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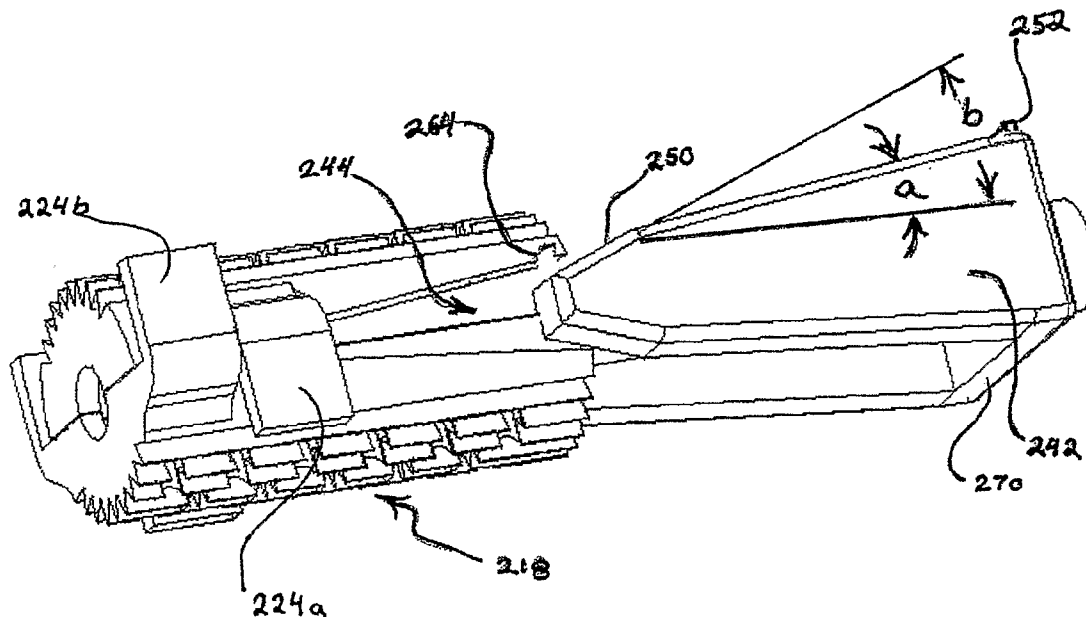
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(54) Title: LINEARLY EXPANDING SPINE CAGE FOR ENHANCED SPINAL FUSION



(57) Abstract: A linearly expanding spine cage (218) has a minimized diameter in its unexpanded state that is equal to the diameter of an insertion groove cut into adjacent vertebral bodies. The cage conformably engages between the endplates of adjacent vertebrae and is expanded by a U-shaped expansion wedge (242) which engages the sidewalls of the spine cage. Angular deformities can be corrected, and natural curvatures maintained. The cage enhances spinal arthrodesis by creating a rigid spine segment. Expanding linearly (vertically, along the vertical axis of the adjacent spine) rather than uniformly, the cage height increases and holds the vertebrae with fixation forces greater than adjacent bone and soft tissue failure forces. The cage width remains stable, so as to decrease impingement upon a second cage, or upon soft tissue structures in the immediate vicinity, including neural or vascular elements.

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LINEARLY EXPANDING SPINE CAGE FOR ENHANCED SPINAL FUSION

Technical Field

The present invention relates generally to the field of medical devices for stabilizing the vertebral motion segment. More particularly, the present invention relates to a linearly expanding spine cage (LEC), and a method for providing improved spinal intervertebral body distraction and fusion.

Background Art

Inability To Expand And Distract Endplates

Referring to Figure 1, a conventional spine cage or implant **101** is characterized by a cylindrical body comprising a plurality of threads **104** provided on the exterior surface for contact with adjacent vertebral segments or endplates **102a** and **102b**, which are shown as blocks for clarity. Conventional spine cage **101** is typically inserted in tandem between vertebral segments **102a** and **102b**.

Such existing devices for interbody stabilization, such as conventional spine cage or implant **101**, have important and significant limitations. These limitations include an inability to expand and distract the endplates. Separation of the endplates serves to create lordosis within the spine. Current devices for interbody stabilization include static spacers composed of titanium, PEEK, a high performance thermoplastic polymer produced by VICTREX, (Victrex USA Inc., 3A Caledon Court; Greenville, SC 29615), carbon fiber, or resorbable polymers. Current interbody spacers do not improve interbody lordosis and can contribute to the formation of a kyphotic segment and the clinical problem of "flatback syndrome." Separation of the endplates increases space available for the neural elements, specifically the neural foramen. Existing static cages do not reliably improve space for the neural elements. Therefore, what is needed is an expanding cage that will increase space for neural elements centrally and in the neural foramen.

Poor Interface Between Bone and Biomaterial

Another problem with conventional devices for interbody stabilization includes poor interface between bone and biomaterial. Conventional static interbody spacers form a weak interface between bone and biomaterial. Although the surface of such implants is typically provided with a series of circumferential threads or grooves **104**, such threads are uniform

and are in parallel with applied horizontal vectors or side to side motion. That is, the threads offer no resistance to movement applied to either side **106** of the endplates (as opposed to force applied to the front or back. Thus, nonunion is common in allograft, titanium, and polymer spacers, due to motion between the implant and host bone. Conventional devices typically do not expand between adjacent vertebrae.

Therefore, what is needed is a way to expand an implant to develop immediate fixation forces that can exceed the ultimate strength at healing. Such an expandable implant ideally will maximize stability of the interface and enhance stable fixation. The immediate fixation of such an expandable interbody implant advantageously will provide stability that is similar to that achieved at the time of healing. Such an implant would have valuable implications in enhancing early post-operative rehabilitation for the patient.

Large Diameter Devices Require Wide Exposure Of Neural Structures

Another problem of conventional interbody spacers is their large diameter requiring wide exposure. Existing devices used for interbody spacers include structural allograft, threaded cages, cylindrical cages, and boomerang-shaped cages. Conventional devices have significant limitation with regard to safety and efficacy. Regarding safety of the interbody spacers, injury to neural elements may occur with placement from an anterior or posterior approach. A conventional spine cage lacks the ability to expand linearly in a vertical direction without also changing position or expanding laterally, thus working against stable fixation.

The risks to neural elements are primarily due to the disparity between the large size of the cage required to adequately support the interbody space, and the small space available for insertion of the device, especially when placed from a posterior or transforminal approach. Existing cylindrical interbody implants are characterized by a width that is equal to their height. Therefore, implantation requires a wide exposure and potential compromise of vascular and neural structures. Given the proximity of nerve roots and vascular structures to the insertion site, and the solid, relatively large size of conventional hollow devices, such constraints predispose a patient to foraminal (nerve passage site) violation, and possible neural and vascular injury.

Therefore, what is needed is an expanding spine cage that is capable of insertion with minimal invasion into a smaller aperture. Such a minimally sized spine cage advantageously could be expanded by instrumental force application. Due to the small size of the cage, the nerves can be anatomically separated from the cage proximity, thus allowing a greater level

of safety during the surgical procedure. Such an expandable implant would permit a more narrow exposure in the space outside of the vertebral body, with expansion inside of the interbody space.

What is also needed is a smaller expanding spine cage that is easier to operatively insert in a patient with minimized trauma in contrast to conventional, relatively large devices that create needless trauma to nerve roots in the confined space of the vertebral region.

Limited Capacity For Interbody Bone Formation

Existing interbody implants have limited space available for bone graft. Adequate bone graft or bone graft substitute is critical for a solid interbody arthrodesis. It would be desirable to provide an expandable interbody cage will provide a large volume of bone graft material to be placed within the interbody space. Additionally, conventional interbody implants lack the ability to stabilize endplates completely and prevent them from moving. Therefore, what is also needed is an expanding spine cage wherein the vertebral endplates are subject to forces that both distract them apart, and hold them from moving. Such an interbody cage would be capable of stabilization of the motion segment, thereby reducing micro-motion, and discouraging pseudo arthrosis (incomplete fusion) and pain.

Ideally, what is needed is a spine cage or implant that is capable of increasing its expansion diameter to a calculated degree. Such a spine cage would permit restoration of normal spinal alignment after surgery and hold the spine segments together rigidly, mechanically, until healing occurs. What is also needed is an expanding cage or implant that is capable of holding vertebral or joint sections with increased pullout strength to minimize the chance of implant subsidence in the healing period.

It would also be desirable if such a cage could expand linearly (vertically, along the vertical axis of the entire spine) rather than uniformly which would take up more space inside the vertebral body surfaces.

Disclosure of Invention

An aspect of the invention comprises a linearly expanding spine cage (LEC) comprising two halves joined along a common longitudinal axis to form a cylinder with a minimized diameter in its unexpanded state that is equal to the diameter of an insertion groove cut in adjacent vertebral bodies. The LEC is thus conformably engaged between the endplates of adjacent vertebra to effectively distract the

intervertebral area, restore space for neural elements, stabilize the motion segment and eliminate pathologic segmental motion. The LEC enhances spinal arthrodesis by creating a rigid spine segment.

The LEC provides a significant advantage by enabling a comparatively large quantity of bone growth enhancing agents to be contained within its interior and communicated directly to adjacent bone over a maximized surface area due to a perforated design with apertures dispersed through multiple rows of corrugations, ridges, points, troughs or other features for bone engagement provided on radial surfaces of LEC halves. Importantly, this results in fixation forces greater than adjacent bone and soft tissue failure forces.

By expanding linearly (vertically, along the vertical axis of the entire spine) rather than uniformly (which would take up more space inside the vertebral body surfaces), the cage height increases to hold the vertebrae, while the width remains stable so as to decrease impingement upon a second cage, or upon soft tissue structures in the immediate vicinity (neural elements).

Generally, two LECs are used for fusion through the anterior approach – though the surgeon can choose any insertional vector. The cages may be inserted in parallel, or obliquely to accommodate located anatomy, and to adjust deformities such as scoliosis, kyphosis, and spondylolisthesis.

The clinical goals of the LEC and method for its insertion reduce pain, improve function, and permit early mobilization of the patient after fusion surgery. Since the LEC pullout forces are greater than vertebral body failure forces, patients can mobilize more quickly than was previously possible. Once healing (fusion or arthrodesis) does occur, the implants become incorporated and their role becomes quiescent.

The present LEC provides more internal to external graft bone space exposure, easier insertion, less risk of insertional damage to nerve roots and other tissue, and thus a substantially improved immediate and long term result. The specialized exterior on the outside of the LEC seeks to balance multiple projections, tines, or other bone engaging features that will hold firmly adjacent bone to prevent prosthetic extrusion, while being sufficiently rounded so as to avoid injuring nearby nerve or vascular structures. Bone ingrowth is encouraged by the perforated design of the LEC and the exterior corrugations that greatly increase the surface area of the LEC that

conformably engages adjacent vertebral bone. By avoiding a square or rectangular configuration, the LEC is less prone toward subsidence.

Brief Description of Drawings

The drawings are heuristic for clarity. The foregoing and other features, aspects and advantages of the invention will become better understood with reference to the following descriptions, appended claims and accompanying drawings in which:

Figure 1 is a perspective view of a conventional non-expanding cylindrical spine cage, resembling products in current use.

Figure 2 is a perspective view of two cannulas inserted between vertebrae for placement of a spine cage and a cutting tool according to an aspect of the invention.

Figure 3 is the perspective view of Figure 2 with an upper vertebra removed for clarity.

Figure 4 is a perspective view of an insertion tool for positioning a spine cage between vertebrae according to an aspect of the invention.

Figure 5 is a perspective view of a linearly expanding spine cage (LEC) according to an aspect of the invention.

Figure 6A is a perspective view of the interior of a first half of the LEC of Figure 5 according to an aspect of the invention.

Figure 6B is a perspective view of the interior of a second half of the LEC of Figure 5 according to an aspect of the invention

Figure 7 is a perspective view of the LEC of Figure 5 showing the expansion mechanism according to an aspect of the invention.

Figure 8 is a perspective interior view of the LEC of Figure 5 showing the expansion mechanism according to an aspect of the invention.

Figure 9 is a stylized view of the LEC showing linear expansion into corresponding grooves in bone according to an aspect of the invention.

Figure 10A is a stylized cross-sectional view of the placement of two LECs between vertebral structures for adjustment of spinal alignment according to an aspect of the invention.

Figure 10B is a stylized cross-sectional view of the vertical expansion of a first LEC relative to a second LEC for adjustment of spinal alignment according to an aspect of the invention.

Figure 10C is perspective view showing how the angle of the expansion wedge in the LEC can be selected to impart varying degrees of expansion to the LEC for a full range of adjustment of spinal alignment according to an aspect of the invention.

Mode(s) For Carrying Out the Invention

Referring to Figure 2, vertebral segments **202a** and **202b** are shown with an 8 mm gap representing an average intervertebral space **204**. The vertebral segments **202a** and **202b** are shown as blocks for clarity. A complete discectomy is performed prior to the insertion of the LEC.

As is well understood by one skilled in the art, the intervertebral disc occupying space **204** will be removed using standard techniques including rongeur, curettage, and endplate preparation to bleeding subchondral bone. The posterior longitudinal ligament will be divided to permit expansion of the intervertebral space.

The intervertebral space **204** will be distracted to 10 mm using a rotating spatula (Not shown. This is a device that looks like a wide screw driver that can be placed into the disc space horizontally and turned 90 degrees to separate the endplates).

Referring to Figure 2 through Figure 5, one or two 10mm cage cannulas **206** are inserted between the vertebral segments **202a** and **202b**. It will be appreciated that the present cannulas can be made smaller than conventional cannulas due to the expanding nature of the 10 mm spine cage and thereby minimize trauma to nerve roots in the spinal column. Each cannula has a fork **208** on the front end which is 10mm tall. The fork properly levels the vertebrae for operation. Each cannula also has four spikes **210** which tap into the vertebrae above and below thereby preventing bone movement during the operation. For clarity, only the two top spikes are shown. Additional spikes may be added if needed.

It will be appreciated that the spiked tips **210** of the insertion cannulas advantageously stabilize the working surfaces of the vertebral segments to a high degree such that all bone movement and misalignment is substantially prevented during the operation. With a narrow cannula in place, the neural and vascular elements are protected and a safe working channel is created for endplate preparation and cage placement. Insertion of the cage follows tapping of the endplates, or vertebral segments.

Referring to Figure 3 and Figure 4, a 10mm diameter motorized cutting tool **212** is inserted through a cannula. Cutting tool bit **214** is attached to the distal end of motorized cutting tool **212**. The cutting bit is shaped like a hole saw which will cut and capture bone debris. This tool may not be necessary in the setting of an adequate discectomy. The non-cutting end of the cutting tool bit may be provided with a depth marking to indicate the depth of the cut. A limiter, such as a hard stop or “step off” can be added to prevent cutting too deeply.

Once the cutting tool is removed, the vertebral surface will have a radial or rounded cut **216** acting as a base for stabilized, conformable receipt of a 10 mm diameter spine cage. Figure 5 shows two such radial cuts or grooves **216** made by cutting tool **212** for placement of a spine cage. However, a tap with a fixed end point may be adequate to make a path for the cage to be inserted.

An important aspect of the invention is that the LEC cage **218** is, for example, only on average about 10mm in width -the same diameter as the groove **216** made by cutting tool **212**. This is critical because conventional cages are 14-16mm high and wide, making them quite difficult to insert. Such conventional cages require large cannulas for insertion and subject nerve roots to trauma and injury. Mispositioning such a cage by as little as 3 mm can severely injure a nerve root.

In contrast, the present LEC cage can expand to a greater dimension without requiring so much space in insertion. As set forth above, this enables the present cannula to be much smaller than a conventional cannula. This safeguards the nerve roots and minimizes trauma. The 10 mm limitation is an example only. Thus, the cannula can be made as small as possible to take advantage of the unique expandable attributes of the LEC.

As will be explained in greater detail *infra*, the LEC can expand linearly to a vertical height by approximately 30 -40 per cent. The LEC is characterized by expansion ranges of, for example, from 7mm up to 10 mm; from 9mm up to 12 mm; or 12 mm up to about 16 mm. Due to the wide expansion range, a cannula advantageously can be as small as possible for insertion of the smaller LEC in its unexpanded state.

Referring to Figure 4, an insertion tool **220** is provided in the cannula through its distal opening. The cannula in Figure 4 has been removed for clarity. The insertion tool is provided with a fork end **222** that conformably holds, for example, a 10 mm LEC for insertion into precut groove **216**.

It will be appreciated that the interior surface of the cannula advantageously matches or closely conforms to the exterior profile of the insertion tool and LEC, thereby properly orienting the LEC and preventing the LEC from rotating in the cannula. This further aids in precise placement of the LEC without injury to nearby nerve roots.

Referring to Figure 4, as the insertion tool **220** is pushed toward the vertebrae **202b**, the fork end **222** of the LEC insertion tool pushes on the wing sections **224a**, **224b** of the LEC cage thereby moving the LEC forward into position. Wing sections **224** act as a means for stabilizing and perfectly aligning the two halves of LEC **218** during the expansion process as will be explained *infra*. The wings of the LEC help to orient the LEC properly between the vertebrae. The insertion tool **220** also has depth markings **226** to indicate depth of insertion. A hard stop also can be added to prevent over travel.

Referring to Figures 5, 6A, and 6B, it will be appreciated that cylindrical cage **218** comprises two halves, an upper half **218a** and a lower half **218b** wherein the radial surface of each upper and lower half conformably engages with the corresponding surface of radial cut **216** in each vertebral segment **202a** and **202b**. (**202a** is omitted for clarity) in which the LEC **218** is positioned. This is possible due to the minimized shape of the non-expanded spine cage which enables its radius to be substantially the same as that of cutting head **214** and cut or groove **216**. This minimized diameter of the LEC further aids in precise placement of the LEC without injury to nearby nerve roots.

Referring again to Figures 5, 6A, and 6B, each half **218a**, **218b** of the LEC **218** is provided with a series of parallel longitudinally extending ridges **238** disposed along the longitudinal axis of each bone contacting exterior surface of each LEC half **218a**, **218b**. These parallel longitudinal extending ridges are characterized by a substantially pyramidal cross section (see Figures 6A and 6B) and form multiple rows of rigid engagement surfaces providing strong frictional engagement against slippery bone surfaces, extending the length of the LEC. The parallel ridges are disposed orthogonally with respect to lateral or rotational forces applied to the vertebrae. Due to the plurality of the ridges and depth of their pyramidal cross sections, the ridges strongly resist applied rotational forces. The multiple engagement surfaces provided by the ridges **238** also effectively increase the surface area of the LEC **218** in contact with the radial groove **216** in the bone. The multiple engagement

surfaces provided by the ridges **238** strongly lock the LEC in substantially invariant engagement with corresponding vertebral segments **102a** and **102b** by force from expansion of each LEC half with a corresponding vertebral body or segment.

It will be appreciated that providing other equivalent bone engaging features such as a multiplicity of pointed surfaces, corrugations or points extending over bone contacting surfaces of each LEC half **218a**, **218b** similarly provides a maximized surface area for bone engagement and fixation.

When seated in position, the surface configuration of the LEC prevents the LEC from rotating in the groove in the vertebral surface. This further enhances stable fixation of the LEC with the bone and prevents rollover and misalignment.

The cylindrical configuration of the LEC and matching radius of grooves **216** provide initially a 360° mating surface or bone to implant interface. This effectively doubles pullout forces with respect to the surface contact currently available in spinal reconstruction. Thus, the LEC is capable of withstanding at least 2000 Newtons (force pounds) in the perioperative period. In sitting, a person is capable of withstanding typically 1200 Newtons; when standing 800N, and when forward bending and heavy lifting up to 10,000N of intervertebral body force. Titanium is a preferential material for the LEC that achieves at least a 2000 Newton pullout force in the perioperative period.

The foregoing features enable the LEC to expand into the vertebrae with greater fixation forces than would be currently possible with known conventional devices. Thus, the requirements for additional stabilization procedures are reduced. This means that instead of achieving spine fusion by a series of conventional operative procedures, given the immediate solid fixation that accrues from the present LEC, operative procedures may be reduced in number, potentially to one operation. This advantageously would save the patient from pain, and the risks attendant with multiple anesthetics.

Due to the enhanced fixation and lateral stability, healing time is greatly reduced. Typically, once tissue is reconnected to bone, patients are only 30-40 per cent healed after three –four weeks; 60-70 per cent by six weeks; are 85 per cent healed by 12 weeks; and 100 per cent healed in about a year. This means, even though skin healing occurs, such superficial healing masks the long term need for joint immobilization to allow complete healing to occur. Such need for long-term

immobilization has negative impacts on patients, their family, their employer, their livelihood and their future.

In contrast, the present LEC provides substantially immediate bone to implant fixation that is stabilized against rotational forces. This achieves an accelerated bone to implant fixation time without joint immobilization.

Due to the substantially immediate bone fixation, lateral stability and elimination of the need for immobilization, the LEC can be used for large animals; for example horses or large dogs such as 200 lb. mastiffs, which cannot follow instructions regarding limiting activities after injury and repair.

Once the LEC has been seated in position in radial groove **216**, the cannula spikes **210** are removed from the vertebrae and the LEC is expanded. Pulling the cannula out slightly removes the spikes from the vertebrae and allows the vertebrae to be spread.

Referring to Figures 5, 6A and 6B, LEC **218** comprises an upper half cylinder **218a** and a lower, complementary cylinder half **218b**. The cylinder halves **218a**, **218b** are joined along a longitudinal axis to define a cylinder, the LEC, with an interior space for holding a quantity of bone growth enhancing agents as will be explained. Cylinder halves **218a**, **218b** also each comprise an integral, expansion alignment structure or generally U shaped wing **224a**, **224b** integrally formed with each respective LEC half. The upper wing **224a** extends tangentially generally downward from the surface of the first cylindrical half **218a**. The lower wing **224b** extends upward from the radial surface of second cylindrical half **218b**, immediately adjacent the first wing. During insertion, the wings form complementary U-shaped end pieces that lock together the upper and lower portions **218a**, **218b** of the LEC, holding the LEC **218** together in the closed position while the LEC is inserted in its non expanded state into the substantially congruent groove **216** in a vertebral segment.

The complementary adjacent sides of the wings **224a**, **224b** slidably move against each other in opposite directions during expansion. The wings provide complementary contacting surfaces for equalizing force distribution in each respective LEC half such that the halves expand equally in opposite directions. The wings work cooperatively to control expansion in a linear direction and to maintain the alignment of respective halves of the cage during expansion process. When the LEC is in its fully expanded state, the wings cooperate to neutralize or block natural potentially

deforming compression and shear forces. The wings thus provide controlled linear expansion of the two halves of the LEC and maintain each half in their predetermined alignment with the vertebral groove **216** during and after expansion.

Referring to Figures 6A, 6B and 7 it is understood that the controlled expansion stabilization and alignment provided by the wings also is provided by side walls **225a**, **225b** that define expansion slot **244** in the sides of the LEC halves. Thus, the wings are optional. The expansion slot **244** in turn conformably receives the angled sides of expansion wedge **242**. The sides or sidewalls **225a**, **225b** of the LEC halves **218a**, **218b** may be angled to form different dimensions for the expansion slot **244**, into which the expansion wedge **242** advances. As the U shaped parallel sides of the expansion wedge **242** advance into the slot **244**, they slide conformably against the sidewalls, holding the sidewalls of the LEC halves from both sides, thereby stabilizing the linear expansion of the LEC halves vertically.

Referring to Figures 4, 5, 7, 8 and 10C, the expansion mechanism is as follows. A rotary screwdriver or equivalent rotary driver **240** is inserted through an aperture in the center of the insertion tool **220** for making contact with an expansion means in the interior of the LEC **218**. The distal end of the rotary driver makes contact with the head of a screw **246**. Screw **246** operatively cooperates with nut **248** provided in the interior of the LEC. As the driver rotates the head of screw **246**, the screw head **246** pushes against the base of expansion wedge **242**. And, the wedged shaped, angled side portion **250** of expansion wedge **242** moves forward into a receiving slot **244**. Receiving slot **244** is defined by the sides **225a**, **225b** of respective LEC halves **218a**, **218b** in the side of the cage **218**.

Figure 8 shows a means for expanding the LEC linearly and generally orthogonally with respect to an axis of insertion. The exact angle of expansion can be predetermined by using an expansion wedge having a specific angle and height. Importantly, the expansion means also maintains the original diameter or radial dimension of each LEC half that remains in conformable contact with the bone, and thus does not interfere with the substantially immediate fixation achieved between the bone and multiple rows of corrugations or frictional engagement surfaces **238** provided on the radial surfaces of each LEC half **218a**, **218b**.

Means are provided for translating a rotary motion into a linear, vertical motion that expands the LEC vertically with respect to its axis of insertion, or at a desired angle determined by the angle of the expansion wedge to provide a full range

of spinal correction. In Figure 8 the expansion wedge **242** advances forward on an angled surface in expansion slot **244** defined by side walls **225b**, **225a** and provided on each side of the LEC. The forward movement of the expansion wedge simultaneously expands each cage half **218a**, **218b** at a predetermined angle, while maintaining the integrity of the sidewalls of the LEC during expansion for enclosing the bone growth enhancing material contained within the LEC. As the screw head **246** turns and pushes against the base of expansion wedge **242**, the expansion wedge **242** moves forward into the receiving slot **244**, and expands the halves of the cage **218** in a linear direction. The expansion wedge **242** moves all the way forward in the slot **244** and at the point of full expansion, comes to rest in a conformable end receiving space **252**.

As will be explained further with reference to Figure 10C, one of an assortment of expansion wedges having different angles and /or heights for the sides of the expansion wedge **242**, may be selected for insertion into the slot **244** for imparting a full range of desired spinal correction. This is done by simply selecting an expansion wedge characterized by a desired height and angulation of one or both sides.

Thus, by turning the screwdriver, the expansion wedge **242** advances forward into the receiving slot **244** of the LEC **218** and the LEC expands linearly in a vertical direction at an angle predetermined by the angle and height of wedge **242**. Once fully expanded, the ends of the expansion wedge **242** are trapped conformably within the receiving slot **244** and an end receiving space **252** defined by wings **224a**, **224b** of the LEC. This locks expansion wedge **242** in place and prevents the expansion wedge **242** from deforming and buckling outward during expansion and thereafter. The side slot **244** and end receiving space **252** also provide a substantially smooth interface between the expansion wedge and exterior of the LEC. Once expansion is complete, the driver, screw, nut and LEC insertion tool are removed from the cannula, leaving only the expanded LEC locked in place.

It will be appreciated that the driver in combination with the screw and the expansion wedge provide a means for translating an applied rotational force into a precisely determined linear vector for expanding the halves LEC **218** vertically along the vertical axis of the entire spine, rather than uniformly (that is, without increasing diameter, which would take up more space inside the vertebral body surfaces).

Referring to Figures 5, 6A, and 6B, multiple rows of corrugations or frictional engagement surfaces **238** extend along the longitudinal axis of each LEC half **218a**, **218b**. Multiple rows of corrugations or frictional engagement surfaces provide external protuberances or bone engaging ridges on the surface of each LEC half **218a**, **218b**. This effectively maximizes the surface area of the LEC that remains in contact with the bone.

The LEC halves **218a**, **218b** are expanded vertically in a linear direction in accordance with the rotation of the driver **240** and screw **246**. The precise linear height can be directly determined by the rotation of the driver or by the use of an expansion wedge of a known size and angle. The expansion process presses the LEC halves **218a**, **218b**, strongly into the predrilled vertebral bone grooves **216**, thereby securing the adjacent vertebrae to enhance stability during arthrodesis (fusion) healing.

Slots or apertures **254** in Figures 6A and 6B are provided through the exterior surface and extend into the interior of each LEC half **218a**, **218b**. The slots **254** act as sites for internal bone graft material egress, and increase contact areas between the internal bone graft material and the external boney prepared endplates. It will be appreciated that the maximized surface area of corrugations or bone-engaging surfaces are provided with the series of apertures **254** which provide channels for bone in-growth. Thus, the surface area for communicating bone graft material from the interior of the LEC to the bone is effectively increased, and the LEC provides a maximized surface area of bone fixation as compared to conventional devices utilizing smooth or threaded surfaces. The effectively maximized surface area also increases avenues for feed through of bone growth enhancing agents in the cylinder to facilitate bone fusion and ingrowth into the LEC with resulting fixation forces greater than adjacent bone and soft tissue failure forces.

An additional advantage of the multiple rows of bone engaging surfaces or corrugations **238** is to provide a maximized surface area of enhanced bone fusion for a minimal sized implant. Thus, bone engaging surfaces of LEC **218** can be provided with a coating such as hydroxyapatite, bone morphogenic protein and or certain enzyme substances that have the propensity to enable bone osteo-inductive and osteo-conductive principles for better healing responses. Alternatively, such morphogenic proteins and enzyme substances for promoting bone growth are advantageously contained in the hollow interior of LEC **218**. These substances communicate with the

bone-engaging surfaces through the slots **254** that act as conduits for bone in growth. The LEC and its slots **254** are also designed to permit suture free fusion. The slots **254** provide apertures and curvature angles in the areas intended for bone egress between the interior bone graft or bone substitute products, and the outer vertebral bone interface (the interface between vertebral segments **202a**, **202b** and bone engagement surfaces of LEC **218**) involved in the fusion process can be used by a surgeon to pull the interspinal ligament, or other structures through the LEC, thus creating an intentional immediate interface or padding to avert interspinal nerve injuries.

Since the LEC is inserted in a closed or non-expanded state, its interior may advantageously contain bone graft material, bone growth enhancing agents, medication or other agents that promote healing. During the expansion process the expansion wedge **242** progressively moves forward along the sides of the LEC as previously explained. This advantageously keeps the sides of the LEC substantially sealed while simultaneously allowing the LEC to expand in a vertical direction. Thus, medication and bone graft enhancing material contained within the interior of the LEC remain therein during the expansion process.

As the exterior of the LEC presses into the adjacent bone by the force of vertical expansion, the slots provide egress zones for absorption of bone growth enhancers, such as bone morphogenic proteins or other enzyme substances contained within the interior of the LEC. The slots **254** also provide areas for bone in growth thus promoting stable healing. As healing advances, pullout forces are greater than vertebral body failure forces, and patients can mobilize more quickly. Once healing (fusion or arthrodesis) does occur, the implants become incorporated and their role becomes quiescent.

Figure 9 is a representation showing the LEC being expanded. The LEC halves **318a**, **318b** expand linearly to a height 30 –40 percent greater than the original diameter of the LEC. The height increases to hold the vertebrae **202a**, **202b** while the width remains stable so as to decrease impingement upon a second cage, or upon neural elements or soft tissue structures in the immediate vicinity. It is understood that the top and bottom surfaces of LEC halves **318a** and **318b** are in contact with and fit conformably into the congruent surfaces of groove **216** provided in the vertebrae **202a**, **202b** since the radius of the unexpanded LEC is substantially the same as the radius of the cutting tool that formed groove **216**.

When the expansion is at a maximum, that is, the LEC is in the fully expanded state, the driver, in combination with the screw, are removed through the insertion tool and the insertion tool is detached from the cage. U shaped expansion wedge **242** has been drawn all the way into its end receiving space **252** in the interior of the LEC and locks the cage in its linearly expanded position.

Once detached from the insertion tool, the expanded LEC is securely set in groove **216** between two vertebral bodies **202a, 202b**. Since the force of fixation is greater than the bone failure strengths, early patient mobilization after surgery is feasible. Force to failure will be approximately 4000 Newtons.

Referring to Figures 10A and 10B, generally, two LECs **918a, 918b** are used for fusion through an anterior approach, though the surgeon can use any insertional vector including a posterior approach. LECs **918a, 918b** may be inserted in parallel or obliquely to accommodate located anatomy and to adjust deformities such as scoliosis, kyphosis, and spondylolisthesis. Typically, two LECs **918a, 918b** are provided, one on each end of a vertebral body or endplate **220b** in an intervertebral space **920**. This enables linear expansion into vertebral endplates **220a, 220b** which enhances fixation. By increasing fixation forces, earlier mobilization of the patient is encouraged, reducing the need for multiple fixation operations, and all associated risks (anesthesia, surgery complications) are decreased.

The LEC enables selective adjustment of spinal alignment. Due to the known angulation and height of the sides of the expansion wedge, and known radius of the driver and screw, it is possible to expand either LEC **918a** or **918b** vertically and linearly to a predetermined height H_1, H_2 .

Referring to Figure 10A, angular correction can be made for scoliosis by elevating or expanding either the medial or lateral side of the cage by dialing in or adjusting an amount of expansion to correct a problem with the natural spine angulation as noted on an AP (anterior/posterior) X ray plane. This adjustment is accomplished by selecting particular sized or expansion wedges as they relate to the cage recipient site. Once the expansion wedge is contained inside the cage, during intraoperative assembly, a preplanned selected cant or angular variation from pure linear expansion is realized. The amount of selected cant is calculated to coordinate with the scoliotic curve, so as to facilitate realignment toward normal

For correction of lordosis (as seen on a lateral X-ray view, naturally noted in both the lumbar and cervical regions of the spine), the LEC (anterior cage) can be

expanded so that it widens or expands more anterior linearly symmetrically than posterior, thus creating a trapezoidal construct that fills in the disc space more naturally, both expanding into the vertebral endplates, and filling the normally wider anterior space in such a manner that the “flat back syndrome” is eliminated. This promotes fusion in a normal or physiologic alignment.

Referring to Figures 10A and 10B, the shape of the linear expansion can be selected or dialed in depending on a selection by the surgeon before or during surgery to adjust alignment so as to: (a) maintain or correct for lumbar lordosis, thereby avoiding the “flat back syndrome”; (b) create more physiologic right or left bending angles to deal with scoliosis in complex reconstruction or salvage cases; (c) fill perceived or actual gaps in spinal bone encountered during surgery such as induced by trauma or by osteoporotic collapse.

It will be appreciated that due to the placement of the two LECs, one on each side of a vertebral body, it is now possible to adjust spinal alignment as shown in Figure 10B by expanding a first LEC **918a** to a greater predetermined height H_1 necessary to bring the two vertebral endplates **220a** and **220b** into normal alignment. The ability to linearly expand each spine cage to a predetermined height with improved stability and substantially immediate fixation makes it now possible to impart normal lordosis to a spinal column.

The present LEC enables three dimensional correction of spinal malalignments, and maintenance of natural curvatures. Thus, the present LEC may provide a cure for scoliosis or other forms of spinal misalignment. Structural interbody support of the anterior column of the spine has clear biomechanical and clinical benefits compared with conventional posterior/lateral arthrodesis. Biomechanically, interbody support improves the stability of the anterior column of the spine and permits load sharing with the region of the spinal motion segment that is exposed to highest loads improving stiffness and reducing rates of implant failure.

Clinically, interbody structural support enhances the rate of successful arthrodesis and is associated with improved clinical outcomes. The present LEC may be placed from an anterior approach to the spine or from a posterior or transforaminal approach. The posterior or transforaminal approach is popular because it permits circumferential arthrodesis of the spine in a single surgery, eliminating the morbidity of a separate anterior approach. Currently, anterior only surgery is unreliable due to inadequate initial stabilization of the spinal motion segment. With a linearly

expandable cage such as the present LEC and consequent rigid interbody fixation, the need for posterior augmentation is advantageously eliminated. Since the LEC expands into the vertebrae with greater fixation forces, the requirements for additional stabilization procedures will be reduced. By starting with a smaller fusion cage, such as the LEC, the surgeon can better approach the destination with less tissue dissection and consequently less injury to nerve roots and soft tissues around the spine.

Referring to Figure 10C, it will be appreciated that the present linearly expandable cage **218** provides options for achieving total lordosis correction. This is achieved by using an assortment of pre selected expansion elements **242** wherein wedge shaped angled surface **250** (referred to here as a wedge for clarity) is characterized by an angle such as, for example a , b , or any convenient angle, for imparting a desired lordotic curvature. A physician imparts a desired lordotic curvature by simply selecting different wedges characterized by different sizes and angles, such as angle a or b as shown.

As the expansion element **242** is drawn into receiving slot **244** during the expansion process, the angle and height of the wedge **250** determines the angle of correction and the fully extended height of expansion of cage **218**. The final extent of expansion of the cage occurs when expansion lock **262** (a projection provided on the distal end of the wedge **250**) slides into engagement with and is locked in place by a corresponding recess **264** provided in the surface of the cage **218** that defines the end of travel for the wedge in the receiving slot **244**. It will be appreciated that two corresponding sets of projections **262** and corresponding recesses **264** are provided on the upper and lower surfaces of the wedge and receiving slot for locking engagement to strongly lock the cage in position in its fully expanded state. Only one set is shown for clarity.

The advantages of inserting two parallel cages as shown in Figures 10A and **10B** over a single cage are: ease of access/ability to differentially distract in the medial/lateral plane. Selecting various sizes and angles for the sides of the expansion wedge enable predetermined expansion of the LEC halves linearly and vertically; either symmetrically vertically or offset vertically when wedge sides vary in angulation. This enables the LEC to be linear in one plane and either parallel and oblong or trapezoidal in another plane.

Expansion wedges **242** could be chosen to have angled surfaces **250**, such as angle a or b in Figure 10C, that correspond to 4mm increments as follows: 0 degrees;

4 degrees for providing 0-8 degrees of correction, then wedge angles of 0 degrees and 12 degrees. This would provide total lordosis options of 0, 4, 8, 12, 16, 20 and 28 degrees.

It is advantageous to have an assortment of heights and angles for the expansion wedge. This enables a physician to pre select, before surgery, a desired reconstructive change size to be implanted in a vertebrae in accordance with actual size vertebral segments shown in X rays. The base 270 of the expansion wedge 242 should be 3mm thick, assuming a 20mm long cage, since lordotic endplates are 3mm posterior dimension and anterior height= $4.4\text{mm} (= \tan(\text{wedge angle}) / (20 + (3 / \tan(\text{wedge angle})))$. Expansion wedges should be available in 2mm height increments.

In accordance with an aspect of the invention the foregoing features now make it possible to expand a 10 mm spine cage to 20 mm (more commonly to between 10 and 17 mm), while correcting trapezoidally for lordosis, kyphosis or even scoliosis requirements. The foregoing flexibility- the ability to predetermine height of expansion and degree of spinal correction by pre selecting expansion wedges having different sizes and angles, and inserting two expansion wedges in parallel provides an anatomically correct range of spinal correction in three dimensions.

An important advantage of the expandable cage is that the device permits a posterior (single stage) operation to create the lordosis that may normally require a combined anterior and posterior approach. The anterior-based linear cage may permit a single stage surgery if a physician adds a permanent staple to the position of the cannula set screws to provide tension anteriorly. The reason that stand-alone anterior cages are inadequate and require posterior support is that the approach disrupts the anterior tension band (the anterior longitudinal ligament and disc annulus).

By stapling across the implant vertically it is possible to create an anterior plate or tension band that will reconstitute the anterior column stability in extension, enabling a physician to avoid a posterior approach. These staples (two in parallel in vertical orientation) can be placed in the position of the prongs from the insertion canula.

While the invention has been described in connection with what are presently considered to be the most practical and preferred embodiments, it is to be understood that the invention is not limited to the disclosed embodiments and alternatives as set

forth above, but on the contrary is intended to cover various modifications and equivalent arrangements included within the scope of the following claims.

For example, equivalent fixation features can be provided for stabilizing the cage within the bone. Other configurations for the overlapping wing portions of the LEC halves may be utilized to provide interlocking capability and maintain linear expansion.

Also, other compositions of additives, such as various types of biogenic materials for enhancing bone growth can be added to the interior portion of the LEC. Other materials for construction of the LEC may be substituted for Titanium without departing from the scope of the invention.

As one skilled in the art will readily appreciate from the disclosure of the present invention, processes, machines, compositions of matter, methods, or steps, presently existing or later to be developed that perform substantially the same function or achieve substantially the same result as the corresponding embodiments described herein may be utilized according to the present invention. Therefore, persons of ordinary skill in this field are to understand that all such equivalent processes, arrangements and modifications are to be included within the scope of the following claims.

CLAIMS

I claim:

1. A linearly expanding spine cage (LEC) for insertion through a cannula along an axis of insertion in a radial groove cut in the bone of adjacent first and second vertebral bodies and for providing immediate fixation and stabilization thereof comprising;
 - a first half cylindrical shell having a radial surface for conformable engagement in the groove cut in the first vertebral body,
 - a second half cylindrical shell, complementary with respect to the first half cylindrical shell, including a radial surface for conformable engagement in the groove cut in the second vertebral body, the first and second cylindrical shells being joined in an unexpanded state along a longitudinal axis in common with the axis of insertion, such that the half cylindrical shells define a cylinder with an interior space for holding a quantity of bone growth enhancing agents, and
 - the radius of the cylinder in its unexpanded state is less than the radius of the cannula and substantially equal to the radial groove cut in the vertebral bodies; and
 - expansion means for expanding the first and second cylindrical shells linearly and orthogonally to the axis of insertion while maintaining constant fixation between the radial surfaces and conformably engaged vertebral bodies.
2. A linearly expanding spine cage as in claim 1 wherein the first and second radial surfaces further comprise multiple rows of corrugations or bone engaging ridges extending in parallel along the longitudinal axis of each LEC half to provide maximized surface area for bone engagement and fixation.
3. A linearly expanding spine cage as in claim 1 wherein the first and second radial surfaces further comprise a multiplicity of radially extending pointed surfaces, projections, or like features that provide a maximized surface area for bone engagement and fixation.

4. A linearly expanding spine cage as in claim 1 wherein the first and second radial surfaces are provided with a plurality of slots or through holes for maximized feed through of bone growth enhancing agents contained in the interior of the LEC to facilitate bone ingrowth through the slots for enhanced bone fixation, such that fixation forces are greater than adjacent bone and soft tissue failure forces.

5. A linearly expanding spine cage as in claim 1 wherein the expansion means further comprises a U shaped expansion wedge comprising first and second angled sides joined by a base, the angled sides adapted for advancement between the two halves of the LEC upon application of force to the base, such that advancement of the wedge expands the LEC halves linearly in accordance with the angle imparted by the wedge, while bone engaging surfaces remain fixed.

6. A linearly expanding spine cage as in claim 5 wherein height and angle of expansion of the LEC are predetermined by selecting an expansion wedge having sides of a desired height and angle to provide a complete range of spinal correction.

7. A spine cage linearly expandable between adjacent vertebral segments in a vertical direction, the spine cage characterized in its non-expanded state by a minimized longitudinal radius substantially equal to the radius of a cutting head for minimally invasive insertion in a radial groove cut by the cutting head in first and second adjacent vertebral segments comprising:
a first half cylinder comprising a radial surface including a plurality of corrugations or rows of bone engaging projections for increasing surface area and enhancing fixation with the corresponding radial cut in the first vertebral segment, and having a pair of sidewalls extending tangentially from each side of the radial surface, with a portion of each sidewall defining a first angled surface; and
a second half cylinder comprising a radial surface including a plurality of corrugations or rows of bone engaging projections for increasing surface area and enhancing fixation with the corresponding radial cut in the second vertebral segment and having a pair of sidewalls extending tangentially from each side of the radial surface, defining a second angled surface, such that the first and second angled surfaces form an angled slot on each side of the cage;

an expansion means comprising first and second angled wedges joined by a base, the wedges being adapted for slidable advancement into the slot, such that upon application of force to the base, the wedges move forward in the slot, expanding the first and second halves in a desired linear direction according to the angle and height of each wedge, while facilitating locking engagement between the radial surfaces and adjacent vertebral segments by force from expansion of each radial surface with a corresponding vertebral body.

8. A linearly expanding spine cage as in claim 7, wherein bone engaging surfaces of the spine cage are provided with a coating such as hydroxyapatite, bone morphogenic protein and or certain enzyme substances that have the propensity to enable bone osteo-inductive and osteo-conductive effects for an improved healing response.

9. A method for correcting spinal deformities using a linearly expanding spine cage (LEC), being linear in one plane and either parallel and oblong or trapezoidal in another, the LEC comprising two halves joined in an unexpanded state along a common longitudinal axis to form a cylinder having a diameter equal to an insertion bore cut in adjacent vertebral bodies, the LEC including a wedge for expanding the LEC halves linearly and vertically at a desired angle with respect to a spinal column comprising:

- determining a desired change in height and angle of alignment in any of three dimensions of a first and second adjacent vertebral body;
- selecting one or more expansion wedges, each wedge comprising angled sides joined by a base wherein the sides of the selected wedge are characterized by an appropriate angle for achieving the desired correction;
- cutting one or more insertion bores through adjacent vertebral bodies such that each bore extends transversely with respect to the spine;
- inserting the LEC with corresponding selected expansion wedge into the one or more bores such that each half of the LEC conformably engages a corresponding half of the bore in the adjacent vertebral bodies;
- advancing the expansion wedge into the LEC to impart desired vertical height and angle of correction while maintaining fixed conformable

engagement between each LEC half and corresponding vertebral body.

10. A method for correcting spinal deformities according to claim 9 further comprising the step of varying angulation of the angled sides of the expansion wedge to impart linear symmetrical vertical expansion or offset vertical expansion to the LEC halves for effecting a desired angle of correction to a spinal column in any of three dimensions.

11. A method for correcting spinal deformities using a linearly expanding spine cage (LEC) as in claim 9 further comprising the step of providing a series of bone engaging features, such as ridges, corrugations, points, or the like extending over the surface of each LEC half to provide a maximized bone engaging surface area for enhanced bone fusion and to facilitate locking engagement by force from expansion of each LEC half with its corresponding engaged vertebral body.

12. A method for correcting spinal deformities using a linearly expanding spine cage (LEC) as in claim 9 further comprising the step of:
providing a series of slots or apertures extending through the bone engaging surface of each LEC half to facilitate bone ingrowth into the LEC.

13. A method for correcting spinal deformities using a linearly expanding spine cage (LEC) as in claim 9 further comprising the step of providing a quantity of bone growth enhancing agents in the cylinder formed by the LEC halves to facilitate bone fusion and ingrowth into the LEC with fixation forces greater than adjacent bone and soft tissue failure forces.

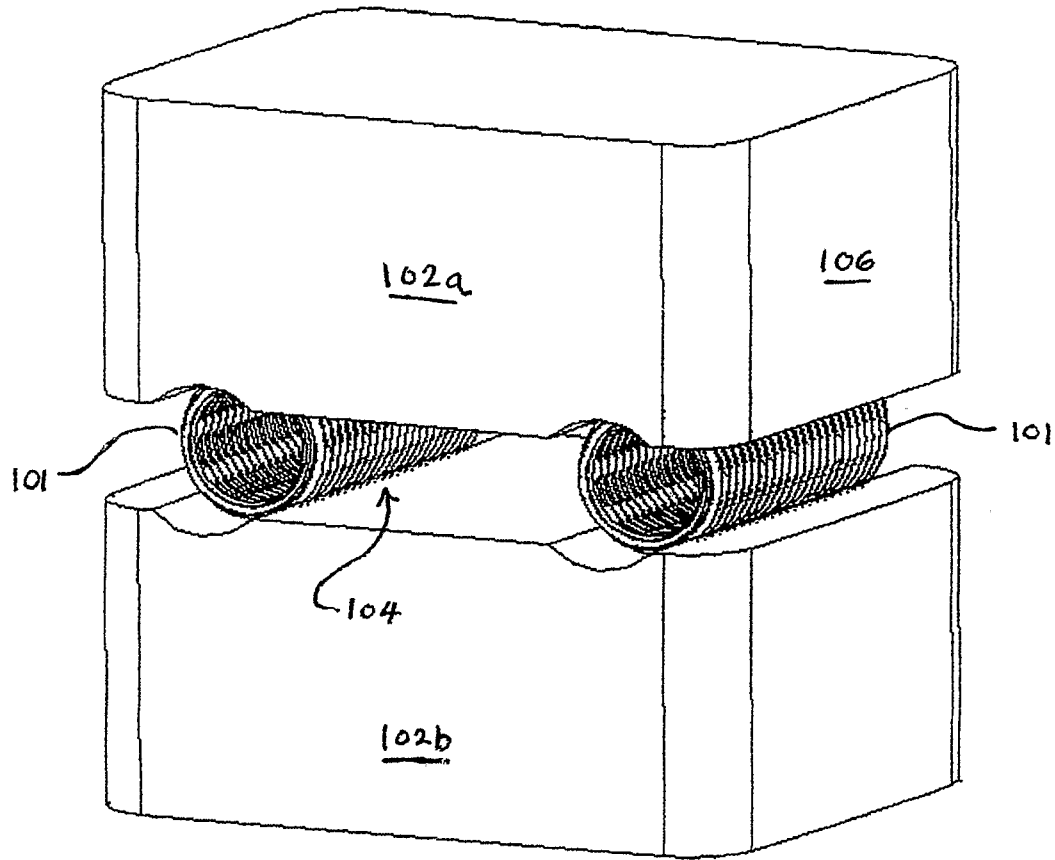


FIG 1
PRIOR ART

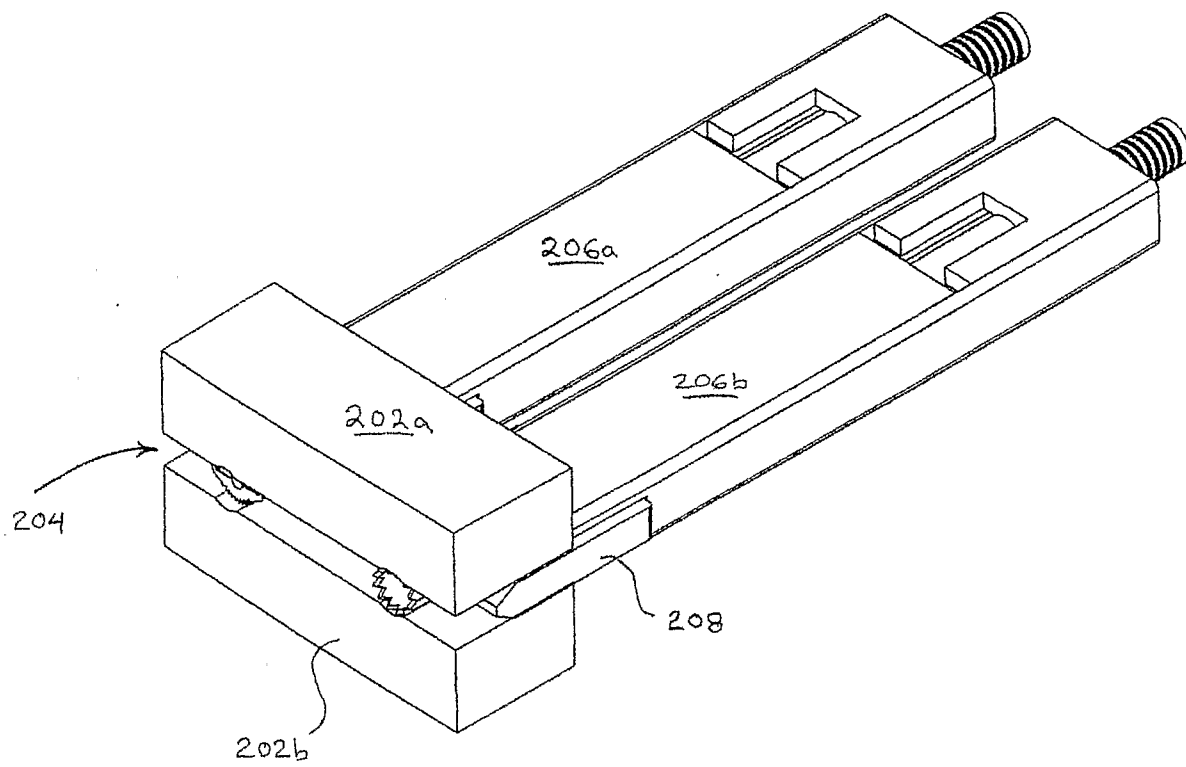


FIG 2

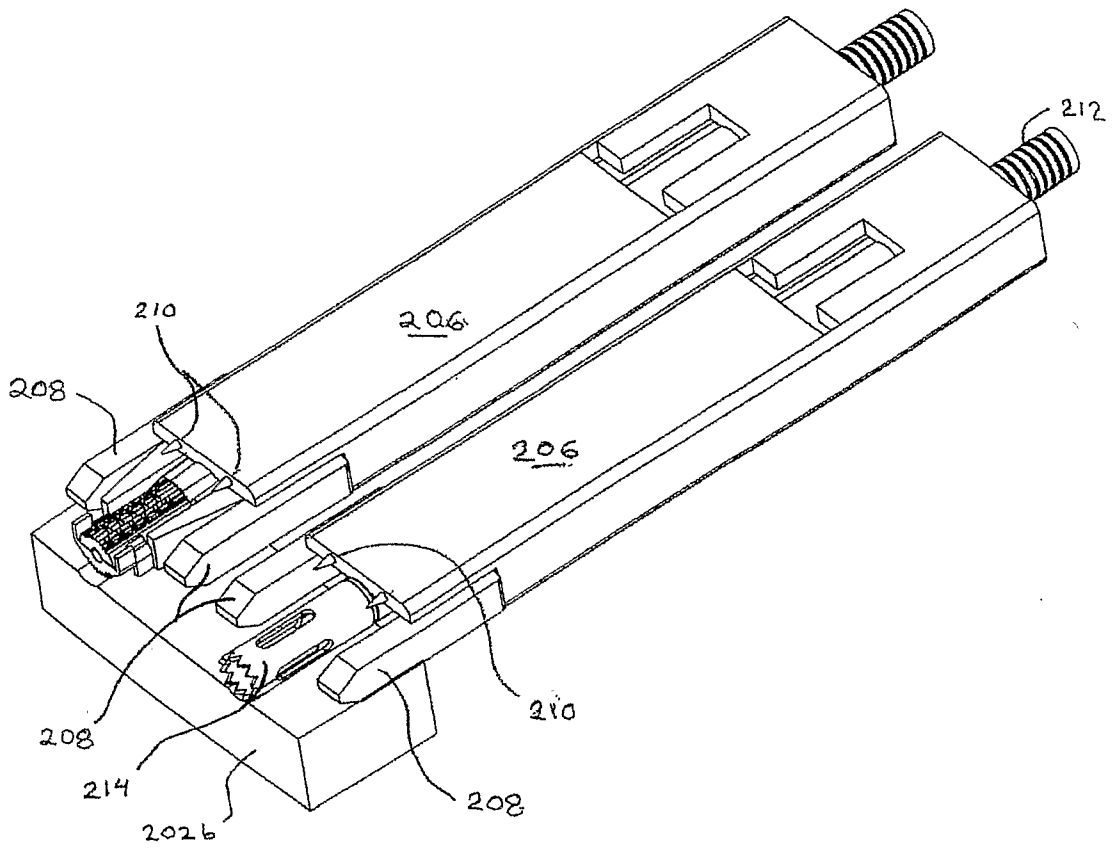


FIG 3

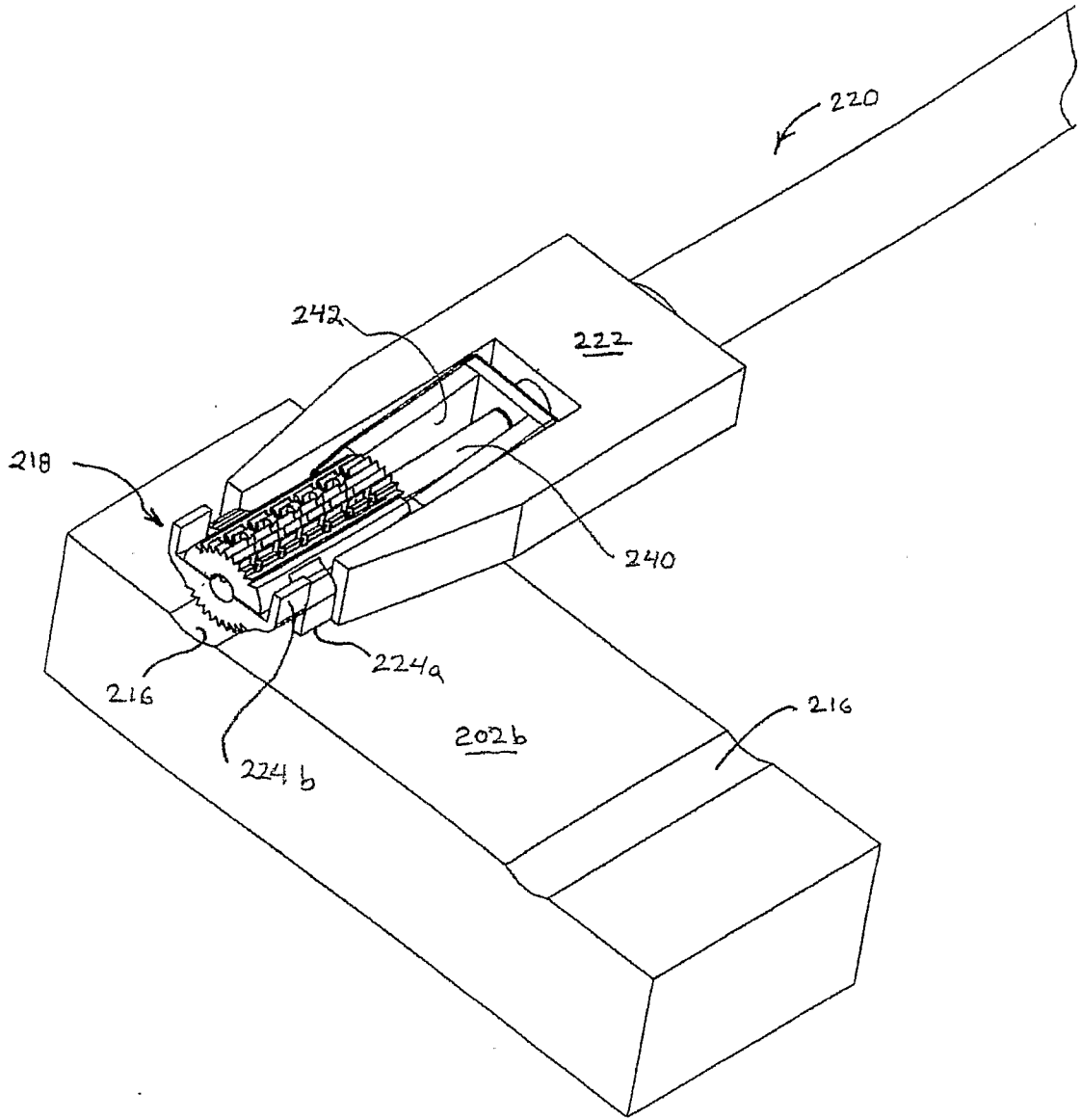


FIG 4

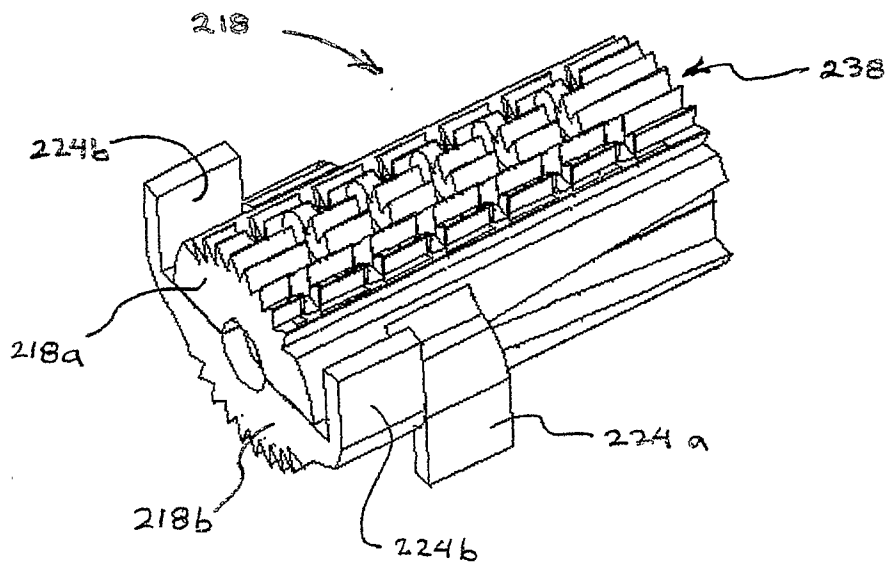


FIG 5

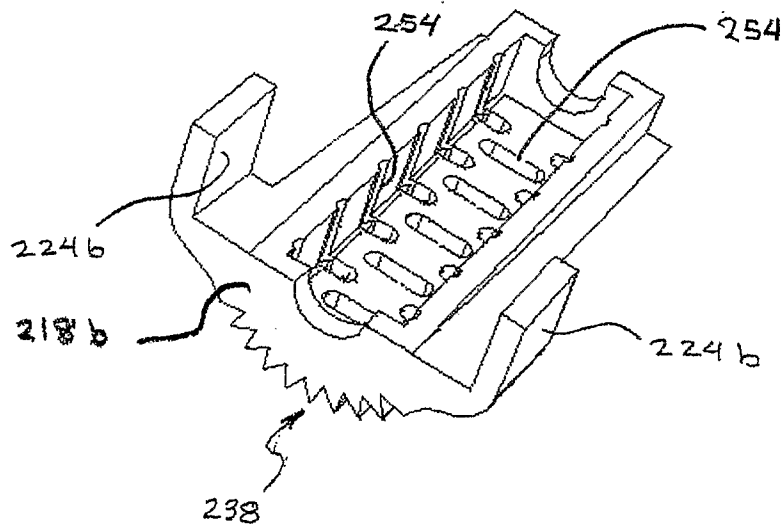


FIG 6A

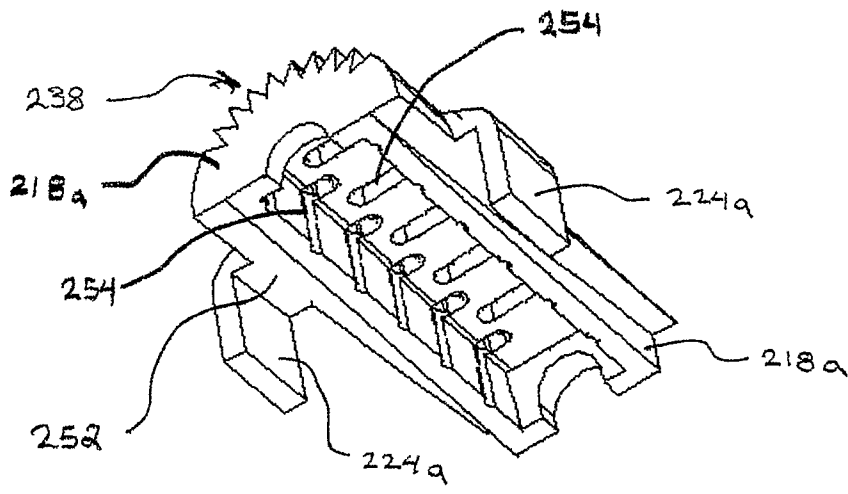


FIG 6B

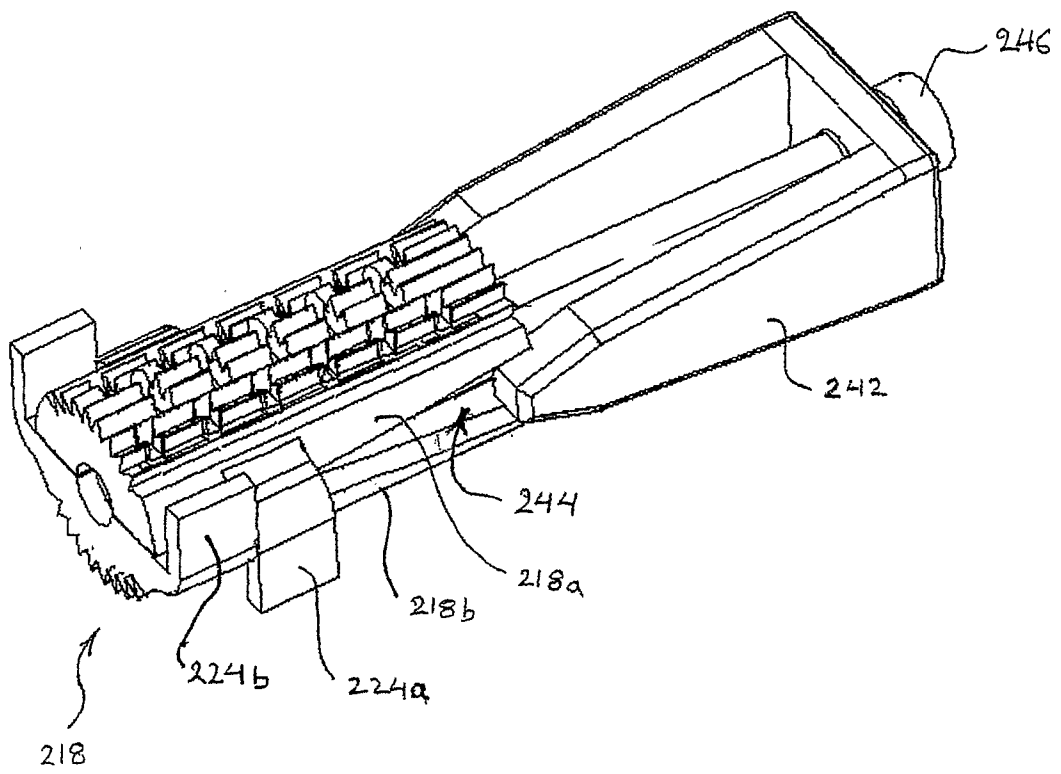


FIG 7

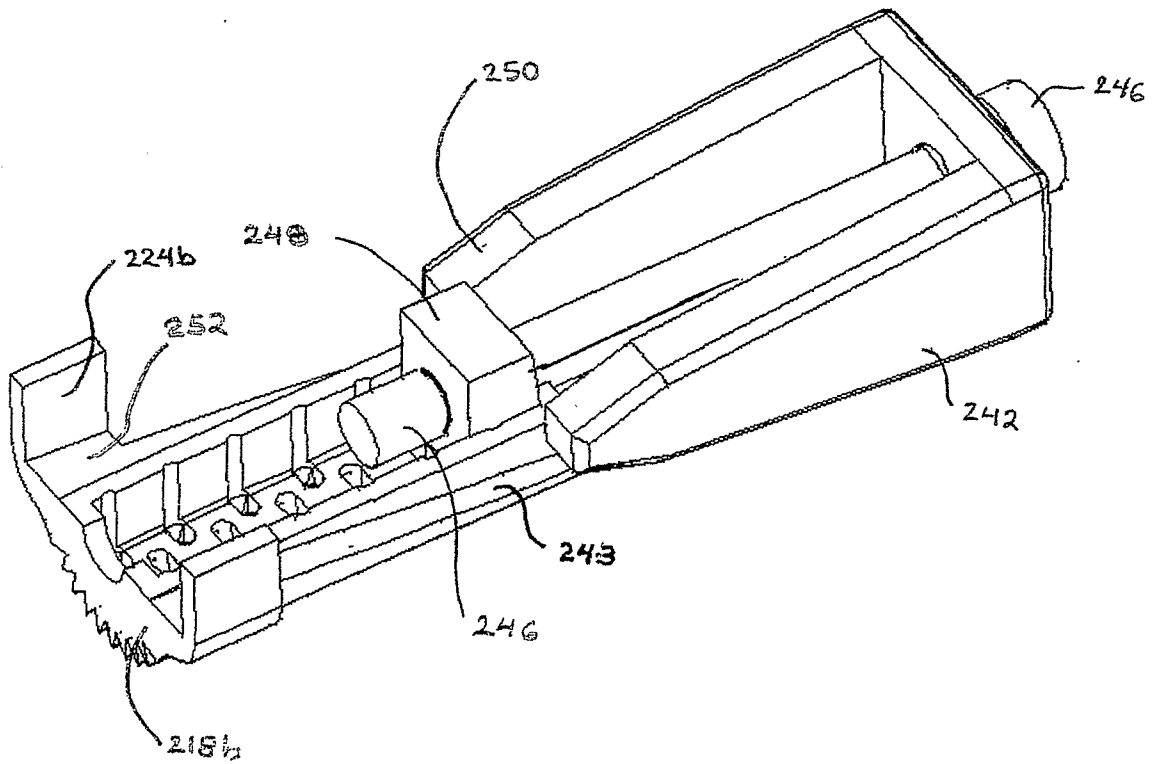


FIG 8

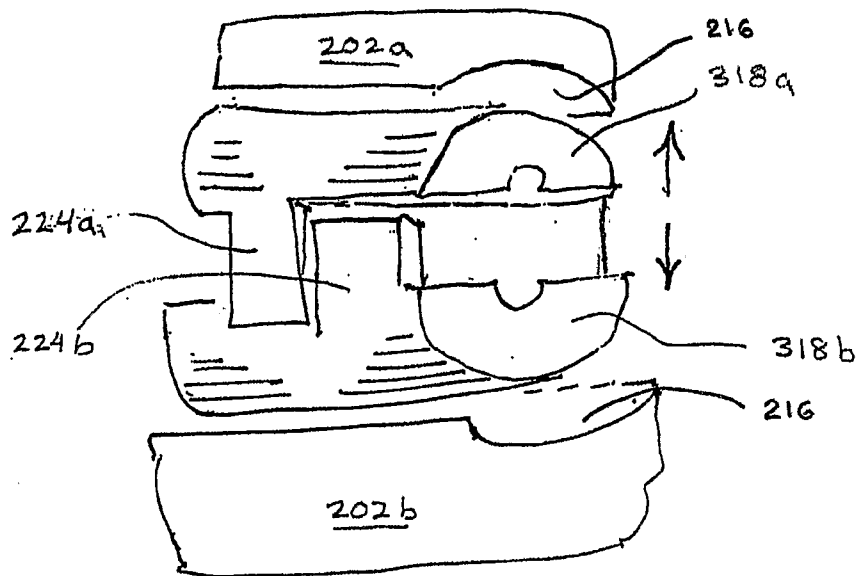


FIG 9

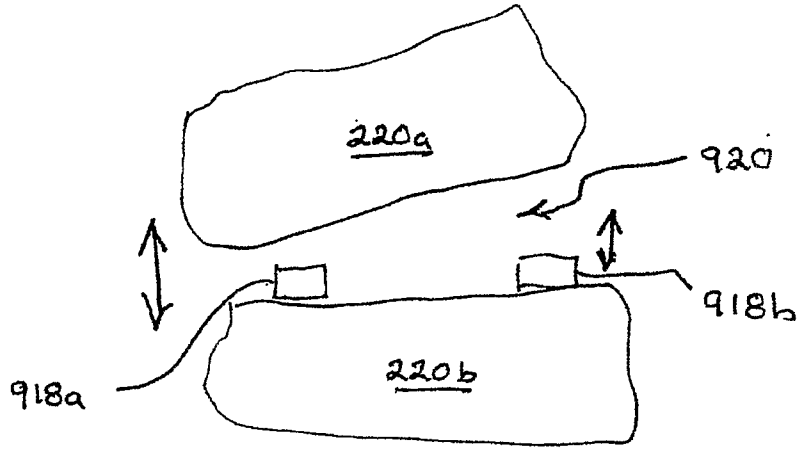


FIG 10A

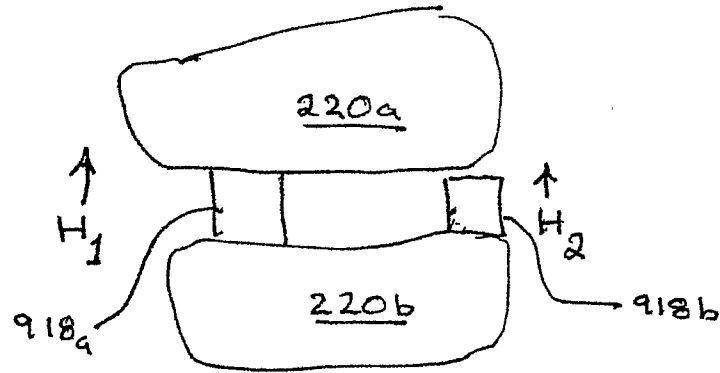


FIG 10B

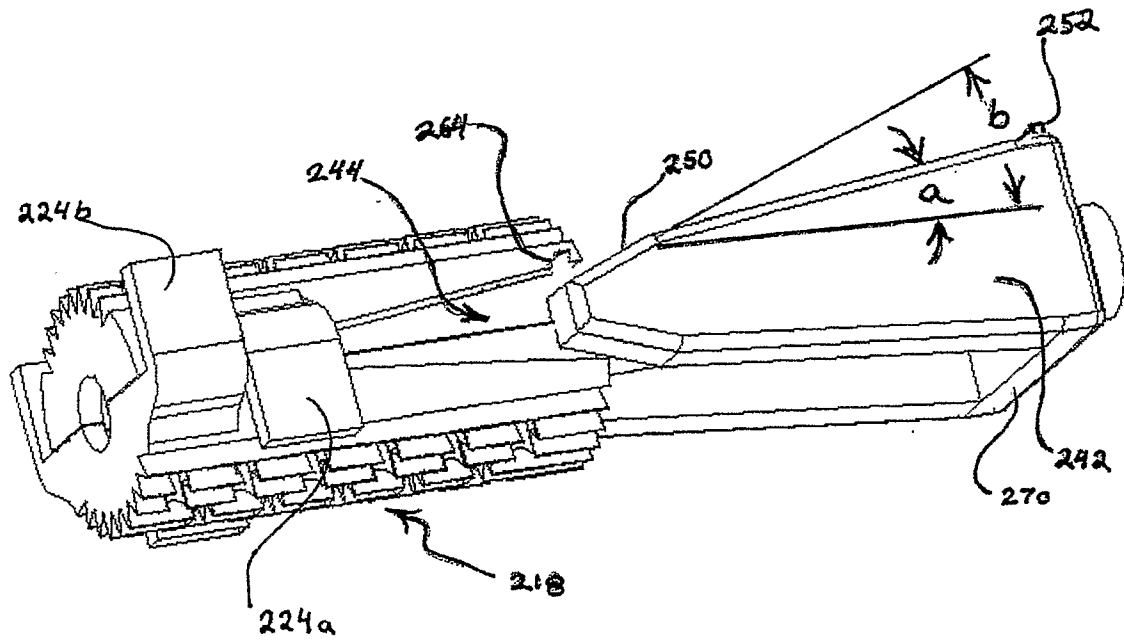


FIG 10c

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2006/031528

A. CLASSIFICATION OF SUBJECT MATTER
 INV. A61F2/44 A61F2/46

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)
 A61F

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

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

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 665 122 A (KAMBIN PARVIZ [US]) 9 September 1997 (1997-09-09)	1, 3, 4, 6
Y	column 3, line 5 - line 59	2, 3
Y	EP 1 481 654 A1 (ULRICH GMBH & CO KG [DE]) 1 December 2004 (2004-12-01)	2, 3
A	paragraph [0022] - paragraph [0027]	7
A	EP 1 290 985 A2 (IQL IND QUIRURGICAS DE LEVANTE [ES]) 12 March 2003 (2003-03-12) figures 9-12	5, 7
X	WO 02/09626 A (ADVANCED PROSTHETIC TECHNOLOGI [US]; COHEN HOWARD [US]; BIRO LADISLAU) 7 February 2002 (2002-02-07) page 19, line 15 - line 23	1
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Further documents are listed in the continuation of Box C.

See patent family annex.

* Special categories of cited documents :

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

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

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

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

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

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

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

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

Z document member of the same patent family

Date of the actual completion of the international search

1 December 2006

Date of mailing of the international search report

03/01/2007

Name and mailing address of the ISA/

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INTERNATIONAL SEARCH REPORT

International application No

PCT/US2006/031528

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 02/38062 A2 (BOEHM FRANK H JR [US]; MELNICK BENEDETTA D [US]) 16 May 2002 (2002-05-16) page 7 - page 9 -----	1
A	WO 2004/019829 A (SDGI HOLDINGS INC [US]) 11 March 2004 (2004-03-11) figures -----	7

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2006/031528

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. Claims Nos.: 9-13
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

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

Remark on Protest

- The additional search fees were accompanied by the applicant's protest.
- No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2006/031528

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
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