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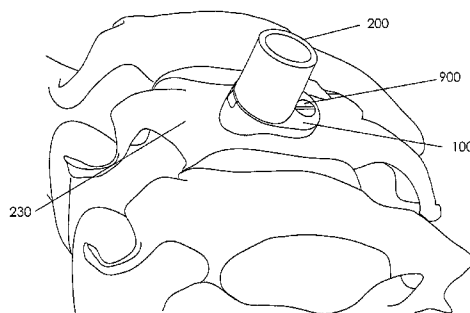


FIG. 6

(57) Abstract: A system and method are provided for making an access channel through a vertebral body to access a site of neural compression, decompressing it, and repairing the channel to restore vertebral integrity. System elements include an implantable vertebral plate, a guidance device for orienting bone cutting tools and controlling the path of a cutting tool, a bone cutting tool to make a channel in the vertebral body, a tool for opening or partially-resecting the posterior longitudinal ligament of the spine, a tool for retrieving a herniated disc, an implantable device with osteogenic material to fill the access channel, and a retention device that lockably-engages the bone plate to retain it in position after insertion. System elements may be included in a surgery to decompress an individual nerve root, the spinal cord, or the cauda equina when compressed, for example, by any of a herniated disc, an osteophyte, a thickened ligament arising from degenerative changes within the spine, a hematoma, or a tumor.



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**TRANSCORPOREAL SPINAL DECOMPRESSION AND REPAIR
SYSTEM AND RELATED METHOD**

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority to US Provisional Patent Application No. 60/972,192 of Lowry *et al.*, entitled "Transcorporeal spinal decompression and repair system and related method", as filed on September 13, 2007.

FIELD OF INVENTION

[0002] The invention relates to devices and methods of spinal surgery. More particularly, the invention provides an implant for use in spinal repair surgery and a method for preparing the vertebral volume to receive the implant.

INCORPORATION BY REFERENCE

[0003] All publications, patents and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication, patent or patent application was specifically and individually indicated to be incorporated by reference.

[0004] In particular, U.S. Patent Application No. 11/855,124 of Lowry *et al.* (filed on September 13, 2007, entitled "Implantable bone plate system and related method for spinal repair"), U.S. Provisional Patent Application 60/972,199 of Lowry *et al.* (filed on September 13, 2007, entitled "Device and method for tissue retraction in spinal surgery") as well as the U.S. Patent Application (Atty. Docket 10323.702.200) of the same inventors and title, being filed concurrently with the present application, U.S. Provisional Patent Application No. 60/976,331 of Lowry *et al.* (filed on September 28, 2007, entitled "Vertebrally mounted tissue retractor and method for use in spinal surgery"), and U.S. Provisional Patent Application No. 60/990,587 of Lowry *et al.* (filed on November 27, 2007, entitled "Methods and systems for repairing an intervertebral disk using a transcorporeal approach") are all incorporated by this reference.

BACKGROUND OF THE INVENTION

[0005] The performance of cervical discectomy, excision of tissue, and neural element decompression procedures have become standard neurosurgical approaches for the treatment of disorders of the spine and nervous system, as may be caused, for example, by disc degeneration, osteophytes, or tumors. The compressive pathologies impinge onto a neural element, causing a compression of nerve tissue that results in a symptomatic response such as loss of sensation or strength, occurrence of pain, or other related disorders. The majority of these procedures are performed with an anterior approach to the cervical spine. Disc and bone tissue are removed, a neural decompression is achieved, and a spinal repair procedure is performed.

[0006] The current conventional repair procedure includes a vertebral fusion in which a biocompatible implant is inserted and secured between the affected adjacent vertebrae. A bone plate is then rigidly

attached to the two vertebrae adjacent to the implant, immobilizing these vertebral segments and

preventing the expulsion of the implant from the intervertebral space. Subsequently, osteogenesis of the vertebrae into the implant occurs, and ultimately the adjacent vertebrae fuse into a single bone mass. The fusion of the vertebral segments, however, can lead to problematic results. For example, the immobility of the fused vertebral joint is commonly associated with the progressive degeneration of the adjacent segments, which, in turn, can lead to degeneration of the intervertebral discs on either side of the fused joint.

[0007] Implantation of an artificial disc device offers an alternate approach to vertebral fusion. The objective of the artificial disc device is to preserve the relative motion of the vertebrae across the joint and to restore normal articulating function to the spinal column. In spite of the benefits that these procedures have brought to patients, both fusion and disc replacement have inherent problems. The surgeries are extensive, recovery time is relatively long, and there is often a loss of function, particularly with the use of fusion implants. The long-term biocompatibility, mechanical stability, and durability of replacement disc devices have not been well established. Further, there is no clinical consensus that the use of a replacement disc reduces the risk of adjacent segment degeneration.

[0008] Methods for surgery on the spine and cervical discs from an anterior approach were first developed in the 1950's, and a number of variations have been developed since then. Each anterior cervical discectomy procedure, however, has had to face the challenge represented by removing the tissue overlaying the compressing lesion (*i.e.*, the herniated disc material, osteophyte or tumor) after having dissected through the soft tissue anterior to the spine. Early procedures exposed the compressing tissue by first making a cylindrical bone-and-disc defect in the spine centered on the disc space in sagittal and coronal planes, and generally following the plane of the disc itself. Later procedures made use of a rectangular, box-like defect in the disc space centered on the disc space and generally following the plane of the disc.

[0009] Procedures recently developed by Jho (referenced below) were motivated by the concern that procedures like those described above destroyed more of the natural disc tissue than was necessary to remove a laterally-positioned disc herniation or osteophyte (a bone spur). An alternative procedure, an uncovertebrectomy, was therefore developed that involved the removal of only the lateral-most aspect of the disc space, and the vertebral bone above and below it, which together comprise the entire uncovertebral joint. (See Choi *et al.*, "Modified transcorporeal anterior cervical microforaminotomy for cervical radiculopathy: a technical note and early results", *Eur. Spine J.* 2007 Jan 3; Hong *et al.*, "Comparison between transuncal approach and upper vertebral transcorporeal approach for unilateral cervical radiculopathy - a preliminary report", *Minim Invasive Spine Surgery*, 2006 Oct; 49 (5):296-301; and Jho *et al.*, "Anterior microforaminotomy for treatment of cervical radiculopathy: part 1: disc-preserving functional cervical disc surgery", *Neurosurgery* 2002 Nov; 51 (5 Suppl.): S46-53.) This new type of procedure allows much of the disc space to remain untouched. While preserving more of the disc space and disc material than its predecessor procedures, the uncovertebrectomy nevertheless does

obliterate the uncovertebral joint, and there is concern in the field regarding the eventual development of spinal instability at that disc level. Further, drilling bone at high speed adjacent to the nearby vertebral artery and sympathetic nerve process increases the concern of a higher risk of vertebral artery, secondary soft tissue injury, and Horner's Syndrome.

5 [0010] In another refinement of the uncovertebrectomy procedure, an anterior cervical microforamenotomy, the uncinat process and the lateral disc tissue may be left largely intact as a hole is drilled through the bone adjacent to the disc space near the uncinat process. In both uncovertebrectomy and anterior microforamenotomy, the exposure and decompression of the neural elements generally follow the plane of the disc space. While vertebral artery injury and spinal instability remain concerns
10 with both procedures, the risk associated with anterior microforamenotomy is considered less than that of uncovertebrectomy.

[0011] An additional refinement of both uncovertebrectomy and anterior microforamenotomy is a transcorporeal decompression procedure (also referred to as an upper vertebral transcorporeal foramenotomy or a transcorporeal discectomy) may have advantages. This procedure differs from its disc
15 space-preserving precedent procedures in several ways. First, the axis of the access hole drilled to expose the compressing pathology (*e.g.*, herniated disc fragment) does *not* parallel the plane of the disc, but instead entirely avoids the disc space plane anteriorly and captures the disc only at its most posterior aspect. Second, while uncovertebrectomy and anterior cervical microforamenotomy are applicable only to lateral pathology, the transcorporeal decompression is potentially applicable to compressing pathology
20 located laterally in the disc space region, bilaterally, or in the midline. Further, the procedure is performed from a substantially medial position on the vertebra assuring maximal distance from the vertebral artery and other sensitive soft tissue and thereby minimizing the risk of accidental injury.

[0012] Multiple technical challenges remain, however, in optimizing the transcorporeal cervical decompression procedure for general surgical use. First, manually orienting and controlling a hand-held
25 cutting tool to make an access channel is a subjective and error-prone procedure. The target pathology is wholly behind and/or within the bony structure of the vertebra and is not visible in any way when approached from a traditional anterior approach to the cervical spine. As the channel is essentially being driven blindly, it can easily fail to capture the targeted pathology being within the range of the posterior opening of the access channel. Consequently the surgeon needs to prolong the procedure, and explore the
30 space by excising tissue until the pathology is found. The exploration typically leads to the access channel becoming larger than necessary and undesirably irregular, thus putting surrounding bone at risk of fracturing during or after the procedure. Given the proximity of many target pathologies to the uncovertebral joint and the vertebral artery, it is likely that exploration of the space will lead to removal of the stabilizing bone and disc tissue. This tissue damage or loss can cause spinal instability, and may
35 further result in accidental perforation of the vertebral artery.

[0013] Second, a manual drilling process increases the risk of over penetration into the spinal canal, with highly undesirable consequences.

[0014] Third, the posterior longitudinal ligament, once exposed in the access channel, can be difficult to open. The objective is to remove the ligament cleanly from the access channel area so as to provide unobstructed visualization of the compressed neural tissue. Current surgical techniques are subjective and time-consuming, often producing a shredding of the ligament within the access channel rather than its removal therefrom, thereby impeding the visualization of the underlying target pathology or dura mater protective layer.

[0015] Fourth, currently available microsurgical instruments are not well-suited for retrieving the herniated disc or bone fragments that may be found deep to the posterior longitudinal ligament.

[0016] Fifth, after the decompression is complete, the present solutions for filling the void remaining in the vertebra are not completely satisfactory. Demineralized bone matrix putties or similar materials can fill the defect but they offer no resistance to the normal compressing or torsional forces until calcification occurs. Such materials may also impose a new source of compression on the exposed neural structures if too much putty is applied or if the vertebra deforms or sustains a compression fracture subsequently because of the absence of an implant that sufficiently resists compressive forces.

[0017] Sixth, after a solid implant plug is placed in the surgically-formed access channel, there is presently no anterior cervical plate suited to preventing its outward migration. Currently available anterior cervical plates are designed to be placed across two or more adjacent vertebrae at or near the midline, not laterally, as would be needed for lateral compressing lesions. Existing plates also are designed as motion-restriction or motion-prevention devices to be placed bridging across a disc space rather than onto a single vertebral body, consequently they are too large and are counterproductive in the application such as that described above where the objective is to preserve the articulation and relative motion of the adjacent vertebrae.

[0018] Accordingly, there is a need for a system and method whereby any compressing spinal pathology may be removed or moved so as to decompress the neural elements involved while desirably also (1) preserving native disc and bone tissue and the natural motion of the spine with natural disc material, (2) minimizing the risk of injury to the vertebral artery, (3) minimizing the risk of structural spinal instability, (4) minimizing the risk of an inadequate decompression, (5) minimizing the risk of injury to the protective dura mater layer, (6) minimizing the risk of post operative bleeding and/or (7) minimizing the risk of a subsequent vertebral body fracture due to an unrepaired defect within it.

SUMMARY OF THE INVENTION

[0019] The invention provides a system and method for forming and repairing an access channel through a vertebral body, typically a cervical vertebral body, for the purpose of gaining access to a site in need of a medical intervention. In its formation, the channel originates on the anterior surface of the vertebral body, and it then provides access from the anterior approach. The channel follows a prescribed trajectory to a prescribed exit on the posterior surface of the vertebral body, and provides an opening at the site of sufficient size to address the medical need. The access channel is typically formed in cervical

vertebral bodies. The nature of the medical need typically includes the need for a decompression procedure, as may occur as a result of a problematic portion or the whole of a herniated disc, an osteophyte, a thickened ligament, a tumor, a hematoma, a degenerative cyst, or any other compressing pathology. The medical intervention may be as minimal as observing the site, or performing exploration, or it may include a diagnostic procedure, or delivering a therapy, or it may include a surgery. A typical surgery performed through the access channel can include decompressing a neural element, such an individual nerve root, a spinal cord, or a cauda equina.

[0020] The system of the invention further includes an implantable bone repair device having an external geometry complementary to the internal geometry of the access channel, and a method for repairing or healing the channel by implanting such device. Some embodiments of the device include materials that are biocompatible, biologically absorbable, or any material known to be able to substitute for bone, and to be able to be stably and effectively integrated into bone. The device may further include as well as biologically active agents, such as osteogenic agents, that promote healing of the wound represented by the access channel, and fusion of the device such that it integrates into the vertebral body.

[0021] In some embodiments, the implantable bone repair device includes an assembly with a porous body that includes actual bone tissue. Such bone tissue may be provided by the bone removed during the formation of the channel itself, or it may come from another site from the patient as an autologous graft, or it may be provided by a separate donor.

[0022] The system to form and repair an access channel includes a bone cutting tool with a cutting element, a bone plate configured to be secured to the anterior surface of the vertebral body and having an opening sized to receive the cutting element; and a trajectory control sleeve configured to detachably engage the bone plate and having a cylinder configured to receive the cutting element. The bone plate and the trajectory control sleeve, when mutually engaged, are configured to cooperate to guide the cutting element to form the access channel with a prescribed trajectory from the anterior entry to the prescribed posterior opening.

[0023] Embodiments of a method for prescribing of the point of anterior entry and the channel trajectory toward the posterior opening are typically provided by a physician who observes the cervical spine of the patient radiographically. From such observation of patient anatomy and the site of pathological interest, the physician prescribes a trajectory according to a cranio-caudal axis and a medial lateral axis with respect to a point of entry on the anterior surface of vertebral body. Such radiographic observation may occur before the attachment of the bone plate, to be summarized below, and/or after the attachment of the bone plate.

[0024] Returning to summarizing the system for forming the access channel, some embodiments include fixation elements to secure the bone to the anterior surface of the vertebral body. The bone plate may include openings to accommodate fixation elements to secure the bone plate to the anterior surface of the vertebral body. In some embodiments, the bone plate and fixation elements are configured of a biocompatible material. In some embodiments, the bone plate and the fixation elements have a

[0025] Embodiments of the trajectory control sleeve may be configured to direct the bone cutting tool on a trajectory prescribed by the method above, the prescribed trajectory being an angle according to a cranio-caudal axis and a medial lateral axis with respect to a reference plane tangential to the access channel entry on the anterior surface of vertebral body.

[0026] Embodiments of the bone plate provide a reference plane such that the trajectory control sleeve, when secured to the bone plate, may be configured with a range of angles formed on two axes with respect to the plane of the bone plate, a cranio-caudal axis and a medial lateral axis, the range of the angles varying between about 1 degree and about 30 degrees from an angle perpendicular to the plate. In typical embodiments, the range of the angles varies between about 10 degrees and about 30 degrees from the perpendicular angle. In some embodiments, the system includes a plurality of trajectory control sleeves, the sleeves varying in regard to angles formed with respect to a plane represented by the bone plate when secured thereto, the angles ranging between about 10 degrees and about 30 degrees cranio-caudally from a perpendicular angle.

[0027] In some embodiments, the trajectory control sleeve and the bone plate have mutually-engageable features that orient the engagement of the trajectory control sleeve on the bone plate in a configuration that allows the trajectory control sleeve to guide the cutting tool into the vertebral body with the prescribed trajectory. And in some embodiments, the trajectory control sleeve includes a contact surface for engaging a corresponding surface on the bone cutting tool, the surfaces configured so as to limit the penetration of the cutting tool into the vertebral body to a prescribed depth.

[0028] In some embodiments, the posterior surface of the bone plate includes one or more penetrating elements configured to impinge into the vertebral bone tissue to improve fixation and resist the torsional forces associated with bone cutting procedures. In some embodiments, the bone plate includes an anatomically-orienting feature to establish the position of the bone plate relative to the medial centerline of the vertebral body. In some embodiments, the bone plate includes a biocompatible material. And in some embodiments, at least a posterior surface of the bone plate is of sufficiently porous composition to support in-growth of bone.

[0029] In various embodiments, the bone-cutting tool is any of a drill, a reamer, a burr, or cylindrical cutting tool, such as a core cutter or a trephine. In some of these embodiments, the cutting element of the bone-cutting tool has a cutting diameter of between about 5 mm and about 7 mm.

[0030] As noted above, embodiments of the implantable bone repair device have an external geometry complementary to the internal geometry of the access channel. These bone repair device embodiments may be sized to be insertable through an opening of the bone plate, the opening also being sized to receive the bone cutting element. In some embodiments, the bone repair device includes an abutting surface configured to engage a corresponding surface of the bone plate through which it is implanted, the engagement of these surfaces adapted to prevent the bone repair device from penetrating too deeply into

or through the access channel of the vertebral body. In some embodiments, the bone repair device includes receiving features in or on its anterior surface configured to accommodate the attachment of an insertion tool.

[0031] In some of these embodiments, bone repair device and the bone plate have mutually engageable orientation and locking features. In various embodiments, the locking engagement results from the application of an axial force to snap the locking feature into a corresponding retaining feature of the bone plate. In other embodiments, the locking engagement results from the application of a torsional force to engage the locking feature into a corresponding retaining feature in or on the bone plate.

[0032] In some embodiments of the surgical system the bone repair device comprises a porous cage with a porosity sufficient to permit through movement of biological fluids, such as blood, and bone cells. The composition of the porous cage portion of the device may include any of a polymer, a metal, a metallic alloy, or a ceramic. An exemplary polymer may polyetheretherketone (PEEK), which may be present in the form of PEEK-reinforced carbon fiber, or hydroxyapatite-reinforced PEEK. In some embodiments of the bone repair device with a porous cage, the porous cage device includes a closeable opening through which harvested bone material (such a native bone from the access channel site) may be passed. And in some of these embodiments, the porous cage device includes a closeable cap configured to increase pressure on the harvested bone within the cage as the cap is closed. Further, some embodiments include an internal element adapted to enhance compressive force applied to the contents of the porous cage upon application of compressive force to the cage, such force inducing extrusion of harvested bone and blood from within the cage through its porous structure to the external surfaces of the cage.

[0033] Some embodiments of the surgical system include a trajectory and depth visualization device. In some of these embodiments, the trajectory and depth visualization device includes a radio-reflective feature so as to confirm the location of the bone plate device on the appropriate vertebral body and to facilitate the extrapolation of the projected trajectory of the bone cutting tool using a radiographic image. In some embodiments, the trajectory and depth visualization device includes visual markings to indicate the distance from the point of contact with the vertebral body and cutter penetration control feature on the bone cutter guide device.

[0034] A method for performing a procedure through a vertebral body overlaying a site in need of a medical procedure includes attaching the bone plate on the anterior surface of the vertebral body, engaging the trajectory control sleeve to the bone plate, inserting a bone cutting tool through the trajectory control sleeve, and forming an access channel body by removing bone with the bone cutting tool (the channel having a centerline co-incident with the centerline of the trajectory control sleeve through the vertebral), disengaging the trajectory control sleeve from the bone plate, and performing the medical procedure through the open space provided by the access channel and the opening on the posterior surface of the vertebral body.

[0035] The access channel follows a prescribed trajectory from an anterior entry point to a prescribed opening on a posterior surface of the vertebral body in the locale of the site in need of the medical

procedure. The prescription for the points of entry and exit and the vectors of the access channel are determined by radiographic observations and measurements, as summarized above. In some embodiments of the method, forming the access channel includes forming the channel with a constant, circular cross-section along a single, straight axis aligned with the trajectory control sleeve.

5 [0036] Before engaging the trajectory control sleeve to the bone plate, the method may include selecting the sleeve to be used in the procedure such that when the sleeve and the bone plate are engaged, the sleeve has an angular orientation relative to the bone plate that is consistent with the prescribed trajectory of the access channel. Further, before attaching the bone plate to an anterior vertebral surface, the method may include exposing one or more vertebral bodies in a spinal column by anterior incision.
10 Further still, after performing the medical procedure, the method may include leaving the bone plate attached to the vertebral body.

[0037] In some embodiments of the method, after engaging the trajectory control sleeve to the bone plate, the method may include inserting a radiopaque locating device into the trajectory control sleeve device, radiographically observing the locating device and determining therefrom an extrapolated
15 trajectory of the access channel toward the posterior surface of the vertebral body, and verifying that the extrapolated trajectory is consistent with the prescribed trajectory such that the point of exit at the posterior surface is proximal to the targeted site of interest.

[0038] In some embodiments of the method, after engaging the trajectory control sleeve to the bone plate, the method may include inserting a depth-measuring device into the trajectory control sleeve device
20 to establish an optimal depth of penetration of the bone-cutting tool into the vertebral body, the depth being influenced by the disposition of the bone plate against a variable topography of the anterior surface of the vertebral body.

[0039] In some embodiments, after the completing the medical procedure through the access channel, the method further includes repairing the access channel with an implantable bone repair device, the
25 device having an external geometry complementary to the internal geometry of the channel. In typical embodiment of the method, repairing the access channel includes implanting the bone repair device through the bone plate and into the channel. And in some of these embodiments, the method includes securing a proximal portion of the bone repair device to the bone plate.

[0040] In some embodiments of the method, repairing the access channel includes in-growing bone
30 from the vertebral body into at least a portion of the surface of the bone repair device. And in some embodiments, repairing the access channel includes stimulating bone growth within the bone repair device by providing an osteogenic agent within the repair device.

[0041] In some embodiments of the method, repairing the access channel includes placing a portion of
35 harvested native bone tissue within a bone repair device that comprises a porous cage. In these embodiments, the method may further include allowing or promoting intimate contact between the bone tissue within the bone repair device and bone tissue of the vertebral body. The method may further

include perfusing at least some bone tissue or bone-associated biological fluid from the bone repair device into the vertebral body. Still further, the method may include healing together the harvested native bone tissue within the bone repair device and bone tissue of the vertebral body.

[0042] In some embodiments of the system, the bone plate and the trajectory control sleeve are an integrated or integrally-formed device. In this embodiment, thus the system includes a bone cutting tool with a cutting element and an integrated device comprising a bone plate portion and trajectory control sleeve portion. The bone plate portion is configured to be secured to an anterior surface of the vertebral body and has an opening sized to receive the cutting element. The trajectory control sleeve portion has a cylinder configured to receive the cutting element of the bone cutting tool, and the integrated device is configured to guide the bone cutting tool to form the access channel with a prescribed trajectory from the anterior entry to the prescribed posterior opening.

[0043] A method for performing a procedure through a vertebral body overlaying a site in need of a medical procedure with the integrated device summarized above includes attaching the integrated device on an anterior surface of the vertebral body, inserting a bone cutting tool through the trajectory control sleeve portion of the device, forming an access channel through the vertebral body by removing bone with the bone cutting tool, the access channel prescribed as summarized above, disengaging the integrated device from the bone plate, and performing the medical procedure through the access channel and the opening on the posterior surface of the vertebral body.

[0044] In some embodiments of the system and method, the bone plate or integrally formed bone plate portion does not lie directly over the anterior entry location for the access channel. Rather, the bone plate or bone plate portion is attached to the anterior surface of the vertebral body adjacent to the entry location, and supports a trajectory control sleeve or sleeve portion which may be located adjacent to the entry location.

BRIEF DESCRIPTION OF THE FIGURES

[0045] **Figure 1** is a view of an implantable bone plate device viewed from an anterior perspective.

[0046] **Figure 2** is a view of an implantable bone plate device viewed from a posterior perspective.

[0047] **Figures 3A and 3B** provide views of a trajectory control sleeve attachment. **Figure 3A** shows a trajectory control sleeve in a side view.

[0048] **Figure 3B** provides a side cross-sectional view of the trajectory control sleeve, showing how the angle of the sleeve relative to its base forms an asymmetrical opening in the base.

[0049] **Figure 3C** shows the trajectory control sleeve from a proximally-directed perspective.

[0050] **Figure 4** is an anterior perspective of the trajectory control sleeve mounted to an implantable bone plate.

[0051] **Figure 5** is a lateral view of the trajectory control sleeve mounted to an implantable bone plate.

[0052] **Figure 6** is a perspective view showing an implanted bone plate screwed a vertebral body and

[0053] **Figure 7** is an anterior view showing an implanted bone plate screwed to a vertebral body and a trajectory control sleeve mounted thereon.

[0054] **Figure 8** is a lateral view showing an implanted bone plate screwed to a vertebral body and
5 with a trajectory control sleeve mounted thereon.

[0055] **Figures 9A – 9B** show various views of a trajectory pin and a drill depth gauge. **Figure 9A** is a perspective view of a trajectory pin and a drill depth gauge assembled together

[0056] **Figure 9B** is a perspective view of an embodiment of the depth gauge sub-assembly.

[0057] **Figure 10** is a lateral view of the trajectory pin assembly shown in **Figure 9A** engaged in a
10 trajectory control sleeve.

[0058] **Figure 11** is a cross sectional view showing a trajectory pin in full engagement with vertebral bone and a trajectory control sleeve.

[0059] **Figure 12** is an anterior perspective view of a trajectory pin and depth gauge engaged within a trajectory control sleeve.

[0060] **Figure 13** is a cross section view showing a bone drill in position relative to a bone plate and
15 trajectory control sleeve prior to cutting bone tissue.

[0061] **Figure 14** is a perspective view of a bone plate after drilling has been completed and the trajectory control sleeve has been disengaged from the implanted bone plate.

[0062] **Figure 15** is a perspective view of a spinal repair implant in the pre-insertion position relative
20 to the implanted bone plate.

[0063] **Figure 16** is a perspective view of a spinal repair implant installed into an access channel through an implanted bone plate.

[0064] **Figure 17** is an anterior perspective view of an alternate embodiment of an implantable bone plate.

[0065] **Figures 18A and 18B** are views of the trajectory control sleeve mounted on the bone plate embodiment of **Figure 17**. **Figure 18A** shows the trajectory control sleeve and bone plate from distally directed perspective.

[0066] **Figure 18B** shows the trajectory control sleeve and bone plate from a side view.

[0067] **Figure 19** shows an implantable bone plate *in situ* on a vertebral surface.

[0068] **Figure 20** shows a perspective view of an implantable bone plate and trajectory control sleeve
30 *in situ* on the vertebra surface.

[0070] **Figure 21** shows a drill cutter engaging vertebral bone tissue through the trajectory control sleeve.

[0071] **Figure 22** shows an access channel through an implanted bone plate and into vertebral bone tissue.

5 [0072] **Figures 23 and 24** show an intra-vertebral repair device engaging vertebral bone through the bone plate. **Figure 23** shows the repair device being held by a surgeon immediately prior to inserting into the access channel.

[0073] **Figure 24** shows the surgeon's finger pressing the repair device through the bone plate and into the access channel.

10 [0074] **Figures 25A and 25B** show views of an intravertebral repair device embodiment with a proximal abutting surface orthogonal to the body of the device. **Figure 25A** shows the device from a proximally-directed perspective.

[0075] **Figure 25B** shows the device of **Figure 25A** from a distally-directed perspective.

15 [0076] **Figures 26A and 26B** show views of an intravertebral repair device embodiment with a proximal abutting surface canted with respect to main axis of the body of the device. **Figure 26A** shows the device from a side view.

[0077] **Figure 26B** shows the device of **Figure 26A** from a proximally-directed perspective.

20 [0078] **Figures 27A and 27B** show views of an intravertebral repair device embodiment with a convex external profile, wider in its central portion, narrower at proximal and distal ends. **Figure 27A** shows the device from a proximally-directed perspective.

[0079] **Figure 27B** shows the device of **Figure 27A** from a distally-directed perspective.

[0080] **Figure 28** shows the primary components of an exemplary system associated with the creation and repair of the intra-vertebral access channel.

25 [0081] **Figure 29** shows a typical access channel that may be produced with the inventive systems and methods.

[0082] **Figure 30** shows a cross sectional view of an access channel being formed in a vertebral body with a hollow cutting tool, a trephine, which forms an access channel with a removal bone plug.

[0083] **Figure 31** shows an exploded view of a bone repair device with a porous body configured to hold bone tissue, and to allow compression of the tissue upon closing the porous body.

30 [0084] **Figure 32** shows a cut away cross sectional view of the bone repair device of **Figure 31** in assembled form.

[0085] **Figure 33** shows an external view of the assembled bone repair device of **Figure 33** with bone tissue and associated fluid being extruded under pressure.

[0086] **Figure 34** shows an alternative embodiment of an assembled bone repair device with a porous body and with an internal pressure-amplifying feature.

[0087] **Figure 35** shows a bone repair device with a porous body containing bone tissue poised in a position from where it is about to be implanted in an access channel within a vertebral body.

5 [0088] **Figure 36** shows the bone repair device of **figure 35** implanted in the vertebral body, and locked into a bone plate.

[0089] **Figure 37** shows a lateral cross sectional view of a bone repair device with a porous body containing bone tissue, in situ, within an access channel in a host vertebral body.

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DETAILED DESCRIPTION OF INVENTION

[0090] An inventive surgical system and associated method of use are provided for transcorporeal spinal procedures that create and use an anterior approach to an area in need of surgical intervention, particularly areas at or near a site of neural decompression. Removal or movement of a source of compressing neural pathology is achieved via a surgical access channel created through a single vertebral
15 body instead of through a disc space or through an uncovertebral joint (involving 1 or 2 vertebrae). The access channel has a specifically prescribed trajectory and geometry that places the channel aperture at the posterior aspect of the vertebra in at or immediately adjacent to the targeted compressing pathology, thus allowing the compressing neural pathology to be accessed, and removed or manipulated. The access channel is formed with precise control of its depth and perimeter, and with dimensions and a surface
20 contouring adapted to receive surgical instruments and an implanted bone repair device.

[0091] The channel may be used to access and operate on the compressing pathology, more particularly to remove or to move a portion or the whole of a herniated disc, an osteophyte, a thickened ligament, a tumor, a hematoma, a degenerative cyst, or any other compressing pathology. As a part of the procedure, the posterior longitudinal ligament posterior to the transcorporeal access channel may be
25 opened or removed through the access channel, thereby permitting the visualization or removal of any compressing pathology otherwise obscured by the ligament.

[0092] The invention preserves native bone and disc tissue that is sacrificed by prior art procedures, and further preserves the natural motion of the vertebral joint. The procedure also preserves at least the anterior half of the vertebral endplate of the vertebral body upon which the cutting occurs. Removal or the
30 movement of the compressing pathology can proceed even when a portion of the compressing pathology resides beyond the limits of the transcorporeal access channel. Further, removal of the compressing pathology may occur without inducing posterior or inward compression on the dura mater protective layer surrounding the spinal cord and exiting nerve roots, or exerting direct pressure on the spinal cord or exiting nerve roots. Also, the compressing pathology removal may occur without lacerating the dura
35 mater protective layer surrounding the spinal cord and exiting nerve roots.

[0093] Embodiments of the system and method also pertain to therapeutic occupation and repair of the

vertebral body void created by making such an access channel. This repair is achieved by inserting an implantable vertebral repair device that has a conformation complimentary to the internal geometry of the access channel after the procedure is complete, and by securing the implant in the inserted position by means of a vertebral bone plate. The external surface of the vertebral repair device is in substantial contact with the internal surface of the access channel after insertion is complete, thereby substantially restoring structural and mechanical properties of the vertebrae. Such repair occurs without directly or indirectly inducing compression of underlying dura mater or neural structures. The repair further occurs without the subsequent anterior migration of the vertebral repair device, which could cause injury to soft tissue structures located anterior to the spine.

[0094] In some embodiments, the implanted device has a bioabsorbable composition that allows replacement of the implant device by in-growth of native bone tissue, or which is incorporated into the native bone tissue. As a whole the system increases the objectivity of considerations associated with spinal surgery, reduces patient risk, and contributes to better and more predictable surgical outcomes.

[0095] Various aspects and features of the invention will now be described in the context of specific examples and with the illustrations provided by **Figures 1 – 37**.

[0096] A number of tools and instruments are included in or used within the system and methods described herein. **Figure 28** shows some of these system elements: an implantable vertebral plate **100**, a cutting tool guide **200**, a confirmation device or depth gauge **300**, a collar **310** for the confirmation device, a cutting tool **400**, an implantable device **500**, and an implant locking device **600**.

[0097] An implantable vertebral plate **100** is adapted to attach to the anterior surface of a vertebra. A trajectory control sleeve **200** is adapted to detachably mount the implanted bone plate **100** to establish the entry point, trajectory, and depth of an access channel created through the vertebral body. A confirmation device **300** is adapted to temporarily engage the cutter tool guide for the purposes of confirming placement of the trajectory control sleeve on the correct vertebra, for visualizing the projected trajectory of the bone cutting device, and for measuring the actual distance between the trajectory control sleeve and the anterior bone surface so as to accurately and predictably penetrate through the vertebra without impinging on the dura-mater or other neural tissue at the posterior aspect of the channel. The pin-shaped confirmation device **300** is typically radio-reflective or radiopaque, thus allowing confirmation of all geometries on a surgical radiograph taken prior to the excision of any tissue.

[0098] A cutting tool **400** is generally adapted to remove bone material and create the vertebral access channel; the tool **400** has the precise cutting geometry necessary to produce the prescribed access channel geometry within the vertebral bone. The access channel provides various forms of advantage for aspects of procedures as described further below.

[0099] A surgical cutting instrument is used to open or partially remove the posterior longitudinal ligament which can obscure a view of the pathology of interest, but becomes observable by way of the access channel. A cutting tool used to remove osteophytes (bone spurs) at or adjacent to the base of the

vertebral body can be approached by way of the access channel proximal to the neural elements to be decompressed. An instrument for grasping or moving herniated disc material or other compressing pathology can be provided access to the site located at or near the base of the access channel.

[00100] An implantable bone repair device **500** is adapted repair the vacant vertebral volume created by the formation of the access channel.

[00101] An implant locking device **600** is adapted to retain the implant in the desired position. The locking device is adapted to positively engage the anterior surface of the repair implant and engagably lock it in place with respect to the implanted bone plate device **100**. Fasteners such as elements **600** and **900** (seen in later figures) are applied to retain a bone plate or locking cap (see in other figures) in a desired position.

[00102] Each of these aforementioned system elements and their role in surgical procedures on the spine are described in further detail below.

[00103] **Figures 1 and 2** show anterior and posterior views, respectively, of an implantable transcorporeal bone plate device **100** with a first or anterior facing surface **101** and a second or posterior facing surface **102**, the posterior facing surface being configured to be proximal or in contact with the anterior surface of a vertebral body after implantation. The device further has one or more holes **103** that form an aperture between surfaces **101** and **102** to accommodate and secure retention screws there to secure the device **100** to vertebral bone.

[00104] Embodiments of implantable bone repair described and depicted herein are may include a multiple number of orifices, as for example, for inserting attachment elements, or for viewing, that have various sizes and typically are circular or ovular in form. These are merely exemplary forms and profiles of openings which may vary depending on particulars of the application of the device, such that size and profile may vary, and for example, by taking the form of any of circular, trapezoidal, multilateral, asymmetrical, or elongated openings.

[00105] The device also has a passage **104** for receiving and detachably-engaging a bone cutting guide device such as a drill or ream. The device **100** further may have one or more engaging features **105** configured to receive and engage a corresponding feature on the trajectory control sleeve in a manner that prevents relative motion of the trajectory control sleeve and its accidental disengagement from the implanted bone plate. The device may have one or more protrusions **106** on the posterior surface (**Figure 2**), the protrusions being adapted to impinge into or through the cortical bone so as to increase the stability of the implant on the bone and to allow for temporary placement of the device prior to insertion of the bone screws through the opening **103**. Protrusions **106** further act to stabilize the bone implant and to transfer loads around the vertebral access channel after a surgical procedure is complete, thereby further reducing the risk of bone fractures or repair device expulsion.

[00106] **Figures 3A – 3C** show a side view and perspective view, respectively, of an embodiment of a trajectory control sleeve **200** for a bone cutting tool, a rotary cutting tool, for example, such as a drill,

burr, reamer, or trephine. **Figure 3A** shows a trajectory control sleeve in a side view, while **Figure 3C**

shows the trajectory control sleeve from a proximally-directed perspective. The trajectory control sleeve **200** has an internal cylinder **202** there through to allow passage of a bone-cutting tool, such as a drill or trephine, and to establish and control the angle α of penetration of the drill through a vertebral body. As

seen in **Figure 3B** the angle α refers to the angular difference from a right angle approach with respect to the plane formed by an implantable bone plate **100** to which the trajectory control sleeve is engaged.

More specifically, angle α can represent a compound angle according to a cranio-caudal axis and a medial lateral axis with respect to a reference plane tangential (such as would be represented by an implanted

bone plate) to the access channel entry on the anterior surface of vertebral body. The angle α is prescribed

by a physician by making use of radiographic images of the spine that focus on the target vertebrae and the underlying pathology that are the subject of surgical or diagnostic interest. Such procedures are

typically performed prior to surgery, and they may be repeated after the bone plate is attached to the

surgical site. **Figure 3C** provides a cross sectional view of an exemplary control sleeve **200**, which shows

the tilt of the annular ring **203** in accordance with angle α , and the consequent off-center opening at the

base of the trajectory sleeve, which generally aligns with the base of the bone plate when the two components are engaged.

[00107] In some embodiments of the system and method, a transcorporeal access channel is formed

using a trephine type device such as those provided by Synthes, Inc (West Chester PA), which offers particular advantages. The trephine device produces a cylindrical channel through the vertebral bone

while maintaining the core to be removed in an intact state. The core can be removed from the trephine after the tool itself has been removed from the vertebral body, and the bone tissue can be subsequently re-used as graft volume after the surgical procedure is completed.

[00108] Trajectory control sleeve **200** has a surface **201** adapted to be in intimate contact with and be co-planar to an anterior facing surface **101** of a bone plate implant device **100** (after engaging the device,

as in **Figure 4**) so as to assure that the axial distance **d** is well established and controlled. The trajectory

control sleeve **200** further has an annular abutting surface **203** surrounding the opening of the internal cylinder **202**, the surface being adapted to positively engage a corresponding feature such as a flange or collar of the drill so as to prevent its over-penetration into the vertebral body. This abutment may be

internal or external to the guide device as shown in **Figure 4** and **Figure 3A** respectively. Trajectory

control sleeve **200** also has an engaging and interlocking feature **204** adapted to detachably-engage a corresponding feature **105** (see **Figure 5**) on the implantable bone plate **100**. The trajectory control sleeve

200 is further generally adapted to protect surrounding vascular and soft tissue from accidental injury or cutting by providing a solid protective sheath around the sharp edges of the drill while it is operating.

[00109] **Figures 4 and 5** show a perspective view and side view, respectively, of trajectory control

sleeve **200** and an implantable bone plate **100** in their mutually interlocked positions. **Figure 4** shows the internal cylinder **202** for providing access, guiding and controlling the penetration of a drill into vertebral

bone. **Figure 4** further shows an alternate embodiment of the device that has an abutting surface **203**, in

which the abutting surface is internal to the trajectory control sleeve. **Figure 5** shows the planar engagement of the anterior surface of an implanted bone plate **101** with the corresponding surface **201** of the trajectory control sleeve. This engagement establishes a reference plane **210** from which angle α and distance **d** are controlled and referenced relative to the vertebral body. **Figure 5** further shows the engagement of the detachable locking features **205** of the trajectory control sleeve and of the bone plate **105**.

[00110] **Figures 6 – 8** relate to the placement of a mutually-engaged bone plate **100** and a trajectory control sleeve **200** to a vertebral body **230**, in preparation for creating an access channel through the vertebral body. **Figure 6** provides a surface perspective view of bone plate **100** in an implanted position on a vertebral body **230**, the plate secured by a bone screw **900**, and further shows trajectory control sleeve **200** in its engaged position on the bone plate **100**. **Figure 7** shows an anterior view of a bone plate **100** and trajectory control sleeve **200** mutually engaged and, the engaged assembly in its installed position on vertebral body **230**. A bone screw **900** is inserted at or near the medial centerline **231** of the vertebral body **230**, thus positioning the center point **220** of the trajectory control sleeve cylinder at a prescribed distance **l** from the centerline. As seen in **Figure 8**, an angle β is the complement to angle α shown in **Figure 5**. After installation of the bone plate implant **100** on a vertebral body **230**, the reference plane **210** may be delineated relative to the vertebral body **230** and as a baseline reference for the angle and depth of drill penetration into the vertebral body.

[00111] **Figures 9A and 9B** show a pin or plug type confirmation device **300** used for confirming vertebral position prior to excision of bone or other tissue and a collar **310** into which the confirmation device is inserted. A standard procedure in spinal surgery is to insert a radiographically reflective screw or pin into the vertebral body and to take an x-ray of the cervical spine prior to beginning any procedure so as to assure that the procedure is being performed at the correct vertebral level. In the embodiment described the confirmation device **300** is slidably inserted within the internal diameter of the control sleeve **200** and progressed axially therethrough until the proximal end of the device **300** is in contact with the anterior surface of the vertebral body. A radiographic image is taken inter-operatively and reviewed prior to the excision of any vertebral bone tissue. The examination includes an extrapolation of the trajectory through the vertebral body so as to confirm that the actual point of exit at the posterior surface of the vertebra is at the surgically prescribed location. Further, the axial distance from the both the anterior and/or posterior surfaces of the vertebra are measured and used as references to control the depth of bone cutting necessary to produce the access channel and to prevent over penetration into the dura mater or neural tissue. In some instances the device **300** may be used during the bone cutting procedure as a checking device to determine the actual progression of the channel across the vertebra.

[00112] **Figure 9B** shows a trajectory confirmation pin **300** and a collar **310** that slidably-engages the external diameter of the pin by way of features **320** that engage complementary features **321** on the internal diameter of the collar. In this exemplary embodiment, the trajectory pin features **320** are convexities that are complementary to concave collar feature **321**. Collar **310** can slide axially along the

length of the pin diameter **320** and frictionally-engage the pin diameter in a manner that requires an axial force to be applied to the collar to induce axial movement. Collar **310** has a surface of engagement feature **330** that is adapted to make intimate contact with the annular surface **203** of the trajectory control sleeve when the pin is inserted into the trajectory control sleeve. Once surfaces **203** and **330** are engaged, insertion force **F** (**Figure 9A**) applied by a surgeon causes pin **300** to travel axially through the internal diameter of collar **340**, increasing the distance **L2** between point **350** on the tip of the pin and the control surface **330** of the collar **310**.

[00113] **Figures 10 – 12** relate to the use of a trajectory confirmation pin **300**, a collar **310**, and trajectory control sleeve **200** in the context of a bone plate **100** in place, as implanted in a vertebral body **230**. An embodiment of a pin device **300** is temporarily inserted into the internal cylinder of the trajectory control sleeve **200** and an x-ray is taken. The x-ray confirms the location of the vertebral body **230** and an anterior-to-posterior extrapolation along the centerline of the device through the image of vertebral body indicates the trajectory of the drill or cutting tool and the projected point of exit at or near the posterior longitudinal ligament. Angular and distance measurements may be made using the radiograph, and if adjustments are required, the surgeon disengages the trajectory control sleeve and installs another device with the desired geometry.

[00114] **Figure 11** shows the confirmation pin **300** at its maximum depth of penetration through the transparently rendered trajectory control sleeve **200** and bone plate implant **100**. In this position, tip **350** of the pin device is in intimate contact with the surface of the vertebral bone **230**. Because of the mechanical engagement of the collar **310** on the external surface, the collar remains in position relative the bone-contacting tip of the pin **350**. Upon removal of the pin, distance **L2** (see **Figure 9A**), as measured between the collar surface **330** and the pin contact tip **350**, provides a reference dimension with which the penetrating depth of the bone drill can be controlled by setting a mechanical stop that engages the annular surface **203** of the trajectory control sleeve. For ease of use, the surface of the confirmation pin **300** may have linear graduations.

[00115] **Figure 13** shows a bone cutting tool **400**, such as a drill, burr, or reamer, inserted through the trajectory control sleeve **200** and the bone plate implant **100** with the tip of the cutting tool **420** at the initial point of contact on the vertebral body. Cutting tool **400** has a mechanical stop **450**. The distance **D4** from the drill tip **420** to the lower surface **430** of the drill stop **450**, is a prescribed dimension equivalent to the measured distance **L2** (see **Figure 9A**) plus the desired depth of penetration into the vertebral body, such depth being established by the surgeon through radiographic analysis.

[00116] **Figure 14** shows a surgical access channel **470** in a vertebral body **230**, as viewed through the bone plate implant **100** after drilling has been completed and the trajectory control sleeve has been removed from the plate. After removal of the trajectory control sleeve, a neural decompression or other surgical procedure is performed through the access channel. On completion of the procedure, an intra-vertebral bone implant **500** is inserted (**Figures 15 and 16**) into access channel **470** to fill and close it, restore mechanical strength and stability to the host vertebral body **230**, and to provide a medium within

[00117] In some embodiments of the invention, the intra-vertebral access channel 470 (**Figure 14**) of an implantable bone plate has a diameter of about 5 mm to about 8 mm. This size creates a surgical field that is sufficiently open enough for typical procedures, and is sufficiently large enough to minimize the

5 possibility that the access channel will not intersect the area of neural compression. In some embodiments, the angle of entry α provided by the access channel is about 10 – 30 degrees, with the center of the point of entry being generally at mid-point on the cranio-caudal length of the vertebra. While these dimensions are typical, alternative embodiments of bone plate implants may have varying widths and geometries so as to accommodate wide anatomical variations. In various alternative embodiments, trajectory control sleeve devices also may include a wide range of angles and depths for the same reason.

[00118] With a combination of the angle of entry, the point of entry into the vertebral body, and the size of drill used to create the access channel 470, some embodiments may result in a penetration of the posterior disc space in the posterior 20% – 30% of the disc volume 480, leaving the vertebral end plate 490 and the native disc tissue 495 substantially intact. **Figure 29** illustrates a typical access channel 470
15 that may be formed using a 6 mm drill diameter, about a 10 degree angle of entry, with an entry point on the cranio-caudal centerline of the vertebral body.

[00119] **Figure 15** shows an intra-vertebral implantable bone repair device 500 positioned for implantation within the vertebra 230 through the bone plate implant 100. Various embodiments and features of a bone repair device are described in U.S. Provisional Patent Application No. 60/990,587 of
20 Lowry *et al.* (filed on November 27, 2007, entitled "Methods and systems for repairing an intervertebral disk using a transcorporal approach"), which is incorporated herein in its entirety by this reference. In the embodiment shown, implant 500 has an abutting surface 520 adapted to engage with a corresponding surface of the bone plate implant. This arrangement prevents excess penetration of the implant through the access channel and prevents the implant from compressively engaging neural elements. **Figure 16**
25 shows the implantable device 500 in the final installed position relative to the bone plate 100. The device 500 has a locking mechanism 510, such as a conventional bayonet mount, for engaging the bone plate in order to prevent migration of the implant within or out of the access channel.

[00120] **Figure 17** shows an alternative embodiment 620 of an implantable bone plate as previously described and shown in **Figures 1 and 2**. In this present embodiment, bone plate 620 has a larger lateral
30 dimension to accommodate particular anatomies that may be encountered, including those of patients, for example, with small stature, degenerative bone conditions, or osteophytes or other abnormalities that may require alternate fixations. To assure accurate location of the device relative to the medial centerline of the vertebra, implant device 620 may include a viewing port 650 or some other positioning indicator. **Figures 18A and 18B** show anterior perspective and side views, respectively, of the engagement of a
35 trajectory control sleeve 200, as previously described, with the alternative bone implant device embodiment 620.

[00121] In another alternate embodiment, an implantable bone plate and bone cutting device may be

formed as a unitary device and temporarily fixed to the vertebral body. In this embodiment an intra-vertebral access channel is created using the temporarily implanted device; subsequently, the device is removed, the surgical procedure performed, and the access channel repaired using the intra-vertebral implant as previously described. In this embodiment, a bone cutting device may have a least two cutting diameters or widths, the first being that necessary to produce the access channel, the second being a larger diameter configured to remove an annulus of bone on the anterior vertebral surface so as to provide an abutting surface against which the implant would rest in order to prevent over-penetration of the intra-vertebral repair implant within the vertebra.

[00122] Figures 19 – 24 show exemplary devices being put to exemplary use to evaluate the practical viability, fit, and the functionality of methods for their use. Figure 19 shows an implantable bone plate 100 *in situ* on a vertebral surface 230. Figure 20 shows a perspective view of the implantable bone plate and trajectory control sleeve 200 *in situ* on the vertebral surface. Figures 21 – 24 include a view of surgeon's finger to show scale and feasibility of manual manipulation of elements of the inventive system. Figure 21 shows a bone cutting tool 400 engaging vertebral bone tissue through the trajectory control sleeve 200. Figure 22 shows an access channel 470 through the implanted bone plate and into vertebral bone tissue. Figure 23 shows an intra-vertebral repair device 500 being readied for engaging vertebral bone through the bone plate 100.

[00123] Figures 25A – 27B show embodiments of alternative external geometries of the intra-vertebral implantable devices 500 as may appropriate for particular patients or procedures. Figures 25A and 25B show views of what may be considered a default embodiment of an intravertebral repair device with a proximal abutting surface orthogonal to the body of the device. Figure 25A shows the device from a proximally-directed perspective, while Figure 25B shows it from a distally-directed perspective. Figures 26A and 26B show an embodiment wherein abutting surface 520 is canted at an angle not orthogonal to the central axis of the device 500. Figures 27a and 27b show an intra-vertebral implant device 500 with a convex external profile where dimension D4 is nominally larger than the internal diameter of the access channel so as to compressively engage the cancellous bone tissue. Such a compressive engagement can improve the interference fit of the device therein and to inter-diffuse cancellous bone tissue within the implant volume to improve osteogenesis.

[00124] Figure 28 shows an assemblage of some of these system elements, and was described at the outset of the detailed description; shown is an implantable vertebral plate 100, a cutting tool guide 200, a confirmation device or depth gauge 300, a collar 310 for the confirmation device, a cutting tool 400, an implantable device 500, and an implant locking device 600. Figure 29 provides an exemplary embodiment of the invention that was discussed earlier in the context of the formation of an access channel, in conjunction with associated description of Figures 14 – 16.

[00125] Implantation of the patient's own bone tissue (an autologous graft) is a generally advantageous approach to repairing bone, as autologous grafting typically yields high success rates and a low rate of surgical complications. Accordingly, some embodiments of the invention include using core bone tissue

harvested from the forming of the access channel, and implanting the plug, intact, in the form of bone repair graft. An advantage to recovering and making use of bone derived from the channel includes the absence of a need to harvest bone from a second site. Embodiments of the invention, however, do include harvesting bone from secondary sites on the patient, such as the iliac crest, as may be appropriate in the practice of the invention under some circumstances. In some embodiments, for example, it may be advantageous to supplement bone derived from the access channel with bone from other sites. In still other embodiments, under various clinical circumstances, it may be appropriate to make use of bone from donor individuals. Bone from other autologous sites or other donor individuals may be used as a repair device in the form of an appropriately formed plug, or bone may be fragmented or morselized, and packaged as a solid plug, or bone may be included as a preparation provided in a porous cage, as described further below.

[00126] Some embodiments of methods provided make use of a trephine type bone cutting system, as noted above. With a trephine bone cutting system, the external diameter of the bone tissue core is about equal to the internal diameter of the trephine device, while the internal diameter of the access channel is about equal to the external diameter of the device. Thus, a trephine-derived bone plug from forming the access channel provides an appropriately-sized piece to be inserted into the channel for repair and healing, but does not necessarily make intimate contact with the inside surface of the channel due to the width of the kerf created by the trephine.

[00127] Optimal healing and recovery from implantation of bone material into an access channel occurs when there is an intimate or compressive engagement of the graft material with the vertebral bone tissue (substantially cancellous bone), as this intimate association provides for rapid blood perfusion and bone healing while providing mechanical support during healing. Accordingly, an embodiment of the bone repair device provided herein includes a device with bone tissue inside a porous cage, as described in detail below.

[00128] The porosity of the cage is a particularly advantageous feature for allowing cell to cell contact through the boundary of the device. To some degree, it may also allow cell migration, however the most advantageous factor in promoting rapid healing is cell to cell contact that initiates sites of tissue unification, which can then spread, stabilize a healing zone around the graft or bone repair device, and ultimately lead to effective fusion and integration of the graft within the host vertebral body.

[00129] A porous cage, as provided by this invention, also has a compressibility, such that when the contents of the cage are subject to a compressive force, however transient and minimal, blood or plasma and bone cells that are present in the harvested cancellous bone are forced outward into the environment within and around the access channel site. Extrusion of biological fluid in this manner, advantageously packs bone tissue closer together within the cage, and bathes the periphery of the graft and the host-graft intersectional zone with a medium that is optimal for exchange of dissolved gas and nutrients that are critical in the initial stages of healing. Some embodiments of the invention include bathing the bone tissue preparation in a supportive liquid medium before implantation. Such bathing may occur prior to placing

the bone tissue preparation in the porous cage and/ or after placing the preparation in the cage. The liquid medium may be any appropriate cell culture medium, and may be further supplemented with biological agents, such as osteogenic agents or other growth factors.

[00130] Embodiments of the implantable porous cage bone repair device, as provided herein,

5 encapsulate the bone tissue contained therein, and provide mechanical stability to the access channel during healing. These embodiments compensate for the volumetric loss associated with the bone cutting process of the trephine and promote contact between the bone volume within the device and the surrounding vertebral bone tissue. The device, as a whole, and like other bone repair embodiments provided, cooperates with the implanted bone plate so that the orientation and penetration depth of the
10 implant device within the access channel may be controlled. These forms of control assure that the device does not over-penetrate through the channel, thereby compressing the dura mater or neural elements within the vertebra, and assuring that the implanted device cannot migrate in an anterior direction out of the access channel.

[00131] Exemplary embodiments of the porous cage device and associated method of use will now be
15 described in further detail, and in the context of **Figures 30 – 37**.

[00132] **Figure 30** provides a cross-sectional view of a vertebral body **809** with a bone plate **801** attached to the anterior bone surface **810**. Mounted on the bone plate is a trajectory control sleeve **802** cooperating with the bone plate **801** to establish and control the trajectory of a bone cutting tool **804** with a cutting surface **808** through the vertebral body to direct the trajectory of the formed access channel to a
20 prescribed point of exit at the posterior surface of the vertebra **820**, in the locale of a site of medical interest.

[00133] The depicted exemplary bone cutting tool **804** is a hollow bone cutting tool, a trephine, with an external diameter **805** selected to be complementary to the internal diameter of the trajectory control sleeve **802**, and to cooperate therewith so as to assure that the centerlines of the bone cutting tool and the
25 trajectory control sleeve are substantially co-incident during the bone cutting process. The trephine **804** progresses through the vertebral body **820** from an anterior to posterior direction until the cutting surface **808** penetrates the cortical bone at the posterior surface of the vertebra proximal to the spinal cord **850**. Upon removal of the trephine from within the vertebral body, a core of bone tissue within the interior of the trephine is extracted from the wound opening, thus creating or exposing an open access channel from
30 the anterior surface of the vertebral body to the neural elements and the prescribed site of medical interest immediately behind the posterior wall of the same vertebral body.

[00134] **Figure 31** shows components of an exemplary bone repair device in a linearly exploded view from an external perspective. At the top, a cap **950** is above a vertebral bone core **860**; the bone core is positioned for placement in a porous cage **900**. **Figure 32** is a cross-sectional view of the fully assembled
35 device **905**. According to the inventive method, the vertebral bone core **860** is placed within an implantable intravertebral bone repair device **900** with a porous wall, and encapsulated by a cap or closing element **950**. In this exemplary embodiment the cap has a screw thread **951** disposed to engage a

mating thread **901** on the body **900** of the implantable device; the cap further has a compression element **952** disposed to exert a compressive force **F** on the bone graft core **860** when the cap is being closed on the body **900** of the repair device, and consequently inducing extrusion of native tissue within the device, through open pores **902** contained within the perimeter wall of the implant device. As described above, the bone tissue placed within the body of the repair device is not necessarily an integral bone plug intact from the trephine used to form the channel; the bone tissue may be a fragmented or morselized preparation, it may include bone from another site on the patient, and it may include bone from another donor.

[00135] **Figure 33** provides an external perspective view of an assembled bone repair device **905**. This view captures a moment shortly after the cap **950** has been closed, and by such closing has increased the pressure on the bone tissue contained within the device. By virtue of this elevated pressure within the porous walled body **900**, bone core graft tissue and associated biological fluid are extruding through the porous perimeter wall. In some embodiments of the method, the cap **950** is closed on the porous body **900** of the repair device immediately prior to insertion of the assembled device **905** into the access channel within the host vertebral body, and in some embodiments of the method, the cap is closed after insertion of the porous body **900**, thereby forming the complete assembly **905 in situ**.

[00136] **Figure 34** shows a cross sectional view of an alternate embodiment of the porous body portion **900'** of an assembled repair device **905'** that includes an internal tissue expander feature **920** disposed to induce radial extrusion of the bone core tissue through the orifices.

[00137] **Figures 35 and 36** show similar views of the porous cage device embodiment **905** as were provided earlier by **Figures 15 and 16** for solid bone repair device **500** embodiments. **Figure 37** shows a cross sectional view of the implanted device **905** within an intravertebral access channel **470**. Upon completion of the surgical procedure through the access channel, the bone repair implant assembly **905** (containing the harvested bone graft core **860**) is introduced into the transcorporeal access channel through the aperture **830** in the implanted bone plate device **100**. In one exemplary embodiment, the bone repair assembly **905** has an abutting surface disposed to cooperate with a mating surface of engagement **871** on the bone plate implant. The completed mating of the bone repair assembly **905** with the bone plate **100** prevents the distal tip **890** of the implant assembly from penetrating into the spinal cord volume posterior to the vertebral body.

[00138] The implantable repair device assembly **905** further has an orientation and locking feature **951** disposed to engage a mating feature **950** on the implantable bone plate **100** so as to control the radial orientation of the implant with respect to the bone plate and to lockably engage the bone repair implant device with the bone plate implant so as to prevent migration or expulsion of the bone repair implant assembly **905** out of the access channel. Such radial orientation of the implant relative to the access channel may be particularly advantageous when the bottom or distal end of the repair device body **900** is formed at an angle (not shown) to completely fill the access channel.

[00139] As a consequence of the implantation of the bone repair assembly **905** within the access

channel, the general mechanical integrity of the vertebral body has been restored, the internal void of the access channel has been filled in a manner such that native disc material **980** cannot migrate into the channel, bone tissue (typically autologous) has been re-implanted in a manner that establishes intimate contact between the bone graft and the cancellous bone of the vertebra thereby promoting blood perfusion and rapid bone healing.

5

CLAIMS

What is claimed is:

1. A surgical system to form and repair an access channel through a vertebral body, the channel
5 having an anterior surface entry and a posterior surface opening, the system comprising:
a bone cutting tool with a cutting element;
a bone plate configured to be secured to the anterior surface of the vertebral body; and
a trajectory control sleeve configured to detachably engage the bone plate and having a cylinder
10 configured to receive at least a portion of the bone cutting tool, the bone plate and the trajectory
control sleeve, when mutually engaged, configured to cooperate to guide the cutting element to
form the access channel with a prescribed trajectory from the anterior entry to the prescribed
posterior opening.
2. The surgical system of claim 1 further including fixation elements to secure the bone plate to the
anterior surface of the vertebral body, the plate and fixation elements configured such that the bone
15 plate may be permanently implanted.
3. The surgical system of claim 1 wherein the bone plate includes openings to accommodate fixation
elements to secure the bone plate to the anterior surface of the vertebral body.
4. The surgical system of claim 1 wherein the trajectory control sleeve is configured to direct the bone
cutting tool on the prescribed trajectory, the prescribed trajectory having an angle according to a
20 cranio-caudal axis and a medial lateral axis with respect to a reference plane tangential to the access
channel entry on the anterior surface of the vertebral body.
5. The surgical system of claim 4 wherein the angle is a compound angle.
6. The surgical system of claim 1 wherein the bone plate provides a reference surface and wherein the
trajectory control sleeve, when secured to the bone plate, may be configured with a range of angles
25 formed with respect to the surface of the bone plate on two axes, a cranio-caudal axis and a medial
lateral axis, the range of the angles varying between about 1 degree and about 30 degrees from a
perpendicular angle.
7. The surgical system of claim 6 wherein the range of the angle varies between about 10 degrees and
about 30 degrees from the perpendicular angle.
- 30 8. The surgical system of claim 1 including a plurality of alternately attachable trajectory control
sleeves, the sleeves varying in regard to an angle formed with respect to a plane represented by the
bone plate when secured thereto, the angles ranging between about 1 degrees and about 30 degrees
from a perpendicular angle.
9. The surgical system of claim 1 wherein the trajectory control sleeve and the bone plate have

mutually-engageable features that orient the engagement of the trajectory control sleeve on the bone plate in a configuration that allows the trajectory control sleeve to guide the cutting tool through the vertebral body along the prescribed trajectory.

10. The surgical system of claim 1 wherein the trajectory control sleeve includes a contact surface for engaging a corresponding surface on the bone cutting tool, the surfaces configured so as to limit the penetration of the cutting tool into the vertebral body to a prescribed depth.
11. The surgical system of claim 1 wherein the posterior surface of the bone plate includes one or more penetrating elements configured to impinge into the vertebral bone tissue.
12. The surgical system of claim 1 wherein the bone plate includes an anatomically-orienting feature to establish the position of the bone plate relative to the medial centerline of the vertebral body.
13. The surgical system of claim 1 wherein the bone plate includes a biocompatible material.
14. The surgical system of claim 1 wherein at least a posterior surface of the bone plate is of sufficiently porous composition to support in-growth of bone.
15. The surgical system of claim 1 wherein the bone-cutting tool is any of a drill, a ream, a core cutter or a trephine.
16. The surgical system of claim 15 wherein the cutting element of the bone-cutting tool has a cutting diameter between about 5 mm and about 7 mm.
17. The surgical system of claim 1 further comprising an implantable bone repair device having an external geometry complementary to the internal geometry of the access channel.
18. The surgical system of claim 17 wherein the bone repair device is sized to be insertable through an opening of the bone plate, the opening being sized to receive the bone cutting element.
19. The surgical system of claim 17 wherein the bone repair device includes a bio-compatible material.
20. The surgical system of claim 17 wherein the bone repair device includes a bio-absorbable material.
21. The surgical system of claim 17 wherein the bone repair device includes an osteogenic agent.
22. The surgical system of claim 17 wherein the bone repair device and the bone plate have mutually engageable orientation and locking features configured to form a locking engagement.
23. The surgical system of claim 22 wherein the locking engagement results from the application of an axial force to snap the locking feature into a corresponding retaining feature of the bone plate.
24. The surgical system of claim 22 wherein the locking engagement results from the application of a torsional force to engage the locking feature into a corresponding retaining feature in or on the bone plate.

25. The surgical system of claim 17 wherein bone repair device includes receiving features in or on its anterior surface configured to accommodate the attachment of an insertion tool.
26. The surgical system of claim 17 wherein the bone repair device comprises a porous cage with a porosity sufficient to permit through movement of blood and bone cells.
- 5 27. The surgical system of claim 26 wherein the composition of the porous cage comprises any of a polymer, a metal, metallic alloy, or a ceramic.
28. The surgical system of claim 27 wherein the polymer of the composition may include polyetheretherketone (PEEK), PEEK-reinforced carbon fiber, or hydroxyapatite-reinforced PEEK.
29. The surgical system of claim 26 wherein the porous cage device includes a closeable opening
10 through which bone material may be passed.
30. The surgical system of claim 26 wherein the porous cage device includes a closeable cap configured to increase pressure within the cage as the cap is closed.
31. The surgical system of claim 26 wherein the porous cage device includes a minimally compressive internal element adapted to enhance compressive force applied to contents of the porous cage upon
15 application of compressive force to the cage.
32. The surgical system of claim 1 further comprising a trajectory and depth visualization device.
33. The surgical system of claim 32 wherein the trajectory and depth visualization device includes a radio-opaque feature to allow confirmation of the location of the bone plate device on the appropriate vertebral body and to facilitate the extrapolation of the projected trajectory of the bone
20 cutting tool using a radiographic image.
34. The surgical system of claim 32 wherein the trajectory and depth visualization device includes visual markings to indicate a distance from a point of contact with the vertebral body and cutter penetration control feature on the bone cutter guide device.
- 35 A method for performing a procedure through a vertebral body overlaying a site in need of a
25 medical procedure comprising:
attaching a bone plate on an anterior surface of the vertebral body;
engaging a trajectory control sleeve to the bone plate;
inserting at least a portion of a bone cutting tool through the trajectory control sleeve;
forming an access channel with a prescribed trajectory from an entry point on the anterior surface to
30 an opening on the posterior surface of the vertebral body in the locale of the site in need of the
procedure by removing bone with the bone cutting tool;
disengaging the trajectory control sleeve from the bone plate; and
performing the medical procedure through the access channel and the opening on the posterior

36. The method of **35** further comprising, before engaging the trajectory control sleeve to the bone plate, selecting the sleeve to be used such that when the sleeve and the bone plate are engaged, the sleeve has an angle relative to the bone plate that is consistent with the prescribed trajectory of the access channel.
37. The method of claim **35** further comprising, after performing the medical procedure, leaving the bone plate attached to the vertebral body.
38. The method of claim **35**, after engaging the trajectory control sleeve to the bone plate, further comprising:
inserting a radiopaque locating device into the trajectory control sleeve device,
radiographically observing the locating device and determining therefrom an extrapolated trajectory of the access channel toward the posterior surface of the vertebral body; and
verifying that the extrapolated trajectory is consistent with the prescribed trajectory.
39. The method of claim **38** wherein the verifying step includes verifying the extrapolated trajectory of the access channel in a cranio-caudal direction and a medial lateral direction.
40. The method of claim **35**, after engaging the trajectory control sleeve to the bone plate, further comprising: inserting a depth-measuring device into the trajectory control sleeve device to establish an optimal depth of penetration of the bone-cutting tool into the vertebral body, the depth being influenced by the disposition of the bone plate against the anterior surface of the vertebral body.
41. The method of claim **35** wherein performing the medical procedure may include any of performing a medical observation, an exploratory procedure, a diagnostic procedure, a surgical procedure, or a therapeutic delivery procedure.
42. The method of claim **41** wherein performing the surgical procedure includes decompressing a neural element.
43. The method of claim **42** wherein decompressing a neural element may include decompressing any of an individual nerve root, a spinal cord, or a cauda equina.
44. The method of claim **35** wherein the site in need of a medical procedure may include a portion or the whole of a herniated disc, an osteophyte, a thickened ligament, a tumor, a hematoma, a degenerative cyst, or any other compressing pathology.
45. The method of claim **35** wherein the forming the access channel includes forming the channel with a constant, circular cross-section along a single, straight axis aligned with the trajectory control sleeve.
46. The method of claim **35** further comprising, following the medical procedure, repairing the access channel with an implantable bone repair device, the device having an external geometry

complementary to the internal geometry of the channel.

47. The method of claim 46 wherein repairing the access channel includes implanting the bone repair device through the bone plate and into the channel.
48. The method of claim 47 further comprising securing a proximal portion of the bone repair device to the bone plate.
49. The method of claim 46 wherein repairing the access channel includes in-growing bone from the vertebral body into at least a portion of the surface of the bone repair device.
50. The method of claim 46 wherein repairing the access channel includes stimulating bone growth within the bone repair device by providing an osteogenic agent within the repair device.
51. The method of claim 46 wherein repairing the access channel includes placing a portion of harvested bone tissue within a bone repair device that comprises a porous cage.
52. The method of claim 51 further comprising allowing intimate contact between the bone tissue within the bone repair device and bone tissue of the vertebral body.
53. The method of claim 51 further comprising perfusing at least some bone tissue or bone-associated biological fluid from the bone repair device into the vertebral body.
54. The method of claim 53 wherein the perfusing step comprises compressing bone tissue inside the porous cage.
55. The method of claim 54 wherein the compressing step is at least partially performed after the porous cage has been placed inside the access channel.
56. The method of claim 51 further comprising allowing the bone tissue within the bone repair device to heal together with the bone tissue of the vertebral body.
57. A surgical system to form and repair an access channel through a vertebral body, the channel having an anterior surface entry and a posterior surface opening, the system comprising:
a bone cutting tool with a cutting element; and
an integrated device comprising a bone plate portion and trajectory control sleeve portion, the bone plate portion configured to be secured to an anterior surface of the vertebral body, the trajectory control sleeve portion having a cylinder configured to receive at least a portion of the bone cutting tool, the integrated device configured to guide the bone cutting tool to form the access channel with a prescribed trajectory from the anterior entry to the prescribed posterior opening.
58. A method for performing a procedure through a vertebral body overlaying a site in need of a medical procedure comprising:
attaching an integrated device comprising a bone plate portion and trajectory control sleeve portion

on an anterior surface of the vertebral body;

inserting at least a portion of a bone cutting tool through the trajectory control sleeve;

forming an access channel through the vertebral body by removing bone with the bone cutting tool,
the access channel following a prescribed trajectory from an anterior entry point to a prescribed
5 opening on a posterior surface of the vertebral body in the locale of the site in need of the medical
procedure;

disengaging the integrated device from the vertebral body; and

performing the medical procedure through the access channel and the opening on the posterior
surface of the vertebral body.

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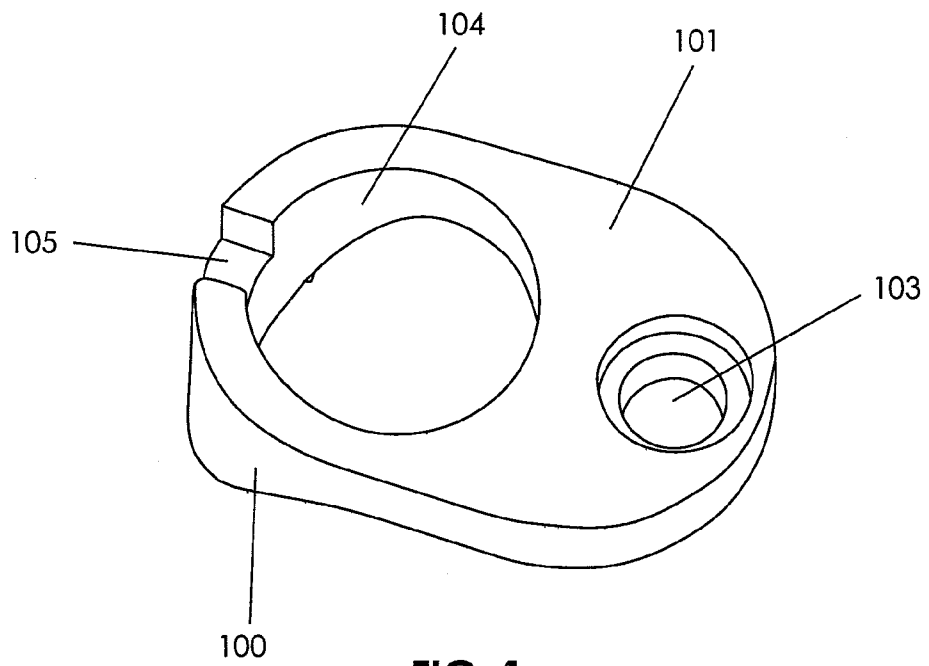


FIG. 1

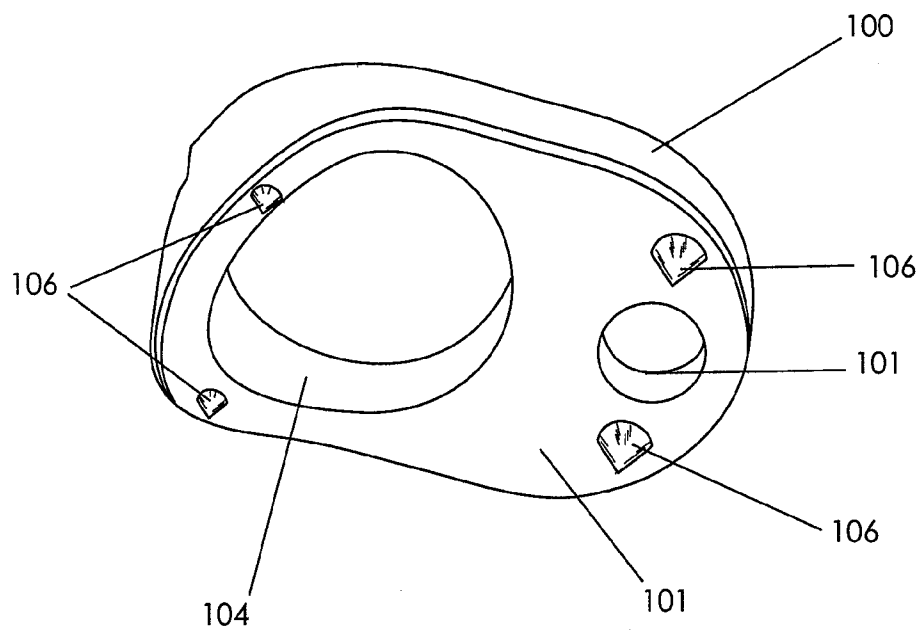


FIG. 2

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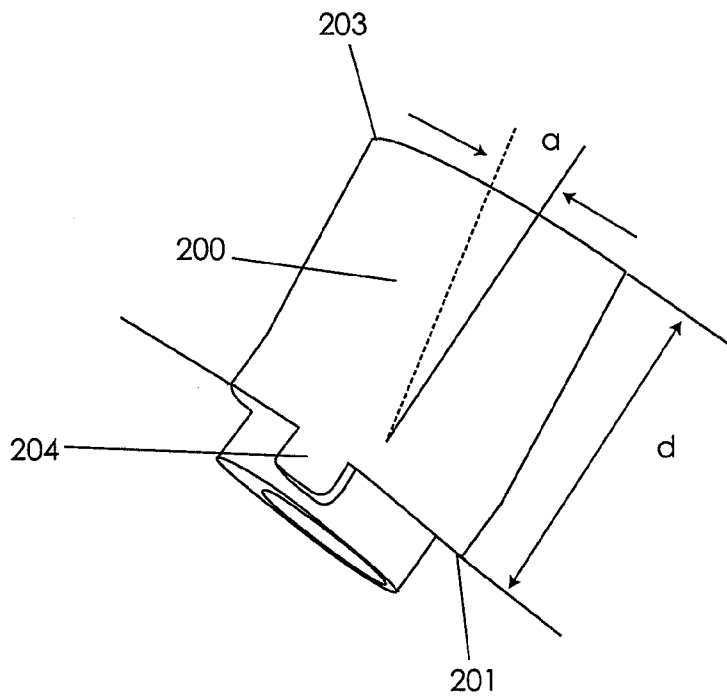


FIG. 3A

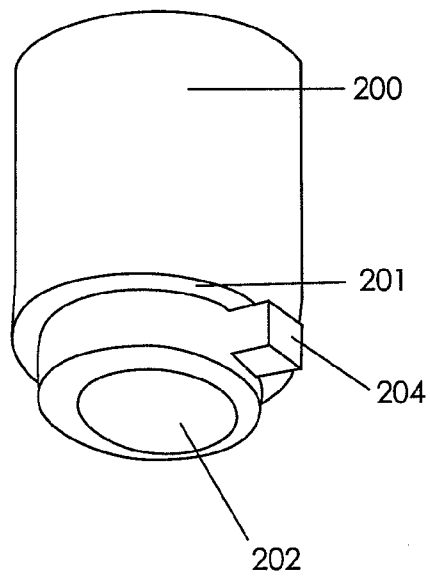


FIG. 3C

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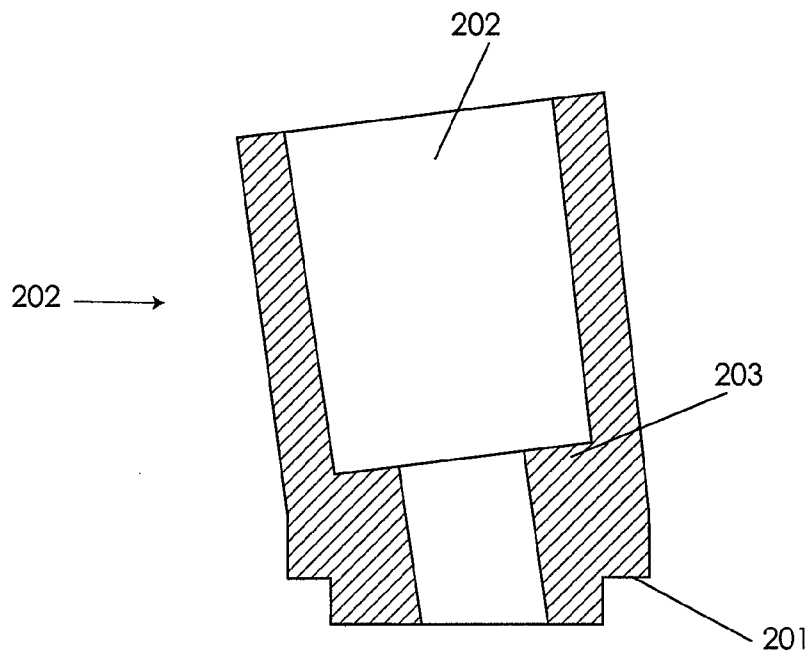


FIG. 3B

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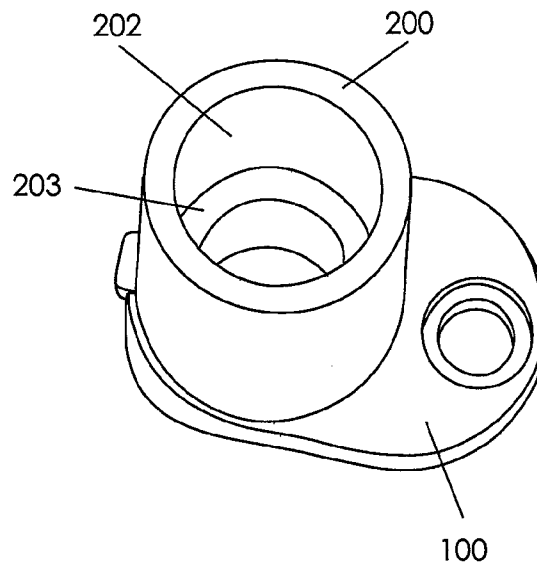


FIG. 4

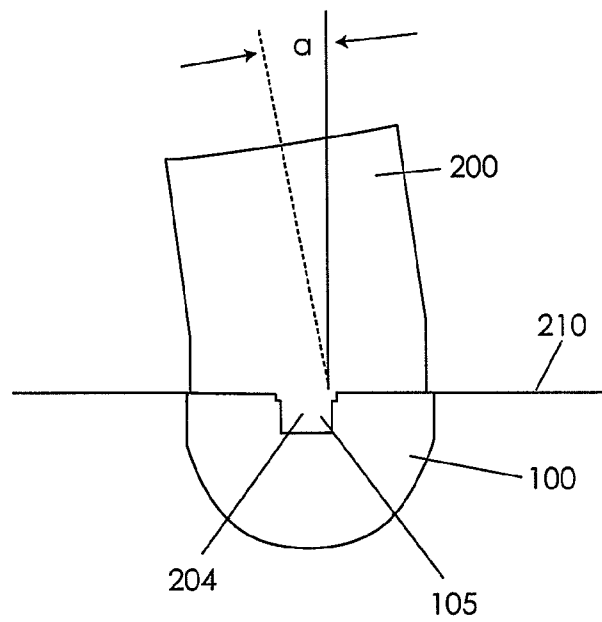


FIG. 5

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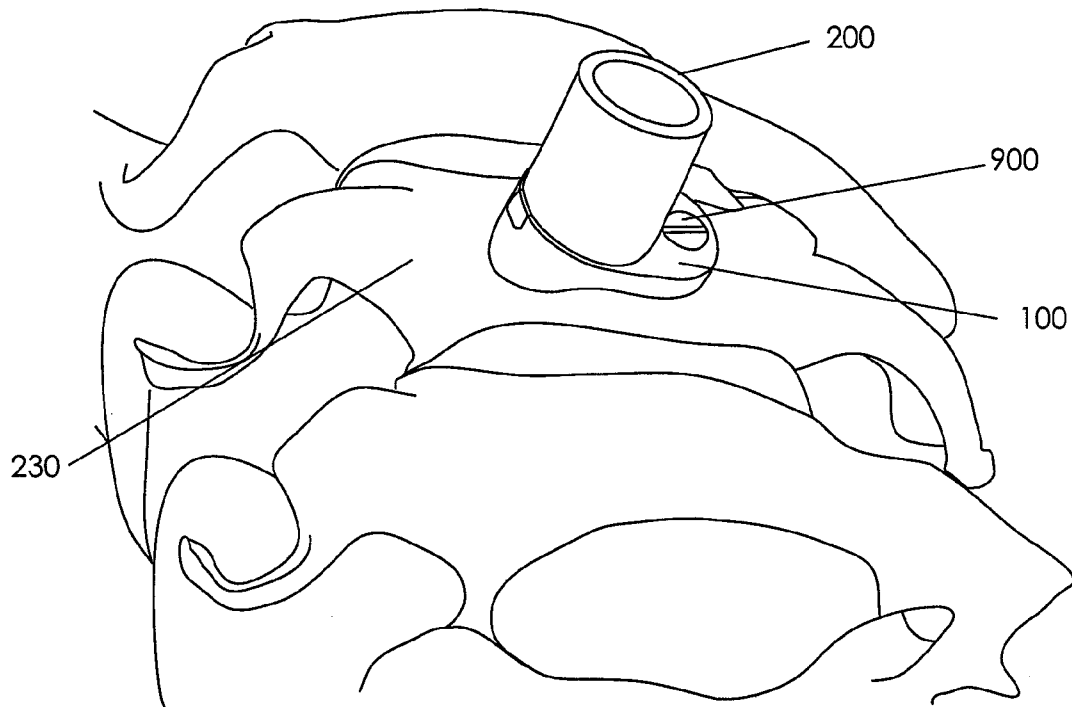


FIG. 6

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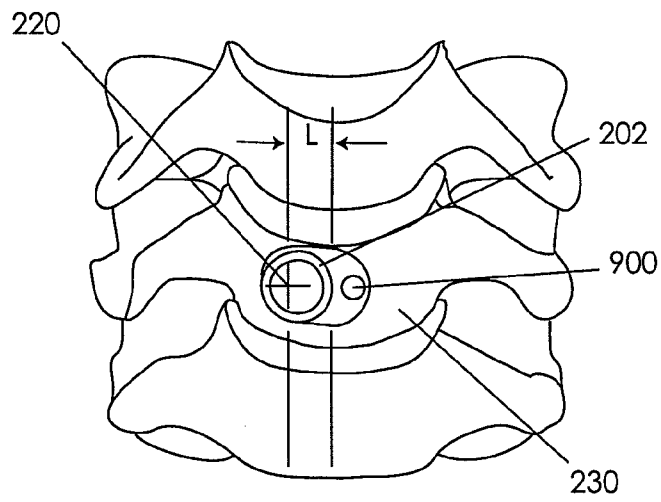


FIG. 7

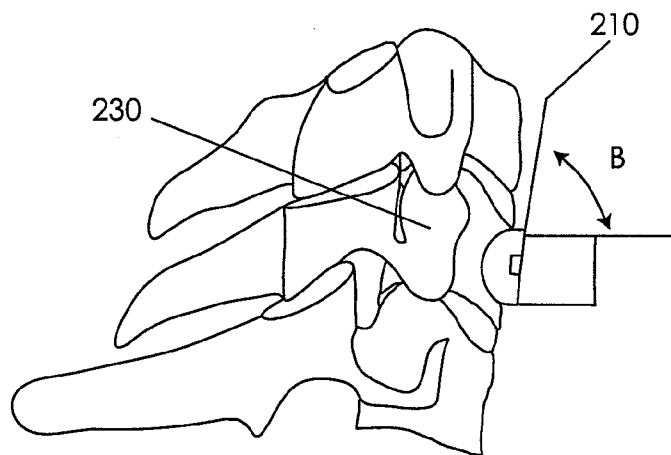
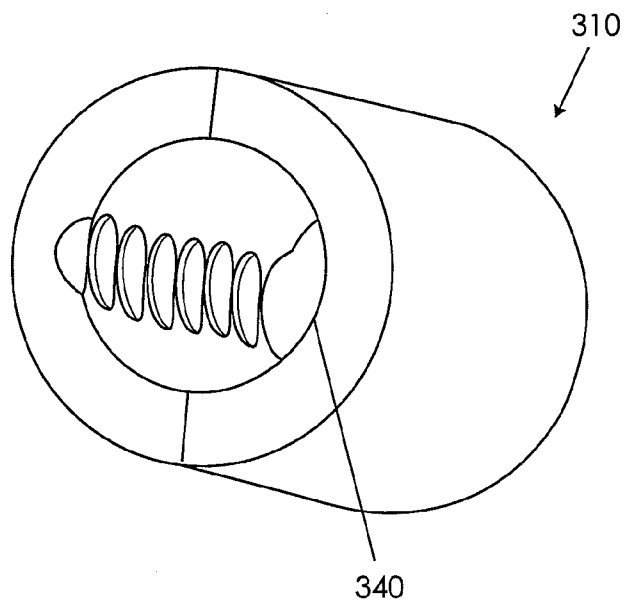
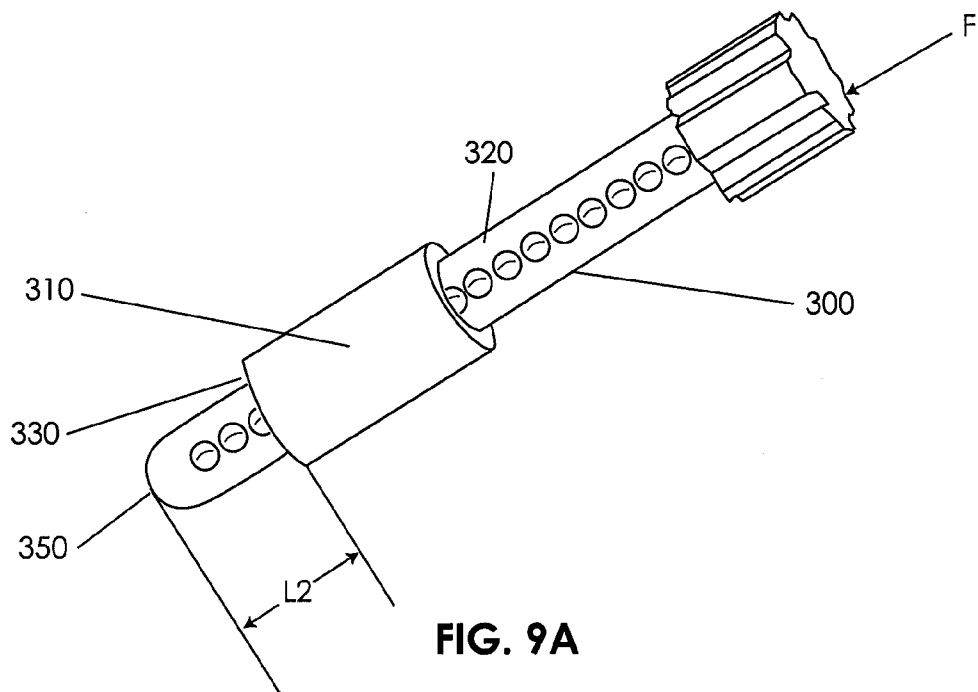


FIG. 8

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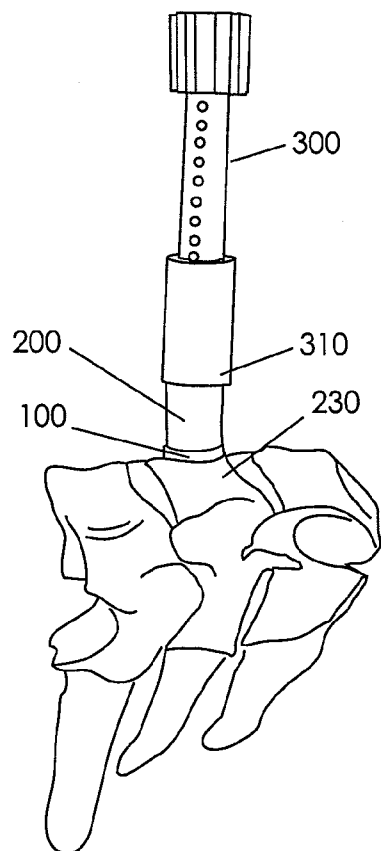


FIG. 10

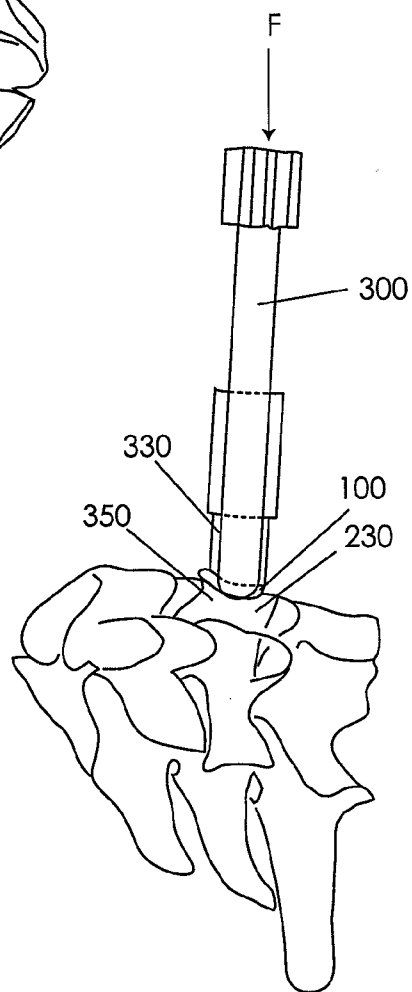


FIG. 11

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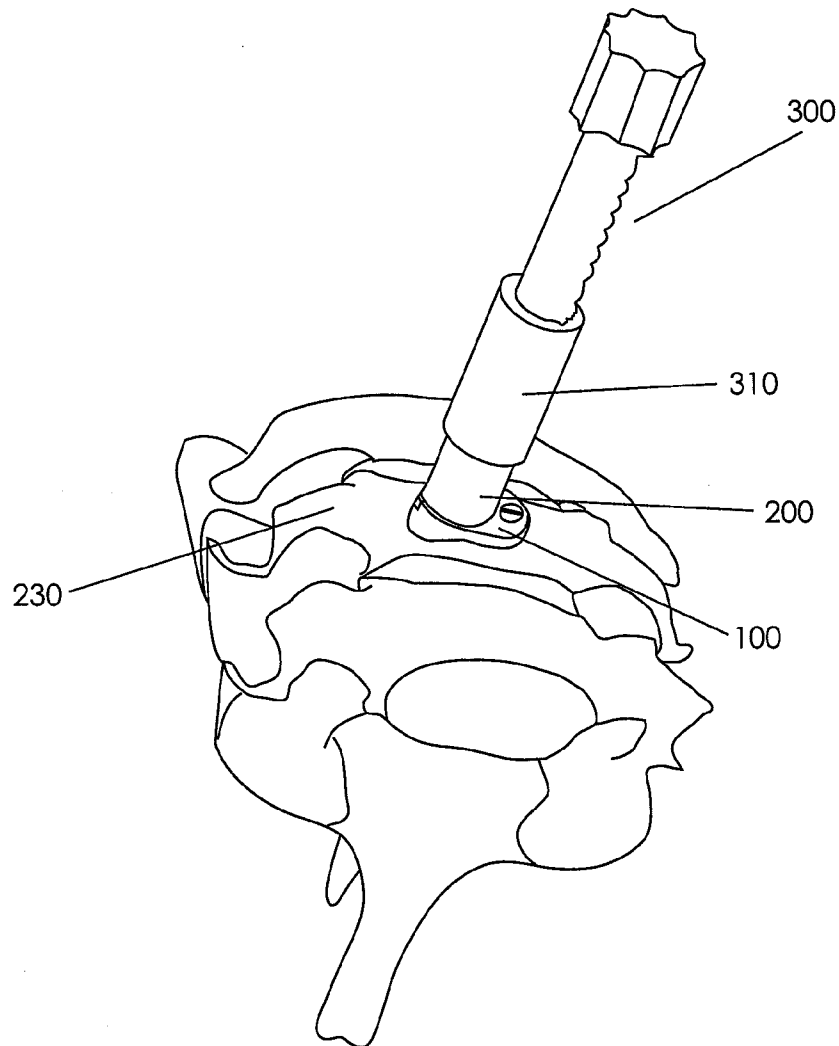


FIG. 12

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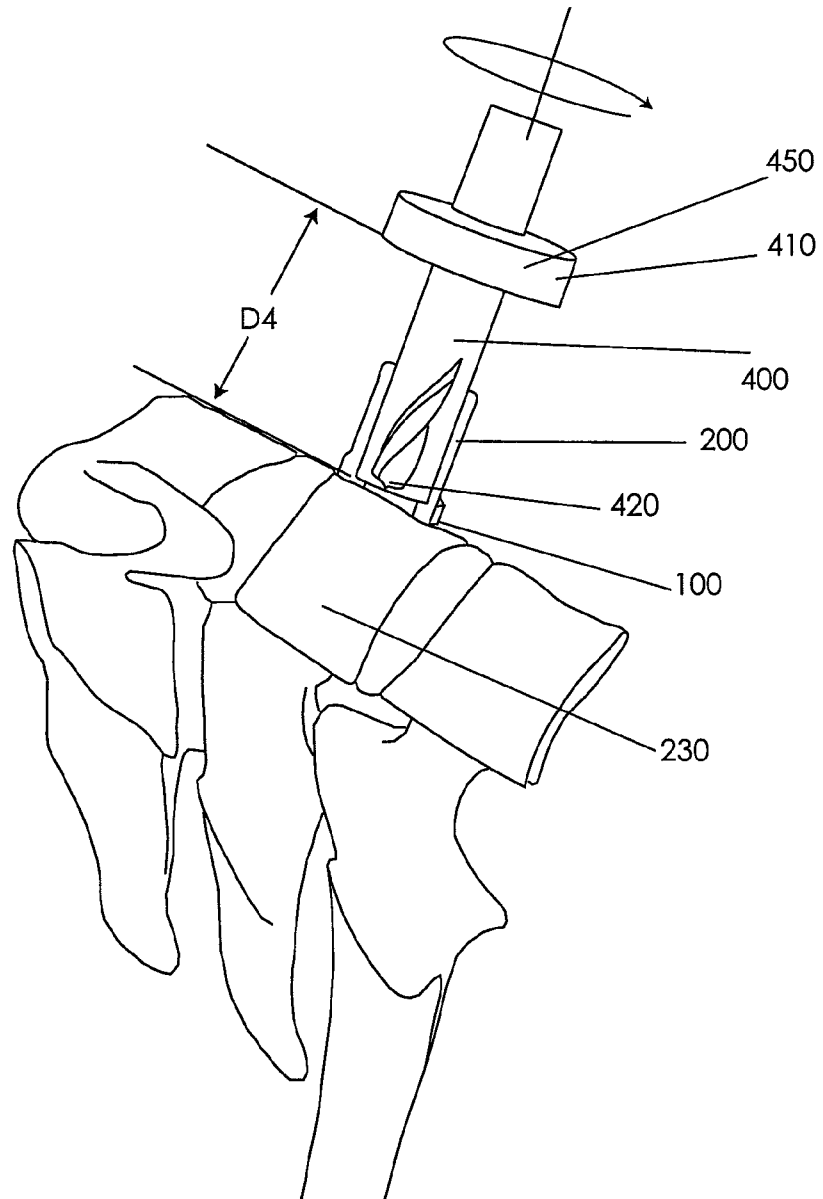


FIG. 13

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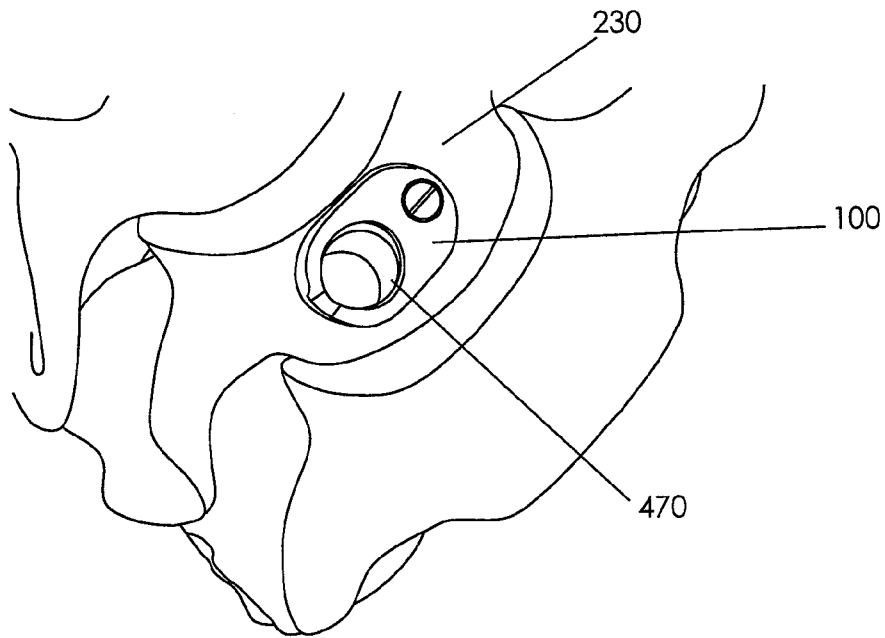


FIG. 14

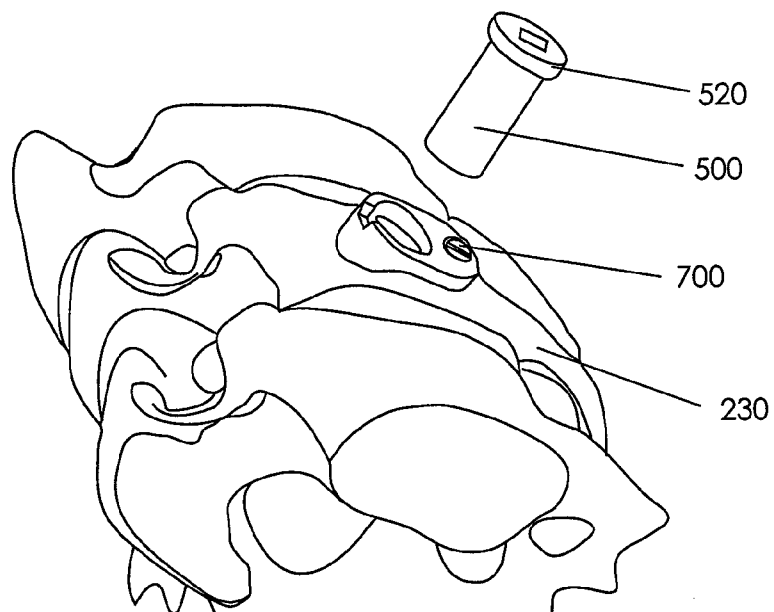


FIG. 15

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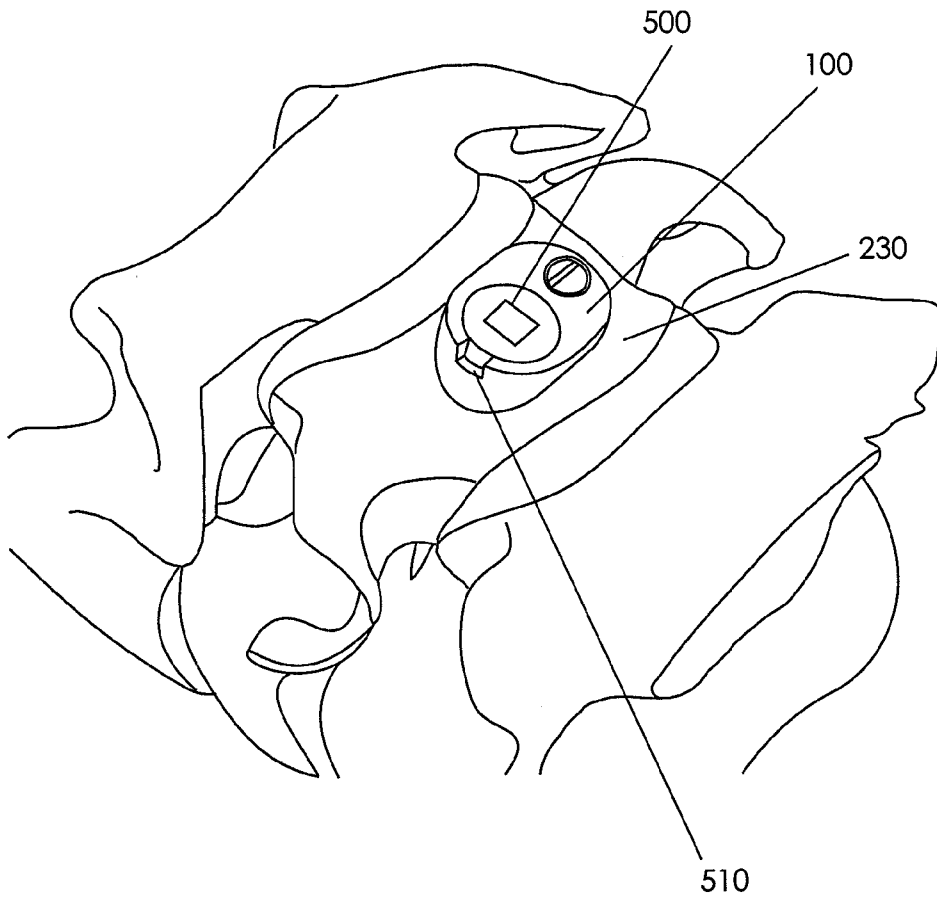


FIG. 16

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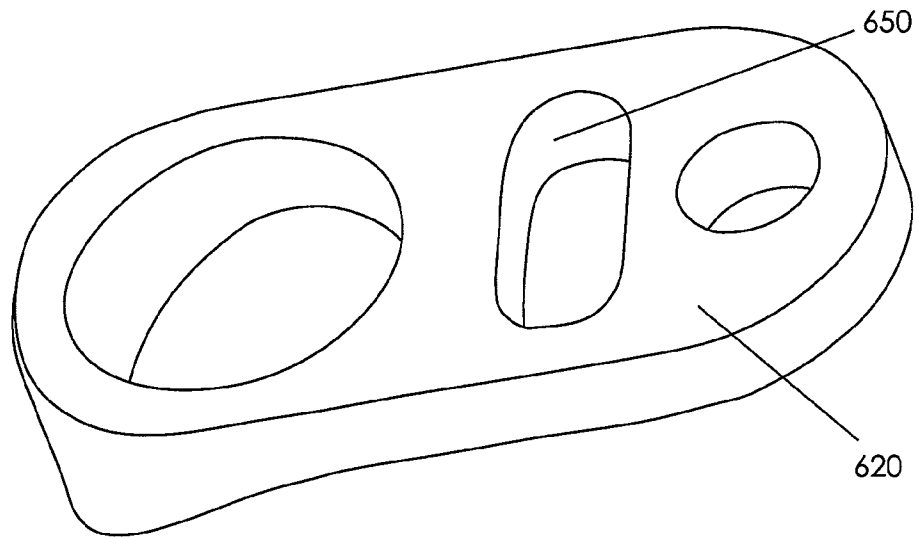


FIG. 17

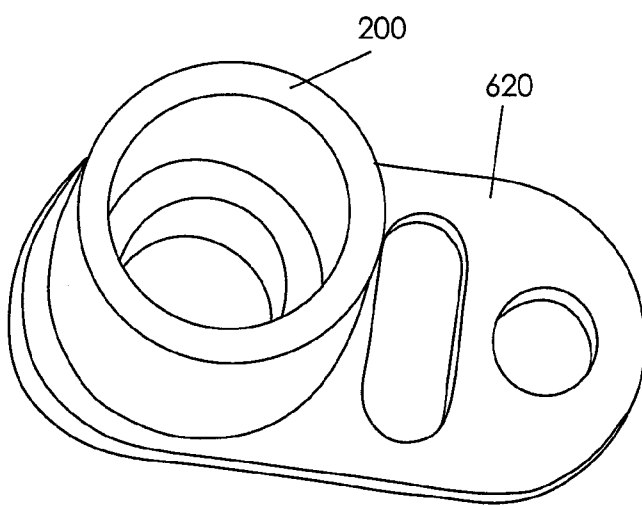


FIG. 18

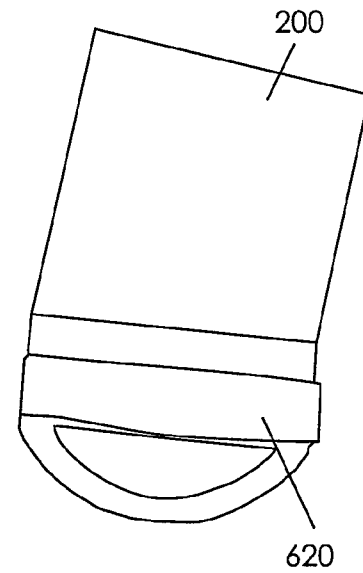


FIG. 19

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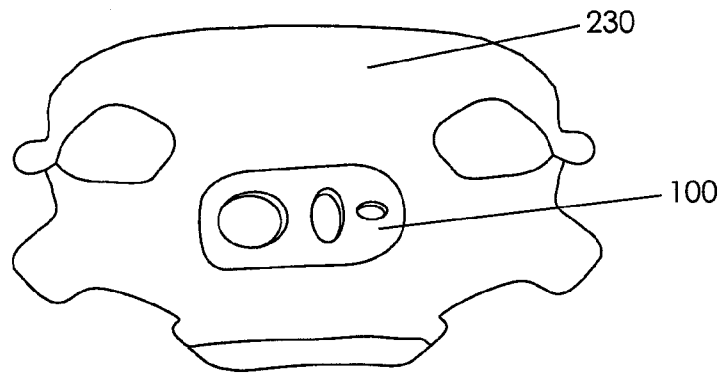


FIG. 19

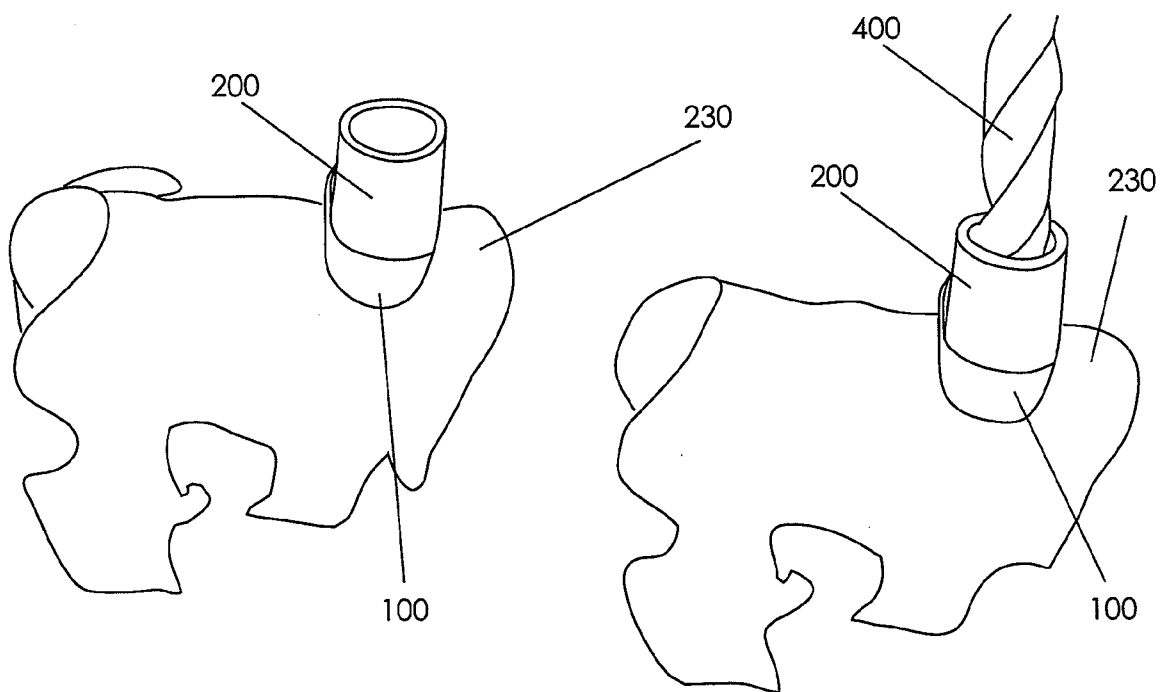


FIG. 20

FIG. 21

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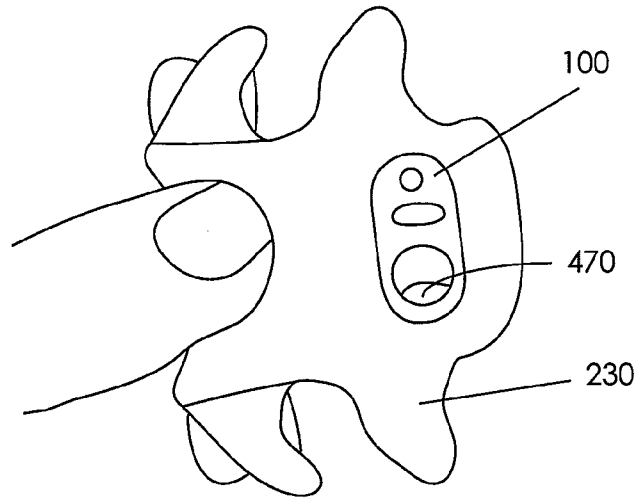


FIG. 22

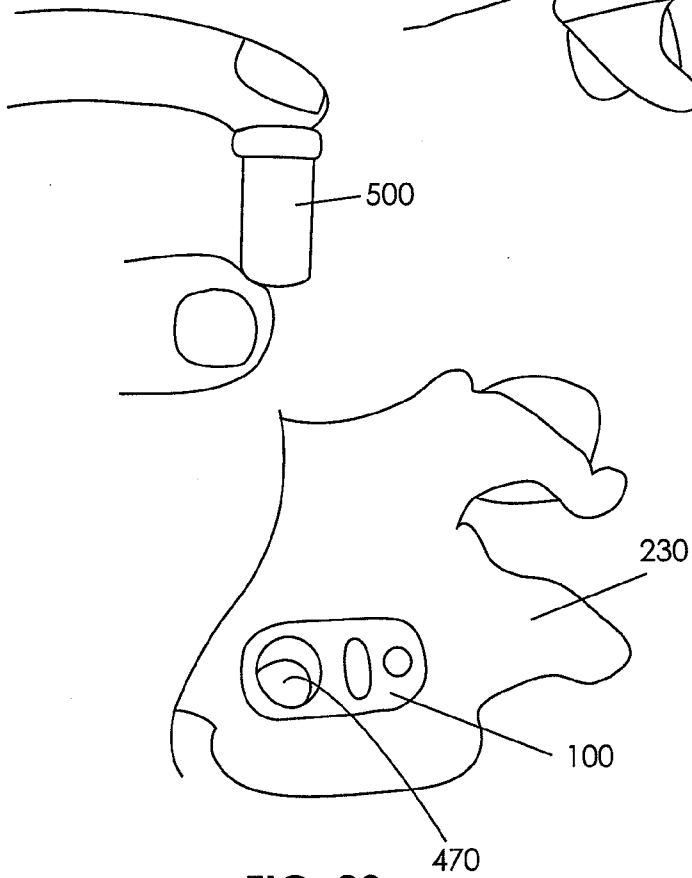


FIG. 23

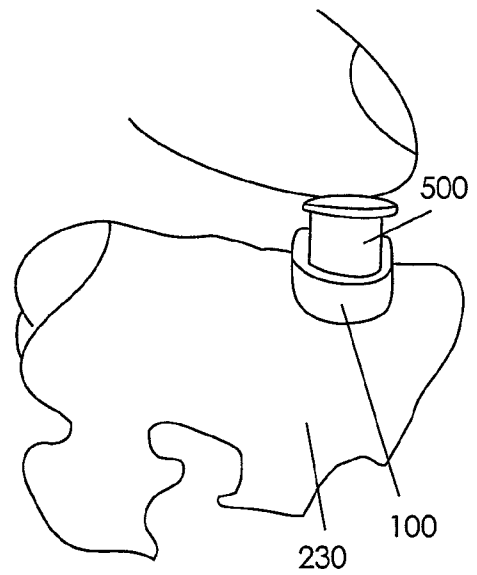


FIG. 24

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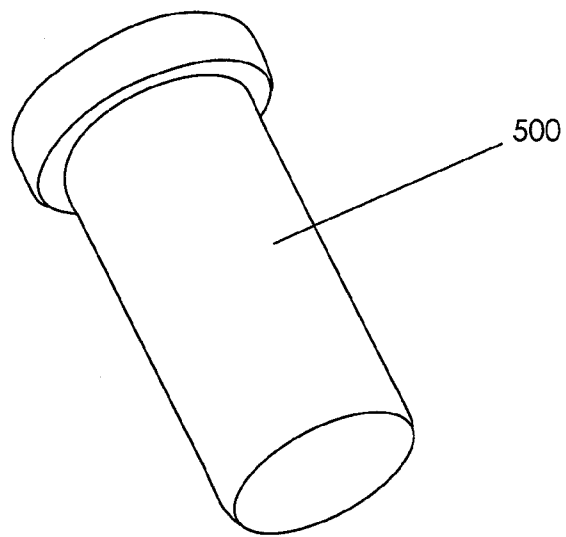


FIG. 25A

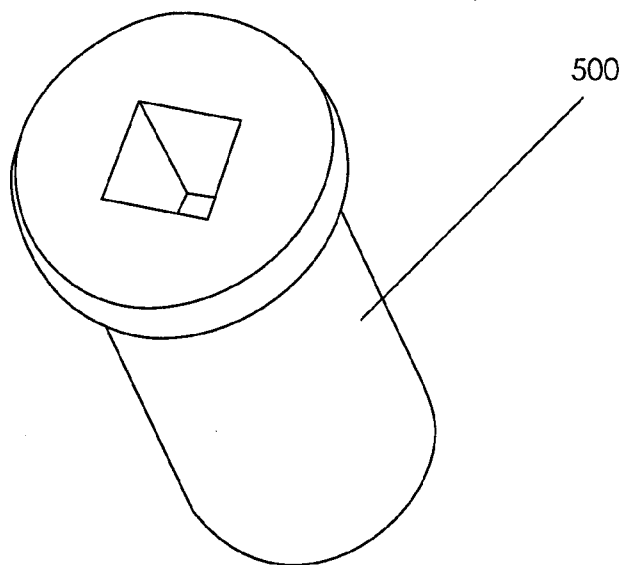


FIG. 25B

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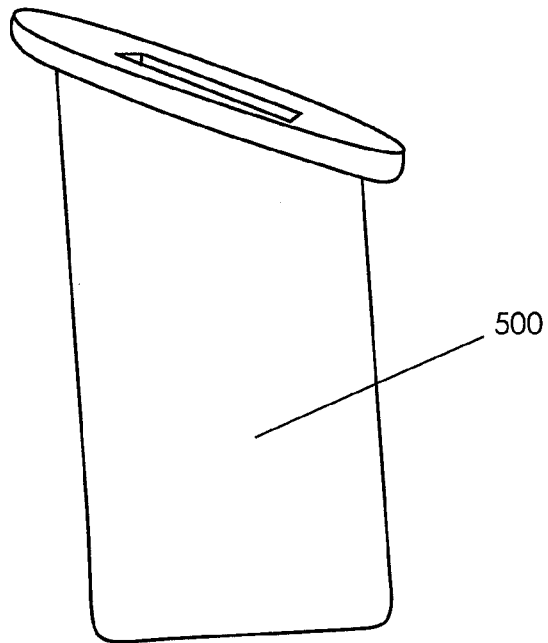


FIG. 26A

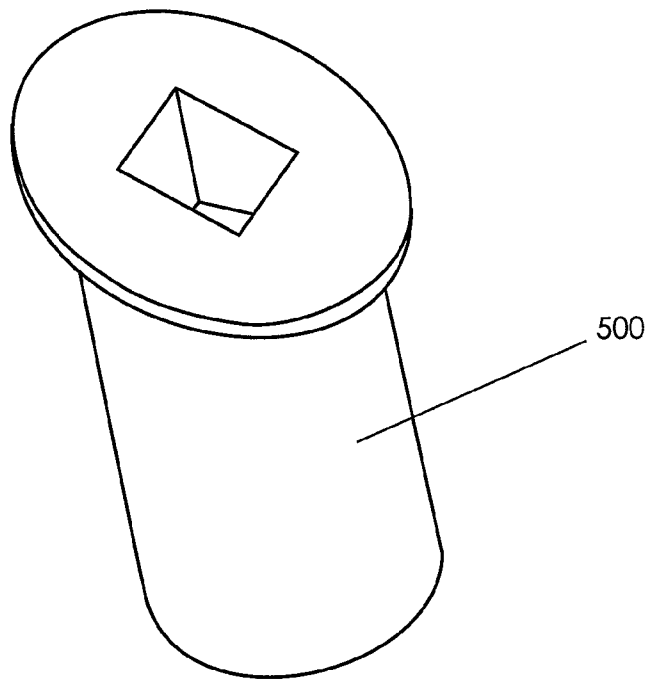


FIG. 26B

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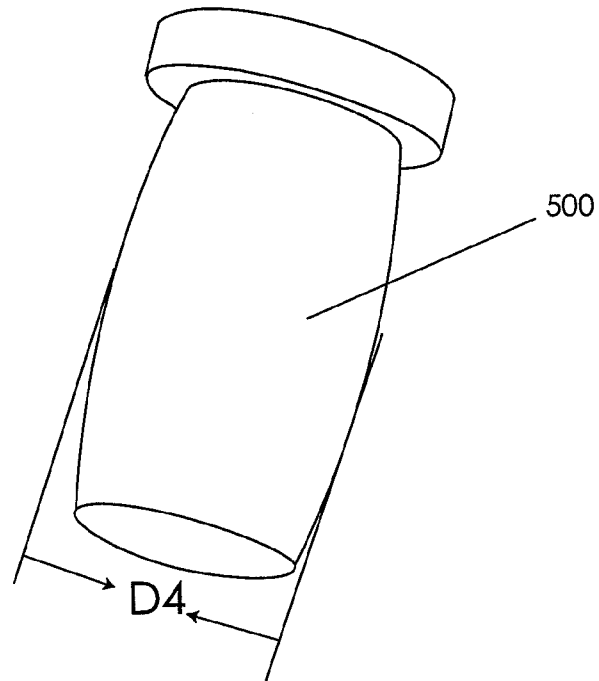


FIG. 27A

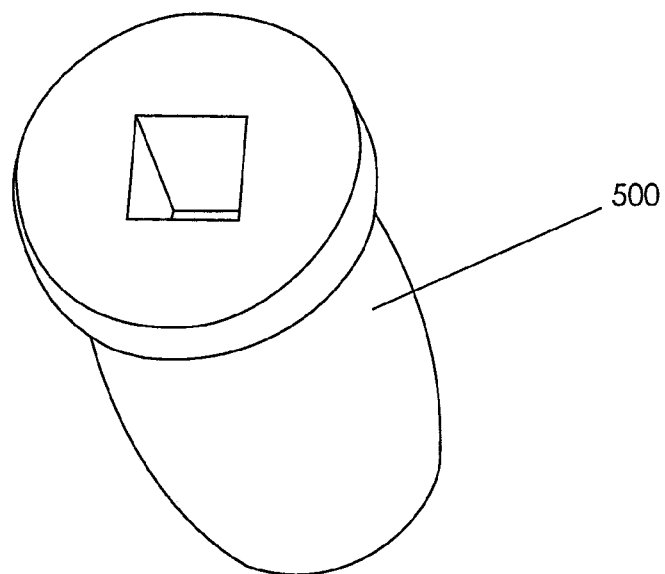


FIG. 27B

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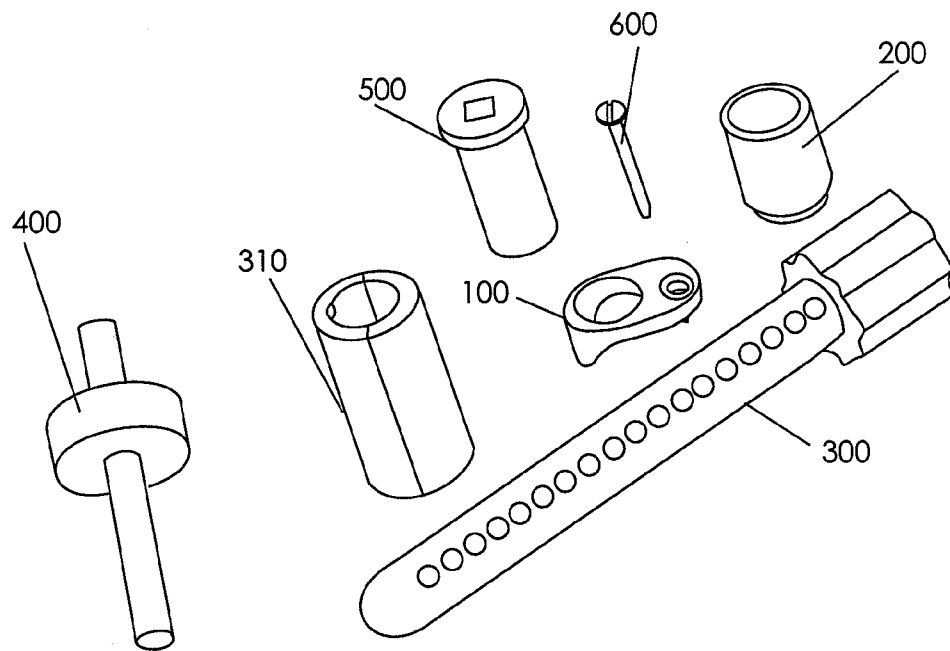


FIG. 28

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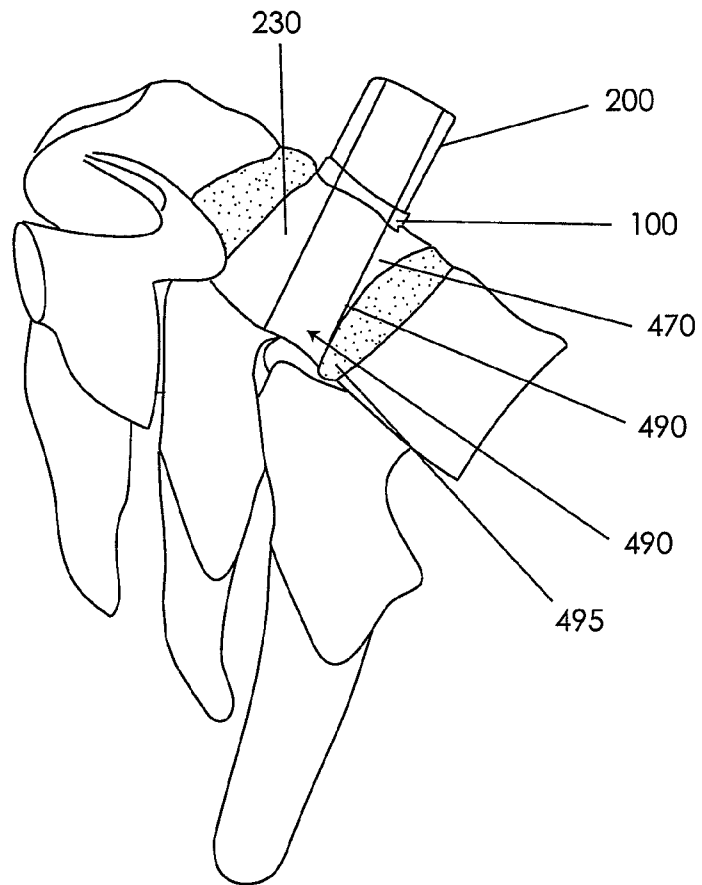


FIG. 29

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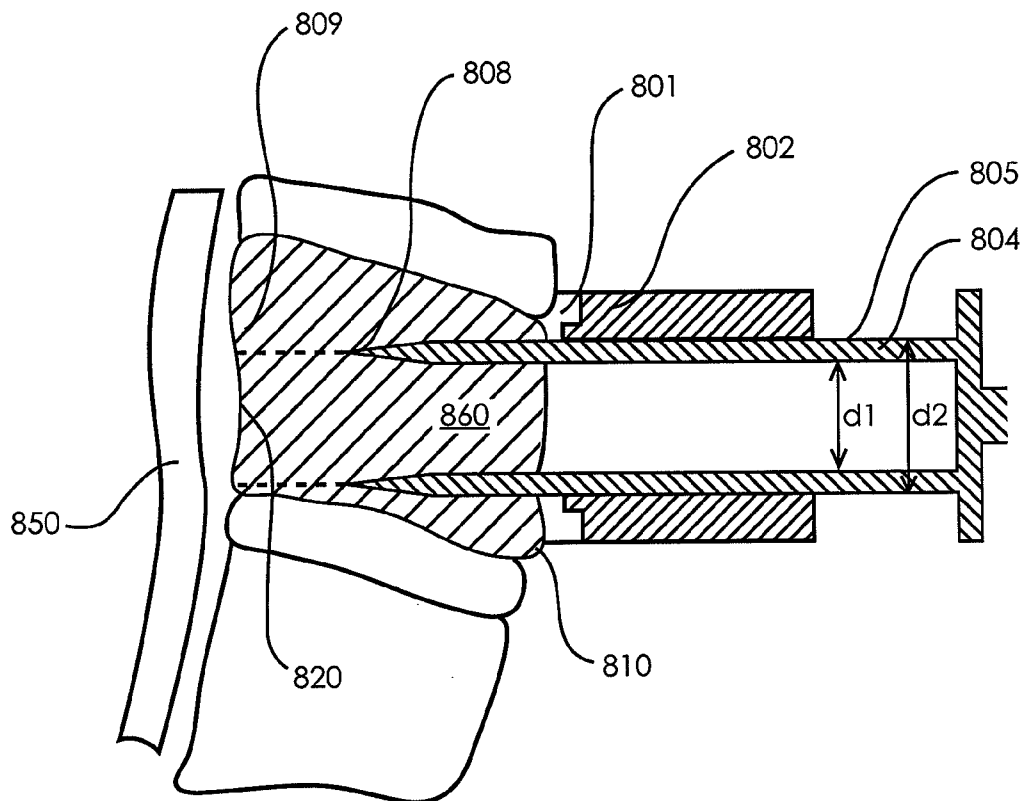


FIG. 30

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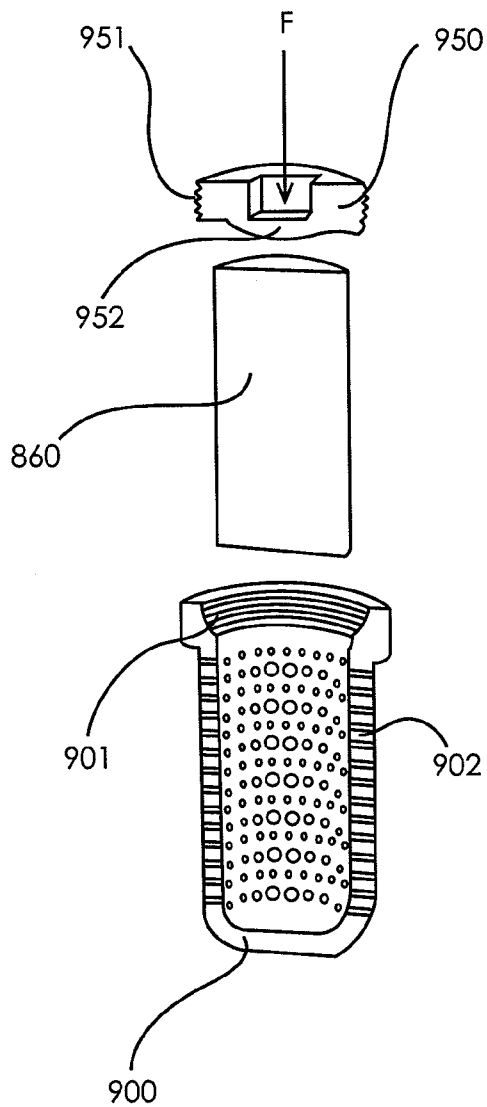


FIG. 31

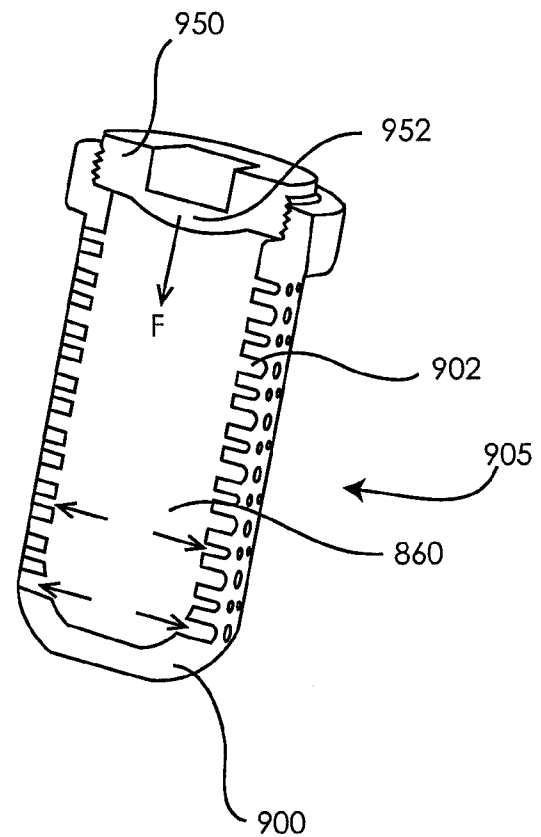


FIG. 32

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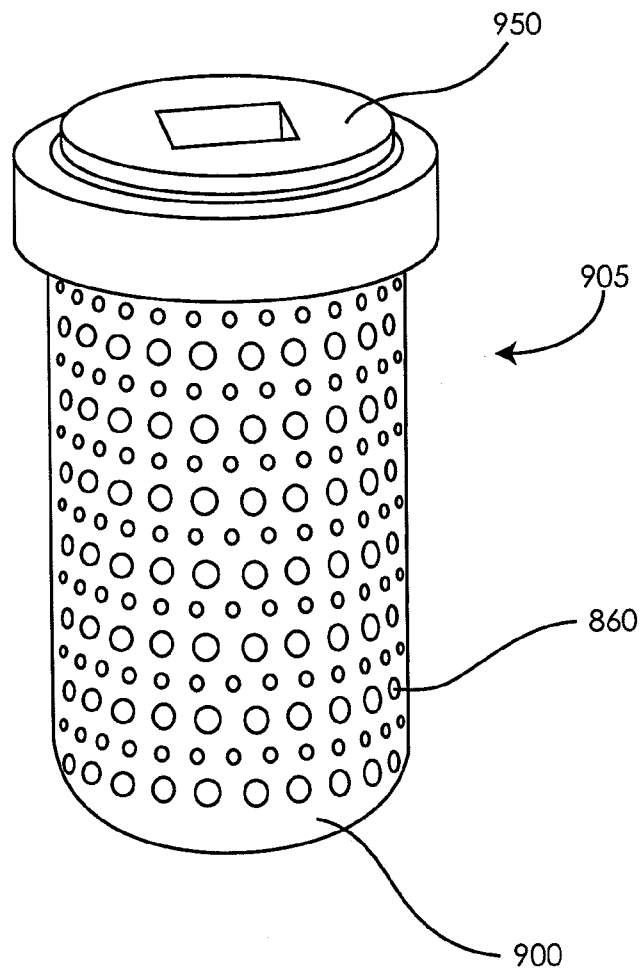


FIG. 33

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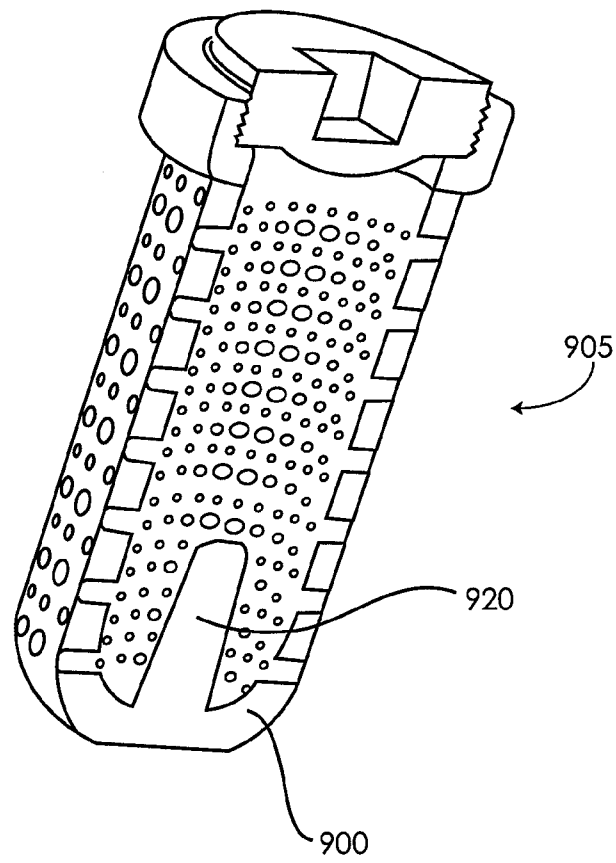


FIG. 34

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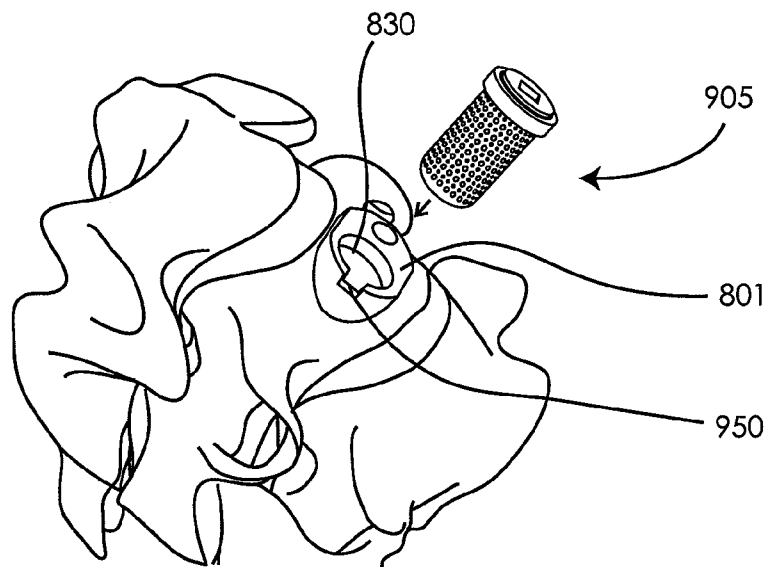


FIG. 35

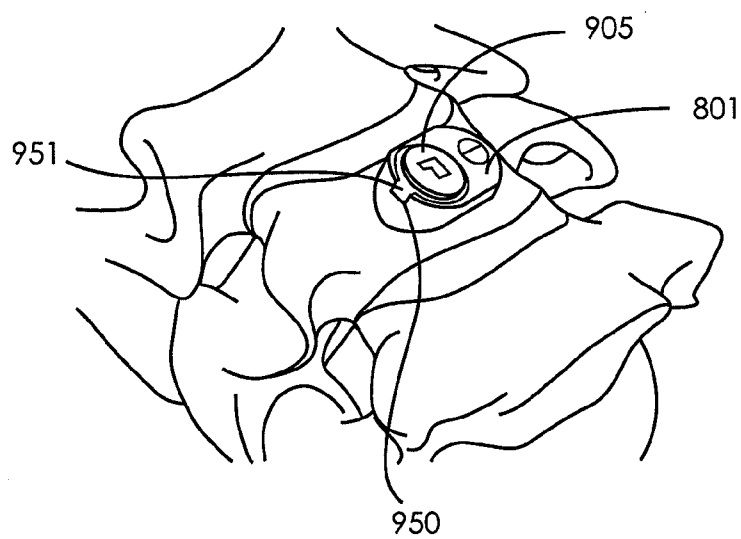


FIG. 36

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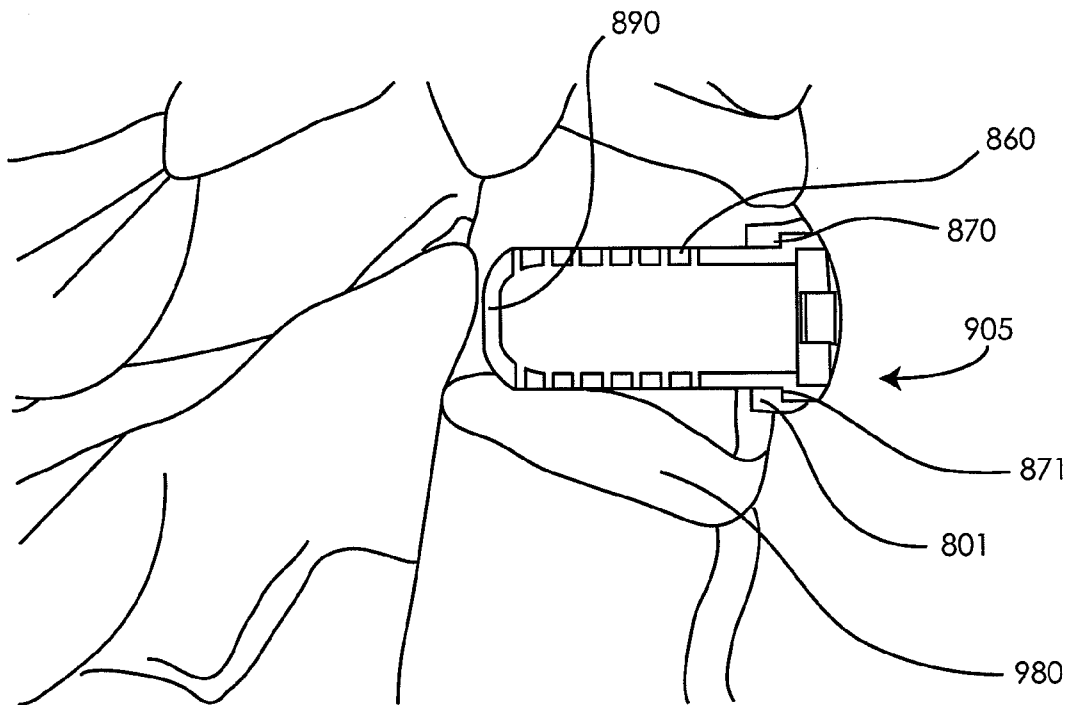


FIG. 37

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2008/076286

A. CLASSIFICATION OF SUBJECT MATTER INV. A61B17/17 A61B17/16 A61B17/70 A61F2/46 A61F2/44		
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 A61F		
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	US 2004/204717 A1 (FANGER JONATHAN [US] ET AL) 14 October 2004 (2004-10-14) paragraph [0007] paragraph [0038] - paragraph [0039]; figures 1,3	1-17,57
Y	-----	18-31
Y	US 5 741 253 A (MICHELSON GARY KARLIN [US]) 21 April 1998 (1998-04-21) column 7, line 51 - column 9, line 45; figures 2-5,4A-4D	18-31
X	US 6 193 721 B1 (MICHELSON GARY K [US]) 27 February 2001 (2001-02-27) column 24, line 1 - line 19; figure 37 ----- -/--	1-16,57
<div style="display: flex; justify-content: space-between;"> <input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C. <input checked="" type="checkbox"/> See patent family annex. </div>		
<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>* Special categories of cited documents :</p> <p>*A* document defining the general state of the art which is not considered to be of particular relevance</p> <p>*E* earlier document but published on or after the international filing date</p> <p>*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)</p> <p>*O* document referring to an oral disclosure, use, exhibition or other means</p> <p>*P* document published prior to the international filing date but later than the priority date claimed</p> </div> <div style="width: 50%;"> <p>*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</p> <p>*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</p> <p>*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.</p> <p>*&* document member of the same patent family</p> </div> </div>		
Date of the actual completion of the international search <div style="text-align: center; font-weight: bold;">8 December 2008</div>		Date of mailing of the international search report <div style="text-align: center; font-weight: bold;">17/12/2008</div>
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel: (+31-70) 340-2040, Fax: (+31-70) 340-3016		Authorized officer <div style="text-align: center; font-weight: bold;">Ducreau, Francis</div>

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2008/076286

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 066 142 A (SERBOUSEK JON C [US] ET AL) 23 May 2000 (2000-05-23) figure 1 -----	1-16, 57
X	US 2005/043738 A1 (RYAN CHRISTOPHER J [US]) 24 February 2005 (2005-02-24) figures 1,2 -----	1, 57
A	US 6 371 986 B1 (BAGBY GEORGE W [US]) 16 April 2002 (2002-04-16) the whole document -----	1, 17-31

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2008/076286

Box No. 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. ☒ Claims Nos.: 35-56, 58
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 No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

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

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers allsearchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2008/076286

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2004204717 A1	14-10-2004	NONE	
US 5741253 A	21-04-1998	US 7452359 B1	18-11-2008
US 6193721 B1	27-02-2001	AU 6145998 A	26-08-1998
		AU 6268798 A	26-08-1998
		JP 4153045 B2	17-09-2008
		JP 2002515799 T	28-05-2002
		JP 2002515800 T	28-05-2002
		JP 4012556 B2	21-11-2007
		JP 2006075618 A	23-03-2006
		JP 2006116349 A	11-05-2006
		JP 2008086817 A	17-04-2008
		JP 2008119491 A	29-05-2008
		JP 2008086827 A	17-04-2008
		WO 9834553 A1	13-08-1998
		WO 9834556 A1	13-08-1998
US 6066142 A	23-05-2000	EP 0995403 A1	26-04-2000
US 2005043738 A1	24-02-2005	AU 2004266701 A1	03-03-2005
		BR PI0413648 A	17-10-2006
		CA 2536160 A1	03-03-2005
		CN 1882287 A	20-12-2006
		EP 1659962 A2	31-05-2006
		JP 2007502669 T	15-02-2007
		KR 20060125684 A	06-12-2006
		WO 2005018427 A2	03-03-2005
US 6371986 B1	16-04-2002	CA 2287020 A1	27-04-2000
		US 2002055782 A1	09-05-2002
		US 2004158327 A1	12-08-2004