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(71) Applicant *(for all designated States except US)*: **ARCHUS ORTHOPEDICS, INC.** [US/US]; 8624 - 154th Avenue Northeast, Redmond, WA 98052 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **AUGOSTINO, Teena, M.** [US/US]; 15719 Northeast 136th Place, Redmond, WA 98052 (US). **McLEER, Thomas, J.** [US/US]; 23913 Northeast 69th Place, Redmond, WA 98052 (US). **REILEY, Mark, A.** [US/US]; 360 Magnolia Avenue, Piedmont, CA 94611 (US).

(74) Agents: **O'REGAN, Cecily, Anne** et al.; Wilson Sonsini Goodrich & Rosati, 650 Page Mill Road, Palo Alto, CA 94301-1050 (US).

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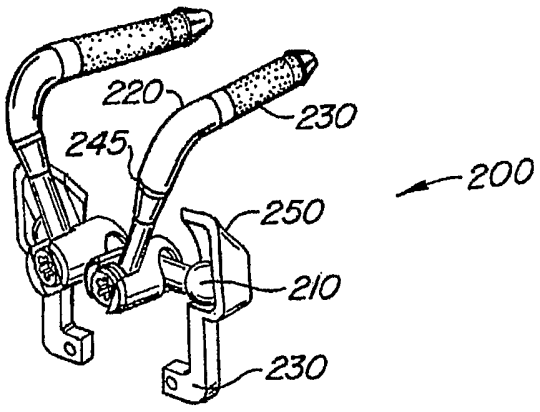
(54) **Title:** ADJACENT ELVEL FACET ARTHROPLASTY DEVICES, SPINE STABILIZATION SYSTEMS, AND METHODS



(57) **Abstract:** The invention discloses an implantable facet arthroplasty device suitable for treating adjacent level disease. The device is designed for implantation between a first vertebra and a second vertebra. Components of the device include: a crossbar; a first component having a first attachment mechanism adapted to attach to a first location of a spinal fusion device attached to a first vertebra and a second attachment mechanism adapted to attach to the crossbar; and a second component having a second attachment mechanism adapted to attach to a second location of a spinal fusion device attached to the first vertebra and a second attachment mechanism adapted to attach to the crossbar. The first component articulates relative to the second component and the first vertebra articulates relative to the device itself.

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ADJACENT LEVEL FACET ARTHROPLASTY DEVICES, SPINE STABILIZATION SYSTEMS, AND METHODS

CROSS-REFERENCE

This application claims the benefit of U.S. Provisional Application No. 60/602,826, filed August 18, 2004 and U.S. Provisional Application No. 60/691,946 filed June 17, 2005, which are incorporated herein by reference in their entireties.

This application is related to the following co-pending U.S. patent applications: application Serial No. 10/973,939, filed October 25, 2004; and application Serial No. 10/973,834, filed October 25, 2004 which are also incorporated herein by reference in their entireties.

BACKGROUND OF THE INVENTION

Field of the Invention. This invention relates to devices, including devices for replacing or restoring part of bone, systems and methods for treating spinal pathologies. The devices, systems and methods of the invention are designed to achieve spinal stabilization and facet replacement. The devices, systems and methods are also designed to achieve spine fusion at a portion of the spine in combination with spine stabilization adjacent the fused section.

Background of the Invention. Back pain, particularly in the small of the back, or lumbosacral region (L4-S1) of the spine, is a common ailment. In many cases, the pain severely limits a person's functional ability and quality of life. Back pain interferes with work, routine daily activities, and recreation. It is estimated that Americans spend $50 billion each year on low back pain alone. It is the most common cause of job-related disability and a leading contributor to missed work.

Through disease or injury, the laminae, spinous process, articular processes, facets and/or facet capsule(s) of one or more vertebral bodies along with one or more intervertebral discs can become damaged which can result in a loss of proper alignment or loss of proper articulation of the vertebra. This damage can result in anatomical changes, loss of mobility, and pain or discomfort. For example, the vertebral facet joints can be damaged by traumatic injury or as a result of disease. Diseases damaging the spine and/or facets include osteoarthritis where the cartilage of joints is gradually worn away and the adjacent bone is remodeled, ankylosing spondylolysis (or rheumatoid arthritis) of the spine which can lead to spinal rigidity, and degenerative spondylolisthesis which results in a forward displacement of the lumbar vertebra on the sacrum. Damage to facet joints of the vertebral body often can also results in pressure on nerves, commonly referred to as "pinched" nerves, or nerve compression or impingement. The result is pain, misaligned anatomy, and a corresponding loss of mobility. Pressure on nerves can also occur without facet joint pathology, *e.g.*, a herniated disc.

One conventional treatment of facet joint pathology is spine stabilization, also known as intervertebral stabilization. Intervertebral stabilization desirably controls, prevents or limits relative motion between the vertebrae, through the use of spinal hardware, removal of some or all of the intervertebral disc, fixation of the facet joints, bone graft/osteo-inductive/osteo-conductive material (with or without concurrent insertion of fusion cages) positioned between the vertebral bodies, and/or some combination thereof, resulting in the fixation of (or limiting the motion of) any number of adjacent vertebrae to stabilize and prevent/limit/control relative movement between those treated vertebrae. Stabilization of vertebral bodies can range from the insertion of motion limiting devices (such as intervertebral

spacers, artificial ligaments and/or dynamic stabilization devices), through devices promoting arthrodesis (rod and screw systems, cable fixation systems, fusion cages, *etc.*), up to and including complete removal of some or all of a vertebral body from the spinal column (which may be due to extensive bone damage and/or tumorous growth inside the bone) and insertion of a vertebral body replacement (generally anchored into the adjacent upper and lower vertebral bodies). Various devices are known for fixing the spine and/or sacral bone adjacent the vertebra, as well as attaching devices used for fixation, including: U.S. Patent Nos. 6,290,703, 5,782,833, 5,738,585, 6,547,790, 6,638,321, 6,520,963, 6,074,391, 5,569,247, 5,891,145, 6,090,111, 6,451,021, 5,683,392, 5,863,293, 5,964,760, 6,010,503, 6,019,759, 6,540,749, 6,077,262, 6,248,105, 6,524,315, 5,797,911, 5,879,350, 5,885,285, 5,643,263, 6,565,565, 5,725,527, 6,471,705, 6,554,843, 5,575,792, 5,688,274, 5,690,6306,022,3504,805,6025,474,5554,611,581, 5,129,900, 5,741,255, 6,132,430; and U.S. Patent Publication No. 2002/0120272.

One common concern with existing spinal fusion techniques relates to the increased stresses experienced in vertebra adjacent to fused spinal levels. Where one or more functional spine units (a functional spinal unit comprising a pair of adjacent vertebrae and the intervertebral disc and facet joints there between) are fused (or motion is reduced or limited in some manner), the stresses and strains normally accommodated by that flexible unit (now fused or less flexible) are transferred (at least partially) to adjacent spinal units. Where these increased stresses begin to damage and/or degrade other spinal units – which can often occur in levels directly adjacent to the fused level(s) - the degradation is often called "adjacent-level disease" or adjacent segment disease. *See,* Kulkarni, et al. "Accelerated spondylotic changes adjacent to the fused segment following central cervical corpectomy: magnetic resonance imaging study evidence" J. Neurosurg. 100 (1 Suppl Spine):2-6 (2004). Where an adjacent level degrades to the point of requiring surgical intervention, the affected/degraded spinal unit is generally fused (or motion is limited and/or controlled in some manner), further exacerbating the stresses experienced by the remaining unfused levels, and often resulting in multiple-level or "daisy chained" fusions to the spine over time. The spine can be fused using, for example, a spinal fixation system. *See also* U.S. Patent Nos. 6,280,443, 6,086,590, 6,190,388, and 5,800,433; and EP Patent No. 1205152 A1.

More recently, various treatments have been proposed and developed as alternatives to spinal fusion. Many of these treatments seek to restore (and/or maintain) some or all of the natural motion of the treated spinal unit, and can include intervertebral disc replacement, facet joint resurfacing, and facet joint replacement. Such solutions typically include devices that do not substantially impair spinal movement. *See,* U.S. Patent Nos. 6,610,091, 6,811.567, 6,902,580, 5,571,171, and Re 36,758; and PCT Publication Nos. WO 01/158563, WO 2004/103228, WO 2005/009301, and WO 2004/103227.

SUMMARY OF THE INVENTION

One aspect of the present invention includes the realization that there exists a need for a device for use on adjacent level facets that provides stabilization and protects the joint between two adjacent vertebra that are adjacent a fused or immobilized section of spine. There also exists a need for a system and/or device that can be attached at a spinal level already containing pedicle screws and/or other types of spinal instrumentation (including spinal fusion hardware such as rods and screws or other types of fusion and/or non-fusion spinal instrumentation) that relieves stress experienced by the unfused levels vertebra. Moreover, there exists a need for a facet joint replacement system having components that can be selectively attached to pre-existing spinal hardware (and/or can be used with limited modifications to the pre-existing spinal hardware or hardware added for treating various surgical conditions) as well

as to various anatomical structures, including the lamina, pedicles and/or directly to the vertebral body or bodies (or some combination thereof, including simultaneous anchoring to spinal hardware and anatomical locations), as desired by the physician. Furthermore, there exists a need for a facet joint replacement system that can be implanted into vertebral levels which desirably reinforces and/or stabilizes the facet joint/intervertebral disc complex adjacent and/or in the vicinity of one or more fused spinal levels, to treat, reduce and/or prevent the onset of adjacent level disease in one or more non-fused spinal segments. Furthermore, there exists a need for a facet joint and intervertebral disk replacement system that can be used to revise or "take down" and already-fused spinal segment (or segments) and restore partial or full natural motion to that segment or segments. Furthermore, there exists a need for a facet joint replacement system that can be used to revise one or more fused levels of a multi-level arthrodesis, such that motion can be restored to at least a portion of the multi-level arthrodesis (*i.e.*, one section of a four level arthrodesis can be "taken down", leaving two single-level arthrodeses separated by an articulating section containing the facet joint replacement system.

In an embodiment of the invention, an implantable facet arthroplasty device for association with a first vertebra and a second vertebra comprising: a crossbar; a first component having a first attachment mechanism adapted to attach to a first location of a spinal fusion device attached to a first vertebra and a second attachment mechanism adapted to engage the crossbar; and a second component having a second attachment mechanism adapted to attach to a second location of a spinal fusion device attached to the first vertebra and a second attachment mechanism adapted to engage the crossbar, wherein, the first component articulates relative to the second component; further wherein the first vertebra articulates relative to the facet arthroplasty device. The device can further comprise a first arm having a bone engaging end adapted to attach to a vertebral body at a first end and adapted to engage the crossbar at a second end. Additionally, the device can be configured to engage a caudal vertebral body or a cephalad vertebral body. Arthroplasty devices suitable for use with the invention include spinal fusion devices, such as devices that comprise a pair of elongaged members configured to extend along a portion of the spine adjacent a cephalad vertebra and a caudal vertebra and a plurality of attachment mechanisms for mounting the fusion device to the vertebra. In some embodiments, a second arm having a bone engaging end adapted to attach to a vertebral body at a first end and adapted to engage the crossbar at a second end. The second arm can be configured to engage a caudal vertebral body or a cephalad vertebral body. The first arm can be adapted to articulate relative to a second arm, in some embodiments.

In another embodiment of the invention, an implantable spinal restoration device comprising: an elongated member configured to extend along a portion of a length of a spine adjacent a cephalad vertebra and a caudal vertebra; an attachment mechanism adapted to attach the elongated member to a portion of the spine; a facet arthroplasty element; a support component having a first end and a second end sized to span a portion of the vertebral body and adapted to receive the facet arthroplasty element at the first end and the second end; and a connector adapted to connect the support component to the elongated member. Embodiments can also include an arm with a bone engaging end adapted to attach to a vertebra at a first end and adapted to attach to the support component at a second end. The arm can also be configured to engage a caudal vertebral body and/or a cephalad vertebral body. A second arm can also be provided having a first end adapted to engage a vertebral body at a first end and second end adapted to engage the crossbar. The first arm can be configured to articulates relative to the second arm. The support component can also be configured such that it is sized to span a portion of a vertebral body between a left lamina and a right lamina, such as a portion of a vertebral body between a left pedicle and a right pedicle. Thus, the support component can be further adapted to have an adjustable width. Additionally, the facet arthroplasty element is positioned relative to the support component to provide a symmetric anatomical solution. The facet arthroplasty

element can also be positioned relative to the support component to provide an asymmetrical anatomical solution. Additionally, the ends of the support component are adapted to receive an opening in the facet arthroplasty element. The facet arthroplasty element can also be selected from a plurality of facet arthroplasty elements each having an opening with a different depth. Embodiments of the invention can provide for even distribution of the weight on the vertebral body.

A further embodiment of the invention includes an adaptable implantable spine stabilization device, comprising: a crossbar having a first end and a second end; a pair of vertebral engaging elements each having a bone engaging end and an end adapted to couple to the crossbar; and a pair of anchoring elements each having a first end having a surface adapted to receive a crossbar end and second end adapted to fix the anchoring element to a spinal fusion system. The device can further comprise an arm with a bone engaging end adapted to attach to a vertebra at a first end and adapted to attach to the support component at a second end. Further, the arm can be configured to engage a caudal vertebral body or a cephalad vertebral body. The second arm of an embodiment can be configured to engage a vertebral body at a first end and second end adapted to engage the crossbar. In such an instance, the first arm can be configured to articulate relative to the second arm. Further, the support component can be sized to span a portion of a vertebral body between a left lamina and a right lamina, or span a portion of a vertebral body between a left pedicle and a right pedicle. The support component may be further adapted to have an adjustable width. Embodiments of the invention can provide positioned relative to the support component to provide a symmetric anatomical solution, or an asymmetrical anatomical solution. The ends of the support component can also be adapted to receive an opening in the facet arthroplasty element. Additionally, each facet arthroplasty element can be selected from a plurality of facet arthroplasty elements each having an opening with a different depth. The weight can also be evenly distributed on the vertebral body using the support component.

An embodiment of the invention includes a method for revising spinal fusion surgery to provide support to adjacent vertebra comprising: accessing a spinal location having a spinal fusion device, comprising a pair of elongated members, attached adjacent a caudal vertebral body and a cephalad vertebral body; attaching a facet arthroplasty device comprising an articulating attachment mechanism adapted to receive a crossbar and an attachment mechanism adapted to connected to the elongated member of the spinal fusion device; and closing the wound. In a method of an embodiment, the vertebra adjacent the spinal fusion device are stabilized.

Yet another embodiment of the invention includes an implantable adjacent level arthroplasty device for implantation between a first vertebra and a second vertebra having a vertebra engaging a fusion device comprising: a crossbar; a first component having a first attachment mechanism adapted to attach to a first location of a spinal fusion device attached to a first vertebra and a second attachment mechanism adapted to attach to the crossbar; and a second component having a second attachment mechanism adapted to attach to a second location of a spinal fusion device attached to the first vertebra and a second attachment mechanism adapted to attach to the crossbar, wherein, the first component articulates relative to the second component; further wherein the first vertebra articulates relative to the facet arthroplasty device.

INCORPORATION BY REFERENCE

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

BRIEF DESCRIPTION OF THE DRAWINGS

The novel features of the invention are set forth with particularity in the appended claims. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

FIG. 1 is a lateral view of a normal human spinal column;

FIG. 2 is a superior view of a normal human lumbar vertebra;

FIG. 3 is a lateral view of a functional spinal unit;

FIG. 4 is a posterolateral oblique view of a vertebrae;

FIG. 5 is a perspective view of the anatomical planes of the human body;

FIGS. 6A-B is a side view and a posterior view of a spinal fixation system;

FIGS. 7A-C are views of one embodiment of an adjacent level facet arthroplasty device;

FIGS. 8A-C are views of another embodiment of an adjacent level facet arthroplasty device; **FIG. 8D** illustrates yet another embodiment;

FIG. 9A is a dorsal view of the embodiment of **FIG. 7A** connected to a spinal fusion device; **FIG. 9B** is a side view of the device of **FIG. 9B**; **FIG. 9C** is a perspective view of the device;

FIG. 10A is a dorsal view of the embodiment of **FIG. 8A** connected to a spinal fusion device; **FIG. 10B** is a side view of the device of **FIG. 8B**; **FIG. 10C** is a perspective view of the device;

FIG. 11A is a dorsal view of another embodiment of a facet replacement system where the devices are implanted in combination with a spinal fixation system; **FIG. 11B** is a side view of the device installed; **FIG. 11C** is a perspective view of the device installed;

FIGS. 12A-U depict various connection and attachment systems suitable for use with the invention;

FIG. 13 is a flow chart of a method according to the invention; and

FIG. 14 is a flow chart of another method according to the invention.

DETAILED DESCRIPTION OF THE INVENTION

While preferred embodiments of the present invention have been shown and described herein, it will be obvious to those skilled in the art that such embodiments are provided by way of example only. Numerous variations, changes, and substitutions will now occur to those skilled in the art without departing from the invention. It should be understood that various alternatives to the embodiments of the invention described herein may be employed in practicing the invention. It is intended that the claims that follow define the scope of the invention and that methods and structures within the scope of the claims and equivalents thereof are covered thereby.

The invention relates to implantable devices, including prosthesis suitable for implantation within the body to restore

and/or augment connective tissue such as bone, and systems for treating spinal pathologies. The invention relates generally to implantable devices, apparatus or mechanisms that are suitable for implantation within a human body to restore, augment, and/or replace soft tissue and connective tissue, including bone and cartilage, and systems for treating spinal pathologies. In various embodiments, the implantable devices can include devices designed to replace missing, removed or resected body parts or structure. The implantable devices, apparatus or mechanisms are configured such that the devices can be formed from parts, elements or components which alone, or in combination, comprise the device. The implantable devices can also be configured such that one or more elements or components are formed integrally to achieve a desired physiological, operational or functional result such that the components complete the device. Functional results can include the surgical restoration and functional power of a joint, controlling, limiting or altering the functional power of a joint, and/or eliminating the functional power of a joint by preventing joint motion. Portions of the device can be configured to replace or augment existing anatomy and/or implanted devices, and/or be used in combination with resection or removal of existing anatomical structure.

The devices of the invention are designed to interact with the human spinal column *10*, as shown in **FIG. 1**, which is comprised of a series of thirty-three stacked vertebrae *12* divided into five regions. The cervical region includes seven vertebrae, known as **C1-C7**. The thoracic region includes twelve vertebrae, known as **T1-T12**. The lumbar region contains five vertebrae, known as **L1-L5**. The sacral region is comprised of five fused vertebrae, known as **S1-S5**, while the coccygeal region contains four fused vertebrae, known as **Co1-Co4**.

An example of one vertebra is illustrated in **FIG. 2** which depicts a superior plan view of a normal human lumbar vertebra *12*. Although human lumbar vertebrae vary somewhat according to location, the vertebrae share many common features. Each vertebra *12* includes a vertebral body *14*. Two short boney protrusions, the pedicles *16, 16'*, extend dorsally from each side of the vertebral body *14* to form a vertebral arch *18* which defines the vertebral foramen.

At the posterior end of each pedicle *16*, the vertebral arch *18* flares out into broad plates of bone known as the laminae *20*. The laminae *20* fuse with each other to form a spinous process *22*. The spinous process *22* provides for muscle and ligamentous attachment. A smooth transition from the pedicles *16* to the laminae *20* is interrupted by the formation of a series of processes.

Two transverse processes *24, 24'* thrust out laterally, one on each side, from the junction of the pedicle *16* with the lamina *20*. The transverse processes *24, 24'* serve as levers for the attachment of muscles to the vertebrae *12*. Four articular processes, two superior *26, 26'* and two inferior *28, 28'*, also rise from the junctions of the pedicles *16* and the laminae *20*. The superior articular processes *26, 26'* are sharp oval plates of bone rising upward on each side of the vertebrae, while the inferior processes *28, 28'* are oval plates of bone that jut downward on each side. *See also* **FIG. 4.**

The superior and inferior articular processes *26* and *28* each have a natural bony structure known as a facet. The superior articular facet *30* faces medially upward, while the inferior articular facet *31* (see **FIG. 3**) faces laterally downward. When adjacent vertebrae *12* are aligned, the facets *30* and *31*, capped with a smooth articular cartilage and encapsulated by ligaments, interlock to form a facet joint *32*. The facet joints are apophyseal joints that have a loose capsule and a synovial lining.

As discussed, the facet joint *32* is composed of a superior facet and an inferior facet. The superior facet is formed by the vertebral level below the joint *32*, and the inferior facet is formed in the vertebral level above the joint *32*. For

example, in the **L4-L5** facet joint shown in **FIG. 3**, the superior facet of the joint ***32*** is formed by bony structure on the ***L5*** vertebra (*i.e.*, a superior articular surface and supporting bone ***26*** on the **L5** vertebra), and the inferior facet of the joint ***32*** is formed by bony structure on the **L4** vertebra (*i.e.*, an inferior articular surface and supporting bone ***28*** on the **L4** vertebra). The angle formed by a facet joint located between a superior facet and an inferior facet changes with respect to the midline depending upon the location of the vertebral body along the spine. The facet joints do not, in and of themselves, substantially support axial loads unless the spine is in an extension posture (lordosis). As would be appreciated by those of skill in the art, the orientation of the facet joint for a particular pair of vertebral bodies changes significantly from the thoracic to the lumbar spine to accommodate a joint's ability to resist flexion-extension, lateral bending, and rotation.

An intervertebral disc ***34*** between each adjacent vertebra ***12*** (with stacked vertebral bodies shown as ***14, 15*** in **FIG. 3**) permits gliding movement between the vertebrae ***12***. The structure and alignment of the vertebrae ***12*** thus permit a range of movement of the vertebrae ***12*** relative to each other. **FIG. 4** illustrates a posterolateral oblique view of a vertebrae ***12***, further illustrating the curved surface of the superior articular facet ***30*** and the protruding structure of the inferior facet ***31*** adapted to mate with the opposing superior articular facet. As discussed above, the position of the inferior facet ***31*** and superior facet ***30*** varies on a particular vertebral body to achieve the desired biomechanical behavior of a region of the spine.

Thus, the overall spine comprises a series of functional spinal units that are a motion segment consisting of two adjacent vertebral bodies, the intervertebral disc, associated ligaments, and facet joints. *See,* Posner, I, *et al.* A biomechanical analysis of the clinical stability of the lumbar and lumbrosacral spine. **Spine** 7:374-389 (1982).

As previously described, a natural facet joint, such as facet joint ***32*** (**FIG. 3**), has a superior facet ***30*** and an inferior facet ***31***. In anatomical terms, the superior facet of the joint is formed by the vertebral level below the joint, which can thus be called the "caudal" portion of the facet joint because it is anatomically closer to the tail bone or feet of the person. The inferior facet of the facet joint is formed by the vertebral level above the joint, which can be called the "cephalad" portion of the facet joint because it is anatomically closer to the head of the person. Thus, a device that, in use, replaces the caudal portion of a natural facet joint (*i.e.*, the superior facet ***30***) can be referred to as a "caudal" device. Likewise, a device that, in use, replaces the cephalad portion of a natural facet joint (*i.e.*, the inferior facet ***31***) can be referred to a "cephalad" device.

When the processes on one side of a vertebral body ***14*** are spaced differently from processes on the other side of the same vertebral body, components of the devices on each side would desirably be of differing sizes as well to account for anatomical difference that can occur between patients. Moreover, it can be difficult for a surgeon to determine the precise size and/or shape necessary for an implantable device until the surgical site has actually been prepared for receiving the device. In such case, the surgeon typically can quickly deploy a family of devices possessing differing sizes and/or shapes during the surgery. Thus, embodiments of the spinal devices of the present invention include modular designs that are either or both configurable and adaptable. Additionally, the various embodiments disclosed herein may also be formed into a "kit" or system of modular components that can be assembled *in situ* to create a patient specific solution. As will be appreciated by those of skill in the art, as imaging technology improves, and mechanisms for interpreting the images (*e.g.*, software tools) improve, patient specific designs employing these concepts may be configured or manufactured prior to the surgery. Thus, it is within the scope of the invention to provide for patient specific devices with integrally formed components that are pre-configured.

A configurable modular device design, such as the one enabled by this invention, allows for individual components to be selected from a range of different sizes and utilized within a modular device. One example of size is to provide caudal and cephalad stems of various lengths. A modular implantable device design allows for individual components to be selected for different functional characteristics as well. One example of function is to provide stems having different surface features and/or textures to provide anti-rotation capability. Other examples of the configurability of modular implantable device of the present invention as described in greater detail below.

Implantable devices of the present invention are configurable such that the resulting implantable spinal device is selected and positioned to conform to a specific anatomy or desired surgical outcome. The adaptable aspect of embodiments of the present invention provide the surgeon with customization options during the implantation or revision procedure. It is the adaptability of the present device systems that also provides adjustment of the components during the implantation procedure to ensure optimal conformity to the desired anatomical orientation or surgical outcome. An adaptable modular device of the present invention allows for the adjustment of various component-to-component relationships. One example of a component-to-component relationship is the rotational angular relationship between a crossbar mount and the crossbar. Other examples of the adaptability of modular device of the present invention as described in greater detail below. Configurability may be thought of as the selection of a particular size of component that together with other component size selections results in a "custom fit" implantable device. Adaptability then can refer to the implantation and adjustment of the individual components within a range of positions in such a way as to fine tune the "custom fit" devices for an individual patient. The net result is that embodiments of the modular, configurable, adaptable spinal device and systems of the present invention allow the surgeon to alter the size, orientation, and relationship between the various components of the device to fit the particular needs of a patient during the actual surgical procedure.

In order to understand the configurability, adaptability, and operational aspects of the invention, it is helpful to understand the anatomical references of the body ***50*** with respect to which the position and operation of the devices, and components thereof, are described. There are three anatomical planes generally used in anatomy to describe the human body and structure within the human body: the axial plane ***52***, the sagittal plane ***54*** and the coronal plane ***56*** (see **FIG. 5**). Additionally, devices and the operation of devices are better understood with respect to the caudal ***60*** direction and/or the cephalad direction ***62***. Devices positioned within the body can be positioned dorsally ***70*** (or posteriorly) such that the placement or operation of the device is toward the back or rear of the body. Alternatively, devices can be positioned ventrally ***72*** (or anteriorly) such that the placement or operation of the device is toward the front of the body. Various embodiments of the spinal devices and systems of the present invention may be configurable and variable with respect to a single anatomical plane or with respect to two or more anatomical planes. For example, a component may be described as lying within and having adaptability or operability in relation to a single plane. For example, a stem may be positioned in a desired location relative to an axial plane and may be moveable between a number of adaptable positions or within a range of positions. Similarly, the various components can incorporate differing sizes and/or shapes in order to accommodate differing patient sizes and/or anticipated loads.

FIG. 6A is a view of a portion of the spine ***10*** having a spinal fusion implant ***100*** (such as the spinal fusion rod and screw system commercially available from SeaSpine corporation) from a side view positioned in the sagittal plane. The spinal implant ***100*** has a rod ***110*** which is anchored to the spine ***10*** with one or more anchors ***120***, such as bone screws that penetrate the vertebral body ***14***. The anchors ***120*** are fixed to the rod ***110*** via attachment mechanisms ***115***. **FIG. 6B** is a dorsal view of a portion of the spine ***10*** having a spinal implant ***100***. The spinal implant has a pair

of rods *110, 110'* which are anchored to the spine *10* with one or more anchors *120* (shown in FIG. 9A) fixed to the rods *110, 110'* via attachment mechanisms *115*.

Other spinal fixation systems can also be employed without departing from the scope of the invention. For example, systems using cables to stabilize the spine instead of rods can be employed. It is also contemplated the device can be used in combination with fixation systems positioned anteriorly, posteriorly, and laterally with respect to the spinal column.

FIG. 7A is a posterior view of an anchorable facet replacement device *200* according to one embodiment of the present invention. The device *200* includes a crossbar *205*, a pair of cephalad arms *220, 220'* and a pair of connectors *230, 230'*. In this exemplary embodiment, the facets *30* and *31* of the vertebral body are replaced by the cooperative operation of the crossbar *205*, the cephalad arms *220, 220'* and the adaptable crossbar mounts *276* that join the cephalad arms *220, 220'* to the crossbar *205*, interacting with the caudal device *250*. The components of the cephalad implantable device *200* are designed to provide appropriate configurability and adaptability for the given disease state, patient specific anatomy and spinal level where the implant occurs.

The crossbar *205* has a first end *210* and a second end *215*. The crossbar *205* can be formed from a two piece bar where the first end *210* is attached to a threaded male portion having threads (not shown). The crossbar second end *215* can be attached to a threaded female portion sized to receive the threads. It is contemplated that the threaded ends allow for the width of the crossbar to be adjusted to mate with the width between caudal bearings *250*. Additional alternative embodiments of the crossbar *205* could include a series of solid crossbars of varying widths and/or thicknesses, or an adjustable crossbar having some form of locking or biasing mechanism (such as a spring-loaded tensioner or detent mechanism, *etc.*), as would be appreciated by those of skill in the art. Further, in an alternative embodiment, the end *210* can be configured to have a threaded male portion (instead of female portion) that fits within a female threaded portion of the crossbar *205* without departing from the scope of the invention.

A pair of cephalad arms *220* are also illustrated in the exemplary embodiment of the anchorable, adaptable implantable device *200* of the present invention. Each cephalad arm *220, 220'* includes a bone engaging end *225, 225'* and an end *240, 240'* adapted to couple to the crossbar *205*. The caudal end *240* adapted to engage the crossbar *205* includes an arm *245* and an elbow *247*. The caudal end *240* is attached to the crossbar using the crossbar mount *276*. The bone engaging cephalad end *225* includes a cephalad stem *230* and a distal tip *235*. The cephalad stem *230* and the distal tip *235* are threaded or otherwise configured to engage the bone. Alternatively, the distal tip *235* could be formed integrally with the cephalad stem *230*, of the same or a different material as the cephalad stem *230*. The surface of the cephalad stem *230* can be a textured surface or any other modified surface such as, for example, a surface that assists or promotes bony in-growth.

The crossbar mount *275* is a connection structure to couple the cephalad prosthesis elements *220* to the crossbar *205*. In the illustrated embodiment, the crossbar mount *275* includes a cephalad arm engaging portion *272*, a crossbar engaging portion *274* and a fixation element *276*. Embodiments of the crossbar mount *275* provide adaptability between the cephalad prosthesis elements *220* and the crossbar *205* and the loading characteristics of the crossbar ends *10, 215* and the caudal prosthesis *250*.

A pair of caudal bearing elements *250* are also illustrated in the exemplary embodiment of the configurable and adaptable cephalad stabilization device *200* of the present invention. Each of the caudal bearing elements *250* includes a caudal cup *251*. The caudal cup *251* includes a surface *255* adapted to receive a crossbar end and a

surface to engage the caudal stem head engaging surface. Caudal connectors ***230, 230'*** are provided to connect the implantable device ***200*** to the rods ***110, 100'*** of the spinal implant ***100*** below the connection mechanism ***115***. The clamping mechanism ***230*** can attach to various portions of the spinal implant ***100***, including the rods ***110, 110'*** or the connection mechanism ***115***. Other devices can be provided that are attached to all or part of the spinal implant ***100***, including cross-connectors and/or lateral rod connectors (not shown), or combinations thereof. The clamping mechanisms ***230, 230'*** can further be adapted to lock onto the spinal implant ***100*** by providing an additional connection mechanism ***231*** such as a bolt.

FIG. 7B illustrates the implantable device ***200*** from a side view; FIG. 7C illustrates the device ***200*** from a perspective view. As will be appreciated by those of skill in the art, in some instances, the device can be configured to function with only a single cephalad arm, thus allowing for a 3-point fixation mechanism, that in-turn is connected to the spinal fusion device. Where a 3-point fixation design is used, the cephalad arm ***220*** can be coupled to the cross-bar ***205*** such that the length of the arm ***220*** from the bone engaging end ***225*** to the cross-bar engaging end ***240*** crosses the midline of the vertebra along the vertical length of the sagittal ***54*** plane. Other attachment mechanisms can be provided without departing form the scope of the invention.

FIG. 8A is a posterior view of an anchorable facet replacement device ***300*** according to an alternate embodiment of the present invention. The device ***300*** includes a crossbar ***305***, a pair of cephalad arms ***320, 320'*** and a pair of cephalad connectors ***330, 330'***. In this exemplary embodiment, the facets ***30*** and ***31*** of the vertebral body are replaced by the cooperative operation of the crossbar ***305***, the cephalad arms ***320, 320'*** and the adaptable crossbar mounts ***275*** that join the cephalad arms ***320, 320'*** to the crossbar ***305*** join the device to an implant, interacting with the caudal device ***350***. The components of the caudal implantable device ***300*** are designed to provide appropriate configurability and adaptability for the given disease state, patient specific anatomy and spinal level where the implant occurs.

The crossbar ***305*** has a first end ***310*** and a second end ***315***. The crossbar ***305*** can be formed from a two piece bar where the first end ***310*** is attached to a threaded male portion having threads (not shown). The crossbar second end ***315*** can be attached to a threaded female portion sized to receive the threads. It is contemplated that the threaded ends allow for the width of the crossbar to be adjusted to mate with the width between caudal bearings ***350***. Additional alternative embodiments of the crossbar ***305*** could include a series of solid crossbars of varying widths and/or thicknesses, or an adjustable crossbar having some form of locking or biasing mechanism (such as a spring-loaded tensioner or detent mechanism, *etc.*), as would be appreciated by those of skill in the art. Further, in an alternative embodiment, the end ***310*** can be configured to have a threaded male portion (instead of female portion) that fits within a female threaded portion of the crossbar ***305*** without departing from the scope of the invention.

A pair of caudal bearing elements ***350*** are also illustrated in the exemplary embodiment of the configurable and adaptable device ***300*** of the present invention. Each of the caudal bearing elements ***350*** includes a caudal cup ***351*** and a fixation element ***360***. The caudal cup ***351*** includes a surface ***355*** adapted to receive a crossbar end and a surface to engage the caudal stem head engaging surface. The fixation element ***360*** includes a caudal stem ***365*** and a distal tip ***370***. Alternatively, the distal tip ***370*** can be formed integrally with the caudal stem ***365***, of the same or a different material as the caudal stem ***365***. The caudal stem ***365*** and distal tip ***370*** can be threaded or otherwise configured to engage.

Cephalad connectors ***330, 330'*** are provided to connect the implantable device ***300*** to the rods ***110, 100'*** of the spinal

implant *100* below the connection mechanism *115*. The clamping mechanism *330* can attach to various portions of the spinal implant *100*, including the rods *110, 100'* or the connection mechanism *115*. Other devices can be provided that are attached to all or part of the spinal implant *100*, including cross-connectors and/or lateral rod connectors (not shown), or combinations thereof. The clamping mechanisms *330, 330'* can further be adapted to lock onto the spinal implant *100* by providing an additional connection mechanism *331* such as a bolt or a screw.

FIG. 8B illustrates the implantable device *300* from a side view; FIG. 8C illustrates the device *300* from a perspective view. Similar to the modifications described above with respect to FIG. 7, as will be appreciated by those of skill in the art, in some instances, the device can be configured to provide a single caudal arm, thus providing a 3-point fixation mechanism that, in turn, is connected to the spinal fusion device. Where a 3-point fixation design is used, the caudal arm *320* can be coupled to the cross-bar *305* such that the length of the arm *320* from the spinal fusion engaging end to the cross-bar engaging end *340* crosses the midline of the vertebra along the vertical length of the sagittal *54* plane.

FIG. 8D illustrates an implantable device *300* suitable for use in a fusion system wherein the fusion system is being converted mid-length to provide for motion at a target joint. The device *301* has a cross-bar *305* which engages twp caudal cups *350* on either end. Caudal arms *320, 320* are provided to connect the device to a spinal fixation device (such as device *100).* Cephalad connectors *230, 230'* are provided to connect the device to a second spinal fixation device. This, the implantable device *301* provides an articulable device between two implanted devices that stabilize the spine both in the caudal and cephalad direction. Either of the caudal arms *320, 320'* or the cephalad connectors *230, 230'* can be configured to engage the spinal fusion device *100* along the rod *110*, the anchors *120* or the attachment mechanisms *115.* Configurations can include, providing an aperture to receive, for example, a screw which engages the fusion device *100*, or configuring the arm *320, 320'* or connector *230, 230'* to hook around the fusion device, *e.g.,* around the rod.

FIGS. 9A, 9B and 9C illustrate a spinal fusion implant *100* and facet replacement device *200* (see FIG. 7A) implanted on a portion of a spine *10.* The spinal fusion implant *100* has been depicted at an angle relative to the facet replacement device *200*. However, as will be appreciated by those skilled in the art, the orientation of the spinal fusion implant *100* and the facet replacement device *200* can be varied, as desired. For purposes of illustration the anchoring mechanism of the spinal fusion implant *100* have not been depicted in each depiction to avoid obscuring the invention. The design of the device *200* is such that it can be implanted during an open surgical procedure, or can be implanted through less-invasive and/or minimally-invasive means. In a desirable embodiment, the various components of the device *100* can be delivered percutaneously. Moreover while various components described can be implanted into the pedicles, these components, and variations thereof, can be implanted or secured to the pedicles, the lamina, the vertebral body, or combinations thereof. FIGS. 10A, 10B and 10C illustrate an alternative system *98* for achieving spine stabilization and facet function restoration.

FIG. 11A illustrates an implanted system *97* from the dorsal view. Two or more vertebra are stabilized with a spinal fusion implant *100* and the facet joint to the next adjacent cephalad vertebra is partially or completely replaced by a device *200* while the facet joint to the next adjacent caudal vertebra is partially or completely replaced by a device *300*. FIG. 11B illustrates the implanted system *97* from the side view; FIG. 11C illustrates the system from a perspective view. As will be appreciated by those of skill in the art, the length of the spine stabilization system *100* employed can vary depending upon the number of vertebra to be fused. As will be appreciated by those of skill in the art, the device of FIG. 8D can also be employed in a system, such as *97*, to provide a combination of fusion with articulation.

FIG. 12 illustrates various connection and attachment designs useful, in whole or in part, in embodiments of the invention. FIG. 12A illustrates a connector *400* having a bearing *402* connected to an arm *404*. The connector *400* has an arm holder *406* that connects the arm *404* to a sleeve *410*. The connector illustrated in FIG. 12B enables a spinal implant, such as those depicted above, to be anchored to the spine *10* by positioning a portion of the vertebral body within the hook *410*. The rod *110* (shown in FIGS. 7-8) of the spinal implant can then be inserted laterally through the opening *412* defined between the lateral portion *414* of extension *416* and flange *418* of connector portion *420*. The rod may then be axially displaced along the U-shaped channel *422*. The fastener (not shown) can be threaded through the lateral portion *414* of extension *416* along the axial portion *424*, and into threaded engagement with threads of flanges *418, 418'* which cause the lower portion of fastener to engage the elongate rod *110* (FIG. 6) and press the rod *110* tightly against the bottom of the u-shaped channel *422*. FIG. 12C illustrates another internal fixation device suitable for use with this invention. The internal fixation device *430* attaches to a fixation rod *110, 110'* and comprises a hook *432* with a screw device *434* with an axis *436*. The hook *432* has an actual hook element *438* and a shackle element *440* which grips a portion of the spine. The shackle element *440* is used to fasten the fixation rod *110* and the hook *432* on each other. The shackle element *440* forms a groove with a groove bottom *442*, against which the fixation rod *110, 110'* rests, and two lateral walls *444, 444'* following the groove bottom *442*. The two lateral walls *444, 444'* of the shackle element *440* are clamped together by means of the screw device having the axis *436* by means of which the fixation rod *110, 110'* can be clamped in place with its area received in the shackle element *440*.

FIG. 12D illustrates a transverse connector *450* suitable for use with the present invention. The connector *450* joins two elongated spinal stabilizers *452, 452'*, (but which could also comprise plates), fixed to a number of vertebrae by means of anchoring members which are not shown. The transverse connector has a linking assembly having a first *454* and a second part *456* which each have an end portion terminating in a clamp *458, 458'*. A variety of clamping structures could be used. They can be the same or different. For example, the clamp on one side could be closed while the clamp on the opposing side could be open. However, preferably, the clamps each include a recess *458, 458'* which receive a respective rod. Setscrews *461* can be employed and received in threaded bores each terminating in a beveled area *462, 462'* which biases the rod into a retaining contact with the recess. The longitudinal axis of the setscrew is offset from the longitudinal axis of the rod receiving recess so that the setscrew will bias the rod into the recess. The setscrews may include internal hexes, or other suitable torque driving means, for tightening. When they are assembled the recesses *458, 460* are both open toward a central medial line or toward each other. This arrangement can be used for initial placement of the connector on the rod *110* (FIG. 6). Thus, the connector assembly can be placed onto the rods and then tightened with respect to the length. The second member *456* of the transverse connector includes a bore *462*, which receives an extension portion *464* which extends outwardly from the clamp *458* of the first part *454*. The extension can move in and out of the bore *462* to contract or expand the length of the space connected and the extension *464* can rotate in the bore *462* to change the relative angle of the openings of the rod recesses of the clamps to accommodate a varying relative angle of the longitudinal axis of the rods *110*. Further, the first and second members, *454, 456* can include a limit mechanism such as a flanged end on the extension *464*. When employed, this flanged end is inserted into a vertical keyway *466* which is a vertical slot in the first member having an enlarged opening that is slightly larger than the diameter of the annular flange, and which will accommodate entry of the larger diameter flanged end. An undercut can be provided on either side of the keyway to allow for captured movement of the flanged end in the keyway, but allow for restriction against movement out of the keyway *466*. A vertical slotted area is slightly wider than the diameter of the extension. Thus, the keyway *466* restrains the flanged end in the vertical keyway *466* as it is slid downward toward the bore *462*.

When the extension comes to the end of the keyway ***466***, it can be moved inward in the bore ***462***.

FIG. 12E illustrates a bar ***110*** with a threaded screw connector ***470***. A hollow connector ***472*** is provided to engage the rod ***110***. A fastener ***474*** pivotally connects the bone anchoring bolt ***476***, having threads ***478***, such that the connector ***470*** can attach a bar or cable ***110*** to a bone.

FIG. 12F illustrates a perspective view of a mounting device ***480***. The device ***480*** comprises a connector ***482*** with two screws ***484, 484'*** adapted to form a screw-nut link by engaging the duct ***486*** of the head ***488*** of the connector. The connector has two vertical plane faces ***490*** comprising a front face and a rear face, which faces are substantially parallel and extend continuously over the full height of the connector. The connector also has two horizontal plane faces comprising a top face and a bottom face ***492, 492'*** that are parallel to each other and substantially perpendicular to the above-mentioned vertical faces ***490***. The connector has a generally cylindrical duct ***486*** extending parallel to the front and rear faces ***490***, halfway between them, and perpendicular to the top and bottom faces ***492, 492'*** through which it opens out. The connector is axially symmetrical about the axis of the duct ***486***. The connector has two slots ***494, 494'*** extending generally parallel to the top and bottom faces ***492, 492'*** in two side faces ***496*** of the connector that extend perpendicularly to the front and rear faces ***490***. Each slot ***494, 494'*** is generally of channel section being defined by a top face ***498*** parallel to the top face ***492*** of the connector, a web face parallel to the side faces ***496*** of the connector, and a bottom face ***498'*** facing the top face ***498*** and extending perpendicularly to the front and rear faces ***490*** while being slightly inclined towards the inside of the connector. The angle between the top and bottom faces ***498, 498'*** of the slot can lie in the range 2 to 10°, for example. The slots ***494, 494'*** co-operate with the duct ***486*** which extends between them to define a housing for receiving a cross-member ***500***, as described below. Furthermore, on either side of the axis of the duct ***486***, the slots ***494, 494'*** define two junctions between which the duct ***486*** and the housing extend. A portion of the connector extending above the junctions forms a head ***502***. The two side faces ***496*** on the head ***502*** are shaped like two sectors of a common cylinder that is coaxial with the duct ***486***. The connector has a bottom cylindrical face ***504*** contiguous with the bottom face ***498*** of the connector, perpendicular to the duct ***486***, and halfway between the two side faces ***496***. Between them, the slots ***494, 494'*** and the cylindrical face ***504*** define two jaws ***506, 506'*** each connected to the head ***502*** by the two junctions. On each junction, the connector has a notch ***508*** extending away from the jaws ***506, 506'*** towards the head ***502***. The diameter of the duct ***486*** is smaller in the head ***502*** than in the remainder of the connector. Inside the head ***502***, the duct ***486*** has a thread.

It has two screws ***484*** each adapted to form a screw-nut link by engaging in the duct ***486*** of the head ***502*** of a respective connector. Each screw ***484*** has a hexagonal socket ***510*** for receiving a hexagonal key for turning the screw ***484*** received in the duct ***486***. The device has two rectilinear longitudinal rods ***512, 512'*** for extending along the backbone of a patient, each being fixed to the vertebrae by anchor members using techniques known in the art. The two rods ***512, 512'*** typically have a circular profile as illustrated with a diameter the same as the cylindrical face ***504*** between the jaws. The jaws ***506, 506'*** are adapted to make surface-on-surface contact with the rod. The cylindrical faces ***504*** of the jaws together extend over a circular arc of total extent exceeding 180° and selected as a function of the properties of the material of the connector so as to enable the jaws ***506, 506'*** to be engaged on the rod ***512, 512'*** by being snap-fastened thereon. The cylindrical faces ***504*** of the jaws present a geometrical outline which extends beyond the bottom face ***492'*** of the connector ***482***. Thus, when the rod ***512, 512'*** is engaged between the jaws ***506, 506'***, the rod projects beyond the jaws in a radial direction. Finally, the device has a rectilinear cross-member ***514*** of generally rectangular section adapted to be received in the housings, passing right through the connectors ***482***.

FIG. 12G illustrates another connection system *520*. A rod *110* is received through aperture *522* in a pivotal head *524* attached to an anchoring dowel *526* for anchoring the device *520* to the bone.

In FIG. 12H, the positioning and locking device *530* is made up of an upper jaw member *532* and a lower jaw member *534* having opened faces which are machined with assembly notches *536* to allow one to be positioned and pivoted against the other, leaving an opening *538* at the opposite end. A bushing, or hollow shaft, *540* passes through the two jaws *532, 534* at right angles and then through the opposite end of the jaws, with respect to the gripping jaw opening. Bushing *540*, at its upper part *542*, has the shape of a cone frustum with slots *544* which start from this upper part *542* and run in the direction of the axis of the bushing to end about halfway down the length thereof. The lower part of bushing *540* is threaded at *546* and is screwed into a nut *548* which clamps the two jaws *532, 534* together. A spring in the form of a staple *550* or bent wire is housed inside holes *552* each made in each one of the jaws *532, 534* also on the opposite side to the opening of the gripping jaw. Upper jaw *532* has a conical recess in its upper part and a cylindrical bore to accommodate bushing *540* and lower jaw *534* has a bore which has two opposed flat surfaces to play a part in holding bushing *540* in place especially against rotation, these flat surfaces not being depicted in the drawing. Bushing *540* can have a smaller diameter in its threaded lower part *546* and in its central part has two opposed flat surfaces, not shown in the drawing, which engage the flats on lower jaw *534* to prevent bushing *540* from rotating relative to the jaws and allow the nut to be locked. Between bushing *540* and the bores of jaw *534, 536* there is a clearance that allows the jaws device *530* to be pivoted outwardly against the face of staple spring *550*, prior to the tightening operation. The clearance allows the jaws *532, 534* to be parted just enough for clipping an element between the faces of each jaw, for example, onto a rod or a hoop along which device *530* can slide and therefore change position. A rod *110* may be inserted into bushing *540* and locked in position by the clamping action of the conical position of the upper part of bushing *540* which deforms inwardly as nut *548* is tightened pulling the bushing downwardly into the conical recess of upper jaw *532*. This causes upper part of bushing *540* to deform inwardly in the area of slots *544*. This rod *110* may remain fixed in a concrete assembly position so that one can adjust the relative positions of all the elements of the device prior to the final operation of tightening the assembly.

FIG. 12I is a perspective view of the constructed clamp *550* with a small cut-away to show the junction between the pin connector *552* and the connecting rod *110*. Tightening the bolt *554* draws the pin *556* against the distal outer surface *558* of the clamp body *560*. This action braces the pin against the clamp preventing the rotation of the pin connector *552* and thus the pin *556*. Moreover, the pin *556* is prevented from moving axially with respect to connector *552*. Tightening the bolt *554* additionally draws the rod-engaging surface *580* of the connector *552* into engagement with the connecting rod *110*. This interference has a number of effects that further prohibit any movement of the tightened clamp *550*. First, friction between the rod-engaging surface *580* and the outer surface of the rod *110* further prevents any rotation of the pin connector *552*. Additionally, the force exerted by the pin connector at this junction pushes the rod *110* in the direction of arrow *b*. This ensures that the rod *110* is seated against the back wall *582* of the slot *584* providing a good rigid mechanical junction between the connecting rod *110* and the clamp body *560* preventing rotation of the clamp body around or sliding along the connecting rod *110*. The clamp body *560* does not substantially squeeze-down on or close over the connecting rod when the bolt *554* is tightened. It is only the interference between the rod-engaging surface and the rod *110* that prevents movement between the rod *110* and clamp *550*.

FIG. 12J illustrates an attachment mechanism *570* has a threaded nut *572* having female threads *574* for engaging the shaft *576* of an anchoring shaft *578*. The threaded nut *572* has a clamp *580* for engaging a rod *110*. The clamp *580*

forms an adjustable aperture *582*. The aperture *582* is adjusted by tightening a fastener *584*.

FIG. 12K illustrates a bone bolt *590* suitable for use with the invention. Bone bolt *590* is shown attached to a clamp *592* with the longitudinal axis *L1*, and clamp *592* is shown attached to a spinal implant rod *594* with a longitudinal axis *L2*. Clamp *592* includes a clamp bolt *596*, an arm *598*, a rod interface washer *600*, a set screw *602*, and a nut *604*. Clamp bolt *596* has an aperture *606* for receiving rod *594*, and while the aperture is shown closed around rod *594*, it will nevertheless be understood that an open-sided aperture may also be used to permit top-loading of rod *594* into clamp *592*. Set screw *602* is inserted through a threaded opening *608* and into aperture *606* in clamp bolt *596* so as to allow set screw *602* to push against rod *594*. Arm *598* has a bore *610* for receiving bone bolt *590*. Arm *598* is simultaneously tightened to clamp *592* when set screw *602* is tightened against rod *594*. As set screw *602* pushes against rod *594*, rod *594* pushes against rod interface washer *600*, which pinches arm *598* between rod interface washer *600* and stop *612*. In this manner, set screw *602* acts as a compression member to tighten clamp *592* and achieve substantial fixation of arm *598* to rod *594*.

FIG. 12L depicts fasteners *620* suitable for use in the invention. The fastener *620* has an aperture *622* for receiving a rod *110* (not shown) and is adopted to allow the diameter of the aperture *622* to increase and decrease in order to facilitate engaging the rod *110*. A bolt *624* is provided to communicate through a second aperture *626* to decrease the aperture *622* that received the rod.

FIG. 12M retainer assembly *630* includes a set screw *632* and a generally rectangular retainer block *634* into which angular member *636* and rod *110* extend. Block *634* has a rod passage *638* which receives rod *110*. Rod *110* (not shown) can have a substantially circular cross-section; however, rods having various other cross-sections, such as hexagonal or oval cross-sections, could be used with corresponding modifications to rod passage *638*. Block *634* also includes a transverse passage *640* which receives inner end portion *642* of angular member *636* and communicates with rod passage *638*. Transverse passage *640* includes a plurality of mating surfaces *644* which engage similarly shaped retaining surfaces or teeth *646* that project radially outwardly from inner end portion *642* of angular member *636*. Meshing engagement between mating surfaces *644* on block *634* and teeth *648* on inner end portion *642* prevents rotational movement of angular member *636* about a longitudinal central axis *650* of inner end portion *642*. It is understood that mating surfaces of various shapes may be formed in transverse passage *640* to receive similarly shaped retaining surfaces formed on block *634*.

FIG. 12N illustrates another attachment mechanism *660*. Pincers *662* attached to the vertebras, formed by two curved claws with opposite concavities, one of which *664* forms part of the body *666* of the pincer and the other *668* independent, with a cylindrical lateral prolongation *610* which on passing tightly through the body *666* of the pincer allows it to make axial or turning displacements to adapt the relative position of the two claws to the shape and sizes of the zone of the vertebra where it is fastened. There is a prisoner screw *670* for immobilization of the movable claw *668* in the suitable position, as well as another prisoner screw *672* to retain insertion of the connecting prolongation *674* of the pincer-bar connectors *676* tautening wire *678* through-orifice *679* for lateral displacement of the vertebras.

FIG. 12O illustrates yet another attachment mechanism *680*. A crossbar *682* is provided with a clamping mechanism *684* having a sizable aperture *686*. The sizable aperture *686* is adjustable by adjusting screw *688*. The aperture *686* is configured to, for example, receive a rod *110*.

FIG. 12P illustrates an alternate mechanism *640*. A pair of parallel rods *642, 642'* are provided. The first parallel

rod *642* is integrated with a connector *644* for the second parallel rod *642'*. The second parallel rod *642'* can be fed through an aperture *646* on the connector *644*. A nut *648* is provided to secure the second nut *642'* in the aperture *646*.

FIG. 12Q illustrates a connector *770* having a rod *110* connected to a crossbar *772*. The rod is secured through an aperture *774*. A nut *776* is provided to secure the rod *110*.

FIG. 12R illustrates a connector assembly *780* suitable for use with the invention from a perspective view, an end view and a top view. The assembly attaches spinal implant rod *110* with a longitudinal axis L1 to the shaft of a vertebral anchor with the longitudinal axis. Connection assembly *780* includes a bolt *782*, a clevis *784*, a rod interface washer *786*, and a set screw *788*. Bolt *782* has an aperture *790* for receiving a rod *110* in a spinal implant system. While a closed aperture is depicted, it will be appreciated than an open-sided aperture may also be used to permit top loading the of the connector rod. Set screw *786* is inserted through a threaded opening *792* in bolt *786* and into aperture *790* to allow set screw *786* to push against rod *A*. Clevis *784* is a u-shaped piece with a bore *794* for receiving a vertebral anchor or bolt *B* and is simultaneously tightened when set screw *788* is tightened against rod **A.** The shaft *B* may be roughened and the interior of clevis *784* may be correspondingly roughened to increase friction between the pieces. As set screw *788* pushes against rod *A*, rod A pushes against rod interface washer *786*. This force pinches the ends *796* and *798* of clevis *784* together between rod interface washer *786* and stop *800*, which tightens clevis *784* together between rod interface washer *786* and stop *790*.

FIG. 12S depicts a multiaxial connector *700* suitable for the invention. The connector *700* has a first connecting element *702* perforated with a bore *704* designed to receive the second threaded part *706* of the fixing screw *708*, another bore *710* comprising in its inner part an annular track *712* with spherical profile and a slot *714* passing through the bore *704* to emerge inside the bore *710* at the annular track *716*, a second connecting element *718* perforated with a bore *720* designed to receive the lining rod *722* of a threaded hole *724* co-operating with a clamping screw *726* for locking the rod in translation and linking means *728* forming a ball joint enabling the first and second elements to be coupled together such that the elements can pivot relative to each other to present the linking rod *729* in specific angular positions and to laterally offset the linking rod relative to the pivoting centre of the elements.

FIG. 12T illustrates a connection assembly *730* having a longitudinal member *732* and a housing *734*. Longitudinal member *732* has an aperture *736* for receiving a rod *110*, for example in a spinal system. Open sided apertures can be used to permit top loading of the rod. A threaded opening *738* is provided to communicate with a set screw *740*. The housing *734* has a passageway *742* for receiving a shaft or shank of a vertebral anchor.

FIG. 12U illustrates a connection assembly *750* used with an offset connector or spindle. The assembly *750* has aperture threaded bolt *752* for connection to bone. The fence bolt *752* fits within an aperture *754* of an anchor *756*. A cross member *758* connects the anchor *756* to a rod holder *760*. A rod *110* fits within an aperture *762* of the rod holder. A set screw *764* is provided to fix the location of the rod in the aperture. A second set screw *766* is provided to fix the location of the fence bolt *752* within the aperture *754* of anchor *756*.

A variety of connectors that would be suitable for use in the invention include, for example, those described in U.S. Patent Nos. 6,231,575, 6,309,391, 6,340,361, 6,342,054, 6,368,320, 6,749,361; U.S. Patent Publication Nos. 2002/0049446, 2002/0042613, 2002/0013585, 2002/0013588, 2002/0082601; European Patent Nos. 1205152, 1103226; PCT Patent Publication Nos. WO 01/30248, WO 02/34150, WO 01/67972, WO 02/02024, WO 01/06939,

WO 02/24149.

Turning now to FIG. 13, a flow chart depicting a method is depicted. Initially, an incision is created ***800*** to access a target location of the spine. As will be appreciated, this devices of this application can be implanted concurrently with the implantation of a spinal fusion device, such as a rod and screw, or in a subsequent procedure. If the devices are implanted concurrently with the fusion device, then the physician would proceed with first implanting the spinal fusion device ***801.*** Alternatively, where the fusion device has already been implanted (*e.g.*, where this procedure revises the prior surgical procedure), then the physician accesses the implanted fusion device ***802*** immediately following creating the incision ***800***. Thereafter, the physician can select one or more adjacent level arthroplasty devices ***804*** to use with the implanted spinal fusion device. Once the devices are selected ***804***, the devices are then implanted ***806***. As will be appreciated by those of skill in the art, due to the modularity of the designs employed, it is possible for the physician to choose a first adjacent level arthroplasty device, implant it in conjunction with the spinal fusion device and then select a different device based on, for example, experience or *in situ* appearance of the suitability of the device. Additionally, adjustments to the connection of the adjacent level arthroplasty device can be made without departing from the scope of the invention. Once the physician is satisfied with the selection, the incision is then closed ***808***.

FIG. 14 depicts the flow chart for an alternate embodiment of a method of the present invention, particularly well suited for revision of an already-fused functional spinal unit, to partial or full natural motion. Initially, an incision is created ***900*** to access a target location of the spine. The spinal fusion device can be implanted ***901*** at that time or during a previous procedure. As discussed, this procedure is well suited for a subsequent procedure. The physician then exposes at least a portion of the spinal fusion instrumentation ***902***. Thereafter, the physician can remove and/or modify the components of the existing spinal fusion instrumentation. Removal and/or modification includes the resecting of individual fusion components, such as rods. If necessary, the physician can access the intervertebral disk space ***903*** to separate any arthrodesis across the disk space as well as remove any fusion cages and/or other associated intervertebral fusion devices (including intervertebral spacer and/or dynamic stabilization devices) ***904***. If desired, the physician can implant an artificial disk or nucleus replacement ***905***. The physician can select one or more adjacent level arthroplasty devices ***906*** to use with the remaining components of the spinal fusion instrumentation. Once the devices are selected ***906***, the devices are then implanted ***907***.

As will be appreciated by those of skill in the art, due to the modularity of the designs employed, it is possible for the physician to choose a first adjacent level arthroplasty device, implant it in conjunction with the spinal fusion device and then select a different device based on, for example, experience or *in situ* appearance of the suitability of the device. Additionally, adjustments to the connection of the adjacent level arthroplasty device can be made without departing from the scope of the invention. Once the physician is satisfied with the selection, the incision is then closed ***908***. It should also be appreciated that the present method could be used to revise the fusion of a single functional spinal unit, or could be used in any portion or location of a spinal fusion spanning multiple spinal levels.

CLAIMS

WHAT IS CLAIMED IS:

1. An implantable facet arthroplasty device for association with a first vertebra and a second vertebra comprising:

(a) a crossbar;

(b) a first component having a first attachment mechanism adapted to attach to a first location of a spinal fusion device attached to a first vertebra and a second attachment mechanism adapted to engage the crossbar; and

(c) a second component having a second attachment mechanism adapted to attach to a second location of a spinal fusion device attached to the first vertebra and a second attachment mechanism adapted to engage the crossbar,

wherein, the first component articulates relative to the second component; further wherein the first vertebra articulates relative to the facet arthroplasty device.

2. The implantable facet arthroplasty device of claim 1 further comprising a first arm having a bone engaging end adapted to attach to a vertebral body at a first end and adapted to engage the crossbar at a second end.

3. The implantable facet arthroplasty device of claim 2 wherein the first arm is configured to engage a caudal vertebral body.

4. The implantable facet arthroplasty device of claim 2 wherein the first arm is configured to engage a cephalad vertebral body.

5. The implantable facet arthroplasty device of claim 1 further comprising a spinal fusion device.

6. The implantable facet arthroplasty device of claim 5 wherein the spinal fusion device comprises a pair of elongated members configured to extend along a portion of the spine adjacent a cephalad vertebra and a caudal vertebra and a plurality of attachment mechanism for mounting the spinal fusion device to the cephalad vertebra and the caudal vertebra.

7. The implantable facet arthroplasty device of claim 2 further comprising a second arm having a bone engaging end adapted to attach to a vertebral body at a first end and adapted to engage the crossbar at a second end.

8. The implantable facet arthroplasty device of claim 7 wherein the second arm is configured to engage a caudal vertebral body.

9. The implantable facet arthroplasty device of claim 7 wherein the second arm is configured to engage a cephalad vertebral body.

10. The implantable facet arthroplasty device of claim 7 wherein the first arm articulates relative to the second arm.

11. An implantable spinal restoration device comprising:

(a) an elongated member configured to extend along a portion of a length of a spine adjacent a cephalad vertebra and a caudal vertebra;

(b) an attachment mechanism adapted to attach the elongated member to a portion of the spine;

(c) a facet arthroplasty element;

(d) a support component having a first end and a second end sized to span a portion of the vertebral body and adapted to receive the facet arthroplasty element at the first end and the second end; and

(e) a connector adapted to connect the support component to the elongated member.

12. The implantable spinal restoration device of claim 11, further comprising an arm with a bone engaging end adapted to attach to a vertebra at a first end and adapted to attach to the support component at a second end.

13. The implantable spinal restoration device of claim 12, wherein the arm is configured to engage a caudal vertebral body.

14. The implantable spinal restoration device of claim 12, wherein the arm is configured to engage a cephalad vertebral body.

15. The implantable spinal restoration device of claim 12, further comprising a second arm having a first end adapted to engage a vertebral body at a first end and second end adapted to engage the crossbar.

16. The implantable spinal restoration device of claim 15, wherein the first arm articulates relative to the second arm.

17. The implantable spinal restoration device of claim 11, wherein the support component is sized to span a portion of a vertebral body between a left lamina and a right lamina.

18. The implantable spinal restoration device of claim 11, wherein the support component is sized to span a portion of a vertebral body between a left pedicle and a right pedicle.

19. The implantable spinal restoration device of claim11, wherein the support component is further adapted to have an adjustable width.

20. The implantable spinal restoration device of claim 11, wherein the facet arthroplasty element is positioned relative to the support component to provide a symmetric anatomical solution.

21. The implantable spinal restoration device of claim 11, wherein the facet arthroplasty element is positioned relative to the support component to provide an asymmetrical anatomical solution.

22. The implantable spinal restoration device of claim 11, wherein the ends of the support component are adapted to receive an opening in the facet arthroplasty element.

23. The implantable spinal restoration device of claim 11, wherein the facet arthroplasty element is selected from a plurality of facet arthroplasty elements each having an opening with a different depth.

24. The implantable spinal restoration device of claim 11, further comprising evenly distributing the weight on the vertebral body using the support component.

25. An adaptable implantable spine stabilization device, comprising:

(a) a crossbar having a first end and a second end;

(b) a pair of vertebral engaging elements each having a bone engaging end and an end adapted to couple to the crossbar; and

(c) a pair of anchoring elements each having a first end having a surface adapted to receive a crossbar end and second end adapted to fix the anchoring element to a spinal fusion system.

26. The adaptable implantable spine stabilization device of claim 25, further comprising an arm with a bone engaging end adapted to attach to a vertebra at a first end and adapted to attach to the support component at a second end.

27. The adaptable implantable spine stabilization device of claim 25, wherein the arm is configured to engage a caudal vertebral body.

28. The adaptable implantable spine stabilization device of claim 25, wherein the arm is configured to engage a cephalad vertebral body.

29. The adaptable implantable spine stabilization device of claim 25, further comprising a second arm having a first end adapted to engage a vertebral body at a first end and second end adapted to engage the crossbar.

30. The adaptable implantable spine stabilization device of claim 25, wherein the first arm articulates relative to the second arm.

31. The adaptable implantable spine stabilization device of claim 25, wherein the support component is sized to span a portion of a vertebral body between a left lamina and a right lamina.

32. The adaptable implantable spine stabilization device of claim 25, wherein the support component is sized to span a portion of a vertebral body between a left pedicle and a right pedicle.

33. The adaptable implantable spine stabilization device of claim 25, wherein the support component is further adapted to have an adjustable width.

34. The adaptable implantable spine stabilization device of claim 25, wherein the facet arthroplasty element is positioned relative to the support component to provide a symmetric anatomical solution.

35. The adaptable implantable spine stabilization device of claim 25, wherein the facet arthroplasty element is positioned relative to the support component to provide an asymmetrical anatomical solution.

36. The adaptable implantable spine stabilization device of claim 25, wherein the ends of the support component are adapted to receive an opening in the facet arthroplasty elements.

37. The adaptable implantable spine stabilization device of claim 25, wherein the facet arthroplasty element is selected from a plurality of facet arthroplasty elements each having an opening with a different depth.

38. The adaptable implantable spine stabilization device of claim 25, further comprising evenly distributing the weight on the vertebral body using the support component.

39. A method for revising spinal fusion surgery to provide support to adjacent vertebra comprising:

(d) accessing a spinal location having a spinal fusion device, comprising a pair of elongated members, attached adjacent a caudal vertebral body and a cephalad vertebral body;

(e) attaching a facet arthroplasty device comprising an articulating attachment mechanism adapted to receive a crossbar and an attachment mechanism adapted to connected to the elongated member of the spinal fusion device; and

(f) closing the wound.

40. The method for revising spinal fusion surgery of claim 39 wherein the vertebra adjacent the spinal fusion device are stabilized.

41. An implantable adjacent level arthroplasty device for implantation between a first vertebra and a second vertebra having a vertebra engaging a fusion device comprising:

(g) a crossbar;

(h) a first component having a first attachment mechanism adapted to attach to a first location of a spinal fusion device attached to a first vertebra and a second attachment mechanism adapted to attach to the crossbar; and

(i) a second component having a second attachment mechanism adapted to attach to a second location of a spinal fusion device attached to the first vertebra and a second attachment mechanism adapted to attach to the crossbar,

wherein, the first component articulates relative to the second component; further wherein the first vertebra articulates relative to the facet arthroplasty device.

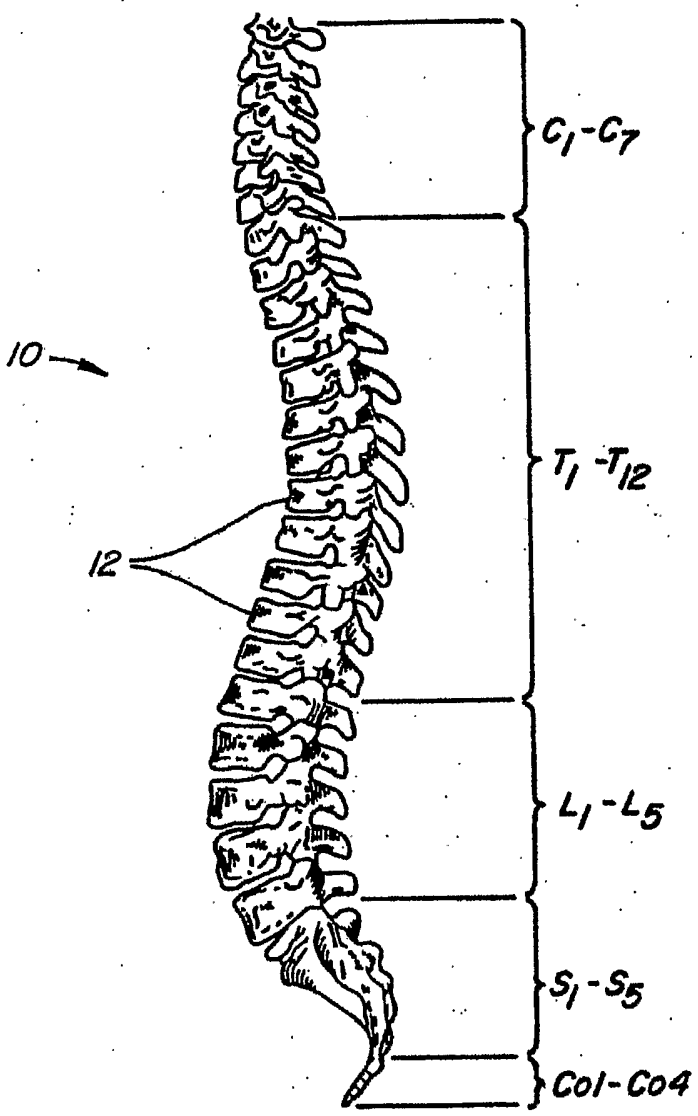

FIG. 1

PRIOR ART

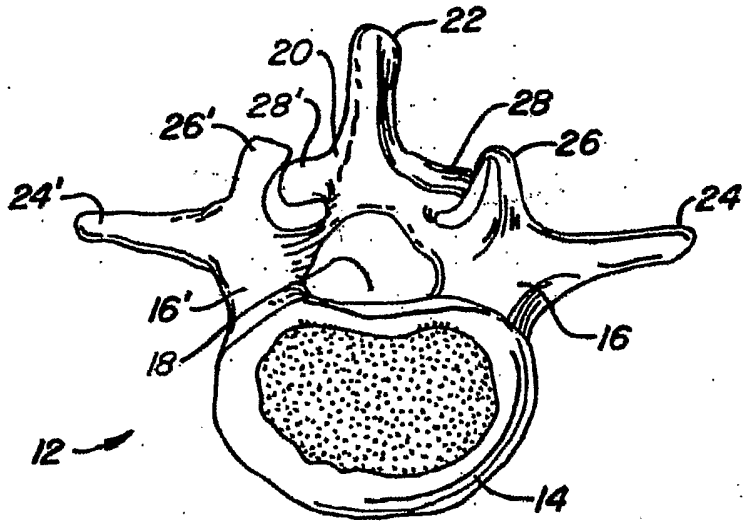

FIG. 2

PRIOR ART

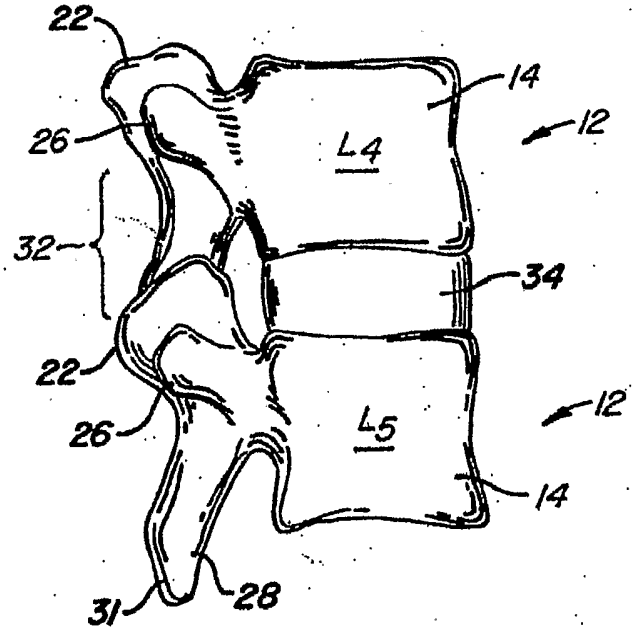

FIG. 3

PRIOR ART

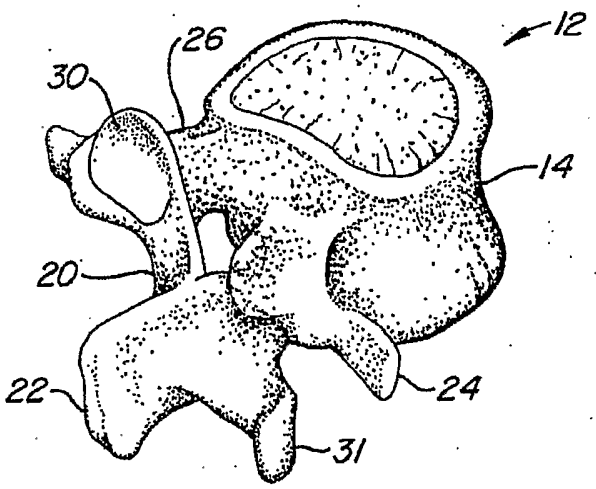

FIG. 4

PRIOR ART

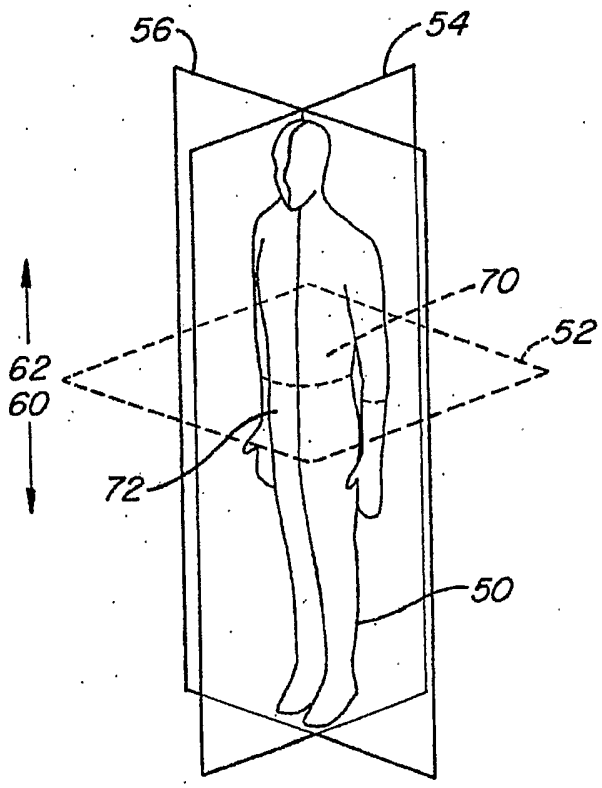

FIG. 5

PRIOR ART

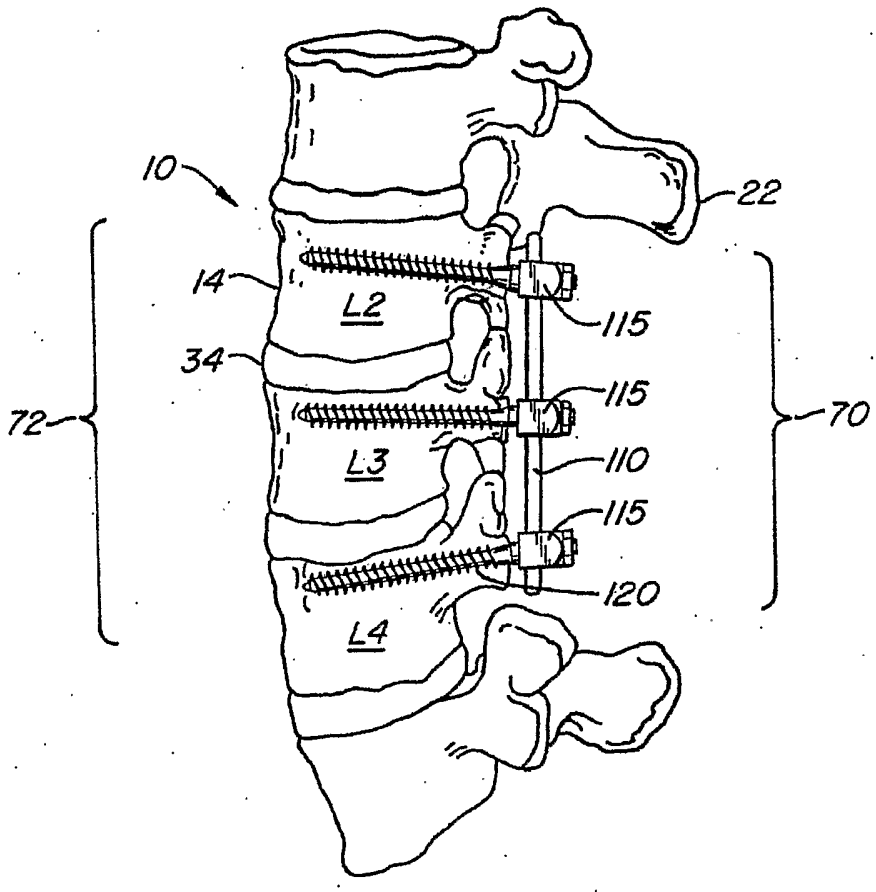

FIG. 6A

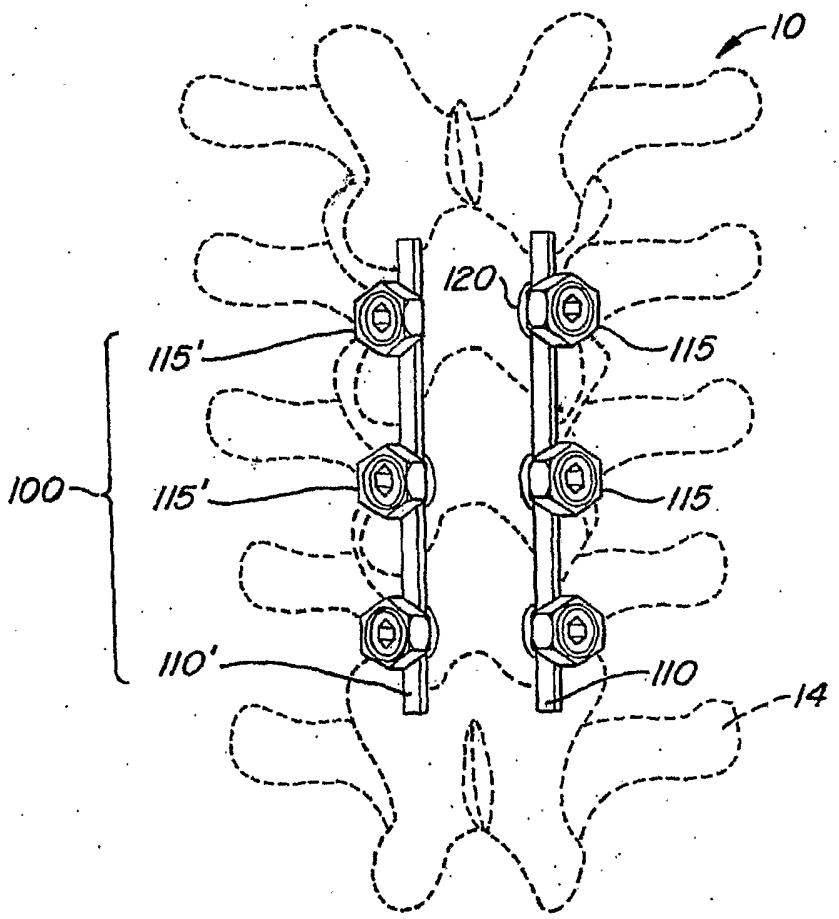

FIG. 6B

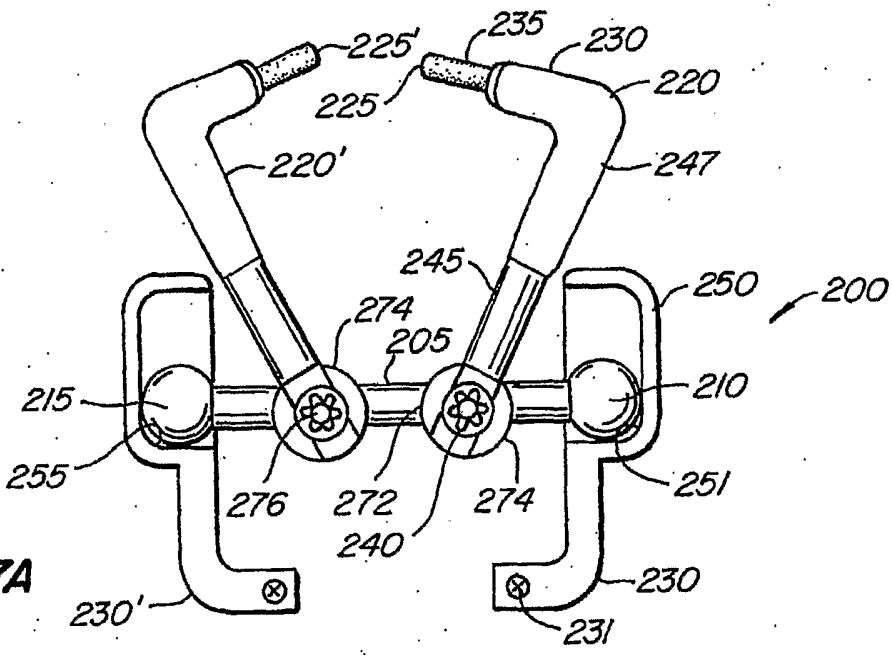

FIG. 7A

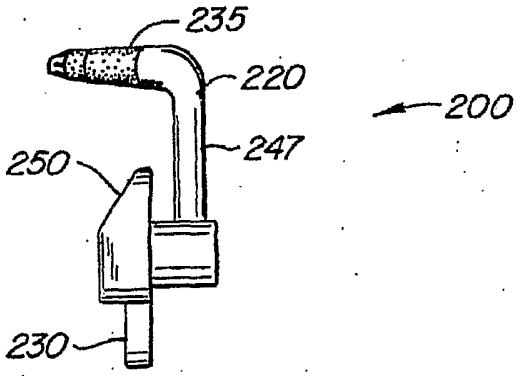

FIG. 7B

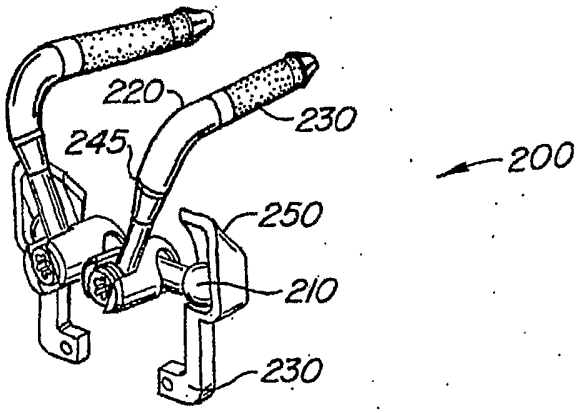

FIG. 7C

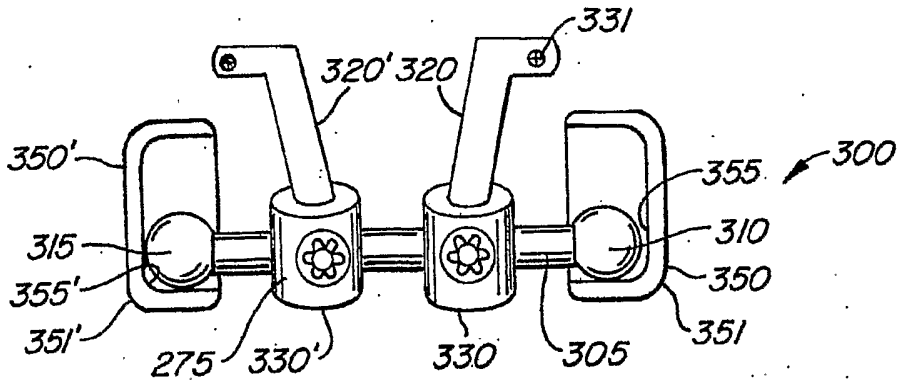

FIG. 8A

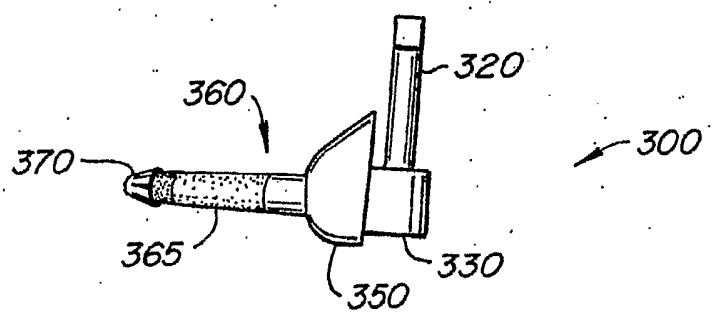

FIG. 8B

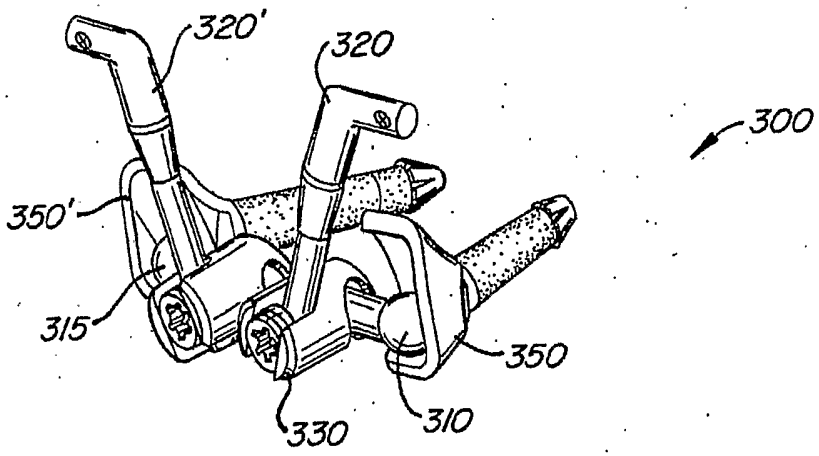

FIG. 8C

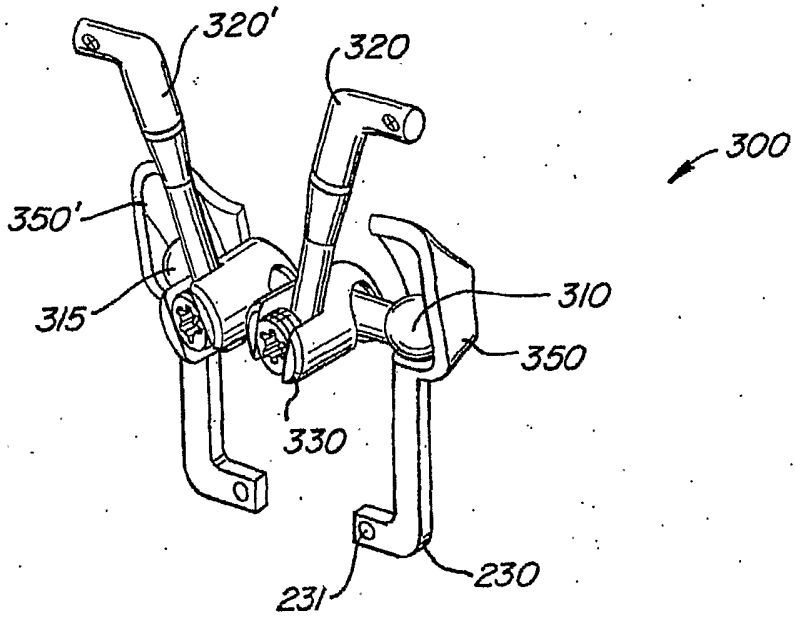

FIG. 8D

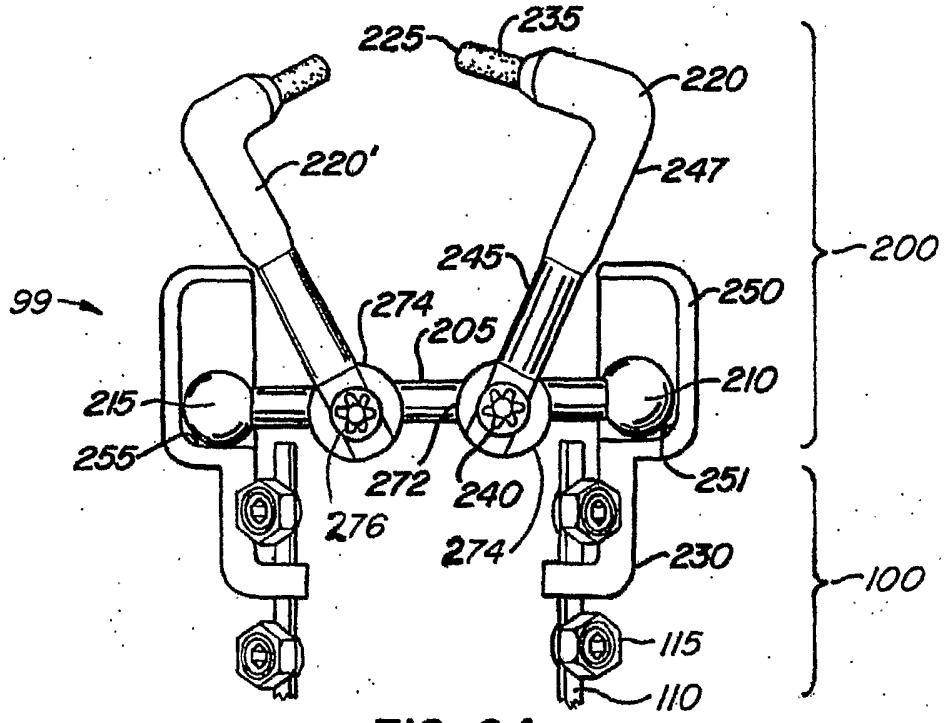

FIG. 9A

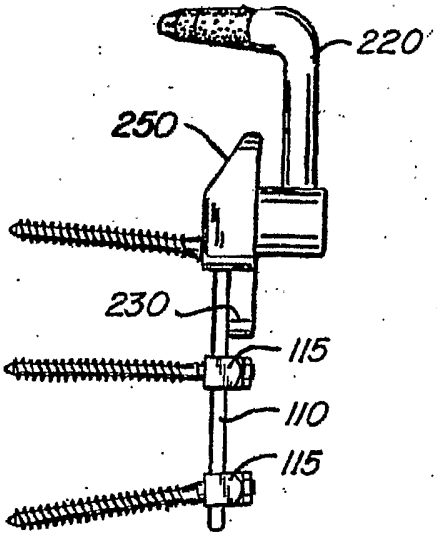

FIG. 9B

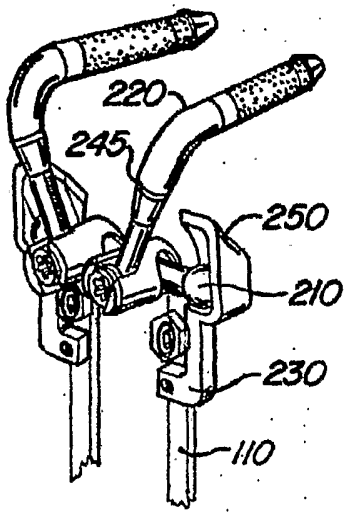

FIG. 9C

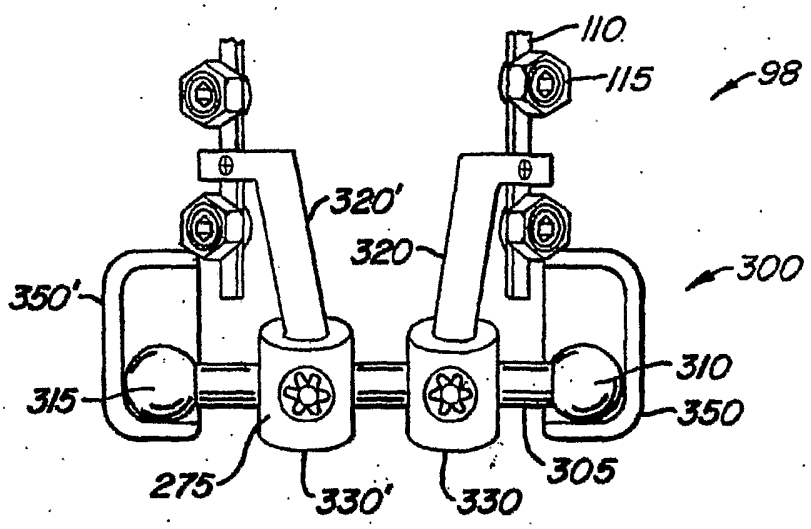

FIG. 10A

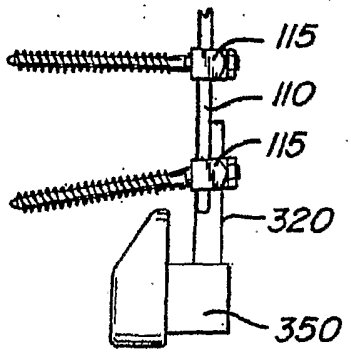

FIG. 10B

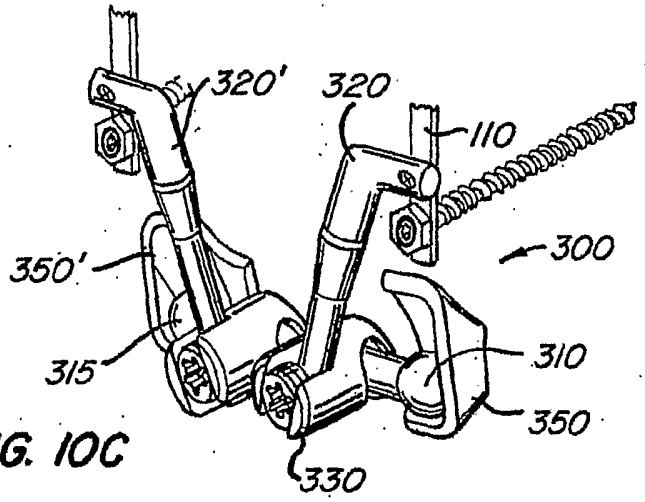

FIG. 10C

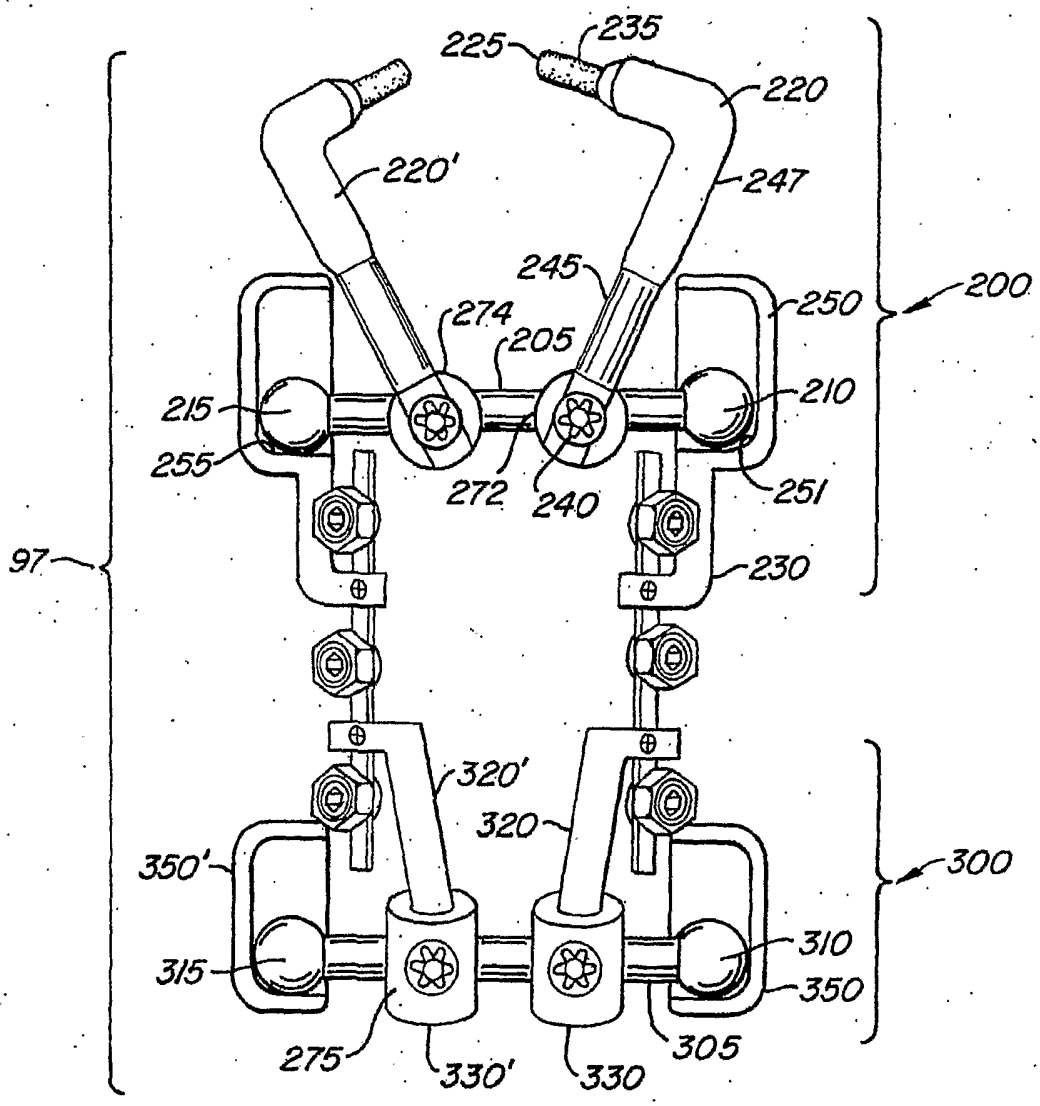
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FIG. IIA

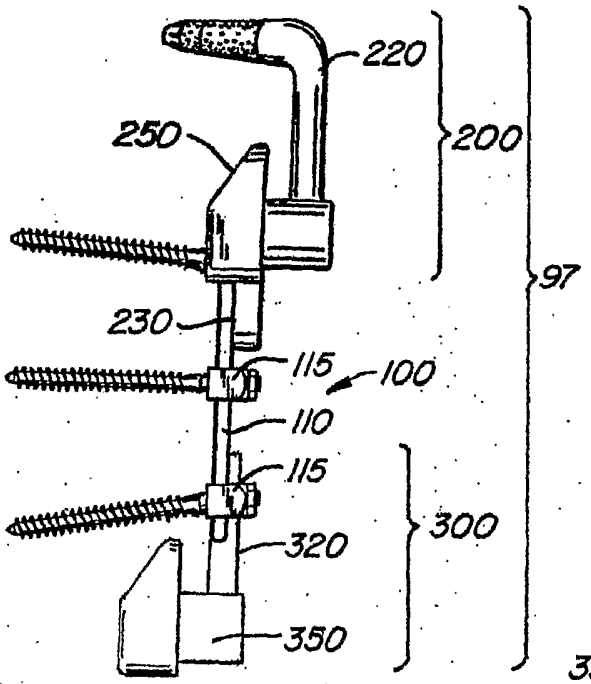


FIG. 11B

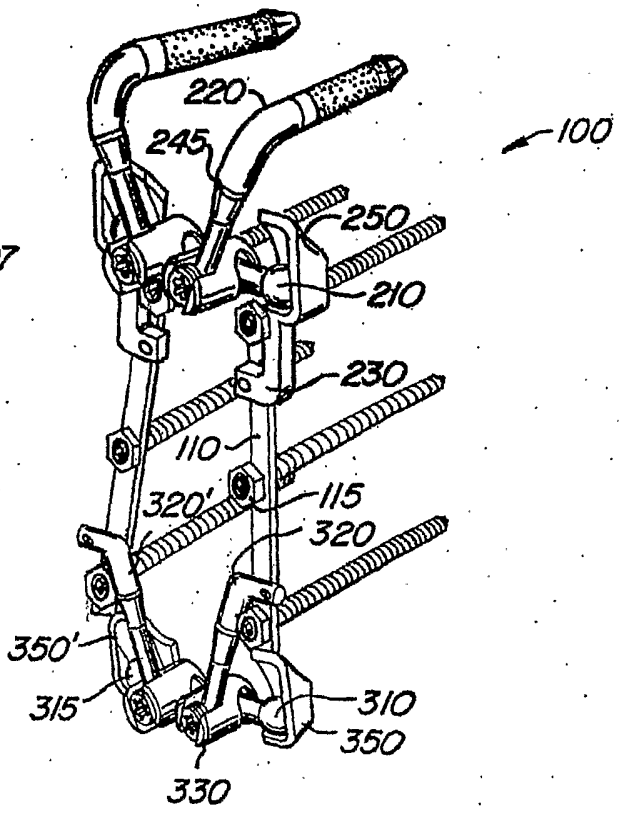


FIG. 11C

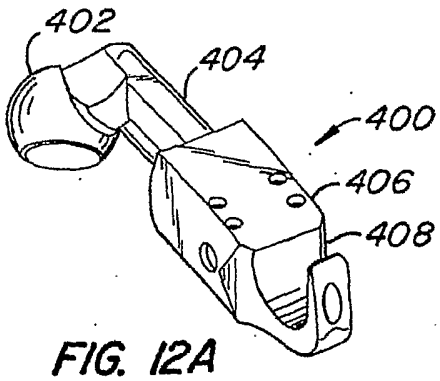


FIG. 12A

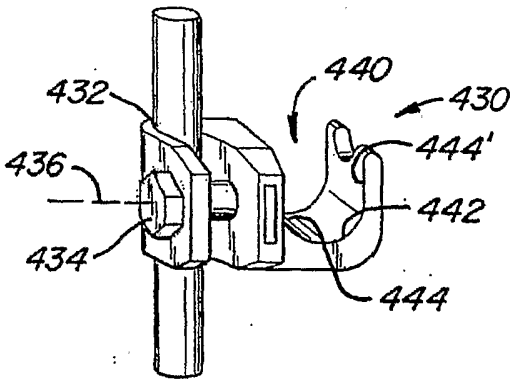


FIG. 12C

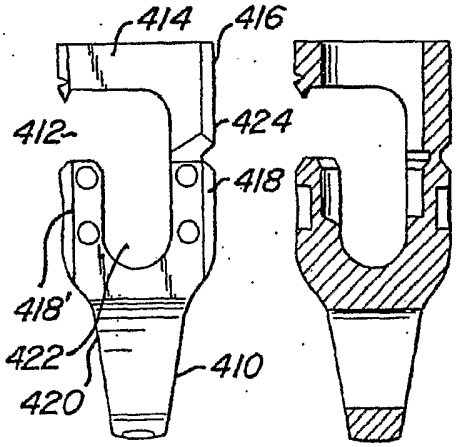


FIG. 12B

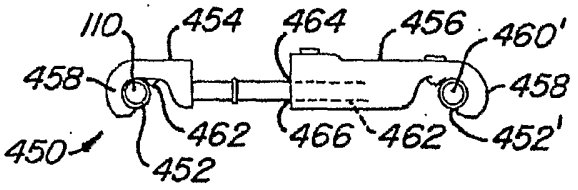
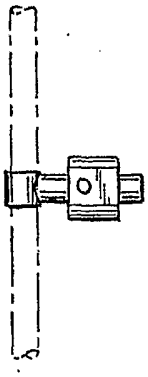


FIG. 12D



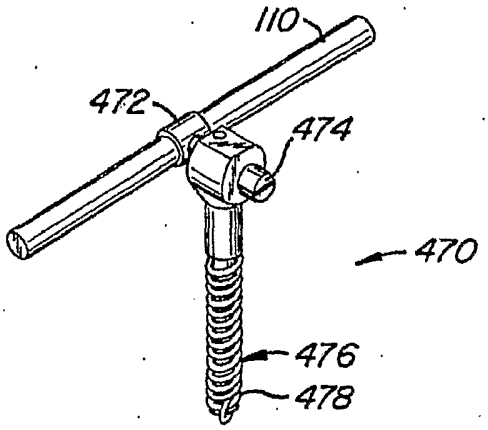
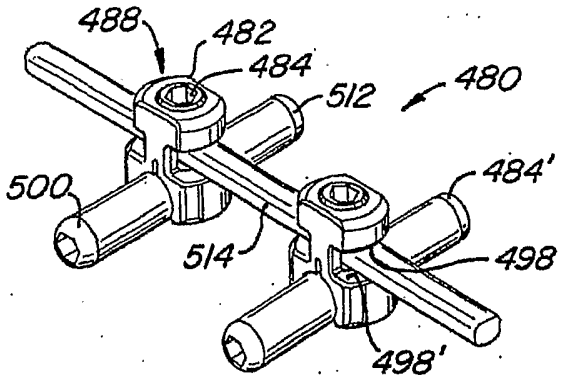


FIG. 12E



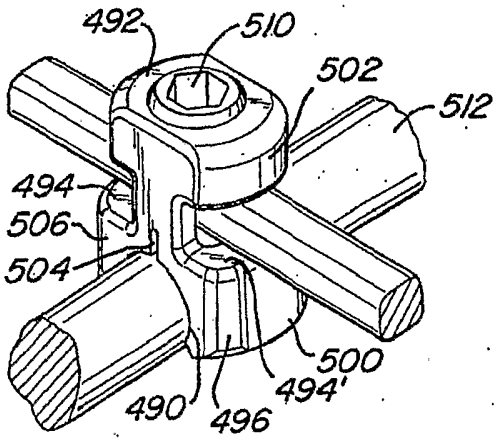


FIG. 12F

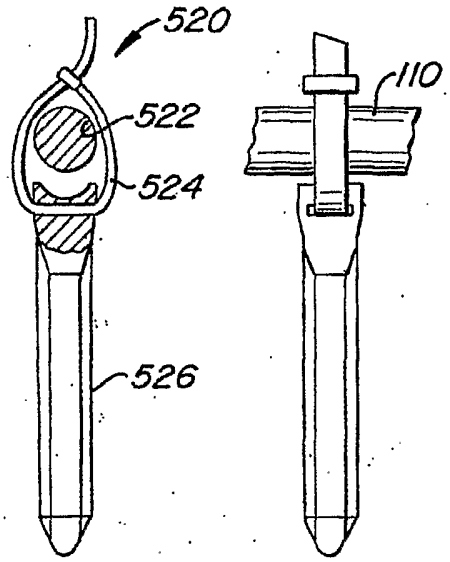
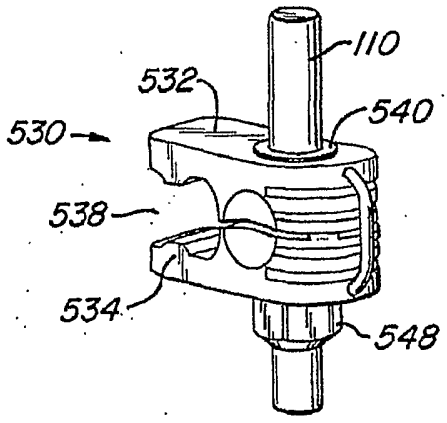


FIG. 12G



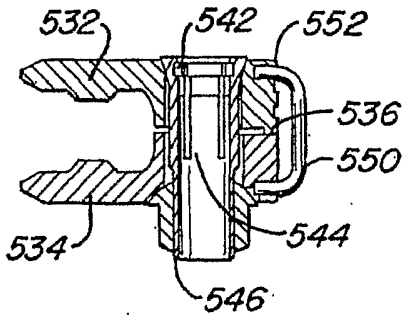


FIG. 12H

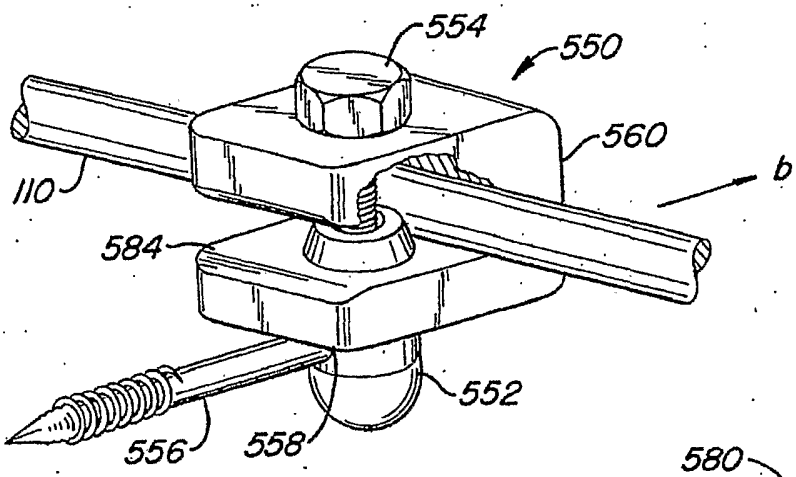
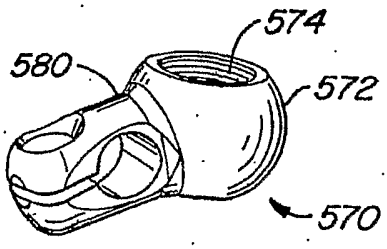


FIG. 12I



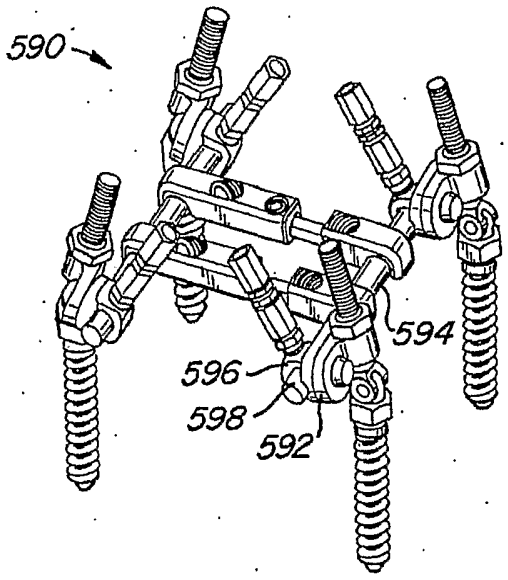


FIG. 12K

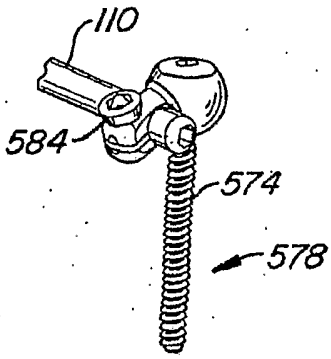


FIG. 12J

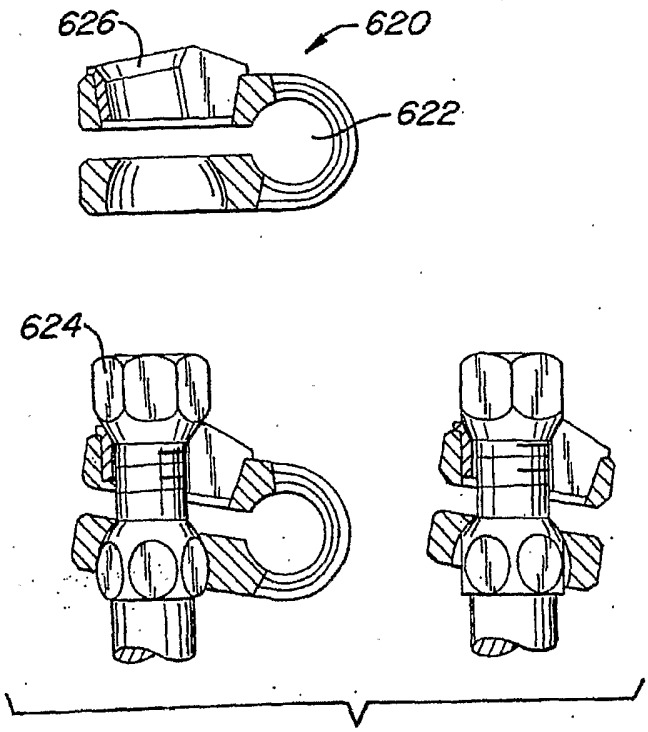


FIG. 12L

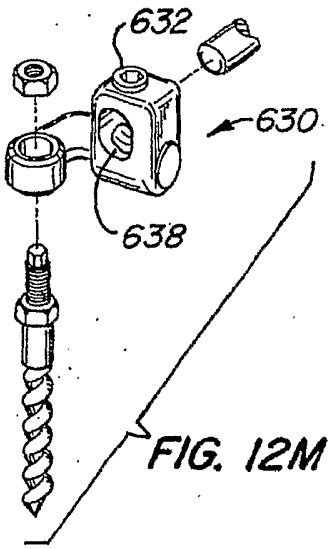


FIG. 12M

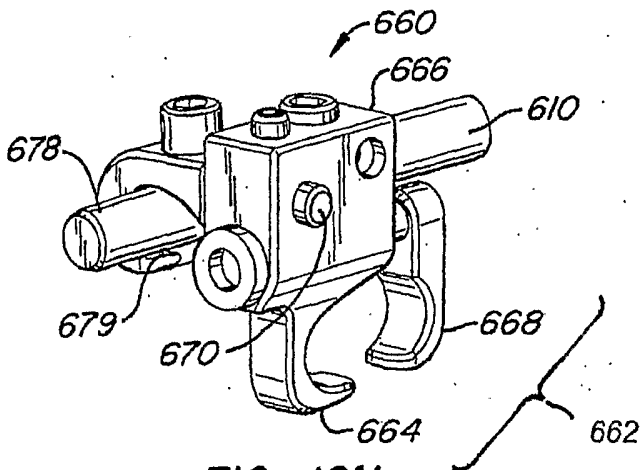


FIG. 12N

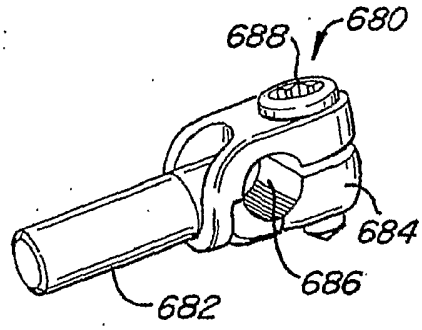


FIG. 12O

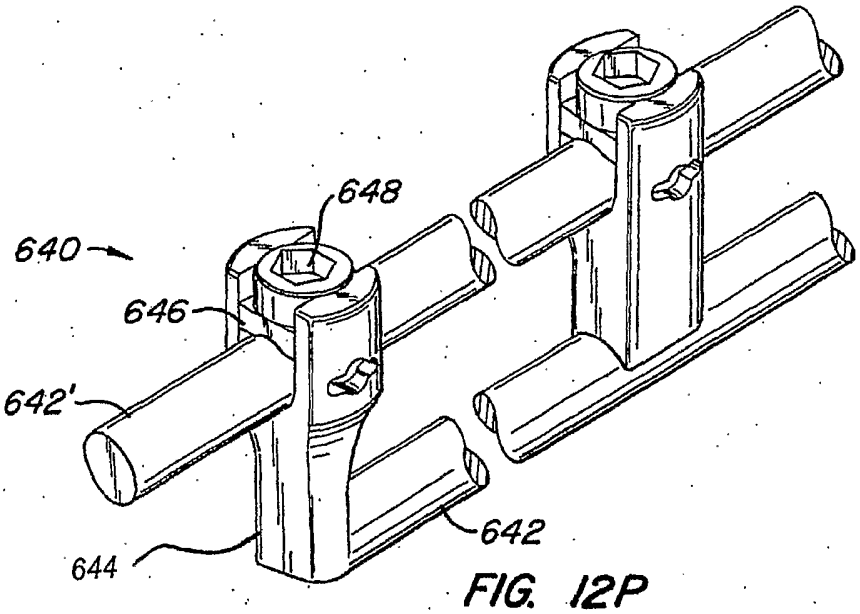


FIG. 12P

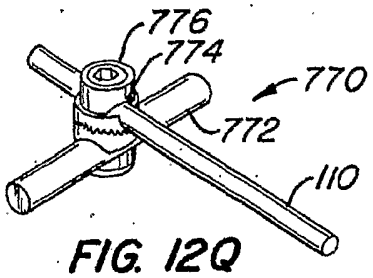


FIG. 12Q

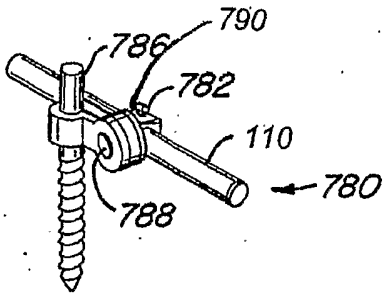
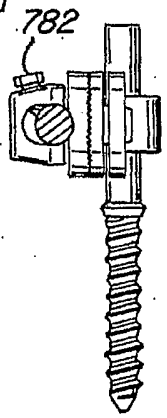
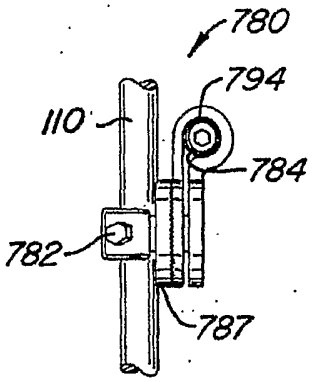


FIG. 12R





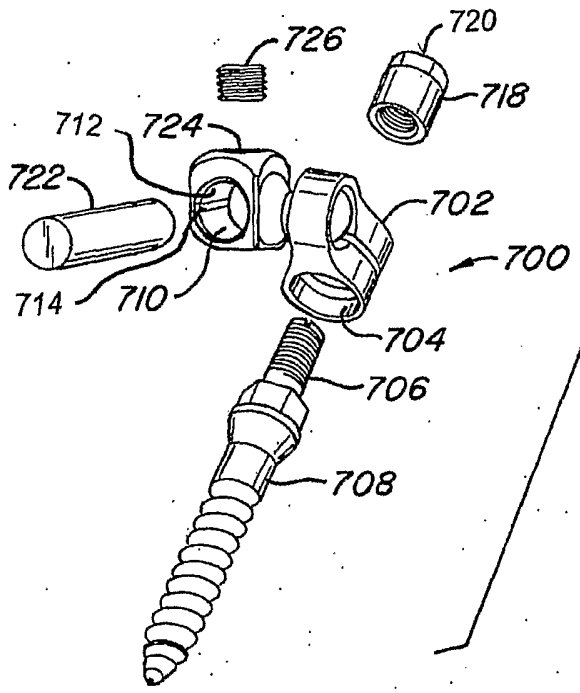


FIG. 12S

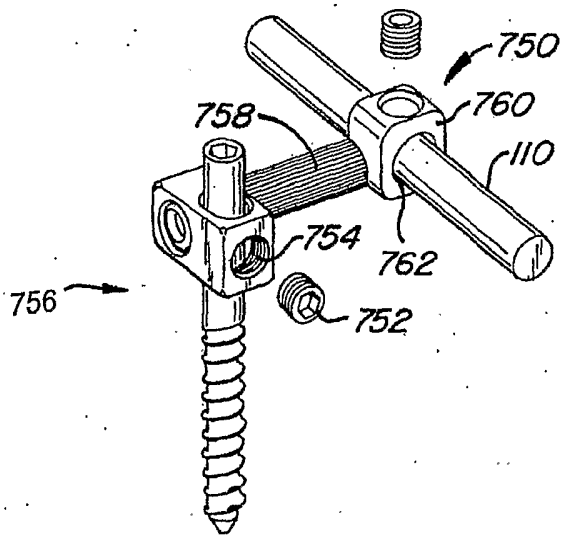


FIG. 12U

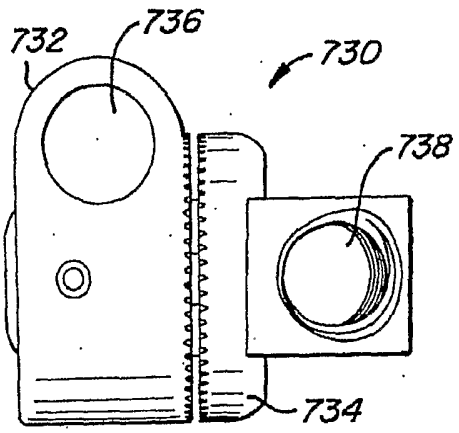


FIG. 12T

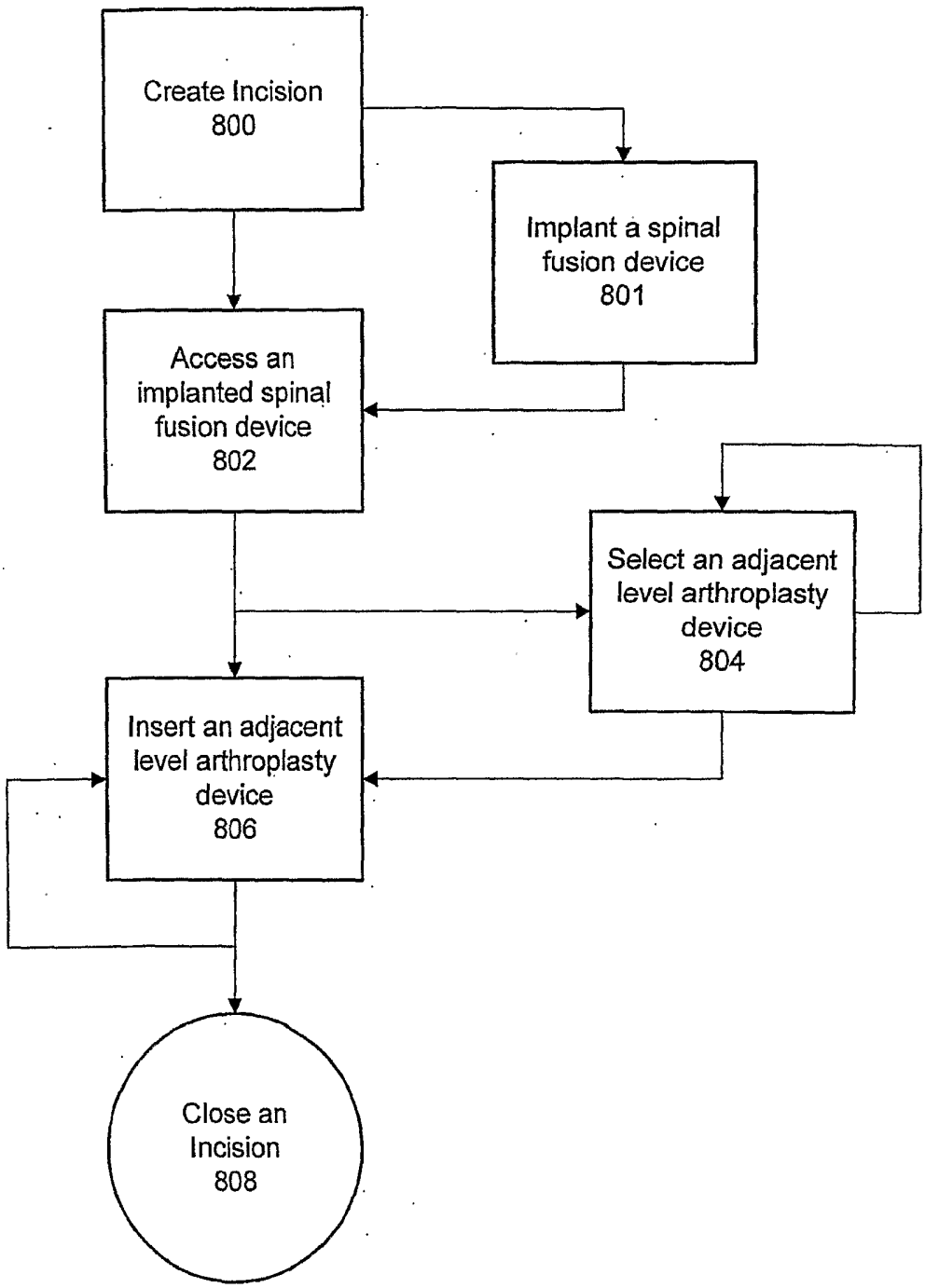

Create Incision
800
Implant a spinal fusion device
801
Access an implanted spinal fusion device
802
Select an adjacent level arthroplasty device
804
Insert an adjacent level arthroplasty device
806
Close an Incision
808

Fig. 13

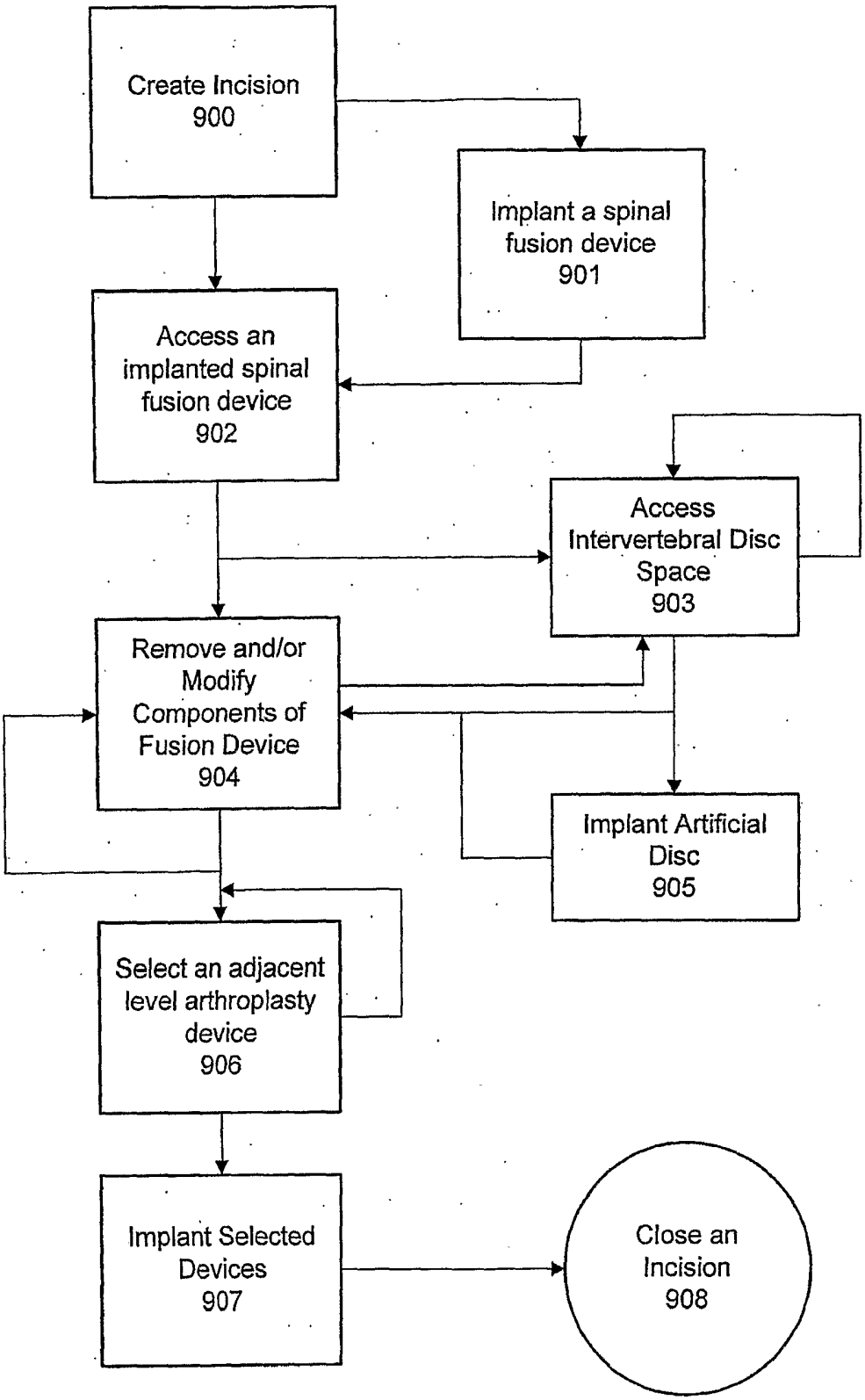

Create Incision
900
Implant a spinal fusion device
901
Access an implanted spinal fusion device
902
Access Intervertebral Disc Space
903
Remove and/or Modify Components of Fusion Device
904
Implant Artificial Disc
905
Select an adjacent level arthroplasty device
906
Implant Selected Devices
907
Close an Incision
908

Fig. 14

INTERNATIONAL SEARCH REPORT

Application No
PCT/US2005/029441

A. CLASSIFICATION OF SUBJECT MATTER
A61B17/70 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.
A	US 2002/123806 A1 (REILEY MARK A) 5 September 2002 (2002-09-05) abstract; figures 3-9	1,11,25, 41
A	US 2004/049272 A1 (REILEY MARK A) 11 March 2004 (2004-03-11) abstract; figures 11-13	1,11,25, 41
A	FR 2 749 155 A (ALBY ALBERT P) 5 December 1997 (1997-12-05) abstract; claim 1; figure 1	1,11,25, 41
A	FR 2 726 459 A (DESAUGE JEAN PIERRE) 10 May 1996 (1996-05-10) abstract; claim 1; figure 2	1,11,25, 41

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

☒ Patent family members are listed in annex.

° Special categories of cited documents :

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
16 November 2005	24/11/2005

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

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INTERNATIONAL SEARCH REPORT

application No.
PCT/US2005/029441

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

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

1. [X] Claims Nos.: 39-40
because they relate to subject matter not required to be searched by this Authority, namely:

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

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

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

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

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

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

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

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

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

Remark on Protest

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

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

INTERNATIONAL SEARCH REPORT

Information on patent family members

Application No
PCT/US2005/029441

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