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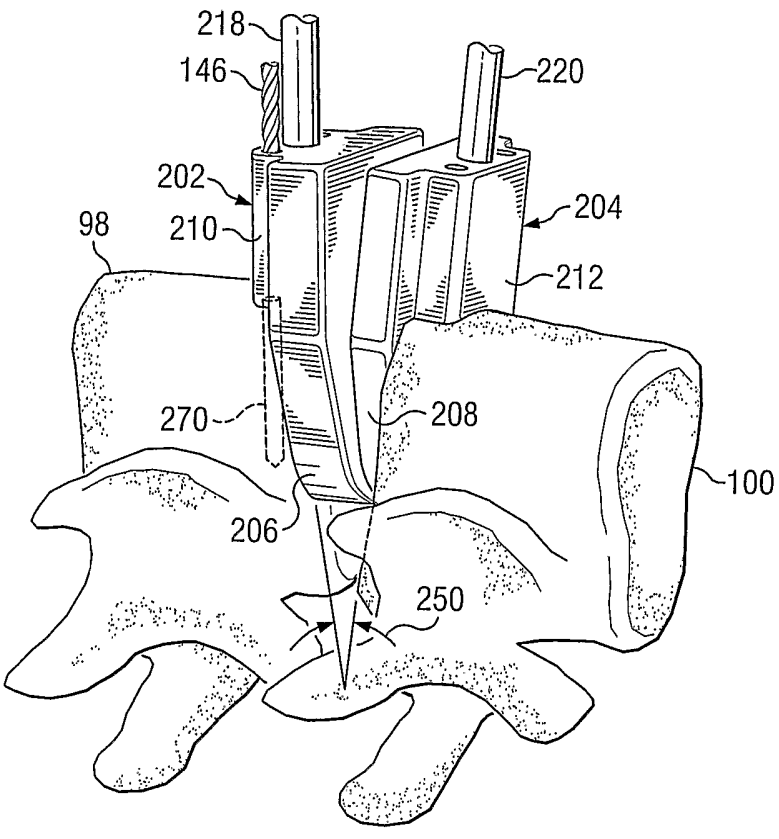
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[Continued on next page]

(54) Title: ADJUSTABLE DRILL GUIDE



(57) Abstract: An intervertebral disc space preparation guide (200) comprises a first member (202) and a second member (204) . The first member includes a first spacer portion (206) adapted for insertion in an intervertebral disc space and a first cutting block portion (210) through which a first bore extends. The second member includes a second spacer portion (208) adapted for insertion in an intervertebral disc space and a second cutting block portion (212) through which a second bore extends. The first member is movably connected to the second member.

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ADJUSTABLE DRILL GUIDE

BACKGROUND

The present invention relates to artificial spinal discs, and instruments and methods associated with the implantation of such artificial spinal discs.

Current spinal therapies for treating problematic spinal discs are moving from rigid fixation of adjacent vertebrae across the problematic disc space, such as with rods or plates, to maintaining the relative motion of the adjacent vertebrae, such as with artificial spinal discs. For instance, an artificial spinal disc may be utilized to treat degenerative disc disease, including a herniated nucleus pulposus and/or posterior osteophytes, which causes radiculopathy and/or myelopathy. Radiculopathy is compression of a spinal nerve root, while myelopathy is compression of the spinal cord. Both are conditions that may result in an individual experiencing pain or tingling in the arms, legs, back and/or neck.

Current artificial spinal discs have drawbacks relating to their fixation to the adjacent vertebrae and their ability to be revised, or removed, after their implantation. For instance, current artificial discs may have special contours that need to be machined into the endplates of the adjacent vertebrae. Further, current artificial discs may require special machining of the vertebrae and/or implantation instrumentation to accommodate spikes, fins, or other structures extending into the adjacent vertebrae that are used to fixate the disc to the vertebrae. Additionally, current artificial discs may include bone in-growth surfaces across the entire vertebrae-contacting surface. This makes it difficult to remove the artificial disc, as is sometimes required, once the artificial disc is implanted.

Similarly, the associated implantation instruments and methods have a number of drawbacks relating to their complexity or to their suitability for use in more sensitive areas of the spine, such as in the cervical spine. For instance, some implantation systems require the use of many different instruments and devices to prepare the disc space and properly insert the artificial disc. Further, some implantation systems rely on impacting, or hammering, features into the bone to accommodate the artificial disc. Such impaction techniques may be suitable in certain areas of the spine, like in the lumbar spine, but are

not as desirable in other areas of the spine, like the cervical spine, where the proximity of the spinal cord and nerve roots would favor more delicate procedures.

SUMMARY

In one embodiment, an intervertebral disc space preparation guide comprises a first member and a second member. The first member includes a first spacer portion adapted for insertion in an intervertebral disc space and a first cutting block portion through which a first bore extends. The second member includes a second spacer portion adapted for insertion in an intervertebral disc space and a second cutting block portion through which a second bore extends. The first member is movably connected to the second member.

In another embodiment, a method of preparing an intervertebral disc space to receive an implant, the method comprises the step of creating a non-parallel angle between first and second vertebral endplates and inserting at least a portion of a cutting guide between the first and second vertebral endplates. The cutting guide includes a first member movably connected to a second member. The method further comprises the step of moving the first member with respect to the second member to place the first member in contact with the first vertebral endplate and to place the second member in contact with the second vertebral endplate and the step of inserting a cutting device through a portion of the first member to cut a first formation parallel to the first vertebral endplate.

BRIEF DESCRIPTION OF THE DRAWINGS

The various embodiments of the present invention will hereinafter be described in conjunction with the appended drawings provided to illustrate and not to limit the present invention, wherein like designations denote like elements, and in which:

Fig. 1 is a perspective view of an artificial spinal disc system;

Fig. 2 is a front view of the artificial spinal disc system of Fig. 1;

Fig. 3 is a bottom view of a second or inferior member of the artificial disc system of Fig. 1;

Fig. 4 is a perspective view of an inner surface of a first or superior member of the artificial disc system of Fig. 1;

Fig. 5 is a perspective view of an inner surface of a second or inferior member of the artificial disc system of Fig. 1;

Fig. 6 is a bottom or inferior view of an inner surface of a first or superior member of the artificial disc system of Fig. 1;

Fig. 7 is a bottom or inferior view of an inner surface of a second or inferior member of the artificial disc system of Fig. 1;

Fig. 8 is a rear view of another artificial spinal disc system;

Fig. 9 is a cross-sectional view along line 9-9 of the artificial disc system of Fig. 8;

Fig. 10 is a flowchart of a method of implanting an artificial spinal disc system;

Fig. 11 is a representation of a patient positioned for spinal surgery, including a method of forming an access channel to access the natural spinal disc and the adjacent vertebral bodies;

Fig. 12 is a representation of a method of removing the natural spinal disc of Fig. 11;

Figs. 13-14 are representations of a method of forming a predetermined contour in one or both end plates of adjacent vertebral bodies of Fig. 11;

Fig. 15 is a representation of a prepared disc space following the procedure of Figs. 13-14;

Fig. 16 is a representation of determining a size of the prepared disc space of Fig. 15;

Figs. 17-18 are representations of a rail cutter guide and method for forming one or more fin or rail guide channels in one or both end plates adjacent to the prepared disc space of Fig. 15;

Figs. 19-20 are representations of a bone removal mechanism being utilized in conjunction with the rail cutter guide of Figs. 17-18;

Fig. 21 is a representation of a temporary fixation of the rail cutter guide with respect to one or more adjacent vertebrae using temporary fixation members;

Fig. 22 is a representation of the prepared disc space of Fig. 15 with the addition of fin or rail guide channels formed via the methods of Figs. 17-21;

Fig. 23 is a perspective view of an artificial spinal disc system and an implant inserter for holding and inserting the disc system into the disc space of Fig. 22;

Fig. 24 is a perspective view of a representation of a method of inserting an artificial spinal disc system into the disc space of Fig. 22;

Fig. 25 is a perspective view of a representation of a method of removing the implant inserter from the implanted artificial spinal disc system of Fig. 24;

Fig. 26 is a front or anterior view of a portion of a spine that includes an artificial spinal disc implanted in the disc space of Fig. 22;

Fig. 27 is a perspective view of another cutter guide according to an embodiment of the present disclosure;

Fig. 28 is a cross sectional view of a portion of the cutter guide depicted in Fig. 27;

Fig. 29 is an environmental view of the cutter guide of Fig. 27;

Fig. 30 is a perspective view of another cutter guide according to an embodiment of the present disclosure; and

Fig. 31 is a perspective view of another cutter guide according to an embodiment of the present disclosure.

DETAILED DESCRIPTION

The present invention relates to artificial disc systems, and methods and devices associated with implanting these disc systems into a spine. One example of an artificial disc system is the system described in U.S. Patent No. 6,113,637, which is hereby incorporated by reference. The artificial disc systems provide predetermined bone in-growth areas that allow for revising or removing the artificial disc after implantation and bony in-growth. Further, the artificial disc systems include structural features that improve instrument accessibility in performing such a revision. Additionally, the artificial disc

systems include structures for stabilizing the disc within the associated vertebrae. And, the associated instruments and devices simplify the implantation of the artificial disc systems, as well as providing less traumatic insertion of the systems into the disc space.

Referring to Figs. 1-3, one embodiment of an artificial spinal disc system 10 includes a first member 12 movable relative to a second member 14 via an articulation component 17. Each of first and second members 12, 14 include at least one bone-contacting surface 16, 18 for placement against a portion of an adjacent vertebral bone. Each bone-contacting surface 16, 18 may include at least one bone in-growth surface 20, 22 of a predetermined size and shape, and in a predetermined position and orientation on the respective surface 16, 18. The predetermined size, shape, positioning and orientation of bone in-growth surface 20, 22 allows for a calculated amount of bone growth into the disc members 12, 14 for secure fixation to the adjacent bone, while allowing for easy removal of the disc member from the adjacent bone after bone in-growth occurs if such removal is required at a later date by changing medical needs. Further, the top surface 24, 26 of bone in-growth surface 20, 22 may have a predetermined spacing 28, 30 (Fig. 2) above the remaining portion of bone-contacting surface 16, 18 to allow for increased penetration and/or compression of the adjacent vertebral bone into bone in-growth surface 20, 22 upon implantation of artificial disc system 10. Additionally, each member 12, 14 may include at least one bone in-growth area indicator 32, 34 that identifies the location of the bone in-growth surface 20, 22. For instance, after artificial disc system 10 is implanted, bone in-growth area indicator 32, 34 provides a visual marker that can be seen by the naked eye, such as through an incision that exposes a surface of the system 10, or by medical diagnostic equipment, such as x-ray, ultrasound, magnetic resonance, computed tomography, positron emission technology, and other such diagnostic techniques. Further, bone in-growth area indicator 32, 34 may further include an instrument access guide 36, 38 that cooperates with a medical instrument, such as an osteotome, used in removing artificial disc system 10. Instrument access guide 36, 38 directs the instrument to the exact position of bone in-growth surface 20, 22, thereby avoiding unnecessary work in non-bone-in-growth areas of bone-contacting surface 16, 18 and without interfering with other structures that may be present on surfaces 16, 18. Thus, artificial disc system 10 provides features for secure fixation to adjacent vertebral bone while allowing for easy removal of all or a portion of the system if later required by changing medical needs.

Bone in-growth surface 20, 22 generally has a size that is substantially less than the overall size of the respective bone-contacting surface 16, 18. Further, bone in-growth surface 20, 22 may be positioned on respective bone-contacting surface 16, 18 such that after implantation bone in-growth surface 20, 22 is located proximal to cancellous bone portions, rather than cortical bone portions, of the adjacent vertebral bone. Such positioning, for example, may be at the center of member 12, 14 for a disc system that substantially spans the disc space or vertebral endplate. Alternatively, such positioning may be off-center with respect to member 12, 14 if the disc system only spans a portion of the disc space or vertebral end plate. Additionally, bone in-growth surface 20, 22 may be positioned at a predetermined spacing 40, 42 from an edge 44, 46 of member 12, 14 that is exposed after implantation of the system 10, such as an edge that is not within the disc space between the adjacent vertebrae. Predetermined spacing 40, 42 allows for easier entry of an instrument, such as an osteotome, that is used to separate member 12, 14 from the vertebral bone after bony in-growth has occurred. Furthermore, bone in-growth surface 20, 22 may lie in a single plane, or may lie in one or more planes, which may be intersecting planes, if more secure fixation and bony in-growth is desired. Suitable examples of bone in-growth surface 20, 22 may include surfaces that are chemically-etched, machined, sprayed, layered, fused, coated or textured in any manner or with any material that allows for the growth and attachment of bone.

Bone in-growth indicator 32, 34 may include any type of marker, such as an indentation, an embedded marker, coatings, projections, etc., on any surface of member 12, 14. Further, instrument access guide 36, 38 may include any surface or combination of surfaces that work in cooperation with a surface or portion of a medical instrument used from separating member 12, 14 from bone. Alternatively, instrument access guide 36, 38 may comprise a marker to indicate a position in computer- and/or image- guided surgery.

Further, referring to Fig. 2, securing of the artificial disc system 10 to bone may be enhanced by applying a bone growth promoting substance 49 to a bone contacting surface 16, 18 of the artificial disc system. In particular, bone growth promoting substance 49 may be applied to one or more bone in-growth surfaces 22 to encourage bone to growth into this area. Suitable examples of bone growth promoting substances

include bone morphogenic protein ("BMP"), LIM mineralization protein ("LMP"), demineralized bone matrix ("DBM"), mesenchymal stem cells, blood platelet gel, and other similar materials.

Articulation component 17 may be a structure integral with, or separable from, one or both of first member 12 and the second member 14. Referring to Figs. 4-7, for example, in one embodiment articulation component 17 includes a joint 48 defined by at least a partly convex or curvilinear surface 50, such as a substantially spherical ball, projecting from first member 12 movable in at least a partly concave or curvilinear surface 52, such as an elongated socket, formed within second member 14.

Alternatively, articulation component 17 may be an entirely separate member or combination of members, such as a ball, disc, nucleus, flexible and/or elastic component, etc., positionable in combination with first and second members 12, 14 to allow relative rotational and/or translational motion between the first and second members. Furthermore, first and second member 12, 14 and articulation member 17 may be interconnected to form a single assembly.

Additionally, artificial disc system 10 may include at least one fin or rail member 54 projecting out of bone contacting surface 16, 18 on at least one of first or second member 12, 14. Fin or rail member 54 provides surfaces 56, 58 positioned substantially normal to bone contacting surface 16, 18 that oppose translational or rotational movement of member 12, 14 within adjacent vertebral bone in a plane parallel to the surfaces 16, 18. It should be noted, however, that the particular orientation of surfaces 56, 58 may be adjusted to resist relative motion in any desired plane or direction. Additionally, fin or rail member 54 may include a top engagement surface 60, such as may be formed by teeth, knurling, texturing, etc., that further resists movement of member 12, 14 within bone. For example, for an artificial spinal disc system 10 inserted into the disc space from the anterior side, top engagement surface 60 may resist movement of the implanted disc in the anterior direction by allowing bone to grow or be positioned in the medial lateral direction between portions of the top engagement surface. Surface 60 may be oriented to resist relative motion between member 12, 14 and bone in a different direction, but in the same plane, as surfaces 56, 58. It should be noted, however, that surfaces 56, 58 and 60 may be oriented in a manner to resist any combination of directions of relative motion.

Additionally, top engagement surface 60, as well as surface 56, 58 may be formed with angled or other biased surfaces that have a greater resistance to motion in one or more desired directions. For example, top engagement surface 60 may include a plurality of teeth defined by at least two surfaces, where at least one surface is substantially normal to bone contacting surface 16, 18 and the other wall is substantially non-orthogonally-angled relative to bone contacting surface 16, 18.

Further fin or rail member 54 may lie along a line oriented parallel to an insertion direction, where the insertion direction is a direction in which artificial spinal disc system 10, or either individual member 12, 14, is inserted into position between adjacent vertebrae. It should be understood, however, that fin or rail member 54 may lie along a curvilinear line, and may be angled with respect to the insertion direction. Additionally, fin or rail member 54 may be of any predetermined length. For example, fin or rail member 54 may be of a length greater than or less than the overall edge-to-edge length of artificial spinal disc system 10. For instance, fin or rail member 54 may be of a length such that it is spaced apart from any edge of the disc system 10, or one or both ends of the fin or rail member may be substantially parallel with an edge of the disc system. When an end of fin or rail member 54 is parallel with an edge of disc system 10, such as exposed edge 44, 46, then the fin or rail member may act as bone in-growth indicator 32, 34 and/or instrument access guide 36, 38.

Additionally, artificial spinal disc system 10 may include tabs 62 or other longitudinally extending members that allow the disc system to be held with an insertion instrument. For instance, tabs 62 may include one or more connector structures 64 (Fig. 2), such as an internal wall that defines a cavity or hole, that correspond with engaging features on an insertion instrument that is utilized to hold and/or insert one or both members 12, 14. Alternatively, connector structure 64 may include projections that extend into corresponding holes or cavities in the insertion instrument. Further, tabs or extending members 62 may prevent movement of member 12, 14 relative to the overlapping bone after implantation. For example, for a disc system 10 that is inserted between adjacent vertebrae from the anterior side, tabs or extending members 62 project away from the disc space and over the anterior portion of the vertebral body, thereby preventing relative movement of the member 12, 14 in the posterior direction.

First member 12, second member 14 and articulation component 17 each may be formed from any combination of one or more different biocompatible materials. Suitable materials include stainless steel, cobalt chrome, titanium, rubber, elastomer, polymers, etc., including all alloys and variations of these materials.

Referring to Figs. 8 and 9, in another embodiment, artificial spinal disc system 70 may include a first member 12 movable relative to a second member 72, where such movement has a predetermined range of motion 74, in at least one direction, greater than the natural range of motion 76 of the natural disc being replaced. For instance, in an embodiment where articulation component 17 comprises a convex surface 50 interacting with a concave surface 52, the concave surface 52 may have a predetermined range of motion 74 corresponding to an anterior-to-posterior translation greater than that of the natural range of anterior-to-posterior translation of the natural disc being replaced. For example, for a spinal disc anterior-to-posterior translation typically corresponds to flexion and extension movements of the spinal motion segment, which movements would typically be constrained by natural tissue, including muscle, tendons, annulus fibrosus and/or facet joints. Thus, it may not be necessary to provide physical constraints within disc system 70 that limit the movement of first member 12 and second member 72, and hence articulation component 17, as the natural structure of the tissue adjacent the implanted artificial spinal disc system 70 may naturally limit the relative motion of the disc system. It should be noted that the predetermined range of motion 74 may be in any combination of one or more directions or planes, and may complete overlap the natural range of motion 76, be biased toward one side of the natural range of motion, or be within one side but extend beyond the other side of the natural range of motion. Additionally, although not required, artificial spinal disc system 70 may include a safety stop 78 positioned outside of the natural range of motion 76 to ultimately limit the movement of first member 12 relative to second member 72. Safety stop 78 may be formed in first member 12, second member 72 or in articulation component 17.

Referring to Fig. 10, embodiments of a method of implanting an artificial spinal disc system includes performing pre-operative planning (Block 80), removing the existing natural disc (Block 82), preparing the intervertebral space for receiving the artificial disc system (Block 84), and inserting and securing the artificial disc system (Block 86). The

action of pre-operative planning may include examining the patient, taking x-rays or performing other diagnostic procedures to analyze the natural disc at issue, analyzing and/or calculating the existing or natural range of motion of the spinal motion segment, and/or measuring the natural disc space at issue to determine an appropriate size artificial disc system. The action of removing the natural disc may include a procedure such as a discectomy or partial discectomy, or any other procedure that removes all or a portion of the natural disc nucleus pulposus. The action of preparing the intervertebral space for receiving the artificial disc system may include contouring the end plates of the adjacent vertebrae. Such contouring may include forming parallel surfaces, forming concave surfaces, or forming any other shape in the end plate to receive the artificial disc system.

In particular, as will be discussed in more detail below, the action of contouring the end plates may further include machining at least one fin or rail opening to receive a corresponding at least one fin or rail member associated with the artificial disc system.

The action of machining may include removing a channel of bone from the end plate using tool having a surface adapted for removing bone, where the tool is capable of rotating, vibrating, reciprocating or otherwise acting on the end plate to remove bone. Further, the action of inserting and securing the artificial disc system may include holding a single component or the entire assembled artificial disc system and moving it into the prepared intervertebral disc space until it reaches a predetermined desired position. Securing the artificial disc system may occur naturally due to the compressive forces acting across the implanted artificial disc system, or may occur due to the contouring of the end plates, or may occur due to supplemental fixation techniques such as applying a screw or other component to hold a component of the system to the vertebral bone, or may occur as some combination of these techniques. Further, securing of the artificial disc system may be further achieved by applying a bone growth promoting substance to a bone contacting surface of the artificial disc system. Suitable examples of bone growth promoting substances include bone morphogenic protein ("BMP"), LIM mineralization protein ("LMP"), demineralized bone matrix ("DBM"), mesenchymal stem cells, blood platelet gel, and other similar materials. It should be noted that the above method may be achieved through an open surgical site, or in a minimally invasive manner such as through a tube or channel that allows from a relatively small opening in the skin and tissue of the patient compared to the open procedure.

Referring to Figs. 11-26, an embodiment of a method of implanting an artificial spinal disc system in the cervical portion of the spine includes positioning the patient for surgery, performing a discectomy and decompressing the disc space, preparing the adjacent vertebral endplates, and inserting the artificial spinal disc. Referring to Fig. 11, the patient 90 may be positioned such that their neck 92 is in a neutral position corresponding to the natural lordosis of the cervical spine. After making an incision, an access channel 94 to the natural spinal disc 96 and/or adjacent vertebrae 98, 100 may be maintained by an opener mechanism 102, such as one or more retractor blades or an endoscopic port or channel, respective examples including a TRIMLINE retractor blade or an X-TUBE endoscopic port both manufactured by Medtronic Sofamor Danek USA (Memphis, TN).

Then, referring to Fig. 12, the natural spinal disc 96 is removed using a disc removal instrument 104, such as a curette, osteotome or any instrument specifically designed for removal of all or a portion of the natural disc. After removal of all or a portion of the natural spinal disc 96, the disc space is decompressed, such as by using the Smith-Robinson decompression technique.

Referring to Figs. 13-15, after removal of the natural disc, referred to as a discectomy, and decompression, at least one contouring device 106 may be utilized to form a predetermined contour 108, 110 which may generally correspond to the bone contacting surface of the artificial disc, into one of both of the adjacent vertebral bodies 98, 100. For example, in one embodiment, the vertebral end plates are machined to be flat and parallel, such as by using a cylindrical burr. It should be noted, however, that other contouring devices 106, such as mills, cutters, saws, etc., and other predetermined shape-forming devices may be used to remove bone from the end plates. In order to avoid subsidence of the artificial disc system into the end plates, the machining process may be performed to preserve as much cortical bone as possible. Additionally, referring specifically to Fig. 13, it should be noted that a reference device 112, such as a frame or such as markers, may be used in conjunction with contouring device 106 to control or guide the movements of the contouring device. For instance, reference device 112 may be attached to one or both adjacent vertebrae 98, 100 so as to provide geometric guidance to contouring device 106.

After end plate contouring is complete, then the prepared disc space 114 (Fig. 15) may be ready for disc insertion and all external distraction may be removed.

Referring to Fig. 16, in order to determine the proper size artificial disc to use, an implant trial 116 may be inserted determine the size of the prepared disc space 114. In some embodiments that desire to avoid excessive compressive forces on the artificial disc system, the properly sized implant trial 116 fits snug in the prepared disc space 114 but does not distract the adjacent vertebrae 98, 100. Additionally, the fit of implant trial 116 may be confirmed diagnostically, such as with fluoroscopy. Referring to Fig. 17, once the appropriate sized implant trial 116 is determined, the correspondingly sized rail cutter guide 118 is selected and used to prepare one or more fin or rail channels in the endplates in correspondence with the fin or rail member on the artificial disc system.

Referring to Figs. 17-22, one embodiment of a rail cutter guide 118 includes at least one machining guide 120 positioned on guide body 122 and having a size 124 to provide a reference to a bone cutting device 126 to form a fin or rail member channel 128 in one or both adjacent vertebrae 98, 100 corresponding in position and size to the fin or rail guide member on the artificial spinal disc system. In embodiments having more than one machining guide 120, referring specifically to Fig. 19, each machining guide 120 may have a predetermined longitudinal spacing 121 and/or a predetermined lateral spacing 123 with respect one or more of the other machining guides. Such predetermined spacing 121, 123 is advantageous for insuring formation of at least two fin or rail member channels 128 (Fig. 22), either in one vertebral end plate or in adjacent end plates, that are in alignment with the predetermined spacing of at least two or more fin or rail members on an artificial spinal disc selected to be implanted.

Further, rail cutter guide 118 may include a spacer portion 130 sized and having a thickness 132 (Fig. 20) corresponding to a desired disc spacing, such as the natural neutral disc spacing of the prepared disc space 114. Additionally, guide body 122 or spacer portion 130 may include predetermined recesses 131 sized to accommodate at least a portion of a bone removal device. Rail cutter guide 118 may further include a permanent or removably attachable handle 134 for manipulating the position of the guide. Referring specifically to Fig. 17, rail cutter guide 118 may further include an engagement structure 136, such as a protrusion or an extension, that interacts with urging mechanism 138, such as a hammer-like or moving-weight type device, for moving the guide 118 into proper position. Rather than, or in addition to, being

referenced to the prepared disc space 114 and/or the adjacent vertebrae 98, 100 via spacer portion 130, rail cutter guide 118 may include one or more reference markers 140 so as to insure a desired positioning with respect to the adjacent vertebrae. The desired positioning, for example, may include a cephalad-caudal positioning, a lateral positioning, a depth within the prepared disc space 114 positioning, and any combination thereof. For example, reference marker 140 may include a limiting structure 142 projecting from guide body 122 so as to limit the depth of penetration of the guide body into prepared disc space 114. Further, one or more reference markers 140 may be associated with any other structure having a known position relative to one or both vertebrae 98, 100 and/or prepared disc space 114.

Referring back to Fig. 17, to position the rail cutter guide 118 relative to the adjacent vertebral bodies 98, 100, urging mechanism 138 may be utilized to move the rail cutter guide 118 into a desired position. For instance, in one embodiment, rail cutter guide 118 is impacted until all limiting structures 142 touch the anterior surface of the adjacent vertebrae 98, 100. Referring to Fig. 19-22, after removing urging mechanism 138, a bone removal mechanism 144 may be movable relative to machining guide 120 to create fin or rail member channel 128 (Fig. 22). In one embodiment, for example, bone removal mechanism 144 may include a drill bit 146 attachable to either an actuation mechanism 148, such as a power source or a manual drill bit handle. In this embodiment, drill bit 146 is inserted into one port formed within machining guide 120 on rail cutter guide 118, and operates to form one channel 128 in the endplate. Referring specifically to Fig. 21, it may be desired to secure the relative position of rail cutter guide 118 and the first-formed channel 128 (not shown) in order to insure proper geometric alignment of successive channels. In such a situation, a temporary fixation mechanism 150, such as a pin or screw, may be secured to rail cutter guide 118, such as to machining guide 120. Then, the successive channels 128 may be formed, and additional temporary fixation mechanisms 150 may be applied. Referring specifically to Fig. 22, after removing any temporary fixation mechanisms I50 and rail cutter guide 118, one or both endplates should have one or more properly positioned channels 128.

Referring to Figs. 23-26, an artificial spinal disc system 10 or 70, such as the PRESTIGE Cervical Disc manufactured by Medtronic Sofamor Danek USA (Memphis, TN) may be attached onto an implant inserter 152. In one embodiment, for example, the implant inserter 152 includes four inserter prongs 154 (only 3 are visible in Fig. 23), attached to legs 155 positioned within outer sheath 156, that fit into holes 64 within tabs 62. Outer sheath 156 is advanced to apply a force across the prongs 154 to hold the disc system 10 or 70. The one or more fin or rail members 54 are aligned with one or more channels 28 on the endplates of the adjacent vertebrae 98, 100, and the disc system 10 or 70 is inserted into the prepared disc space 114. Insertion may be aided by urging mechanism 138, and disc system 10 or 70 is advanced until the anteriorly positioned tabs 62 come into contact with the anterior surface of the adjacent vertebral bodies 98, 100. Disc system 10 or 70 may then be released by implant inserter 152, for example by sliding back outer sheath 156 and gently removing implant inserter 152. Final placement of disc system 10 or 70 between adjacent vertebrae 98, 100 may be verified using medical diagnostic equipment, such as by using fluoroscopy. The surgery may be completed using standard closure procedures.

Thus, the present invention includes various embodiments of artificial spinal discs having predetermined bone in-growth areas and additional features to aid in the removal or revision of the implanted artificial disc. Additionally, the present invention includes various embodiments of fin or guide rail channel-forming mechanisms, and of methods of implanting artificial discs having at least one fin or guide rail member.

Referring now to Fig. 27, a cutting guide 200 may be used to create tracks or holes in adjacent vertebral bodies. These tracks or holes may correspond in size and position to rails, fins, bone screws, fasteners or other features included in an artificial disc system. The cutting guide 200 may include an upper member 202 and a lower member 204. The upper member 202 may include a spacer portion 206, and the lower member 204 may include a spacer portion 208. The upper member 202 may also include a cutting block 210, and the lower member 204 may include a cutting block 212. The cutting blocks 210, 212 may serve as penetration limiting extensions. The cutting block 210 may include bores 214, 216 sized to accept an instrument (not shown) such as a drill bit 146. A predetermined spacing 217 may separate the bores 214, 216 to

permit formation of two tracks or holes. In this embodiment the spacing 217 between the bores 214, 216 is generally constant along the length of the bores, resulting in generally parallel tracks or holes. It is understood that the predetermined spacing may vary along the length of the bores to create nonparallel tracks or holes as the profile of the artificial disc may warrant. Similar bores may be located in the cutting block 212.

The cutting guide 200 may further include a permanent or removably attachable handle 218 extending from the upper member 202 and a similar handle 220 extending from the lower member 204.

In an alternative embodiment, slots or recesses, similar to recesses 131, may be formed in the spacer portion 206, 208 to accommodate the passage of at least a portion of drill bit 146 when forming rails in the adjacent vertebral bodies. In another alternative embodiment, the upper members and the lower members may include reference markers to insure a desired positioning with respect to the adjacent vertebral bodies. The desired positioning, for example, may include a cephalad-caudal positioning, a lateral positioning, a depth (anterior- posterior) within the disc space, and any combination thereof.

Referring now to Fig. 28, the upper and lower members 202, 204 may be movably connected to each other by a pivot mechanism 221. In this embodiment, the pivot mechanism is a ball and socket type joint formed by a domed recess 222 formed in the upper member 202 and a domed cap protruding from the lower member 204. Tabs 224 and 226 may extend from the domed recess 222. The domed cap 228 may include an indention 230 sized to allow pass through of the tab 224. A second indention 232 may be located opposite the indention 230 and may be sized to allow pass through of the tab 226. The upper member 202 may be connected to the lower member 204 by aligning the tabs 224, 226 with the indentions 230, 232 and inserting the domed cap 228 into the domed recess 222. After the domed cap 228 has been inserted into the domed recess 222, the lower member 204 may be turned relative to the upper member 202 to lock the cap 228 within the recess 222 and align the upper member 202 with the lower member 204.

The spacer portions may be provided in a variety of thicknesses to accommodate the distraction and lordotic angle used for a particular patient, and different thicknesses

may be used for the upper and lower spacer portions. In the embodiment of FIG. 28, the spacer portion 206 has a thickness 240 that is greater than a thickness 242 of the spacer portion 208.

The preferences of the surgeon and/or the condition of the patient may determine whether, during surgery, the patient's spine will be held in a more natural position with the targeted vertebral endplates generally parallel or whether the patient will be placed in lordosis with the targeted vertebral endplates angled relative to one another. When a patient is placed in lordosis, the cutting guide 200 may be used to form the tracks or holes generally parallel to the respective vertebral endplates. For instance, in one embodiment as shown in FIG. 29, the adjacent vertebral bodies 98, 100 may be positioned relative to each other at an anterior-posterior angle 250 which may range from approximately 0 to 10 degrees. Additionally or alternatively, the vertebral bodies 98, 100 may be angled in a lateral direction. With the patient positioned at the desired lordotic angle 250, the cutting guide 200 may be inserted between adjacent vertebrae 98, 100. As the cutting guide 200 is inserted, the pivoting mechanism 221 formed by the domed cap 228 within the domed recess 222 may adjust to the angle 250. The spacer portions 206, 208 may be inserted until the protruding cutting blocks 210, 212 limit further insertion by touching the anterior surface of the vertebral bodies 98, 100, respectively.

The cutting guide 200 may be manually held in position with the spacer portions 206, 208 firmly against the endplates of the vertebral bodies. Alternatively, as shown in the embodiment of FIG. 30, a separation device 260 may be introduced to hold the upper member 202 and the lower member 204 in place. The separation device 260 may include a through bore 262, an angled leg 264, and an alignment leg 266. The handle 218 may be inserted through the bore 262 and the angled leg 264 may be positioned on a surface of the handle 220 facing the handle 218. The angled leg 264 may move along a flat surface of the handle 220, along a groove in the handle 220, or by any other moving connection means contemplated by one skilled in the art. The alignment leg 266 may prevent any unwanted lateral pivoting of the upper member 202 with respect to the lower member 204. The separation device 260 may slide along the handle 218 as far as possible until the device 260 pushes apart the arms 218, 220 and

correspondingly pushes the upper and lower members 202, 204 against the endplates of vertebral bodies 98, 100, respectively.

After the cutting guide 200 is positioned, the drill bit 146 may be inserted through bore 216 to drill a hole 270 in the vertebral body 98 parallel to the endplate. The drill bit 146 may then be inserted into bore 214 to drill a hole in the vertebral body 100 parallel to the hole 270 and parallel to the endplate of vertebral body 98. The drill bit 146 may then be used with lower member 204 in a similar manner to drill holes in vertebral body 100. It is understood that the holes may be drilled in any sequence chosen by the surgeon. It is also understood that with alternative configurations of the upper and lower members, the drill bit 146 may be used to create rails or tracks rather than holes.

Referring now to FIG. 31, in another embodiment, a cutting guide 300 may be used to create formations such as tracks or holes in adjacent vertebral bodies. These tracks or holes may correspond in size and position to rails, fins, fasteners or other features found on an artificial disc system. The cutting guide 300 may include an upper member 302 and a lower member 304. The upper member 302 may include a spacer portion 306, and the lower member 304 may include a spacer portion 308. The upper member 302 may also include a cutting block 310, and the lower member 304 may include a cutting block 312. The cutting block 310 may include bores 314, 316 (not visible) sized to accept an instrument such as a drill bit 146. A predetermined spacing may separate the bores 314, 216 to permit formation of two tracks or holes. Similar bores may be located in the cutting block 312. The cutting guide 300 may further include a permanent or removably attachable handle 318 extending from the upper member 202 and a similar handle 320 extending from the lower member 304.

The upper and lower members 302, 304 may be movably connected to each other by a pivot mechanism 321. In this embodiment, the pivot mechanism is formed by an upper hinge component 322 extending from the upper member 302 coupled to a lower hinge component 324 protruding from the lower member 304. The lower hinge component 324 may include a U or J-shaped latch which may be coupled to a shaft portion of the upper hinge component 322. A J-shaped latch may allow the lower hinge component 324 to become more easily separated from the upper hinge portion. A coil

spring 326 may be attached between the upper member 302 and lower member 304 and may exert a force to push apart the upper and lower members to create an angle therebetween. It is understood that the coil spring 326 is only one example and that other types of mechanisms such as screws, jacks, and inflatable bodies may be used to hold the upper and lower members 302, 304 against the respective vertebral endplates.

Although only a few exemplary embodiments of this invention have been described in detail above, those skilled in the art will readily appreciate that many modifications are possible in the exemplary embodiments without materially departing from the novel teachings and advantages of this invention. For instance, all or predetermined portions of the bone-contacting surfaces of the artificial disc systems may comprise bone in-growth surfaces. Accordingly, all such modifications and alternative are intended to be included within the scope of this invention as defined in the following claims. Those skilled in the art should also realize that such modifications and equivalent constructions or methods do not depart from the spirit and scope of the present disclosure, and that they may make various changes, substitutions, and alterations herein without departing from the spirit and scope of the present disclosure. It is understood that all spatial references, such as "horizontal," "vertical," "top," "upper," "lower," "bottom," "left," and "right, " are for illustrative purposes only and can be varied within the scope of the disclosure. In the claims, means-plus-function clauses are intended to cover the structures described herein as performing the recited function and not only structural equivalents, but also equivalent structures.

What is claimed is:

1. An intervertebral disc space preparation guide comprising:
a first member including
a first spacer portion adapted for insertion in an intervertebral disc space and
a first cutting block portion through which a first bore extends; and
a second member including
a second spacer portion adapted for insertion in an intervertebral disc space and
a second cutting block portion through which a second bore extends,
wherein the first member is movably connected to the second member.

2. The guide of claim 1 wherein the first spacer portion is pivotally connected to the second spacer portion.

3. The guide of claim 2 wherein the first spacer portion is pivotally connected to the second spacer portion by a ball and socket type joint.

4. The guide of claim 3 wherein the ball and socket type joint includes a domed shaped protrusion extending from the first member and a domed shaped recess formed in the second member.

5. The guide of claim 4 further comprising a locking mechanism for preventing the domed shape protrusion from separating from the domed shape recess.

6. The guide of claim 4 wherein the domed shaped protrusion comprises at least one indention and the domed shape recess comprises at least one tab and wherein the at least one tab is inserted through the at least one indention and the dome shaped protrusion is turned relative to the domed shape recess to lock the first member to the second member.

7. The guide of claim 2 wherein the first spacer portion is pivotally connected to the second spacer by a hinge joint.

8. The guide of claim 7 wherein the hinge joint includes a shaft formed on the first spacer portion and a J-shaped latch formed on the second spacer portion.

9. The guide of claim 1 wherein a third bore extends through the first cutting block portion and a fourth bore extends through the second cutting block portion.

10. The guide of claim 9 wherein the first bore is parallel to the third bore.

11. The guide of claim 1 wherein the first spacer portion comprises a recess extending from the first bore.

12. The guide of claim 1 wherein a coil spring extends between the first member and the second member.

13. The guide of claim 1 wherein the intervertebral disc space comprises a lordotic angle between a first vertebral endplate and a second vertebral endplate and wherein the first and second spacer portions are adapted to contact the first and second vertebral endplates, respectively.

14. The guide of claim 13 wherein the lordotic angle ranges between 0 and 10 degrees.

15. The guide of claim 1 wherein the first and second spacer portions have different thicknesses.

16. The guide of claim 1 wherein the first cutting block portion comprises a penetration limiting extension.

17. The guide of claim 1 further comprising a separation device for holding the first member against a first vertebral endplate and for holding the second member against the second vertebral endplate.

18. The guide of claim 1 further comprising a first handle extending from the first member and a second handle extending from the second member.

19. The guide of claim 18 further comprising a separation device extending between the first handle and the second handle.

20. The guide of claim 19 wherein the separation device includes a connection portion and a first leg and wherein the connection portion is adapted to move along the first handle until the first leg is wedged against the second handle.

21. The guide of claim 19 further comprising a second leg for maintaining alignment of the first handle and the second handle.

22. An assembly for preparing a disc space between a first vertebral body having a first vertebral endplate and a second vertebral body having a second vertebral endplate, the assembly comprising:

a first spacer portion integrally formed with a first cutting block; and

a second spacer portion integrally formed with a second cutting block;

wherein the first spacer portion is pivotally connected to the second spacer portion.

23. The assembly of claim 22 wherein the first cutting block comprises a through bore and wherein the through bore is adapted to guide a cutting device to cut a hole in the vertebral body parallel to the vertebral endplate.

24. The assembly of claim 22 wherein the first cutting block comprises a through bore and wherein the through bore is adapted to guide a cutting device to cut a groove in the vertebral endplate parallel to the plane of the vertebral endplate.

25. The assembly of claim 22 wherein first vertebral endplate forms an angle with respect to the second vertebral endplate and wherein the first spacer portion is positioned against the first vertebral endplate and the second spacer portion is positioned against the second vertebral endplate.

26. The assembly of claim 25 wherein the angle is between 0 and 10 degrees.

27. A method of preparing an intervertebral disc space to receive an implant, the method comprising:

creating a non-parallel angle between first and second vertebral endplates of first and second vertebral bodies, respectively;

inserting at least a portion of a cutting guide between the first and second vertebral endplates, the cutting guide including a first member movably connected to a second member;

moving the first member with respect to the second member to place the first member in contact with the first vertebral endplate and to place the second member in contact with the second vertebral endplate; and

inserting a cutting device through a portion of the first member to cut a first formation in the first vertebral body.

28. The method of claim 27 wherein the first formation is an elongated hole parallel to the first vertebral endplate.

29. The method of claim 27 wherein the first formation is a track in the first vertebral endplate parallel to the plane of the first vertebral endplate.

30. The method of claim 27 further comprising inserting the cutting device through a portion of the second member to cut a second formation parallel to the second vertebral endplate.

31. The method of claim 27 further comprising cutting a second formation parallel to the first vertebral endplate.

32. The method of claim 27 further comprising manipulating a ball and socket type joint to move the first member with respect to the second member.

33. The method of claim 27 further comprising manipulating a hinge joint to move the first member with respect to the second member.

34. The method of claim 27 further comprising creating an anterior-posterior angle of between 0 and 10 degrees between the first and second vertebral endplates.

35. The method of claim 27 further comprising creating a lateral angle between the first and second vertebral endplates.

36. The method of claim 27 wherein the first member comprises a penetration limiting extension and the step of inserting comprises inserting the cutting guide until the penetration limiting extension touches a vertebral body.

37. An apparatus for guiding a bone cutting mechanism, the apparatus comprising:

a first guide member comprising a first spacer portion integrally formed with a first cutting block portion, wherein a first bore, sized to accept the bone cutting mechanism, extends through the first cutting block portion; and

a second guide member comprising a second spacer portion integrally formed with a second cutting block portion, wherein a second bore, sized to accept the bone cutting mechanism, extends through the second cutting block portion,

wherein the first member is movably connected to the second member.

38. The apparatus of claim 37 wherein the first cutting block portion comprises a penetration limiting projection.

39. The apparatus of claim 37 wherein the first bore extends through the penetration limiting projection.

40. The apparatus of claim 37 wherein the first member is movably connected to the second member by a ball and socket type joint.

41. The apparatus of claim 37 wherein the first member is movably connected to the second member by a hinge joint.

42. The apparatus of claim 37 further comprising a separation device for holding the first member at a non-parallel angle with respect to the second member.

43. The apparatus of claim 42 wherein the separation device is a spring.

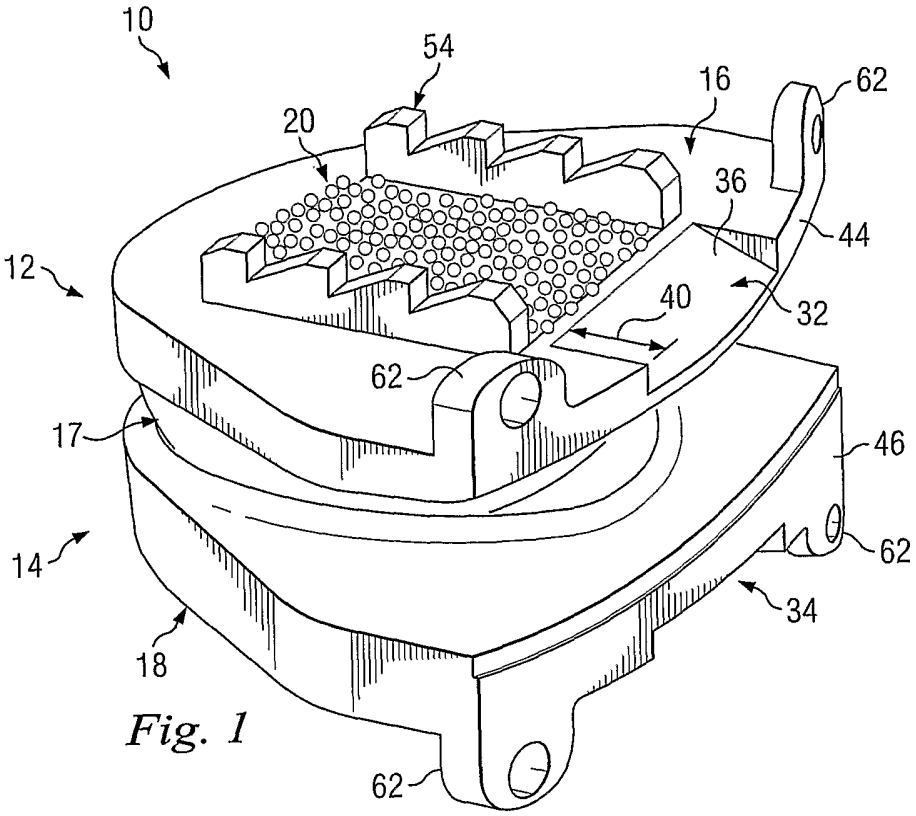

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Fig. 1

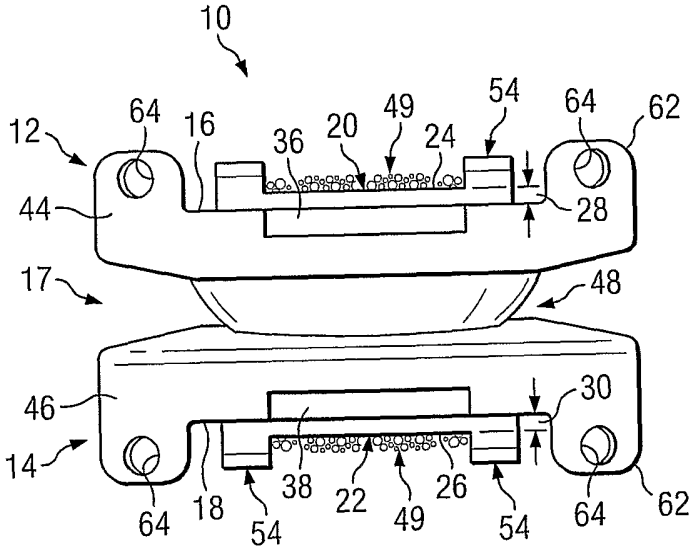

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Fig. 2

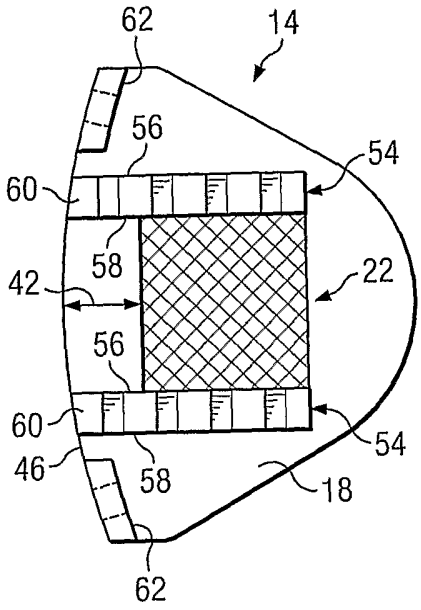


Fig. 3

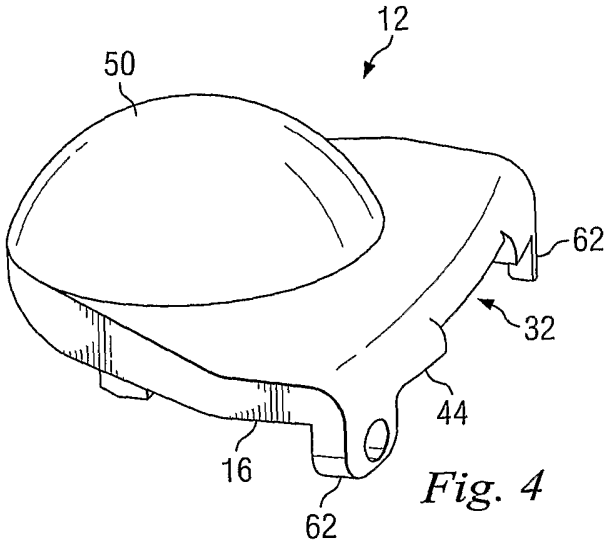


Fig. 4

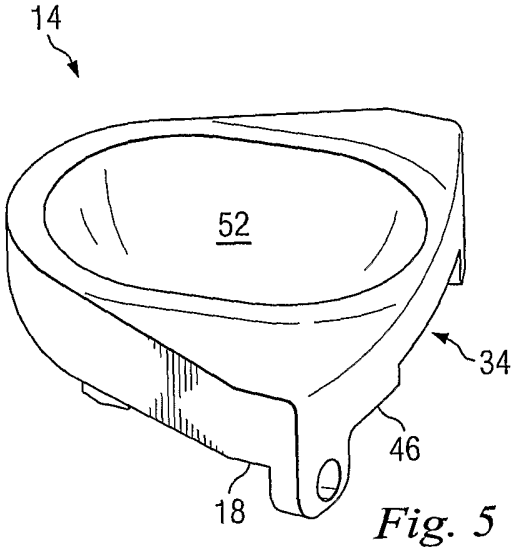


Fig. 5

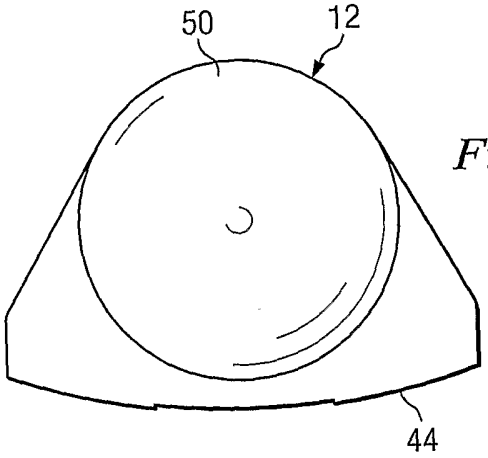


Fig. 6

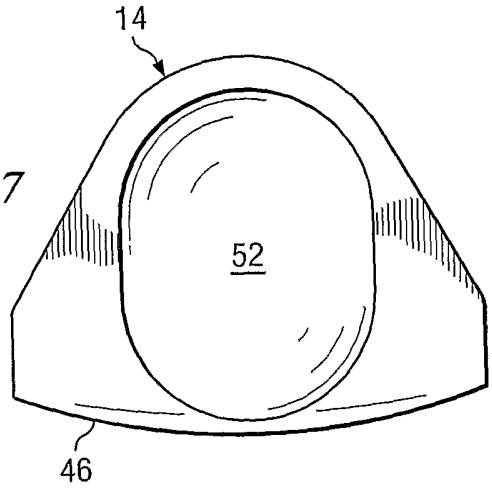


Fig. 7

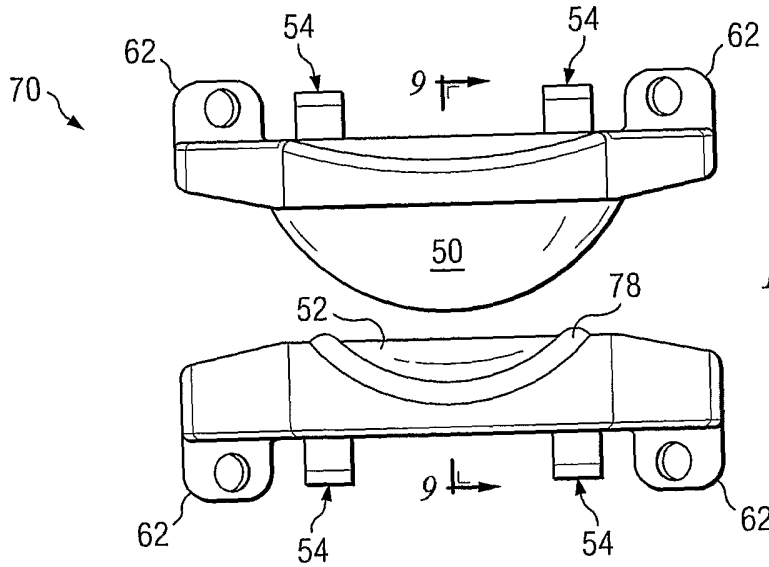


Fig. 8

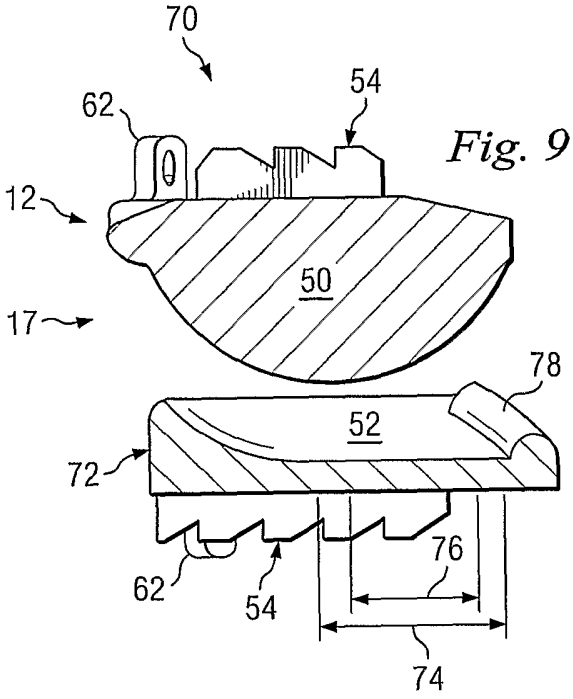

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Fig. 9

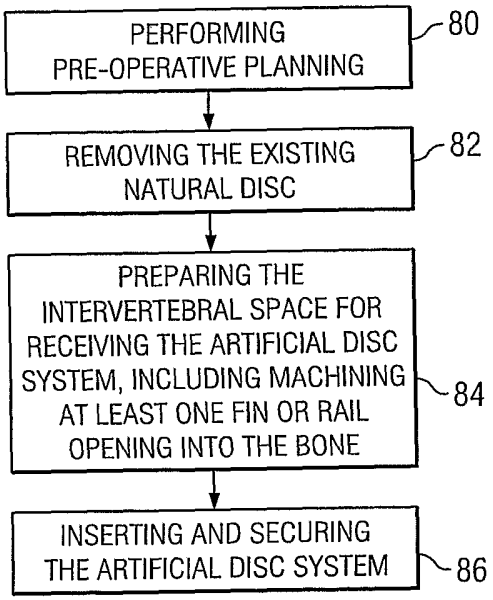

PERFORMING PRE-OPERATIVE PLANNING
80
REMOVING THE EXISTING NATURAL DISC
82
PREPARING THE INTERVERTEBRAL SPACE FOR RECEIVING THE ARTIFICIAL DISC SYSTEM, INCLUDING MACHINING AT LEAST ONE FIN OR RAIL OPENING INTO THE BONE
84
INSERTING AND SECURING THE ARTIFICIAL DISC SYSTEM
86

Fig. 10

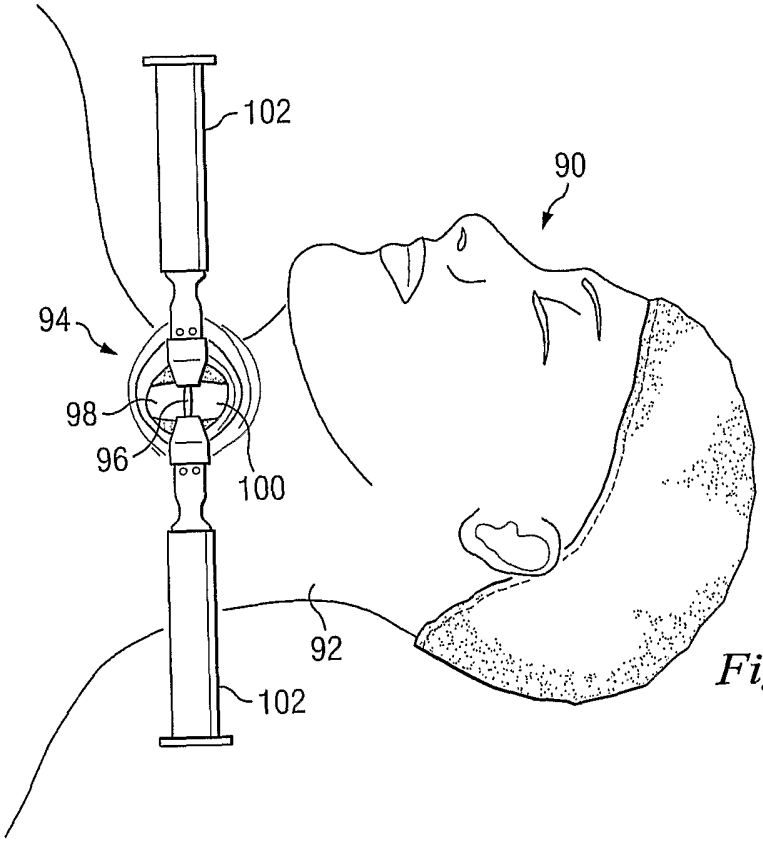


Fig. 11

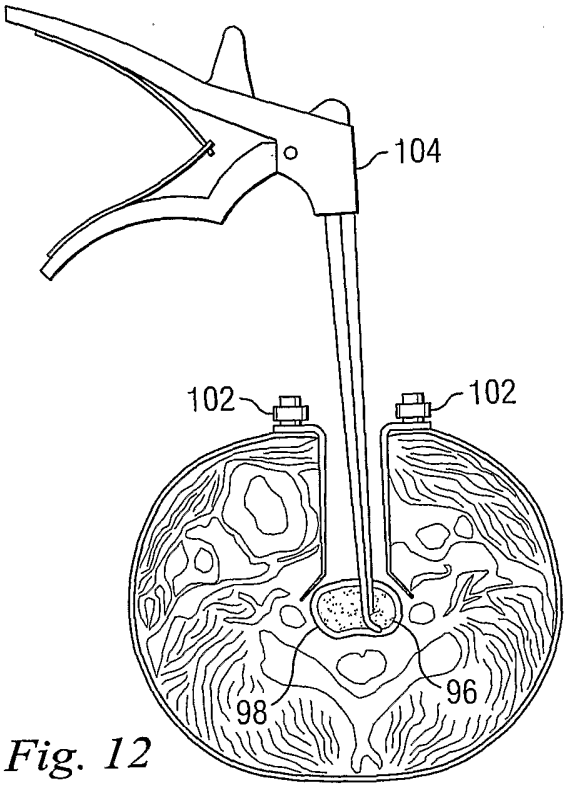


Fig. 12

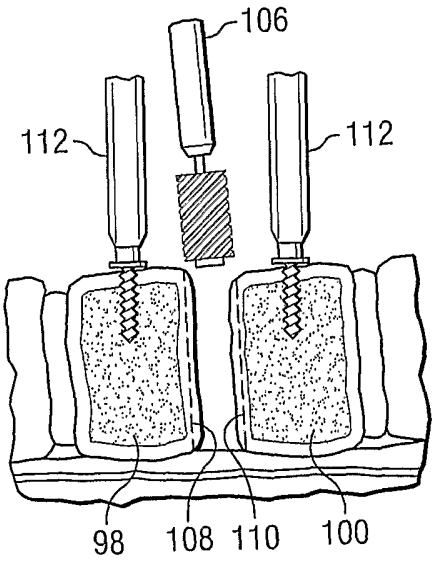


Fig. 13

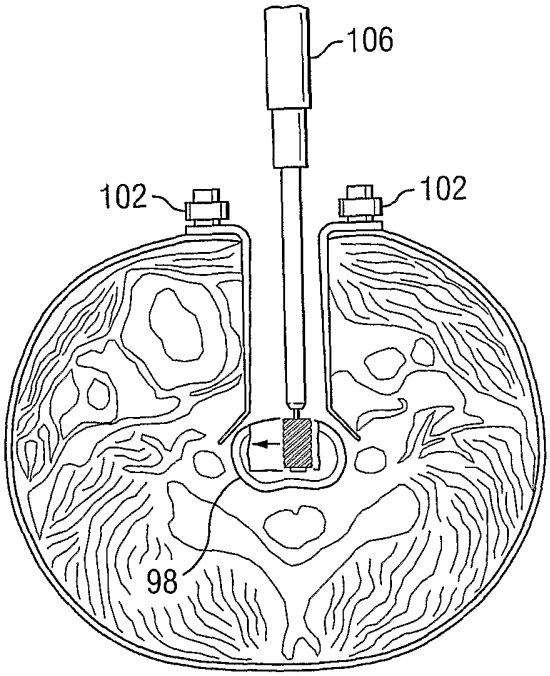


Fig. 14

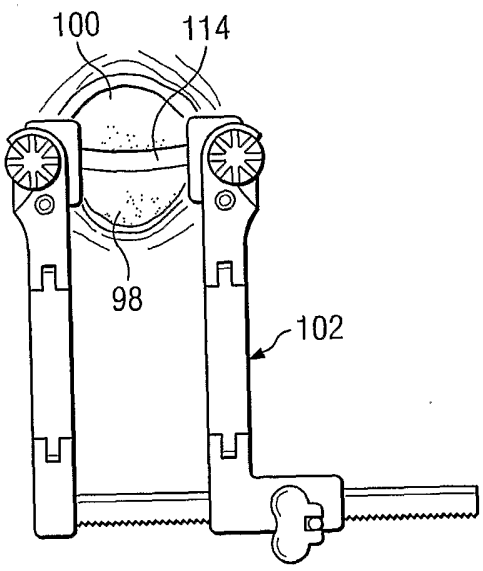


Fig. 15

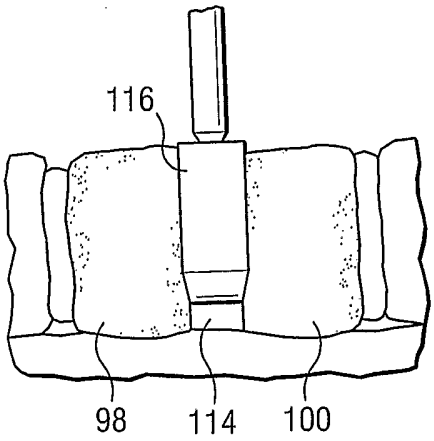


Fig. 16

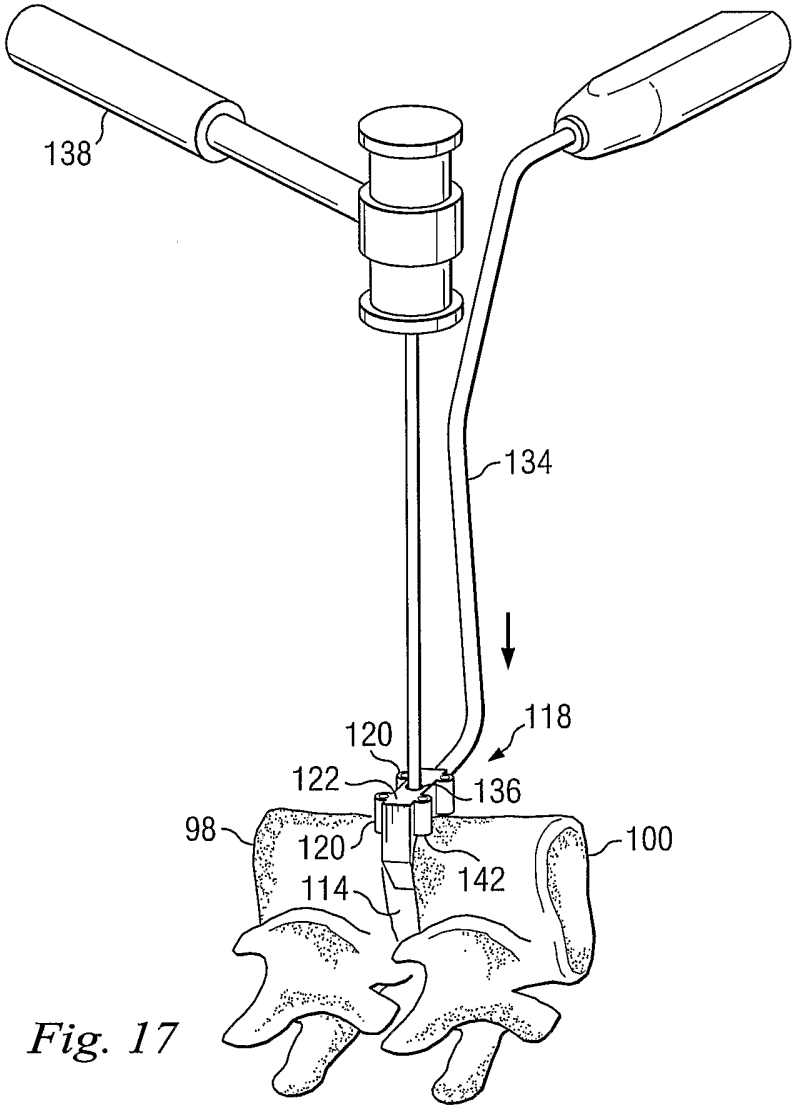


Fig. 17

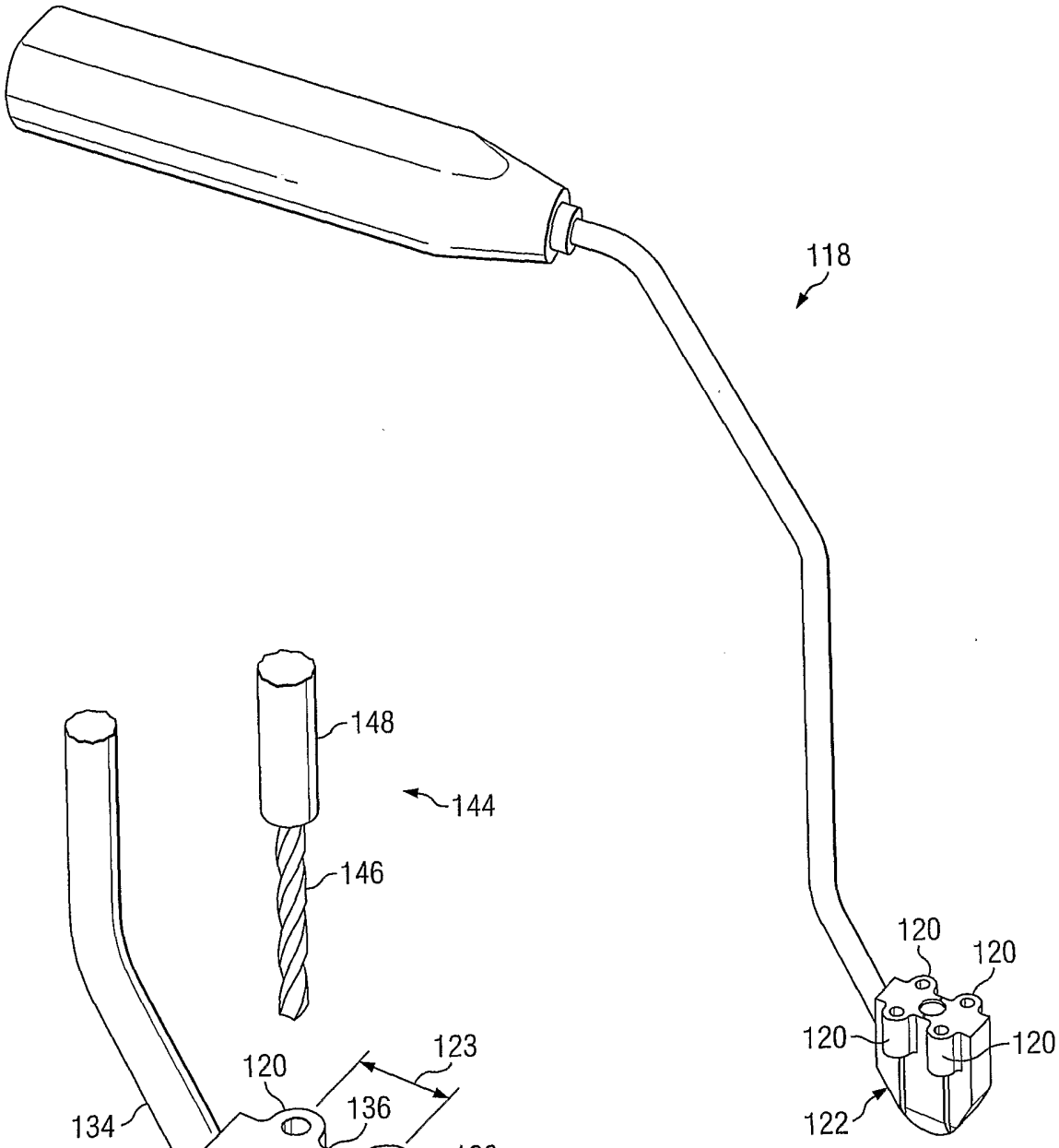

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Fig. 18

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Fig. 19

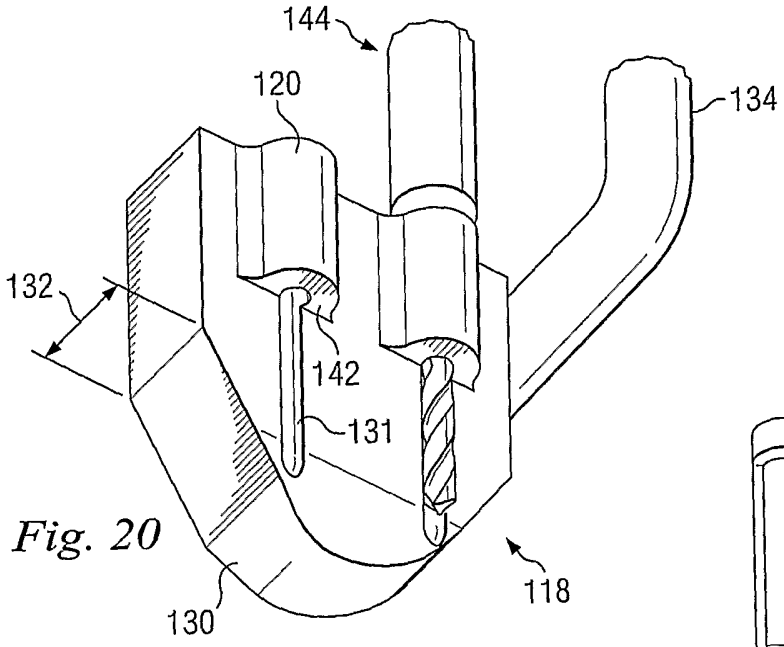

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Fig. 20

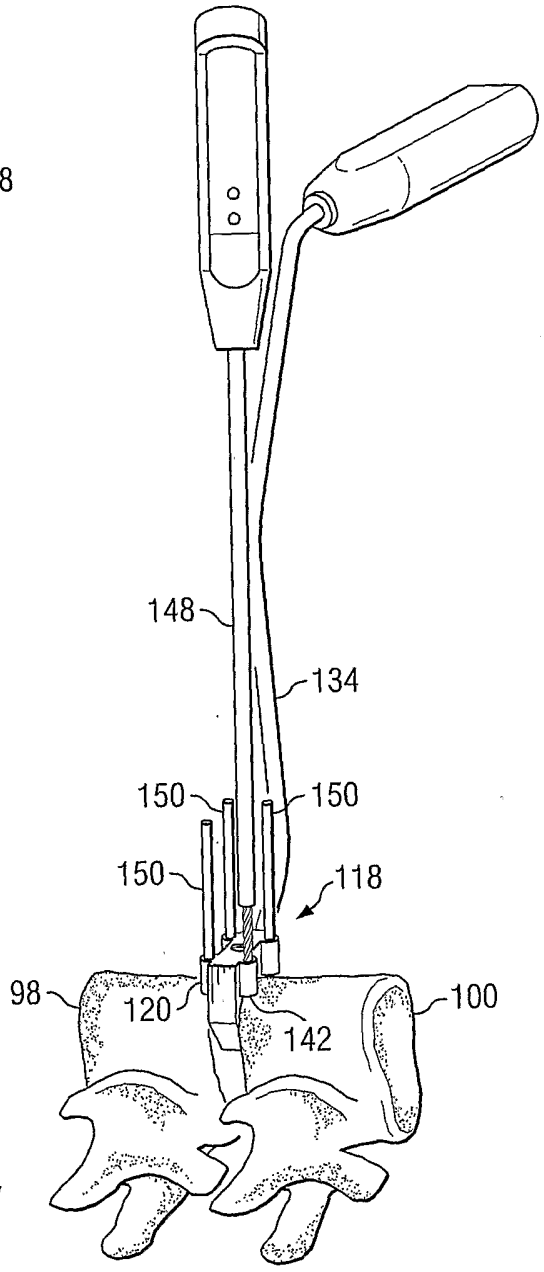

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Fig. 21

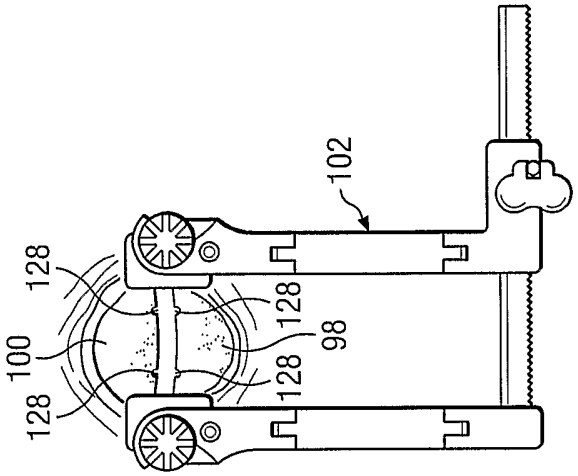

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Fig. 22

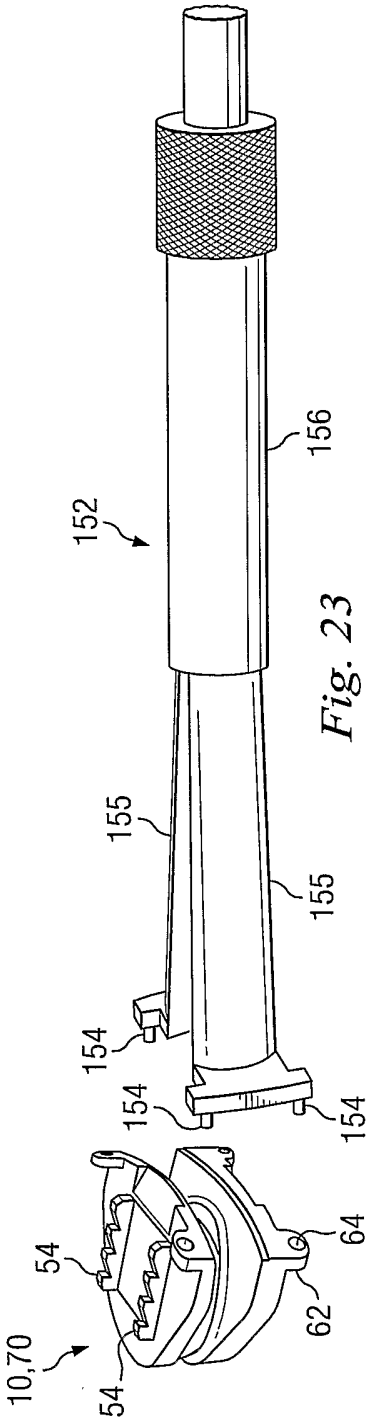

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Fig. 23

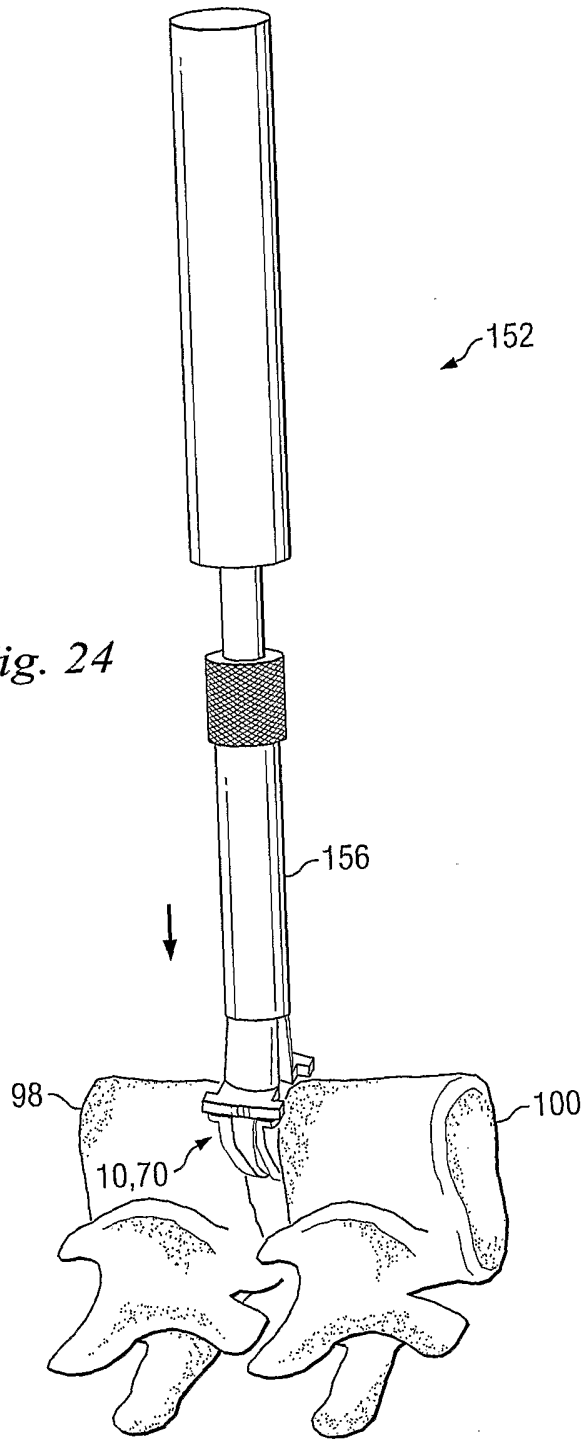


Fig. 24

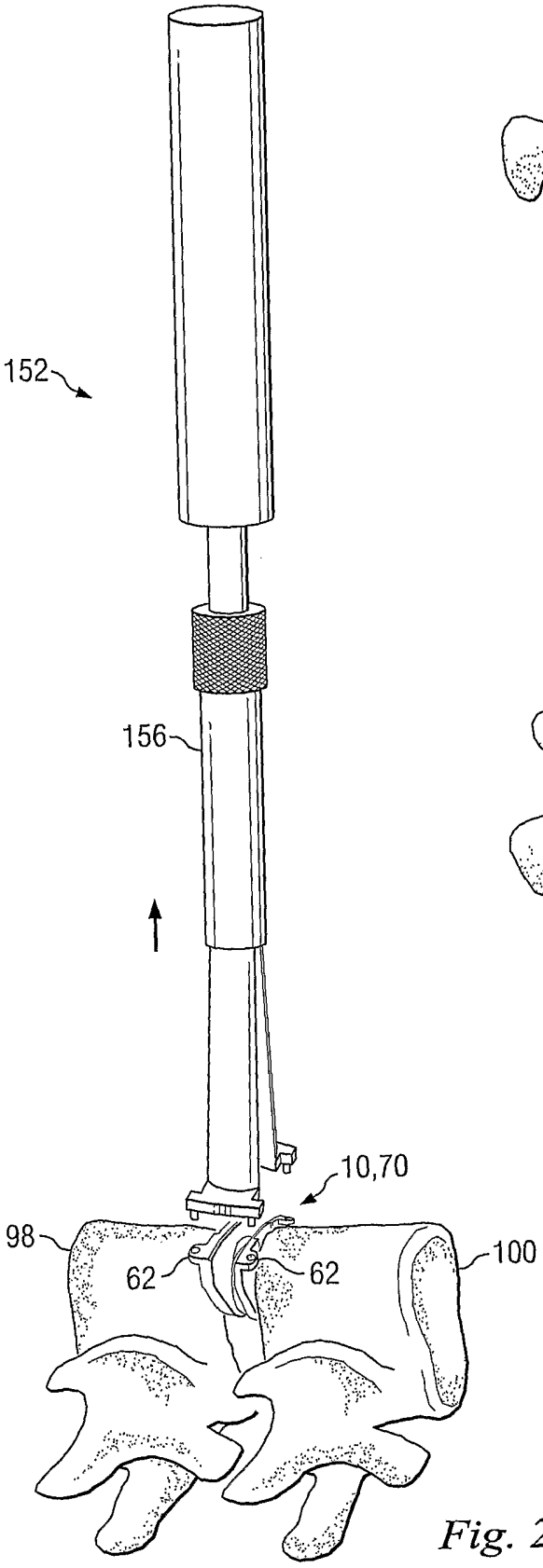


Fig. 25

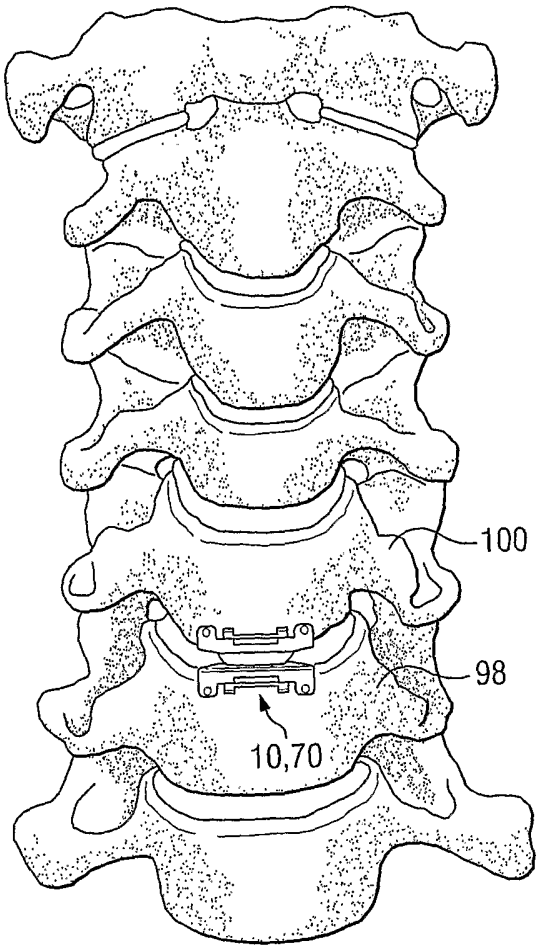


Fig. 26

Fig. 27

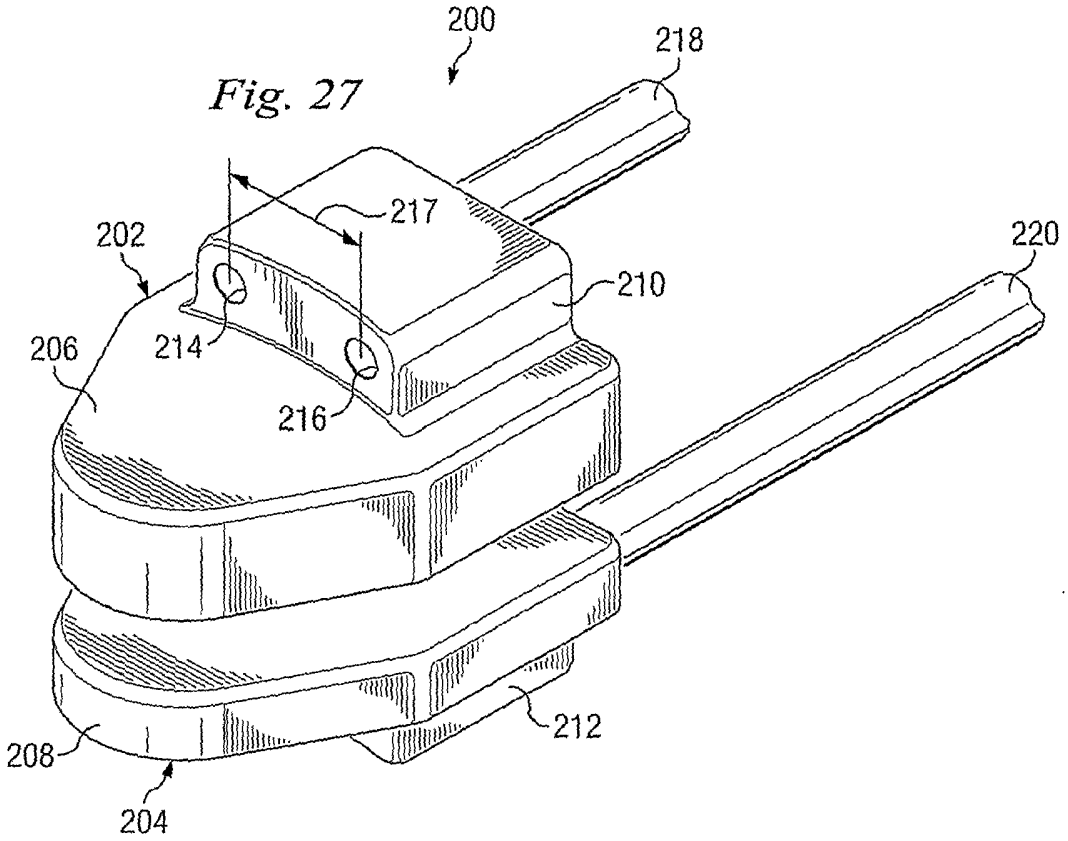
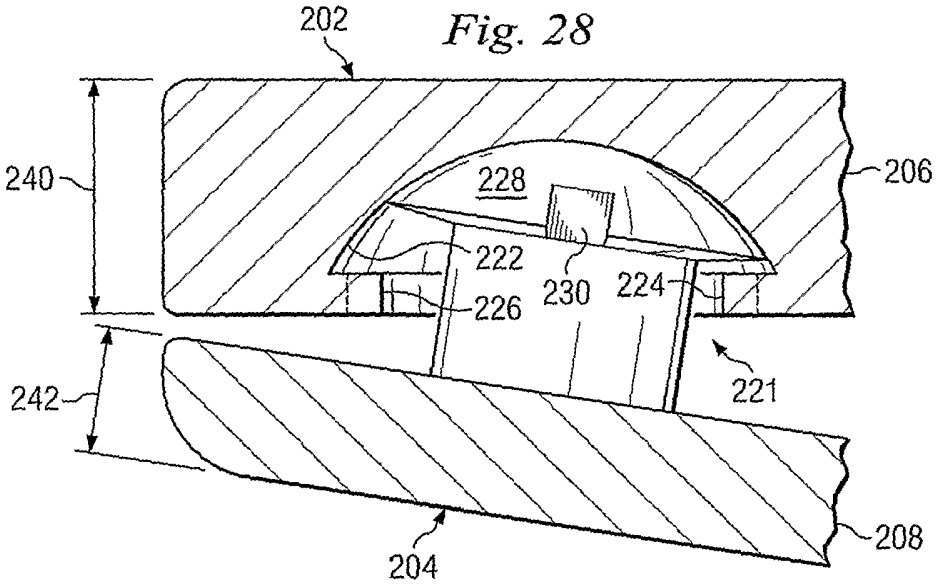

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Fig. 28


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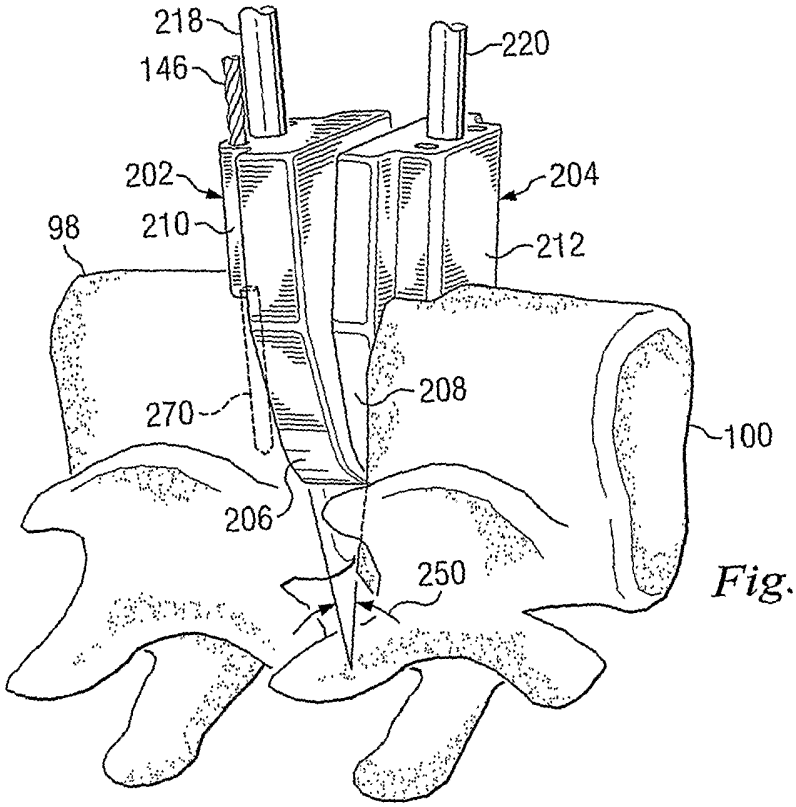


Fig. 29

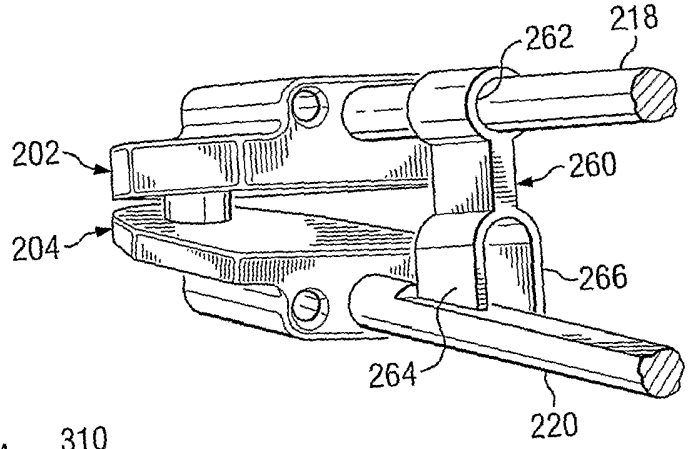


Fig. 30

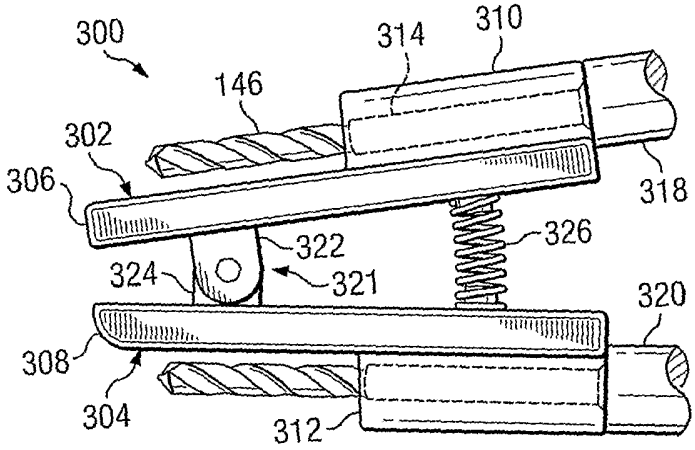


Fig. 31

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2006/001715

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/17

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

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

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

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2004/041131 A (SPINAL CONCEPTS, INC) 21 May 2004 (2004-05-21) page 17, paragraph 3 - page 18, paragraph 2	1-3,7,8, 16-26, 37-42
X	US 2003/236526 A1 (VAN HOECK JAMES E ET AL) 25 December 2003 (2003-12-25) paragraph [0004] - paragraph [0007] paragraph [0027] - paragraph [0030]	1,9-11, 13-21, 37-39

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
10 May 2006	18/05/2006

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Buchmann, G

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2006/001715

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 27-36
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

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

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2006/001715

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2004041131 A	21-05-2004	AU 2003287370 A1	07-06-2004
		CA 2502292 A1	21-05-2004
		EP 1567098 A2	31-08-2005
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		EP 1515655 A1	23-03-2005
		JP 2005529708 T	06-10-2005
		WO 2004000140 A1	31-12-2003