis **94b** of the modular segment **32b** and is accessible from the proximal end **66b** of the modular segment **32b**. The mounting port **152b** can further include internal detents **156** that extend from one side of an internal wall **158b** of the mounting port **152b**. In one embodiment, the detents **156** can each define a triangular or right trian-

gular profile **162**, wherein a proximal face **164** of each detent **156** is inclined relative to the rail axis **94b** and a distal face **166** of the detent **156** is orthogonal to or only slightly acute relative to the rail axis **94b**.

[0079] Referring to FIGS. 11, 11A and 11B, the A/B insertion tool **36a**, used to augment insertion of both the A- and B-modular segments **32a** and **32b** is depicted in an embodiment of the invention. The A/B insertion tool **36a** includes a shaft portion **172a** with a flag **174a** extending from a proximal end **176a** and a tip portion **178a** extending from a distal end **182a**. The tip portion **178a** defines a rotation axis **184a** and further defines notches **186** formed on one side that are shaped and positioned complementary to the detents **156** of the mounting ports **152**. In certain embodiments, the shaft portion **172a** includes a cross-section **188a** that has the same profile as the rail head **92** of the modular segments **32**. Accordingly, when in the proper rotational orientation about the rotation axis **184a**, the shaft portion **172a** effectively provides a proximal extension of the rail head **92**. In the depicted embodiment, the shaft portion **172a** of the A/B insertion tool **36a** defines a “D-shaped” profile **190a** having an arcuate portion **192a** and a flat face portion **194a**. The flag **174a** of the A/B insertion tool **36a** can be “L-shaped” as depicted in FIG. 11, with a short leg **196a** of the flag **174a** extending from the flat face portion **194a** of the D-shaped shaft portion **172a**.

[0080] Referring to FIGS. 12 and 12A, assembly of the A/B insertion tool **36a** and one of the A- and B-segments **32a** and **32b** is depicted in an embodiment of the invention. In one embodiment, the assembly can be augmented by a segment loading platform **200**. In one embodiment, the segment loading platform **200** includes a segment bay **202** that is aligned with a “U-shaped” channel **204** having an arcuate portion **206** concentric about a loading axis **208**. The segment bay **202** is configured with a bottom portion **212** configured to accept and register the rail portion of the modular segment **32a** or **32b**. The U-shaped channel **204** is dimensioned for sliding engagement with the D-shaped profile **190a** of the shaft portion **172a**.

[0081] One of the A- or B-segments **32a** or **32b** is placed in the segment bay **202** so that the rail portion **82** of the segment **32** is properly registered within the bottom portion of the segment bay. The shaft portion **172a** of the A/B insertion tool **36a** is placed within the U-shaped channel **204** of the segment loading platform **200** so that the arcuate portion **192a** of the D-shaped profile **190a** registers against the arcuate portion **206** of the U-shaped channel **204**. The registrations of the modular segment **32a** or **32b** and the shaft portion **172a** of the A/B insertion tool **36a** aligns the rotation axis **184a** of the tip portion **178a** and the rail axis **94a** (and therefore the mounting port **152a** or **152b**) of the corresponding modular segment **32a** or **32b**. The registrations also rotationally orient the tip portion **178a** of the A/B insertion tool **36a** and the mounting port **152a** or **152b** of the modular segment **32a** or **32b** so that the notches of the tip portion **178a** are aligned with the detents **156a** or **156b** of the mounting port **152a** or **152b**. The tip portion **178a** is slid into the mounting port **152a** or **152b** until each of the plurality of detents **156a** or **156b** of the mounting port **152a** or **152b** occupies a corresponding one of the notches **186a** on the tip portion **178a**.

[0082] It is noted that the C-segment **32c** does not include a mounting rail, and therefore cannot include a mounting port that is concentric with a rail portion. Accordingly, the

C-segment includes a mounting port **152c** formed in the body portion **84c**, the mounting port **152c** defining an axis **214** that is parallel with and on the same transverse plane **72c** as the slot axis **116c** and having the same aspects as the mounting ports **152a** and **152b** of the A- and B-segments **32a** and **32b**.

[0083] Referring to FIGS. 13A through 13H, an assembly sequence is depicted for the three-segment prosthesis **34b** of FIG. 2B. An A-segment/insertion tool assembly **220a** comprising the A-segment **32a** and the A/B insertion tool **36a** is first placed in an evacuated disc nucleus space (FIG. 13A; evacuated disc nucleus space not depicted). A B-segment/insertion tool assembly **220b** comprising the B-segment **32b** and another A/B insertion tool **36b** is then slid over a proximal end **222a** of the A-segment/insertion tool assembly **220a** and translated along the shaft **172a** of the A/B insertion tool **36a** of the A-segment/insertion tool assembly **220a** (FIG. 13B). During this step, the open side **128b** of the elongate slot **112b** of the B-segment **32b** is aligned to pass over the short leg **196a** of the L-shaped flag **174a** of the A-segment insertion tool **36a** of the A-segment/insertion tool assembly **220a**, which also places the elongate slot **112b** of the B-segment **32b** in proper orientation for translation along the D-shaped shaft **172a** of the A/B insertion tool **36b** of the B-segment/insertion tool assembly **220b**.

[0084] The B-segment **32b** is then slid over the rail portion **82a** of the A-segment **32a** until the B-segment **32b** registers against the stop portion **98a** of the A-segment **32a** (FIG. 13C). The open side **128b** of the elongate slot **112b** slides over the web **88b** of the rail portion **82b**, the open side **128b** having been properly aligned when slid over the short leg **196a** of the L-shaped flag **174a**. The user can determine that the B-segment **32b** is in place when the flags **174a** and **174b** of the A/B insertion tools **36a** and **36b** of the A- and B-segment insertion tool assemblies **220a** and **220b** are aligned. Upon registration of the B-segment **32b** against the stop portion **98a** of the A-segment **32a**, the barb portions **96a** on the rail portion **82a** of the A-segment **32a** should be registered within the recesses **118b** of the B-segment **32b**. However, the user can tug the B-segment/insertion tool assembly **220b** in the proximal direction relative to the A-segment/insertion tool assembly **220a** to assure that the barb portions **96a** are set within the recesses **118b**.

[0085] The A/B insertion tool **36a** of the A-segment/insertion tool assembly **220a** is then removed. Removal is accomplished by rotation the A/B insertion tool **36a** of the A-segment/insertion tool assembly **220a** 180° about the rotation axis **184a** (FIG. 13D). This action causes the notches **186a** of the tip portion **178a** of the A/B insertion tool **36a** of the A-segment/insertion tool assembly **220a** to rotate away from the detents **156a** in the mounting port of the A-segment **32a**, thus enabling the A/B insertion tool **36a** of the A-segment/insertion tool assembly **220a** to be removed from the mounting port **156a** with reduced interference from the detents **156a**. The A/B insertion tool **36a** of the A-segment/insertion tool assembly **220a** is then removed from the mounting port **152a**, leaving only the A- and B-segments **32a** and **32b** coupled to the B-segment/insertion tool assembly **220b** (FIG. 13E).

[0086] A C-segment/insertion tool assembly **220c** comprising the C-segment **32c** and the C insertion tool **36c** is then aligned so that the slot portion **112c** of the C-segment **32c** is slid over a proximal end **222b** of the B-segment/insertion tool assembly **220b**, and the C-segment/insertion

tool assembly **220b** being translated along the shaft **172b** of the insertion tool **36b** of the B-segment/insertion tool assembly **220b** (FIG. 13F). The C insertion tool **36c** is described in more detail below in the discussion attendant to FIG. 19. The C-segment **32c** is then slid over the rail portion **82b** of the B-segment **32b** until the C-segment **32c** registers against the stop portion **98b** of the B-segment **32b** (FIG. 13G). The insertion tool **36b** of the B-segment/insertion tool assembly **220b** is then removed (FIG. 13H). The steps depicted at FIGS. 13F through 13H are conducted in the same manner as the steps depicted at FIGS. 13B through 13E.

[0087] The insertion tool of the C-segment/insertion tool **36c** is removed by rotating the insertion tool **36c** 180° (FIG. 13H) and removing it from the mounting port **152c**, thereby leaving the prosthesis fully assembled in place (FIG. 2B).

[0088] In certain embodiments, supplemental tools can be included and utilized in for enhanced manipulation of the modular segments. The supplemental tools are of particular utility when handling modular segments that are of a homogeneous, compliant material. The supplemental tools can include the removal tool **44**, the A-segment stabilizer **46**, the B-segment stabilizer **48** and the C-segment stabilizer **52** (FIG. 1).

[0089] Referring to FIGS. 14 and 14A, the removal tool **44** is depicted in an embodiment of the invention. The removal tool **44** includes a handle portion **232** and a shaft portion **234**. The shaft portion **234** defines a bore **236** having an inner diameter **238** concentric about a central axis **242**. The inner diameter **238** of the bore **236** is dimensioned large enough to slide over the D-shaped profile **190a** or **190b** of the A- and B-segment insertion tool **36a** or **36b**, as well as the round profile of the C-segment insertion tool **36c**. The removal tool **44** includes a slot **244** on one side thereof, the slot **244** extending on one side of the removal tool and from a location **246** proximate a proximal end **248** of the removal tool **44** through a distal end **252** of the removal tool **44**.

[0090] Referring to FIGS. 15A through 15D, operation of the removal tool **44** is depicted in an embodiment of the invention. Typically after the insertion tool has been rotated 180° to disengage the detents **156** and notches **186** (FIGS. 15A and 15B), the central axis **242** of the removal tool **44** is aligned with the rotation axis **184** of the insertion tool **36** and slid over the proximal end **176** of the insertion tool **36**, the slot **244** being aligned to pass over the short leg **196** of the L-shaped flag **174**. The shaft portion **234** of the removal tool **44** is slid over the shaft portion **172** of the insertion tool **36** until the distal end **252** of the removal tool **44** is brought into contact with the modular segment **32** (FIG. 15C). The insertion tool **44** is then pulled out of the mounting port **152** by application of a clamping force **F** between the flag portion **174** of the insertion tool **36** and the handle portion **232** of the removal tool **44** (FIG. 15D). The operator typically applies the clamping force **F** by squeezing the flag portion **174** and the handle portion **232** between the index finger and the thumb or palm of the hand.

[0091] Functionally, while the act of rotating a given insertion tool **36** 180° makes removal of the insertion tool **36** from the mounting port **152** easier, the friction between the tip portion **178** of the insertion tool **36** and the modular segment **32** can still be substantial, in part because the detents **156** are compressed against the cylindrical surface of the tip portion **178** after the 180° rotation. The removal tool

44 provides a controlled, mechanically leveraged way to remove insertion tools 36 in situ while maintaining a low profile.

[0092] Referring to FIGS. 16, 16A, 17, 17A and 17B, the A- and B-segment stabilizers 46 and 48 are depicted in embodiments of the invention. The A- and B-segment stabilizers 46 and 48 include many common aspects, which are indicated in the figures with like-numbered numerical references. The A-stabilizer 46 includes a shaft portion 262 having a handle 264 attached at a proximal end 266. The shaft portion 262 includes what is effectively a channel structure 268 defining a channel 272 on one side thereof, the channel structure 268 including opposed flanges 274 and 276 separated by a flat portion 278. The channel 272 thus defined is dimensioned to enable insertion tools 36 to slidably translate therein, with the flat portion 278 of the D-shaped shaft 172 engaged with the flat portion 278 of the A-segment stabilizer 46. At a distal end 282, the flat portion 278 includes an extension portion 284 that extends beyond the opposed flanges 274, 276, the extension portion 284 including a slot 286 formed thereon. The slot 286 is formed along an elongate axis 292 and is accessible from the distal end 282.

[0093] The B-segment stabilizer 48 also includes the channel structure 268 extending from the proximal end 266 to near the distal end 282. At the proximal end 266, the B-segment stabilizer includes a ramp portion 294 formed within the channel 272. In the absence of a handle, the B-segment stabilizer includes a grip portion 296 formed on the proximal end 266. Near the distal end 282, the B-segment stabilizer 48 includes an additional guide structure 302 that effectively defines an asymmetric H-beam profile 304. The channel structure 272 and guide 302 structure define the channel 272 continuously along the length of the B-segment stabilizer 48. The guide structure 302 includes opposed flanges 274 and 276 that extend normal to the flat portion 278 in both directions. The guide structure 302 also includes opposed lip portions 306 that extend toward each other to define a gap 308 therebetween.

[0094] Referring to FIGS. 18A and 18B, operation of the A-segment stabilizer 46 is depicted in an embodiment of the invention. Prior to insertion of the A-segment 32a into the evacuated disc nucleus space, the A-segment/insertion tool assembly 220a is loaded into the channel 272 of the A-segment stabilizer 46 (FIG. 18A). After or simultaneously with the loading, the A-segment stabilizer 46 is translated toward the A-segment 32a until the web 88a of the rail portion 82a registers within the slot 286 (FIG. 18B).

[0095] For the B-segment stabilizer 48, the guide structure 302 is slid over the distal end 176a of the A insertion tool 36a to capture the D-shaped shaft portion 172a of the A insertion tool 36a (shown in phantom in FIG. 17A) between the flange portions 274, 276 and lip portions 306 of the guide structure 302 of the B-segment stabilizer 48. The channel 272 of the B-segment stabilizer 48 is translated over the B-segment/insertion tool assembly 220b until the web 88b of the rail portion 82b is registered in the slot 286. In the depicted embodiment, the B-segment stabilizer 48 does not include a handle akin to the A-segment stabilizer 46 because such a handle would create clutter and interference amongst the flags 178a and 178b of the A- and B-insertion tools 36a and 36b. In this way, additional guidance and control for coupling the B-segment 32b to the A-segment 32a is provided in situ.

[0096] The ramp portion 294 guides the flags 174a and 174b at the proximal ends of the insertion tools 36a and 36b away from each other during assembly of the prosthesis 34. This prevents the flag 174b of the A/B insertion tool 36B from catching on the flag 174a of the adjacent A/B insertion tool 36a.

[0097] Removal of the A- and B-segment stabilizers 46 and 48 is accomplished by disengaging them from the web 88a, 88b of the respective rail portion 82a, 82b in the proximal direction.

[0098] Referring to FIGS. 19, 19A and 19B (referred to collectively as FIG. 19), the C insertion tool 36c is depicted in an embodiment of the invention. The C insertion tool 36c includes a shaft portion 172c having a tip portion 178c at a distal end 182c and a flag portion 174c at a proximal end 176c. In one embodiment, the flag portion 174c extends in an opposite direction from the flag portions 174a, 174b of the A/B insertion tools 36a, 36b. The tip portion 178c defines a tip portion axis 310. The notch aspects 186c of the tip portion 178c for the C insertion tool 36c can be the same as for the A/B insertion tool 36a. The shaft portion 172c of the C insertion tool 36c is essentially cylindrical about a cylindrical axis 312. In the depicted embodiment, the cylindrical axis 312 of the shaft portion 172c and the tip portion axis 310 of the tip portion 178c are eccentric (FIGS. 19A and 19B).

[0099] Referring to FIGS. 20, 20A and 20B, the C-segment stabilizer 52 is depicted in an embodiment of the invention. The C-segment stabilizer 52 includes a hollow shaft portion 322 having a handle 324 on a proximal end 326 and an guide structure 328 near a distal end 332. The hollow shaft portion 322 includes structure defining a slot 334 extending on a first side 336 of thereof and from a location 338 proximate the proximal end 326 and through the distal end 332 of the C-segment stabilizer 52. The guide structure 328 comprises two opposing flanges 342 and 344 that extend from a second side 346 of the hollow shaft portion 322, the second side 346 being opposite the first side 336. The opposing flanges 342, 344 each include lip portions 352 that extend toward each other to define a gap 356 therebetween. The A/B insertion tool 36b and the C insertion tool 36c are depicted in phantom in FIG. 20B.

[0100] In operation, the hollow shaft portion 322 of the C-segment stabilizer 52 is aligned with the cylindrical axis 312 of the C insertion tool 36c and with the slot 334 aligned to pass over the flag portion 174c. The C-segment stabilizer 52 is then translated over the C insertion tool 36c until the distal end 332 engages the C-segment 32c.

[0101] Functionally, the guide structure 328 captures the D-shaped shaft 172c of the adjacent A/B insertion tool 36b between the flanges 324 and 344 of the guide structure 328, to further assist the user in guiding the B-segment 32b into the evacuated disc nucleus space. The slot 334 of the C-segment stabilizer enables passage of the hollow shaft portion 322 over the shaft flag portion 174c of the C insertion tool 36c. Likewise, the gap 356 enables passage of the guide structure 328 over the flag portion 174b of the A/B insertion tool 36b. The inner diameter of the hollow shaft 322 is dimensioned so that the A/B insertion tool 36b cannot be inserted in the C-segment stabilizer. Thus, the round hollow shaft 322 of the C-segment stabilizer 52 serves as a key to prevent insertion of the AB insertion tool 36a therein. The eccentricity of the tip portion 178c relative to the shaft portion 172c allows room for the structure of the hollow

shaft portion **322** between the insertion tools **36b** and **36c**. The distal end **332** of the C-segment stabilizer **52** provides a bearing surface that spreads the force of the insertion operation over a larger area, thus preventing deformation of the C-segment **32c** during insertion of the C-segment **32c**.

[0102] A purpose of the A-, B-, and C-segment stabilizers **46**, **48** and **52** generally is to enable manipulation the respective A-, B- and C-segments **32a**, **32b** and **32c** during implantation, as well as maneuvering the prosthesis **34** within the evacuated disc nucleus space while the prosthesis **34** is at various stages of assembly. The stabilizers **46**, **48**, **52** reduce the risk of the tip portion **178** of the various insertion tools **36** becoming dislodged from the respective mounting port **152** during positioning of the partially or fully assembled prosthesis **34**.

[0103] In certain embodiments, various of the components discussed above are included as a kit. The kit can include some or all of the components presented in FIG. 1. The kit can also include operating instructions on a tangible medium such as a paper document, a compact disc (CD), a digital video disc (DVD), or a central computer accessed, for example, over the internet. The operating instructions can include various of the instructions and sequences described above.

1. A modular disc nucleus prosthesis adapted for implantation in an evacuated disc nucleus space, the prosthesis comprising:

a plurality of modular segments, each including a superior side, an inferior side, a proximal end, and a distal end opposite the proximal end, the superior and inferior sides being disposed on opposing faces of a transverse plane of the respective modular segment, said transverse plane being orthogonal to a superior/inferior coordinate of the respective modular segment when in an implanted configuration, each of said plurality of modular segments being adapted to interlock with an adjacent one of said plurality of modular segments in a side-by-side arrangement on said transverse plane when in said implanted configuration,

said plurality of modular segments including:

a first end modular segment including a first end body portion and a first end rail portion, said first end rail portion extending from a flanking face of said first end body portion said first end rail portion defining a first end rail axis that passes through the proximal end and the distal end of said first end modular segment, said first end rail axis lying on said transverse plane of said first end modular segment, said first end rail portion including a plurality of diametrically opposed barbs that extend radially outward relative to said first end rail axis and parallel to the superior/inferior coordinate of said first end modular segment, said first end rail portion having a first end rail cross-section that is normal to said first end rail axis,

wherein said first end rail portion includes a web and a rail head, said web being disposed between said rail head and said flanking face and extending along said transverse plane, wherein said rail head includes planar faces that intersect said web at one of a right angle and an acute angle;

an opposing end modular segment including a body portion that defines an opposing end elongate slot having an interior surface, said opposing end elongate slot passing through said body portion of said opposing

end modular segment to define an opposing end slot axis, said opposing end slot axis lying on a transverse plane that is normal to the superior/inferior coordinate of said opposing end modular segment, said body portion of said opposing end modular segment defining a opposing end body cross-section normal to said opposing end slot axis, said body portion of said opposing end modular segment further defining a plurality of recesses that are recessed from said interior surface of said opposing end elongate slot, each of said plurality of recesses extending radially outward relative to said opposing end slot axis and parallel to the superior/inferior coordinate of said opposing end modular segment,

wherein said body portion of said opposing end modular segment includes a superior lip portion and an inferior lip portion, each of the lip portions being adjacent said opposing end elongate slot and extending parallel to said opposing end slot axis and each protruding toward said transverse plane of said opposing end modular segment, each of said superior lip portion and said inferior lip portion of said opposing end modular segment defining an interior face that complements said planar faces of said rail head.

2. The prosthesis of claim 1, wherein:

said opposing end body cross-section is complementary to said first end rail cross-section of said first end rail portion for sliding engagement between said first end modular segment and said opposing end modular segment along said first end rail axis;

each of said plurality of recesses of said opposing end modular segment is positioned and dimensioned complementary to a corresponding one of said plurality of barbs of said first end modular segment;

said diametrically opposed barbs of said first end rail portion are adapted for capture within said plurality of recesses of said body portion of said opposing end modular segment when in the implanted configuration; and

said first end modular segment and said opposing end modular segment are adapted to interlock with each other to define an implanted configuration presenting a substantially continuous periphery that generally corresponds to said evacuated nucleus disc space.

3. The prosthesis of claim 1, said plurality of modular segments including:

an intermediate modular segment including an intermediate body portion and an intermediate rail portion, said intermediate rail portion extending from a flanking face of said intermediate body portion, said intermediate rail portion defining an intermediate rail axis that passes through the proximal end and the distal end of said intermediate modular segment, said intermediate rail portion including a plurality of diametrically opposed barbs that extend radially outward relative to said intermediate rail axis and parallel to the superior/inferior coordinate of said intermediate modular segment, said intermediate rail portion having an intermediate cross-section normal to said intermediate rail axis,

wherein said intermediate body portion defines an intermediate elongate slot having an interior surface, said intermediate elongate slot passing through said intermediate body portion to define an intermediate slot axis, said intermediate rail axis and said intermediate

slot axis being substantially parallel to each other and lying on the transverse plane of said intermediate modular segment, said intermediate body portion defining an intermediate body cross-section normal to said intermediate slot axis, said body portion of said intermediate modular segment further defining a plurality of recesses that are recessed from said interior surface of said intermediate elongate slot and extend radially outward relative to said intermediate slot axis and parallel to the superior/inferior coordinate of said intermediate modular segment,

said intermediate body portion including a superior lip portion and an inferior lip portion, each being adjacent said intermediate elongate slot and extending parallel to said intermediate slot axis and each protruding toward said transverse plane of said intermediate modular segment.

4. The prosthesis of claim 3, wherein:

said intermediate body cross-section is complementary to said first end rail cross-section of said first end rail portion for sliding engagement between said first end modular segment and said intermediate modular segment along said first end rail axis, each of said plurality of recesses of said intermediate modular segment being positioned and dimensioned complementary to a corresponding one of said plurality of diametrically opposed barbs of said first end modular segment, said diametrically opposed barbs of said first end rail portion being configured for capture within said plurality of recesses of said intermediate modular segment when in the implanted configuration; and

said opposing end body cross-section is complementary to said intermediate rail cross-section for sliding engagement between said opposing end modular segment and said intermediate modular segment along said intermediate rail axis, each of said plurality of recesses of said opposing end modular segment being positioned and dimensioned complementary to a corresponding one of said plurality of diametrically opposed barbs of said intermediate modular segment, said diametrically opposed barbs of said intermediate rail portion being

adapted for capture within said plurality of recesses of said body portion of said opposing end modular segment when in the implanted configuration; and said first end modular segment being adapted to interlock with said intermediate modular segment and said intermediate modular segment being adapted to interlock with said opposing end modular segment to define an implanted configuration presenting a generally continuous periphery that generally corresponds to said evacuated nucleus disc space.

5. The prosthesis of claim 1, wherein each modular segment is of a homogenous material having a compressive modulus between about 2 and about 100 MPa.

6. The prosthesis of claim 1, wherein said first end segment further comprises a stop portion at the distal end of said first end segment.

7. The prosthesis of claim 1, wherein said first end rail portion defines a first mounting port accessible from the proximal end of said first end modular segment.

8. The prosthesis of claim 1, wherein the transverse plane corresponds to a central transverse plane.

9. The prosthesis of claim 3, wherein each of said plurality of modular segments includes structure defining a mounting port disposed on and accessible from said proximal end, said mounting port including an interior surface and a plurality of detents that extend from a first side of said interior surface, wherein a second side opposite said first side defines a cylindrical surface.

10. A system for configuring the modular disc nucleus prosthesis of claim 9, the system comprising:

a plurality of insertion tools, one for each of said plurality of segments and each including a tip portion having a plurality of notches formed on one side thereof, said tip portion extending along a rotation axis and being dimensioned for insertion into said mounting ports of said modular segments, said notches being configured to mate with said detents within said mounting port, wherein said tip portion is selectively releasable from the corresponding one of said mounting ports by rotating said insertion tool about said central axis.

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