(19) World Intellectual Property Organization

International Bureau



(10) International Publication Number

WO 2008/060401 A2

(43) International Publication Date 22 May 2008 (22.05.2008)

(51) International Patent Classification: A61F 2/44 (2006.01)

(21) International Application Number:

PCT/US2007/023017

(22) International Filing Date: 31 October 2007 (31.10.2007)

(25) Filing Language: **English**

English (26) Publication Language:

(30) Priority Data:

PCT/US2006/039595

9 October 2006 (09.10.2006) US

11/544,136 9 October 2006 (09.10.2006) US

(63) Related by continuation (CON) or continuation-in-part (CIP) to earlier application:

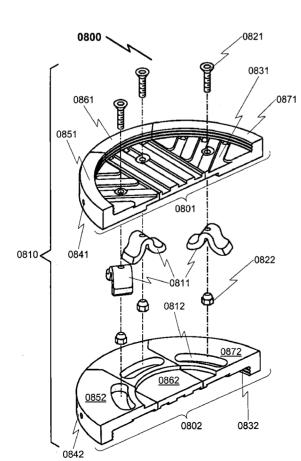
US 11/544,136 (CIP) 9 October 2006 (09.10.2006) Filed on

(71) Applicants and

- (72) Inventors: CARVER, Donna Jean [US/US]; Donna Jean Carver, 1100 Saddle Court, Mansfield, TX 76063-5730 (US). BARRIE, Chad, Anthony [US/US]; Chad Anthony Barrie, 501 Blueberry Hill Lane, Mansfield, TX 76063-3637 (US). **HERRERA**, **John**, **David** [US/US]; John David Herrera, 2005 Wahoo Drive, Mansfield, TX 76063-8528 (US).
- (74) Agent: KLUGHART, Kevin, Mark; 2516 Lillian Miller Parkway, Suite 115, Denton, TX 76210-7205 (US).
- (81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY,

[Continued on next page]

(54) Title: ARTIFICIAL SPINAL DISC REPLACEMENT SYSTEM AND METHOD



(57) Abstract: An artificial spinal disc implant system for intervertebral disc replacement (0810) is disclosed which is formed from an upper (0801) and lower (0802) bracket which mate to upper and lower spinal vertebrae via upper (0831) and lower (0832) vertebral contact surfaces on the upper (0801) and lower (0802) brackets. The upper (0801) and lower (0802) brackets are joined together via springs (0811) connected to the upper bracket (0801) which rest in spring guide tracks (0812) on the lower bracket. The springs (0811) are connected to the upper bracket (0801) via the use of spring fasteners (0821, 0822). The upper (0801) and lower (0802) brackets may be installed in sections (0851, 0861, 0871, 0852, 0862, 0872) using laparoscopic surgical techniques and are attached to upper/lower spinal vertebrae respectively via adhesive means applied using injection holes/ports (0841, 0842) in the upper (0801) and lower (0802) brackets respectively.



TJ, TM, TN, TR, TT, TZ, UA, UG, US (patent), 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, MT, 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).

Declarations under Rule 4.17:

- as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))
- of inventorship (Rule 4.17(iv))

Published:

- without international search report and to be republished upon receipt of that report
- the filing date of the international application is within two months from the date of expiration of the priority period
- with information concerning one or more priority claims considered void

-- 1 --

SPECIFICATION

TITLE OF INVENTION

ARTIFICIAL SPINAL DISC REPLACEMENT SYSTEM AND METHOD

CROSS REFERENCE TO RELATED APPLICATIONS

This patent application is a continuation-in-part of 5 United States Patent Application for "ARTIFICIAL SPINAL DISC REPLACEMENT SYSTEM AND METHOD", S/N 11/544,136, docket DJC-2006-002 filed on 10/9/2006, and submitted to the USPTO via 10/9/2006 with tracking Mail on Express 10 ER618467378US. Applicant claims benefit pursuant to 35 U.S.C. § 120 of this Utility Patent Application and hereby incorporates by reference this Utility Patent Application. New matter contained in the current document is generally illustrated in FIGs. 41 - FIG. 51 and referencing text contained herein. 15

Applicant claims benefit pursuant to 35 U.S.C. § 119 and hereby incorporates by reference Provisional Patent Application for "ARTIFICIAL SPINAL DISC REPLACEMENT SYSTEM AND METHOD", S/N 60/725,460, docket DJC-2005-001, filed 10/10/2005, and submitted to the USPTO with Express Mail on 10/10/2005 with tracking number ER618466616US.

-- 2 --

PARTIAL WAIVER OF COPYRIGHT

All of the material in this patent application is subject to copyright protection under the copyright laws of the United States and of other countries. As of the first effective filing date of the present application, this material is protected as unpublished material.

5

10

15

However, permission to copy this material is hereby granted to the extent that the copyright owner has no objection to the facsimile reproduction by anyone of the patent documentation or patent disclosure, as it appears in the United States Patent and Trademark Office patent file or records, but otherwise reserves all copyright rights whatsoever.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH

OR DEVELOPMENT

Not Applicable

REFERENCE TO A MICROFICHE APPENDIX

Not Applicable

-- 3 --

FIELD OF THE INVENTION

The field of the present invention relates to the use of artificial spinal disc replacements, including systems and methods associated with same, and generally includes apparatus associated with United States Patent Classification 623/17.16 and methods of installing these apparatus on patients.

5

20

25

DESCRIPTION OF THE PRIOR ART

Artificial Disc Replacement Revision

In a recent study, (a multi-center prospective clinical trial of 688 patients, 375 of whom were randomized to receive either a artificial disc or a single level lumbar spinal fusion), although the rate of revision was 2% lower in the artificial disc, the results showed that a revision may still be necessary in an artificial disc replacement nearly as often as it is in traditional spinal fusion surgery.

In clinical trials (one 2-year study recently presented to the FDA panel) comparing artificial disc replacement to spinal fusion surgery, results have already proven that artificial disc patients were able to maintain flexibility, experienced improvements in pain and functional ability, required shorter hospital stays, and had greater satisfaction with the outcome of their procedure.

Current State of the Art (0100, 0200)

There are currently several types of artificial disc replacements on the U.S. market. Some of these artificial

-- 4 --

discs are known as the Charite, Prodisc, Maverick, and the There have been other artificial discs in the past (such as the Acroflex), but those have suffered distressing failure for the patients. Examples of the present state of spinal disc replacements are generally the art in illustrated in FIG. 1 (0100) extracted from United States Patent 6,764,512 issued to Arnold Keller on 7/20/2004 for PLASTIC IMPLANT WITH CHANNEL FOR RADIOGRAPHIC CONTRAST WIRE, and FIG. 2 (0200) extracted from United States Patent 6,726,720 issued to Raymond Ross, Michael O'Neal, and Mark Boomer on 4/27/2004 for MODULAR DISC PROSTHESIS. (0200) is commonly referred to as the Charite spinal disc replacement, and is widely used in the arena of spinal disc replacement.

5

10

15

20

25

30

Prior Art Surgical Procedures (0300)

The current procedure for performing the artificial disc replacement is typically done with two surgeons, working together. A general or vascular surgeon approaches the spine through and incision in the abdomen (as generally illustrated in FIG. 3 (0300)) and carefully moves internal organs and blood vessels out of the way (0311) to provide access to the spine (0301). Then a spine surgeon uses special tools to remove the damaged disc and creates a space between the two vertebrae for the implantation of the artificial disc. The procedure general takes one to two hours, and as illustrated in FIG. 3, is highly invasive and subjects the patient (0310) to risks of infection and other surgical complications.

In a spinal fusion surgery, the damaged disc is removed and the vertebrae are joined together using bone grafts and metal screw and/or cages so that motion can no longer occur in this area of the spine. Often times with spinal fusion

-- 5 --

surgery, the bone graft used to pack the disc space is bone that the surgeon has to remove from the patient's hip. This means that the patient ends up having two incisions, the second one being over the superior crest of the ilium where the bone is harvested (scraped off). During recovery, the patient may experience pain in the hip at the harvest site. Patients usually have to wear a brace for about three months after surgery and may need to be fitted with a bone stimulator to promote healing at the fusion site.

BACKGROUND OF THE INVENTION

10

15

20

25

30

Overview (0300)

intervertebral ("spinal") disc as generally illustrated in FIG. 3 (0301) performs several functions intervertebral including maintaining normal ("spacer"), absorbing and transferring forces of spinal disturbances ("shock absorber") and a fulcrum of motion. A normal intervertebral disc is comprised of a gelatinous central portion called the nucleus pulposus and surrounded by an outer ligamentous ring called the annulus fibrosus. The gelatinous nuclear material directs the forces of axial loading outward and the annular fibers help distribute that force. The annulus fibrosus has overlapping radial bands to "seal" the nucleus and allow intradiscal pressures to rise as the disc is loaded, as well as allow torsional stresses to be distributed through the annulus under normal loading without rupture.

Unfortunately, injury to the spine or spinal discs is a common occurrence in the workplace, resulting in significant pain and suffering for patients so afflicted. About 65 million Americans suffer from low back pain every year, according to the American Association of Neurological

-- 6 --

Surgeons (AANS). Americans spend about USD\$50 billion each year on low back pain, which represents the most common cause of job-related disability and lost work days in the United States. More than 12 million people are reported to have degenerative disc disease and more than 200,000 have lumbar spinal fusion surgery every year. Lumbar spinal fusion surgery is a common surgical treatment for low back pain or degenerative disc disease and is often effective in reducing pain, but it limits range-of-motion (ROM) and may transfer extra stress to discs above and below the fusion site.

Spinal Disc Injury Overview

10

15

20

25

The vertebral column has 24 individual vertebrae arranged in cervical, thoracic and lumbar regions. sacral and coccygeal vertebrae are fused. The seven mobile cervical vertebrae support the neck and the (6-8 lb) head. The cervical spine is normally curved into lordosis. twelve thoracic vertebrae support the thorax, head, They articulate with the 12 ribs bilaterally. thoracic spine is curved into kyphosis. The five lumbar vertebrae support the upper body, torso and low back. column of these vertebrae becomes curved at the onset of walking (1-2 years of age) into lordosis. The sacrum is the keystone of a weight bearing arch involving the hip bones. The vertebral curvatures may be affected (usually exaggerated) by posture, activity, obesity, pregnancy, trauma, and / or disease. A significant, possibly disabling, lateral curve of the spine which may occur for many reasons is called scoliosis.

The intervertebral disc consists of the annulus fibrosus (concentric interwoven collegenous fibers integrated with cartilage cells) attached to the vertebral bodies above and below, and the more central nucleus

-- 7 **--**

pulposus (a mass of degenerated collagen, proteoglycans and The discs make possible movement between the water). vertebral bodies. With aging, the discs dehydrate and thin, resulting in a loss of disc height. The cervical and lumbar 5 discs, particularly, are subject to early degeneration from one or more of a number of causes. Weakening and / or tearing of the annulus can result in a broad-based bulge or a localized (focal) protrusion of the nucleus and adjacent annulus. As such, this event can compress a spinal nerve root.

10

15

20

25

30

Each pair of individual, unfused vertebrae constitutes a motion segment, the basic movable unit of the back. Combined movements of motion segments underlie movement of the neck and the middle and low back. Each pair of vertebrae in a motion segment, except C1-C2, is attached by joints: a partly movable, intervertebral disc three anteriorly, and a pair of gliding synovial (zygapophyseal) joints posteriorly. Ligaments secure the bones together and encapsulate the facet joints (joint The vertebral or neural canal transmits the capsules). spinal cord. The spinal cord is the lower extension of the central nervous system. It takes off from the medulla oblongata at the foramen magnum of the skull and ends as the conus medullaris at the vertebral level of L1 or L2. bulges slightly in the lower cervical and lumbar segments where it gives off the roots of spinal nerves destined for the upper and lower limbs, respectively. The cord is ensheathed by three coverings (meninges): the inner pia mater, arachnoid, and the outer dura mater. The spinal cord is a center for spinal reflexes, a source of motor commands for muscles below the head, and a receiver of sensory input below the head. Located bilaterally between each pair of vertebral pedicles are passageways, each intervertebral foramen, that are transmitting the spinal

-- 8 --

nerves from the spinal cord. Spinal nerves are collections of axons of sensory and motor neurons located in or adjacent to the spinal cord. Spinal nerves arise from nerve roots that come directly off the spinal cord. Thirty-one pairs of spinal nerves supply the body structure with sensory and motor innervation, except for those areas covered by the cranial nerves. From above to below, there are 8 cervical spinal nerves (C1-C8), 12 thoracic (T1-T12), 5 lumbar (L1-L5), 5 sacral (S1-S5), and one coccygeal (Co1).

The planes (orientation) of the articular facets determine the direction and influence the degree of motion segment movement. The plane of the cervical facets is angled coronally off the horizontal plane about 30 degrees. Considerable freedom of movement of the cervical spine is permitted in all planes (sagital, coronal, horizontal). The thoracic facets lie more vertical in the coronal plane and are virtually non-weightbearing. The range-of-motion here is significantly limited in all planes, less so in rotation. The plane of the lumbar facets is largely sagittal, resisting rotation of the lumbar spine, transitioning to a more coronal orientation at L5-S1. The L4-L5 facet joints permit the greatest degree of lumbar motion in all planes.

10

15

20

25

30

Extension of the weight bearing joints is an antigravity function and extensor muscles of these joints tend to keep the standing body vertically straight. The center of gravity of an average human being standing with perfect posture is just anterior to the motion segment of S1-S2. Flexion of the neck and torso moves the center of gravity forward, loading the posterior cervical, thoracic and lumbar paraspinal extensor muscles. The muscles acting on the vertebral column, hip, knee and ankle joints make possible erect standing walking and running postures.

The deep muscles of the back and posterior neck extend, rotate or laterally flex one or more of the 24 paired facet

-- 9 --

joints and the 22 intervertebral disc joints of the vertebral column. The long muscles move several motion segments with one contraction, while short muscles can move one or two motion segments at a time. The erector spinae group comprises the principal extensors of the vertebral motion segments. Oriented vertically along the longitudinal axis of the back, they are thick, quadrilateral muscles in the lumbar region, splitting into smaller, thinner separate bundles attaching to the ribs, and upper vertebrae and head. Erector spinae arises from the lower thoracic and lumbar spines, the sacrum, ilium, and intervening ligaments. The transversospinalis group extends the motion segments of the back and rotates the thoracic and cervical vertebral joints.

5

10

15

20

25

30

These muscles generally run from the transverse processes of one vertebra to the spine of the vertebra above, spanning three or more vertebrae. The semispinales are the largest muscle of this group, reaching from midthorax to the posterior skull, the multifidi consist of deep fasciculi spanning 1-3 motion segments from sacrum to C2. The rotators are well defined only in the thoracic region. The small, deep-lying muscles cross the joints of only one They are collectively major postural motion segment. Electromyographic evidence has shown that these short muscles remain in sustained contraction for long periods of time during movement and standing / sitting They are most prominent in the cervical and postures. lumbar regions.

The neck is a complex tubular region of muscles, viscera, vessels and nerves surrounding the cervical vertebrae. The muscles of the neck are arranged in superficial and deep groups. The anterior and lateral muscle groups are divided into triangular areas by the sternocleidomastoid muscle. The posteriolateral border is the trapezius muscle.

-- 10 --

Biomechanical studies have shown that people bear load through the middle and posterior thirds of the disc. Spinal researchers have measured the amount of sliding and tilting at healthy spinal joints. During motions, the joint can be injured with stresses of only 6-7 kg and, in some cases, the disc could be injured and in others, a ligament might be injured. As our spine becomes older, it goes through certain changes related to its age through the process of simple wear and tear. The disc becomes thinner and more brittle and even cracked in places and they lose their elasticity and water content thus becoming less of a spinal stabilizer.

10

15

20

25

30

It is a prevalent misconception that most disc herniations result from a single event or trauma, microtrauma, primarily from repetitive flexion and rotation movement, leads to a degenerative cascade that frequently results in a herniated nucleus pulposus. While the clinical presentation of disc herniation varies because of the level size and position of the herniation, there are commons signs and symptom patterns that exist. About 80% of population experience pain with radiation into the extremity along the anatomic distribution of the affected nerve root. Neural compression or irritation may precipitate motor weakness, reduced reflexes, and sensory loss. Compensatory posturing frequently occurs. About 90% of all lumbar disc herniations occur at the L4-L5 and L5-S1 levels.

Conservative treatment varies and includes traction, manual therapy techniques, electrotherapeutic modalities, other physical agents, dynamic muscular stabilization through physical therapy exercise, functional restorative education, and pharmacologic intervention (including oral or transdermal analgesics, NSAIDS, muscle relaxers, oral corticosteroids, and / or epidural steroids). Failure to respond to an active conservative treatment regimen for at

-- 11 --

least six weeks is just one of the indications for lumbar discectomy. Additional rationales for lumbar discectomy include severe, incapacitating pain that eludes all forms of medicinal and physical pain control measures, recurrent episodes of sciatica, significant neurologic deficit with significant positive straight leg raise test, bowel and bladder involvement, and progressive neurologic deficit are some of the strong indications for surgical intervention. The goals of rehabilitation are focused on return to maximal functional status and include reduction of pain frequency intensity; maintenance of mobility; maximizing and paraspinal strength, flexibility and conditioning; and prevention of recurrence of injury.

10

15

20

25

30

Discectomy via laminectomy is gradually being replaced by lumbar microdiscectomy as the standard of care for the surgical treatment of lumbar disc herniation. minimally invasive surgical techniques addressing lumbar herniation include percutaneous and Microdiscectomy offers advantages over the discectomy. traditional laminectomy and discectomy by combining a smaller surgical exposure with far superior visualization of the operating field. Moreover, this less invasive surgical approach results in decreased perioperative bleeding and hematoma formation and less paraspinal muscle dennervation and fibrosis. Improved visualization of the operating field allows for more precision in surgical technique, better nerve decompression, less chance of iatrogenic injury and a reduction in the amount of peridural scar tissue formed these All benefits lead postoperatively. postoperative pain and morbidity and a shorter hospital stay for the patient.

There has been a rapid evolution in the development and use of spinal fixation devices for lumbar spine fusion surgery. They are simply categorized as anterior or

-- 12 --

posterior fixation devices. The most common and most controversial fixation devices are the pedicle screw and rod/plate systems. Anterior fixation devices include screw and rod/plate systems as well interbody cages. as Essentially, these devices are hollow cylinders made of 5 titanium, carbon, or bone. The cages are filled with autogenous bone graft and inserted between vertebral bodies. The patient's autogenous iliac crest is the standard source of bone graft material to fill the interbody cage. The goal of lumbar fusion is the union of two or more vertebrae. Most patients with interbody fixation become mobile and more independent than those with a non-instrumented spinal fusion, but the patients must wear a post-operative lumbar orthosis for an extended period and therefore require an extensive recovery time.

10

15

20

25

Different surgeons use different techniques to perform The traditional approach is through a a lumbar fusion. midline posterior incision. The posterior lumbar interbody (PLIF) is a particularly demanding procedure associated with higher incidence of post-surgical nerve injuries than the posterolateral fusion. Some surgeons have moved to using an anterior approach (ALIF), but the ALIF cannot stand alone to withstand the forces of daily patient use and surgeons have found that, in order to prevent collapse or lack of fusion altogether, they have to protect the graft with posterior instrumentation which is placed either on the same day of surgery or in another procedure. A "360" circumferential fusion is also done in this manner.

-- 13 --

OBJECTIVES OF THE INVENTION

Deficiencies in Prior Art Addressed

The common approach to stabilizing damaged or disrupted intervertebral discs is to fuse the vertebrae above and below the damaged disc. Although proven as a successful approach to permanently stabilize the injured area, fusion has the following drawbacks:

Fusion unnecessarily eliminates a portion of the spine's normal range-of-motion (ROM);

- 10 Fusion increases the stressors imposed on the adjacent mobile vertebra;
 - Fusion often causes subsequent breakdown of the intervertebral disc above and below the fused vertebrae;
- 15 Fusion causes osteophyte formation at the levels adjacent to the fusion;
 - Almost half of patients still have lumbar pain after the fusion procedure.
- The present invention allows for preservation of the intervertebral disc space without immobilization of the vertebrae, thereby reducing the risk of breakdown of the adjacent vertebrae above and below and allowing full ROM at the level of the damaged disc.

By using special instrumentation and scopes with the present invention, implantation through laparoscopic spinal surgery requires only three to four small incisions, much like those a patient might experience when having another minor surgery such as a cholecystectomy or appendectomy. There are numerous benefits of this minimally invasive surgery versus surgical incisions made with traditional

-- 14 --

fusion surgery. The most significant benefit is a reduced hospital stay and reduced recuperation time.

Exemplary Invention Objectives

One skilled in the art will recognize that the present invention provides significant improvements to the patient as compared to the prior art. Accordingly, the objectives of the present invention are (among others) to circumvent the deficiencies in the prior art. Some of these benefits which may be present in some embodiments include (but are not limited to) the following objectives:

To provide an ARTIFICIAL SPINAL DISC REPLACEMENT SYSTEM AND METHOD that overcomes the deficiencies in the prior art.

Preservation of ROM in the patient.

- The replacement disc will remain secure without the need for screws into the spinal vertebrae.
 - The procedure to install the invention may be laparoscopic, thereby alleviating the need for major patient surgery. As an alternative, minimally invasive surgery may be utilized using a lateral insertion procedure.
 - The present invention will reduce the need for expensive post-operative care (physical therapy, hospital, physician visits, etc.).
- 25 All repairs to the invention can be done laparoscopically. As an alternative, minimally invasive surgery may be utilized using a lateral insertion procedure.
- The present invention is modular and can be used in cervical or lumbar region and potentially thoracic regions of the spine.

-- 15 **--**

The present invention will rotate within limitations of the quide tracks.

The present invention will allow bending of vertebrae for forward flexion, extension, and lateral flexion.

The present invention can be made of any material that will allow for optimum spine function. The material selection for any component described, implied, or suggested herein can be manufactured using any surgical or bio-compatible materials, including but not limited to the use of LIQUID METAL ® or any version or chemical compositions thereof.

The present invention can consist of brackets and spring design.

The present invention brackets can be attached with an adhesive.

15

20

30

The present invention upper bracket can have a protrusion which will be threaded to allow for efficient attachment of the spring assembly.

The present invention spring assembly can be fully customizable for permanent ROM limitations if necessary due to physical limitations of existing vertebrae in the patient.

The present invention springs can be altered for elasticity for acceptable movement.

25 The present invention springs can be attached via specialized fasteners.

The present invention disc replacement can consist of, but is not limited to, brackets and springs and nuts.

The present invention can be used in osteoporotic, osteopenic, or normally aged bone.

-- 16 --

The present invention will not interrupt biomechanical alignment of the spine.

The present invention can adjust the disc height to maintain intervertebral space, or increase or decrease this spacing.

5

10

15

20

25

30

The present invention may incorporate a fusion block wherein three blocks when attached to an upper bracket will not allow ROM to occur thereby simulating a fusing of the vertebrae together. Each of the fusion blocks in this configuration can occupy the complete spring guide track and be secured by threaded projections located in the upper brackets.

The present invention may incorporate miniaturization and/or enlargement of the upper and/or lower bracket segments to provide increased stability for the implant.

The present invention anticipates integration of bracket segments into a single-piece bracket of sufficient size to provide implant stability. This integration may occur for the upper and/or lower brackets.

The present invention anticipates that the orientation of the upper and/or lower bracket segments or unitary upper and/or lower bracket's machined contours that interface with the vertebrae surface may be in any orientation necessary for ease of production and surgical installation.

The present invention permits the use of angled threaded projections, angled spring guide tracks, and/or spherical bearings at each of the threaded projections which allows for spinal wedge angle alignment of the upper and/or lower brackets to the upper and/or lower vertebrae securing spring and/or fusion block. This

-- 17 --

flexibility permits custom fitting of the surgical implant to each individual patient.

One skilled in the art will recognize that this list of advantages is not exhaustive and may have application to some embodiments of the present invention and not others. While these objectives should not be understood to limit the teachings of the present invention, in general these objectives are achieved in part or in whole by the disclosed invention that is discussed in the following sections. One skilled in the art will no doubt be able to select aspects of the present invention as disclosed to affect combination of the objectives described above.

10

15

20

BRIEF SUMMARY OF THE PRESENT INVENTION

Contrast With Prior Art

The common approach to stabilizing damaged or disrupted intervertebral discs is to fuse the vertebrae above and below the damaged disc. Although proven as a successful approach to permanently stabilize the injured area, fusion unnecessarily eliminates a portion of the spine's normal range-of-motion, increases the stressors imposed on the adjacent mobile vertebra, often causing subsequent breakdown of the intervertebral disc above and below the fused vertebrae, osteophyte formation at the levels adjacent to the fusion, and almost half of patients still have lumbar pain after the procedure. The present invention avoids 25 these drawbacks of the prior art and preserves full ROM in the patient.

-- 18 --

Overview (0400)

Artificial prosthesis have been commonly used to replace painful joints in hips and knees for more than 20 years and these are among the most successful and reliable operations performed today. Securing these replacements has been done with a variety of adhesives and/or bone glues. The present invention advances this concept forward by teaching a spinal disc replacement system that can be fixed to the spine vertebrae with adhesive using laparoscopic techniques (0401) as illustrated in FIG. 4 (0400).

Placement (0500, 0600, 0700)

10

15

20

25

30

The present invention relates generally to a spinal implant for use in intervertebral disc replacement. It is an articulating implant that restores proper intervertebral spacing, preserves spinal range-of-motion (ROM) and flexibility, and eliminates nerve root and/or spinal cord compression. As illustrated in FIG. 5 (0500), the present invention (0810) (with suitable modifications for size and placement) is applicable for use at any point (0501, 0502, 0503) along the spinal column (0510).

A more detailed depiction of the placement of the present invention in the spinal column is illustrated in FIG. 6 (0600), wherein the exemplary spinal disc replacement (0810) is inserted between an upper (0601) and lower (0602) vertebrae in the spinal column. As previously mentioned, the present invention is amenable for used at any point along the spinal column. It is an articulating implant that restores proper intervertebral spacing, preserves spinal ROM and flexibility, and eliminates nerve root and/or spinal cord compression.

-- 19 --

Further detail of the present invention is generally illustrated in the perspective view of FIG. 7 (0700), wherein an exemplary embodiment (0810) is placed between two spinal vertebrae (0701, 0702). While a wide variety of invention embodiments is anticipated, the general placement as illustrated in FIG. 7 provides some insight into general application of the present invention.

5

10

15

20

25

30

General Assembly and Component Breakdown (0800)

The present invention is generally illustrated in the detailed exploded view of FIG. 8 (0800), wherein it is comprised of an upper bracket (0801), lower bracket (0802), and spring(s) (0811) separating the brackets (0801, 0802). The present invention will allow for preservation of the intervertebral disc space without immobilization of the vertebrae, thereby reducing the risk of breakdown of the adjacent vertebrae above and below and allowing full ROM at the level of the damaged disc.

The upper bracket (0801) and lower bracket (0802) are generally not attached to the skeletal structure using screws as had been done by many of the other disc replacements on the market currently. Screws placed into fragile bone have the potential for breaking the bone and causing failure of the hardware / spinal replacement. Adhesive is much less invasive and has been proven successful many times over in hip and shoulder replacement Upper (0831) and lower (0832) surgeries worldwide. vertebral contact surfaces provide adhesion surfaces for adhesive to the upper/lower brackets mate upper/lower vertebrae. The upper/lower corresponding brackets are designed to include a hole in the bracket for adhesive / bone glue to be injected, as in item (0841).

-- 20 **--**

The brackets as illustrated can be constructed of a variety of materials, including but not limited to titanium, chromium, cobalt, or a variety of plastics. Research indicates that many preferred exemplary embodiments employ material selection (optimally a titanium alloy) that is selected to support a spring specification of at least 1800 Newtons within the size of 3 to 8 mm spring width.

Additionally, as is illustrated in FIG. 8 (0800) and in other drawings, the system may be fabricated in multiple segments for the upper (0851, 0861, 0871) and lower (0852, 0862, 0872) brackets in a "jigsaw" or interlocking fashion to facilitate assembly within the context of a laparoscopic surgical procedure. The benefits of the modular design are that the disclosed spinal disc replacement can be placed in either cervical, thoracic, or lumbar areas and are adjustable for any body size.

10

-- 21 --

BRIEF DESCRIPTION OF THE DRAWINGS

For a fuller understanding of the advantages provided by the invention, reference should be made to the following detailed description together with the accompanying drawings wherein:

- FIG. 1 illustrates a prior art embodiment of an artificial spinal disc implant extracted from United States Patent 6,764,512 issued to Arnold Keller on 7/20/2004 for PLASTIC IMPLANT WITH CHANNEL FOR RADIOGRAPHIC CONTRAST WIRE;
- 10 FIG. 2 illustrates a prior art embodiment of an artificial spinal disc implant extracted from United States Patent 6,726,720 issued to Raymond Ross, Michael O'Neal, and Mark Boomer on 4/27/2004 for MODULAR DISC PROSTHESIS;
- FIG. 3 illustrates a typical surgical procedure associated with prior art embodiments of artificial spinal disc implants;
 - FIG. 4 illustrates a preferred exemplary embodiment of the present invention;
- FIG. 5 illustrates a typical laparoscopic surgical 20 procedure associated with some preferred embodiments of the present invention;
 - FIG. 6 illustrates a typical spinal disc placement procedures associated with some preferred exemplary embodiments of the present invention;
- 25 FIG. 7 illustrates a side view of a preferred exemplary embodiment of the present invention as typically installed between two spinal vertebrae;
- FIG. 8 illustrates a detail exploded view of a preferred exemplary embodiment of the present invention illustrating the major components of a typical embodiment of same;

-- 22 --

- FIG. 9 illustrates a detail back side view of a preferred exemplary embodiment of the present invention as typically placed on a lower spinal vertebrae;
- FIG. 10 illustrates a perspective view of a preferred exemplary embodiment of the present invention installed between two spinal vertebrae;
 - FIG. 11 illustrates a perspective view of a preferred exemplary embodiment of the present invention and details adhesive injection holes/ports on the upper and lower brackets;

10

- FIG. 12 illustrates an exemplary edge chamfer technique useful in manufacturing some preferred exemplary embodiments of the upper and/or lower bracket as taught by the present invention;
- 15 FIG. 13 illustrates an exemplary edge rounding technique useful in manufacturing some preferred exemplary embodiments of the upper and/or lower bracket as taught by the present invention;
- FIG. 14 illustrates a bottom view of a preferred 20 exemplary embodiment of the present invention;
 - FIG. 15 illustrates a bottom perspective view of a preferred exemplary embodiment of the bottom bracket used in some embodiments of the present invention;
- FIG. 16 illustrates a top exploded perspective view of a preferred exemplary embodiment of the upper bracket used in some embodiments of the present invention;
 - FIG. 17 illustrates a bottom exploded perspective view of a preferred exemplary embodiment of the upper bracket used in some embodiments of the present invention, showing the lateral view of the upper bracket of the spinal implant including the vertebral contact surface, cylindrical threaded projection, nut, spring and the insertion holes for adhesive;

-- 23 --

- FIG. 18 illustrates a bottom perspective view of a preferred exemplary embodiment of the upper bracket used in some embodiments of the present invention;
- FIG. 19 illustrates a preferred exemplary embodiment of the lower bracket used in some preferred embodiments of the present invention, showing the lateral view of the lower bracket of the spinal implant including vertebral contact surface, spring guide track, inset overhang of the guide track, the insertion holes for adhesive;

5

- 10 FIG. 20 illustrates the lateral view of the spring guide track in the lower bracket vertebral contact surface with springs from the upper bracket assembly properly positioned;
- FIG. 21 illustrates a side view of a preferred exemplary embodiment of the upper bracket of the present invention;
 - FIG. 22 illustrates a front view of a preferred exemplary embodiment of the top and bottom bracket assemblies and springs of the present invention;
- 20 FIG. 23 illustrates a side view of a preferred exemplary embodiment of the top and bottom bracket assemblies and springs of the present invention;
 - FIG. 24 illustrates a back sectional view of a preferred exemplary embodiment of the top and bottom bracket assemblies of the present invention as applied to a typical spinal upper and lower vertebrae;
 - FIG. 25 illustrates an exploded view of a preferred exemplary embodiment of the present invention using screw/nut fasteners for the springs;
- 30 FIG. 26 illustrates a side sectional view of the preferred exemplary embodiment illustrated in FIG. 25;
 - FIG. 27 illustrates an exploded view of a preferred exemplary embodiment of the present invention using

-- 24 --

screw/"U" bracket fasteners as an alternative spring
fastening means;

- FIG. 28 illustrates a side sectional view of the preferred exemplary embodiment illustrated in FIG. 27;
- FIG. 29 illustrates an exploded view of a preferred exemplary embodiment of the present invention using rivet fasteners for the springs;
 - FIG. 30 illustrates a side sectional view of the preferred exemplary embodiment illustrated in FIG. 29;
- 10 FIG. 31 illustrates an exploded view of a preferred exemplary embodiment of the present invention using threaded projections common to the upper bracket and nut fasteners for the springs;
- FIG. 32 illustrates a side sectional view of the preferred exemplary embodiment illustrated in FIG. 31;
 - FIG. 33 illustrates a preferred exemplary embodiment of the present invention wherein the lower bracket is non-coplanar;
- FIG. 34 illustrates a side sectional view of the 20 preferred exemplary embodiment illustrated in FIG. 33;

- FIG. 35 illustrates a preferred exemplary embodiment of the present invention wherein the upper/lower bracket vertebral contact surface has been partially surface conditioned to promote improved adhesion to the upper spinal vertebrae;
- FIG. 36 illustrates a preferred exemplary embodiment of the present invention wherein the upper/lower bracket vertebral contact surface has been fully surface conditioned to promote improved adhesion to the upper spinal vertebrae;
- FIG. 37 illustrates a preferred exemplary embodiment of the present invention wherein the upper/lower bracket vertebral contact surface has been partially knurled to promote improved adhesion to the upper spinal vertebrae;

-- 25 --

- FIG. 38 illustrates a preferred exemplary embodiment of the present invention wherein the upper/lower bracket vertebral contact surface has been fully knurled to promote improved adhesion to the upper spinal vertebrae;
- FIG. 39 illustrates an alternative preferred exemplary embodiment of a spring structure suitable for use in some preferred exemplary embodiments of the present invention;

5

10

15

- FIG. 40 illustrates a preferred exemplary method embodiment of a surgical procedure useful in installing some embodiments of the present invention;
- FIG. 41 illustrates a perspective view of a preferred exemplary embodiment of the present invention wherein the upper bracket is of unitary (one-piece) construction and utilizes spherical bearings to achieve attachment of the springs via the spring fasteners;
- FIG. 42 illustrates a side view of a preferred exemplary spherical bearing / spring fastener / spring structure as utilized in the preferred exemplary embodiment of FIG. 41;
- FIG. 43 illustrates a detailed side assembly view of a preferred exemplary spherical bearing / spring fastener structure as utilized in the preferred exemplary embodiment of FIG. 41;
- FIG. 44 illustrates an alternate side view of a preferred exemplary spherical bearing / spring fastener / spring structure as utilized in the preferred exemplary embodiment of FIG. 41;
 - FIG. 45 illustrates a side view of an alternative to the spherical bearing structure illustrated in FIGs. 41-44, wherein the upper bracket utilizes a chamfered receiving machine screw socket capable of permitting movement of the spring fastener as it is attached to the upper bracket;

-- 26 **--**

FIG. 46 illustrates a perspective view of a preferred embodiment of the present invention lower bracket wherein the bracket further comprises unitary construction and the use of fusion blocks to mate to the lower bracket;

- FIG. 47 illustrates an alternate perspective view of a preferred embodiment of the present invention lower bracket wherein the bracket comprises unitary construction, enlarged (larger than half-circle) surface area, and side injection ports to permit application of adhesive;
- 10 FIG. 48 illustrates an alternate perspective assembled view of a preferred embodiment of the present invention lower bracket and springs wherein the bracket comprises unitary construction and side injection ports to permit application of adhesive;
- 15 FIG. 49 illustrates a top view of a preferred embodiment of the present invention lower bracket wherein the bracket size is extended from other embodiments to provide additional support over the spinal column;
- FIG. 50 illustrates an alternative preferred exemplary 20 embodiment wherein the upper and/or lower bracket incorporates side injection ports to permit application of bone adhesive from the side of the patient;
 - FIG. 51 illustrates a side sectional view of a preferred exemplary embodiment of the present invention wherein the upper and/or lower bracket is non-co-planar and the vertebrae mating surface is convex.

25

Referring now in detail to the figures wherein like reference numbers like parts throughout, preferred forms of the present invention will now be described.

-- 27 --

DESCRIPTION OF THE PRESENTLY PREFERRED EXEMPLARY

EMBODIMENTS

While the present invention is susceptible of embodiment in many different forms, there is shown in the drawings and will herein be described in detailed preferred embodiment of the invention with the understanding that the present disclosure is to be considered as an exemplification of the principles of the invention and is not intended to limit the broad aspect of the invention to the embodiment illustrated.

5

10

15

20

The numerous innovative teachings of the present application will be described with particular reference to the presently preferred embodiment, wherein these innovative teachings are advantageously applied to the particular problems of an ARTIFICIAL SPINAL DISC REPLACEMENT SYSTEM AND METHOD. However, it should be understood that this embodiment is only one example of the many advantageous uses of the innovative teachings herein. In general, statements made in the specification of the present application do not necessarily limit any of the various claimed inventions. Moreover, some statements may apply to some inventive features but not to others.

Fastener Coatings Not Limitive

While several preferred embodiments may incorporate special coatings on fasteners to promote integration into the spinal column or to promote self-locking of the fastener, the present invention scope is not limited by the specific fastener coatings listed herein.

-- 28 **--**

Fastener Configuration Not Limitive

In many preferred exemplary embodiments, the spinal implant disclosed herein may make use of a variety of fasteners for fixation of springs used between the upper/lower brackets. One skilled in the art will recognize that the exact fastener style may be determined by a variety of factors and is not necessarily limited to the exact configurations detailed herein. Fastener styles including but not limited to fastener head, fastener body, threading, recesses, locking mechanisms, and the like may be varied without loss of generality in the teachings of the present invention. Therefore, the term "fastener" or "fastening" should be given its broadest definition within the context of the teachings of the present invention.

10

15

20

25

Location Not Limitive

The present invention is designed to be implemented as a spinal disc replacement, and within this context a variety of location placements within the spinal column are generally illustrated within this document. However, nothing within this description is intended to limit the scope of placement of the spinal disc replacement, and the teachings of the present invention may be applied (with appropriate structural modification to account for location) to placement within any portion of the patient's spinal column. The drawings and written description should not in any way limit the scope of where the invention may be applied with respect to placement within the spinal column.

Surface Conditioning Not Limitive

In some preferred embodiments the vertebral contact 30 surfaces are conditioned for advantageous adhesion between

-- 29 --

the contact surface and the associated spinal vertebrae via the use of adhesive or some other fastening means. While several exemplary methods of surface conditioning are illustrated herein, the scope of the invention is not limited by any specific method mentioned herein, as one skilled in the art can enumerate a variety of such methods.

5

10

15

20

25

Fastener Orientation Not Limitive

Additionally, the present invention should not be limited in scope by the orientation of fasteners which are illustrated in the attached drawings and described herein. One skilled in the art will recognize that fastener orientation may in many circumstances be a preferential decision that is not directly tied to the function of the invention or the scope of the disclosed invention. As such, fastener orientation should not limit the invention scope.

Fabrication Materials Not Limitive

The elements of this spinal implant can be fabricated from biocompatible materials including, without limitation, LIQUID METAL ®, titanium, surgical alloys, surgical metals, stainless steel, chrome-molybdenum alloy, cobalt-chromium alloy, zirconium oxide ceramic, non-absorbable polymers, polymer compounds, and other anticipated biocompatible metallic or polymeric materials, or any version or chemical composition thereof. One skilled in the art will recognize that the teachings of the present invention are not limited by the type of material used in the manufacture of the disclosed spinal disc replacement.

Fixative Not Limitive

In many preferred exemplary embodiments, the spinal 30 implant disclosed herein makes use of an adhesive for

-- 30 --

fixation to adjacent vertebrae within the spinal column. One skilled in the art will recognize that the teachings of the present invention are not limited by the type of adhesive or fixative means used in the installation of the 5 disclosed spinal disc replacement. While adhesive is clearly the preferred method of attachment in some preferred embodiments, one skilled in the art will recognize that other fixation means, including but not limited to screws, clasps, or other fixation means may be possible without limiting the teachings of the present invention.

Spring Fixation Not Limitive

10

15

20

In many preferred exemplary embodiments, the spinal implant disclosed herein may make use of cylindrical threaded projections, bolts, nuts, or other fasteners for fixation of springs used between the upper/lower brackets. One skilled in the art will recognize that the teachings of the present invention are not limited by the means by which the springs are fastened to the upper or lower bracket. One skilled in the art will recognize that the spring feature taught by the present invention can also be integrated into the fabrication of the upper/lower bracket itself, with no loss of generality in the disclosed invention.

Component Part Count Not Limitive

While the component count illustrated and discussed 25 herein may be applicable to many preferred embodiments, the present invention anticipates that components sectioned or combined in many embodiments not illustrated.

-- 31 **--**

Surface Coatings Not Limitive

In many preferred exemplary embodiments, the spinal implant disclosed herein may make use of a variety of material coatings such as nylon, Teflon®, or other materials to reduce friction between moving parts or improve overall long term wear characteristics of the spinal implant. One skilled in the art will recognize that the teachings of the present invention are not limited by any surface coatings which may be applied to any of the components described by the teachings of the present invention.

Orientation Not Limitive

10

15

20

25

30

In many preferred exemplary embodiments, the spinal implant disclosed herein comprises an upper bracket having springs which rest in spring guide tracks that are formed within a lower bracket, the upper/lower bracket structure being connected respectively to upper/lower vertebrae via vertebral contact surfaces on the upper/lower brackets. Note, however, that the orientation of the structure is not critical, and the orientation of the upper/lower bracket may be swapped such that the upper bracket contains the spring quide tracks and the lower bracket contains the springs.

Furthermore, one skilled in the art will recognize that while the present invention discloses a single spring guide track, the present invention may incorporate multiple spring guide tracks, and these tracks may reside on one or more of the upper/lower brackets. The present invention specifically anticipates situations in which the spring guide tracks are on both upper and lower brackets, with springs being placed to mate to these guide tracks on the bracket not containing the particular guide track.

-- 32 --

Thus, the springs illustrated herein and their associated guide tracks may be replicated/mirrored with no loss of generality in the teachings of the present invention.

Spinal Interface Not Limitive

5

10

15

20

25

In many preferred exemplary embodiments, the spinal implant disclosed herein may make use of an irregular spinal interface as generally illustrated in the drawings. One purpose of such an irregular interface is to promote adhesion to the spinal column when the system is fixed to the spinal column using adhesive. However, one skilled in the art will recognize that the teachings of the present invention are not limited by any particular surface interface as generally illustrated in the drawings, and that other spinal interface structures (including flat) may be suitable in some circumstances without departing from the teachings of the present invention.

Multi-Part Construction Not Limitive

The present invention as illustrated herein may be comprised of an upper and lower bracket, with each of these assemblies being composed of a plurality of sections that are assembled together during a typical laparoscopic surgical procedure. While the examples illustrated herein comprise three upper bracket sections and three lower bracket sections, nothing within the scope of the present invention teachings limits the structure to this configuration. The upper/lower brackets may have one or more sectional pieces and may or may not be assembled within the patient during surgery.

-- 33 **--**

Springs Not Limitive

One skilled in the art will recognize that the springs detailed in this disclosure are illustrative only, and do not limit the scope of the claimed invention. "Spring" or "springs" in the context of this disclosure include any material or structure capable of absorbing shock, torsional stress, thrust, or extended wear. This definition includes the field of bearings and the like which are capable of supporting a range of rotational motion. Nothing in the present invention limits the scope to configurations with a plurality of springs, although many preferred embodiments exhibit multiple springs. One skilled in the art will recognize that a wide variety of materials consistent with the application of Hooke's Law can operate as a spring and would be applicable to the teachings of the present invention.

5

10

15

20

25

30

Spring Guide Tracks Not Limitive

One skilled in the art will recognize that the spring quide tracks detailed in this disclosure are illustrative only, and do not limit the scope of the claimed invention. "Spring guide tracks" in the context of this disclosure include any material or structure capable of supporting and/or retaining a "spring" retained by the bracket not containing the spring guide track. Nothing in the present invention limits the scope to configurations with a plurality of spring guide tracks, although many preferred embodiments exhibit multiple spring guide tracks. One skilled in the art will recognize a variety of methods by which a spring may rest in or be retained by a spring guide track, and the illustrations provided herein are only exemplary of the wide variety of methods by which this may be accomplished.

-- 34 --

Surgical Technique Not Limitive

In many preferred exemplary embodiments, the spinal implant disclosed herein may be installed using laparoscopic surgical techniques. However, one skilled in the art will recognize that the teachings of the present invention are not limited by any particular surgical technique, and that the present invention may be installed using a variety of surgical techniques without loss of generality in the teachings of the present invention.

Upper Bracket Construction Not Limitive

10

15

20

25

30

In many preferred exemplary embodiments, the spinal implant disclosed herein may have an upper bracket structure further comprising springs, spring fasteners, and upper vertebral contact surface. The present invention specifically anticipates that this upper bracket structure may in some configurations combine as a unified structure the springs and spring fasteners within the context of the upper bracket. One skilled in the art will recognize that the upper bracket may be fabricated from material in which the springs are integrated into the product, eliminating the need for separate springs and/or spring fasteners.

Adhesive Not Limitive

The terms "adhesive" and "adhesive agent" should be given broad definitions within the context of this disclosure. One skilled in the art will recognize that a variety of adhesive means are available for fixing the upper and/or lower brackets to their respective vertebrae, including but not limited to bone glue, bone cement, or other available bioadhesive substances. A particular adhesive may be chosen based on the embodiment of the present invention manufactured, as is well known in the art.

-- 35 --

Edge Chamfering / Rounding Not Limitive

The present invention detailed herein may incorporate in several preferred embodiments edge chamfering and/or rounding of edged to promote optimal operation of the spinal disc replacement and/or improved compatibility with insertion into the spinal column. One skilled in the art will recognize that the general concept of edge deburring and the like are well known in the art and may be applied to a wide scope of the teachings of the present invention, depending on the particular application. The scope of the present invention is not to be limited in any way by any examples of edge deburring, chamfering, rounding, or the like as illustrated herein.

10

25

Co-Planar Disc Structure Not Limitive

The present invention may be implemented using coplanar upper/lower brackets as illustrated herein in some preferred exemplary embodiments. However, the invention may incorporate non-planar (non-co-planar) disc structures in which the upper and/or lower bracket is tapered rather than co-planar, permitting the replacement disc structure to more fully conform to the requirements of the replaced disc in the patient.

Therefore, nothing in the invention disclosure herein should be construed as limiting the scope of the present invention to co-planar upper and/or lower brackets. One skilled in the art will recognize situations in which non-co-planar upper and/or lower brackets are dictated by patient requirements.

-- 36 --

General System Description (0800)

As generally seen in FIG. 8 (0800), the general spinal disc replacement system comprises an upper bracket (0801), which further comprises spring(s) (0811), and vertebral contact surfaces (0831, 0832). The vertebral contact surfaces (0831, 0832) provides a permanent and rigid connection between the implant and the skeletal structure. The vertebral contact surfaces (0831, 0832) are in many preferred embodiments segmented (0851, 0861, 0871, 0852, 0862, 0872) for ease of installation and providing the ability to use laparoscopic surgical insertion. The upper bracket (0801) mates to a corresponding lower bracket (0802), which has one or more spring guide track(s) (0812) in which the spring(s) (0811) from the upper bracket (0801) ride and in which the springs (0811) are retained.

5

10

15

20

25

30

Fastening Means

While a wide variety of fastening means may be used to attach the spring(s) (0811) to the upper bracket (0801), several exemplary fastener types are illustrated in the drawings, including screws (0821) and nuts (0822). While recessed machine screws are preferred in some embodiments, one skilled in the art will recognize that a wide variety of other fastening means would be equally appropriate. One variation not illustrated in FIG. 8 (0800) would include the use of threaded cylindrical projections (studs) that are inserted into the upper bracket (0801) and onto which nut fasteners (0822) are attached to affect spring retention. The use of "shoulder bolts" or cylindrical fasteners with partial shaft threading is also specifically anticipated. One skilled in the art will recognize that this alternate form of cylindrical threaded projection could encompass a

-- 37 --

stud screwed into the upper bracket or some form of integrated machined threaded cylinder emanating from the upper bracket with no loss of generality in the teachings of the present invention.

5

10

15

20

25

Each individual segment of the vertebral contact surface may contain a cylindrical, threaded projection at it's midpoint on the inferior surface. The cylindrical, threaded projection may hold the nut upon application of the spring (0811). Also located at the midpoint but on the lateral surface are insertion holes on each segment. The three segments of the vertebral contact surface component of the upper bracket are meant to conjoin together to comprise the single unit of the upper bracket in some preferred embodiments. The upper/lower brackets extend from the outer edge of the skeletal structure to the interior, inferior surface of the vertebral body, but generally do not exceed the diameter of the vertebral body.

Either end of the vertebral contact surface (0831, 0832) will be angled toward the skeletal structure so that the surfaces are flush, making a cavity into which adhesive can be filled. The under surface of the bracket that contacts the skeletal surface can be textured / hatched to allow for maximum surface area to improve adhesion of the implant to the bone. The adhesive can be injected through the insertion holes (0841, 0842) on the lateral surface of each segment.

-- 38 **--**

Perspective Installation Views (0900, 1000)

FIG. 9 (0900) and FIG. 10 (1000) provide perspective views of a presently preferred embodiment of the present invention (0810) as installed within the spinal column. FIG. 9 (0900) provides a patient-back perspective view of the present invention (0810) as it rests on the lower vertebrae (0902). FIG. 10 (1000) provides a perspective view of a presently preferred embodiment of the present invention (0810) as installed between an upper (1001) and lower (1002) vertebrae in a typical spinal column.

5

10

15

20

25

Perspective Component Views (1100, 1200, 1300, 1400, 1500)

FIG. 11 (1100), FIG. 12 (1200), FIG. 13 (1300), FIG. 14 (1400), and FIG. 15 (1500), provide perspective component views of a presently preferred embodiment of the present invention (0810). These figures will now be discussed individually.

FIG. 11 (1100) illustrates a perspective view of a presently preferred embodiment of the present invention, and illustrates injection holes/ports for adhesive in the upper (0841) and lower (0842) bracket.

FIG. 12 (1200) and FIG. 13 (1300) illustrate cross sections of typical chamfering or rounding which may be implemented at the edges of any portion of the present invention to facilitate cohesive placement within the spinal column with minimum disruption of patient ROM. Note that one skilled in the art could apply the depicted chamfering/rounding or other well known edge detailing techniques to any portion of the upper and/or lower bracket structured depicted within this disclosure.

-- 39 --

FIG. 14 (1400) and FIG. 15 (1500) illustrate perspective views of a presently preferred exemplary embodiment of the upper and/or lower bracket vertebral interfaces. These perspective views illustrate how the adhesive injection holes/ports (0841, 0842) as generally illustrated in FIG. 8 (0800) extend through the body (1401, 1402, 1403) of the brackets to form placement tracks (1411, 1412, 1413) for adhesive at the vertebral interfaces.

Upper Bracket Exploded Views (1600, 1700, 1800)

FIG. 16 (1600), FIG. 1700 (1700), and FIG. 18 (1800) 10 illustrate exploded views of an exemplary preferred embodiment of the present invention upper bracket. FIG. 16 (1600) is a top perspective exploded view of an exemplary upper bracket, illustrating the sectional nature of the 15 bracket in some preferred embodiments of As mentioned elsewhere, the sectional nature of invention. the upper/lower brackets is preferred in many circumstances, but not necessarily required in some embodiments. FIG. 17 (1700) is a bottom perspective exploded view of an exemplary 20 upper bracket (with springs), illustrating the sectional nature of the upper bracket in some preferred embodiments of FIG. 18 (1800) is a bottom perspective the invention. assembled view of an exemplary upper bracket (with springs), illustrating the sectional nature of the upper bracket in 25 some preferred embodiments of the invention.

-- 40 --

Lower Bracket Assembled Views (1900, 2000)

FIG. 19 (1900) illustrates an assembled view of an exemplary embodiment of the bottom bracket. As mentioned elsewhere, the sectional nature of the upper/lower brackets is preferred in many circumstances, but not necessarily required in some embodiments.

As illustrated in FIG. 19 (1900), the lower bracket is the second element of the spinal implant comprising of two components, vertebral contact surface and the spring guide track. The vertebral contact surface will provide a permanent, rigid connection between the implant and the skeletal structure. The vertebral contact surface is segmented for ease of installation and providing the ability to use laparoscopic surgical insertion.

10

individual segment of the vertebral contact 15 surface contains a spring guide track. The spring guide track is a groove that protrudes from the vertebral contact surface that contains the concave ends of an individual The spring guide track is flat on the bottom and beveled on either side comprising a substantially "U" shape 20 extending along the length of each segment of the vertebral contact surface. At either end of the segmented vertebral contact surface, there will be an inset overhang that will function as an arresting force to over-rotation. implanted, the articulation of the spring with the spring 25 guide track will resist axial compression between vertebrae as well as preventing lateral translation of the implant and inhibiting 360 degree motion at the vertebral level to allow normal support to the axis between the upper and lower vertebrae at the level of the spinal implant. 30 guide track (slide guards) can be altered in length to

-- 41 --

accommodate individuals with limited ROM at vertebral levels above and below the spinal implant use.

5

10

20

25

30

lower bracket vertebral contact surface otherwise the same as the upper bracket vertebral contact surface. Located at the midpoint but on the lateral surface are insertion holes on each segment. The three segments of the vertebral contact surface component of the lower bracket are meant to configure together to comprise the single unit The bracket will extend from the of the lower bracket. outer edge of the skeletal structure to the interior, inferior surface of the vertebral body, but generally not to exceed the diameter of the vertebral body. Either end of the vertebral contact surface will be angled toward the skeletal structure so that the surfaces are flush, making a cavity that the adhesive can fill in to. The under surface 15 of the bracket that contacts the skeletal surface can be textured / hatched to allow for maximum surface area to improve adhesion of the implant to the bone. The adhesive will be injected through the insertion holes on the lateral surface of each segment.

Alternatively, the spring and spring guide track component could be replaced with a series of collapsible cylinders, akin to shock absorbers. A spiral spring could be substituted for the concave/convex spring configuration. The spring could be made as a permanent part of the top bracket and eliminate the bolt and threaded cylinder attachment. The vertebral contact surface could be all one piece instead of a three-segmented jigsaw. The U-shape of the bottom bracket spring guide could be a flat half circle. The adhesive choice for attachment of the upper and lower bracket could be substituted for teeth or other type of sharp protuberance that could be affixed to the vertebrae. The adhesive choice could be substituted with screws used to secure the upper and lower brackets to the skeletal

-- 42 --

structure from the lateral, overlapping portion of the vertebral contact surface. The spring and spring guide track component could be replaced with a collapsible honeycomb structure made of biocompatible material not yet determined, and that would be secured by other means.

5

10

20

25

30

FIG. 20 (2000) illustrates an exemplary embodiment of the bottom bracket as installed on a lower spinal vertebrae (2002) and illustrates how the springs (which are attached to the upper bracket that is not depicted in this illustration) rest in the spring guide tracks on the lower bracket. This spring/guide track configuration provides full ROM for the patient as well as providing shock absorption for the spinal column.

Upper/Lower Bracket Detail (2100, 2200, 2300, 2400)

15 While the upper and lower brackets generally illustrated in FIG. 8 (0800) can take many forms, detailed illustrations of a preferred embodiment of these components is illustrated in FIG. 21 (2100), FIG. 22 (2200), FIG. 23 (2300), and FIG. 24 (2400).

As depicted in FIG. 20 (2000) and FIG. 21 (2100), the spring component of the upper bracket element of the spinal implant will permit pivotal movement between the vertebrae and is the key component to the restoration of ROM in the spinal section. The term pivotal is intended to describe either or both of a rotation or twisting motion about the support axis and/or a tilting motion angularly inclined in any direction relative to the support axis.

The spring has a general configuration of an alternating concave and convex shape. As generally illustrated in FIG. 20 (2000), some preferred invention embodiments will comprise a convex portion of the spring

-- 43 **--**

having a hole to fit into the cylindrical projection of the upper bracket. The two remaining concave portions will fit into the tracks of the lower bracket as illustrated in FIG. 20.

5

10

15

20

25

30

illustrated in FIG. 8 (0800), the nut (0822) As component of the upper bracket element of the spinal implant will attach the spring to the upper bracket. The nut is preferably, but not limited to, hexagonal in shape with a rounded surface contacting the spring component. can only be inserted, therefore, in one direction, so that the rounded end threads onto the cylindrical threaded projection of the upper bracket in the direction that it contacts the spring component first. The rounded end of the nut may in many preferred embodiments correspond with the convex angle of the spring that it is attaching to the upper The nut is preferably fabricated from or coated with materials on threads to aid in fixation (self-locking) such as a low-friction, wearand impact-resistant, biocompatible material such as (for example) polyethylene, non-absorbable polymers or other biocompatible polymeric material.

FIG. 22 (2200) illustrates a side view (from the patient's front perspective) of an exemplary embodiment of the present invention and generally illustrates the adhesive injection holes/ports, three piece preferred sectional design, and tri-spring interface between the upper and lower brackets.

FIG. 23 (2300) illustrates a side view (from the patient's side perspective) of an exemplary embodiment of the present invention and generally illustrates the adhesive injection holes/ports, preferred sectional design, and multi-spring interface between the upper and lower brackets.

-- 44 --

FIG. 24 (2400) illustrates a frontal sectional assembled view (from the patient's back perspective) of an exemplary embodiment of the present invention as installed between upper and lower spinal vertebrae and generally illustrates the spring guide tracks, preferred sectional design, and multi-spring interface between the upper and lower brackets.

5

15

20

25

Fastening Variation - Inverted Acorn Nuts (2500, 2600)

While a wide variety of methods are available for fastening springs to the upper bracket, one preferred embodiment is illustrated in exploded view FIG. 25 (2500) and associated sectional side view FIG. 26 (2600) wherein inverted acorn nuts and inset cap screws are used as fasteners to attach the springs to the upper bracket.

Fastening Variation - Spring Captors (2700, 2800)

While a wide variety of methods are available for fastening springs to the upper bracket, another preferred embodiment is illustrated in exploded view FIG. 27 (2700) and associated sectional side view FIG. 28 (2800) wherein U-shaped spring brackets (U-bolt) are used as a retaining means to attach the springs to the upper bracket.

The cylindrical projection may be enhanced in the form of a U-bolt to replace the upper bracket's cylindrical projection (pseudo screw). The configuration of the U-bolt is exactly as implied by the term "U". The cylindrical projection would be lengthened sufficiently to allow the material to be formed into a "U" configuration, as shown in FIG. 27 (2700).

Both ends of the "U" would be secured to the upper 30 bracket. The ends of the "U" could be deformed as described

-- 45 **--**

in the rivet enhancement, or threaded to accept a low profile nut.

Installation of this type of spring fastener is as follows. A spring would be placed between the vertical legs of the "U" bolt. The ends of the "U" would be inserted into respective drilled holes in the upper bracket sections. The ends would then be secured to the upper bracket using a mechanical process, (e.g. rivet operation, low profile nut, etc.)

Fastening Variation - Rivets (2900, 3000)

10

15

20

25

30

While a wide variety of methods are available for fastening springs to the upper bracket, another preferred embodiment is illustrated in exploded view FIG. 29 (2900) and associated sectional side view FIG. 30 (3000) wherein rivets are used as fasteners to attach the springs to the upper bracket.

The cylindrical projection described previously can be enhanced by replacement of the cylindrical projection with a rivet enhancement. The rivet is a cylindrical piece of surgical compatible material capable of being intentionally deformed to secure the spring to the upper bracket

The rivet may contain a cylindrical diameter over which a spring could be placed. One end of the rivet cylindrical diameter would then be placed in a drilled hole in the upper bracket. The location of this drilled hole would be the same location as the existing cylindrical projection described previously.

The cylindrical diameter ends of the rivet material would be secured in a clamping device. This clamping device would exert sufficient compressive force on the rivet material to cause the material to deform to the curved

-- 46 --

portion of the spring and the flat upper bracket surfaces. The amount of clamping force and resulting deformation of the rivet material would be controlled to allow the spring to function as previously described.

Fastening Variation - Acorn Nuts (3100, 3200)

5

10

15

20

25

While a wide variety of methods are available for fastening springs to the upper bracket, one preferred embodiment is illustrated in exploded view FIG. 31 (3100) and associated sectional side view FIG. 32 (3200) wherein enclosed acorn nuts and inset cap screws are used as fasteners to attach the springs to the upper bracket.

Non-Co-Planar Disc Structure (3300, 3400)

The present invention may be implemented using coplanar upper/lower brackets as illustrated herein in some embodiments. However, the invention may incorporate non-coplanar (non-planar) disc structures in which the upper and/or lower bracket is tapered rather than co-planar, permitting the replacement disc structure to more fully conform to the requirements of the replaced disc in the patient.

This alternate embodiment illustrating non-co-planar structure is depicted in FIG. 33 (3300) with side sectional view illustrated in FIG. 34 (3400) more fully illustrating the tapered nature of the bracket construction. The views in FIG. 33 and FIG. 34 only illustrate one bracket as an example of non-planar (non-co-planar) structures. Note that the present invention anticipates any combination of co-planar and non-planar upper and/or lower brackets.

-- 47 **--**

Vertebral Contact Surface Conditioning (3500, 3600, 3700, 3800)

The present invention anticipates that the contact surface between the upper bracket (upper vertebral contact surface) and the upper spinal vertebrae and/or the surface between the lower bracket (lower vertebral contact surface) and the lower spinal vertebrae may be surface conditioned for improved adhesion between the artificial spinal disc replacement and the surrounding vertebrae.

This surface conditioning can take many forms, including abrasion of the contact surface, chemical treatment, mechanical polishing, machining, and/or knurling. The present invention does not limit the scope of this surface conditioning, and one skilled in the art will be able to delineate a wide variety of surface conditioning techniques appropriate in this application.

10

15

20

25

30

Examples of exemplary embodiments implementing surface conditioning are illustrated in FIG. 35 (3500), FIG. 36 (3600), FIG. 37 (3700), and FIG. 38 (3800). Note, as contrasted in FIG. 35 (3500) and FIG 36 (3600) as well as FIG. 37 (3700) and FIG. 38 (3800) that the surface conditioning may be either partial (3500, 3700) and/or total (3600, 3800). One skilled in the art will recognize that more than one type of surface conditioning may be performed on the upper/lower brackets in some circumstances with no loss of generality in the scope of the present invention.

Alternative Spring Structures (3900)

The exemplary embodiments illustrated herein contain an exemplary spring structure which may be effective in many applications. However, this particular spring structure is not limitive as to the range of spring structures which may be applicable and taught by the present invention. For example, one alternate spring structure is illustrated in

-- 48 **-**-

FIG. 39 (3900). While the spring structure illustrated in FIG. 39 (3900) does not contain any mounting hole, one skilled in the art will recognize that this (or other spring structures detailed herein) could be augmented with a wide variety of mounting holes and/or studs to permit fastening to the upper bracket. One skilled in the art will recognize that a wide variety of other spring structures may be applied to the teachings of the present invention.

10

15

20

25

30

Additionally, note that there is no requirement within the teachings of the present invention that there is more than one spring structure within the One skilled in the art will recognize replacement disc. that the structure illustrated in FIG. 39 (3900) could be fabricated in an arcuate (arc/curved) fashion to mate within the confines of a spring guide track (having one or more cavities) that is machined within the lower bracket. This configuration may include a "wave" style spring structure as illustrated in FIG. 39 (3900), and may include multiple peaks/valleys to ensure the proper spring resistance, contact surface area, and other wear factors required for the application. While a three-peak example is illustrated in FIG. 39 (3900) (and this example does not contain any modification to accommodate the circumferential nature of the spring guide track), one skilled in the art will recognize that these modifications are easily made to the structure of FIG. 39 (3900) to accommodate a singular spring structure if so desired.

Therefore, the term "spring" as used herein should be given its broadest applicable definition consistent with the application to spinal disc replacement. Generally, any material capable of reflexive deformation (with some degree of recovery) would fit this definition. As such, any material subject to Hooke's Law would be a potential

-- 49 --

candidate for application in the teachings of the present invention.

Laparoscopic Surgical Installation

One of the most significant features of the present invention not available in the prior art is that the present invention spinal disc replacement may be installed through laparoscopic surgery. As illustrated in FIG. 3 (0300), the prior art teaches that a spinal disc replacement requires the "gutting" of the patient from the front side of the abdomen, cutting of muscle, and spreading of organs to access the spine from the front of the patient.

10

15

20

25

30

In contrast, as illustrated in FIG. 4 (0400), the present invention teaches that the disclosed spinal disc replacement may be performed laparoscopically from the back side of the patient. By using special instrumentation and scopes, laparoscopic spinal surgery requires only a small incision. There are numerous benefits of this minimally invasive surgery versus surgical incisions made with traditional fusion surgery. The most significant benefit is a reduced hospital stay and reduced recuperation time.

System Variations

No screws will be needed for implantation or stabilization of this device. However there is a pseudoscrew portion that is angled and fits into the spring at the same angle. The spring fits inside the bottom bracket in a glide section, the bottom bracket is recessed so that the spring fits deeply into the bottom bracket and is adjustable for ROM. The spring guide is wider than the spring itself. The connection slot is beveled and is adjustable dependent on the later and forward motion needed / allowed. The bottom and top brackets are inclined to meet the vertebral

-- 50 --

body surface on both sides, The undersurface of the brackets are textured to allow maximal attachment surface area to the bone when the residual space is filled with bone glue. There is a hole in the top and bottom plate of the brackets to allow for a needle insertion to squirt the adhesive into the residual space. There are three plates in the bracket that are jig-sawed (interlocked) together during implantation to ease the operative procedure.

The present invention anticipates a wide variety of variations in the basic theme of construction. The examples presented previously do not represent the entire scope of possible usages. They are meant to cite a few of the almost limitless possibilities.

-- 51 **--**

Generalized Method Embodiment (4000)

The present invention may incorporate a method of using the system as described in an application wherein a spinal disc is replaced within a patient. This method (4000) may be generally described as follows:

5

10

15

20

A method of artificial spinal disc replacement within a patient's spinal column, said method comprising:

- (1) Laparoscopically creating an incision into a portion of said patient's back at the point of spinal disc replacement on said spinal column (4001);
- (2) Inserting an upper bracket through said incision, said upper bracket further comprising springs, spring fasteners, and upper vertebral contact surface (4002);
- (3) Inserting a lower bracket through said incision, said lower bracket further comprising lower vertebral contact surface and spring guide track (4003);
- (4) Mating said upper bracket springs into said lower bracket spring guide track (4004);
 - (5) Fixing said upper bracket upper vertebral contact surface to an upper vertebrae within said spinal column (4005);
- 25 (6) Fixing said lower bracket lower vertebral contact surface to a lower vertebrae within said spinal column (4006).

This method may be augmented and/or modified according to variations in the artificial spinal disc replacement system as described above, and specifically anticipates installation of the spinal disc replacement in sections.

-- 52 --

ENHANCEMENTS / VARIATIONS

Integrated Upper/Lower Brackets (4100)

The present invention has generally been described utilizing a segmented upper/lower bracket assembly as generally illustrated in FIG. 8 (0810). However, as illustrated in FIG. 41 (4100), the system may be embodied utilizing unitary upper and/or lower bracket assemblies. FIG. 41 (4100) illustrates a unitary upper bracket assembly. The integration of the upper and/or lower brackets may prove advantageous and convenient in the insertion of the spinal disc replacement in the patient during surgery.

10

15

The multi-segmented upper/lower brackets illustrated in the various drawings can be integrated as illustrated in FIIG. 41 (4100), and produced and surgically installed as a single piece structure in all variations previously discussed. This single piece concept applies to both the upper and lower brackets as described elsewhere in this document.

Spherical Bearing Interface (4200, 4300, 4400)

One possible preferred embodiment variation generally illustrated in FIG. 41 (4100) is the use of fasteners (4101, 4102, 4103) with spherical bearings (4111, 4112, 4113) as detailed in FIG. 41 (4200), FIG. 43 (4300), and FIG. 44 (4400). The incorporation of a spherical bearing at each of the threaded projection locations within the upper bracket segments and/or a single piece upper bracket allows the threaded projection to adjust to the spinal wedge angle. As the relationship of the threaded projection to the lower bracket spring and spring track angle changes, the spherical

-- 53 **--**

bearing allows the threaded projection to adjust to the needed angle.

As generally illustrated in FIG. 42 (4200), the spherical bearing is a truncated sphere (4201) with an internal bore through the sphere from one flat truncated surface to the opposite flat truncated surface. The spherical bearing curved surfaces are encased in the outer housing (4202), which is then mechanically captured within the upper bracket at the threaded projection location. The method of mechanically capturing the spherical bearing can be by mechanical deformation of the interface area of the spherical bearing to the upper bracket, (e.g., staking), or by other means well known to those skilled in the art.

5

10

15

20

25

Generally, the installation of the spherical bearing within the upper bracket is performed during the manufacturing process. This process requires no mandatory surgical room procedures. As generally illustrated in FIG. 43 (4300), the installed spherical bearing allows for the threaded projection/fastener (4203) to be inserted through the inside diameter of the bearing to secure the spring as described elsewhere in this document.

Movement of the spherical bearing with relation to the upper and lower bracket is generally illustrated in FIG. 44 (4400), wherein this side assembled view illustrates how the spherical bearing permits adjustment of the wedge angle between the upper and lower brackets based on desired patient movement characteristics.

Wedge Angle Fastener Interface (4500)

The concept of spherical bearing interface on the upper 30 bracket can have a variety of embodiments and variations. Each of these attempts to compensate for the spinal wedge angle alignments of the patient. The incorporation of wedge

-- 54 --

alignment features within the framework of this document are not limited by the enhancements noted herein.

One particularly useful preferred embodiment is the use of an angled threaded projection as generally illustrated in (4500), wherein the spring fastener (4501) FIG. 45 contained within a chamfered hole (4502) in the upper This permits changing the threaded projection bracket. installed angle to an appropriate angle (optimally, but not limited to the number of degrees necessary) to allow for a The threaded projection proper spinal wedge angle. installation and function are similar to those already discussed within this document, including but not limited to the range of enhancements discussed herein.

10

15

20

One skilled in the art will recognize that the chamfered hole (4502) can be designed with an enlarged and/or elongated hole to receive the shaft of the spring fastener (4501), permitting some degree of lateral movement of the spring fastener (4501). This permissible movement may in some circumstances provide a degree of ROM similar to that of the spherical bearings discussed previously, and as such should be considered an alternative to the use of spherical bearings in some patient applications.

Fusion Block (4600)

In some circumstances involving special patient conditions (such as replacement of existing spinal fusions or when ROM is not wanted at the spinal segment due to injury or spinal anomalies including disease and instability of the spine) an alternate embodiment of the present invention is applicable which incorporates a spinal fusion implant as generally illustrated in FIG. 46 (4600). This fusion block assembly permits mating of the upper and lower brackets, but does not provide for rotation or tilting of

-- 55 **--**

the spinal implant bracket sections, thus permitting the system to be utilized in situations where spinal fusion is the preferred patient treatment methodology.

In this preferred fusion block embodiment, fusion blocks (4601, 4602, 4603) would be installed in place of the springs described elsewhere in this document. The function of the fusion blocks (4601, 4602, 4603) would be to supply rigidity and not to allow ROM as the springs would normally accomplish.

10 Fusion blocks (4601, 4602, 4603) would be shaped and dimensioned to match the spring guide tracks (now referred to as fusion block guide tracks in this embodiment) and held in place by threaded projections (referred to as fusion block fasteners) as were the springs. Materials for the fusion blocks would include any surgical or biocompatible materials as mentioned previously, as well as surgical metals and/or polymer compounds.

Bracket Size Modulation (4700, 4800, 4900)

De enlarged to fill the maximum surface contact area of the vertebrae, as generally illustrated in FIG. 47 (4700), FIG. 48 (4800), and FIG. 49 (4900), wherein the demarcation line (4901) illustrates the boundary between a conservatively sized bracket (4911) and that of the enlarged surface contact area contrast (4912). These alternate preferred embodiments can be contrasted with the conservatively-sized embodiments illustrated generally by FIG. 8 (0800), in that the demarcation line (4901) delineates the area difference between the sizes of these two embodiments.

The miniaturization or enlargement of any of the items described or detailed herein is anticipated by various

-- 56 -- ·

embodiments of the present invention. This miniaturization and/or enlargement includes implantation of concepts and all surgical methods resembling, but not limited to, the laparoscopic or minimally invasive surgical principles or practices known to those skilled in the art.

5

10

15

20

25

30

Enlargement of the upper and/or lower bracket as generally illustrated in FIG. 49 (4900) can be applied to all figures and diagrams described herein. This enlargement can be applied to all descriptions of either individual bracket segments or one-piece (unitary) brackets for the upper and/or lower brackets.

Enlargement may also be applied to the spring guide tracks, spring, and/or fusion blocks. The enlargement allows increased spring travel and modification of spring/fusion block threaded dimensions, as as increased surface area for adhesion to spinal vertebrae. Generally, enlargement of the upper and/or lower bracket involves increasing the surface area of the bracket beyond that of the half-circle demarcation line (4901) as illustrated in FIG. 49 (4912).

Machined Surface Orientation (5000)

The orientation of the machined surfaces, grooves and contours of the vertebral contact surfaces of the upper and/or lower brackets can be lateral in the direction shown in FIG. 50 (5000) with or without the enlargement concept of the vertebral contact surfaces of the upper and/or lower brackets as generally illustrated in FIG. 49 (4900).

One advantage of this configuration is the ability to perform side insertion / installation of the upper and/or lower brackets during surgery. In this configuration the side placement of adhesive insertion holes/ports (5001,

-- 57 **--**

5002, 5003, 5004, 5005, 5006) permits injection of adhesive from the side of the patient during surgery.

Convex/Concave Mating Surfaces (5100)

5

10

15

20

The present invention anticipates a variety of mating methodologies which may be used to join the upper and/or lower brackets to the surrounding vertebrae. For example, as generally illustrated in FIG. 34 (3400), a typical lower bracket can have a non-coplanar configuration. The present invention also anticipates that any of the upper and/or lower brackets may incorporate convex or concave vertebrae mating surfaces to provide greater conformity to corresponding concave or convex vertebrae to which the bracket mates. An example of this in the form of a convex mating surface is generally illustrated in FIG. 51 (5100) wherein the convex mating surface (5101) is sized to conform to a corresponding vertebrae. One skilled in the art will recognize that irregular mating surface profiles can also be utilized in this application to provide for more substantial mating contact between the upper/lower brackets and the corresponding spinal vertebrae.

-- 58 --

CONCLUSION

5

10

15

spinal disc implant system An artificial intervertebral disc replacement (0810) is disclosed which is formed from an upper (0801) and lower (0802) bracket which mate to upper and lower spinal vertebrae via upper (0831) and lower (0832) vertebral contact surfaces on the upper (0801) and lower (0802) brackets. The upper (0801) and lower (0802) brackets are joined together via springs (0811) connected to the upper bracket (0801) which rest in spring quide tracks (0812) on the lower bracket. (0811) are connected to the upper bracket (0801) via the use of spring fasteners (0821, 0822). The upper (0801) and lower (0802) brackets may be installed in sections (0851,0861, 0871, 0852, 0862, 0872) using laparoscopic surgical techniques and are attached to upper/lower spinal vertebrae respectively via adhesive means applied using injection holes/ports (0841, 0842) in the upper (0801) and lower. (0802) brackets respectively.

for pivotal and rotational movement, thereby preserving full range-of-motion (ROM) in the patient. Alternate embodiments of the invention permit unitary (one-piece) construction of the upper/lower brackets, enlarged surface contact areas for the upper/lower brackets, support for spherical bearings, and integration of fusion blocks. These modifications to the basic spinal implant replacement permit varying degrees of motion as required by the patient as well as a variety of options for insertion of the device via a variety of surgical techniques well known in the art.

-- 59 **--**

CLAIMS

Although a preferred embodiment of the present invention has been illustrated in the accompanying drawings and described in the foregoing Detailed Description, it will be understood that the invention is not limited to the embodiments disclosed, but is capable of numerous rearrangements, modifications, and substitutions without departing from the spirit of the invention as set forth and defined by the following claims.

10 What is claimed is:

-- 60 **--**

An artificial spinal disc replacement system comprising:

5

10

- (a) One-piece upper bracket further comprising a spring, spring fastener, and upper vertebral contact surface;
- (b) One-piece lower bracket further comprising lower vertebral contact surface and spring guide track; wherein
- said upper bracket and said spring are connected to each other via said spring fastener;
 - said spring on said upper bracket rests in said spring
 guide track on said lower bracket, permitting said
 upper bracket to rotate axially on said lower
 bracket;
- said upper bracket is suitable for attachment to an upper spinal vertebrae via said upper vertebral contact surface;
 - said lower bracket is suitable for attachment to a lower spinal vertebrae via said lower vertebral contact surface.
 - 2. The artificial spinal disc replacement system of Claim 1 wherein said upper bracket further comprises lateral injection holes/ports for adhesive.
- The artificial spinal disc replacement system of Claim
 wherein said lower bracket further comprises lateral injection holes/ports for adhesive.

-- 61 **--**

- 4. The artificial spinal disc replacement system of Claim 1 wherein said upper bracket, said spring, and said spring fastener are integrated into a single unitary structure.
- 5 5. The artificial spinal disc replacement system of Claim 1 wherein said upper bracket comprises a plurality of springs.
 - 6. The artificial spinal disc replacement system of Claim 1 wherein said lower bracket comprises a plurality of spring guide tracks.

- 7. The artificial spinal disc replacement system of Claim 1 wherein said upper bracket is enlarged beyond a half-circle to permit maximum surface contact with said upper spinal vertebrae.
- 15 8. The artificial spinal disc replacement system of Claim 1 wherein said lower bracket is enlarged beyond a half-circle to permit maximum surface contact with said lower spinal vertebrae.
- 9. The artificial spinal disc replacement system of Claim
 20 1 wherein said upper vertebral contact surface is convex.
 - 10. The artificial spinal disc replacement system of Claim 1 wherein said upper vertebral contact surface is concave.
- 25 11. The artificial spinal disc replacement system of Claim 1 wherein said lower vertebral contact surface is convex.

-- 62 --

- 12. The artificial spinal disc replacement system of Claim 1 wherein said lower vertebral contact surface is concave.
- 13. The artificial spinal disc replacement system of Claim
 1 wherein said upper bracket further comprises a
 spherical bearing which permits said spring fastener to
 engage said spring through a hole in said spherical
 bearing.
- 14. The artificial spinal disc replacement system of Claim
 10 1 wherein said upper bracket further comprises a
 chamfered hole which permits said spring fastener to
 engage said spring through said chamfered hole in said
 upper bracket.

-- 63 --

15. An artificial spinal disc replacement system comprising:

5

10

wherein

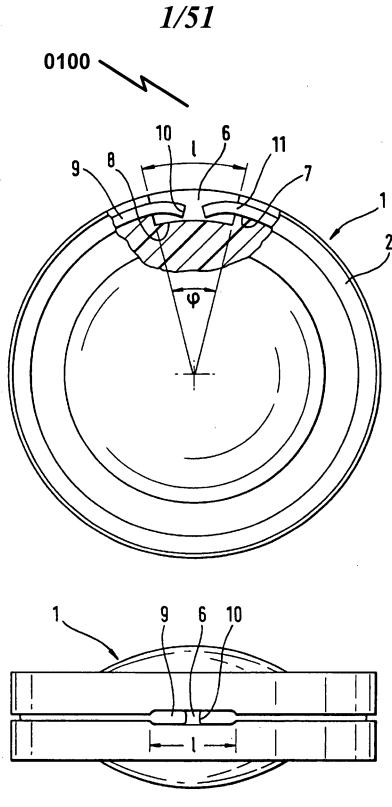
- (a) Upper bracket further comprising a fusion block, fusion block fastener, and upper vertebral contact surface;
- (b) Lower bracket further comprising lower vertebral contact surface and fusion block guide track;
- said upper bracket and said fusion block are connected to each other via said fusion block fastener;
 - said fusion block on said upper bracket rests in said
 fusion block guide track on said lower bracket,
 permitting said upper bracket to be fixed to said
 lower bracket;
- said upper bracket is suitable for attachment to an upper spinal vertebrae via said upper vertebral contact surface;
- said lower bracket is suitable for attachment to a lower spinal vertebrae via said lower vertebral contact surface.
 - 16. The artificial spinal disc replacement system of Claim 15 wherein said upper bracket further comprises lateral injection holes/ports for adhesive.
- 17. The artificial spinal disc replacement system of Claim
 25 15 wherein said lower bracket further comprises lateral injection holes/ports for adhesive.

-- 64 --

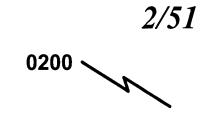
- 18. The artificial spinal disc replacement system of Claim 15 wherein said upper bracket comprises a plurality of fusion blocks.
- 19. The artificial spinal disc replacement system of Claim
 5 15 wherein said lower bracket comprises a plurality of fusion block guide tracks.
 - 20. The artificial spinal disc replacement system of Claim 15 wherein said upper bracket is enlarged beyond a half-circle to permit maximum surface contact with said upper spinal vertebrae.

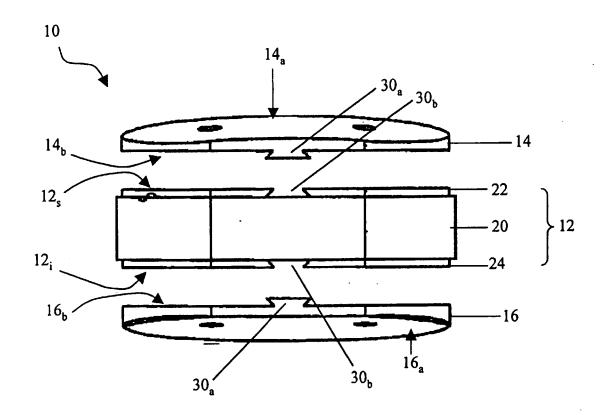
10

- 21. The artificial spinal disc replacement system of Claim 15 wherein said lower bracket is enlarged beyond a half-circle to permit maximum surface contact with said lower spinal vertebrae.
- 15 22. The artificial spinal disc replacement system of Claim 15 wherein said upper vertebral contact surface is convex.
 - 23. The artificial spinal disc replacement system of Claim 15 wherein said upper vertebral contact surface is concave.
 - 24. The artificial spinal disc replacement system of Claim 15 wherein said lower vertebral contact surface is convex.
- 25. The artificial spinal disc replacement system of Claim
 25 15 wherein said lower vertebral contact surface is concave.

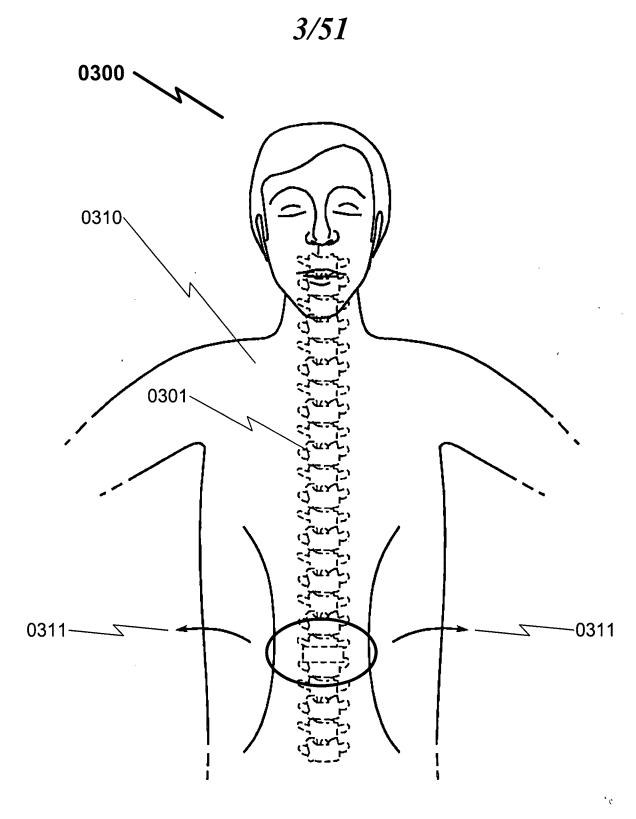


Prior Art

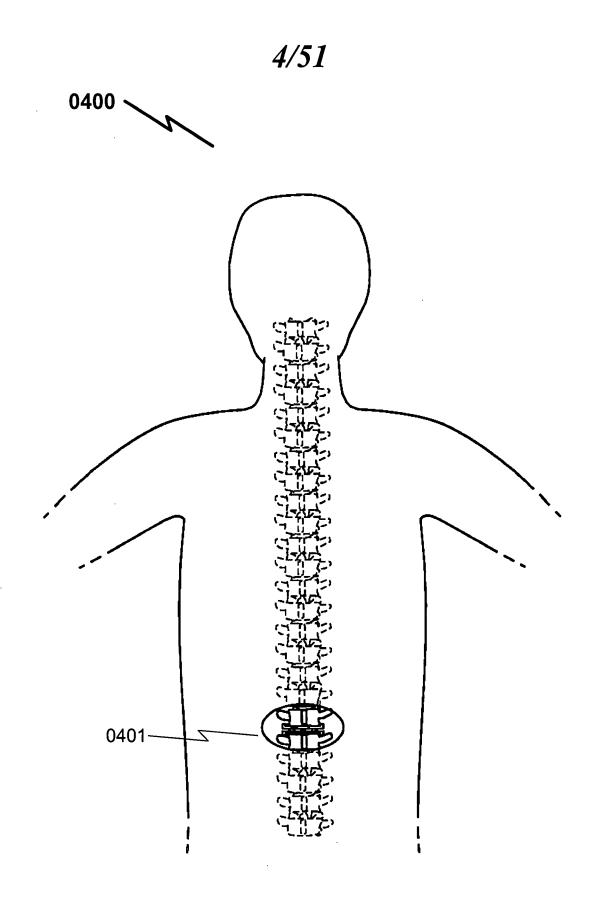


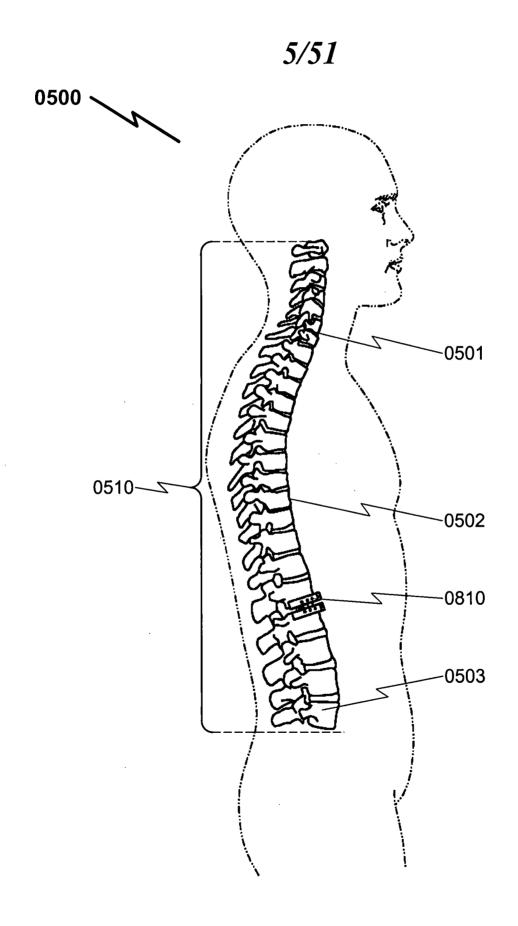


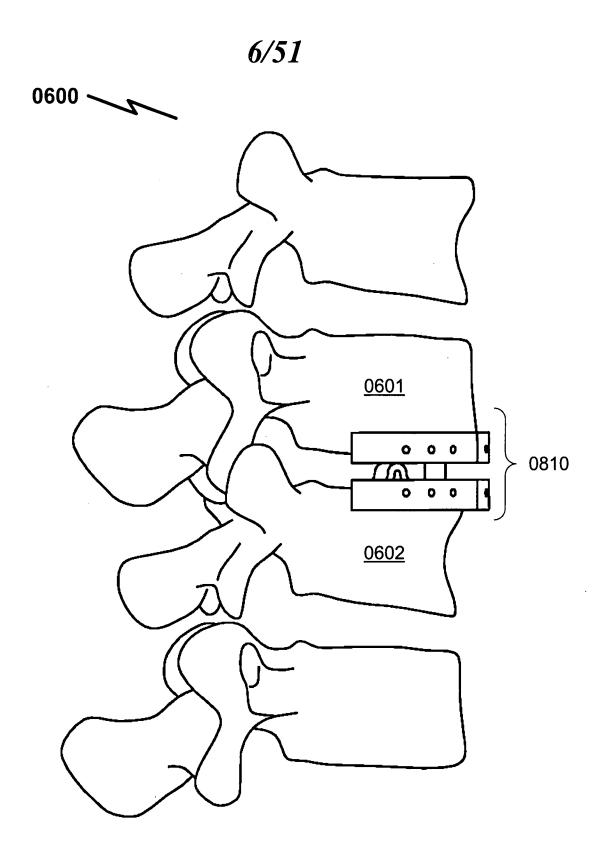
Prior Art

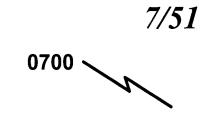


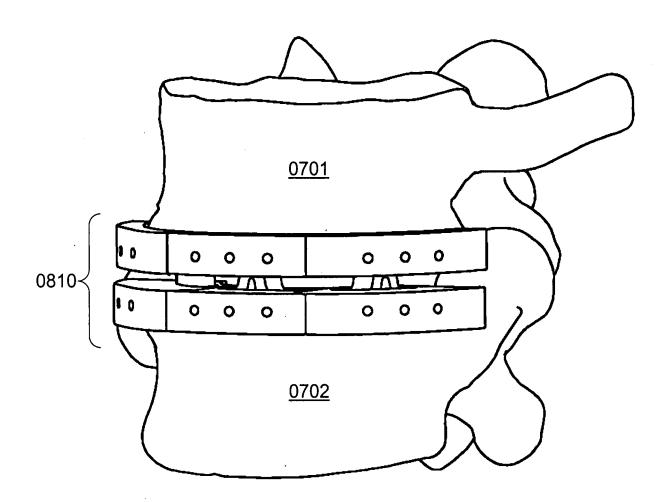
Prior Art

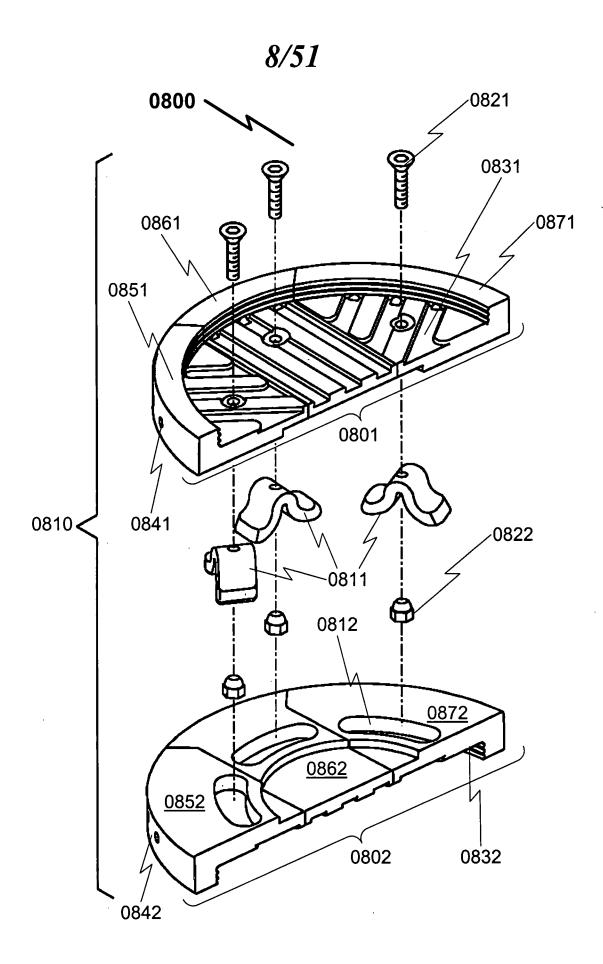


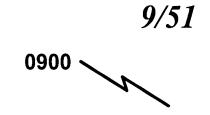


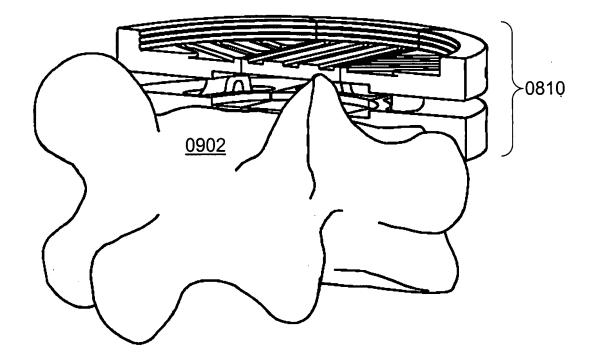


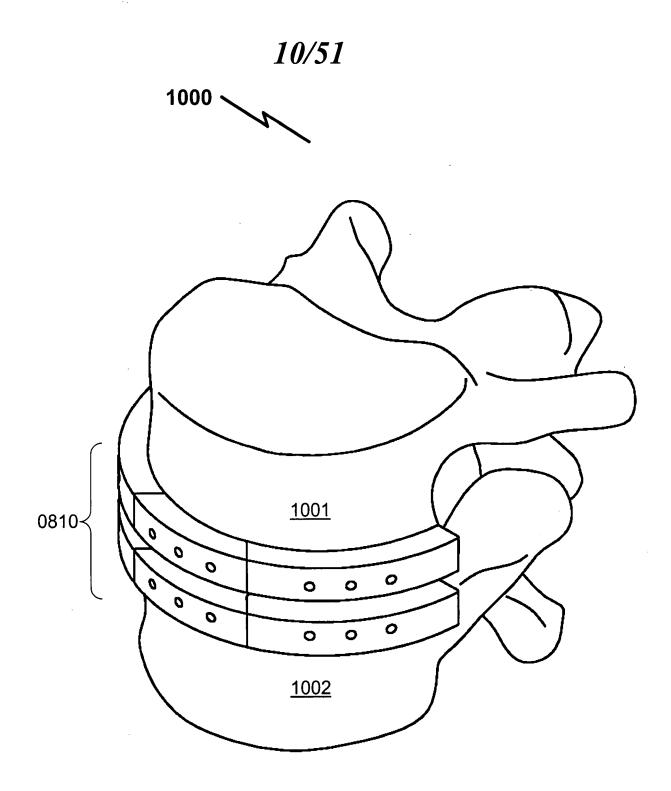


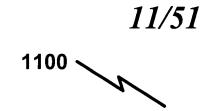


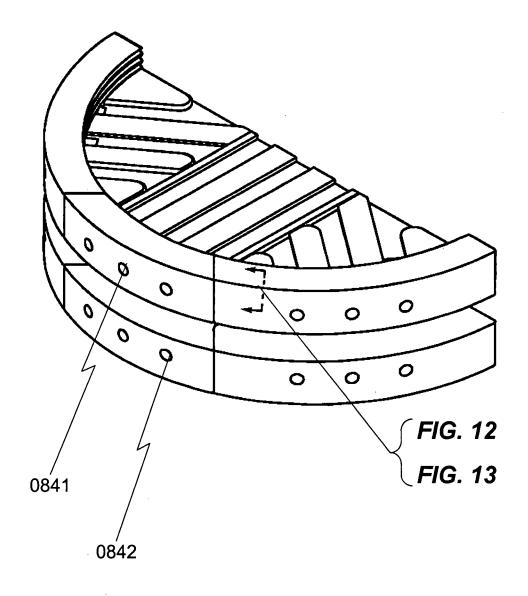


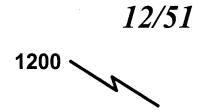


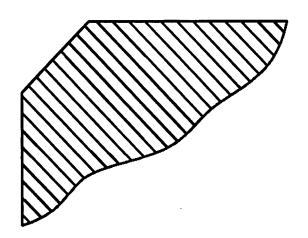


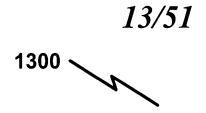


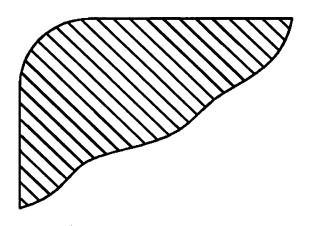


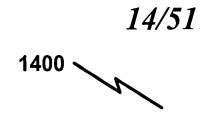


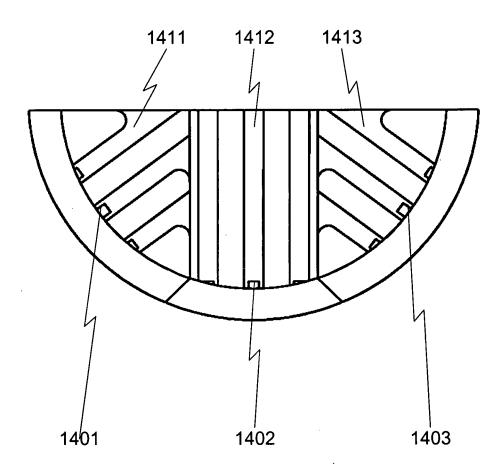


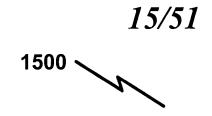


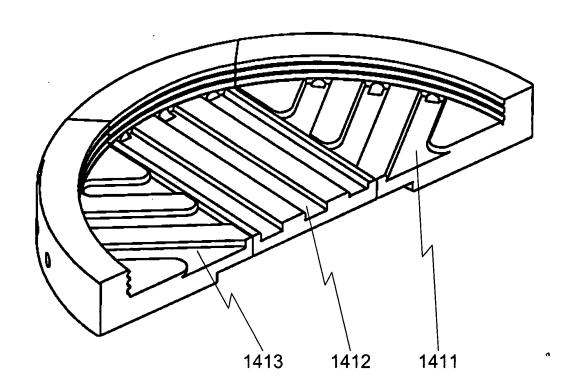


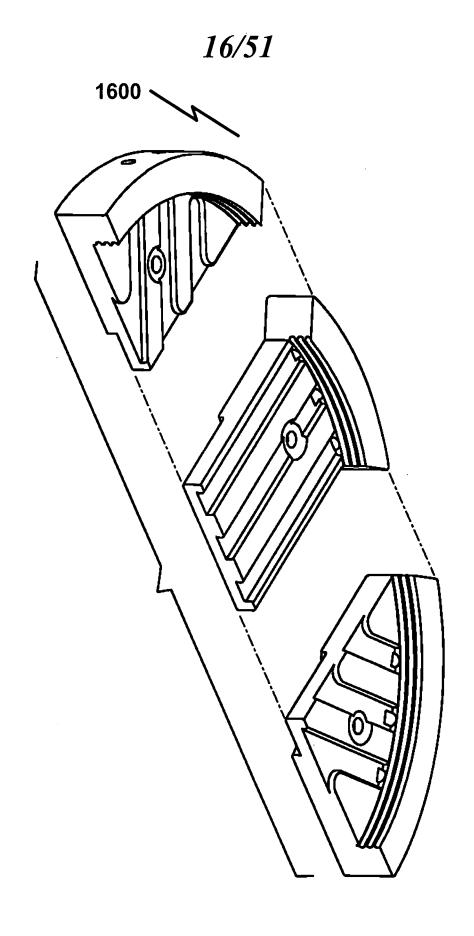


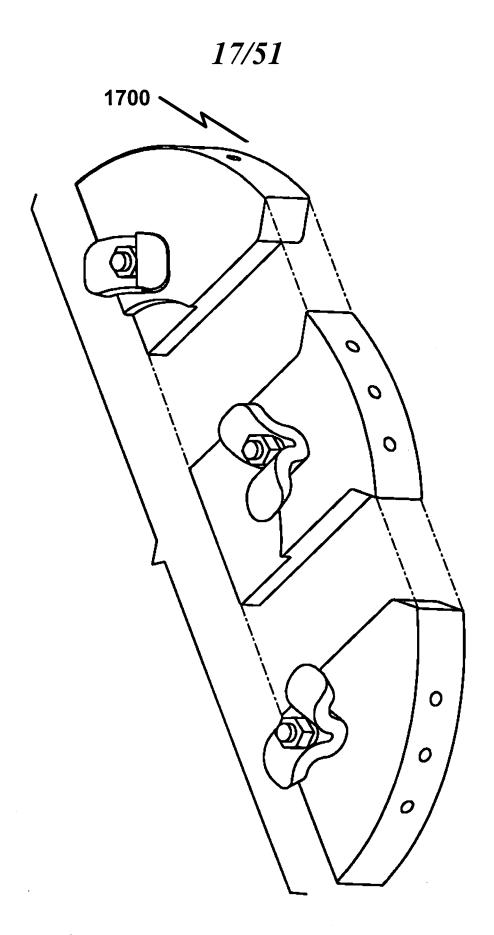


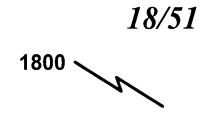


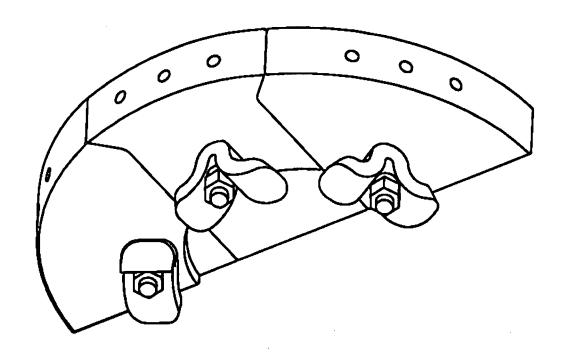


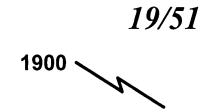


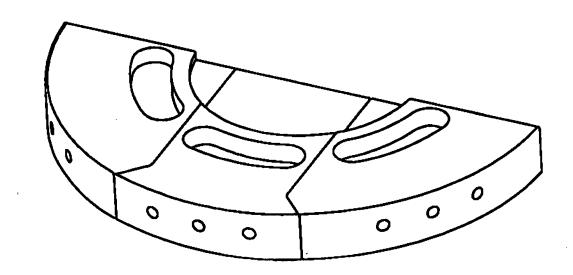


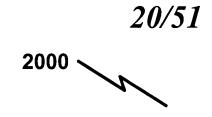


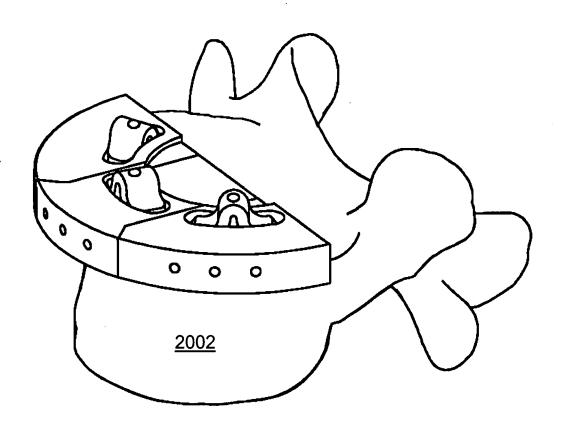


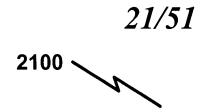


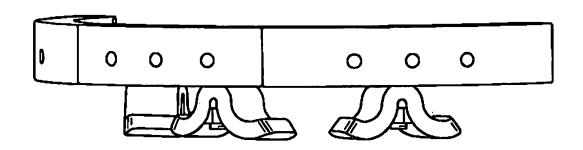


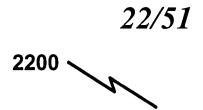




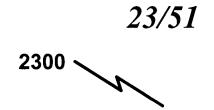


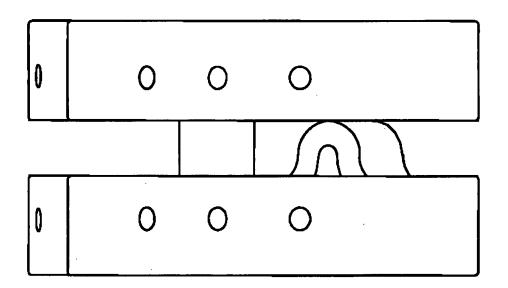


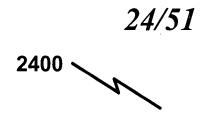


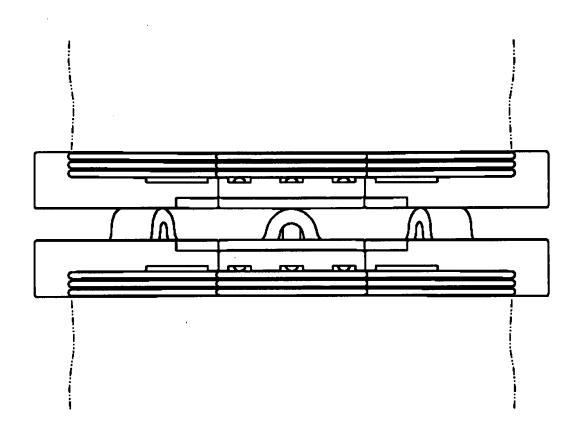


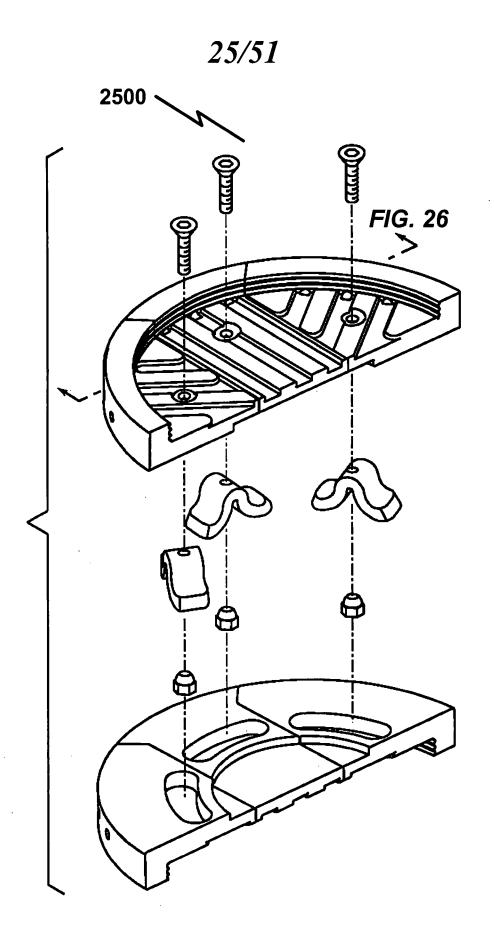
0 0 0	0 0 0	0 0 0
0 0 0	9 9 9	0 0 0

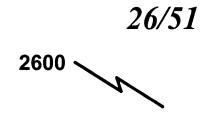


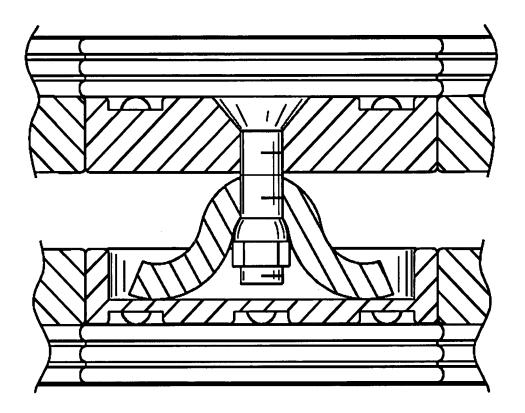


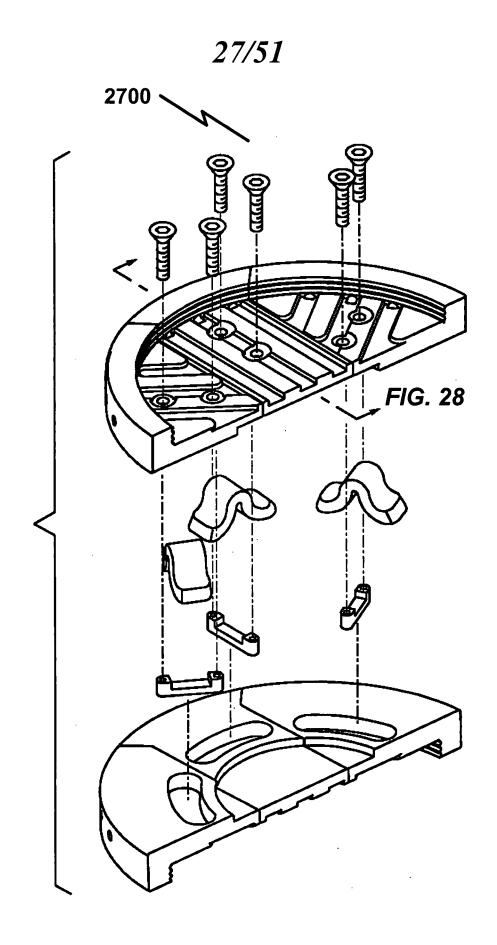


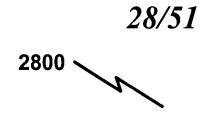


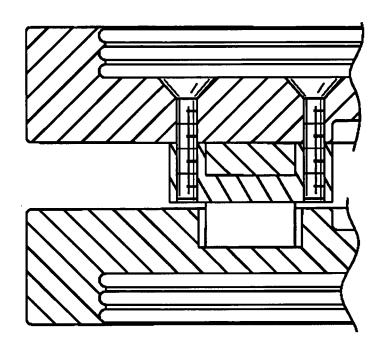


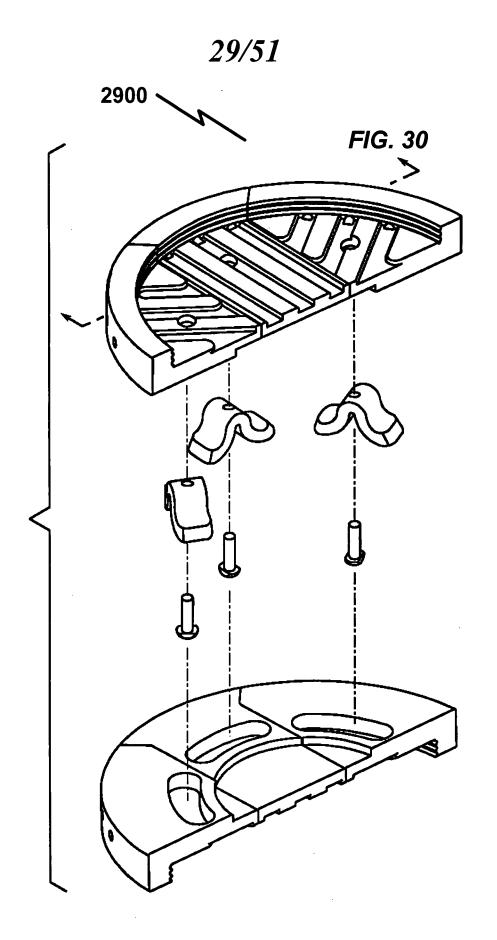


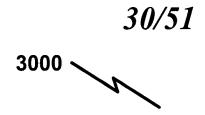


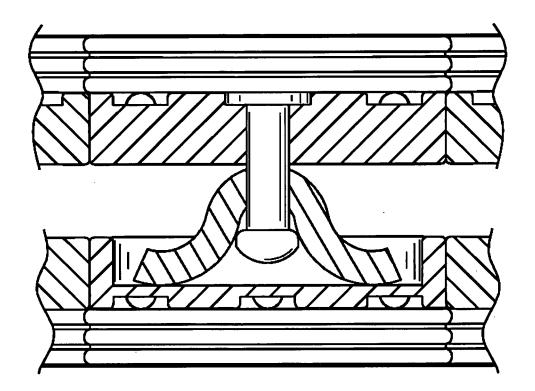


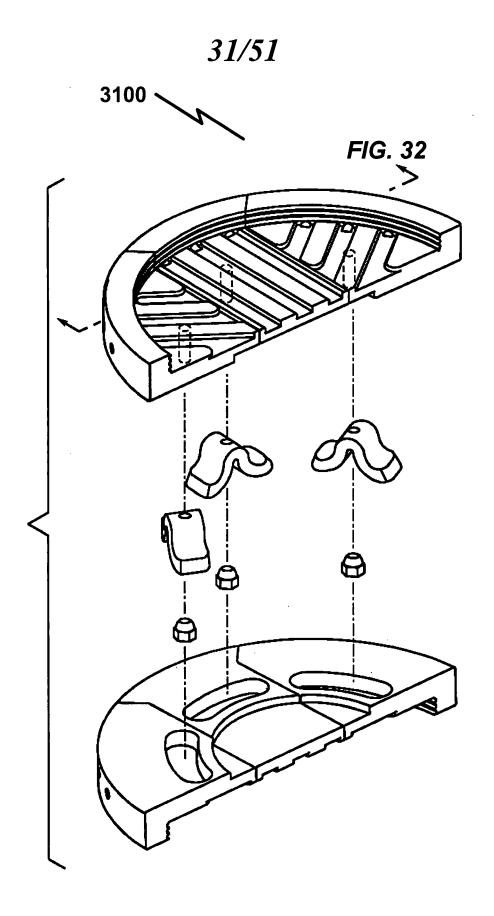


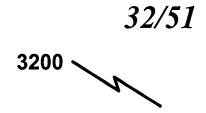


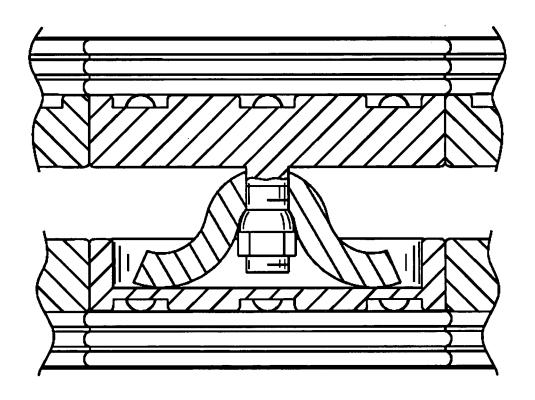


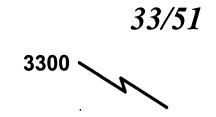


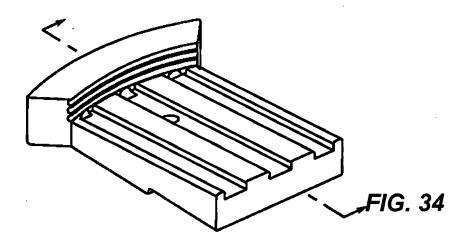


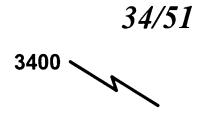


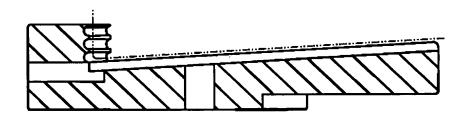


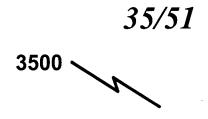


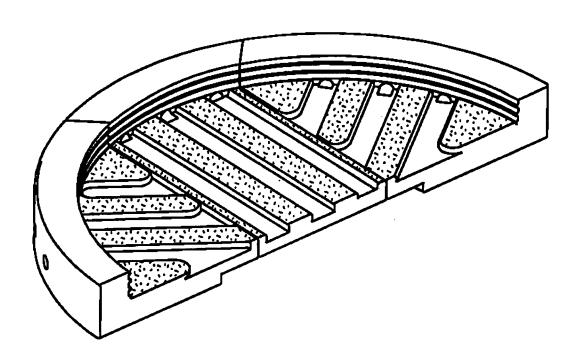


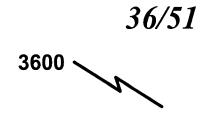


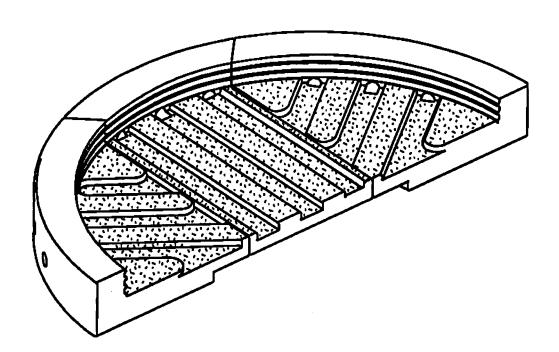


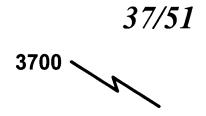


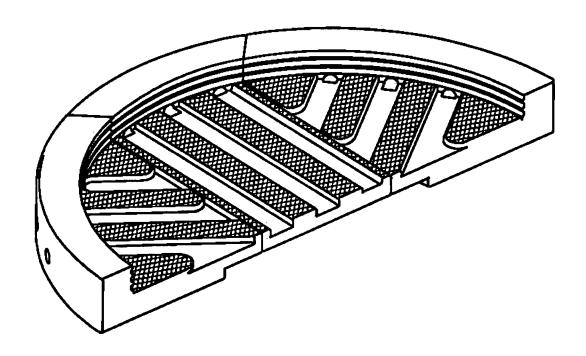


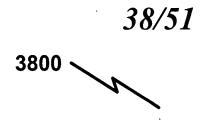


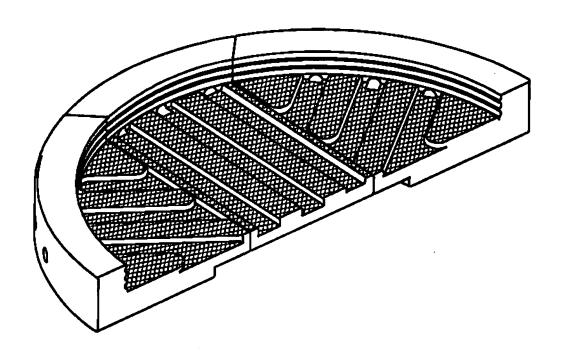


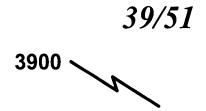


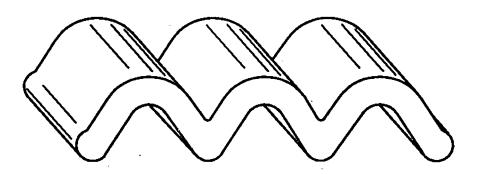












40/51

