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(54) Title: DYNAMIC SPACER DEVICE AND METHOD FOR SPANNING A SPACE FORMED UPON REMOVAL OF AN INTERVERTEBRAL DISC

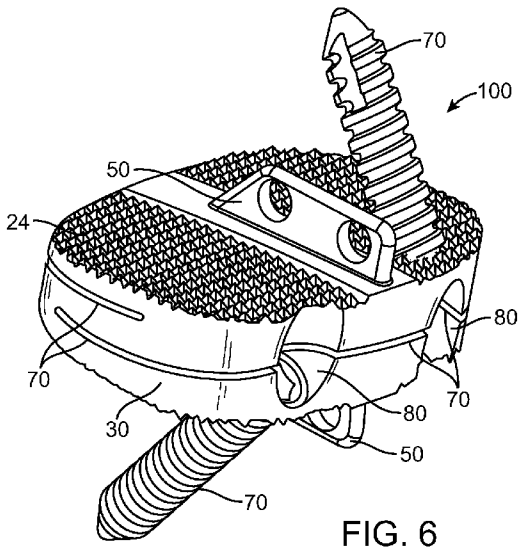

FIG. 6

(57) Abstract: A compliant intervertebral spacer according to the present invention replaces a damage intervertebral disc and functions to maintain disc height and prevent subsidence with a large surface area while substantially reducing patient recovery time. The compliant intervertebral spacer for spanning a space formed by upon removal of an intervertebral disc includes two end plates sized and shaped to fit within an intervertebral space and a compliant connector interconnecting the inner surfaces of the two end plates in a manner which limits motion between the plates to less than a total of 5 degrees of motion in any direction. The intervertebral spacer is configured to permanently maintain the disc space between the two adjacent discs without the use of bridging bone.

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DYNAMIC SPACER DEVICE AND METHOD FOR SPANNING A SPACE FORMED UPON REMOVAL OF AN INTERVERTEBRAL DISC

CROSS-REFERENCES TO RELATED APPLICATIONS

[0001] The present application claims priority from U.S. Provisional Application No. 60/981,665 filed October 22, 2007, entitled "Method and Spacer Device for Spanning Space Formed Upon Removal of an Intervertebral Disc," the full disclosure of which is incorporated herein by reference.

BACKGROUND OF THE INVENTION

[0002] The present invention relates to medical devices and methods. More specifically, the invention relates to intervertebral spacers and methods of spanning a space formed upon removal of an intervertebral disc.

[0003] Back pain takes an enormous toll on the health and productivity of people around the world. According to the American Academy of Orthopedic Surgeons, approximately 80 percent of Americans will experience back pain at some time in their life. In the year 2000, approximately 26 million visits were made to physicians' offices due to back problems in the United States. On any one day, it is estimated that 5% of the working population in America is disabled by back pain.

[0004] One common cause of back pain is injury, degeneration and/or dysfunction of one or more intervertebral discs. Intervertebral discs are the soft tissue structures located between each of the thirty-three vertebral bones that make up the vertebral (spinal) column. Essentially, the discs allow the vertebrae to move relative to one another. The vertebral column and discs are vital anatomical structures, in that they form a central axis that supports the head and torso, allow for movement of the back, and protect the spinal cord, which passes through the vertebrae in proximity to the discs.

[0005] Discs often become damaged due to wear and tear or acute injury. For example, discs may bulge (herniate), tear, rupture, degenerate or the like. A bulging disc may press against the spinal cord or a nerve exiting the spinal cord, causing "radicular" pain (pain in one or more extremities caused by impingement of a nerve root). Degeneration or other damage

to a disc may cause a loss of "disc height," meaning that the natural space between two vertebrae decreases. Decreased disc height may cause a disc to bulge, facet loads to increase, two vertebrae to rub together in an unnatural way and/or increased pressure on certain parts of the vertebrae and/or nerve roots, thus causing pain. In general, chronic and acute damage to intervertebral discs is a common source of back related pain and loss of mobility.

[0006] When one or more damaged intervertebral discs cause a patient pain and discomfort, surgery is often required. Traditionally, surgical procedures for treating intervertebral discs have involved discectomy (partial or total removal of a disc), with or without interbody fusion of the two vertebrae adjacent to the disc. When the disc is partially or completely removed, it is necessary to replace the excised material to prevent direct contact between hard bony surfaces of adjacent vertebrae. Oftentimes, pins, rods, screws, cages and/or the like are inserted between the vertebrae to act as support structures to hold the vertebrae and graft material in place while they permanently fuse together.

[0007] One typical fusion procedure involves inserting a "cage" in the space usually occupied by the disc to maintain the disc space, and to prevent the vertebrae from collapsing and impinging the nerve roots. The cage is used in combination with bone graft material (either autograft or allograft) such that the two vertebrae and the graft material will grow together over time forming bridging bone between the two vertebrae. The fusion process typically takes 6-12 months after surgery. During in this time external bracing (orthotics) may be required. External factors such as smoking, osteoporosis, certain medications, and heavy activity can prolong or even prevent the fusion process. If fusion does not occur, patients may require reoperation.

[0008] One known fusion cage is described in U.S. Patent No. 4,904,261 and includes a horseshoe shaped body. This type cage is currently available in PEEK (polyetheretherketone). PEEK is used because it does not distort MRI and CT images of the vertebrae. However, PEEK is a material that does not allow bone to attach. Thus, fusion with a PEEK cage requires bridging bone to grow through the holes in the cage to provide stabilization.

[0009] It would be desirable to achieve immobilization of the vertebrae and maintain spacing between the adjacent vertebrae without the associated patient discomfort and long recovery time of traditional interbody fusion.

[0010] Another problem associated with the typical fusion procedure is the subsidence of the cage into the vertebral body. The typical fusion cage is formed with a large percentage of open space to allow the bone to grow through and form the bridging bone which immobilizes the discs. However, the large amount of open space means that the load on each segment of the cage is significantly higher than if the cage surface area was larger. This results in the cage subsiding or sinking into the bone over time and allows the disc space to collapse. In addition, the hard cortical bone on the outer surface of the vertebral body that transfers load to the interbody cage or spacer is often scraped, punctured or otherwise damaged to provide blood to the interbody bone graft to facilitate bone growth. This damage to the bone is used effectively to promote bone growth can also lead to subsidence.

[0011] The U.S. Food and Drug Administration approved the use of a genetically engineered protein, or rhBMP-2, for certain types of spine fusion surgery. RhBMP-2 is a genetically engineered version of a naturally occurring protein that helps to stimulate bone growth, marketed by Medtronic Sofamor Danek, Inc. as InFUSE™ Bone Graft. When InFUSE™ is used with the bone graft material it eliminates the need for painful bone graft harvesting and improves patients' recovery time. However, InFUSE™ adds significantly to the cost of a typical fusion surgery. Additionally, even with the bone graft and InFUSE™ bone may fail to grow completely between the two vertebrae or the cage may subside into the vertebrae such that the fusion fails to achieve its purpose of maintaining disc height and preventing motion.

[0012] In an attempt to treat disc related pain without fusion provided by bridging bone, an alternative approach has been developed, in which a movable, implantable, artificial intervertebral disc (or "disc prosthesis") is inserted between two vertebrae. A number of different artificial intervertebral discs are currently being developed. For example, U.S. Patent Application Publication Nos. 2005/0021146, 2005/0021145, and 2006/0025862, which are hereby incorporated by reference in their entirety, describe artificial intervertebral discs. Other examples of intervertebral disc prostheses are the LINK SB CHARITÉ™ disc prosthesis (provided by DePuy Spine, Inc.) the MOBIDISK™ disc prosthesis (provided by LDR Medical), the BRYAN™ cervical disc prosthesis (provided by Medtronic Sofamor Danek, Inc.), the PRODISC™ disc prosthesis or PRODISC-C™ disc prosthesis (from Synthes Stratec, Inc.), the PCM™ disc prosthesis (provided by Cervitech, Inc.), and the MAVERICK™ disc prosthesis (provided by Medtronic Sofomor Danek). Although existing disc prostheses provide advantages over traditional treatment methods, many patients are not

candidates for an artificial disc due to facet degeneration, instability, poor bone strength, previous surgery, multi-level disease, and pain sources that are non-discogenic.

[0013] Therefore, a need exists for improved spacer and method for spanning a space and maintaining disc spacing between two vertebrae after removal of an intervertebral disc. Ideally, such improved method and spacer would avoid the need for growth of bridging bone across the intervertebral space.

BRIEF SUMMARY OF THE INVENTION

[0014] Embodiments of the present invention provide an intervertebral spacer with and without shock absorption and methods of spanning a space formed upon removal of an intervertebral disc.

[0015] In accordance with one aspect of the present invention, a method of spanning a space formed by upon removal of an intervertebral disc includes the steps of: performing a discectomy to remove disc material between two adjacent vertebral bodies; placing an intervertebral spacer between the two adjacent vertebral bodies; and maintaining the disc space between the two adjacent vertebral bodies with the intervertebral spacer without the use of bone graft or bridging bone. The spacer includes two end plates, each end plate having a vertebral body contacting surface and an inner surface, and a connector interconnecting the inner surfaces of the two end plates in a compliant manner which limits motion between the plates to less than a total of 5 degrees of motion in any direction.

[0016] In accordance with another aspect of the invention, an intervertebral spacer for spanning a space formed by upon removal of an intervertebral disc includes two end plates sized and shaped to fit within an intervertebral space and a connector interconnecting the inner surfaces of the two end plates in a compliant manner which limits motion between the plates to less than a total of 5 degrees of motion in any direction. The intervertebral spacer is configured to permanently maintain the disc space between the two adjacent discs without the use of bridging bone.

[0017] In accordance with a further aspect of the invention, a method of spanning a space formed by upon removal of an intervertebral disc includes the steps of: performing a discectomy to remove disc material between two adjacent vertebral bodies; placing an intervertebral spacer between the two adjacent vertebral bodies; and maintaining the disc space between the two adjacent vertebral bodies with the intervertebral spacer within the

intervertebral space. The spacer includes two vertebral body contacting surfaces and means for limiting motion between the two vertebral body contacting surfaces to less than a total of 5 degrees. The vertebral body contacting surfaces have no holes therein or have holes which cover less than 40 percent of the vertebral body contacting surfaces.

[0018] In accordance with another aspect of the present invention, an intervertebral spacer for spanning a space formed by upon removal of an intervertebral disc includes a compliant spacer body sized and shaped to fit within an intervertebral space and two opposite vertebral body contacting surfaces formed on the spacer body. The spacer body limits motion between the vertebral body contacting surfaces to less than a total of 5 degrees and the vertebral body contacting surfaces have no holes therein or have holes which cover less than 40 percent of the vertebral body contacting surfaces.

[0019] In accordance with an additional aspect of the present invention, a method of performing an anterior/posterior fusion, includes the steps of: performing a discectomy to remove disc material between two adjacent vertebral bodies; anteriorly placing an intervertebral spacer between the two adjacent discs; maintaining the disc space between the two adjacent discs with the intervertebral spacer; adjusting an angle between the vertebral bodies posteriorly; and posteriorly placing a stabilization system to fix the angle between the vertebral bodies. The spacer includes a compliant spacer body sized and shaped to fit within an intervertebral space and two opposite vertebral body contacting surfaces formed on the spacer body wherein the spacer body limits motion between the vertebral body contacting surfaces to less than a total of 5 degrees.

BRIEF DESCRIPTION OF THE DRAWINGS

[0020] FIG. 1 is a perspective view of an intervertebral spacer according to one embodiment of the present invention;

[0021] FIG. 2 is a side cross sectional view of the intervertebral spacer of FIG. 1;

[0022] FIG. 3 is a bottom view of the intervertebral spacer of FIG. 1;

[0023] FIG. 4 is a top view of the intervertebral spacer of FIG. 1;

[0024] FIG. 5 is a perspective view of an intervertebral spacer according to another embodiment of the present invention;

[0025] FIG. 6 is a perspective view of an intervertebral spacer according to an embodiment with added screw fixation;

[0026] FIG. 7 is a perspective view of a further intervertebral spacer with added screw fixation; and

[0027] FIG. 8 is a perspective view of an alternative embodiment of another intervertebral spacer.

DETAILED DESCRIPTION OF THE INVENTION

[0028] Various embodiments of the present invention generally provide for an intervertebral spacer having upper and lower plates connected by a central connector which provides some limited amount of axial compliance or rotational motion between the upper and lower plates. The compliant intervertebral spacer according to the present invention can maintain disc height and prevent subsidence with a large surface area while substantially reducing recovery time by eliminating the need for bridging bone.

[0029] One example of an intervertebral spacer 10 for maintaining disc height between two adjacent vertebral discs is shown in FIG. 1. The spacer includes two end plates 20, 22, each end plate having a vertebral body contacting surface 24 and an inner surface 26, and a compliant connector 30 interconnecting the inner surfaces of the two end plates. As will be described below some limited rotational and axial motion may be provided between the two plates to reduce loading on the vertebral body/spacer interface. The compliance of the connector 30 as well as some small amount of translation and rotation is provided by lateral cuts or cuts 70 extending into the connector 30. The intervertebral spacer 10 when implanted between two vertebral discs maintains a desirable disc space between the two adjacent discs similar to that provided by a natural disc and eliminates the long recovery time required to grow bridging bone which is required in the traditional fusion surgery.

[0030] Although the connector 30 has been shown as circular in cross section, other shapes may be used including oval, elliptical, or rectangular. Although the connector has been shown as a single member connecting the plates 20, 22 in the center of the plates one or more compliant connectors may be provided in other configurations and at other locations. By way of example, a compliant connector may be the same or substantially the same diameter and shape as the plates, multiple connectors can be arranged in a rectangular pattern, or a hollow cylindrical connector can be used.

[0031] The upper and lower plates 20, 22 and connector 30 may be constructed from any suitable metal, alloy or combination of metals or alloys, such as but not limited to cobalt chrome alloys, titanium (such as grade 5 titanium), titanium based alloys, tantalum, nickel titanium alloys, stainless steel, and/or the like. They may also be formed of ceramics, biologically compatible polymers including PEEK, UHMWPE (ultra high molecular weight polyethylene) or fiber reinforced polymers. However, when polymer is used for the spacer 10 the vertebral body contacting surfaces 24 may be coated or otherwise covered with metal for fixation. The plates 20, 22 and the connector 20 may be formed of a one piece construction or may be formed of more than one piece, such as different materials coupled together. When the spacer 10 is formed of multiple materials, these materials are fixed together to form a unitary one piece spacer without separately moving parts.

[0032] Different materials may be used for different parts of the spacer 10 to optimize imaging characteristics. For example, the plates may be formed of titanium while the connector is formed of cobalt chromium alloy for improved imaging of the plates. Cobalt chrome molybdenum alloys when used for the plates 20, 22 may be treated with aluminum oxide blasting followed by a titanium plasma spray to improve bone integration. Other materials and coatings can also be used such as titanium coated with titanium nitride, aluminum oxide blasting, HA (hydroxylapatite) coating, micro HA coating, and/or bone integration promoting coatings. Any other suitable metals or combinations of metals may be used as well as ceramic or polymer materials, and combinations thereof. Any suitable technique may be used to couple materials together, such as snap fitting, slip fitting, lamination, interference fitting, use of adhesives, welding and/or the like.

[0033] In some embodiments, the outer surface 24 is planar. Oftentimes, the outer surface 24 will include one or more surface features and/or materials to enhance attachment of the spacer 10 to vertebral bone. For example, as shown in FIG. 2, the outer surface 24 may be machined to have serrations 40 or other surface features for promoting adhesion of the plates 20, 22 to a vertebra. In the embodiment shown, the serrations 40 are pyramid shaped serrations extending in mutually orthogonal directions, but other geometries such as teeth, grooves, ridges, pins, barbs or the like would also be useful. When the bone integration structures are ridges, teeth, barbs or similar structures, they may be angled to ease insertion and prevent migration. These bone integration structures can be used to precisely cut the bone during implantation to cause bleeding bone and encourage bone integration. Additionally, the outer surface 24 may be provided with a rough microfinish formed by

blasting with aluminum oxide microparticles or the like to improve bone integration. In some embodiments, the outer surface may also be titanium plasma sprayed or HA coated to further enhance attachment of the outer surface 24 to vertebral bone.

[0034] The outer surface 24 may also carry one or more upstanding fins 50, 52 extending in an anterior-posterior direction. The fins 50, 52 are configured to be placed in slots in the vertebral bodies. Preferably, the fins 50, 52 each have a height greater than a width and have a length greater than the height. In one embodiment, the fins 50, 52 are pierced by transverse holes 54 for bone ingrowth. The transverse holes 54 may be formed in any shape and may extend partially or all the way through the fins 50, 52. In alternative embodiments, the fins 50, 52 may be rotated away from the anterior-posterior axis, such as in a lateral-lateral orientation, a posterolateral-anterolateral orientation, or the like.

[0035] The fins 50, 52 provide improved attachment to the bone and prevent rotation of the plates 20, 22 in the bone. In some embodiments, the fins 50, 52 may extend from the surface 24 at an angle other than 90°. For example on one or more of the plates 20, 22 where multiple fins 52 are attached to the surface 24 the fins may be canted away from one another with the bases slightly closer together than their edges at an angle such as about 80-88 degrees. The fins 50, 52 may have any other suitable configuration including various numbers angles and curvatures, in various embodiments. In some embodiments, the fins 50, 52 may be omitted altogether. The embodiment of FIG. 1 illustrates a combination of one plate with a single fin 50 and another plate with a double fin 52. This arrangement is useful for double level disc replacements and utilizes offset slots in the vertebral body to prevent the rare occurrence of vertebral body splitting by avoiding cuts to the vertebral body in the same plane for multi-level implants. The combination of the single fin 50 and double fin 52 can also assist the surgeon in placement of the spacer in the correct orientation.

[0036] The spacer 10 has been shown with the fins 50, 52 as the primary fixation feature, however, the fins may also be augmented or replaced with one or more screws extending through the plates and into the bone. For example in the spacer 10 of FIG. 1 the upper fin 50 may be replace with a screw while the two lower fins 52 remain. The plates 20, 22 can be provided with one or a series of holes to allow screws to be inserted at different locations at the option of the surgeon. However, the holes should not be of such size or number that the coverage of the plate 20, 22 is decreased to such and extent that subsidence occurs. Alternately, the screws can pass laterally through one or more of the holes in the fins. When

one or more screws are provided, they may incorporate a locking feature to prevent the screws from backing out. The screws may also be provided with a bone integration coating.

[0037] Some limited holes 60 may also be provided in the plate as shown in FIG. 6 to allow bone in growth. However, if the outer surfaces 24 have holes 60 therein, the holes will cover less than 40 percent of the outer surface 24 which contacts the bone to prevent subsidence of the plates into the vertebral bodies. Preferably the holes will cover less than 25 percent, and more preferably less than 10 percent of the outer bone contacting surfaces. At the option of the surgeon, when the small holes are present in the plates 20, 24, bone graft can be placed in the space between the inner surfaces 26 of the plates to allow bone to grow through the plates.

[0038] The intervertebral spacer 10 shown herein is configured for placement in the intervertebral space from an anterior approach. It should be understood that all approaches can be used including PLIF (posterior lumbar interbody fusion), TLIF (transverse lumbar interbody fusion), XLIF (Lateral extracavitary interbody fusion), ALIF (anterior lumbar interbody fusion), trans-sacral, and other approaches. The shape of the intervertebral spacer would be modified depending on the approach. For example, for a posterior approach, the spacer may include two separate smaller spacers which are either positioned separately side-by-side in the intervertebral space or two spacers which are joined together once inside the intervertebral space. For a lateral approach, the intervertebral spacer may be formed in a more elongated, kidney bean or banana shape with a transversely oriented fin.

[0039] As shown in FIG. 1, the intervertebral spacer 10 is provided with shock absorption or some other limited motion between the two plates 20, 22 by providing a compliant connector 30. The limited motion provided by the compliant connector 30 is designed to reduce to forces on the interface between the outer surfaces 24 and the bone to improve long term fixation of the spacer. The compliance of the connector 30 allows motion between the vertebral bodies to be accommodated by the compliance in the spacer rather than causing one or both of the vertebral bodies to pull away from the plates 20, 22. The compliant connector 30 provides limited relative motion between the plates which may include compliance of up to about 2 mm, rotation of less than 5 degrees, and/or translation of up to about 1 mm.

[0040] In the intervertebral spacer 10 of FIG. 1, the compliance as well as some small amount of translation and rotation is provided by thee lateral cuts or slots 70 extending into the connector 30. The compliant connector 30 is formed as a unitary member with at least

one lateral cut 70 positioned between the inner surfaces 26 to allow the upper and lower plates 20, 22 to move resiliently toward and away from each other. The unitary or one piece construction of the spacer 10 provides significant advantages over multi-part implants both in durability and manufacturability. However, the spacer 10 can also be formed as multiple parts where different properties are desired from the different parts, such as different radiopacities, different strengths, or different flexibility properties. The lateral cuts 70 in the connector 30 allow the connector to function as a compliant member without affecting the function of the upper and lower plates of the spacer 10.

[0041] Preferably the connector 30 is made of metal such as titanium, cobalt chromium alloy, stainless steel, tantalum, nickel titanium or a combination thereof. These materials also can be designed to provide a device which is deformable in the elastic region of the stress/strain curve and will not plastically deform during compression.

[0042] In the embodiment shown in FIGS. 1 and 2, the lateral cuts or slits 70 extend into the core in three different directions which are each 120 degrees from each other. The number of cuts can be varied to change the amount of compliance of the connector 30. When a load is applied to the upper and lower plates 20, 22 the connector 30 will compress with each of the cuts 70 closing and the total amount of compression possible depending on the number, arrangement, and height of the cuts. The cuts 70 form cantilevered portions above and below each of the cuts which function like cantilevers or leaf springs to allow the connector 30 to be compressed.

[0043] The connector 30 can be modified with different numbers of cuts 70 and different cutting directions. There may be one or more than one cut in each of the cutting directions. The material remaining after the cuts 70 are made in the connector is called a column. A shallow cut 70 and a large column provides a stiffer spacer 10 with more stability in shear (less translation of the plates), while a deeper cut and smaller column provides a more compliant spacer and more translation between the plates. The shape of the columns can be varied to vary the properties of the spacer. In the embodiment shown the cuts 70 are at least two thirds of the way through the connector 30 width or diameter, and preferably at least three quarters of the way through the connector width. Although the connector130 has been shown as circular in cross section, other shapes may be used including oval, elliptical, rectangular, and others.

[0044] The cuts 70 may be modified to be non uniform to provide preferential deflection in one or more bending directions. Preferential deflection is useful to provide increase anterior –posterior compliance and less lateral compliance or the other way around.

[0045] FIGS. 1 and 2 illustrate an embodiment of the compliant spacer 10 with lateral cuts 70 in multiple directions with the lateral cuts each having a slot width which is substantially constant along the cuts. This constant width of the cuts 70 provides a device which has a hard stop. However, the lateral cuts 70 can also be designed with varying widths to tailor the compliance properties of the spacer. A variable stiffness shock absorbing spacer may be formed with cuts 70 with tapering widths in which the width of the cuts 70 is smallest where the cut terminates adjacent the column and is largest at the edge of the connector 30 furthest from the column. In this version, each of the cuts 70 acts as a non linear spring providing progressively stiffer behavior upon larger compression. This is due to the fact that progressively more material on the sides of the cuts 70 is in contact as the spacer is compressed. The tapered width cuts 70 can provide the additional benefit of providing a flushing action during operation that moves any accumulated material out of the cuts.

[0046] As shown in FIG 1 and 2, the cuts 70 can include a stress relief at the ends of the cuts which increases the fatigue life of the device by reducing the stress concentration at the ends of the cuts. These stress relief can be provided in any known configuration.

[0047] An alternative embodiment of a shock absorbing spacer would include one or more spiral cuts in the connector and a small central bore through the spacer. A single spiral cut forms a continuous spring element or multiple spiral cuts provide multiple spring elements which provides compliance to the core. Two or more spiral cuts arranged in opposite directions can be formed in the core. Since it is desirable to limit relative rotation between the plates 20, 22 multiple spiral cuts in opposite directions can be used which offset rotation of each other.

[0048] As shown in FIG. 5, some limited holes 60 may also be provided in the plates 20, 22 to allow bone in growth. Holes provided in a typical fusion spacer provide a spacer with little structural support and maximum area for bone growth. Thus, the load transferred across the disc space per unit area of spacer is quite high resulting in possible subsidence of the typical spacer. In the spacer 10 of the present invention, the load transfer is spread across a larger area. If the outer surfaces 24 have holes 60 therein, the holes will cover less than 40 percent of the outer surface 24 which contacts the bone to prevent subsidence of the plates into the

vertebral bodies. Preferably the holes will cover less than 25 percent, and more preferably less than 10 percent of the outer bone contacting surfaces. At the option of the surgeon, when the small holes are present in the plates 20, 22, bone graft can be placed in the space between the inner surfaces 26 of the plates to encourage bone to grow through the plates. The holes 60, when present can take on a variety of shapes including circular, as shown, rectangular, polygonal or other irregular shapes. The holes 60 may extend through the various parts of the spacer including through the connector or through the fins. The holes 60 may change shape or size as they pass through portions of the spacer, for example, holes through the plates and the connector may taper to a smaller interior diameter. The limited motion provided by the compliant spacer 10 can stimulate bone growth through the holes 60 in the spacer.

[0049] FIG. 6 shows another embodiment of a spacer 100 having a single fin 50 on the top and bottom and two screw holes 80 and corresponding fixation screws 90. The screws 90 extend at an angle of about 30 to about 60 degrees with respect to the vertebral body contacting surfaces 24 of the spacer. The spacer 100 also includes a connector 30 between the vertebral body contacting surfaces 24 which is formed in one piece with the upper and lower plates and includes cuts 70 providing compliance to the spacer. The fixation screws 90 can include a locking mechanism, such as a locking thread or a separate locking member which is inserted into the screw holes 80 after the screws are inserted to prevent backing out of the screws.

[0050] FIG. 7 illustrates an alternative embodiment of a spacer 110 having a single superior fin 50, two inferior fins 52, and three alternating holes 80 for receiving bone screws (not shown). The spacer 110 has multiple fixation structures to provide the patient near immediate mobility after the fusion procedure. As an alternative to the alternating angled holes 80, the spacer 110 can be formed with an anterior flange extending from the top and the bottom at the anterior side of the plate. This optional flange can include one or more holes for receiving bone screws placed laterally. The laterally placed bone screws can prevent interference in the event of multilevel fusions and are particularly useful for a cervical fusion where space is more limited.

[0051] FIG. 8 shows a further alternative embodiment of a spacer 120 having multiple cuts 70a-70d. A first slot 70a on the anterior edge of the spacer splits into two cuts 70b toward the posterior edge of the spacer and terminate before the posterior edge of the spacer (not shown). A pair of third cuts 70c are positioned above and below the two cuts 70b and extend

from the posterior edge of the spacer, while a larger fourth slot 70d is provided at a center of the spacer. This arrangement of cuts 70a-70d is designed to tailor the compliance of the spacer 120 for a particular application. Other numbers and arrangements of cuts can also be used.

[0052] According to one embodiment of the invention, the cuts in the shock absorbing spacer according to any of the embodiments described herein may be manufactured by wire EDM (electrical discharge machining), molding, laser cutting , or the like. A number of lateral cuts 70 can vary from 1 to about 20 for a spacer for cervical discs and from 1 to about 40 for a spacer for lumbar discs. A width of the lateral cuts 70 in the direction of the height of the spacer 10 is about 0.01 mm to about 2 mm, preferably about 0.05 to about 1 mm. The cuts can be perpendicular to the axis of the spacer or can be angled. For example a spiral cut can be angled to provide a conical surface of the cut and provide a limit on translation of the plates.

[0053] In one embodiment of the present invention, for a cervical application, the maximum deformation of the shock absorbing spacer is about 0.1 to about 1 mm, and is preferably about 0.2 to about 0.8 mm. For a lumbar application, the maximum deformation of the shock absorbing spacer is about 0.1 to about 2 mm, and is preferably about 0.4 to about 1.5 mm.

[0054] Although motion between the plates 20, 22 of the spacer 10 has been describe herein as provided by lateral cuts, it should be understood that this motion can be provided in a number of other known manners, such as use of resilient materials, or movable joints as long as the motion is limited to the small amount of motion allowable in a patient requiring a fusion procedure including compliance or vertical motion between the plates of up to about 2 mm, rotation between the plates of less than 5 degrees, and translation between the plates of up to about 1 mm. Preferably, the motion for a lumbar application is limited to up to about 2 mm of vertical or axial motion, rotation between the plates of less than 3 degrees, and translation between the plates of up to about 0.5 mm. Preferably, the motion for a cervical application is limited to up to about 1 mm of vertical or axial motion, rotation between the plates of less than 3 degrees, and translation between the plates of up to about 0.5 mm.

[0055] The spacers 10, 100, 110, 120 can be provided in different sizes, with different plate sizes, angles between plates, lordosis angles, and heights for different patients or applications. In addition, the shock absorbing spacer can be provided in different compliances for different

patients. In addition, the compliance and/or height of the spacer can be adjustable, such as by rotating an adjustment screw before or after implantation. The spacers preferably are sized to provide substantial coverage of the vertebral surfaces. For example in an anterior procedure, the plates 20, 22 are preferably sized to cover at least 50 percent of the vertebral surface. In posterior or lateral procedures the coverage of the vertebral surface may be somewhat smaller due to the small size of the access area, i.e. the posterior or lateral spacers may cover about 40 percent or more of the vertebral surface with a one or two part spacer.

[0056] One common fusion procedure, referred to as an anterior/posterior fusion, uses of one or more fusion cages to maintain the disc space while bridging bone grows and also uses a system of posterior screws and rods for further stabilization. Fusing both the front and back provides a high degree of stability for the spine and a large surface area for the bone fusion to occur. Also, approaching both sides of the spine often allows for a more aggressive reduction of motion for patients who have deformity in the lower back (e.g. isthmic spondylolisthesis).

[0057] According to one method of the present invention, the anterior approach is performed first by removing the disc material and cutting the anterior longitudinal ligament (which lays on the front of the disc space). The surgeon then must choose a compliant spacer based on a size of the vertebrae and an estimated angle between the vertebral bodies. After the spacer is positioned anteriorly, the patient is turned over for the implantation of the posterior stabilization system. In instances where the spacer angle selected was incorrect or the surgeon would like to alter the angle of the vertebral bodies to optimize the combined system for the patient the fusion cage does not allow this modification of the angle. The compliant fusion spacer of the present invention provides a particular advantage when used in an anterior/posterior fusion with a posterior stabilization system that it allows the angle between the vertebral bodies to be adjusted somewhat, up to 5 degrees, after implantation of the spacer and before the implantation of the posterior stabilization system to optimize the system for the patient.

[0058] The intervertebral spacers of the present invention may also be used with a posterior stabilization system, dynamic rod stabilization system, or interspinous spacer. In one example, a posterior intervertebral spacer with two parts can be inserted by a PLIF or TLIF approach and used with a posterior stabilization system including screws and rods. This system provides the advantage of maintenance of disc height and stabilization with an entirely posterior approach.

[0059] While the exemplary embodiments have been described in some detail, by way of example and for clarity of understanding, those of skill in the art will recognize that a variety of modifications, adaptations, and changes may be employed. Hence, the scope of the present invention should be limited solely by the appended claims.

WHAT IS CLAIMED IS:

1. A method of spanning a space formed by upon removal of an intervertebral disc, the method comprising:

performing a discectomy to remove disc material between two adjacent vertebral bodies;

placing an intervertebral spacer between the two adjacent vertebral bodies, the spacer comprising two end plates, each end plate having a vertebral body contacting surface and an inner surface, and a connector interconnecting the inner surfaces of the two end plates in a compliant manner which limits motion between the plates to less than a total of 5 degrees of motion in any direction; and

maintaining the disc space between the two adjacent vertebral bodies with the intervertebral spacer without the use of bone graft or bridging bone.

2. The method of Claim 1, wherein the connector is a compliant connector which allows axial motion between the two end plates.

3. The method of Claim 2, wherein the axial motion is limited to less than 2 mm.

4. The method of Claim 1, wherein the connector is a complaint connector which allows rotation between the two end plates.

5. The method of Claim 2, wherein the compliant connector has a plurality of cuts formed therein to create a unitary flexible member.

6. The method of Claim 5, wherein the two end plates and connector are formed of a single piece of metal.

7. The method of Claim 1, further comprising cutting at least one slot in each of the adjacent vertebrae and placing a fin into the slot in each vertebrae.

8. The method of Claim 7, wherein the intervertebral spacer is held in place between the adjacent vertebral bodies by a fixation means, and wherein the fixation means is at least one of a screw, serrations, teeth, pyramids or grooves.

9. An intervertebral spacer for spanning a space formed by upon removal of an intervertebral disc, the spacer comprising:

two end plates sized and shaped to fit within an intervertebral space, each end plate having a vertebral body contacting surface an inner surface;

a connector interconnecting the inner surfaces of the two end plates in a compliant manner which limits motion between the plates to less than a total of 5 degrees of motion in any direction; and

wherein the intervertebral spacer is configured to permanently maintain the disc space between the two adjacent discs with the intervertebral spacer without the use of bridging bone.

10. The spacer of Claim 9, wherein the connector is a compliant connector which allows axial motion between the two end plates.

11. The spacer of Claim 10, wherein the axial motion is limited to less than 2 mm.

12. The spacer of Claim 9, wherein the connector is a complaint connector which allows rotation between the two end plates.

13. The spacer of Claim 12, wherein the compliant connector has a plurality of cuts formed therein to create a unitary compliant member.

14. The spacer of Claim 9, wherein the two end plates and connector are formed of a single piece of metal.

15. The spacer of Claim 9, wherein the connector limits motion between the plates to less than a total of 3 degrees of motion in any direction.

16. The spacer of Claim 9, further comprising at least one fin extending from each of the vertebral body contacting surfaces.

17. A method of spanning a space formed by upon removal of an intervertebral disc, the method comprising:

performing a discectomy to remove disc material between two adjacent vertebral bodies;

placing an intervertebral spacer between the two adjacent vertebral bodies, the spacer comprising two vertebral body contacting surfaces and the including means for limiting motion between the two vertebral body contacting surfaces to less than a total of 5 degrees; and

maintaining the disc space between the two adjacent vertebral bodies with the intervertebral spacer within the intervertebral space, wherein the vertebral body contacting surfaces have no holes therein or have holes which cover less than 40 percent of the vertebral body contacting surfaces.

18. The method of Claim 17, wherein the intervertebral spacer allows axial motion between the two end plates.

19. The method of Claim 18, wherein the axial motion is limited to less than 2 mm.

20. The method of Claim 17, wherein the intervertebral spacer includes a compliant portion which allows rotation between the two end plates.

21. The method of Claim 20, wherein the compliant portion has a plurality of cuts formed therein to create a unitary flexible member.

22. The method of Claim 17, wherein the vertebral body contacting surfaces have holes which cover less than 25 percent of the vertebral body contacting surfaces.

23. An intervertebral spacer for spanning a space formed by upon removal of an intervertebral disc, the spacer comprising:

a compliant spacer body sized and shaped to fit within an intervertebral space;

two opposite vertebral body contacting surfaces formed on the spacer body;

wherein the spacer body limits motion between the vertebral body contacting surfaces to less than a total of 5 degrees; and

wherein the vertebral body contacting surfaces have no holes therein or have holes which cover less than 40 percent of the vertebral body contacting surfaces.

24. The spacer of Claim 23, wherein the compliant spacer body allows rotation between the two end plates.

25. The spacer of Claim 23, wherein the compliant spacer body allows axial motion between the vertebral body contacting surfaces of less than 2 mm.

26. The spacer of Claim 23, wherein the compliant spacer body has a plurality of cuts formed therein to create a unitary flexible member.

27. The spacer of Claim 23, wherein the vertebral body contacting surfaces and the compliant spacer body are formed as a single unitary piece.

28. The spacer of Claim 24, wherein the spacer body limits rotational motion between the plates to less than a total of 3 degrees in any direction.

29. The spacer of Claim 23, further comprising at least one fin extending from each of the vertebral body contacting surfaces.

30. The spacer of Claim 23, wherein the spacer has holes which cover less than 25 percent of the vertebral body contacting surfaces.

31. The spacer of Claim 23, wherein the spacer body includes a plurality of transverse cuts which create a spring element.

32. The spacer of Claim 23, wherein the spacer body includes at least one hole therein and a fixation screw received therein.

33. A method of performing an anterior/posterior fusion, the method comprising:

performing a discectomy to remove disc material between two adjacent vertebral bodies;

anteriorly placing an intervertebral spacer between the two adjacent discs, the spacer comprising a compliant spacer body sized and shaped to fit within an intervertebral space and two opposite vertebral body contacting surfaces formed on the spacer body wherein the spacer body limits motion between the vertebral body contacting surfaces to less than a total of 5 degrees;

maintaining the disc space between the two adjacent discs with the intervertebral spacer;

adjusting an angle between the vertebral bodies posteriorly; and

posteriorly placing a stabilization system to fix the angle between the vertebral bodies.

34. The method of Claim 32, wherein the posteriorly placed stabilization system includes at least one screw placed into each of the vertebral bodies and at least one connector therebetween.

35. The method of Claim 32, wherein the method is performed without the use of bone graft.

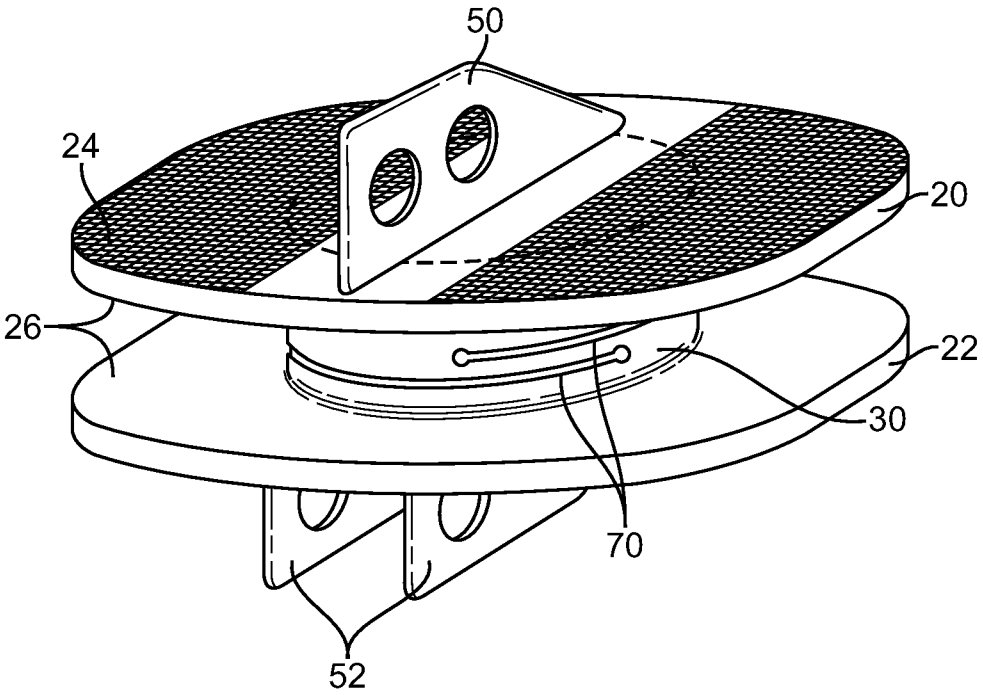

FIG. 1

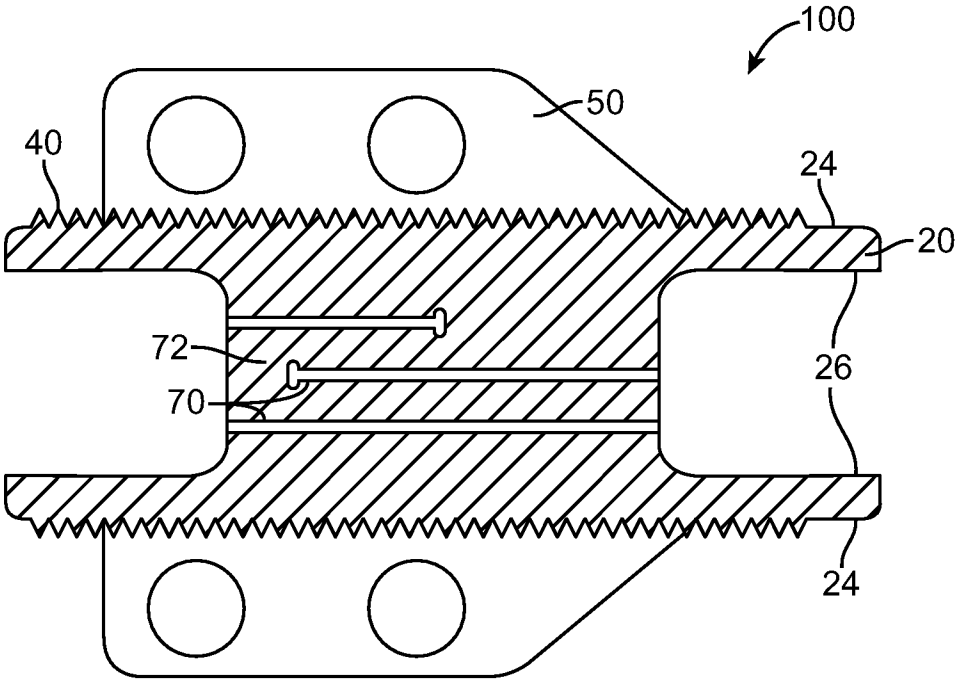

FIG. 2

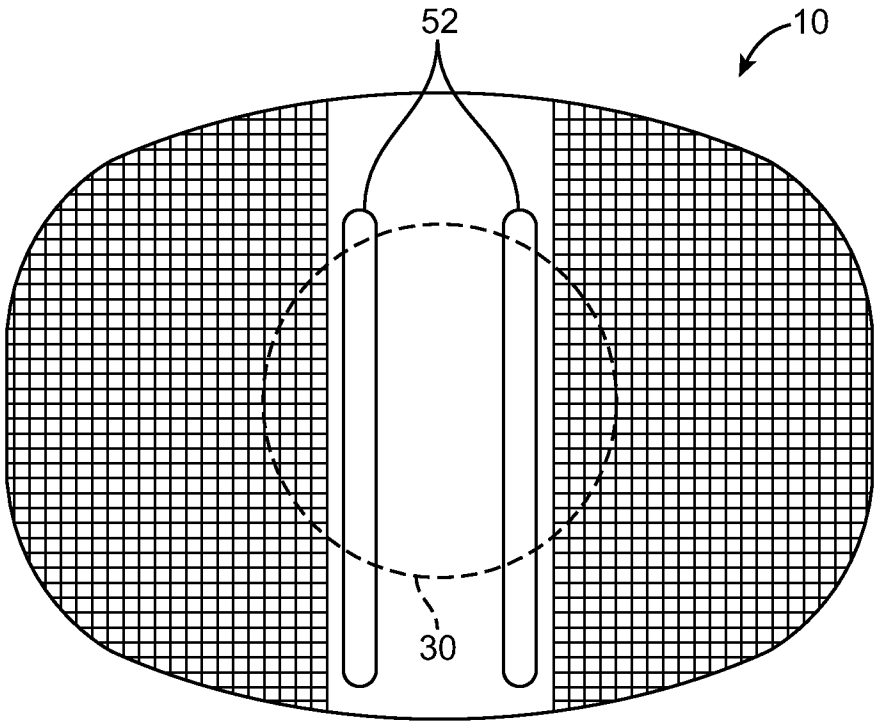

FIG. 3

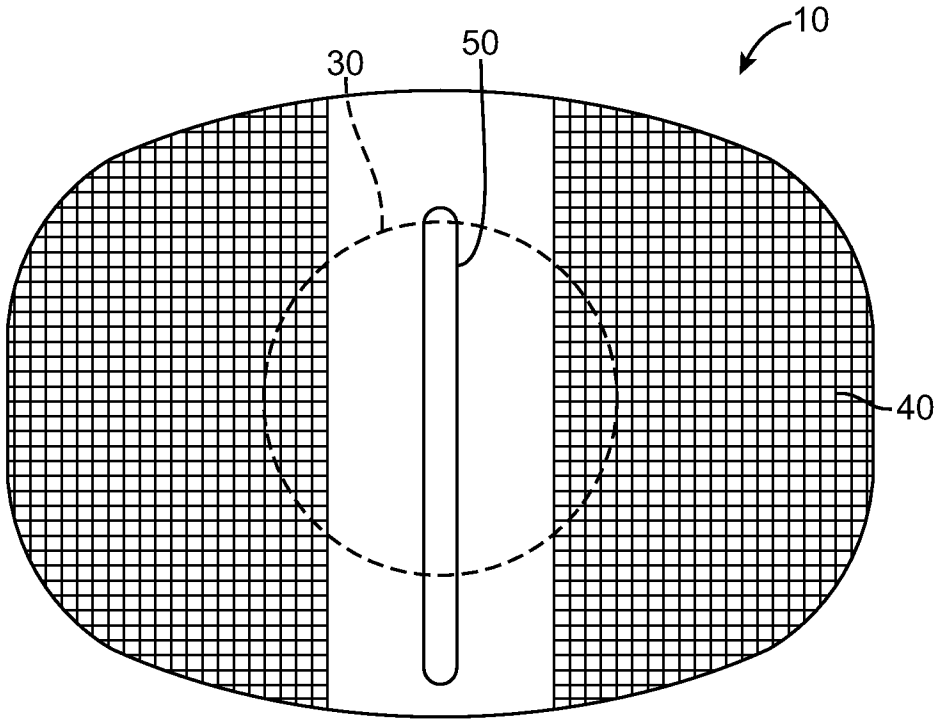

FIG. 4

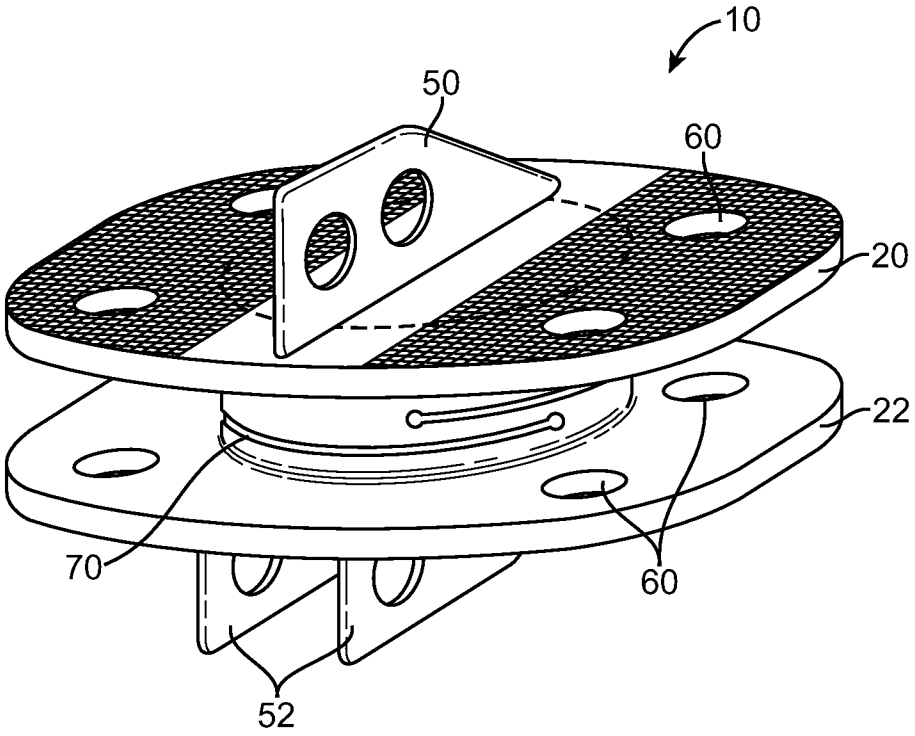

FIG. 5

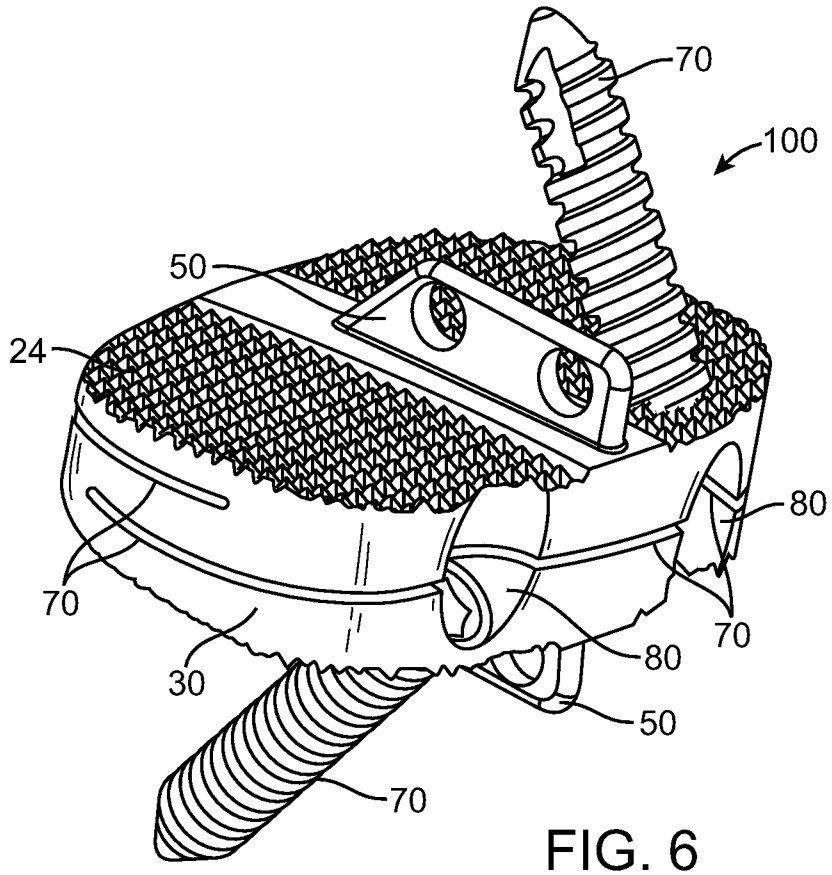

FIG. 6

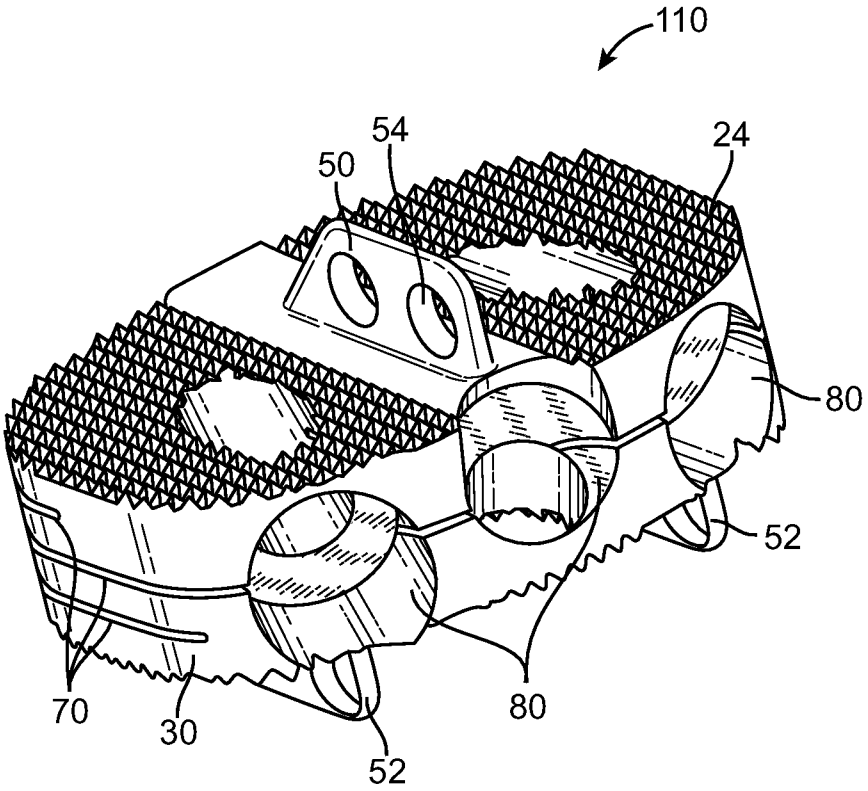

FIG. 7

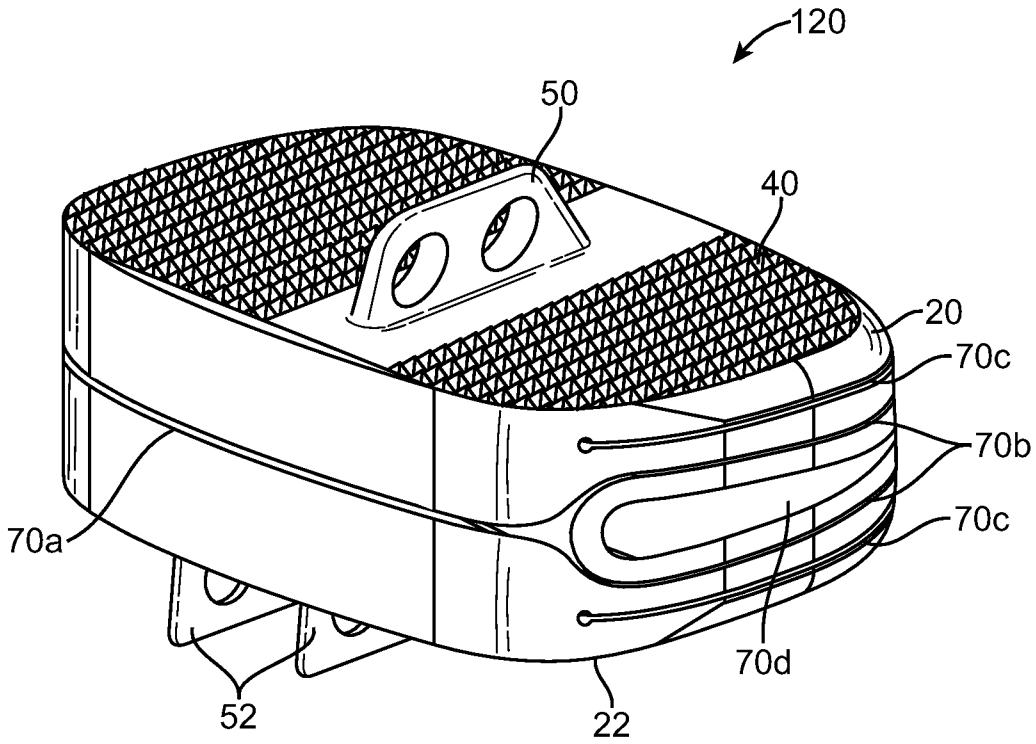

FIG. 8

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2008/080804

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61F 2/44 (2008.04)
USPC - 623/17.15
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - A61F 2/44 (2008.04)
USPC - 623/17.11, 17.15, 17.16

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
MicroPatent, Google Patents

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2005/0021146 A1 (DE VILLIERS et al) 27 January 2005 (27.01.2005) entire document	1, 2, 4, 5, 7-10, 12-13, 16-18, 20-24, 26, 29-35
Y		3, 6, 11, 14, 15, 19, 25, 27, 28
Y	US 6,770,095 B2 (GRINBERG et al) 03 August 2004 (03.08.2004) entire document	3, 11, 15, 19, 25, 28
Y	US 6,136,031 A (MIDDLETON) 24 October 2000 (24.10.2000) entire document	6, 14, 27

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

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
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"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
16 December 2008	29 DEC 2008
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (April 2005)