(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
4 January 2007 (04.01.2007)

PCT

(10) International Publication Number
WO 2007/002409 A3

(51) International Patent Classification:
A61B 17/56 (2006.01) *A61F 2/30* (2006.01)
A61B 17/58 (2006.01)

(21) International Application Number:
PCT/US2006/024491

(22) International Filing Date: 22 June 2006 (22.06.2006)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/693,126 22 June 2005 (22.06.2005) US

(71) Applicant and
(72) Inventor: **RITLAND, Stephen** [US/US]; 1150 N. San Francisco Street, Flagstaff, Arizona 86001 (US).

(74) Agents: **YASKANIN, Mark, L.** et al.; Sheridan Ross P.C., 1560 Broadway, Suite 1200, Denver, Colorado 80202-5141 (US).

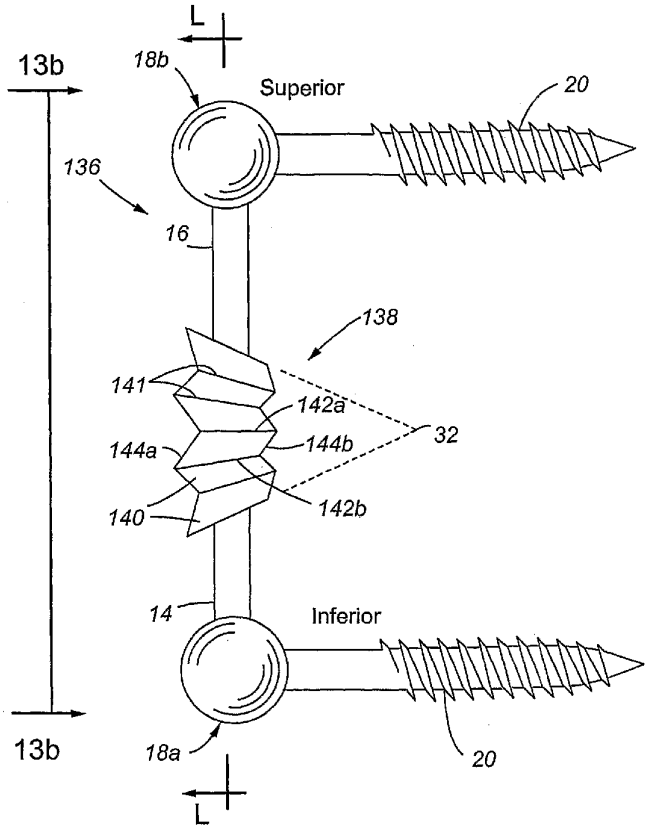
(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*
— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

[Continued on next page]

(54) **Title:** DYNAMIC FIXATION DEVICE AND METHOD OF USE



(57) **Abstract:** A dynamic fixation device is provided that allows the vertebrae to which it is attached to move in flexion within the normal physiological limits of motion, while also providing structural support that limits the amount of translation motion beyond normal physiological limits. The present invention includes a flexible portion and two ends that are adapted for connection to pedicle screws. In at least one embodiment of the present invention, the normal axis of rotation of the vertebrae is substantially duplicated by the dynamic fixation device. The flexible portion of the dynamic fixation device can include a flexible anterior-posterior segment, an anterior-posterior segment bounded by one or more zones with cuts in the rod portions, a flexible accordion-like segment, and/or a hinge portion.

WO 2007/002409 A3

(88) Date of publication of the international search report:
15 November 2007

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

DYNAMIC FIXATION DEVICE AND METHOD OF USE

FIELD OF THE INVENTION

This invention relates generally to securement devices and, more particularly, to a device capable of flexibly securing vertebrae together.

BACKGROUND OF THE INVENTION

The lumbar spine absorbs a remarkable amount of stress and motion during normal activity. For the majority of the population, the healing response of the body is able to stay ahead of the cumulative effects of injury, wear, and aging, and yet still maintain stability with reasonable function. In some cases, however, the trauma or stress exceeds the ability of the body to heal, leading to local breakdown and excessive wear, and frequently also leads to local instability. Accordingly, degenerative change with age superimposed on baseline anatomy in the lumbar spine leads to problems including instability, pain and neurologic compromise in some patients. In some cases, the local anatomy may not provide the same protection to the motion segment, thereby aggravating this breakdown. Although rehabilitation, conditioning, the limitation of stress, and time to recover are effective treatments for most patients, there is a significant failure rate with persistent pain, disability and potential neurologic deficit.

Referring now to Figs. 1, and 2, two side views of a pair of adjacent vertebral bodies are shown. Figure 1 illustrates two vertebra V_1 and V_2 of the spine in a neutral position. As shown in Fig. 2, when a person leans forwards, the spine undergoes flexion. The anterior portion of the spine comprises a set of generally cylindrically shaped bones which are stacked one on top of the other. These portions of the vertebrae are referred to as the vertebral bodies VB_1 and VB_2, and are each separated from the other by the intervertebral discs D. The pedicles P_1 and P_2 comprise bone bridges which couple the anterior vertebral body VB to the posterior portion of each vertebra. At each intervertebral joint or disc D, flexion involves a combination of anterior sagittal rotation and a small amplitude anterior translation.

The intervertebral joint is a complex structure comprising an intervertebral disk anteriorly, and paired zygapophyseal joints posteriorly. The disk functions as an elastic support and connection between the vertebra, and allows for flexion and extension of the spine, as well as limited rotation and translation. The zygapophyseal joints and associated anatomy allow for significant flexion and extension while providing constraints in translation and rotation.

The primary bending motion in the lumbar spine is flexion and extension in an anterior/posterior plane. This occurs in the range approximating 10-15 degrees of flexion and extension. In a young or normal lumbar spine, this motion occurs about an axis in the mid to

posterior portion of the disk. This is associated with a distraction or subluxation of the facet joints or posterior elements of 10-15 mm. This occurs not about a pure axis, but about a neutral zone, or a centroid of rotation associated with the lumbar disk. The normal elasticity of the disk, joints and ligaments, and the degree of play or freedom associated with these joints, as well as the nature of the loads applied to the spine contribute to the size of this region of rotation. In some cases, the recurrent loads and motion on the disk and associated trauma to disk and motion segment exceed the natural rate of healing or repair of the body. In this situation, there is breakdown in the motion segment associated with loss of the normal axis of rotation. As increasing subluxation occurs with segmental motion, there is a dramatic shift in the axis of rotation with displacement occurring within the disk space or frequently to some point outside of the disk. Therefore, in the situation of a failing motion segment, there is breakdown in the centroid of rotation with associated translation of the vertebral segments. This translation is allowed by both breakdown occurring in the disk and instability associated with both wear and degeneration of the zygapophyseal joints. The underlying anatomy of the motion segment and joints allows for significantly greater stress on the disc and contributes to degeneration both in the disk and joints.

Traditionally, surgical treatment has been directed at treating neural compromise, or if the pain, instability, or risk of instability is considered sufficient, a segmental fusion has been considered. More recently, stabilization procedures have been tried over the past several years including artificial disks and ligaments and elastomeric constructs to protect the spine. Arthroplasty techniques to maximize function and reduce the dynamic effects on adjacent segments are a more recent approach with less follow-up as to long-term results. A challenge in designing such a system is constraining motion in a normal physiologic range.

Spinal fusion surgery is a method of fusing at least two mobile segments of the spine to knit them together as one unit and eliminate motion between the segments. Current spinal fixation systems offer several drawbacks. Rigid fusion constructs do not allow relative movement between the vertebrae that are fused using a construct comprising a pedicle screw, connector mechanism, and rigid rod. Furthermore, rigid implants are known to create significant amounts of stress on the components of the construct, including the pedicle screws and the rod, as well as the bone structure itself. These stresses may even cause the rigid rod to break. In addition, the stresses transferred to the pedicle screws may cause the screws to loosen or even dislodge from the vertebrae, thereby causing additional bone damage.

Artificial disks may replace a failing disk and approximate a normal centroid or axis of rotation; however, placement of such a device is technically demanding and replaces the normal disk

with a mechanical replacement with uncertain long-term results. The artificial disk will be subject to wear without the healing potential of the body to heal itself.

It is also desirable with some patients to have a spinal implant system that allows the vertebral column to settle naturally under the weight of the human body. Human bone heals more readily under some pressure. In a rigid spinal implant system, the patient's spinal column may be unnaturally held apart by the structure of the implant. It is possible that this stretching of the vertebrae, in relation to one another, results in delayed or incomplete healing of the bone.

Posterior devices placed with pedicle fixation may provide some stabilization, however, the natural motion of such devices does not necessarily act to mimic normal physiology. In a healthy lumbar spine the axis of rotation or neutral area for motion is situated near the inferior posterior third of the lumbar disk. A desirable artificial system would closely approximate physiologic motion. However, to date, posterior systems have failed to address these concerns.

Several existing patents disclose fusion devices. For example, U.S. Patent No. 5,415,661 discloses a device that includes a curvilinear rod such that the implant supposedly restores normal biomechanical function to the vertebrae of the spine receiving the implant. However, the '661 patent does not disclose a device having structure other than a curvilinear shape that has a radius of curvature of between 0 to 180 degrees. In addition, the '661 patent does not disclose the concept of providing an anteriorly projected pivot point that models the natural articulation of the subject vertebrae by using a structure that provides a virtual rotation zone substantially identical to the rotation zone provided by the patient's vertebrae. In addition, as seen in Fig. 3 of the '661 patent, the device disclosed in the '661 patent utilizes a body 4 having a central section 10 having an anteriorly oriented position relative to its ends 6a, 6b.

U.S. Patent No. 6,293,949 also discloses a spinal stabilization device intended for use along the cervical vertebrae, and intended to be installed along the anterior side of the vertebrae.

U.S. Patent No. 6,440,169 discloses a device that attaches to the spinous processes of two vertebrae and has a leaf spring that allows the device to compress and then recover spontaneously after the stress has ceased. However, the '169 patent does not address a construct that includes an anteriorly projected pivot point that allows the vertebrae to articulate when the spine undergoes flexion.

In view of the above, there is a long felt but unsolved need for a method and system that avoids the above-mentioned deficiencies of the prior art and that provides an effective system that is relatively simple to employ and requires minimal displacement or removal of bodily tissue.

PCT/US2006/024491

SUMMARY OF THE INVENTION

The present invention provides a device that can be implanted and that provides for a specified amount of forward bending motion, thereby allowing anterior sagittal rotation between the vertebrae that receive the implant. Reference is hereby made for the incorporation of the conventional descriptive terms of motion and other content presented in *Clinical Anatomy of the Lumbar Spine and Sacrum* by Nikolai Bogduk, third edition, published by Churchill Livingstone, 1999. Although anterior sagittal rotation or flexion between vertebrae is normal, significant anterior sagittal translation or sliding motion between vertebrae is not. Thus, by allowing some amount of rotational motion while protecting against translation, the patient's condition or injury can be protected, thus promoting the healing process, while subsequently providing some ability to rotate one vertebra relative to an adjacent vertebra, thereby allowing for improved spinal motion following surgery and recovery. Accordingly, as described herein, various implants, including a number of rod configurations having flexible portions are presented that provide a device having the ability to elongate and bend. Thus, it is a first aspect of the present invention to provide a device that elongates, and a second aspect of the present invention to provide a device that bends. More particularly, the present invention is a dynamic fixation device that includes a flexible rod portion, wherein the flexible rod portion can include a geometric shape and/or a hinge portion. These dynamic fixation devices are constructed of a material of an appropriate size, geometry, and having mechanical properties such that they bend, thus allowing the vertebrae associated with the implant to rotate relative to one another, similar to the movement of a natural spine.

A dynamic fixation device is a quasi-flexible, semi-rigid fixation construct that allows some measure of motion between the vertebrae attached to the dynamic fixation device. Dynamic fixation of the lumbar spine provides means of protecting lumbar structures and allows for healing without proceeding to a lumbar arthrodesis. The constraints on such a system are in some ways different than for a rigid or near rigid construct, such as that used for fusion.

At the present time, pedicle fixation is an accepted method of fixing to the spine. In the situation of a lumbar fusion, a relatively rigid construct is appropriate to stabilize the spine and allow healing of the bony structures. In the situation of providing protection to the lumbar structures, a flexible system is appropriate to limit but not stop the motion of lumbar elements. The flexible elements in such a system need to accomplish several objectives. The primary objective is to allow physiologic motion of the spine, while protecting against excessive or non-physiologic movement. A secondary consideration is to protect the pedicle fixation from undue stress that could loosen the fixation at its bony interface.

The normal instantaneous axis of rotation of the lumbar spine occurs typically near the lower posterior third of the disk. Conventional pedicle fixation of the spine typically places the fixation rod or plate at the dorsal aspect of the apophyseal joint or posterior to the joint. Therefore, it is appropriate to consider a construct that effectively shifts this rotation point anteriorly toward the physiologic axis.

A group of geometries exist, which if applied to a posterior device, will constrain the subluxation of the segment and maintain the rotation in or close to the normal zone or axis of rotation. The indication for use is to constrain the stresses and motion within a range which will allow the body's normal healing response to maintain adequate competence in the motion segment to avoid development of instability or neurologic deficit and minimize pain or arthritis. The important features allow for maintenance of physiologic motion without the abnormal subluxation or translation that are associated with a degenerating disk and contribute to further degeneration. Thus, it is a separate aspect of the invention to provide a construct that limits excessive subluxation or translation.

Although the motion is complex related to the range of stresses which may be applied, it is nonetheless possible to provide a device so that while in compression, movement is axial or accompanied by slight dorsal translation, and that while in flexion allows both separation of posterior elements and slight ventral translation allowing rotation about the posterior portion of the disk.

Accordingly, it is an aspect of the present invention to provide a device that allows for some limited motion, thereby decreasing the stresses placed on the various component parts of the implant, as well as the affected vertebrae. It is a further aspect of the present invention to provide a device whose motion is designed to model the bending motion of the spine. Several separate embodiments of the present invention accomplish such tasks.

It is a separate aspect of the present invention to provide a construct that geometrically accommodates the human spinal anatomy, while providing a structural member that provides an anteriorly projected zone of rotation.

In a first embodiment, an implantable elastomeric material may be used, or a surgically implantable alloy can be used that includes a geometric shape having a plurality of arms (e.g., four arms) with an interior open region between the arms. In one example of this embodiment, the geometric shape is rectangular, such that the arms of the geometric shape are situated at 90 degree angles relative to each other. Upon deformation due to flexion of the spine, the geometric shape deforms, and the 90 degree angles between the arms change such that the geometric shape expands

and becomes a parallelogram. In a separate aspect of the invention, the convergence segments of the arms include partially circular corners. Alternatively, the partially circular corners may be of a different shape, such as partially triangular. In a separate aspect of this embodiment, the inside surface of the interior sidewalls of the arms of the geometric shape have an interior surface that is at an angle of 90 degrees relative to a planar surface of the geometric shape. Attached to the exterior of the geometric shape near two opposing corners are two rod arms. The rod arms allow the device to be connected to connectors, which interconnect the device to pedicle screws. In a separate aspect of this embodiment, each rod arm may be situated at different angles and locations along the geometric shape, thereby influencing the location of the projected pivot point in the plane of the geometric shape upon flexion of the spine.

In yet a separate embodiment, a dynamic fixation device utilizes at least two adjacent geometric shapes that act in an accordion manner; however, this embodiment serves to project the effective pivot point anterior relative to the device. Therefore, the projected pivot point mimics the natural rotational axis of the vertebrae to which the device is attached. In a modification of this embodiment, more than two adjacent geometric shapes are combined to form the flexible portion of the device. One aspect of this embodiment and its modification is that smaller geometric shapes may be used with the addition of more geometric shapes. Consequently, a smaller profile dynamic fixation device can be provided, while at the same time having an effective pivot point that is projected anteriorly a sufficient distance to mimic the natural rotational axis of the vertebrae to which the device is attached.

In yet a separate embodiment, a dynamic fixation device is provided that includes a modified geometric shape that serves as the flexible portion of the device. The modified geometric shape incorporates an opening or void space that allows the device to elongate and deform to accommodate flexion of the spine.

In a yet a separate embodiment of the invention, the dynamic fusion device includes a geometric shape with an interior hollow region, preferably having sloped interior sidewalls. This feature allows the device to bend in a direction transverse to the plane of the geometric shape. The angle of the interior sidewalls can vary depending upon the desired amount of projection of the pivot point, which acts as a virtual axis of rotation for the device.

Additional embodiments of the invention include a flexible anterior-posterior segment, an anterior-posterior segment bounded by one or more zones with joints in the rod portions, a flexible accordion-like segment, and/or a hinge portion.

While the dynamic fixation devices described herein act to naturally control the axis or region of rotation within the device, it is also advantageous to consider the disk as part of the construct. If the disk is assumed to be competent as regards axial loads as opposed to translational loads, this competence can be used to control the disk height and concomitantly, the anterior portion of the implant and vertebral construct. Thus, in yet a separate embodiment, this allows a posterior construct having a rotatable anterior-posterior segment to effectively control translation within a specific range of motion of the segmental construct. Although there is a slight translation allowed, this is well within the natural region of rotation. This embodiment preferably includes a hinged portion having pin. If anterior-posterior segment or hinged arm is considered to be an elastomeric segment, its function depends on the translational forces being less than required to cause buckling of this segment. Controlling the shape of cross-section of this segment can allow forward bending of the spine while still maintaining competence in compression in the range of forces encountered in the implanted situation.

For the above described devices, first and second rod arms are attached to either end of the flexible construct, with the other end of the rod arms attached to connectors, which in turn are connected to pedicle screws that are inserted into vertebrae of the spine. During flexion and extension each vertebra exhibits an arcuate motion in relation to the vertebra below. The center of the arc lies below the moving vertebra. The dynamic fusion device provides a device for allowing movement of the vertebrae, with a forwardly or anteriorly projected pivot location that models and substantially aligns with the actual pivot point of rotation for the vertebrae to which the device is attached. Accordingly, the dynamic fusion device of the present invention provides a bendable rod for fusion that mimics the movement of the vertebrae of the spine.

The dynamic portions of the various embodiments of the present invention lengthen as they are elongated and shorten as they compressed. This characteristic allows the devices to be implanted in the spine with a pedicle screw system, and while the actual construct is positioned well dorsal in the spine, it allows the spine to function as though there were a flexible construct in the anterior column of the spine.

In use, a problematic spinal disc is initially identified by a physician. During surgery, an incision is made through the skin and muscle overlying the implant location of the spine. Then a first pedicle screw is inserted into a first vertebra and a second pedicle screw is inserted into a second vertebra. The surgeon then attaches the dynamic fixation device to the pedicle screws using either an adjustable connector or an end connector that is integrally formed as a part of the dynamic fixation device.

Various embodiments have been described in this summary of the invention but such embodiments are by no means to be deemed limiting to the "present invention" and the detailed description, the figures and the claims should be referred to in there totality to appreciate the true scope and breath of the present invention. It should be understood that this Summary of the Invention may not contain all of the aspects and embodiments of the present invention, is not meant to be limiting or restrictive in any manner, and that the invention as disclosed herein is and will be understood by those of ordinary skill in the art to encompass obvious improvements and modifications thereto. Moreover, while much of the above discussion has focused on devices and particular configurations, various aspects of the present invention relate to surgical methods, methods of making such devices and methods of use which are also to be understood as being part of the present invention.

Additional advantages of the present invention will become readily apparent from the following discussion, particularly when taken together with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a side perspective view of two vertebra in a neutral position;

Fig. 2 is a side perspective view of the two vertebra shown in Fig. 1 in a condition of flexion;

Fig. 3a is a side elevation view of a first embodiment of a dynamic fixation device used in conjunction with pedicle screws;

Fig. 3b is a side perspective view of the device shown in Fig. 3a attached to two vertebra in a neutral position;

Fig. 3c is a side perspective view of the device shown in Fig. 3a attached to two vertebra in a flexed position;

Fig. 4a is a side elevation view of a separate embodiment of a dynamic fixation device used in conjunction with pedicle screws;

Fig. 4b is a side perspective view of the device shown in Fig. 4a attached to two vertebra in a neutral position;

Fig. 4c is a side perspective view of the device shown in Fig. 4a attached to two vertebra in a flexed position;

Fig. 5a is a side elevation view of a modification of the dynamic fixation device shown in Fig. 4a used in conjunction with pedicle screws;

Fig. 6a is a front perspective view of a separate embodiment of a dynamic fixation device;

Fig. 6b is a front elevation view of the device shown in Fig. 6a;

Fig. 6c is a rear elevation view of the device shown in Fig. 6a;

Fig. 6d is a side elevation view of the device shown in Fig. 6a;

Fig. 6e is a side perspective view of the device shown in Fig. 6a attached to two vertebra in a neutral position;

Fig. 6f is a side perspective view of the device shown in Fig. 6a attached to two vertebra in a flexed position;

Fig. 7a is a side elevation view of a separate embodiment of a dynamic fixation device used in conjunction with pedicle screws;

Fig. 7b is a side perspective view of the device shown in Fig. 7a attached to two vertebra in a neutral position;

Fig. 7c is a side perspective view of the device shown in Fig. 7a attached to two vertebra in a flexed position;

Fig. 8a is a side elevation view of a separate embodiment of a dynamic fixation device used in conjunction with pedicle screws;

Fig. 9a is a side elevation view of a separate embodiment of a dynamic fixation device used in conjunction with pedicle screws;

Fig. 9b is a side perspective view of the device shown in Fig. 9a attached to two vertebra in a neutral position;

Fig. 9c is a side perspective view of the device shown in Fig. 9a attached to two vertebra in a flexed position;

Fig. 10a is a side elevation view of a separate embodiment of a dynamic fixation device used in conjunction with pedicle screws;

Fig. 10b is a side elevation view of a portion of the device shown in Fig. 10a;

Fig. 10c is a side perspective view of the device shown in Fig. 10a attached to two vertebra in a neutral position;

Fig. 10d is a side perspective view of the device shown in Fig. 10a attached to two vertebra in a flexed position;

Figs. 11a-11d show another device in accordance with embodiments of the present invention;

Figs. 12a-12d show yet another device in accordance with embodiments of the present invention;

Figs. 13a and 13d show still yet another device in accordance with embodiments of the present invention;

 Figs. 14a-14d show another device in accordance with embodiments of the present invention; and

Figs. 15a-15c show another device in accordance with embodiments of the present invention.

The above listed drawings are not necessarily to scale. In addition, the drawings also may be exaggerated to illustrate motion of the devices and/or to illustrate structural detail.

DETAILED DESCRIPTION OF THE INVENTION

While the present invention will be described more fully hereinafter with reference to the accompanying drawings in which particular embodiments and methods of implantation are shown, it is to be understood at the outset that persons skilled in the art may modify the invention herein described while achieving the functions and results of this invention. Accordingly, the descriptions which follow are to be understood as illustrative and exemplary of specific structures, aspects and features within the broad scope of the present invention and not as limiting of such broad scope.

As noted above, at each intervertebral joint or disc D, flexion involves a combination of anterior sagittal rotation and a small amplitude anterior translation. The various embodiments of the present invention allow for controlled rotation while limiting translation within an acceptable, normal physiological range.

Referring now to Fig. 3a, a side elevation view of a first embodiment of a dynamic fixation device 10 is illustrated. The dynamic fixation device 10 includes a geometric shape 12 connected to a first rod end 14 and a second rod end 16. First rod end 14 and second rod end 16 are preferably connected to connectors 18a and 18b that, in turn, are connected to pedicle screws 20. Pedicle screws 20 are inserted into the pedicles of vertebrae when the device is attached to the vertebrae of a patient. Connectors 18a and 18b can be of the type that are integrally formed as part of first rod end 14 and second rod end 16, respectively. Alternately, one or both of the connectors can be a separate type of connector that can be selectively positioned along the length of first rod end 14 or second rod end 16, respectively, such that first rod end 14 and second rod end 16 are adjustable (e.g., slidably) within the connectors prior to tightening the connectors to fixedly interconnect the device 10 to the pedicle screws 20.

Still referring to Fig. 3a, dynamic fixation device 10 is shown in a neutral position. As noted, the dynamic fixation device 10 includes a geometric shape 12 between first rod end 14 and second rod end 16. More specifically, in one embodiment dynamic fixation device 10 includes a substantially rectangular or substantially diamond-shaped geometric shape 12 that has four arms 22a, 22b, 22c and 22d. To the interior of arms 22a, 22b, 22c, and 22d is hollow region or opening

24. In lieu of an open space, opening 24 can be formed of and/or covered by a flexible or an elastic-type webbing material (not shown).

In a separate aspect dynamic fixation device 10, the centerline of geometric shape 12 is offset relative to the longitudinal axis of dynamic fixation device 10. More particularly, as shown in Fig. 3a, dynamic fixation device 10 has a longitudinal axis L-L that passes through the centerline of first rod end 14 and second rod end 16. However, the centerline CL-CL of geometric shape 12 is offset posteriorly to the longitudinal axis L-L of dynamic fixation device 10. This offset provides a preference for the dynamic fixation device 10 to bend in flexion, but resist bending in extension.

It is an aspect of this embodiment that the arms 22a, 22b, 22c, and 22d of geometric shape 12 are situated desired angles (e.g., at approximately 90 degree angles) relative to each other when device 10 is in the neutral position. For example, arm 22a is situated at an angle of about 90 degrees relative to arm 22b and arm 22d. Likewise, arm 22c is situated at an angle of about 90 degrees relative to arm 22b and arm 22d. Upon deformation of geometric shape 12 due to flexion of the spine, geometric shape 12 deforms and the angles between the arms will change.

Still referring to Fig. 3a, in yet a separate aspect of dynamic fixation device 10 the convergence segments 26 between the arms includes reduced dimensions. More particularly, the dimensions of arms 22a and 22b are smaller in the vicinity where arm 22a joins arm 22b. Likewise, the dimension of arms 22b and 22c are also smaller in the vicinity where arm 22b joins arm 22c. This is also the case for the convergence segments between arms 22c and 22d, and between arms 22d and 22a. The decreased dimensions of the arms 22a, 22b, 22c and 22d at the convergence segments 26 allow additional flexibility between the arms. As shown in Fig. 3a, the convergence segments 26 include partially circular corners between the arms. Alternatively, the partially circular corners may be of a different shape, such as partially triangular (not shown). Thus, dynamic fixation device 10 preferably includes narrowing or thinning of the arms in the vicinity of the convergence segments 26. It is to be further noted that convergence segments 26 serve as elastomeric hinges for geometric shape 12.

As shown in the example illustrated in Figs. 3b and 3c, first rod end 14 is shown to remain essentially immobile. Second rod end 16 moves between a neutral or first position 28, as shown in Fig. 3b, and a flexed or second position 30, as shown in Fig. 3c. In moving between first position 28 and second position 30 dynamic fixation device 10 elongates and it also rotates about an effective pivot point 32. The geometric shape 12 provides an effective pivot point 32 that is forward or anterior of the longitudinal axis L-L of first rod end 14 and second rod end 16. During movement

between first position 28 and second position 30, dynamic fixation device 10 experiences deformation, whereby it bends and it elongates.

In use, a surgeon first makes an incision and then inserts pedicle screws 20. Subsequently, first rod end 14 and second rod end 16 of dynamic fixation device 10 are preferably interconnected using connectors 18a and 18b to pedicle screws 20 that are inserted into vertebrae V_1 and V_2 of the spine. During flexion and extension, each vertebra exhibits an arcuate motion in relation to the vertebra below. The center of the arc lies below the moving vertebra. Dynamic fixation device 10 provides a device for allowing movement of the upper vertebra V_1 to a flexed or second position 30, with a forwardly or anteriorly projected pivot location 32, as compared to the location of the longitudinal axis L-L of the device 10 when it is in the neutral position.

In a modification of the embodiment shown in Figs. 3a, the geometric shape 12 can be subdivided into four smaller rectangles (not shown) as opposed to one large rectangle. This modification of using four smaller rectangles to form a geometric shape still acts as a larger rectangle in terms of its effective pivot point. In yet an alternate modification of this embodiment, geometric shape 12 can take the form of a rhomboid (not shown). In this modification, an effective pivot point would be projected forward (or anterior) some distance of the dynamic fixation device. Accordingly, depending upon its construction, the geometric shape 12 allows the pivot point to extend beyond the limits of the device. When the dynamic fixation device 10 is implanted posterior the spinal vertebrae, the device nonetheless allows for a rotation point substantially anterior the device. Thus, depending upon the geometry of the dynamic fixation device, and more particularly, the geometry of geometric shape 12, the present invention allows an effective pivot point 32 to be created that substantially corresponds to the natural pivot point of the patient's spine.

Referring now to Fig. 4a, a side elevation view of a separate embodiment of a dynamic fixation device 34 is shown. The dynamic fixation device 34 of Fig. 4a utilizes two adjacent but connected substantially geometric shapes 36a and 36b. Substantially geometric shapes 36a and 36b act as two accordion shapes that expand and flexibly bend forward as dynamic fixation device 34 is elongated and rotated during bending of the spine. Arrow A depicts the general direction of motion of second rod end 16 during rotation and elongation of the dynamic fixation device 34.

Still referring to Fig. 4a, in one preferred embodiment, substantially geometric shapes 36a and 36b include a plurality of arms. Substantially geometric shape 36a includes an anterior arm 38a and a posterior arm 40a. Similarly, substantially geometric shape 36b includes an anterior arm 38b and a posterior arm 40b. Preferably, anterior arm 38a interconnects to posterior arm 40b by crossing arm 42. Similarly, anterior arm 38b interconnects to posterior arm 40a by crossing arm 44.

Although not required, crossing arm 42 can be hingedly connected to crossing arm 44 using a pin 46 positioned along crossing arm 42 and crossing arm 44. As with dynamic fixation device 10 described above, narrowing or thinning of the arms in the vicinity of the convergence segments 26 is preferred. An opening 24a exists between crossing arm 42, anterior arm 38a and posterior arm 40a of substantially geometric shape 36a, and another opening 24b exists between crossing arm 44, anterior arm 38b and posterior arm 40b. In lieu of an open space, openings 24a and 24b can be formed of a flexible or an elastic-type webbing material (not shown).

Figs. 4b and 4c show dynamic fixation device 34 in its neutral and flexed positions, respectively. The effect of the substantially geometric shapes 36a and 36b is to produce an anteriorly projected effective pivot point 32 that substantially matches the rotational point of the vertebrae to which it is attached. Thus, the device of Fig. 4a-4c substantially limits translational displacement of the vertebrae to which it is attached, while still allowing some amount of flexion. In general, the bending occurring with flexion is equal to the angle change between anterior arm 38a and anterior arm 38b as the construct elongates. Preferably, there is a rigid connection between first rod end 14 and anterior arm 38a, as well as a rigid connection between second rod arm 16 and anterior arm 38b.

In a separate aspect dynamic fixation device 34, the centerline of substantially geometric shapes 36a and 36b is offset posteriorly relative to the longitudinal axis of dynamic fixation device 34. More particularly, as shown in Fig. 4a, dynamic fixation device 34 has a longitudinal axis L-L that passes through the centerline of first rod end 14 and second rod end 16. However, the centerline CL-CL of substantially geometric shape 36a and 36b is offset posteriorly to the longitudinal axis L-L of dynamic fixation device 34. This offset provides a natural fixation for the first rod end 14 to be a continuation of anterior arm 38a, and for second rod end 16 to be a continuation of anterior arm 38b.

Referring now to Fig. 5a, in a modification of the embodiment shown in Fig. 4a, more than two substantially geometric shapes may be incorporated into a dynamic fixation device 34'. More particularly, the dynamic fixation device 34 having substantially geometric shapes 36a and 36b may be modified to include a third, fourth, fifth, or any number of additional substantially geometric shapes. For example, substantially geometric shapes 36a and 36b of the device shown in Figs. 4a illustrate two substantially diamond shaped features, respectively. However, as shown in Fig. 5a, a third substantially diamond shape 36c may be added to geometric shape 36a and 36b. Optional pins 46 may be used between the various substantially geometric shapes. Alternatively, four (not shown), five (not shown) or more geometric shapes may be grouped together to form a dynamic

fixation device. Multiple substantially geometric shapes may differ in size and/or overall shaped configuration, which may be desirous depending upon the number used. For example, where three substantially geometric shapes 36a, 36b and 36c are used, as in dynamic fixation device 34', the overall size of each geometric shape is preferably smaller than the two substantially geometric shapes 36a and 36b illustrated in dynamic fixation device 34, as shown in Fig. 4a. The, addition of added substantially geometric shapes projects the pivot pint 32 proportionally forward for the number of substantially geometric shapes used.

Referring now to Figs. 6a-6f, in yet a separate embodiment of the invention, a dynamic fixation device 50 includes geometric shape 12 with an interior hollow region 24, wherein device 50 bends in a direction transverse to the planar surface 52 of geometric shape 12. The interior hollow region 24 preferably includes sloped interior surface 54. That is, the interior sidewalls 56 have an interior surface 54 that is at an angle θ with the planar surface 52 of geometric shape 12. Angle θ of interior surface 54 can be one constant value, or it can vary within the device. By way of a non-limiting example, θ can be 60 degrees at the top of device 50, and vary to about 90 degrees at the bottom of device 50.

Referring now to Figs. 6a-6c, interior hollow region 24 preferably includes four partially circular corners or convergence segments 26. Attached to two opposing partially circular corners or convergence segments 26 are first rod end 14 and second rod end 16. Each rod end 14 and 16 is situated at an angle of about 135 degrees from each adjacent side of the geometric shape 12. However, in an alternate aspect of this embodiment, the rod ends 14 and 16 may be situated at different angles relative to the arms of the geometric shape 12. As with device 10, partially circular corners or convergence segments 26 may be of a different shape, such as partially triangular. Equivalently, a mechanical hinge rather than an elastomeric hinge may be incorporated at convergence segments 26.

As shown in Fig. 6d, pedicle screws 20 are orientated perpendicular to the planar surface 52 of geometric shape 12. Connectors 18a and 18b are used to attach the pedicle screws 20 to first and second rod ends 14 and 16 of dynamic fixation device 50. The connectors 18a, 18b may be formed as an integral part of dynamic fixation device 50, or the connectors 18a, 18b may be a separate device, as is known to those knowledgeable in the art. In use, the dynamic fixation device 50 expands as it rotates and/or bends when attached to two vertebra that undergo flexion.

Referring now to Figs. 7a-7c, yet a separate embodiment of a dynamic fixation device is shown. Dynamic fixation device 58 includes four substantially straight and rigid arm segments. These consist of lower arm 60a, first middle arm 60b, second middle arm 60c, and upper arm 60d.

Lower arm 60a and upper arm 60d connect to connectors 18a and 18b, respectively, which are then connected to pedicle screws 20. Using pins 46, lower arm 60a is hingedly connected to one end of middle arms 60b and 60c. Upper arm 60d is hingedly connected using pins 46 to the opposite end of middle arms 60b and 60c. Between the four hinge points is an opening 24 that is a quadrilateral shape. During flexion, upper arm 60d moves upward and forward, thereby forcing middle arms 60b and 60c to rotate downward. Thus, the hinged connection of middle arms 60b and 60c to upper arm 60d allows it to move forward, while the connection of middle arms 60b and 60c to lower arm 60a prevents excessive translation or over-rotation. Dynamic fixation device 58 allows for the upper vertebra to move up and forward, yet resists excessive translation of the vertebrae to which it is attached.

Referring now to Fig. 8a, yet a separate embodiment of a dynamic fixation device is shown. The dynamic fixation device 62 shown in Fig. 8a is a dynamic fixation device that features an anterior-posterior segment 64. The dynamic fixation device 62 includes a first rod end 14 having a rod arm 65 that extends at an angle α toward an anterior-posterior segment 64. Angle α is fixed in relation to pedicle screw 20 by the rigid connection between rod arm 65 and lower pedicle screw 20. Similarly, rod arm 73 is fixed by a rigid connection to the upper pedicle screw 20. Rod arm 65 of first rod end 14 is connected to anterior-posterior segment 64 at bend 66. More particularly, bend 66 forming the connection between rod arm 65 and anterior-posterior segment 64 can be a continuous structural piece such that rod arm 65 and anterior-posterior segment 64 are essentially a contiguous solid piece including bend 66. Alternatively, bend 66 may be a hinged connection with a pin that interconnects rod arm 65 to anterior-posterior segment 64. Anterior-posterior segment 64 is separated from rod arm 65 by angle β.

Still referring to Fig. 8a, at bend 66, anterior-posterior segment 64 extends posteriorly to bend 68. Middle rod segment 70 extends from bend 68 at the posterior end of anterior-posterior segment 64 to bend 72 that forms the connection to rod arm 73 of second rod end 16. Bend 72 forms the intersection and the connection between middle rod segment 70 and rod arm 73. Bend 72 can be a continuous structural piece such that middle rod segment 70 and rod arm 73 are essentially a contiguous solid piece including bend 72, or bend 72 can be a connection that interconnects middle rod segment 70 and rod arm 73. The middle rod segment 70 is separated from the anterior-posterior segment 64 by angle ϕ.

First rod end 14 and second rod end 16 preferably are interconnected to pedicle screws 20 using connectors 18a and 18b, respectively. Connectors 18a and 18b can be formed as an integral

part of the end of dynamic fixation device 62, or they can be separate devices, as is known to those knowledgeable in the art.

Still referring to the example of the present embodiment shown in Fig. 8a, dynamic fixation device 62 also has a longitudinal axis L-L that is defined by the center of connectors 18a and 18b. Rod arm 65 generally lies anterior of longitudinal axis L-L, and middle rod segment 70 generally lies posterior of longitudinal axis L-L, with anterior-posterior segment 64 having portions both on the anterior and posterior sides of longitudinal axis L-L.

It is an aspect of the present embodiment that bend 68 preferably acts as a hinge and is able to move down if the vertebrae to which the dynamic fixation device 62 is attached is placed in compression. In addition, bend 68 can move up to accommodate flexion of the vertebrae. This motion of bend 68 and the anterior-posterior segment 64 closely approximates the normal arc of motion of human vertebra. When in compression, bend 68 moves down along a lower arc path 74. Lower arc path 74 is caused when dynamic fixation device 62 is placed in compression and anterior-posterior segment 64 moves toward rod arm 65, thereby decreasing the angle β. In a typical human patient, angle β may decrease up to 30 degrees as bend 68 passes along lower arc path 74. To achieve this motion, bend 68 of dynamic fixation device 62 preferably includes a structure to allow it to act as a hinge. Accordingly, bend 68 may include a pin 75. As illustrated in Fig. 8a, pin 75 is shown in the neutral position. However, in the compressed position, pin 75' is shown in its lower position. When the vertebrae undergo flexion, bend 68 moves up along an upper arc path 76. Upper arc path 76 is caused when dynamic fixation device 62 elongates and anterior-posterior segment 64 moves upward, thereby increasing the angle β. In a typical human implant, angle β may increase up to 30 degrees as bend 68 passes along upper arc path 76. For at least some patients, the neutral position for anterior-posterior segment 64 will be slanted downward from horizontal, with bend 68 positioned lower than bend 66. Thus, angle β would have a lesser amount of allowable compression over flexion extension. In the elongation condition, pin 75" is shown in its upper position. In compression, angle ϕ will decrease, and when the dynamic fixation device elongates during flexion, angle ϕ will increase.

The various embodiments of the present invention allows a slight amount of translational motion of the vertebrae, but the amount of translational motion allowed is within the physiological limits of normal motion of the human vertebrae. For example, for the embodiment shown in Fig. 8a, as pin 75 moves forward along lower arc path 74 and upper arc path 76, the vertebrae will undergo a slight amount of translational movement, as is evidenced by the position of pin 75' and 75", which are moved slightly anterior or forward from the neutral position.

Referring now to Fig. 9a-9c, yet a separate embodiment of a dynamic fixation device is shown. Dynamic fixation device 78 includes three substantially straight arm segments. These consist of lower arm 80a, first middle arm 80b, and upper arm 80c. Lower arm 80a and upper arm 80c connect to connectors 18a and 18b, respectively, which are then connected to pedicle screws 20. Using a pin 46, lower arm 80a is hingedly connected to one end of middle arm 80b. The opposite end of middle arm 80b is hingedly connected (e.g., by a pin 46) to upper arm 80c. During flexion, upper arm 80c moves upward and forward, thereby forcing middle arm 80b to rotate downward. Thus, the hinged connection of middle arm 80b to upper arm 80c allow it to upward with forward rotation, while the connection between middle arm 80b and lower arm 80a prevents excessive translation or over-rotation. Similar to function of the anterior-posterior segment 64 in device 62, middle arm 80b in the present embodiment acts as an anterior-posterior segment that allows a range of motion in flexion, yet prevents the vertebrae from experiencing excessive translation. Thus, dynamic fixation device 78 allows for the upper vertebra to move up and slightly forward, yet resists excessive translation of the vertebrae to which it is attached.

Referring now to Figs. 10a, yet a separate embodiment of a dynamic fixation device is illustrated. Dynamic fixation device 82 includes a first rod member 84 connected to a first rod end 14 and a second rod member 86 connected to a second rod end 16, wherein the first rod end 14 and the second rod end 16 are interconnected to pedicle screws 20 using connectors 18a and 18b, respectively. First rod member 84 and second rod member 86 anteriorly and posteriorly confine a spring 88. In addition, rails 90 confine spring 88 on the lateral sides, and rails 90 also serve to interconnect first rod member 84 to second rod member 86. The structure of dynamic fixation device 82 provides for an articulated device that can also elongate, thus accommodating the natural physiologic motion of two adjacent vertebra when undergoing flexion. The structure and function of these components will be described in detail below.

Still referring to Fig. 10a, first rod member 84 preferably includes a concave surface 92 along its posterior side, wherein the concave surface 92 of first rod member 84 assists in providing anterior confinement of spring 88. Second rod member 86 preferably includes a concave surface 94 along its anterior side, wherein the concave surface 94 of second rod member 86 assists in providing posterior confinement of spring 88.

As noted above, rails 90 (shown in dashed lines) interconnect the first rod member 84 to second rod member 86. Preferably, rails 90 comprise a plate 96 with hinge pins 46 situated through both ends of the plate 96. Plate 96 is shown in Fig. 10b. In one preferred embodiment, first rod member 84 includes a first notch 98 for receiving a first hinge pin 46. Similarly, second rod

member 86 includes a second notch 98 receiving a second hinge pin 46. Plates 96 span the confinement zone 100 of spring 88 and interconnect first rod member 84 and second rod member 86 while laterally containing spring 88 between rod members 84 and 86 and preventing the spring 88 for moving outside of the confinement zone 100. In a separate aspect of the present embodiment, rails 90 may be formed using a single piece. That is, the plate 96 and hinge pin 46 construction may be machined or otherwise constructed of a single piece.

By way of example and not limitation, preferably spring 88 is a cylindrical shaped spring having a proper spring constant for the dynamic fixation device 82. In addition, spring 88 may also take the form of a resilient material, such as a properly sized silicone insert shaped, for example, as a disc or a sphere. During flexion motion of the spine, second rod member 86 moves up and forward. During this movement, the spring 88 rolls between the first rod member 84 and the second rod member 86. Since the spring 88 rolls, friction between first rod member 84 and second rod member 86 is minimal. Thus, the ability of the spring to roll can be modified by adjusting the shape of the spring and the shape and texture of the interior walls of the confinement zone 100. More particularly, the shape and surface texture of concave surfaces 92 and 94 of the first and second rod members 84 and 86, respectively, can be modified to adjust the magnitude and ease of motion in elongation of the second rod member 86 relative to the first rod member 84. Since the spring 88 is cable of being compressed, it deforms, thereby allowing bending. The amount of compression is controlled by the spring characteristics, such as the spring material type, diameter and wall thickness, as well as the shape of the confinement zone 100 and the texture of the concave surfaces 92 and 94. With regard to the shape of the confinement zone 100, the concave surfaces 92 and 94 serve as the compression surfaces of the confinement zone 100 for spring 88. The shape of the curves of the concave surfaces 92 and 94 can be altered to control the degree of spring compression as the construct elongates. For example, referring to Fig. 10a, the curvature of concave surfaces 92 and 94 can be flattened, thereby influencing the reaction of the spring 88 within the confinement zone 100 during flexion extension.

Referring now to Figs. 10c and 10d, dynamic fixation device 82 is shown both in its neutral position and it the flexed position, respectively. For purposes of clarity, the rails 90 are dashed in Figs. 10c and 10d. As compared to the neutral position shown in Fig. 10c, the elongated position of Fig.10d illustrates that spring 88 has rolled up and is also slightly compressed. The characteristics of the spring 88 are chosen such that some desired amount of compression of the spring is allowed during flexion; however, the spring 88 is stiff enough such that unwanted amounts of translation of the vertebrae are resisted.

Dynamic fixation device 82 is allowed to elongate because second rod member 86 is hingedly attached to first rod member 84, thereby allowing vertical motion of second rod member 86 relative to first rod member 84. Thus, the structure of dynamic fixation device 82 provides for an articulated device that can elongate, thus accommodating the natural physiologic motion of the spine.

Dynamic fixation device 82 has application to providing segmentally applied motion control of the spine because each motion segment designated to receive an implant can have a dynamic fixation device implant customized through its dimensions and spring constant, thereby giving the patient controlled motion within a desired normal physiologic range.

In a typical use to span two vertebra, the total length of the dynamic fixation devices 10, 34, 34', 50, 58, 62, 78, and 82 may be approximately 15 to 35mm. The geometric shape portions or hinge structures of the dynamic fixation devices, preferably occupy the central region of the implant that bridges two vertebra. That is, the geometric shapes or hinge structures occupy only a portion of the implant, thereby allowing first rod end 14 and second rod end 16 to be solid rod segments that can be interconnected to a pedicle screw using a connector device. For those devices comprising a geometric shape or hinged structure, these structures will typically occupy approximately 15 to 20mm of the total length.

Referring now to Figs. 11a-11d, a dynamic fixation device 102 in accordance with embodiments of the present invention is shown. The device includes an anterior-posterior segment 104 containing a contoured shape 106 aligned transverse to the spine and/or substantially in an anterior-posterior orientation relative to the spine. The anterior-posterior segment 104 can bend relatively easier in one direction (flexion) than the other (extension). Additionally, the anterior-posterior segment 104 resists motion in the plane of the segment, which corresponds to resisting translational movement. Thus, the dynamic fixation device 102 accommodates at least some rotation of the vertebrae in flexion, while also resisting translation of the vertebrae.

The anterior-posterior segment 104 may have an anterior-posterior dimension of about 20mm and a lateral width of about 10mm; however, dimensions of the anterior-posterior segment are anticipated to vary depending upon a number of factors, including the amount of desired movement, the size of the patient that is the recipient of the implant, and the dimensions and material types used to the construct the device. In accordance with embodiments of the present invention, the dynamic fixation device 102 provides on the order of approximately ten degrees of rotation in flexion and on the order of approximately negative two degrees of rotation in the extension.

Referring now to Fig. 11a, a dynamic fixation device 102 featuring an anterior-posterior segment 104 containing a contoured shape 106 is generally shown. The contoured shape 106 allows the dynamic fixation device 102 to rotate around the effective pivot point 32 when the device 102 is elongated in flexion. The dynamic fixation device 102 includes a first rod member 108 connected to or integral with a first rod end 14 and a second rod member 110 connected to or integral with a second rod end 16, wherein the first rod end 14 and the second rod end 16 are interconnected to pedicle screws 20 using connectors 18a and 18b, respectively. The first rod member 108 and second rod member 110 anteriorly and posteriorly attach to or are integral with the anterior-posterior segment 104. In accordance with at least one embodiment of the invention, the attachments, interconnections or joining portions between the anterior-posterior segment 104 and the rod members 108 and 110 may comprise a flexible connection, such as a living hinge or a pinned connection.

At least portions of the dynamic fixation device 102 may be made from one or more materials that possess the appropriate strength characteristics necessary to withstand loading from the human body when used in medical applications. In addition, the materials may be chosen to provide desired flexibility characteristics. In accordance with embodiments of the present invention, examples of materials that may be used to make at least portions of the dynamic fixation device 102 include, but are not necessarily limited to, polyether ether plastics, such as ketone (PEEK), polyether ketone ketone (PEKK), ultra high molecular weight polyethylene (UHMWPE), and polymethylmethacrylate (PMMA); metals, such as titanium and stainless steel; composites; as well as other tissue compatible materials.

Still referring to the example of the present embodiment shown in Fig. 11a, dynamic fixation device 102 also has a longitudinal axis L-L that is defined by the center of connectors 18a and 18b. Rod member 108 generally lies anterior of longitudinal axis L-L, and rod member 110 generally lies substantially at or posterior of longitudinal axis L-L. In accordance with at least one embodiment of the present invention, the anterior-posterior segment 104 has portions on both the anterior and posterior sides of longitudinal axis L-L. Additionally, the body of the patient in which the dynamic fixation device 102 is to be implanted defines a superior and inferior direction. More particularly, upwards or toward the patient's head is defined as the superior direction and downwards or toward the patient's feet is described as the inferior direction. In at least one embodiment of the present invention, the rod member 108 is oriented in the inferior direction, and the rod member 110 is oriented in the superior direction.

Referring now to Fig. 11b, an enlarged view of the anterior-posterior segment is shown. In accordance with at least some embodiments of the present invention, the anterior-posterior segment 104 includes a contoured shape 106 to assist in allowing motion in one direction versus the other, wherein the contours may comprise shapes such as one or more dimples 112. In the embodiment shown in Fig. 11b, the anterior-posterior segment 104 features a first dimple 112a that lies substantially posterior of longitudinal axis L-L, or at least posterior of a second dimple 112b. In addition, in the embodiment shown in Fig. 11b, the second dimple 112b lies substantially anterior of longitudinal axis L-L. The first dimple 112a comprises a concave surface oriented such that the concavity faces in the inferior direction. The second dimple 112b comprises a concave surface oriented such that the concavity faces in the superior direction. Alternatively, the interior-posterior segment 104 may comprise shapes other than dimples 112. For example, contoured shape 106 may comprise oval-shaped features having concavity in a plurality of orientations, such as the superior and inferior directions. Other shaped anterior-posterior segments 104 are also within the scope of the present invention. The anterior-posterior segment 104 including dimples 112 are made from a material that allows a desired amount of bending. The countered shape 106 with its dimples allows bending at specific locations to occur preferentially in one direction rather than another. In particular, the dimples 112 have a low resistance to bending toward the curve and a high resistance to bending against the curve. As shown in the example illustrated in Figs. 11c and 11d, first rod end 14 is shown to remain essentially immobile. Second rod end 16 moves between a neutral or first position 114, as shown in Fig. 11c, and a flexed or second position 116, as shown in Fig. 11d. In moving between first position 114 and second position 116, dynamic fixation device 102 elongates or accommodates elongation, and it also rotates about a physiologic zone of rotation or an effective pivot point 32. The countered shape 106 thus provides an effective pivot point 32 that is forward or anterior of the longitudinal axis L-L. During movement between first position 114 and second position 116, dynamic fixation device 102 experiences deformation, whereby it bends and it elongates to accommodate at least some motion in flexion of the vertebrae to which it is attached. The effective pivot point 32 is provided by the geometry of the device 102, including the motion of the countered shape 106 during both flexion and extension of the spine. The motion of the spine shown in Fig. 11d is toward the curvature of dimple 112b and against the curvature of dimple 112a. Accordingly, dimple 112b provides a lower resistance to the motion and dimple 112a provides a higher resistance to the motion. This response of the contoured shape 106 allows a point, located approximately at the center of the anterior-posterior segment 104 to approximately travel along the path 113 shown in Fig. 11a and to rotate about the effective pivot point 32. A similar movement

occurs during extension of the spine, wherein the dynamic fixation device 102 becomes compressed slightly. This motion is against the curvature of dimple 112b and towards the curvature of dimple 112a. Accordingly, dimple 112b provides a higher resistance to the motion and dimple 112a provides a lower resistance to the motion. This motion of the anterior-posterior 104 segment allows the dynamic fixation device 102 to move in a way that closely approximates the normal physiologic motion of the human vertebrae. Referring now to Figs. 12a-12d, a dynamic fixation device 118 in accordance with embodiments of the present invention is shown. The device includes flexible rod members 120 and 122, and an anterior-posterior segment 124 aligned transverse to the spine and/or substantially in an anterior-posterior orientation relative to the spine. The dynamic fixation device 118 can bend relatively easier in one direction (flexion) than the other (extension). Additionally, the dynamic fixation device 118 resists motion in the plane of the segment, which corresponds to resisting translational movement. Thus, the dynamic fixation device 118 accommodates at least some rotation of the vertebrae in flexion, while also resisting translation of the vertebrae.

The anterior-posterior segment 124 may have an anterior-posterior dimension of about 20mm and a lateral width of about 10mm; however, dimensions of the anterior-posterior segment are anticipated to vary depending upon a number of factors, including the amount of desired movement, the size of the patient that is the recipient of the implant, and the dimensions and material types used to the construct the device. In accordance with embodiments of the present invention, the dynamic fixation device 118 provides on the order of approximately ten degrees of rotation in flexion and on the order of approximately negative two degrees of rotation in the extension.

Referring now to Fig. 12a, a dynamic fixation device 118 featuring a first flexible rod member 120, a second flexible rod member 122 and an anterior-posterior segment 124 is generally shown. The flexible rod members 120 and 122 allow the dynamic fixation device 118 to rotate around the effective pivot point 32 when the device 118 is extended in flexion. The first flexible rod member 120 is connected to a first rod end 14 which, in turn, is connected to pedicle screw 20 by means of connector 18a. The second flexible rod member 122 is connected to a second rod end 16 which, in turn, is connected to pedicle screw 20 by means of connecter 18b. The first rod member 120 and the second rod member 122, respectively, attach anteriorly and posteriorly to the anterior-posterior segment 124. In accordance with at least one embodiment of the invention, the attachments, interconnections or joining portions between the anterior-posterior segment 124 and

the rod members 120 and 122 may comprise a flexible connection, such as a living hinge or a pinned connection.

At least portions of the dynamic fixation device 118 may be made from one or more materials that possess the appropriate strength characteristics necessary to withstand loading from the human body when used in medical applications. In addition, the materials may be chosen to provide desired flexibility characteristics. In accordance with embodiments of the present invention, examples of materials that may be used to make at least portions of the dynamic fixation device 118 include, but are not necessarily limited to, polyether ether plastics, such as ketone (PEEK), polyether ketone ketone (PEKK), ultra high molecular weight polyethylene (UHMWPE), and polymethylmethacrylate (PMMA); metals, such as titanium and stainless steel; composites; as well as other tissue compatible materials.

Still referring to the example of the present embodiment shown in Fig. 12a, dynamic fixation device 118 also has a longitudinal axis L-L that is defined by the center of connectors 18a and 18b. Rod member 120 generally lies anterior of longitudinal axis L-L, and rod member 122 generally lies substantially at or posterior of longitudinal axis L-L. In accordance with at least one embodiment of the present invention, the anterior-posterior segment 124 has portions on both the anterior and posterior sides of longitudinal axis L-L. Flexible rod members 120 and 122 are provided with joints that allow the rod members to bend. Fig. 12a shows joint 126a of rod member 120, as well as joint 126b of rod member 122. In order to more clearly explain the function of the joints, the following discussion refers to joint 126a of rod member 120. As can be appreciated, joint 126b of rod member 122 functions in a similar manner. Joint 126a connects inferior flexible rod portion 120a and superior flexible rod portion 120b. Joint 126a allows bending of the flexible rod member 120 through the angle λ, which is defined between the inferior flexible rod portion 120a and the anterior-posterior segment 124. Similarly angle μ defines a range of motion for joint 126b.

Fig. 12b shows a detailed view of the joint 126a of the flexible rod member 120. In accordance with at least one embodiment of the present invention, joint 126a is comprised of segment 128 axially bordered by two segments 130. The segments 130 comprise a series of recessed portions 132. In accordance with at least one embodiment of the present invention, the recessed portions 132 are oriented with respect to either the anterior side of the rod member 120 or with respect to the posterior side of the of the rod member 120. Thus, the modified segment 130 comprises a series of recessed portions 132 that alternate between posteriorly oriented recessed portions 132a and anteriorly oriented recessed portions 132b. The recessed portions 132 can be made using techniques known in the art, such as by use of example, removal of material, making

cuts in the rod, or forming the recessed portions 132 by injection molding. In addition, other structures for providing flexibility at joints 126a and 126b are within the scope of the invention, such as thinned sections, crescent-shaped segments, etc.

As shown in the example illustrated in Figs. 12c and 12d, first rod end 14 is shown to remain essentially immobile. Second rod end 16 moves between a neutral or first position 134, as shown in Fig. 12c, and a flexed or second position 136, as shown in Fig. 12d. In moving between first position 134 and second position 136, dynamic fixation device 118 elongates and it also rotates about a physiologic zone of rotation or an effective pivot point 32. The flexible rod members 120 and 122 with one or more joints 126a and 126b, together with the anterior-posterior segment 124 provide an effective pivot point 32 that is forward or anterior of the longitudinal axis L-L. During movement between first position 134 and second position 136, dynamic fixation device 118 experiences deformation, whereby it bends and it elongates to accommodate at least some motion in flexion of the vertebrae to which it is attached. The effective pivot point 32 is provided by the geometry of the device 118, including the bending of joints 126a and 126b. As the dynamic fixation device 118 elongates, joint 126a bends such that the angle λ is increased. Likewise joint 126b bends such that the angle μ is increased. This allows the device to bend as shown in Fig. 12d. As the joints 126a and 126b bend, the dynamic fixation 118 device is allowed to rotate about the effective pivot point 32. This motion allows the dynamic fixation device 118 to move in way that closely approximates the normal motion of the human vertebrae.

Referring now to Figs. 13a-13d, a dynamic fixation device 136 in accordance with embodiments of the present invention is shown. The device includes a partially folded rod segment 138. The partially folded segment 138 can bend relatively easier in one direction (flexion) than the other (extension). Additionally, partially folded segment 138 resists motion in the plane of the segment, which corresponds to resisting translational movement. Thus, the dynamic fixation device 136 accommodates at least some rotation of the vertebrae in flexion, while also resisting translation of the vertebrae.

The partially folded segment 138 may have an anterior-posterior dimension of about 20mm; however, dimensions of the partially folded segment 138 are anticipated to vary depending upon a number of factors, including the amount of desired movement, the size of the patient that is the recipient of the implant, and the dimensions and material types used to the construct the device. In accordance with embodiments of the present invention, the dynamic fixation device 136 provides on the order of approximately ten degrees of rotation in flexion and on the order of approximately negative two degrees of rotation in the extension.

Referring now to Fig. 13a, a dynamic fixation device 136 featuring a partially folded segment 138 is generally shown. The partially folded segment 138 allows dynamic fixation device 136 to rotate around the effective pivot point 32 when the device 136 is elongated in flexion. This folded segment is attached to a first rod end 14 and a second rod end 16. The first and second rod ends 14 and 16 are, in turn, connected to pedicle screws 20 by means of connecters 18a and 18b, respectively. The dynamic fixation device 136 also has a longitudinal axis L-L that is defined by the center of connectors 18a and 18b.

At least portions of the dynamic fixation device 136 may be made from one or more materials that possess the appropriate strength characteristics necessary to withstand loading from the human body when used in medical applications. In addition, the materials may be chosen to provide desired flexibility characteristics. In accordance with embodiments of the present invention, examples of materials that may be used to make at least portions of the dynamic fixation device 136 include, but are not necessarily limited to, polyether ether plastics, such as polyether ether ketone (PEEK), polyether ketone ketone (PEKK), ultra high molecular weight polyethylene (UHMWPE), and polymethylmethacrylate (PMMA); metals, such as titanium and stainless steel; composites; as well as other tissue compatible materials.

Still referring to the example of the present embodiment shown in Fig. 13a, the partially folded segment 138 comprises a series of substantially planar segments 140. The partially folded segment 138 may be made of interconnected elements or, alternatively, machined out of a single piece of material. Flexible joints, such as living hinges 141, connect adjacent planar segments 140. In accordance with at least some embodiments of the present invention, the planar segments 140 have a quadrilateral shape. Each planar segment has two sides 142a and 142b oriented substantially in an anterior-posterior direction and two sides 144a and 144b oriented substantially in a superior-inferior direction. In accordance with at least some embodiments of the present invention, the length of side 144a, located posterior of longitudinal axis L-L, is longer than the length of side 144b, located anterior of longitudinal axis L-L. This difference in length allows the folded segment 138 to unfold in a manner resembling that of a Japanese fan. Fig. 13b shows close-up view of the folded segment 138 viewed from in the posterior to anterior direction.

As shown in the example illustrated in Figs. 13c and 13d, first rod end 14 is shown to remain essentially immobile. Second rod end 16 moves between a neutral or first position 146, as shown in Fig. 13c, and a flexed or second position 148, as shown in Fig. 13d. In moving between first position 146 and second position 148, dynamic fixation device 136 elongates or accommodates elongation, and it also rotates about a physiologic zone of rotation or an effective pivot point 32.

The partially folded segment 138 thus provides an effective pivot point 32 that is forward or anterior of the longitudinal axis L-L. During movement between first position 146 and second position 148, dynamic fixation device 136 experiences deformation, whereby it bends and it elongates to accommodate at least some motion in flexion of the vertebrae to which it is attached.

The folded segment 138 allows the dynamic fixation device 136 to elongate and rotate about an effective pivot point 32. As shown in Fig. 13a and 13b, the planar segments 140 are all angled in a direction towards the spine. In particular, the planar segments 140 are all oriented on lines that converge at a point anterior of the dynamic fixation device 136. This point provides the approximate location of the effective pivot point of the dynamic fixation device 136. As the dynamic fixation device 136 elongates, folded segment 138 unfolds enabling rotation about the effective pivot point 32. This allow the device to bend as shown in Fig. 13d. This motion allows the dynamic fixation device 118 to move in way that closely approximates the normal motion of the human vertebrae in flexion, while also resisting physiologically abnormal amounts of movement in translation.

Referring now to Figs. 14a-14d, a dynamic fixation device 150 in accordance with embodiments of the present invention is shown. The device includes a partially folded rod segment 152. The partially folded segment 152 can bend relatively easier in one direction (flexion) than the other (extension). Additionally, partially folded segment 152 resists motion in the plane of the segment, which corresponds to resisting translational movement. Thus, the dynamic fixation device 150 accommodates at least some rotation of the vertebrae in flexion, while also resisting translation of the vertebrae.

The partially folded segment 152 may have an anterior-posterior dimension of about 20mm; however, dimensions of the partially folded segment 152 are anticipated to vary depending upon a number of factors, including the amount of desired movement, the size of the patient that is the recipient of the implant, and the dimensions and material types used to the construct the device. In accordance with embodiments of the present invention, the dynamic fixation device 150 provides on the order of approximately ten degrees of rotation in flexion and on the order of approximately negative two degrees of rotation in the extension.

Referring now to Fig. 14a, a dynamic fixation device 150 featuring a partially folded segment 152 is generally shown. The partially folded segment 152 allows dynamic fixation device 150 to rotate around the effective pivot point 32 when the device 150 is elongated in flexion. The partially folded segment 152 is attached to a first rod end 14 and a second rod end 16. The first and

second rod ends 14 and 16 are, in turn, connected to pedicle screws 20 by means of connecters 18a and 18b, respectively.

At least portions of the dynamic fixation device 150 may be made from one or more materials that possesses the appropriate strength characteristics necessary to withstand loading from the human body when used in medical applications. In addition, the materials may be chosen to provide desired flexibility characteristics. In accordance with embodiments of the present invention, examples of materials that may be used to make at least portions of the dynamic fixation device 150 include, but are not necessarily limited to, polyether ether plastics, such as ketone (PEEK), polyether ketone ketone (PEKK), ultra high molecular weight polyethylene (UHMWPE), and polymethylmethacrylate (PMMA); metals, such as titanium and stainless steel; composites; as well as other tissue compatible materials.

The partially folded segment 152 comprises a series of planar segments 154. Flexible joints, such as living hinges 156, connect adjacent planar segments 154. The partially folded segment 152 may be made of interconnected elements or, alternatively, machined out of a single piece of material. In accordance with at least some of the embodiments of the present invention, the planar segments 154 have a rectangular shape. Each planar segment 154 has two sides 156a and 156b oriented substantially in an anterior-posterior direction and two sides 158a and 158b oriented substantially in a superior-inferior direction. As shown in Fig. 14a, the dynamic fixation device 150 also has a longitudinal axis L-L that is defined by the center of connectors 18a and 18b. In accordance with at least some embodiments of the present invention, the length of side 158a, located posterior of longitudinal axis L- L, is same as the length of side 158b, located anterior of longitudinal axis L- L. Although the sides of the planar segments 154 are of similar length, if the partially folded segment 154 is made of a sufficiently elastic material, it will accommodate rotation of the dynamic fixation device 150. Fig. 14b shows a close-up view of the folded segment 152 viewed from the posterior to anterior direction.

As shown in the example illustrated in Figs. 14c and 14d, first rod end 14 is shown to remain essentially immobile. Second rod end 16 moves between a neutral or first position 160, as shown in Fig. 14c, and a flexed or second position 162, as shown in Fig. 14d. In moving between first position 160 and second position 162, dynamic fixation device 150 elongates or accommodates elongation, and it also rotates about a physiologic zone of rotation or an effective pivot point 32. The partially folded segment 138 provides an effective pivot point 32 that is forward or anterior of the longitudinal axis L-L. During movement between first position 160 and second position 162,

PCT/US2006/024491

dynamic fixation device 160 experiences deformation, whereby it bends and it elongates to accommodate at least some motion in flexion of the vertebrae to which it is attached.

The folded segment 152 allows the dynamic fixation device 150 to elongate and rotate about an effective pivot point 32. As the spine moves from the neutral position illustrated in Fig. 14c to the flexed position depicted in Fig. 14d, the dynamic fixation device 150 undergoes an elongation. This elongation causes the folded segment 150 to unfold. This allow the device to bend as shown in Fig. 14d. In accordance with embodiments of the present invention, the rotation about the effective pivot point 32 is due to the planar segments and the flexible joint of the partially folded segment being made from a material of sufficient strength and flexibility to allow for the described movement. Such materials may include, but are not limited to PEEK and PEKK. This motion allows the dynamic fixation device 150 to move in way that closely approximates the normal motion of the human vertebrae.

Referring now to Figs. 15a-15c, a dynamic fixation device 170 in accordance with embodiments of the present invention is shown. The device includes a plurality of segments 172 connected by hinges 174. The plurality of hinged segments 172 can bend relatively easier in one direction (flexion) than the other (extension). Additionally, the plurality of hinged segments 172 resists motion in the plane of the segment, which corresponds to resisting translational movement. Thus the dynamic fixation device 170 accommodates at least some rotation at the vertebrae in flexion, while also resisting translation of the vertebrae.

Referring now to Figs. 15a, a dynamic fixation device 170 featuring a plurality of hinged segments 172 is shown. In at least one embodiment of the present invention, the hinges 174 contain pins 176 that are directed forwardly or anteriorly of the dynamic fixation device 170. This orientation of the pins 176 of the hinges 174 provides a forwardly or anteriorly projected pivot point 32 that is similar to the natural pivot point of a first vertebra relative to the second vertebra when the spine undergoes flexion. The dynamic fixation device 170 features an inferior hinged segment 172a, a superior hinged segment 172b, and a interior hinged segment 172c. The inferior and superior hinged segments 172a and 172b each have a hinged connection to connectors 18a and 18b, respectively. The interior hinged segment 172c is disposed between and has a hinged connection to the inferior and superior hinged segments 172a and 172b. Connectors 18a and 18b each attach to a pedicle screw 20. The hinges 174 that connect both ends of the superior hinged segment 172b are shown separated in Fig. 15a in order to illustrate their structure.

PCT/US06/24491

The dynamic fixation device 170 may be made from one or more materials that possess the appropriate strength characteristics necessary to withstand loading from the human body when used in medical applications. In addition, the materials may be chosen to provide desired flexibility characteristics. In accordance with embodiments of the present invention, examples of materials that may be used to make at least a portion of the dynamic fixation device 170 include, but are not limited to: plastics, such as polyether ether ketone (PEEK), polyether ketone ketone (PEKK), ultra high molecular weight polyethylene (UHMWPE), polymethylmethacrylate (PMMA); and more preferably, metals, such as titanium and stainless steel. In addition, the device 170 may be made of a combination of materials, of composites, as well as other tissue compatible materials.

Still referring to the example of the present embodiment shown in Fig. 15a, dynamic fixation device 170 also has a longitudinal axis L-L that is defined by the center of connectors 18a and 18b. In accordance with embodiments of the present invention, inferior hinged segment 172a, superior hinged segment 172b, and interior hinged segment 172c generally lie in a plane perpendicular to the pedicle screws 20 and at an acute angle with respect to the longitudinal axis L-L.

The functionality of the dynamic fixation device 170 is illustrated in Figs. 15b and 15c. Fig. 15b illustrates the dynamic fixation device 170 in neutral position 182, wherein the spine is neither flexed nor extended. The pedicle screw 20 connected to connecter 18a is attached to a lower vertebra. The pedicle screw 20 connected to connector 18b is attached to an upper vertebra. Fig. 15c illustrates the dynamic fixation device 170 in a flexed position 184. In moving between first position 182 and second position 184, dynamic fixation device 170 elongates and it also rotates about an effective pivot point 32. During this flexion movement, the plurality of hinged segments 172 rotate in a more superior-inferior alignment, such that at least the segments 172 and 172b become increasingly aligned parallel with respect to longitudinal axis L-L, thereby providing lengthening to the dynamic fixation device 170 and allowing the upper vertebra to rotate forward relative to the lower vertebra. In addition, the relatively rigid materials used to form the construct resist movement in the anterior-posterior direction, thereby resisting translational motion of the two interconnected vertebrae. This motion of the hinged segments 172 allows the dynamic fixation device 170 to move in a way that closely approximates the normal physiological motion of the human vertebrae. In accordance with embodiments of the present invention, the dynamic fixation device 170 provides on the order of approximately ten degrees of rotation in flexion and on the order of approximately negative two degrees of rotation in the extension.

PCT/US2006/024491

For a dynamic fixation device 170 spanning one joint, it will expand up to approximately 5 to 10mm in length, and will rotate forward up to between 5 to 10 degrees to accommodate flexion of the spine. Obviously, different size dynamic fixation devices 170 may be used to accommodate the specific needs of each individual patient. More particularly, a relatively large dynamic fixation device may be needed for a large man, while a relatively small dynamic fixation device may be needed for a smaller patient, such as child or a petite woman. However, a limited number of sizes may provide adequate coverage for the majority of the patient population. For any given device, a potential elongation of the dynamic fixation device consistent with the desired flexion of the vetebral motion segment and associated distraction of the plane of the fixation device is anticipated.

In accordance with embodiments of the present invention, the hinges as described herein may not comprise a pin. In particular, the embodiments of the present invention illustrated in Fig. 3a, 4a, 5a, 6a, 7a, 8a, 9a, 11a, 12a, 13a, and 14a may contain flexible elements such as a living hinge.

The dynamic fixation devices can be used to flexibly secure a plurality of vertebra. Alternatively, the dynamic fixation devices can be located at specific points where bending of the spine is desired, while a rigid rod may be used at other locations desired by the physician. Where used, rigid rod portions may be curved, thereby influencing the implanted location of the geometric shape hinged structures, and thus the effective pivot point.

The structures of the present invention are made from one or more materials that possesses the appropriate strength characteristics necessary to withstand loading from the human body when used in medical applications. In addition, the materials are compatible with the human body. Preferably, materials include ceramics, plastics, metals, or carbon fiber composites. More preferably, the materials are made from titanium, a titanium alloy, or stainless steel.

The structures of the present invention are made from one or more materials that possesses the appropriate strength characteristics necessary to withstand loading from the human body when used in medical applications. In addition, the materials are compatible with the human body. Preferably, materials include ceramics, plastics, metals, or carbon fiber composites. More preferably, the materials are made from titanium, a titanium alloy, or stainless steel.

Examples of plastic materials with in the scope of the invention include polyether ether ketone (PEEK), polyether ketone ketone (PEKK), any material chosen from the polyaryl ether ketone (PAEK) family, ultra high molecular weight polyethylene (UHMWPE),

polymethylmethacrylate (PMMA), polyethlene terephthalate (PET), fluorinated ethylene propylene (FEP), polyuretheance (PU), polyimide (PI), polybutylene terephthalate (PBT) polyurethane rubber (PUR). Additionaly, silicon and silicon rubber are useable, as well as polysulfone, polyimide , epoxy, and polycyanate.

Elements of the fixation device may be made from a radiolucent polymer, allowing the device, once implanted in a patient, to be seen by radiographic methods. Examples of such radiolucent materials include polyether ether ketone and polyether ketone ketone.

Materials chosen for compatibility with the human body should be resistant to organic and inorganic chemicals, have desirable strength and rigidity properties, be resistance to impact over a wide range of temperatures and be resistant to hydrolysis and corrosion.

In accordance with embodiments of the present invention, elements of the dynamic fixation device that are implanted into bone can be made from bone graft material. Such material can be allographic meaning grown from an organism of the same species, or xenographic, meaning grown from an organism of a different species.

The following patent applications, of which the entire disclosure is herein incorporated by reference, contain exemplary uses of biocompatible materials: US Patent Application No. 2005/0203519, US Patent Application No. 2005/0203517, US Patent Application No. 2006/0041259, US Patent Application No. 2006/0064090, and US Patent Application No. 2003/0109880.

The above described alternative configurations offer different bending characteristics. The dimensions will vary depending upon the specific design necessary for a specific patient. More particularly, the dimensions of geometric shapes and hinged devices will likely be bigger for a large heavy man, as opposed to that needed for a small petite woman. Furthermore, the type of material used to construct the dynamic fixation devices described herein will also impact the required dimensions of the devices. Dynamic fixation devices described herein may be made of a variety of materials, preferably metals or materials demonstrating resilient characteristics, and more preferably, a titanium alloy or surgical stainless steel. Since different materials have different strength and resilient properties, the type of material used will, in part, dictate the dimensions of the rod portion required to achieve a certain function in a specific patient.

Devices disclosed herein can also be made of thermal memory materials or materials that possess different elastic properties at varying temperatures. In this aspect of the invention, the subject component(s) may be heated or cooled to a desired temperature, implanted, then

subsequently allowed to cool or warm to the temperature of the ambient conditions that will exist during the usage period for the subject device, namely, normal body temperature.

It is to be understood that the present invention may have application to medical devices other than spinal implants. For example, the present invention can be used in external fixator systems.

Furthermore, it is understood that the present invention has application outside the medical field. The dynamic fixation device of the present invention is not limited to medical implants. The device could be used in seismic dampening applications. Alternatively, the present invention could be used to secure any two objects, such as in linking mechanisms, and has application to any type of mechanical device with a moving connection. Other applications, by no means exhaustive, may include connecting any articulated device, such as an implement connection to a tractor. It may also be used in heretofore static type connection applications, such as attaching an antenna to a base structure. One of skill in various of the construction arts will appreciate how to make and use the present invention in view of the guidance provided herein (with respect to a surgical application) and in view of the figures set forth herein.

The foregoing discussion of the invention has been presented for purposes of illustration and description. The foregoing is not intended to limit the invention to the form or forms disclosed herein. In the foregoing Detailed Description Of The Invention for example, various features of the invention are grouped together in one or more embodiments for the purpose of streamlining the disclosure. This method of disclosure is not to be interpreted as reflecting an intention that the claimed invention requires more features than are expressly recited in each claim. Rather, as the following claims reflect, inventive aspects lie in less than all features of a single foregoing disclosed embodiment. Thus, the following claims are hereby incorporated into this Detailed Description Of The Invention, with each claim standing on its own as a separate preferred embodiment of the invention.

While various embodiments of the present invention have been described in detail, it is apparent that modifications and adaptations of those embodiments will occur to those skilled in the art. However, it is to be expressly understood that such modifications and adaptations are within the spirit and scope of the present invention, as set forth in the following claims.

PCT/US06/24491

What is claimed is:

1. An implant device for flexibly linking at least two lumbar vertebra of a spine of a patient using two connectors and two pedicle screws, comprising:

a means for forwardly projecting a pivot point;

wherein the means for forwardly projecting the pivot point allows a first of the at least two lumbar vertebra to rotate relative to a second of the at least two lumbar vertebra.

2. The implant device as claimed in claim 1, wherein the means for forwardly projecting comprises an anterior-posterior oriented segment having a contoured shape.

3. The implant device as claimed in claim 1, wherein the means for forwardly projecting comprises an anterior-posterior segment bounded by one or more zones with joints in adjacent rod portions.

4. The implant device as claimed in claim 1, wherein the means for forwardly projecting comprises a flexible fan-like segment.

5. The implant device as claimed in claim 1, wherein the means for forwardly projecting comprises a plurality of hinge portions, at least a first of said plurality of hinge portions oriented transverse to an anterior-posterior axis relative to the spine.

6. An implant device for flexibly linking at least two vertebra of a spine of a patient using two connectors and two pedicle screws, comprising:

a rod having a first end and second end, said first end interconnected to a first of the pedicle screws using a first of the two connectors, and said second end interconnected to a second of the pedicle screws using a second of the two connectors; and

an anterior-posterior rod segment interconnected to the first rod end by a first rod arm of said rod, said anterior-posterior rod segment interconnected to said second rod end by a second rod arm of said rod;

wherein the anterior-posterior rod segment forwardly projects a pivot point that allows a first of the at least two vertebra to rotate relative to a second of the at least two vertebrae.

7. The implant device of Claim 6, further comprising:

a plurality of concave dimples disposed on the anterior-posterior segment, wherein the dimples have a low resistence to bending in a direction toward their concavity and a high resistence to bending in a direction against their concavity.

8. The implant device of Claim 7, wherein said plurality of concave dimples comprises:

PCT/US06/24491

a first dimple oriented such that the concavity of the first dimple faces in an inferior direction; and

a second dimple oriented such that the concavity of the second dimple faces in a superior direction;

wherein the first dimple is disposed posterior of the second dimple.

9. The implant device of Claim 6, further comprising:

a first joint integral with the first rod arm, wherein the first joint allows the first arm to bend; and

a second joint integral with the second arm, wherein the second joint allows the second arm to bend.

10. The dynamic fixation device of claim 6, wherein at least one of said at least two rod members are comprised of materials selected form the group consisting of:

titanium,

polyether ether ketone,

polyether ketone ketone,

ultra high molecular weight polyethylene, and

polymethylmethacrylate (PMMA).

11. An implant device for flexibly linking at least two vertebra of a spine of a patient using two connectors and two pedicle screws, comprising:

a rod having a first end and second end, said first end interconnected to a first of the pedicle screws using a first of the two connectors, and said second end interconnected to a second of the pedicle screws using a second of the two connectors; and

a partially folded portion positioned between said first end and said second end, wherein the partially folded portion elongates during flexion of the spine.

12. The implant device of Claim 11, wherein the partially folded portion comprises a plurality of planar segments interconnected by means of flexible joints, wherein the planar segments are oriented on a plurality axes that converge at a point forward of the partially folded segment, and wherein the orientation of the planar segments forwardly projects a pivot point that allows a first of the at least two vertebra to rotate relative to a second of the at least two vertebra.

13. The implant device of Claim 11, wherein the partially folded portion comprises a plurality of planar segments interconnected by means of flexible joints, wherein the interconnected planar segments are made from a material with sufficient strength and flexibility to allow the

PCT/US06/24491

implant device to rotate around a forwardly projected pivot point, and wherein the rotation of the implant device allows a first of the at least two vertebra to rotate relative to a second of the at least two vertebra.

14. The dynamic fixation device of claim 11, wherein at least one of said at least two rod members are comprised of materials selected form the group consisting of:

titanium,

polyether ether ketone,

polyether ketone ketone,

ultra high molecular weight polyethylene, and

polymethylmethacrylate (PMMA).

15. An implant device for flexibly linking at least two vertebra of a spine of a patient using two connectors and two pedicle screws, comprising:

a rod having a first end and second end, said first end interconnected to a first of the pedicle screws using a first of the two connectors, and said second end interconnected to a second of the pedicle screws using a second of the two connectors;

wherein the rod further comprises a plurality of hinged portions, at least a first of said plurality of hinged portions oriented transverse to the spine; and

wherein the plurality of hinged portions forwardly projects a pivot point that allows a first of the at least two vertebra to rotate relative to a second of the at least two vertebra.

16. The dynamic fixation device of claim 15, wherein at least one of said at least two rod members are comprised of materials selected form the group consisting of:

titanium,

polyether ether ketone,

polyether ketone ketone,

ultra high molecular weight polyethylene, and

polymethylmethacrylate (PMMA).

17. An implant device for flexibly linking at least two vertebra, the device comprising:

a plastic rod comprising more than one cross-sectional area, wherein the rod includes an elastomeric hinge allowing the rod to bend with motion of the two vertebra.

18. The dynamic fixation device of claim 17, wherein at least one of said at least two rod members are comprised of materials selected form the group consisting of:

titanium,

polyether ether ketone,

polyether ketone ketone,

ultra high molecular weight polyethylene, and

polymethylmethacrylate (PMMA).

19. A device for movably interconnecting at least a first vertebra to a second vertebra, the device comprising:

first and second rod portions; and

at least one substantially anterior-posterior aligned member operatively associated with said first and second rod portions;

wherein said first rod portion can be rotated relative to said second rod portion upon flexion of the first vertebra relative to the second vertebra.

20. The dynamic fixation device of claim 19, wherein at least one of said at least two rod members are comprised of materials selected form the group consisting of:

titanium,

polyether ether ketone,

polyether ketone ketone,

ultra high molecular weight polyethylene, and

polymethylmethacrylate (PMMA).

21. A dynamic fixation device for flexibly linking at least two vertebra, the device comprising:

a rod comprising a plastic, wherein at least a portion of said rod comprises a substantially anterior-posterior alignment, and wherein the rod is adapted for allowing the rod to bend with flexion motion of the two vertebra.

22. The dynamic fixation device of claim 21, wherein at least one of said at least two rod members are comprised of materials selected form the group consisting of:

titanium,

polyether ether ketone,

polyether ketone ketone,

ultra high molecular weight polyethylene, and

polymethylmethacrylate (PMMA).

23. An implant device for flexibly interconnecting at least two vertebra, the device comprising:

a plastic rod comprising at least one curved portion, said rod comprising more than one cross-sectional area, wherein the rod anteriorly projects a pivot point, and wherein the rod is adapted to bend with flexion motion of the two vertebra.

24. The dynamic fixation device of claim 24, wherein at least one of said at least two rod members are comprised of materials selected form the group consisting of:

titanium,

polyether ether ketone,

polyether ketone ketone,

ultra high molecular weight polyethylene, and

polymethylmethacrylate (PMMA).

25. A device to be implanted in a patient, the device adapted for movably interconnecting at least a first vertebra to a second vertebra of the patient, the device comprising:

a rod, wherein at least a portion of said rod comprises a plastic, said rod having flexibility characteristics such that once implanted into the patient, the patient is able to bend the first and second vertebra through at least a portion of natural flexion motion, and wherein upon bending the at least one plastic portion of said rod the plastic portion flexes in at least one plane corresponding to such natural flexion motion, wherein such portion is substantially constrained from flexing in a plane substantially perpendicular to a principal plane of such bending motion, wherein the substantial constraint results from the particular geometric construction of said rod.

26. The dynamic fixation device of claim 25, wherein at least one of said at least two rod members are comprised of materials selected form the group consisting of:

titanium,

polyether ether ketone,

polyether ketone ketone,

ultra high molecular weight polyethylene, and

polymethylmethacrylate (PMMA).

27. A rod-shaped element having a rod axis, for use in dynamic fixation of the human spine, comprising:

a first section connected to a first bone anchoring element;

a second section connected to a second bone anchoring element; and

a first flexible element capable of elastic deformation when a force acts on said flexible element transversely to the rod axis,

wherein the first section and the second section are capable of constantly moving relative to each other in the direction of the rod axis.

28. The dynamic fixation device of claim 27, wherein at least one of said at least two rod members are comprised of materials selected form the group consisting of:

titanium,

polyether ether ketone,

polyether ketone ketone,

ultra high molecular weight polyethylene, and

polymethylmethacrylate (PMMA).

29. A dynamic fixation device comprising:

(a) at least two vertebra attachment points;

(b) at least two rod members operatively associated with said attachment points and further operatively associated with each other in a manner to accommodate a natural physiologic motion of two adjacent vertebra when said vertebra are undergoing flexion.

30. The dynamic fixation device as claimed in claim 29, wherein said attachment points comprise pedicle screws.

31. The dynamic fixation device as claimed in claim 29, wherein said rod members are hingedly connected to each other.

32. The dynamic fixation device of claim 29, wherein at least one of said at least two rod members are comprised of materials selected form the group consisting of:

titanium,

polyether ether ketone,

polyether ketone ketone,

ultra high molecular weight polyethylene, and

polymethylmethacrylate (PMMA).

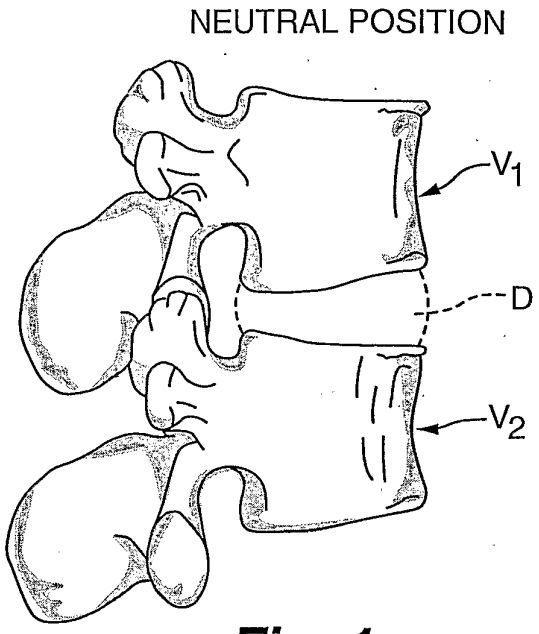


Fig. 1

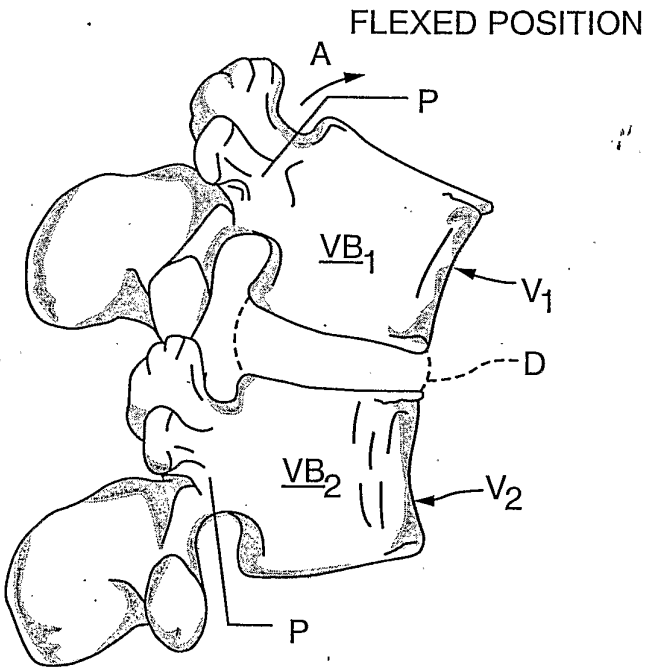


Fig. 2

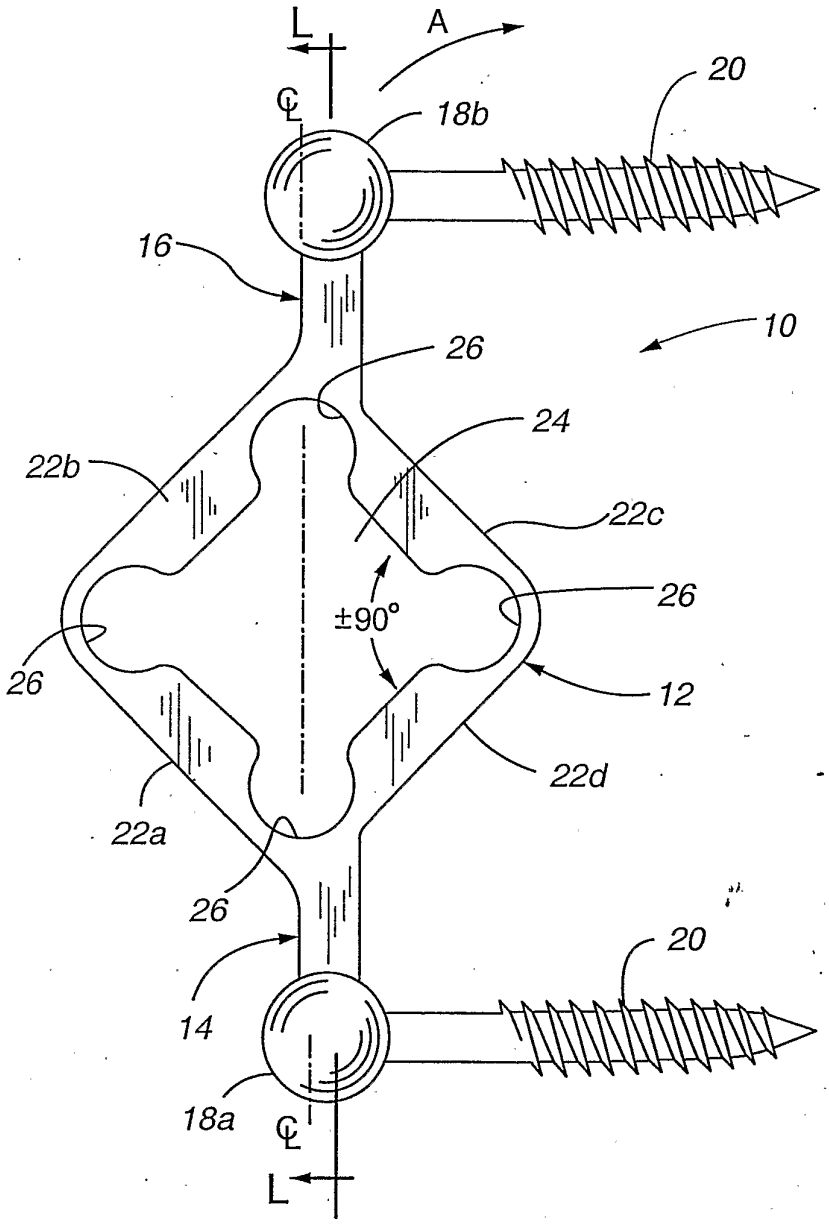


Fig. 3a

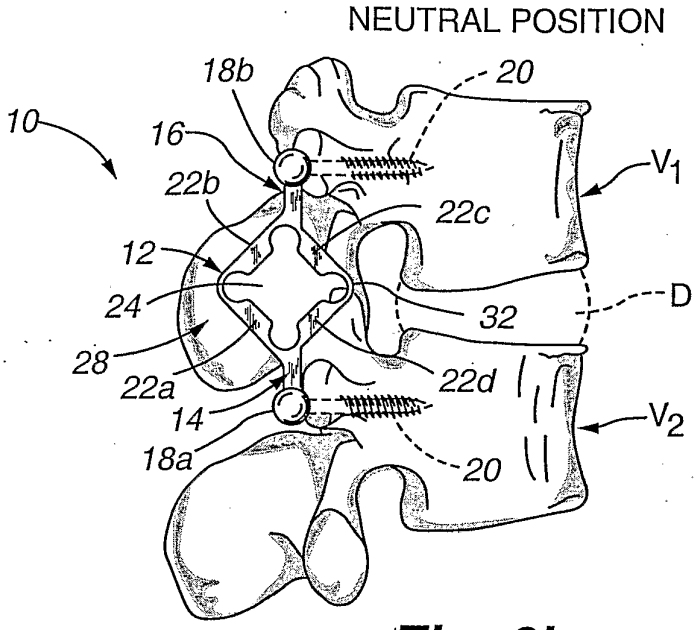

NEUTRAL POSITION
18b
20
10
16
22b
22c
V_1
12
24
32
D
28
22a
22d
14
V_2
18a
20

Fig. 3b

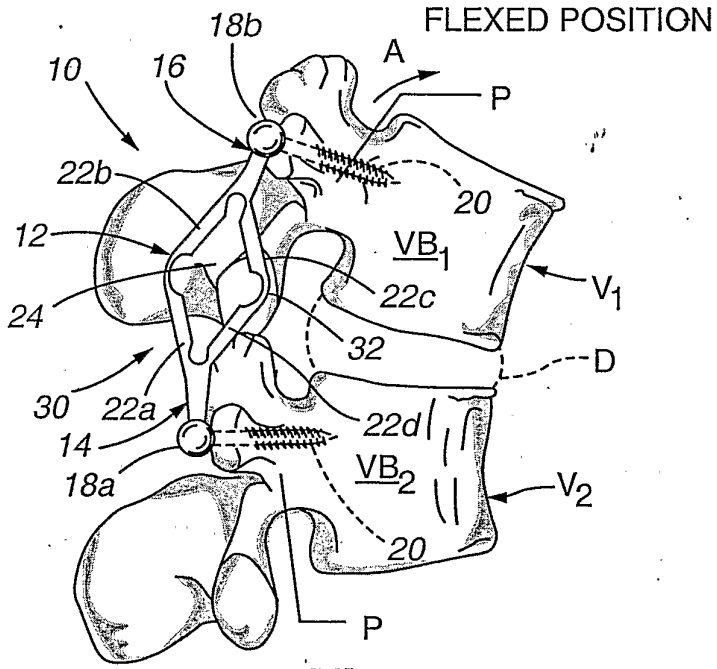

FLEXED POSITION
18b
A
10
16
P
22b
20
12
VB_1
V_1
24
22c
32
D
30
22a
22d
14
VB_2
18a
V_2
20
P

Fig. 3c

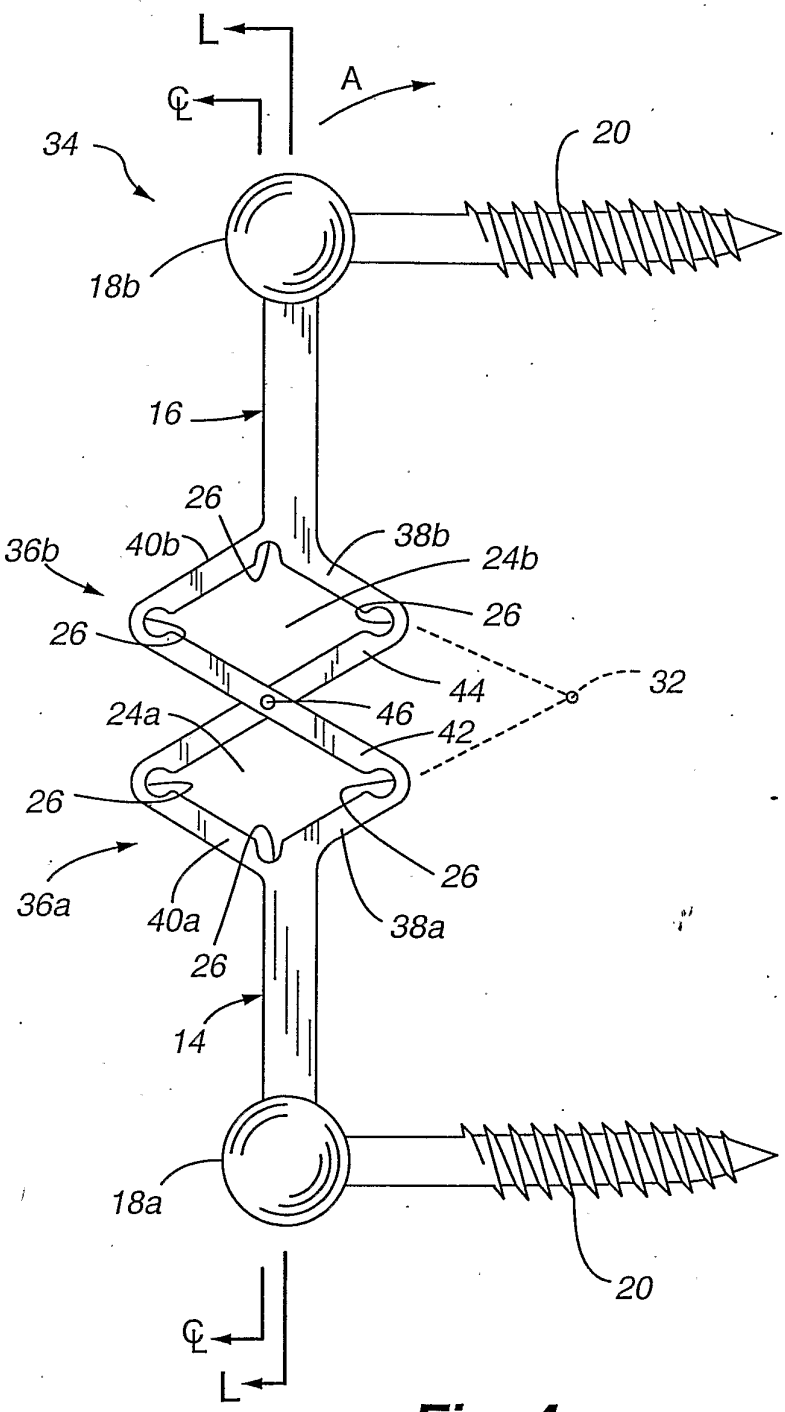

L
A
℄
34
20
18b
16
26
36b
40b
38b
24b
26
26
44
32
24a
46
42
26
26
36a
40a
38a
26
26
14
18a
20
℄
L

Fig. 4a

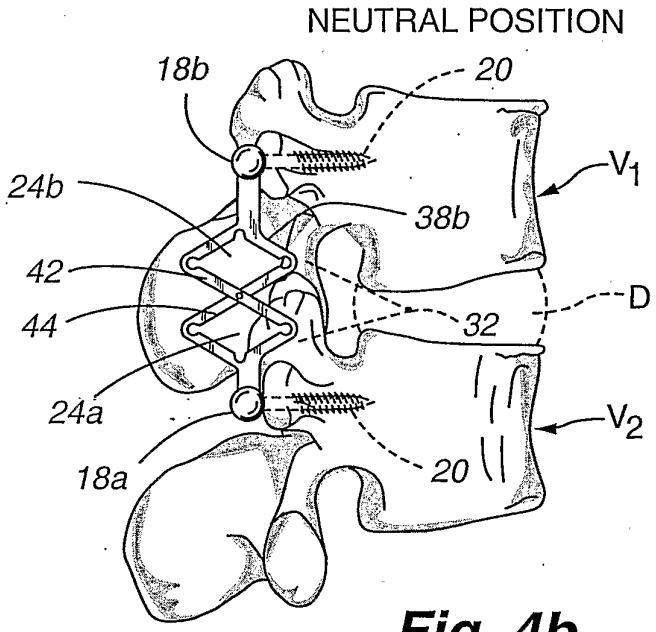

NEUTRAL POSITION
18b
20
24b
38b
V_1
42
D
44
32
24a
V_2
18a
20

Fig. 4b

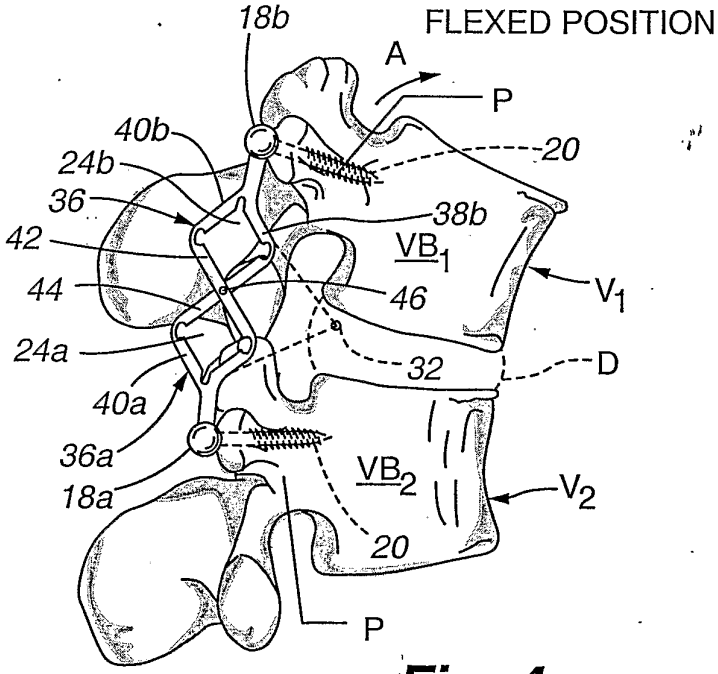

18b
FLEXED POSITION
A
P
40b
20
24b
36
38b
42
VB_1
44
46
V_1
24a
32
D
40a
36a
VB_2
V_2
18a
20
P

Fig. 4c

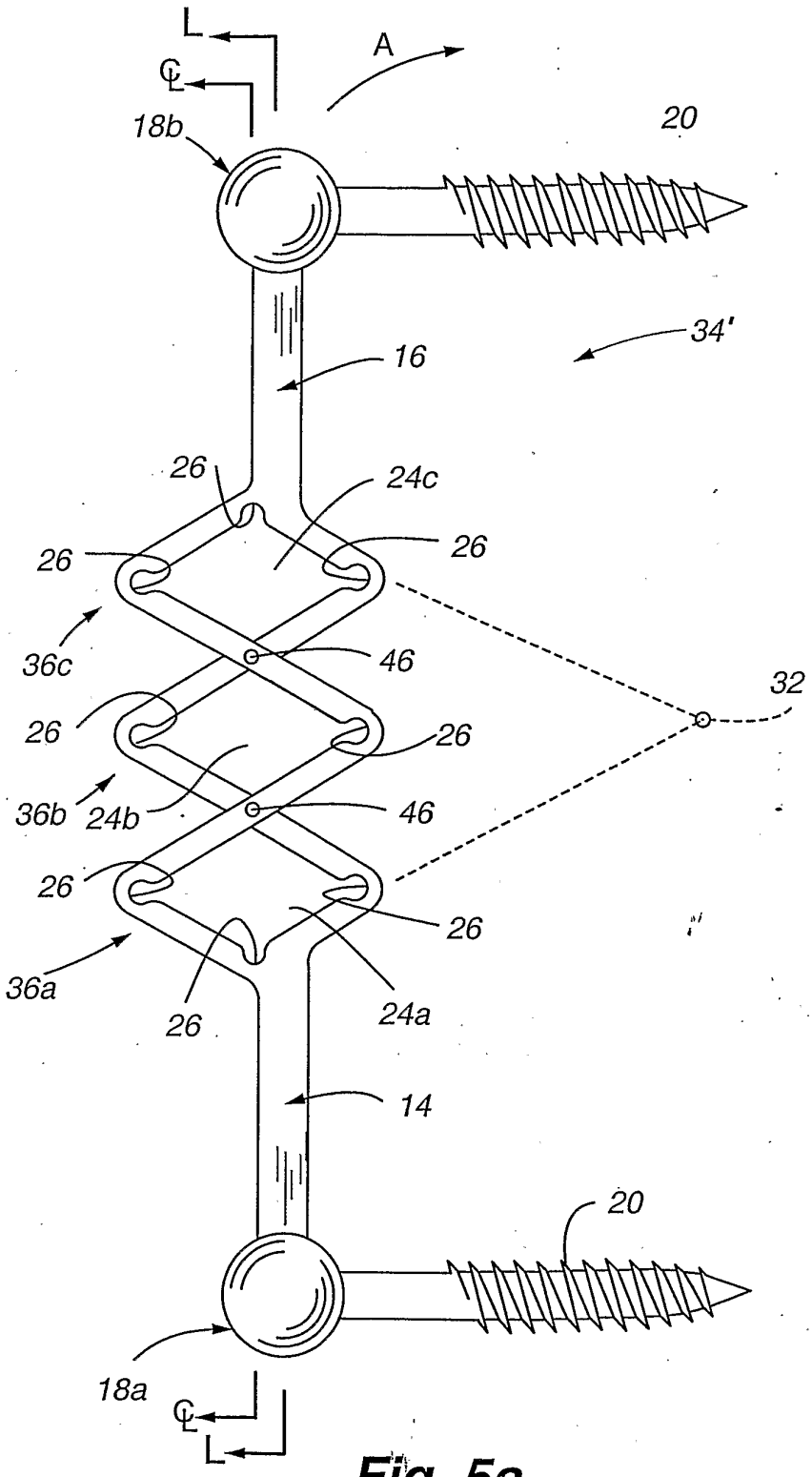

L
A
℄
18b
20
34'
16
26
24c
26
26
36c
46
32
26
26
36b
24b
46
26
26
36a
24a
26
14
20
18a
℄
L

Fig. 5a

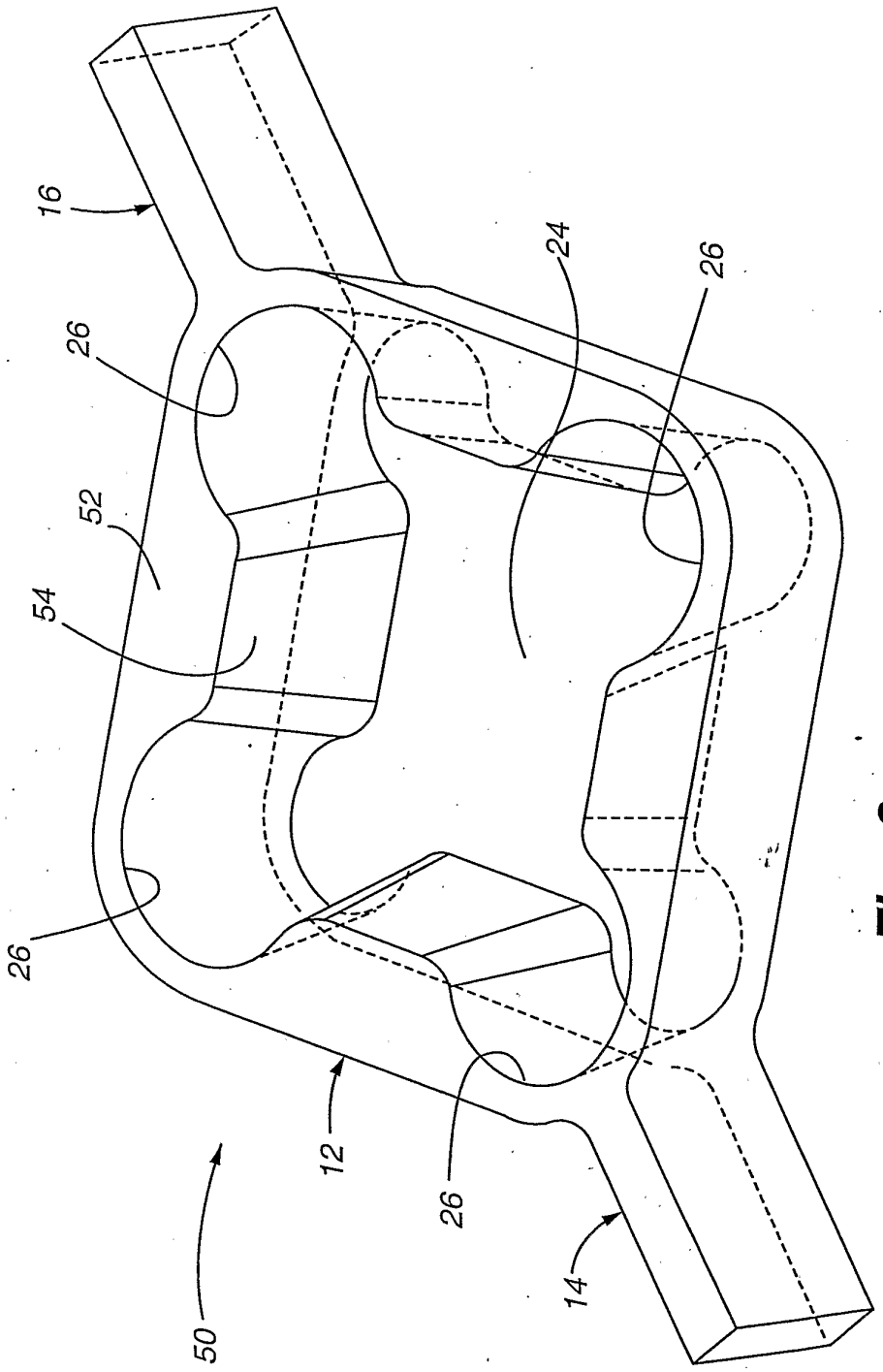


Fig. 6a

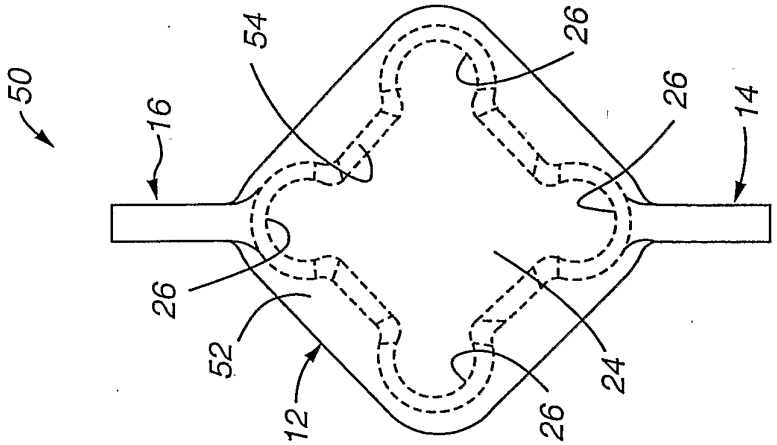


Fig. 6c

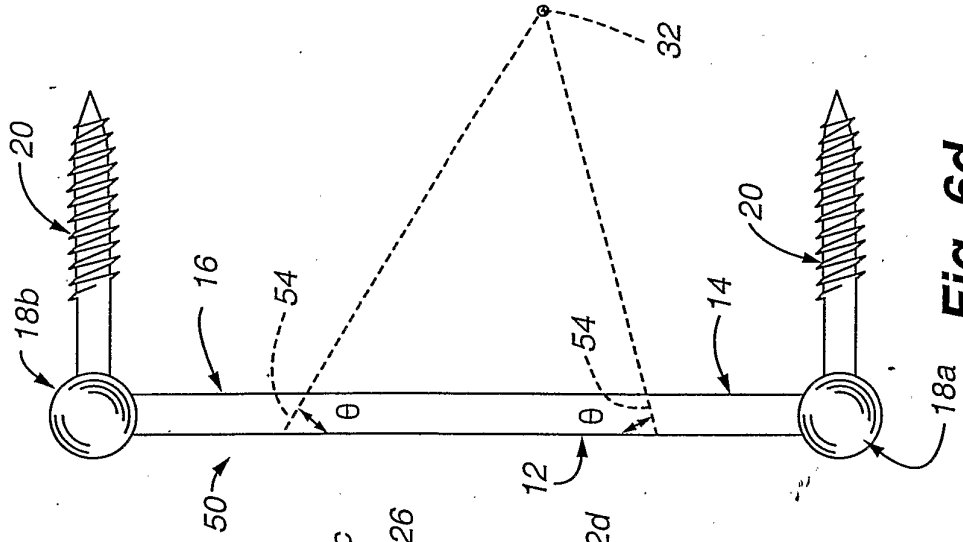


Fig. 6d

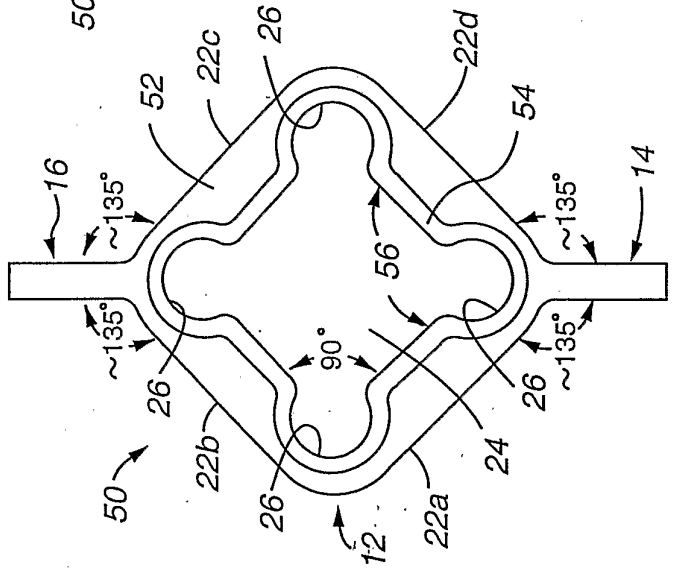


Fig. 6b

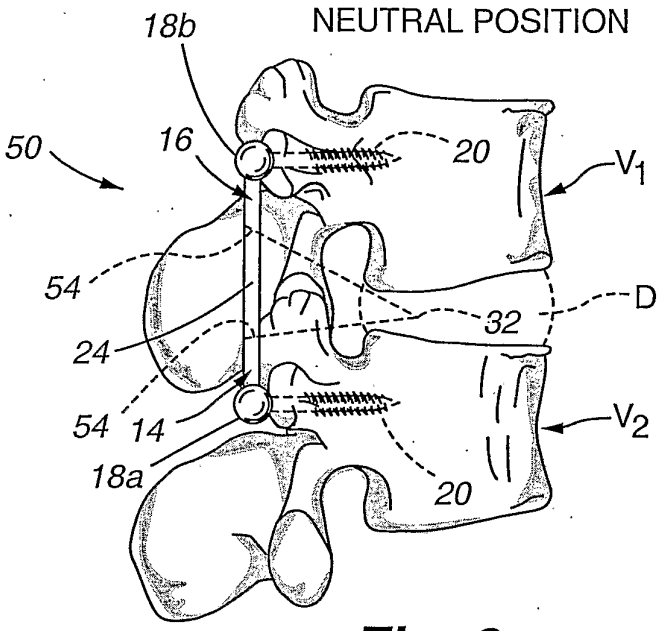

NEUTRAL POSITION
18b
50
16
20
V1
54
D
32
24
54
14
V2
18a
20

Fig. 6e

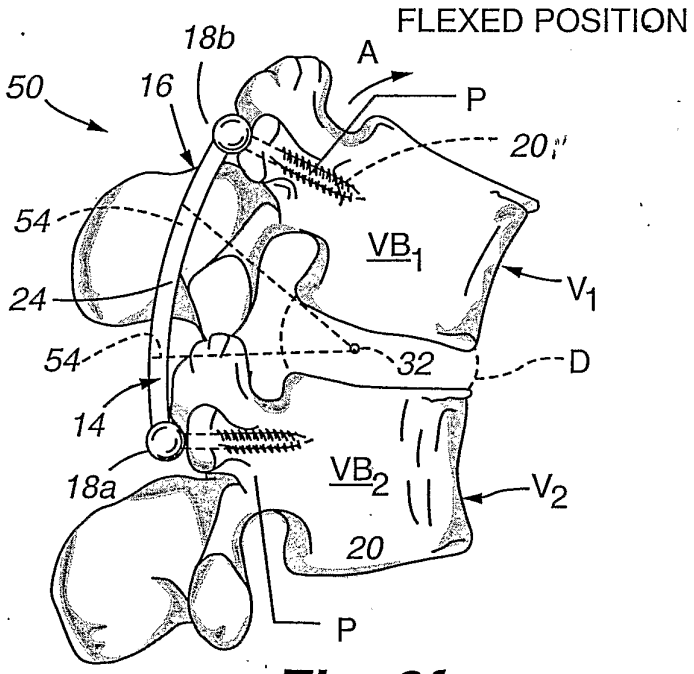

FLEXED POSITION
18b
A
50
16
P
20'
54
VB1
V1
24
54
32
D
14
18a
VB2
V2
20
P

Fig. 6f

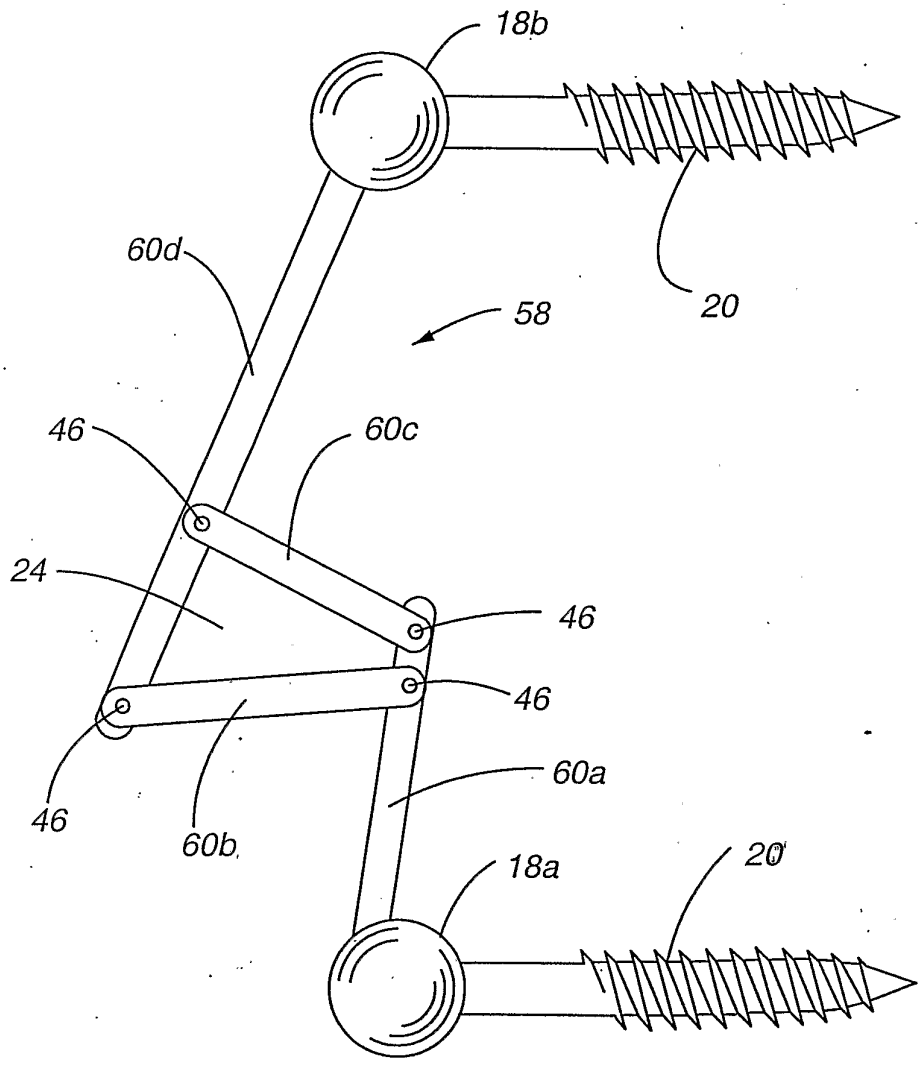


Fig. 7a

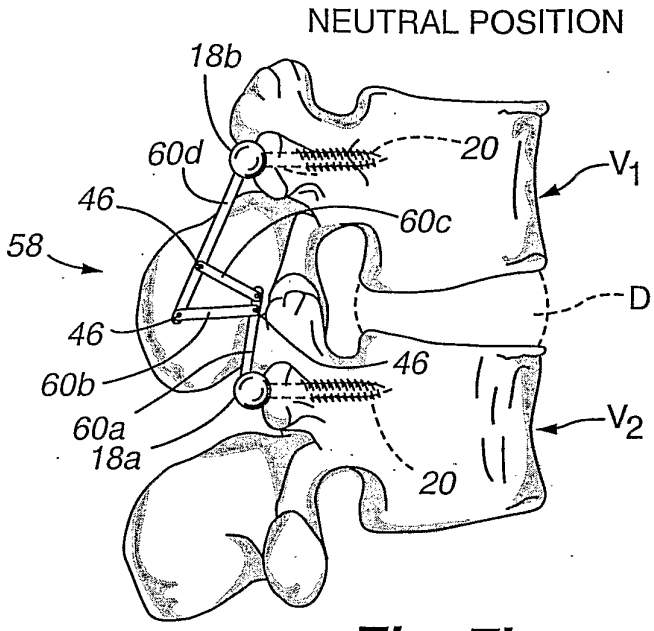

NEUTRAL POSITION
18b
60d
20
V1
46
60c
58
D
46
46
60b
60a
18a
V2
20

Fig. 7b

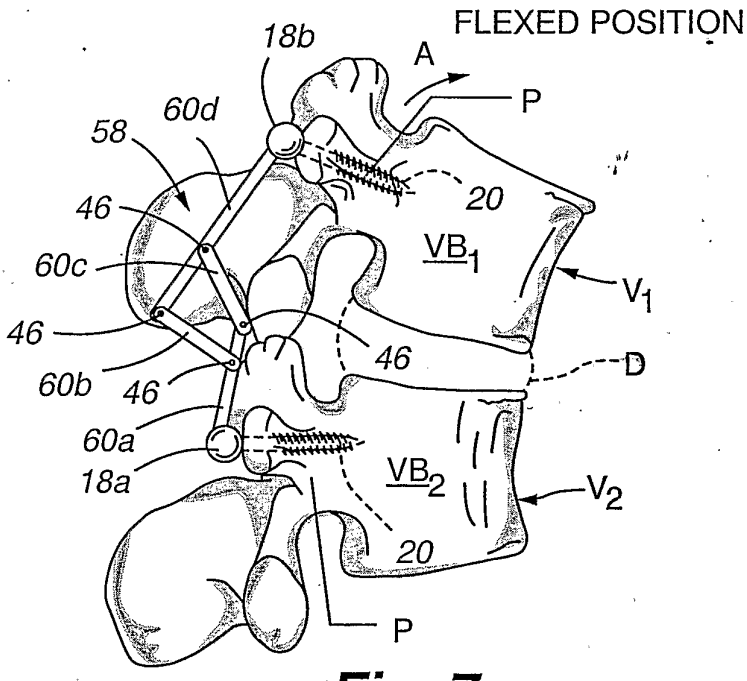

FLEXED POSITION
18b
A
P
60d
58
20
46
VB1
60c
V1
46
46
D
60b
46
60a
18a
VB2
V2
20
P

Fig. 7c

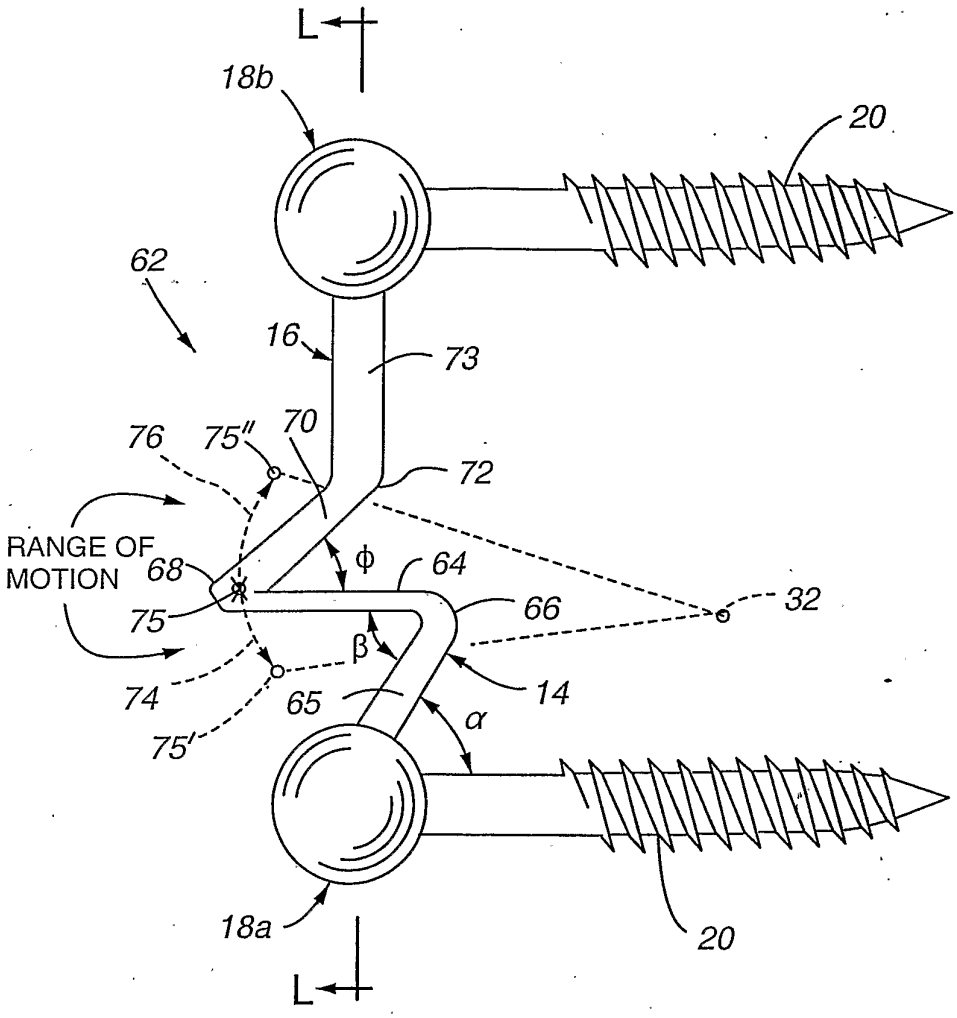

L
18b
20
62
16
73
76
75″
70
72
RANGE OF MOTION
68
ϕ
64
32
75
66
β
74
65
14
α
75′
18a
20
L

Fig. 8a

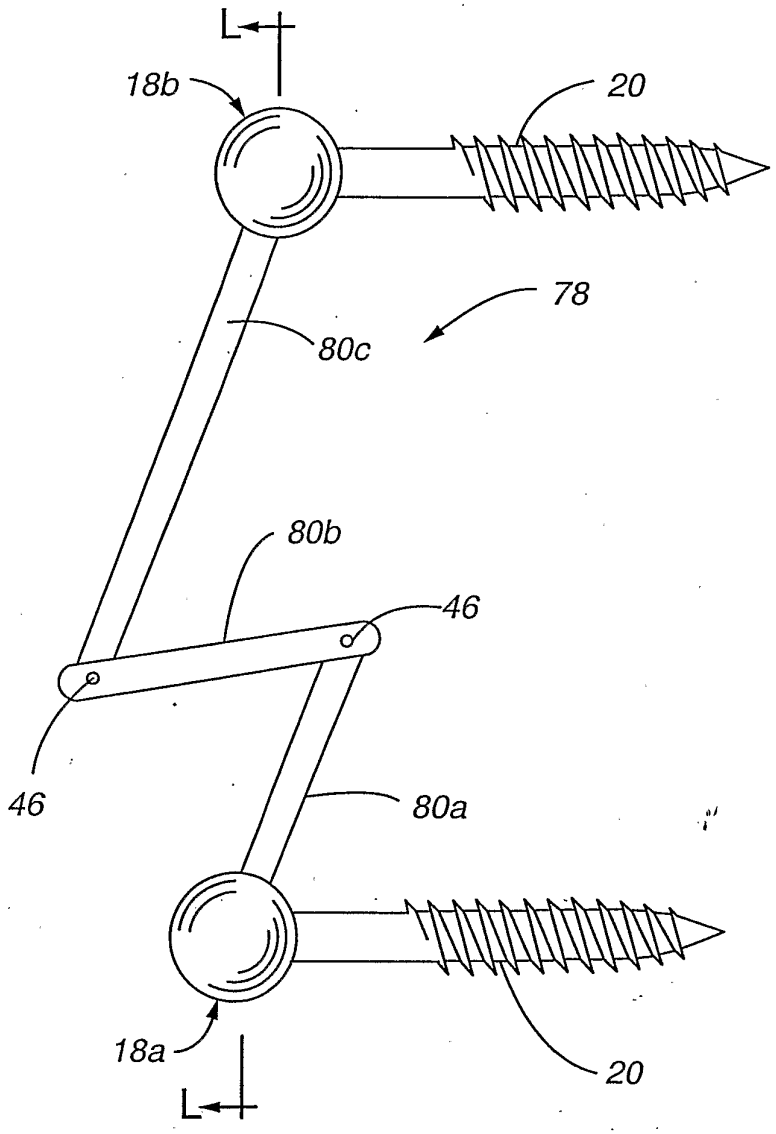


Fig. 9a

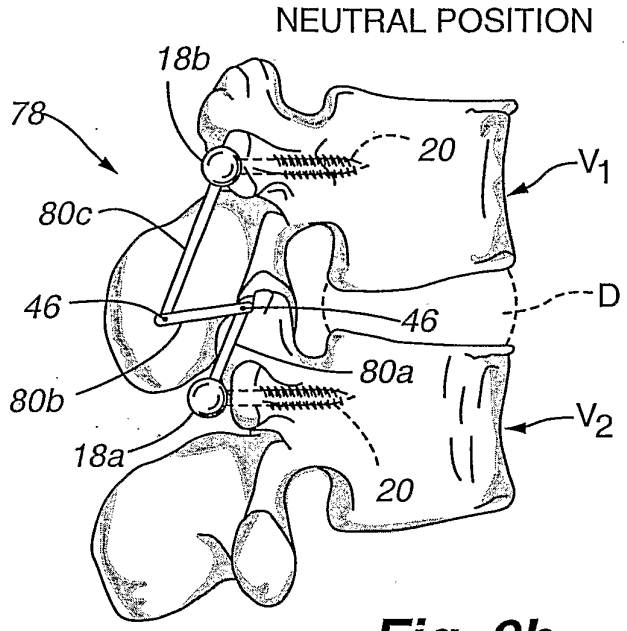

NEUTRAL POSITION
18b
78
20
V_1
80c
46
D
46
80a
80b
V_2
18a
20

Fig. 9b

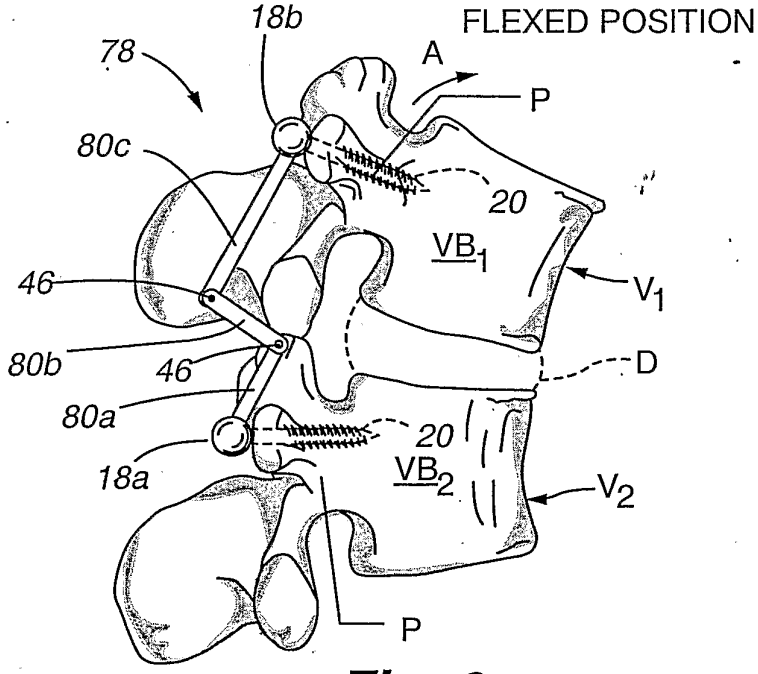

18b
FLEXED POSITION
78
A
P
80c
20
VB_1
46
V_1
80b
46
D
80a
20
18a
VB_2
V_2
P

Fig. 9c

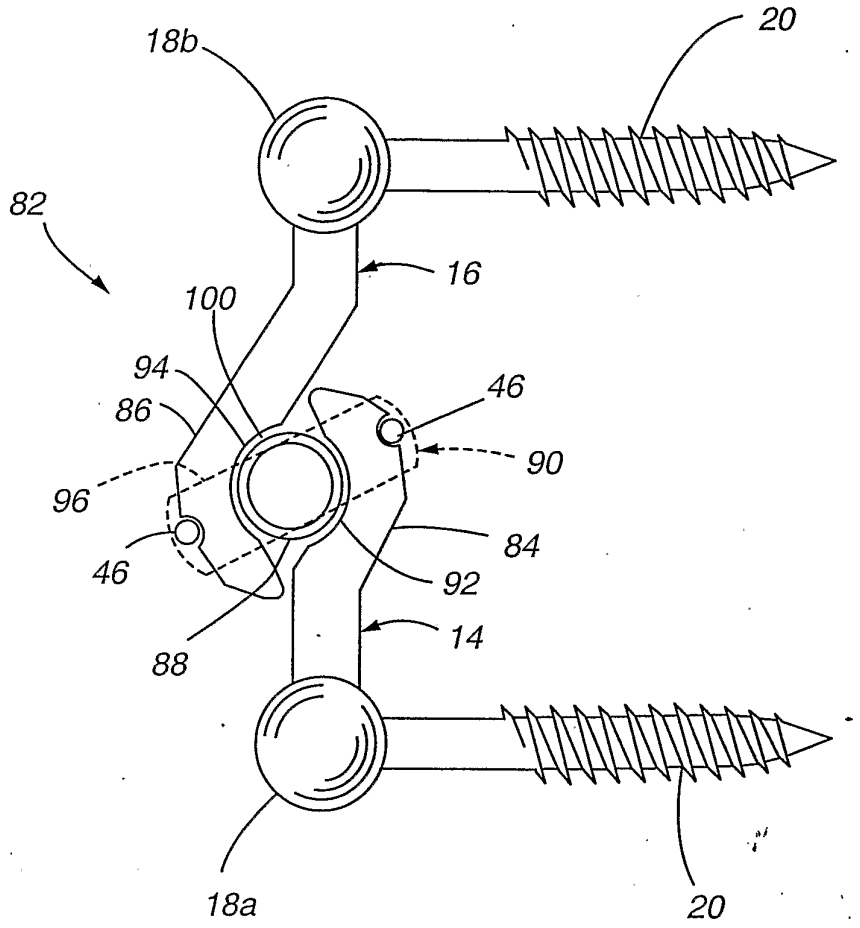


Fig. 10a

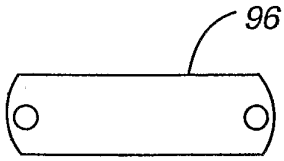


Fig. 10b

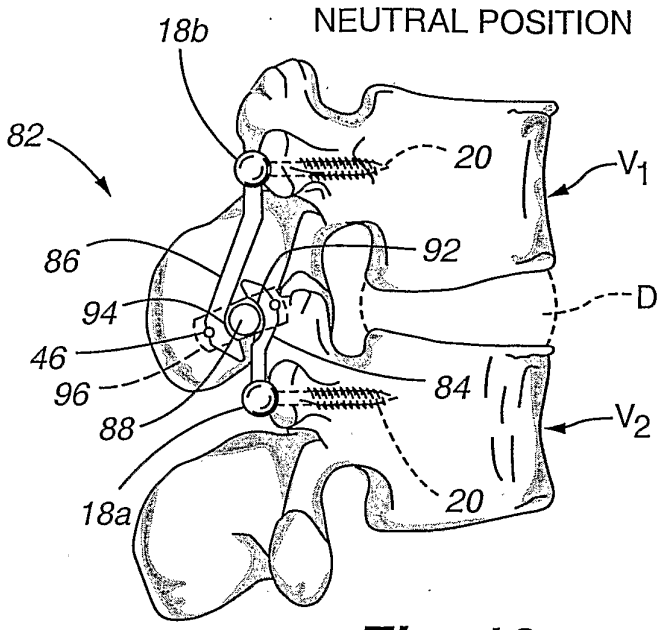


Fig. 10c

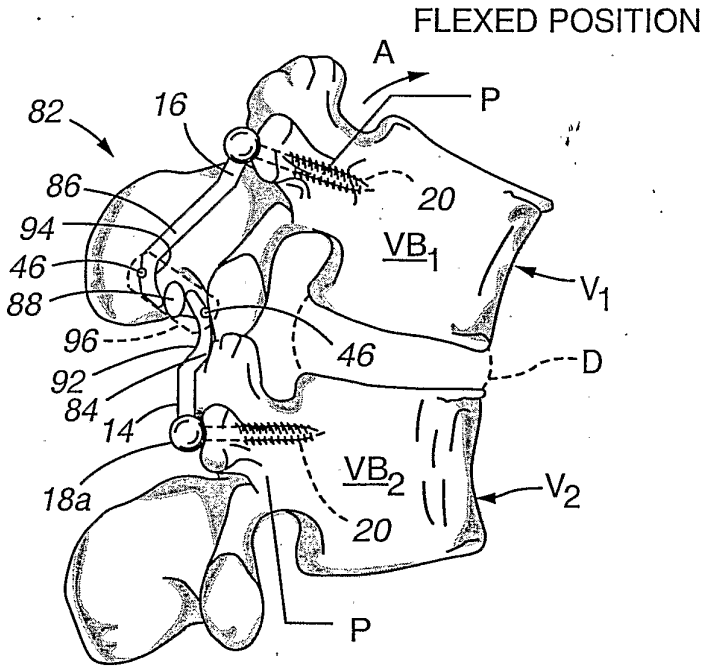


Fig. 10d

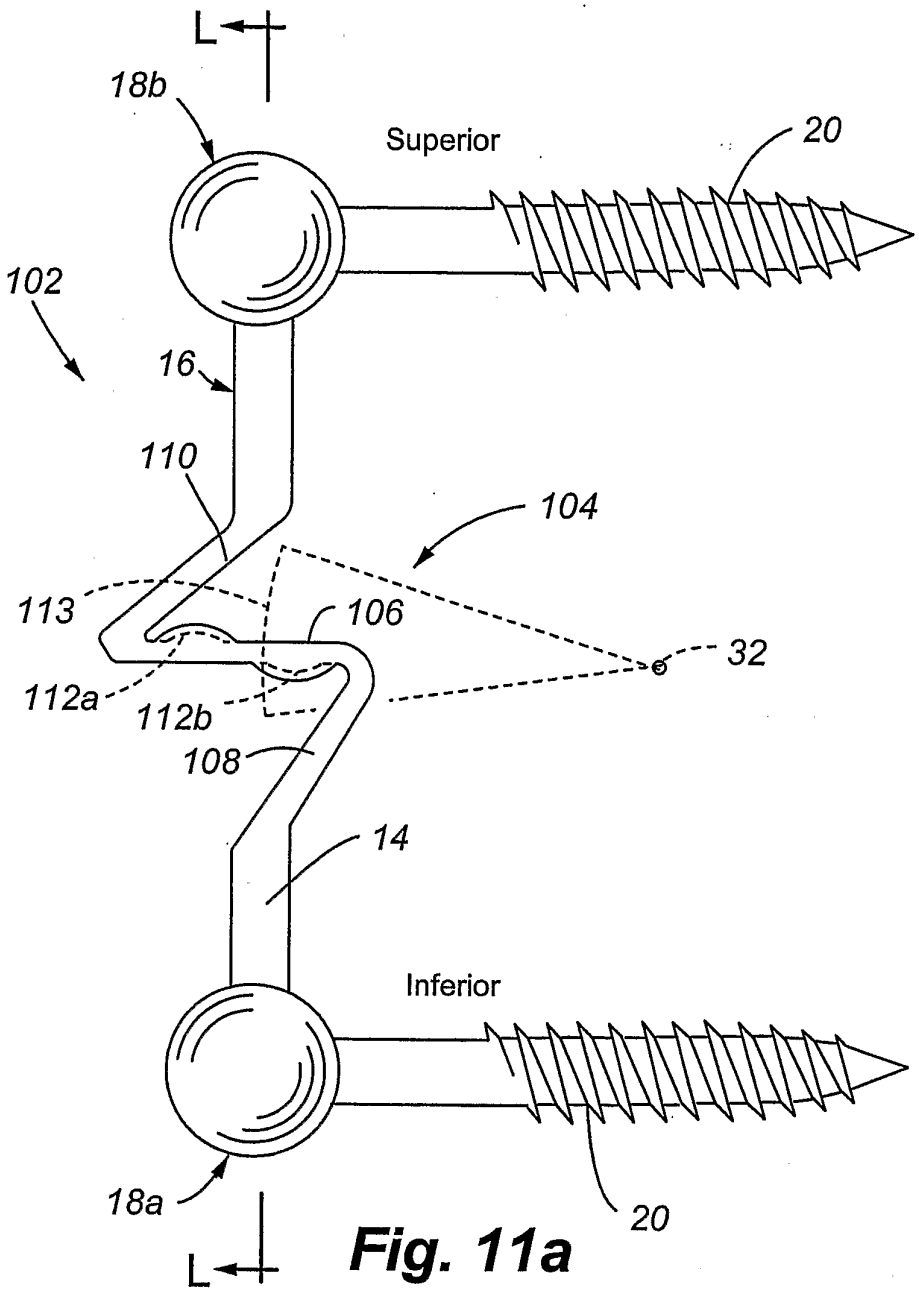


Fig. 11a

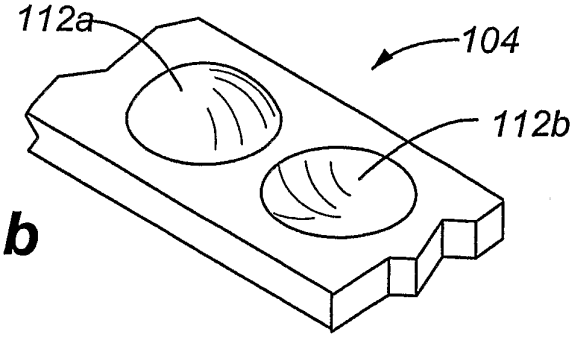


Fig. 11b

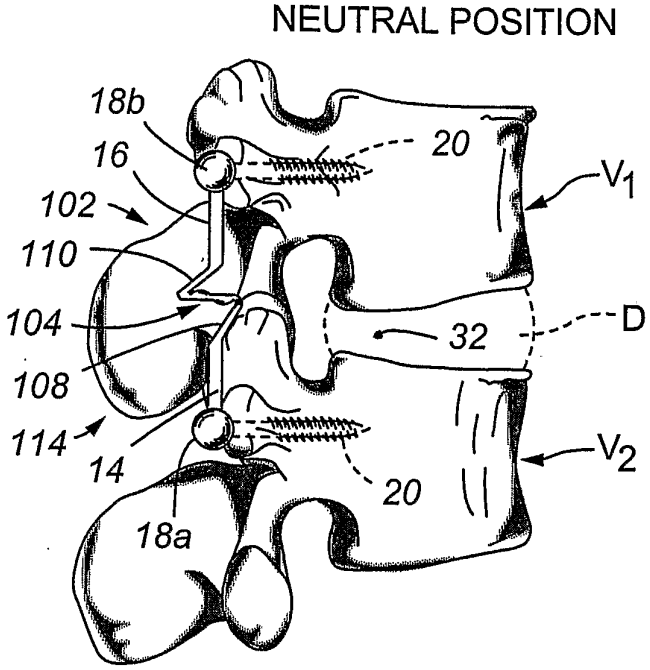


Fig. 11c

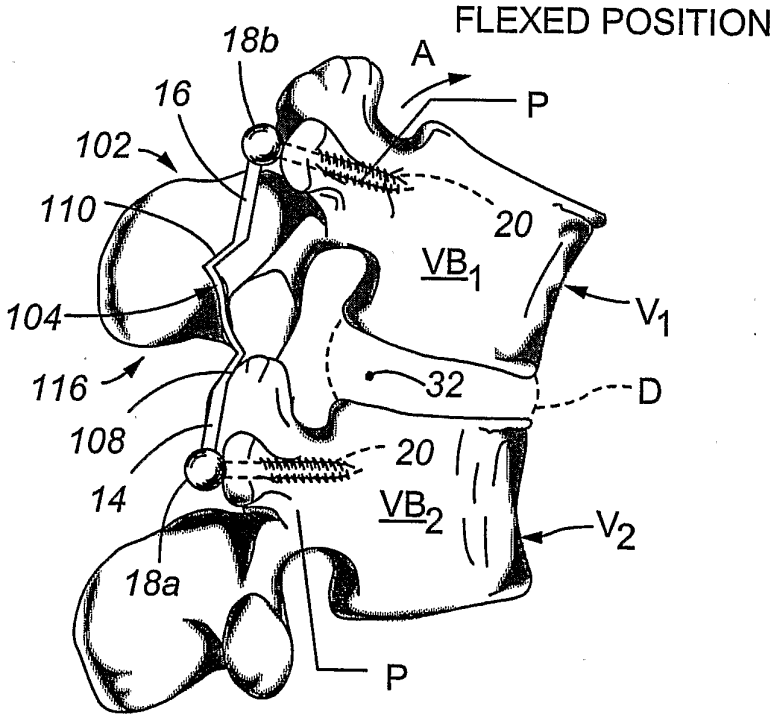


Fig. 11d

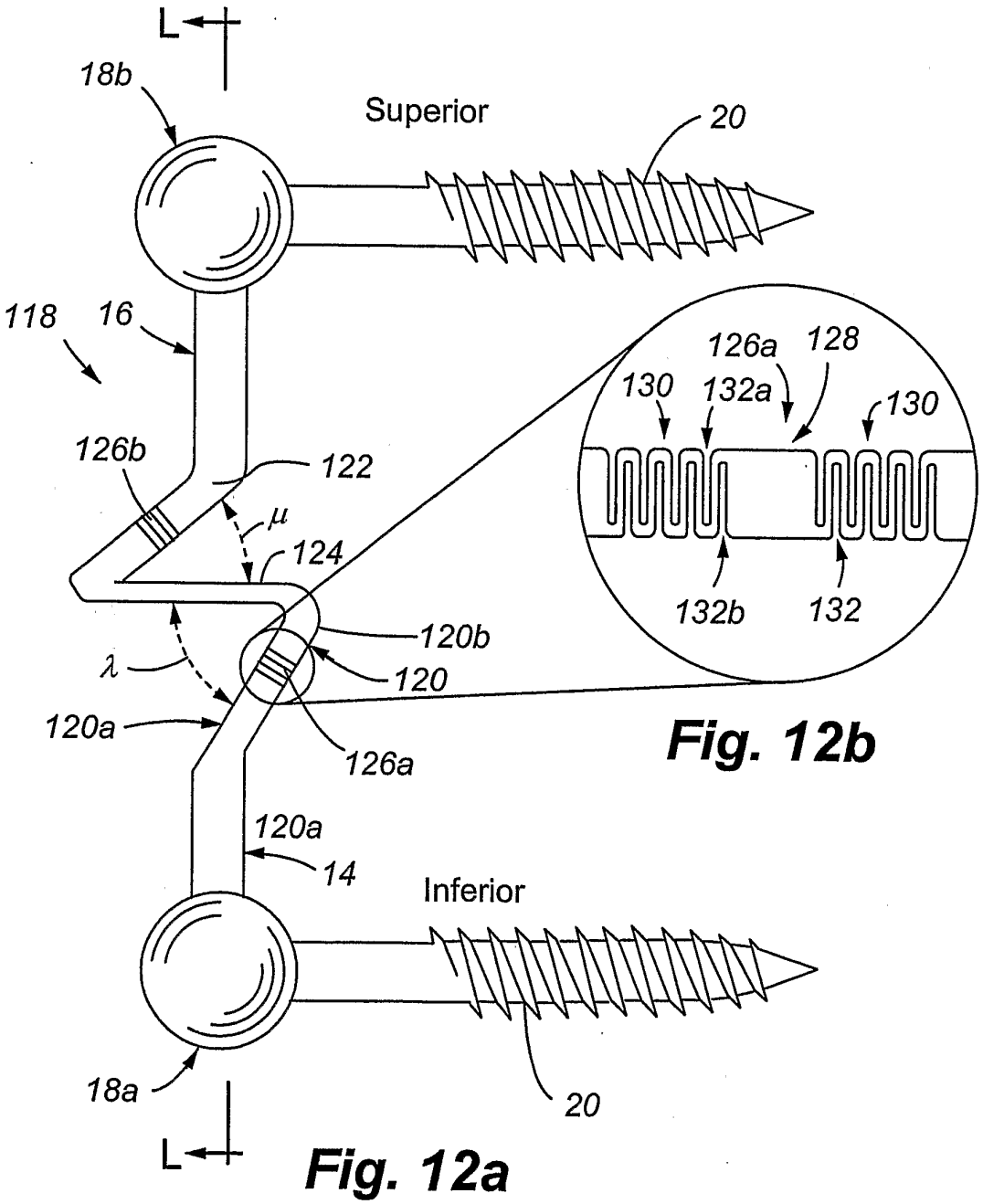


Fig. 12b

Fig. 12a

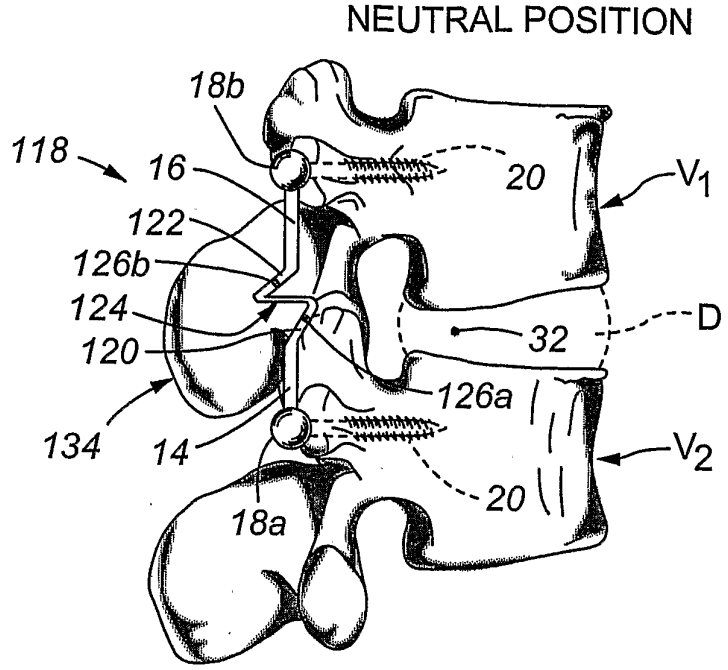


Fig. 12c

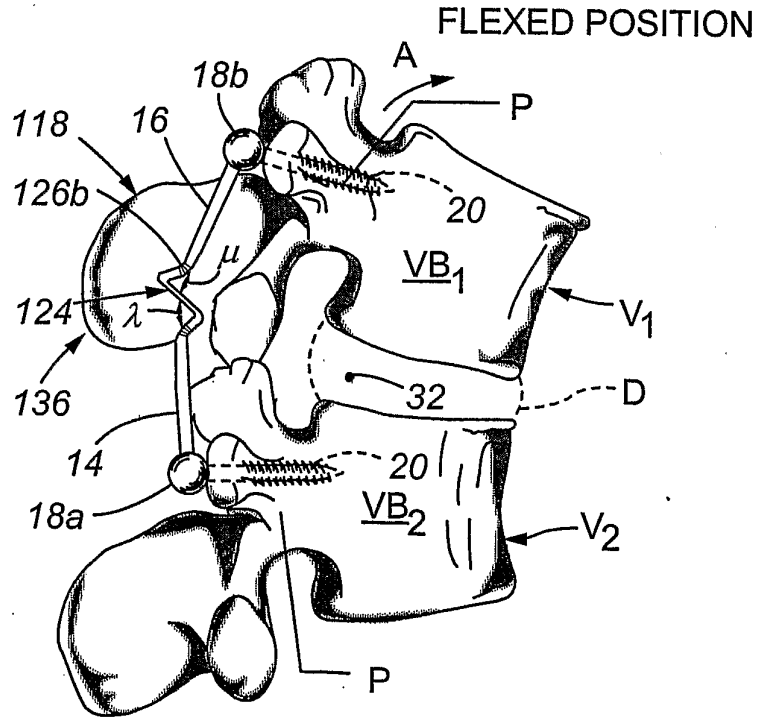


Fig. 12d

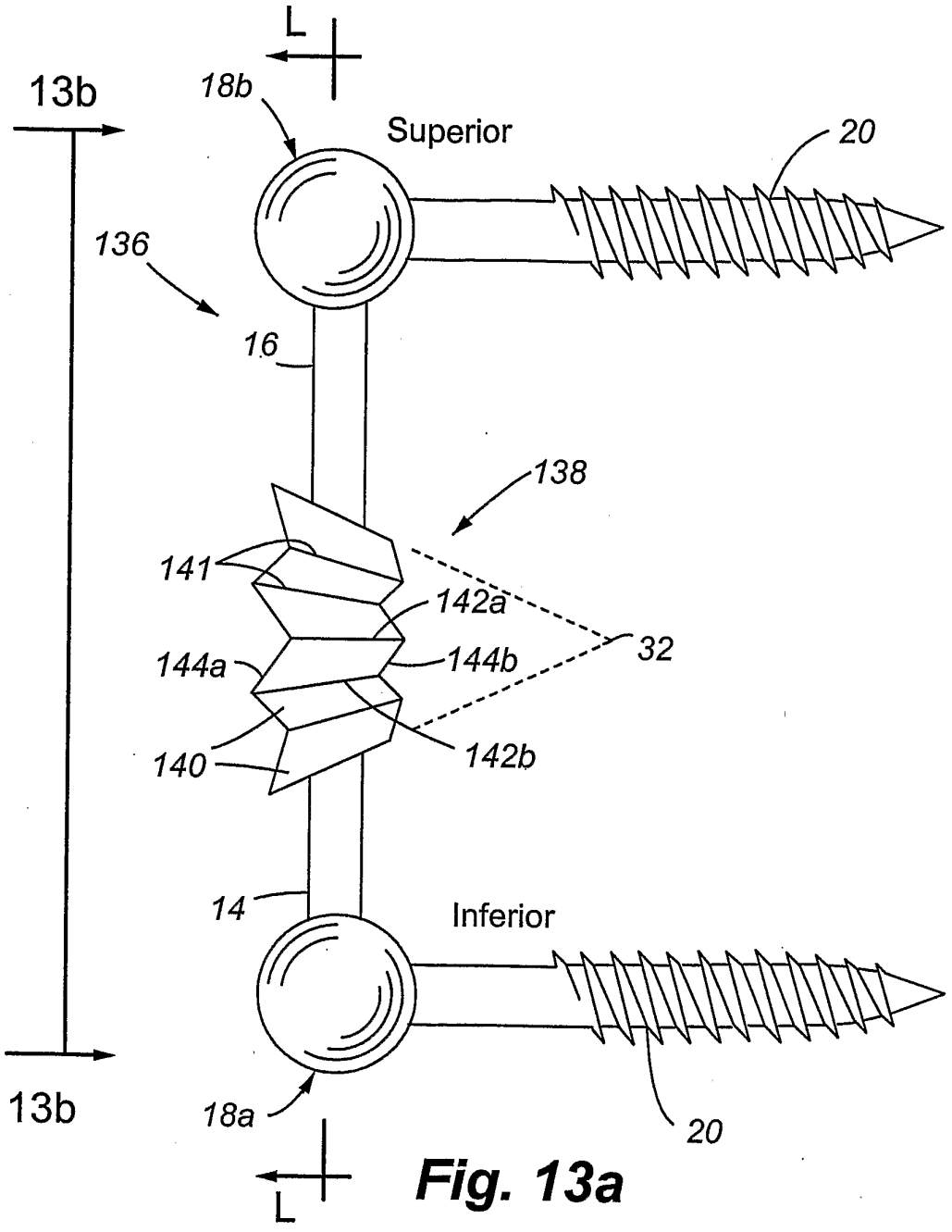


Fig. 13a

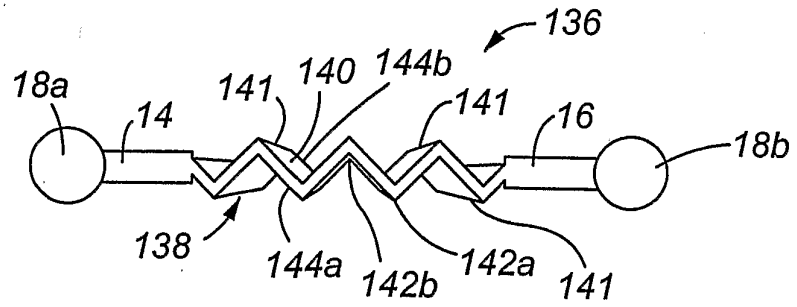


Fig. 13b

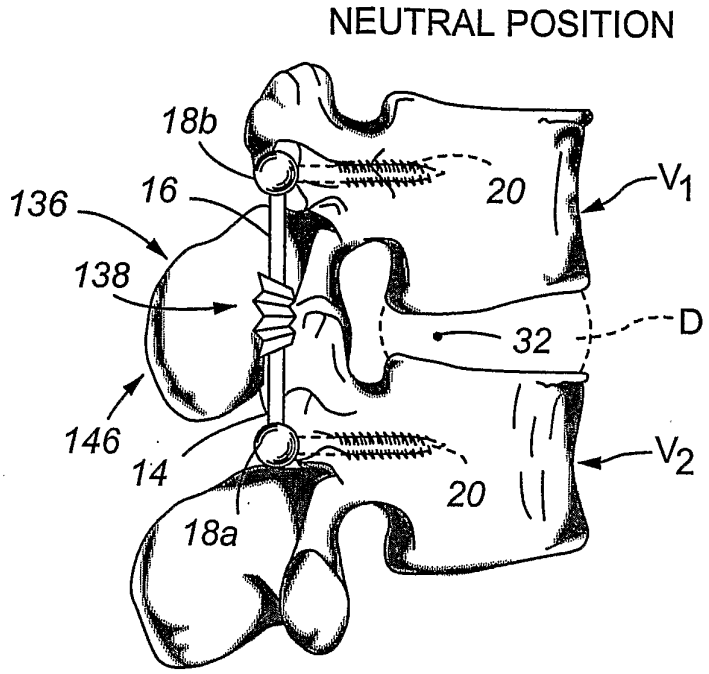


Fig. 13c

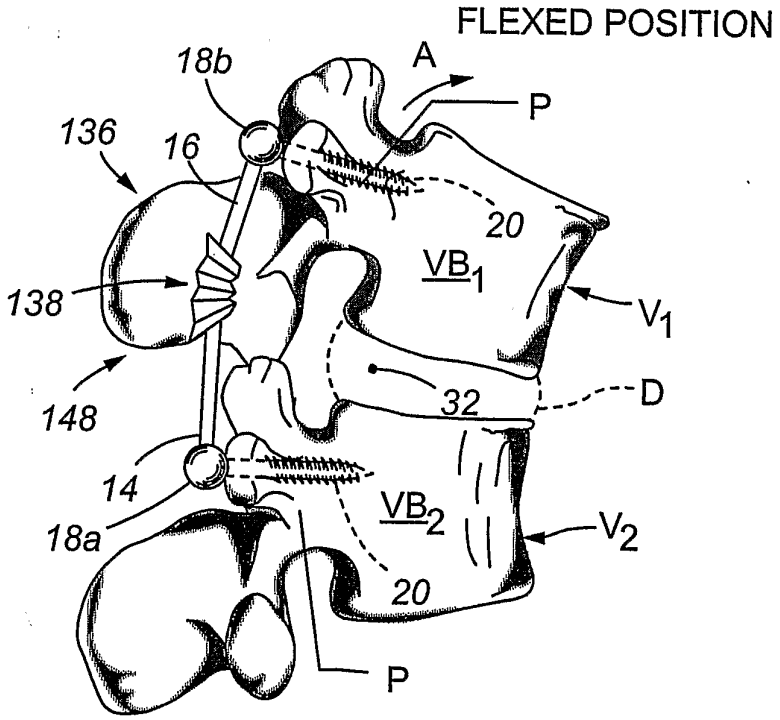


Fig. 13d

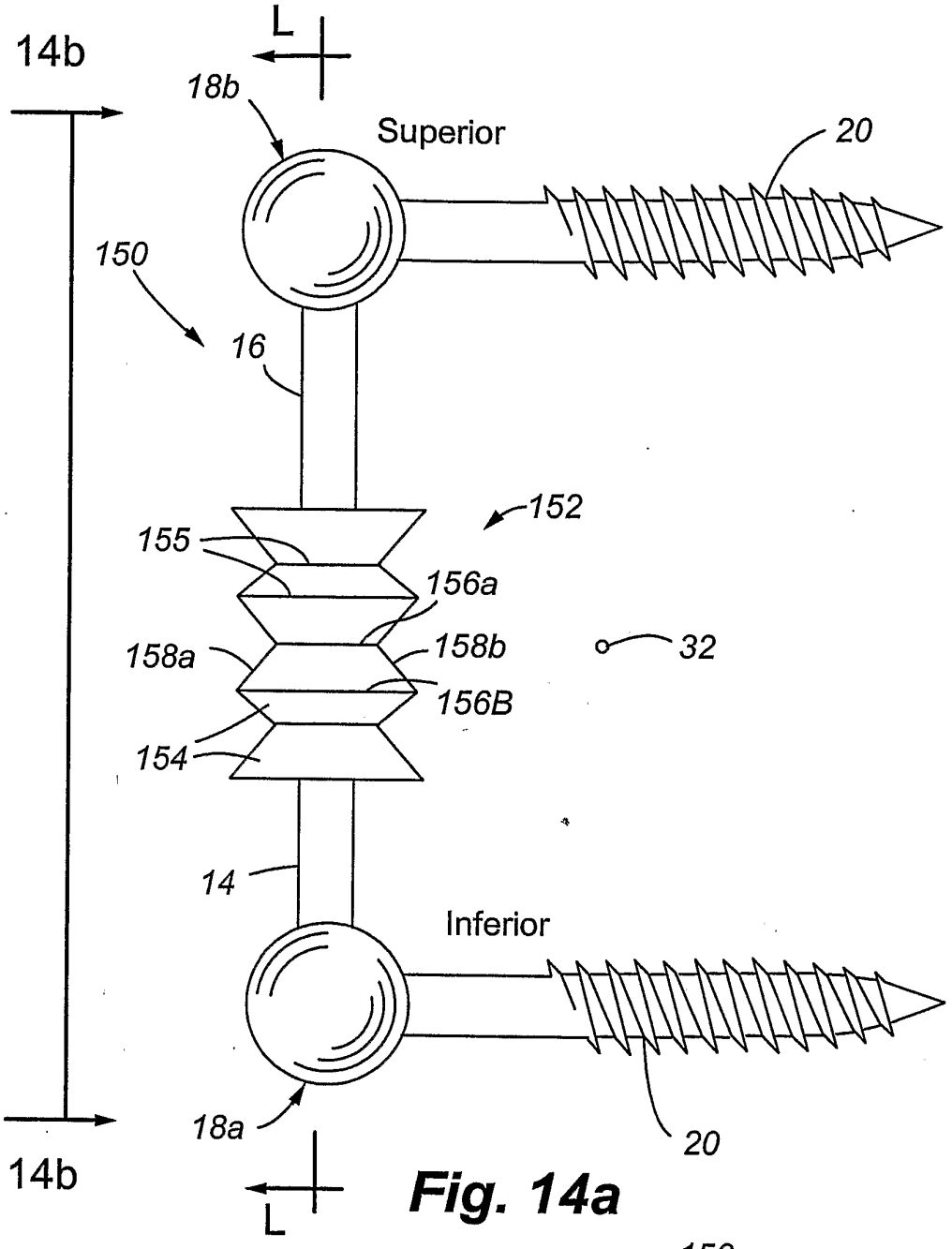


Fig. 14a

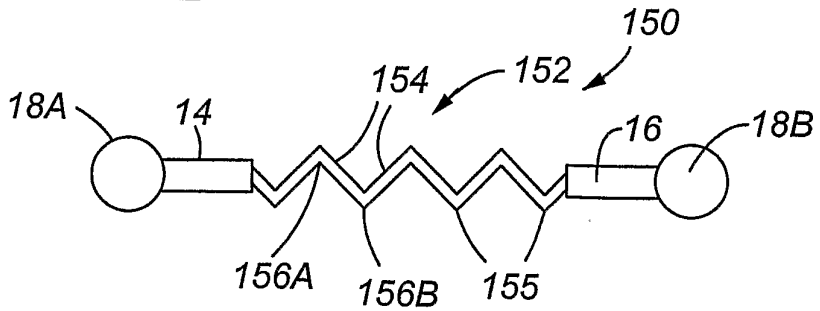


Fig. 14b

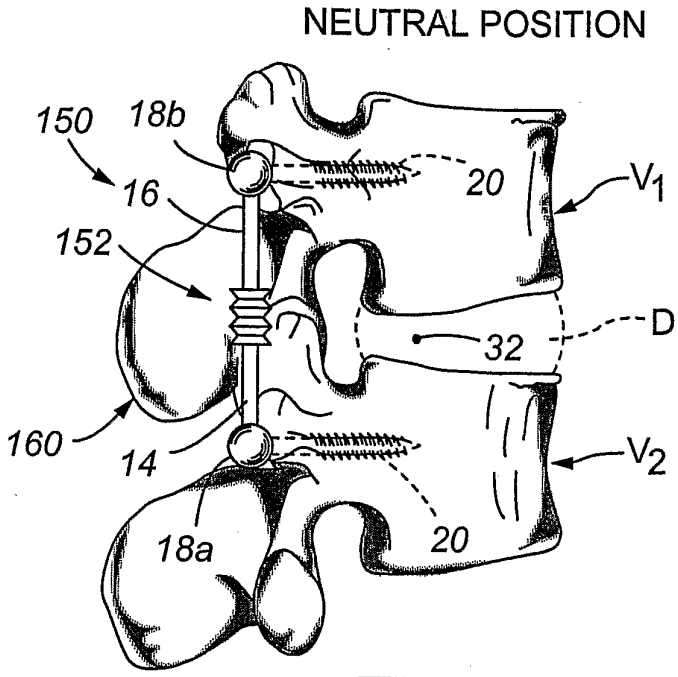


Fig. 14c

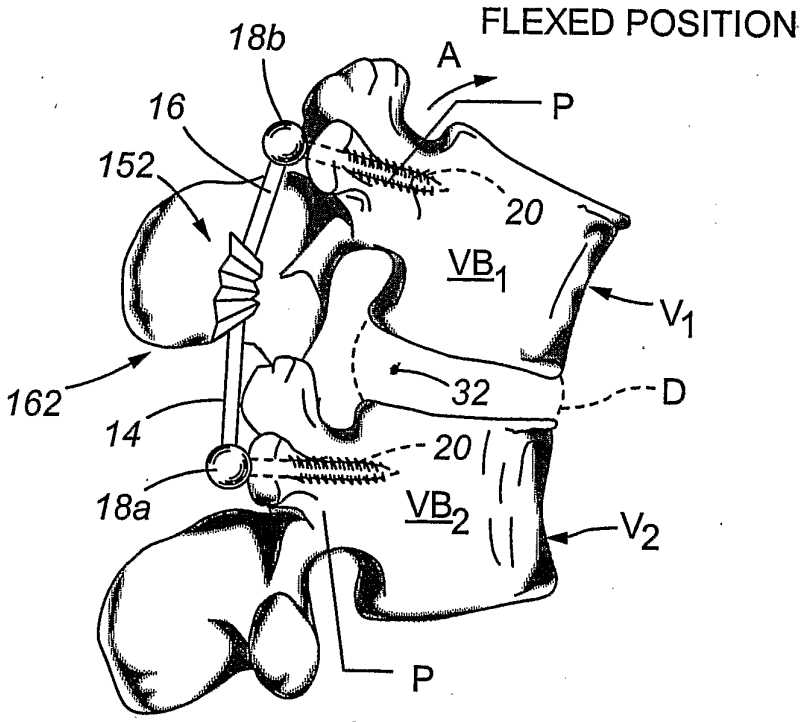


Fig. 14d

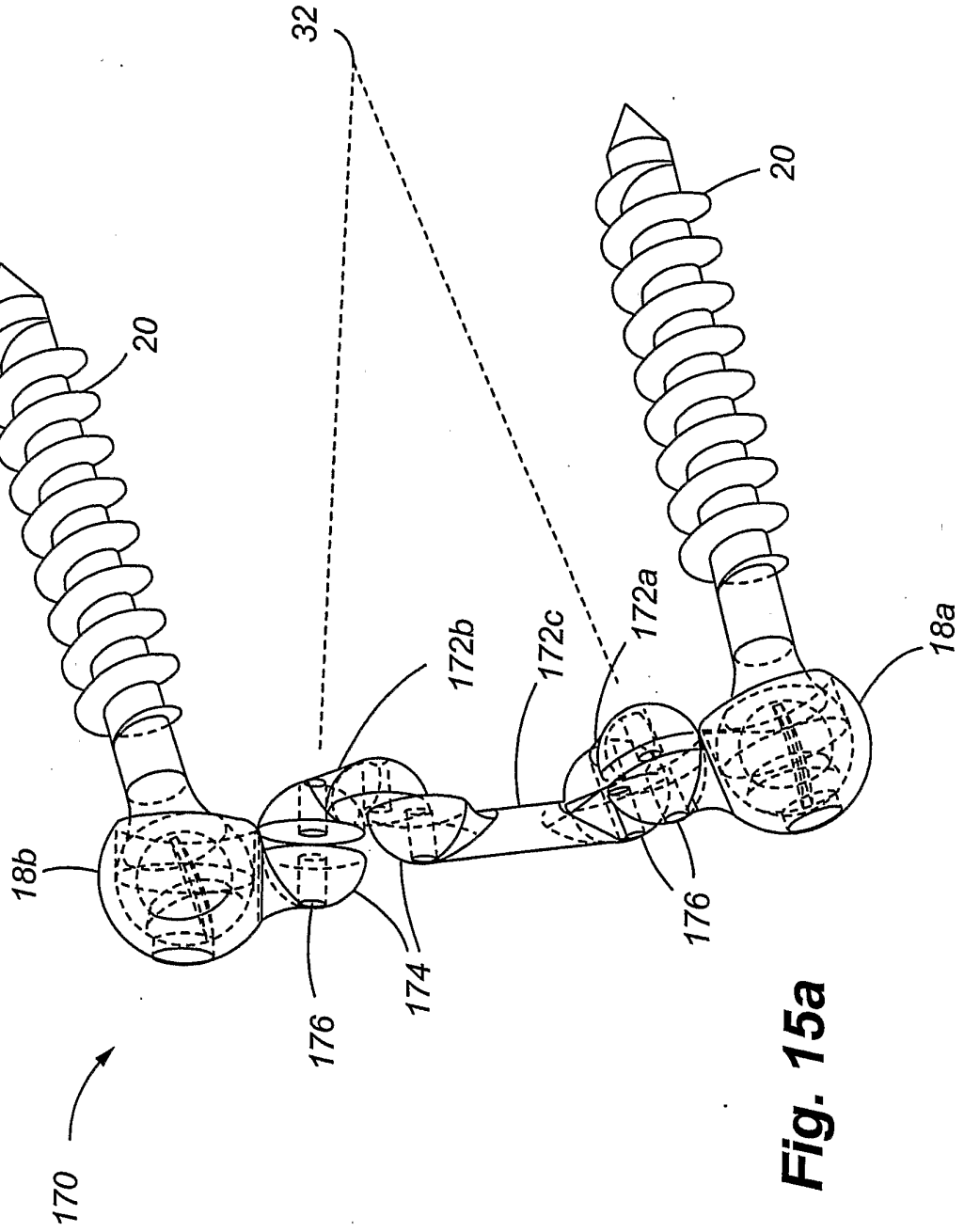


Fig. 15a

Fig. 15b

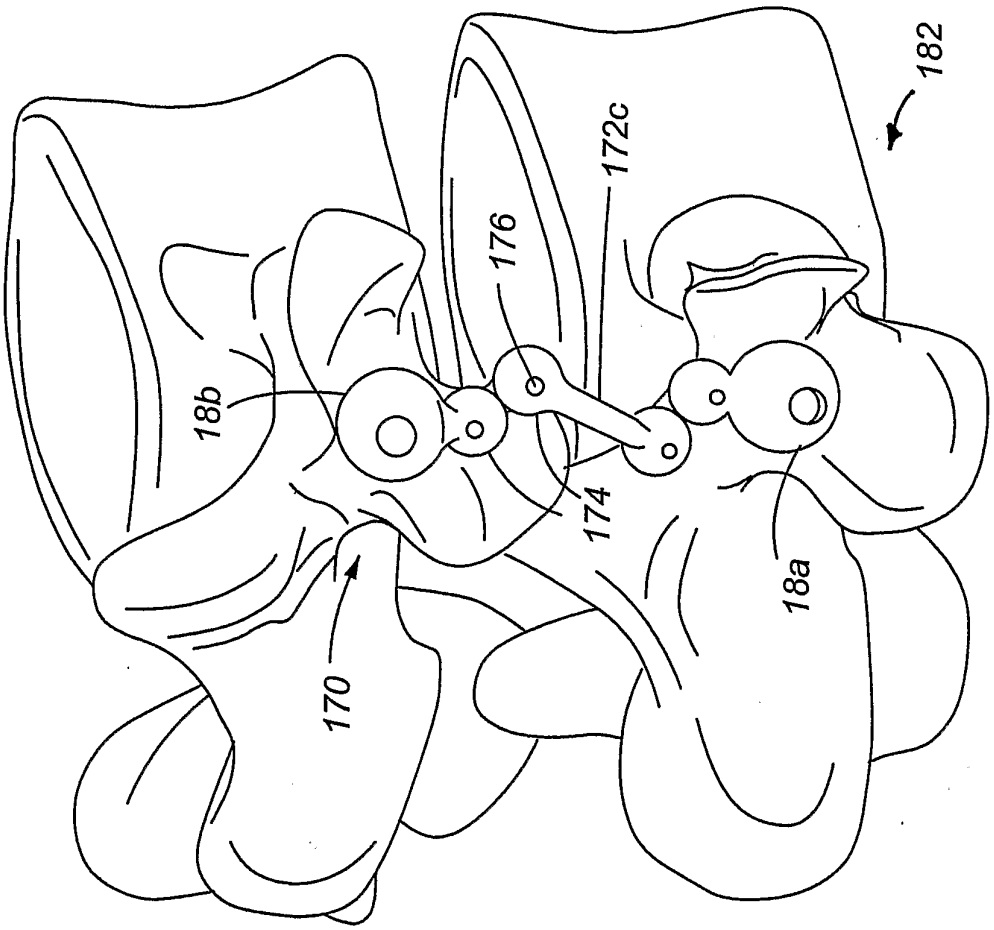


Fig. 15c