



- (51) **International Patent Classification:**
A61F 2/30 (2006.01) *A61F 2/44* (2006.01)
- (21) **International Application Number:**
PCT/US2009/000974
- (22) **International Filing Date:**
17 February 2009 (17.02.2009)
- (25) **Filing Language:** English
- (26) **Publication Language:** English
- (30) **Priority Data:**
12/072,044 22 February 2008 (22.02.2008) US
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- (81) **Designated States (unless otherwise indicated, for every
kind of national protection available):** AE, AG, AL, AM,
AO, 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, ST, SV, SY, TJ, TM, TN, TR, TT, TZ, UA,
UG, US, UZ, VC, VN, ZA, ZM, ZW.
- (84) **Designated States (unless otherwise indicated, for every
kind of regional protection available):** ARIPO (BW, GH,
GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM,
ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ,
TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE,
ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV,
MC, MK, MT, NL, NO, PL, PT, RO, SE, SI, SK, TR),
OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML,
MR, NE, SN, TD, TG).

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(54) **Title:** SPINAL IMPLANT WITH EXPANDABLE FIXATION

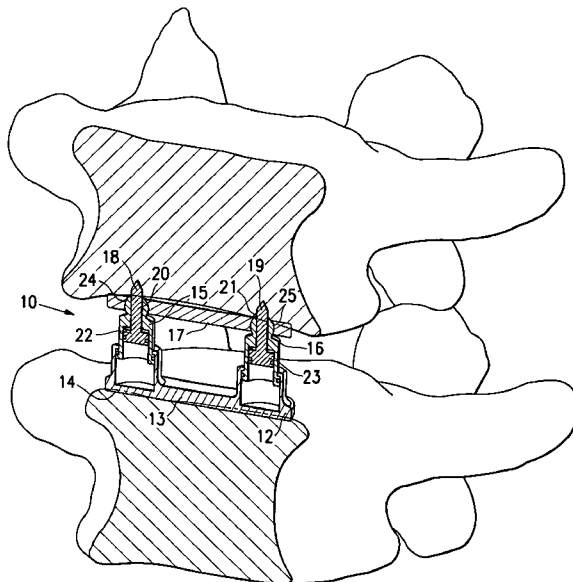


FIG. 5

(57) **Abstract:** A spinal implant which is configured to be deployed between adjacent vertebral bodies. The implant has at least one fixation element (18, 19) with a retracted configuration to facilitate deployment of the implant and an extended configuration so as to engage a surface of an adjacent vertebral body and secure the implant between two vertebral bodies. Preferably, the implant is expandable and has a minimal dimension in its unexpanded state that is smaller than the dimensions of the neuroforamen through which it must pass to be deployed within the intervertebral space. Once within the space between vertebral bodies, the implant can be expanded so as to engage the endplates of the adjacent vertebrae to effectively distract the anterior disc space, stabilize the motion segments and eliminate pathologic spine motion. Angular deformities can be corrected, and natural curvatures restored and maintained.

WO 2009/105182 A1

Published:

— *with international search report (Art. 21(3))*

SPINAL IMPLANT WITH EXPANDABLE FIXATION

FIELD OF THE INVENTION

[0001] The invention relates to devices and methods for stabilizing the vertebral motion segment. More specifically, the field of the invention relates to an expandable spinal implant with fixation elements to fix the implant within an intervertebral space while providing controlled spinal correction in three dimensions for improved spinal intervertebral body distraction and fusion.

BACKGROUND OF THE INVENTION

[0002] A conventional spine cage or implant is characterized by a kidney bean shaped body which is typically inserted in tandem posteriorly through the neuroforamen of the distracted spine after a trial implant creates a pathway. Existing devices for interbody stabilization have important and significant limitations, including inability to expand and distract the endplates while fixing the device to prevent relative movement between the device and an adjacent vertebral body. Current devices for interbody stabilization include static spacers composed of titanium, PEEK, and high performance thermoplastic polymer produced by VICTREX, (Victrex USA Inc, 3A Caledon Court; Greenville, SC 29615), carbon fiber, or resorbable polymers. Moreover, current interbody spacers do not maintain interbody lordosis and can contribute to the formation of a straight or even kyphotic segment and the clinical problem of "flatback syndrome." Separation of vertebral endplates increases space available for the neural elements, specifically the neural foramen. Existing static cages do not reliably improve space for the neural elements. Therefore, what is needed is a spinal implant that will provide space for the neural elements posteriorly between the vertebral bodies, or at least maintain the natural bone

contours to avoid neuropraxia (nerve stretch) or encroachment.

[0003] Conventional devices for intervertebral body stabilization includes poor interface between bone and the biomaterial of the device. Conventional static interbody spacers form a weak interface between bone and biomaterial. Although the surface of such implants is typically provided with a series of ridges or coated with hydroxyapatite, the ridges may be in parallel with applied horizontal vectors or side-to-side motion. That is, the ridges or coatings on the implant offer little resistance to movement applied to either side the endplates. Thus, nonunion is common in allograft, titanium and polymer spacers, due to motion between the implant and host bone.

SUMMARY OF THE INVENTION

[0004] This invention is generally directed to a spinal implant for insertion between superior and inferior vertebral end plates after partial or total removal of a spinal disc. The spinal implant embodying features of the invention is easily installed and is capable of holding the vertebral or joint sections with increased pullout strength to minimize the chance of implant fixation loss during the period when the implant is becoming incorporated into the arthrodesis bone block.

[0005] More specifically, the invention is particularly directed to a spinal impant which has one or more extendable fixation elements that engage or penetrate vertebral end plates and prevent movement between the implant and the vertebral end plates after implantation. The one or more expandable fixation elements have a contracted configuration within the implant so as to not interfere with the insertion of the implant between vertebral bodies and have an extended configuration with a distal tip extending beyond the surface of the implant to engage the vertebral end plates after implantation and fix the position of the implant with respect to the

adjacent vertebral body. The fixation element may be extended in a variety of ways such as with fluid pressure, e.g. hydraulic fluid, by mechanical force, such as a threaded connection with a rotating driving member or other suitable means. Fluidic displacement is preferred. The distal tip of the fixation element should be sharp enough to penetrate into the vertebral end plate.

[0006] Preferably, the spinal implant embodying features of the invention is an expandable spinal implant such as the selectively expanding spine cage described in copending applications Serial No. 11/535,432, filed on September 26, 2006 and Serial No. 11/692,800, filed on March 28, 2007, which provides restoration of disc height between adjacent vertebrae and can provide corrective spinal alignment in a plurality of dimensions. Preferably, the implant has an interior cavity for receiving osteoconductive material to promote the formation of new bone in the intervertebral space subsequent to implanting.

[0007] A spinal implant having features of the invention has a base including a first pressure applying member such as an end plate with a first bone engaging surface, at least one extendable member cooperating with the base and a second upper pressure applying member with a second bone engaging surface coupled to the at least one extendable member. The one or more extendable fixation elements are configured to extend through passageways provided in the second upper pressure applying member and beyond the bone engaging surface thereof to penetrate into the adjacent vertebral end plate and fix the implant with respect the vertebral body. Preferably, the fixation elements are slidably disposed within recesses within the extendable members.

[0008] The selectively expanding spine cage (SEC) or spinal implant embodying features of the invention is particularly suitable for posterior insertion between

superior and inferior vertebral end plates as described in the aforementioned copending applications Ser. No. 11/535,432 and 11/692,800. The SEC has an unexpanded configuration which allows easy deployment and is typically about 0.8 to about 1 cm in maximum short transverse dimension so as to enable minimal invasive insertion posteriorly between vertebral pedicles through a working space of approximately 1 cm in diameter. The extended fixation element extends beyond the tissue engaging surface of the second pressure applying member by at least 0.1 cm, preferably at least 0.25 cm to ensure proper engagement or contact with the end plate of the vertebral body and preferably penetration thereof.

[0009] In one preferred embodiment, at least one and preferably all of the extendable members of the SEC have an extendable fixation element disposed within a recess in the extendable member. In this embodiment, the implant is preferably fluid activated so the extendable members expand the SEC after implantation and be properly positioned between the adjacent vertebral bodies. Additionally, the fixation member is also extended by fluid pressure with or after expansion of the SEC. Preferably, the fluid expansion is by hydraulic fluid from a master cylinder or a syringe located remotely from the patient to enable controlled spinal correction in multiple dimensions and fixation of the SEC in a proper position. Individual cylinders or syringes may also be employed. Advantageously, the hydraulic fluid is a time-controlled curable polymer, such as methylmethacrylate, which has a viscosity and curing time that can be adjusted by the formulation of an appropriate added catalyst, as is well known. When the polymer cures, it hardens and locks the expanded expandable members and the expanded fixation element in position to provide the desired amount of anterior/posterior, medial/lateral, superior/inferior spinal correction immovably in place. Mechanical locking of the

expandable members and/or the fixation elements may also be employed.

[0010] Once inserted between vertebral endplates, the implant advantageously can be expanded with a minimum of force exerted remotely through the hydraulic control lines. The expansion of the implant advantageously is about 20% to about 100% greater than the unexpanded height thereof, typically about 60%. Typical expansion is about 13 mm in the case of a 8mm implant and about 16 mm in the case of a 10 mm implant.

[0011] Since the vertebral end plates are held together at one (the anterior) end by a ligament much like a clamshell, as the implant expands against the vertebral end plates, the amount of vertical expansion can be adjusted to create the desired anterior/posterior correction angle.

[0012] Left and right lateral correction of the spine is achieved by differential vertical expansion of the two or more extendable members of the implant. Each extendable member is preferably independently controlled by a master cylinder or syringe located *ex vivo* (away from the patient) and communicating hydraulically with the slave cylinders for moving the pistons and top plate vertically and laterally for correcting spinal deformities anteriorly or posteriorly, medial or lateral, thus available to provide spinal correction in three dimensions.

[0013] A minimally invasive downsized insertion tool both inserts the unexpanded SEC posteriorly and houses the hydraulic lines communicating between the master cylinder and the slave cylinder. The insertion tool also houses a line for communicating the liquid or slurry bone graft material to the slave cylinder and into the intervertebral space for subsequent fusion. Advantageously, the hydraulic lines are small size tubing to allow for high hydraulic pressure without danger of the lines bursting. The sizes of the slave cylinders and pistons can be varied to increase the

mechanical advantage.

[0014] Due to the mechanical advantage provided by the hydraulic system, the SEC has minimized size and diameter in its unexpanded state that is smaller than the diameter of a prepared neuroforamen. The SEC thus can be inserted posteriorly and is engaged between the endplates of the adjacent vertebra to effectively distract the intervertebral area, restore space for neural elements, stabilize the motion segment and eliminate pathologic segmental motion. The SEC enhances spine arthrodesis by creating a rigid spine segment.

[0015] The SEC provides a significant advantage by enabling a comparatively large quantity of bone growth conductive or inductive agents to be contained within its interior and communicating directly to adjacent bone. Importantly, this results in fixation forces greater than adjacent bone and soft tissue failure forces.

[0016] The hydraulic control system provides a minimally invasive procedure by enabling the surgeon to apply a controlling force away from the patient's body to expand and adjust the spinal implant in three dimensions. Preferably, the expansion is infinitely adjustable to provide a variety of height and lateral angles, and is not limited to incremental positions. The implant can be used to promote fusion, and/or to correct deformities such as scoliosis, kyphosis, and spondylolisthesis.

[0017] The clinical goals of the SEC and the method for its insertion provide a minimally invasive risk of trauma to nerve roots, reduce pain, improve function, and permit early mobilization of the patient after fusion surgery. The fixation elements maintain the implant in a desired position until healing (fusion or arthrodesis) occurs. At this point, the implant is incorporated inside bone and its role becomes quiescent. The present SEC provides more internal and external graft bone space exposure, easier and safer directed insertion, less risk of insertional damage to nerve roots and

other tissue, and thus provide substantially improved immediate and long term results.

[0018] Thus, a key feature of the invention is that an essentially incompressible implant can be inserted posteriorly between vertebral pedicles in only a 1 cm working space. The implant then can be expanded to about 100% to about 200%, typically about 160%, of its original insertion size to provide a closely controlled full range of spinal correction in three dimensions. The one or more expandable fixation elements or spikes ensure that the implant remains in place after deployment. These and other advantages of the invention will become more apparent from the following detailed description and the accompanying exemplary drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0019] **Figure 1** depicts placement of an SEC embodying features of the invention between adjacent lumbar vertebrae.

[0020] **Figure 2** is a front perspective view of the SEC shown in **Figure 1** in an unexpanded state prior to deployment.

[0021] **Figure 3** is a sectional view of the SEC shown in **Figure 2**.

[0022] **Figure 4** is a front perspective view of the SEC of similar to that shown in **Figure 2** in an expanded configuration:

[0023] **Figure 5** is a sectional view of the SEC of **Figure 6** in the expanded configuration.

[0024] **Figure 6** is a partial sectional view of the expanded SEC shown in **Figure 5** in place adjacent to a vertebral body with the pointed ends of a fixation member penetrating the surface of the vertebral body.

DETAILED DESCRIPTION OF EMBODIMENTS OF THE INVENTION

[0025] **Figure 1** illustrates location of spinal implant or SEC **10** between adjacent

lumbar vertebrae in an expanded configuration. A partial or complete discectomy is performed prior to the insertion of the spinal implant **10** in a conventional manner. The SEC **10** is introduced in its unexpanded state to enable it to be inserted posteriorly with minimal trauma to the patient and risk of injury to nerve roots. Once in place the SEC **10** can be expanded to provide both medial and lateral spinal correction. The SEC has an unexpanded height of about 5 to about 15 mm, typically about 10 mm and is expandable to at least 130% to about 180% of the unexpanded height. Typically the SEC is about 9 to about 15 mm, typically about 12 mm wide and about 25 to about 40 mm, typically about 28 mm long to facilitate posterior insertion and thereby minimize trauma to the patient and risk of injury to nerve roots.

[0026] **Figures 2-3** illustrate the SEC **10** in a closed or unexpanded configuration and **Figure 4** illustrates the SEC **10** in an expanded configuration in section or cutaway view to shown the interior structure.

[0027] As shown in these figures, the SEC **10** has a base **12** with a pressure applying end member or plate **13** having a surface **14** for engaging an end surface of an adjacent vertebral body. Extendable support members **15** and **16** cooperate with the base **12**. A second end pressure applying member or plate **17** is coupled to the extendable support members **15** and **16** so that the plate **17** moves with the extension of extendable support members **15** and **16**. The plate **17** may be fixed to only one of the extendable support member but also engageable with the other extendable support member. Each extendable support member may have a separate end plate fixed thereto. As shown in more detail in **Figure 3**, the extendable support members **15** and **16** are provided with fixation elements or spikes **18** and **19** which are slidably disposed within the bores **20** and **21** of extendable support members **15** and **16**. The spikes **18** and **19** are provided with

enlarged bases **22** and **23** which provide a seal with the bores **20** and **21**. The seal allows extension of the spikes **18** and **19** to be extended with the same pressurized hydraulic fluid (not shown) which extends the extendable support members **15** and **16**. The spikes **18** and **19** are provided with pointed distal tips **22** and **23** which extend through passageways **24** and **25** provided in the end pressure plate **17** to ensure contact between the spikes and the adjacent vertebral body as shown in **Figure 5** so as to fix the SEC **10** within the space between the adjacent vertebral bodies. In **Figure 5**, the SEC **10** is shown in the expanded configuration. The SEC **10** has a central cavity **27** for infusion of bone graft material into the intervertebral space when the SEC is fully expanded or during the expansion process

[0028] Additional details of the SEC such as the attachment of hydraulic lines and lines for transmission of a slurry or liquid bone graft material, device and hydraulic fluid delivery accessories and the like can be found in co-pending applications Serial No. 11/535,432 filed on September 26, 2006 and Serial No. 11,692,800, filed on March 28, 2007, which are incorporated herein by reference.

[0029] Since vertebral end plates are held together at one end by a ligament much like a clamshell, expansion of the device **10** against the end plates of adjacent vertebral bodies can be adjusted to create the desired anterior/posterior correction angle.

[0030] The hydraulic fluid used to expand the SEC **10** and to extend the spikes **18** and **19** may advantageously be a time-controlled curable polymer such as methylmethacrylate. The viscosity and curing time of such a polymer can be adjusted by the formulation with an appropriate added catalyst as is well known. Such catalysts are available from LOCTITE Corp., 1001 Trout Brook Crossing, Rocky Hill, Connecticut 06067. When the polymer cures, it hardens and locks the

extendable members **15** and **16** and the spikes **18** and **19** in a desired position to provide the desired amount of spinal correction determined by the physician. Other means may be employed to lock the extendable members and the spikes in a desired position. For example, spring actuated locking fingers may be provided in the bore of one or more of the pistons and one or more of the bores of the spikes which extend outwardly when the piston or spike pass their respective locations upon extension thereof.

[0031] It will be appreciated that the SEC, including its various components should be formed of biocompatible, substantially incompressible material such as titanium, and preferably type 6-4 titanium alloy or other suitable materials which will allow for long term deployment within a patient.

[0032] The extension of extendable members **15** and **16** are preferably individually controlled so that the physician is able to provide a controlled angle of the SEC corrective surface. While only two extendable members are described herein, the SEC **10** may be provided with three or more individually extendable members so that the physician can exercise three-dimensional control of the SEC extension.

[0033] The SEC **10** embodying features of the invention provides advantages that include correction of coronal plane deformity; introduction of interbody lordosis, early stabilization of the interbody space with rigidity that is greater than present spacer devices and the ability to fix the SEC within the intervertebral space. This early stability may improve post-operative pain, preclude the need for posterior implants including pedicle screws, and improve the rate of successful arthrodesis. Importantly, the SEC provides improvement of space available for the neural elements while improving lordosis. As infused osteoinductive/osteoconductive bone graft materials

heal, the patient becomes well and the implant becomes inert and quiescent, embedded in bone, and no longer needed.

[0034] While the invention has been described in connection with what are presently considered to be the most practical and preferred embodiments, it is to be understood that the invention is not limited to the disclosed embodiments and alternatives as set forth above, but on the contrary is intended to cover various modifications and equivalent arrangements included within the scope of the following claims.

[0035] For example, the SEC **10** described herein is expanded by hydraulic fluid. Other expansion means may be employed. For example, a screw mechanism may be employed to expand the SEC and to extend one or more of the spikes into engagement with adjacent vertebral surfaces. Additionally, the spikes which help fix the SEC within the vertebral space are described herein as being extended with the extendable support members. However, the spikes may be slidably disposed in separate bores and extended by means independent of the expansion means of the extendable support members.

[0036] Further, the SEC can be provided with load or pressure sensors that register differential pressure and pressure intensity exerted on the engaging surfaces of the SEC by the patient's vertebrae end plates to generate corrective signals, for example by computer control, that are used, e.g. by the surgeon or by a computer controlled mechanism to realign the patient's spine. The invention may further include a system that makes these adjustments, responsive to sensor signals, in real time and on a continual basis, such that the shapes of the implant changes to realign the patient's spine or mechanism. Preferably, such system is contemplated for use in setting the positions of the pistons during installation of the implant.

[0037] Furthermore, the SEC needs not be rigidly locked into position but may be provided with yieldable material to provide some movement of the end surfaces of the SEC to accommodate spinal movement.

[0038] While particular forms of the invention have been illustrated and described herein, it will be apparent that various modifications and improvements can be made to the invention. Additional details of the spinal implant devices may be found in the patents and applications referenced herein. To the extent not otherwise disclosed herein, materials and structure may be of conventional design.

[0039] Moreover, individual features of embodiments of the invention may be shown in some drawings and not in others, but those skilled in the art will recognize that individual features of one embodiment of the invention can be combined with any or all the features of another embodiment. Accordingly, it is not intended that the invention be limited to the specific embodiments illustrated. It is therefore intended that this invention be defined by the scope of the appended claims as broadly as the prior art will permit.

[0040] Terms such as "element", "member", "component", "device", "means", "portion", "section", "steps" and words of similar import when used herein shall not be construed as invoking the provisions of 35 U.S.C §112(6) unless the following claims expressly use the terms "means for" or "step for" followed by a particular function without reference to a specific structure or a specific action. All patents and all patent applications referred to above are hereby incorporated by reference in their entirety.

WHAT IS CLAIMED IS:

1. A spinal implant for placement in a space between adjacent vertebral bodies, comprising:

- a. a first surface for engaging an end of a first adjacent vertebral body;
- b. a second surface for engaging an end of a second adjacent vertebral body;
- c. at least one extendable member configured to extend at least one of the first and second surfaces from a contracted configuration to an extended configuration in contact with an end of an adjacent vertebral body; and
- d. at least one extendable fixation element having a distal tip configured to penetrate into an end of an adjacent vertebral body, a contracted configuration within the implant to facilitate deployment of the implant between the first and second vertebral bodies and an extended configuration to extend the distal tip beyond the second surface to penetrate into an end of the second adjacent vertebral body and to fix the implant within the space between the first and second adjacent vertebral bodies.

2. The implant of claim 1 wherein the first surface for engaging an end of a first adjacent vertebral body includes a base member and the second surface for engaging an end of a second adjacent vertebral body includes a pressure applying member to extend at least one of the first and second surfaces.

3. The implant of claim 2 wherein at least one support member cooperates with the base and is coupled to the pressure applying member.

4. The implant of claim 3 wherein the pressure applying member has at least one passageway through which the distal tip of the fixation element extends to engage the end of the second vertebral body.

5. The implant of claim 3 wherein the support member is adapted to be extended.

6. The implant of claim 5 wherein the support member is adapted to be extended by fluid.

7. The implant of claim 6 wherein the fluid is hydraulic fluid.

8. The implant of claim 5 wherein the extendable fixation element is extendable with respect to the support member.

9. The implant of claim 5 wherein the extendable fixation element is extendable independent of the support member.

10. The implant of claim 1 wherein the extendable fixation element is adapted to be extended by fluid.

11. The implant of claim 10 wherein the fluid is hydraulic fluid.

12. The implant of claim 10 wherein the hydraulic fluid comprises a curable polymer having a fluid state for providing hydraulic communication of mechanical force to extend the fixation element to engage an adjacent vertebral body.

13. The implant of claim 9 wherein the polymer is cured to a solid state to lock the extended fixation element to hold the spinal implant in the space between vertebral bodies.

14. The implant of claim 13 wherein the polymer comprises methyl methacrylate.

15. The implant of claim 8 wherein the extendable fixation element is slidably disposed within a bore of an extendable member.

16. The implant of claim 15 wherein the extendable fixation element is extended by hydraulic fluid within the bore of the extendable member.

17. The implant of claim 5 including a plurality of extendable support members cooperating with the base.

18. The implant of claim 17 wherein at least two of the extendable support members are adapted to be independently extended.

19. The implant of claim 5 wherein a plurality of support members cooperate with the base and are coupled to the pressure applying member.

20. The implant of claim 19 wherein at least two of the support members have bores and have extendable fixation elements disposed within the bores.

21. A system for treating a patient's vertebral structure, comprising:

- a. a spinal implant having
 - i. a first surface for engaging an end of a first adjacent vertebral body,
 - ii. a second surface for engaging an end of a second adjacent vertebral body,
 - iii. at least one extendable member configured to extend at least one of the first and second surfaces from a contracted configuration to an extended configuration in contact with an end of an adjacent vertebral body, and
 - iv. at least one extendable fixation element having a distal tip, a contracted configuration within the implant to facilitate deployment of the implant between the first and second vertebral bodies and an extended configuration to extend the distal tip beyond the second surface to penetrate into an end of

the second adjacent vertebral body and to fix the implant within the space between the first and second adjacent vertebral bodies; and

- b. means for inserting the spinal implant into a space between two vertebral bodies with the at least one extendable fixation element in the contracted configuration

22. The method of claim 21 wherein the second surface of the implant has a passageway and the fixation element extends through the passageway upon extension to the extended configuration.

23. The system of claim 21 wherein the implant has at least one extendable support member connected between the first and second pressure applying surfaces to expand the implant within the space between two adjacent vertebral bodies.

24. The system of claim 23 wherein the at least one extendable support member has a bore which receives a fixation element which is extended upon extension of the support member.

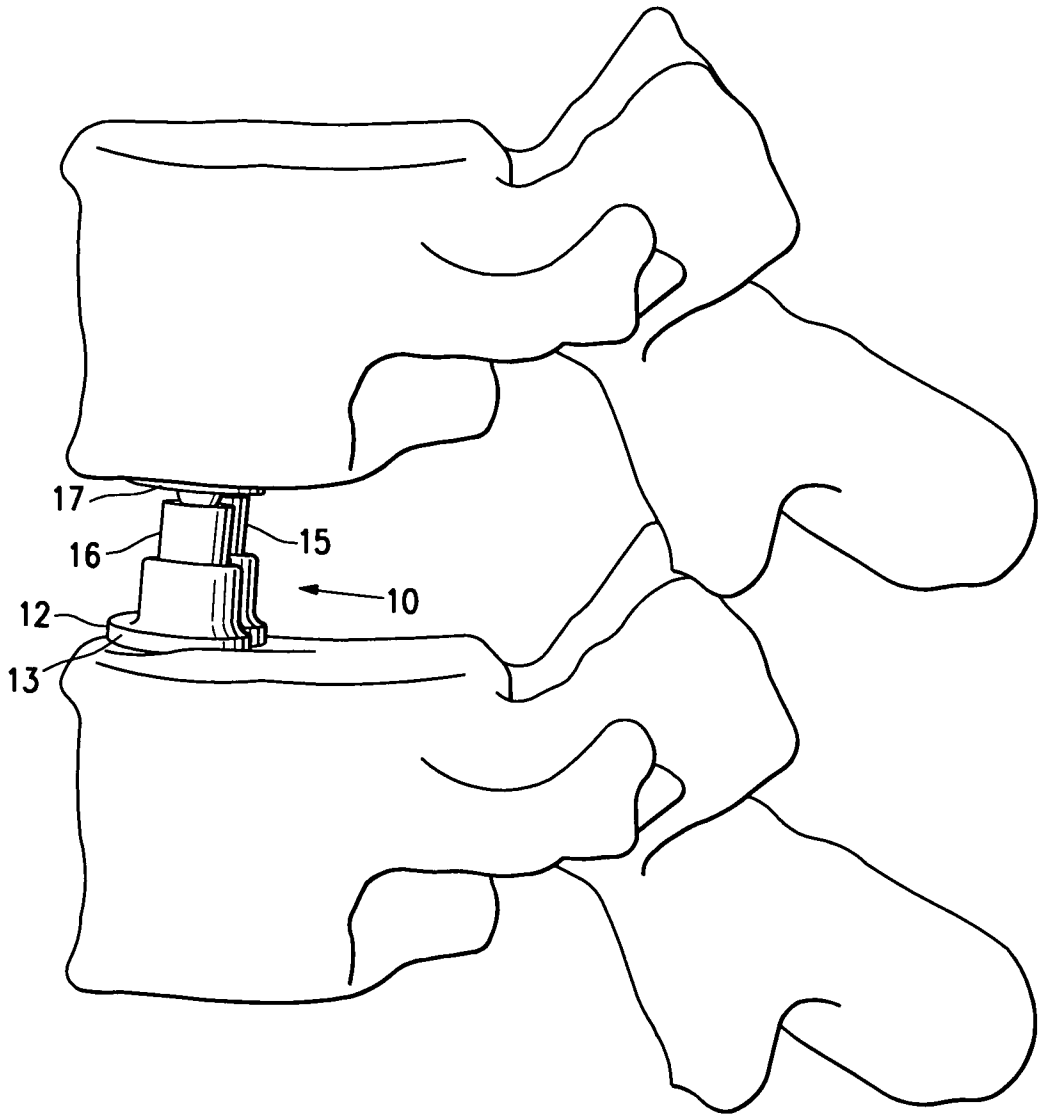


FIG. 1

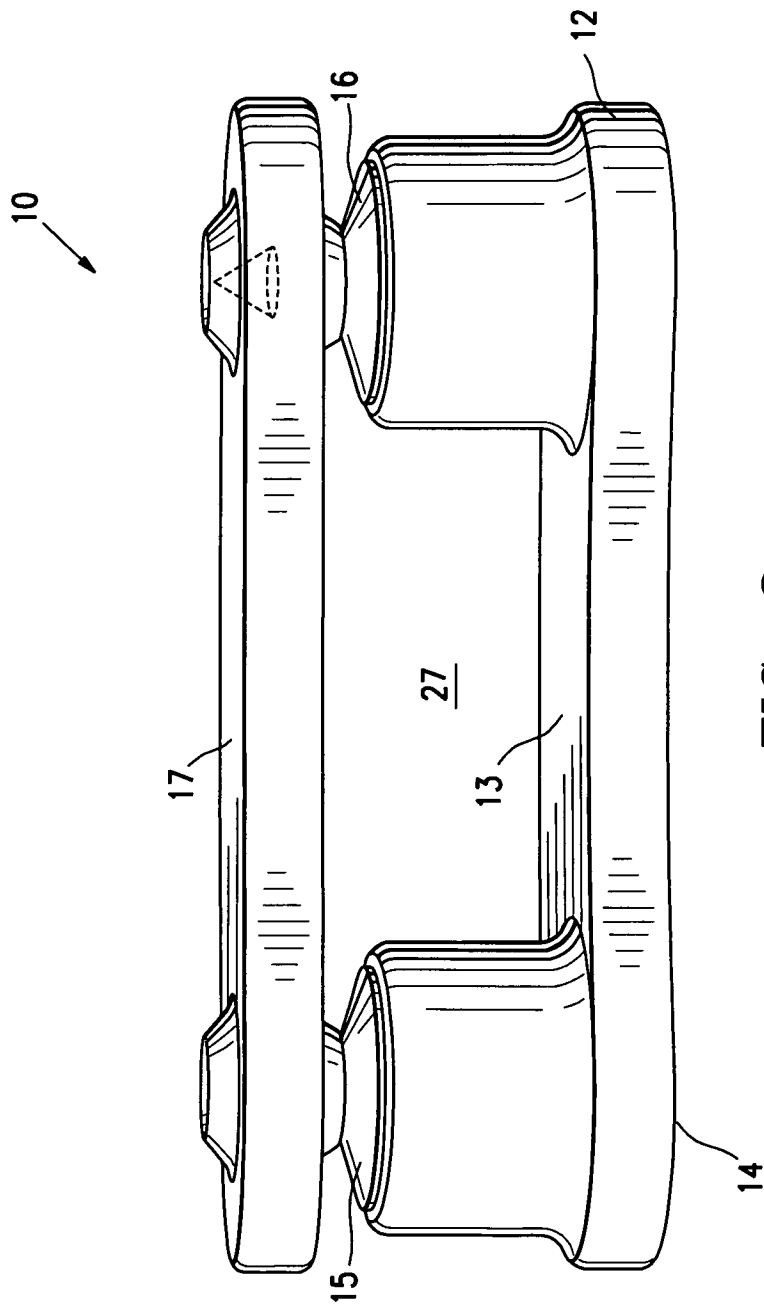


FIG. 2

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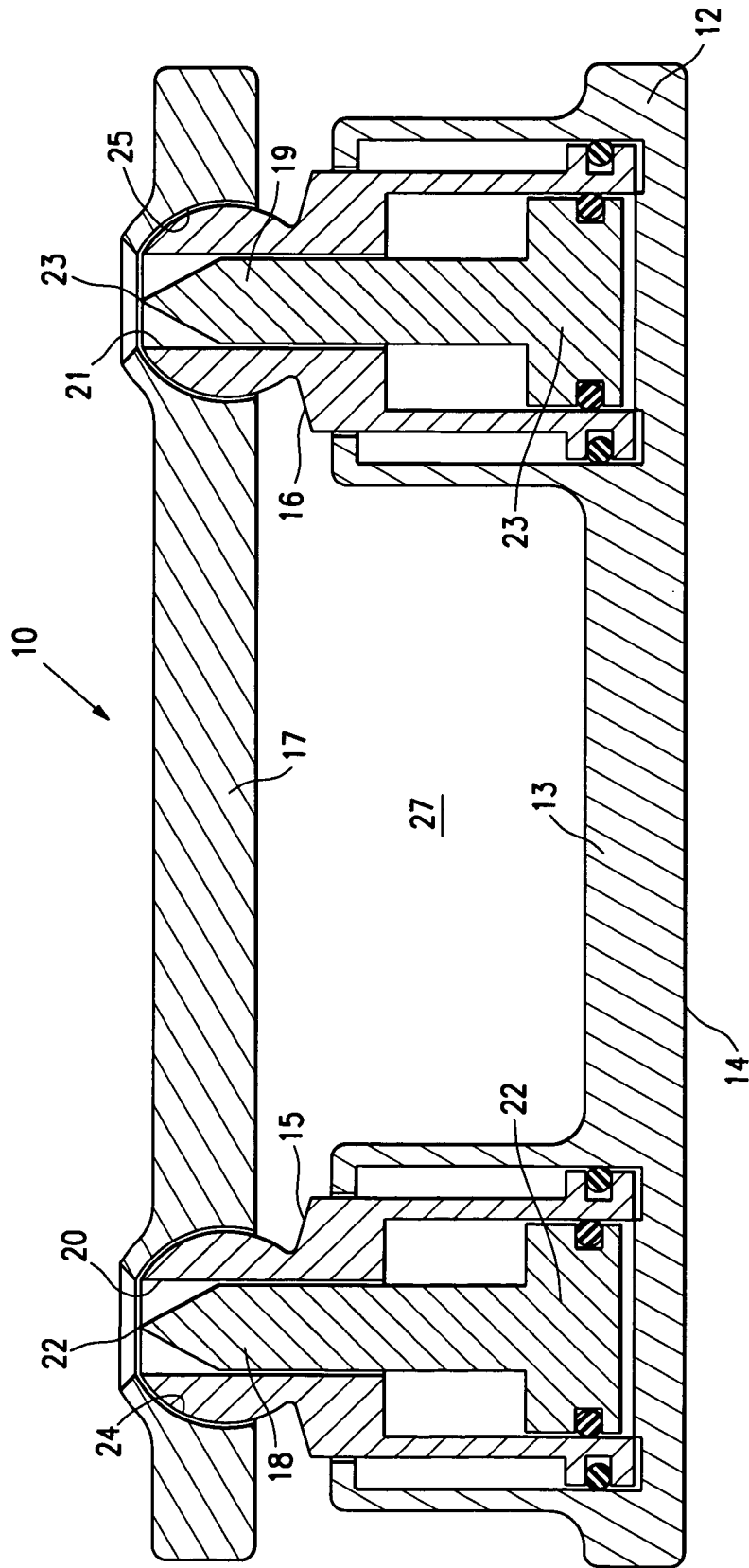


FIG. 3

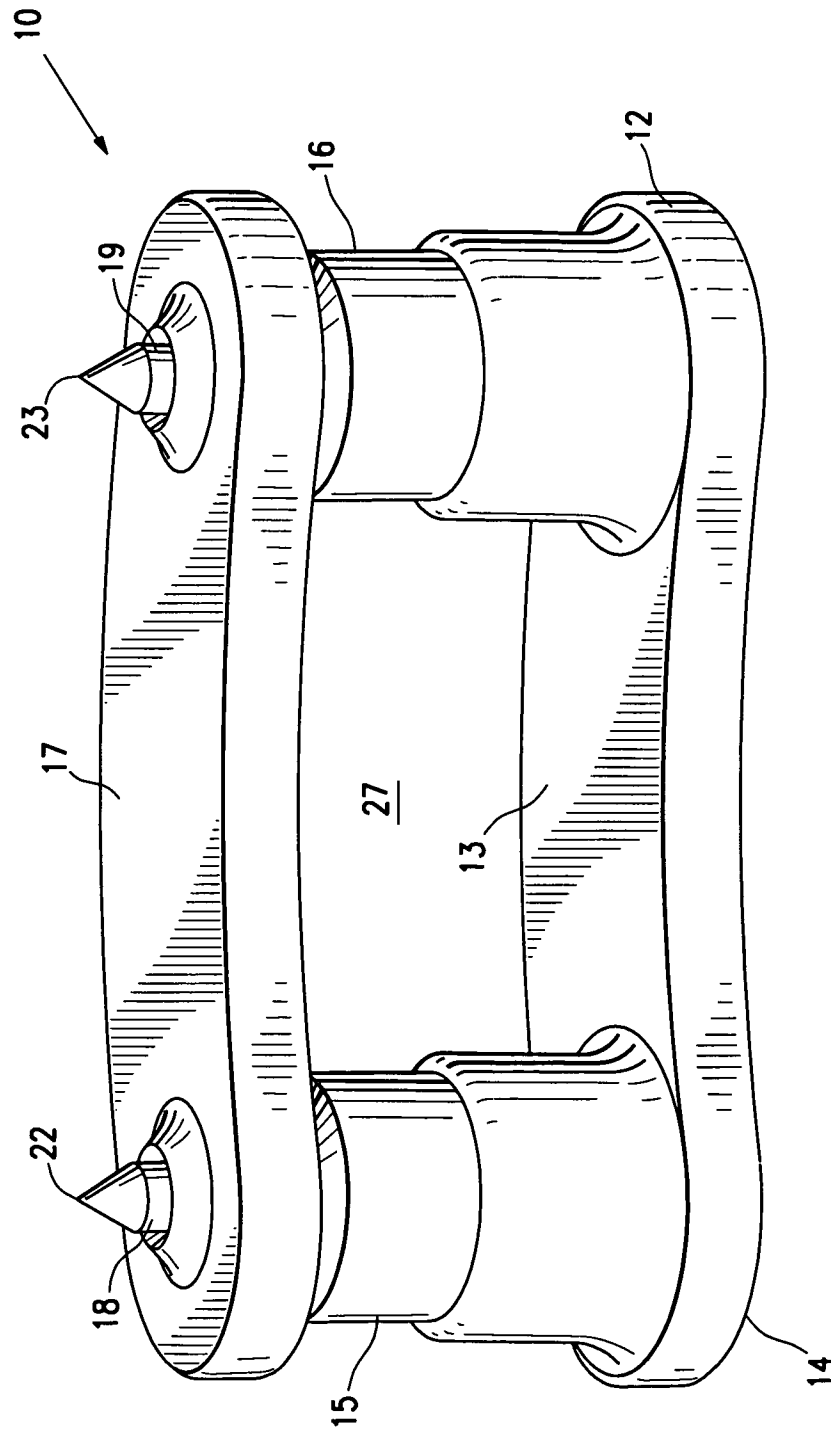


FIG. 4

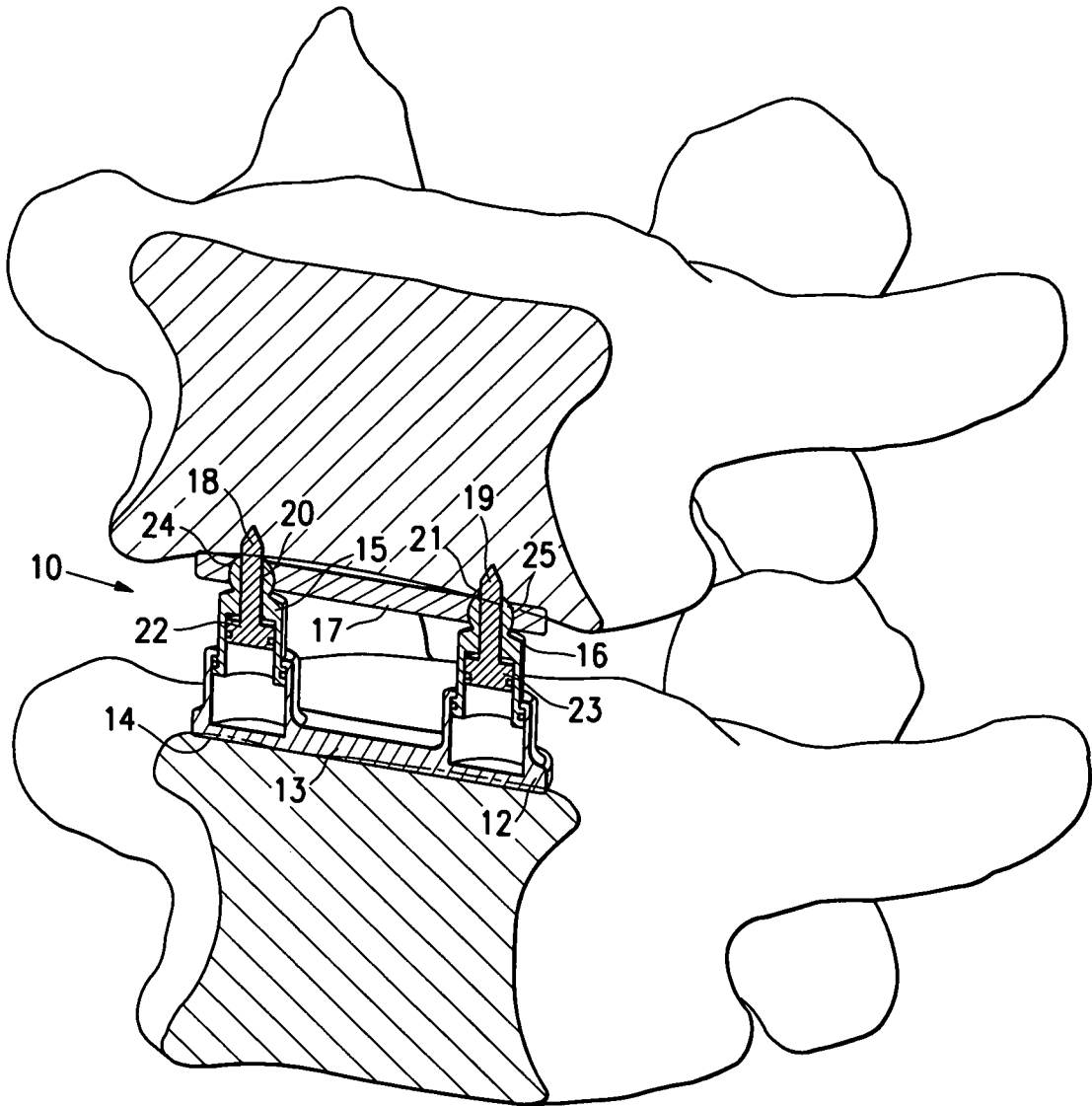


FIG. 5

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2009/000974

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/30 A61F2/44

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61F

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 236 460 A (BARBER FOREST C [US]) 17 August 1993 (1993-08-17)	1-8, 10-16, 21-24
Y	column 1, line 25 - column 4, line 13	9, 14, 17-20
Y	WO 2004/016205 A (COPPEs JUSTIN K [US]; GERBER DAVID [US]; PAUL DAVID [US]; LEE ANDREW []) 26 February 2004 (2004-02-26) paragraphs [0055] - [0067]	9
Y	US 2007/233254 A1 (GROTZ THOMAS [US] ET AL) 4 October 2007 (2007-10-04) paragraphs [0002], [0074] - [0088]	14, 17-20
A	US 2007/050030 A1 (KIM RICHARD C [US]) 1 March 2007 (2007-03-01) paragraph [0084]	1-24

Further documents are listed in the continuation of Box C.

See patent family annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
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Date of the actual completion of the international search

Date of mailing of the international search report

26 May 2009

05/06/2009

Name and mailing address of the ISA/

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No PCT/US2009/000974

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