108

Industria y Comercio
SUPERINTENDENCIA

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
No. 07-051419- -00004-0000
Fecha: 2008-08-11 14:44:00 Dep: 2020 NUECREACIONI
Tra: 11 PATENTEIYII Eve: 378 FASENACIONALI
Act: 329 CTOINFORMACION Folios: 13

FORMULARIO ÚNICO DE CORRECCIONES Y MODIFICACIONES

SOLICITUD DE :

1 ☐ Corrección de error material ☒ Modificación a una solicitud

2 **SOLICITANTE**	Nombre: **SPINE SOLUTIONS, INC.** Dirección: 1302 Wrights Lane East, West Chester, Pennsylvania 19389, Estados Unidos de América. Nacionalidad o Domicilio: Chester, Pennsylvania, Estados Unidos de América Lugar de Constitución: Pennsylvania, Estados Unidos de América Teléfono: Fax: E-mail:	**IDENTIFICACIÓN** **C.C.** ☐ **NIT** ☐ **C.E.** ☐ **Otro** ☐ **Cual** _____ **Número** _____
3 **REPRESENTANTE O APODERADO**	Nombre: JIMENA ESCOBAR URIBE Dirección: Cra. 11 No. 86-53 piso 6 Teléfono: 6 162051/61 Fax: 6 161889 E-mail: Jiescobar@clarkemodet.com.co	**IDENTIFICACIÓN** C.C. ☒ NIT ☐ C.E. ☐ Otro ☐ Cual _____ Número 39.779.452 T.P.68.228

4 **Número del expediente:** 07-051.419

5 **Descripción de la corrección o modificación solicitada:** **Que se anote :**

La **modificación** que consiste en eliminar las antiguas reivindicaciones 10 a 13.
Se limitó la ranura descrita en la reivindicación 1, definiendo sus superficies de piso y de pared lateral.
Se limitó el alcance de la reivindicación 6, definiendo las partes superiores e inferiores del dispositivo y las porciones de las superficies superior e inferior de núcleo.
Se modificó la numeración y dependencia de las antiguas reivindicaciones 14 a 37 (nuevas reivindicaciones 10 a 33).

6 **Comprobante de pago No.** 08 - 59.022 **Fecha** 23 de julio de 2008

7 **Anexos:**

☐ Comprobante de pago de la tasa
☐ Poderes, si fuere el caso
☐ Documento que acredita la existencia y representación legal de las partes, cuando sean personas jurídicas.

8

NOMBRE: JIMENA ESCOBAR URIBE **FIRMA:** _____
C.C. 39.779.452 de Usaquén T.P. 68228

As. 3065/PCT

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SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

No. 07-051419- -00004-0000

Fecha: 2008-08-11 14:44:00 Dep: 2020 NUECREACIONI
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SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

NIT : 800176089-2

RECIBO OFICIAL DE CAJA : 08 - 59,022
FECHA : JULIO 23 DE 2008

***** C O N S I G N A C I O N *****

DEPOSITANTE	TIPO PAGO	BANCO	CUENTA	No. PAGO	FECHA PGO	Vr. PAGO
CLARKE MODET Y CO. COLOMB	CONSIGNACION	BANCO DE BOGOTA	062754387	693136	23/07/2008	50,740,000.00

***** C O N C E P T O *****

CANT.	RENTISTICO	CONCEPTO	TOTAL CONCEPTO
1	50005-01-03 CAMBIO DE MODALIDAD Y MODIFICA	12 MARCAS Y LEMAS COMERCIALES	103,000.00
		TOTAL :	$ 103,000.00

SON: CIENTO TRES MIL PESOS

RESPONSABLE : _____

RECIBO DE CAJA APLICADO AL EXPEDIENTE No._____

3065/P

110

REIVINDICACIONES

1. Un dispositivo intervertebral que comprende:

Una parte superior que tiene una superficie superior para acoplar una vértebra y una superficie inferior que incluye una porción convexa;

Una parte inferior que tiene una superficie inferior para acoplar una vértebra y una superficie superior que tiene una porción convexa; y

Un elemento de núcleo que tiene una porción cóncava superior para acoplar operativamente con dicha porción convexa de dicha parte superior y una porción cóncava inferior para acoplar operativamente con dicha porción convexa de dicha parte inferior, las partes superior e inferior tiene una ranura que circunda sus porciones convexas, la ranura tiene una superficie de piso de ranura y una superficie de pared lateral de ranura que se extiende desde la superficie de piso de ranura hacia la opuesta de las partes superior e inferior, respectivamente.

2. El dispositivo intervertebral de la reivindicación 1, que incluye una ranura circunferencial en el núcleo adaptado para recibir un instrumento de inserción.

3. El dispositivo intervertebral de la reivindicación 1, en donde dicha parte superior comprende un anclaje para acoplar una vértebra.

4. El dispositivo intervertebral de la reivindicación 3, en donde dicho anclaje está en un ángulo de 45 grados con relación a un plano longitudinal transverso a través de un eje mayor de dicho implante.

5. El dispositivo intervertebral de la reivindicación 3, en donde dicho anclaje está en un ángulo entre 0 y 90 grados con relación a un plano longitudinal transverso a través de un eje mayor de dicho implante.

6. Un dispositivo intervertebral comprende:

Una parte superior que tiene una superficie superior para acoplar una vértebra y una superficie inferior que incluye una porción convexa;

Una parte inferior que tiene una superficie inferior para acoplar una vértebra y una superficie superior que tiene una porción convexa, las partes superior e inferior tienen una ranura que rodea sus porciones convexas; y

Un elemento de núcleo que tiene una porción cóncava superior para acoplar operativamente con dicha porción convexa de dicha parte superior y una porción cóncava para acoplar operativamente con dicha porción convexa de dicha parte inferior, el elemento de núcleo tienen superficies circunferenciales superior e inferior de núcleo,

Por lo cual dicha parte superior y dicha parte inferior son trasladables lateralmente con relación la una con la otra al deslizar junto con dichas porciones cóncavas de dicho inserto y por lo menos una porción de dichas superficies de núcleo superior e inferior sobre por lo menos una porción de las ranuras en una posición de doblez máxima del implante intervertebral para limitar el movimiento de las partes superior e inferior más allá de la posición de doblez máxima.

7. El dispositivo de la reivindicación 6, en donde cada una de dicha porción convexa de dicha parte superior y dicha parte inferior comprende una superficie de un elemento incrustado respectivo dimensionado para ser dispuesto en una cavidad respectiva formada en cada dicha partes superior y dicha parte inferior.

8. El dispositivo de la reivindicación 7, en donde dicho elemento de incrustación está compuesto de un

material seleccionado del grupo que consiste de metal, plástico y cerámica.

9. El dispositivo de la reivindicación 8, en donde dicho plástico comprende polietileno.

10. El dispositivo de la reivindicación 6, en donde:

Dicha ranura superior tiene una superficie de piso de ranura en un ángulo con relación a la horizontal;

Dicha ranura inferior tiene una superficie de ranura inferior en un ángulo con relación a la horizontal; y

Dicho elemento de núcleo tiene una superficie angulada superior y una superficie angulada inferior en ángulos en direcciones opuestas a aquel de la superficie de piso de ranura inferior y dicha superficie de piso de ranura inferior, respectivamente.

11. El dispositivo de la reivindicación 10, en donde dicha superficie de piso de ranura superior inferior y dicha superficie de piso de ranura inferior cazan con dicha superficie angulada superior y superficie angulada inferior de dicho núcleo, respectivamente, durante una posición de doblez máxima de dicha parte superior con relación a dicha parte inferior.

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12. El dispositivo de la reivindicación 6, en donde dicho elemento de núcleo tiene una superficie angulada superior y una superficie angulada inferior que se inclinan lejos de la superficie de piso de ranura de dicha ranura superior y dicha ranura inferior, respectivamente.

13. El dispositivo de la reivindicación 12, en donde dicha superficie de piso de ranura superior y dicha superficie de piso de ranura inferior cazan con dicha superficie angulada superior y superficie angulada inferior de dicho núcleo, respectivamente, durante una posición de doblez máxima de dicha parte superior con relación a dicha parte inferior.

14. El dispositivo intervertebral de la reivindicación 6, en donde al menos uno de dicha parte superior y dicha parte inferior comprende un anclaje para acoplar una vértebra.

15. El dispositivo intervertebral de la reivindicación 18, en donde dicho anclaje está en un ángulo entre 0 y 90 grados con relación a un plano longitudinal transverso a través de un eje mayor de dicho implante.

16. El dispositivo intervertebral de la reivindicación 19, en donde dicho anclaje está en un ángulo de 45 grados con relación al plano longitudinal transverso.

17. El dispositivo intervertebral de la reivindicación 6, en donde dicho elemento de núcleo comprende una ranura circunferencial adaptada para recibir un instrumento de inserción.

18. El dispositivo de la reivindicación 6, en donde dicha parte superior y dicha parte inferior permanecen paralelos con respecto al otro cuando dicha parte superior y dicha parte inferior se trasladan lateralmente con respecto a la otra.

19. Un dispositivo intervertebral que comprende:

Una superior que tiene una superficie superior para acoplar una vértebra, dicha parte superior tiene un elemento de incrustación dimensionado para estar dispuesto en una cavidad formada allí;

Dicho elemento de incrustación superior tiene una superficie inferior que incluye una superficie convexa que enfrenta la parte opuesta de dicha cavidad de parte superior;

Una parte inferior que tiene unas superficie inferior para acoplar una vértebra; dicha parte inferior tiene un elemento de incrustación inferior dimensionado para estar dispuesto en una cavidad formada allí; dicho elemento de incrustación inferior tiene una superficie superior que incluye una superficie convexa que enfrenta la parte opuesta de la cavidad de parte inferior; y

Un elemento de núcleo que tiene una porción cóncava superior para acoplar operativamente con dicha superficie convexa de dicha parte superior y una porción cóncava inferior para acoplar operativamente con dicha superficie convexa de dicha parte inferior,

En donde dicha parte superior y dicha parte inferior son trasladables con relación al deslizarse junto con dichas porciones cóncavas de dicho elemento de núcleo.

20. El dispositivo intervertebral de la reivindicación 19, en donde al menos uno de dicha parte superior y dicha parte inferior comprende un anclaje para acoplar una vértebra.

21. El dispositivo intervertebral de la reivindicación 19, en donde dicho anclaje está en un ángulo entre 0 y 90 grados con relación a un plano longitudinal

transverso a través de un eje mayor de dicho implante.

22. El dispositivo intervertebral de la reivindicación 21, en donde dicho anclaje está en un ángulo de 45 grados con relación al plano longitudinal transverso.

23. El dispositivo intervertebral de la reivindicación 19, en donde dicho elemento de núcleo comprende una ranura circunferencial adaptada para recibir un instrumento de inserción.

24. El dispositivo intervertebral de la reivindicación 19, en donde cada uno de dicho elemento de incrustación está compuesto de un material seleccionado del grupo que consiste de metal, plástico y cerámica.

25. El dispositivo de la reivindicación 24, en donde dicho plástico comprende polietileno.

26. El dispositivo de la reivindicación 19, en donde dicha parte superior comprende una ranura superior que rodea dicho elemento de incrustación superior y dicha parte inferior comprende una ranura inferior que rodea dicho elemento de incrustación inferior.

27. El dispositivo de la reivindicación 26, en donde dicho elemento de núcleo se adapta para deslizarse dentro de dicha ranura luego del movimiento de dicha parte superior con relación a dicha parte inferior.

28. El dispositivo de la reivindicación 26, en donde el movimiento de dicha parte superior con relación a dicha parte inferior se limita por dicho elemento de núcleo que limita la superficie de pared de la parte superior y la superficie de pared de la parte inferior de dicha ranura superior y dicha ranura inferior, respectivamente.

29. El dispositivo de la reivindicación 26, en donde:

Dicha ranura superior tiene una superficie de piso de ranura en un ángulo con relación a la horizontal;

Dicha ranura inferior tiene una superficie de piso de ranura en un ángulo con relación a la horizontal; y

Dicho elemento de núcleo tiene una superficie angulada superior y una superficie angulada inferior en ángulos respectivos en direcciones opuestas a aquel de la superficie de piso de ranura inferior y dicha superficie de piso de ranura inferior, respectivamente.

30. El dispositivo de la reivindicación 26, en donde:

Dicha ranura superior tiene una superficie de piso de ranura paralela a la horizontal;

Dicha ranura inferior tiene una superficie de piso de ranura paralela a la horizontal; y

Dicho elemento de núcleo tiene una superficie angulada superior y superficie angulada inferior en ángulos respectivos inclinados lejos de dicha superficie de piso de ranura superior y dicha superficie de piso de ranura inferior, respectivamente.

31. El dispositivo de la reivindicación 30, en donde dicha superficie de piso de ranura superior y dicha superficie de piso de ranura inferior cazan con dicha superficie angulada superior y superficie angulada inferior de dicho núcleo durante el movimiento máximo de dicha parte superior con relación a dicha parte inferior.

32. El dispositivo de la reivindicación 29, en donde dicha superficie de piso de ranura superior y dicha superficie de piso de ranura inferior cazan con dicha superficie angulada superior y superficie angulada inferior de dicho núcleo, respectivamente, durante el

movimiento máximo de dicha parte superior con relación a dicha parte inferior.

33. El dispositivo de la reivindicación 19, en donde dicha parte superior y dicha parte inferior permanecen paralelas con respecto a otra cuando dicha parte superior y dicha parte inferior se trasladan lateralmente con respecto a otra.

Industria y Comercio
SUPERINTENDENCIA

DIVISIÓN DE NUEVAS CREACIONES

RADICACIÓN EXPEDIENTE No. 07-51419

EL EXTRACTO DE LA PRESENTE SOLICITUD DE **PATENTE DE INVENCIÓN**

FUE PUBLICADO EN LA GACETA DE PROPIEDAD INDUSTRIAL No **589** DE

FECHA **29 DE FEBRERO DE 2008** EL TÉRMINO HÁBIL SEÑALADO POR LA

LEY EXPIRA EL **03 DE JUNIO DE 2008**

NOTA: Dentro del plazo de los seis (6) meses siguientes a partir de la fecha de publicación en la gaceta de Propiedad Industrial, deberá solicitar y cancelar el examen de patentabilidad so pena de que la solicitud caiga en abandono, de acuerdo con lo establecido en el Artículo 44 de la Decisión 486/2000.

SE PRESENTARON OPOSICIONES POR PARTE DE TERCEROS.

SI ____X____ NO _____

122

121

US 20040133281A1

(19) **United States**

(12) **Patent Application Publication** (10) **Pub. No.: US 2004/0133281 A1**

Khandkar et al. (43) **Pub. Date: Jul. 8, 2004**

(54) **TOTAL DISC IMPLANT**

(76) Inventors: **Ashok C. Khandkar**, Salt Lake City, UT (US); **Darrel S. Brodke**, Salt Lake City, UT (US); **Ramaswamy Lakshminarayanan**, Salt Lake City, UT (US)

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Woodland Hills, CA 91367 (US)

(21) Appl. No.: **10/737,108**

(22) Filed: **Dec. 15, 2003**

Related U.S. Application Data

(60) Provisional application No. 60/434,092, filed on Dec. 17, 2002.

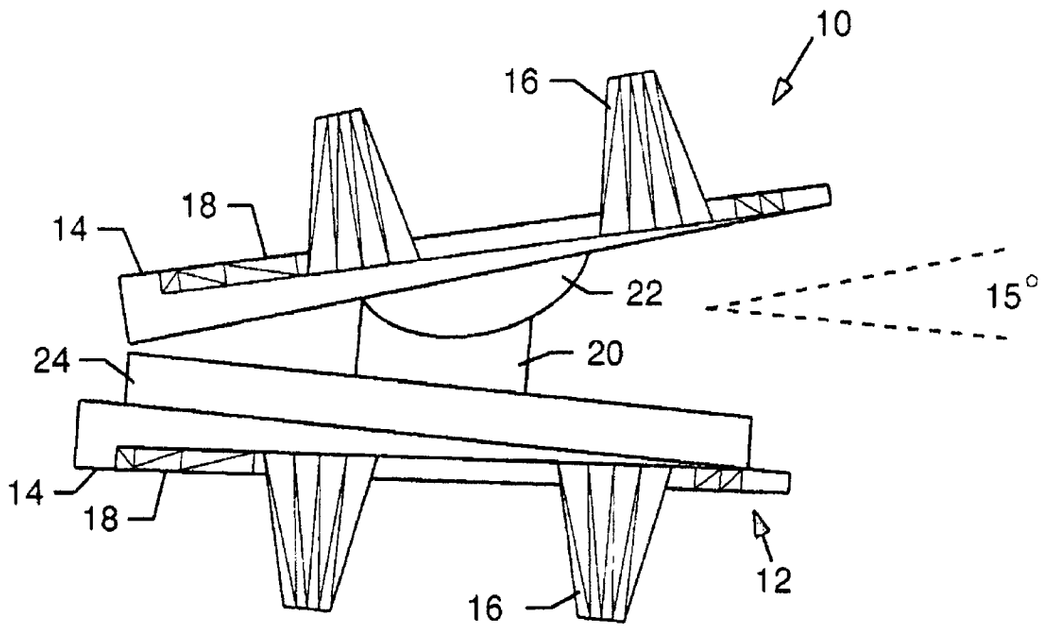
Publication Classification

(51) **Int. Cl.**[7] **A61F 2/44**

(52) **U.S. Cl.** **623/17.16**; 623/17.15

(57) **ABSTRACT**

A total disc implant (TDI) is provided for total replacement of a spinal disc or discs in a human patient or other mammal, wherein the TDI is designed to maintain a substantially full range of natural motion (ROM) following implantation. The TDI generally comprises, in one preferred form, upper and lower end plates for affixation to adjacent vertebral bodies, with an intervening insert disposed therebetween. The end plates each include elongated part-cylindrical surfaces oriented generally perpendicular to each other, with one of said surfaces extending in an anterior-posterior direction and the other extending in a medial-lateral direction. The intervening insert defines concave upper and lower part-cylindrical seats oriented for respectively engaging these part-cylindrical surfaces, wherein these part-cylindrical seats are defined by offset radii to include a somewhat flattened central base region merging smoothly with upwardly curving radiused sides.



cellous regions was critical to implant success[vi, vii]. More recent knee implant designs have included mobile bearing platforms that allow rotation and A-P translation. The articulations have improved conformity and kinematics, which lead to reduced contact stresses. However new problems arise: bearings without stops can dislocate or spin-out, and bearings with stops can wear as they abut against the mechanical stops that prevent dislocation.[viii]

[0010] Diagnostic imaging using radiography or MRI is commonly used to assess the presence of spinal disease, determine range of motion or evaluate the patients progress in healing post surgical treatment[ix, x]. The present generation of total disc replacements use metal end plates which present problems with imaging MRI or in X-Ray-CT imaging, due to the presence of halos and other artifacts.

[0011] Finally, an important requirement for total disc implants is that the articulating disc does not protrude or impinge on the spinal cord or nerve roots, which is a concern with compliant materials.[xi] As has been well established from other articulating joints such as the knee, PE inserts can suffer damage from several modes: creep, pitting, scratching, burnishing, abrasion, delamination and embedded particulates. While there is debate over whether creep or wear is the main cause of dimensional changes in PE inserts[xii, xiii], there is little doubt that damage to PE can and does occur over the long term.

[0012] Thus, there is a need to develop an alternative to the present generation of disc implants, typically with respect to those designed from metal/PE articulations, and to overcome a number of potential drawbacks:

[0013] [a]Long term wear of the articulating PE "disc", especially in cases where small bony fragments are entrapped between the articulating surfaces,

[0014] [b] Osteolysis and subsequent aseptic loosening and instability of the implant as a result of the PE wear debris,

[0015] [c] Protrusion of the disc from the disc space due to creep or fatigue related gradual changes in dimensional characteristics, and

[0016] [d] Difficulty of diagnostic imaging the intervertebral region because of electromagnetic artifacts, halos and radiographic shadows associated with the metal end plates.

[0017] The proposed TDI design of the present invention is geometrically configured to accommodate a substantially full and natural range of motion, and, in the preferred form, is constructed from an alternate ultra-low wear bearing material that restores anatomic function avoids all the drawbacks of current artificial disc designs.

SUMMARY OF THE INVENTION

[0018] In accordance with the invention, a total disc implant (TDI) is provided for total replacement of a spinal disc or discs in a human patient or other mammal, wherein the TDI is designed to maintain a substantially full range of natural motion (ROM) following implantation. In generally, the TDI comprises upper and lower end plates for affixation to adjacent vertebral bodies, wherein this pair of end plates are adapted for accommodating a substantially full and natural range of anterior-posterior (A-P) rotation or flexion, medial-lateral (M-L) rotation or flexion, and axial rotation.

[0019] In one preferred form, the TDI generally comprises the upper and lower end plates for affixation to adjacent vertebral bodies, in combination with an intervening insert disposed therebetween. The upper and lower end plates include elongated and generally convex part-cylindrical surfaces oriented generally perpendicular to each other, with one of said surfaces extending in an anterior-posterior direction and other extending in a medial-lateral direction. The intervening insert defines concave upper and lower part-cylindrical seats oriented generally perpendicular to each other for respectively engaging these part-cylindrical surfaces, but wherein at least one and preferably both of these part-cylindrical seats are defined by offset radii to include a somewhat flattened central base region merging smoothly with upwardly curving radiused sides. With this geometry, the TDI accommodates a substantially full and natural range of motion, including anterior-posterior flexion, medial-lateral extension, and a limited range of axial rotation.

[0020] In an alternative form, an elongated and generally convex part-cylindrical surface is formed on one of the upper and lower end plates, and a generally convex part-cylindrical seat defined preferably by offset radii is formed on the other of the two end plates. When the upper and lower end plates are suitably affixed to adjacent vertebral bodies, the part-cylindrical convex surface is retained in articulating engagement with the part-cylindrical concave seat, in a manner permitting a substantially full and natural range of motion, including anterior-posterior flexion, medial-lateral extension, and a limited range of axial rotation.

[0021] Preferred materials include ceramic, with a most preferred material being sintered silicon nitride (Si_3N_4), for the upper and lower end plates and insert, or a biocompatible metal such as titanium or cobalt-chrome alloy, or a combination of such ceramic and metal materials. Preferred ceramic materials for use in a ceramic-ceramic or a ceramic-metal articulation interface are disclosed in copending U.S. Ser. No. 10/171,376, filed Jun. 13, 2002, which is incorporated by reference herein.

[0022] Other features and advantages of the present invention will become more apparent from the following detailed description, taken in conjunction with the accompanying drawings which illustrate, by way of example, the principles of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0023] The accompanying drawings illustrate the invention. In such drawings:

[0024] **FIG. 1** is an exploded top perspective view showing a total disc implant constructed in accordance with one preferred form of the present invention, and illustrating upper and lower end plates with an insert positioned therebetween;

[0025] **FIG. 2** is a side elevation view of the total disc implant depicted in **FIG. 1**;

[0026] **FIG. 3** is an enlarged side elevation view of the insert;

[0027] **FIG. 4** is a top plan view of the total disc implant of **FIG. 1**, showing axial rotation;

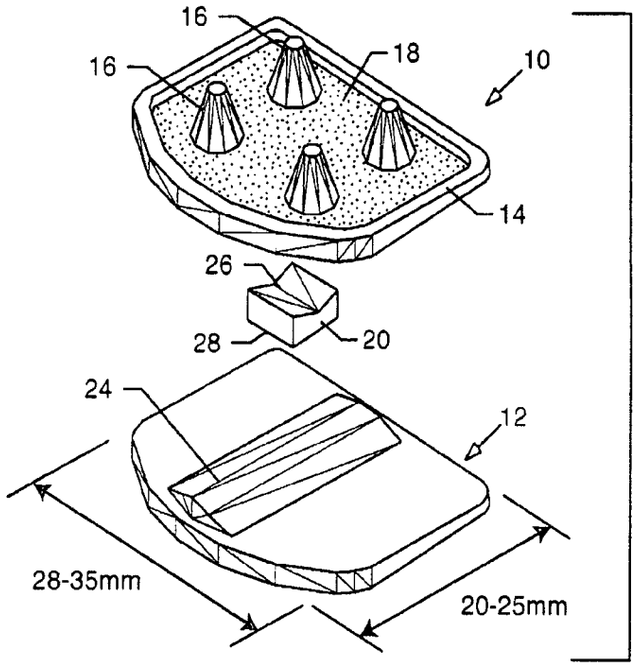


FIG. 1

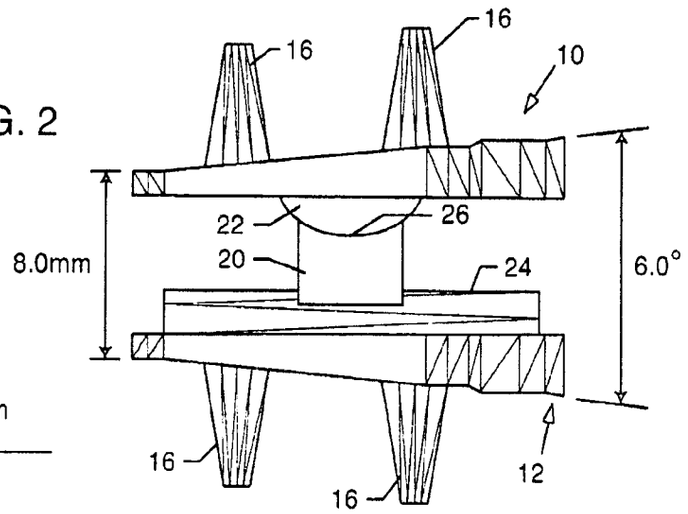


FIG. 2

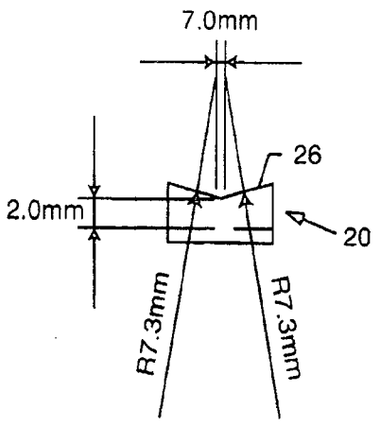


FIG. 3

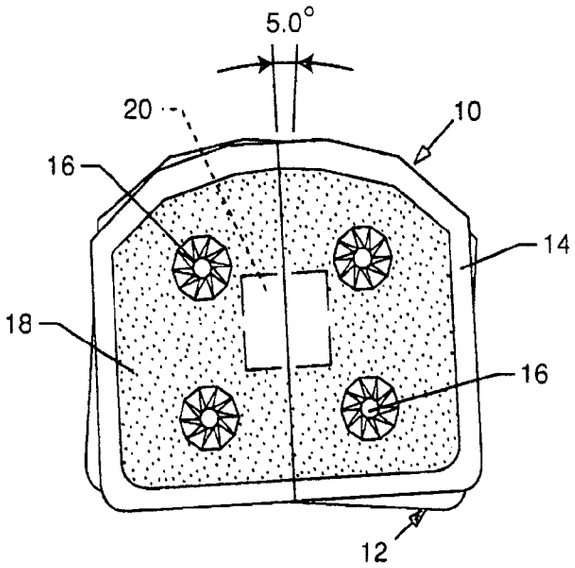


FIG. 4

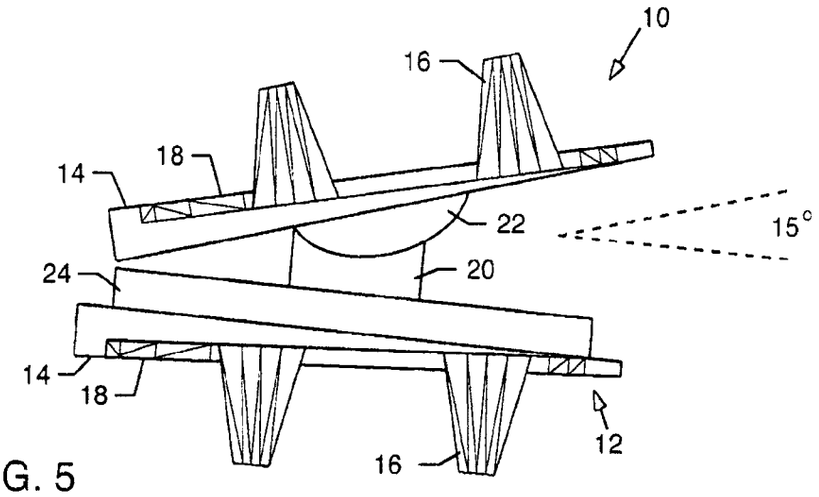


FIG. 5

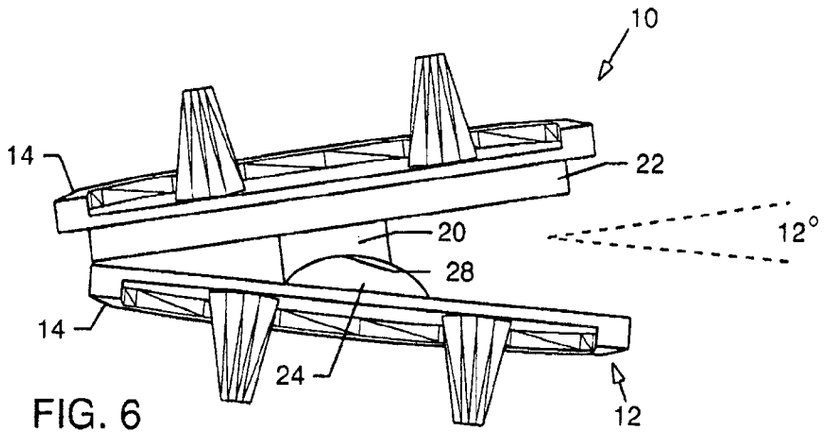


FIG. 6

US006428544B1

(12) **United States Patent**
Ralph et al.

(10) **Patent No.: US 6,428,544 B1**
(45) **Date of Patent: Aug. 6, 2002**

(54) **INSERTION TOOL FOR USE WITH TRIAL INTERVERTEBRAL DISTRACTION SPACERS**

(75) Inventors: **James D. Ralph**, Oakland; **Steven Tatar**, Montvale; **Thomas J. Errico**, Summit, all of NJ (US)

(73) Assignee: **Third Millennium Engineering, LLC**, Summit, NJ (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/906,120**

(22) Filed: **Jul. 16, 2001**

(51) **Int. Cl.**[7] **A61B 17/58**

(52) **U.S. Cl.** **606/99**; 506/86; 506/61; 623 17.11

(58) **Field of Search** 606/99, 100, 61, 606/205, 206, 207, 86; 623 22.11, 17.11, 17.15, 17.16, 18.11

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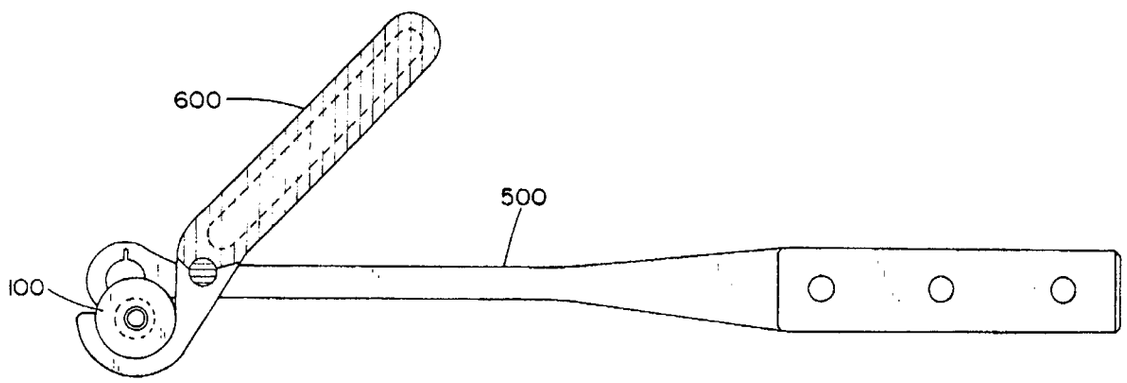
* cited by examiner

Primary Examiner—Pedro Philogene
(74) *Attorney, Agent, or Firm*—Joseph P. Errico; Timothy J. Bortree

(57) **ABSTRACT**

An instrument for inserting and removing an intervertebral spacer into and out from an intervertebral space between adjacent vertebral bones, the spacer having a trunk portion having a longitudinal axis and flange portions at each longitudinal end of the trunk, the instrument including: a shaft having a proximal end and a distal end; the proximal end including a handle; and a holding structure provided at the distal end, which holding structure includes an enclosure within which the trunk of the spacer may be selectively introduced and maintained therein, the holding structure having an opening leading to the enclosure and through which opening the trunk of the spacer may be selectively passed to when forced therethrough.

2 Claims, 13 Drawing Sheets



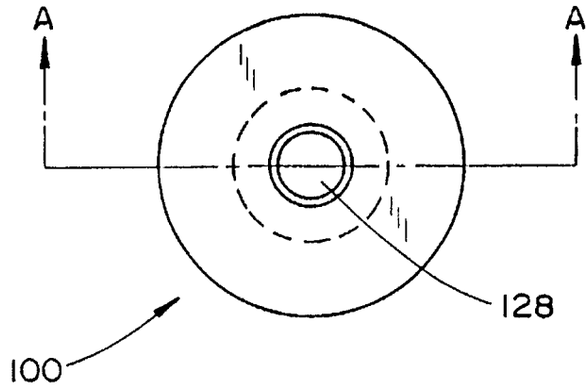


FIG. 1a

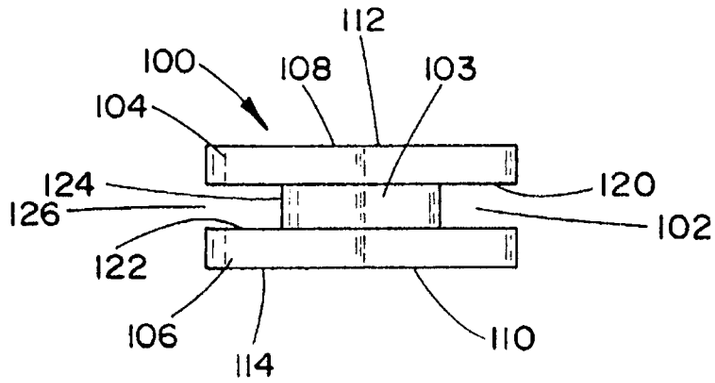
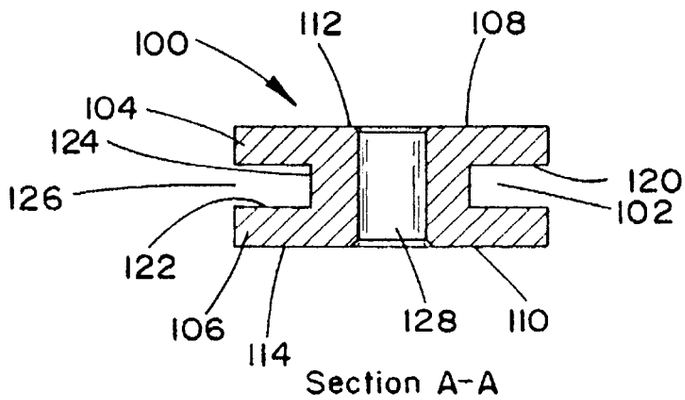


FIG. 1b



Section A-A

FIG. 1c

FIG. **2***d* illustrates a second set of intervertebral spacers of the invention in a side view.

FIGS. **3***a–c* illustrate a third embodiment of an intervertebral spacer of the invention in side, top and side cutaway views, respectively.

FIG. **3***d* illustrates a third set of tapered intervertebral spacers of the invention in a side

FIGS. **4***a–c* illustrate a fourth embodiment of an intervertebral spacer of the invention in side, top and side cutaway views, respectively.

FIG. **4***d* illustrates a fourth set of tapered intervertebral spacers of the invention in a side

FIG. **5***a* illustrates a first embodiment of a spacer insertion tool **500** of the invention in a side view.

FIG. **5***b* is a cutaway view of the insertion tool of FIG. **5***a* holding the spacer of FIGS. **1***a–c*.

FIGS. **6***a–b* illustrates an embodiment of a loading accessory for a spacer insertion tool of the invention in side and top views, respectively.

FIG. **6***c* shows the loading accessory of FIGS. **6***a–b* in operation to load the spacer of FIGS. **1***a–c* into the spacer insertion tool of FIG. **5***a*.

FIG. **6***d* shows the loading accessory of FIGS. **6***a–b* in operation to unload the spacer the spacer insertion tool of FIG. **5***a*.

FIG. **7***a* illustrates another embodiment of a spacer insertion tool of the invention in a side view.

FIG. **7***b* is a cutaway view of the insertion tool of FIG. **7***a* holding the spacer of FIGS. **4***a–c*.

FIGS. **8***a–b* illustrates yet another embodiment of a spacer insertion tool of the invention in open and closed side views, respectively.

FIG. **8***c* is a cutaway view of the insertion tool of FIGS. **8***a–b* holding the spacer of FIGS. **4***a–c*.

DETAILED DESCRIPTION OF THE INVENTION

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

First, the patient spine is exposed through an anterior approach (i.e. the surgeon creates an access hole which permits direct interaction with the anterior and/or anteriolateral portion of the intervertebral bodies). In the case of scoliosis, as well as in other disorders in which the intervertebral space requires distraction and/or repositioning, the surgeon removes the intervertebral disc material, usually leaving some portion of the annulus (the cylindrical weave of fibrous tissue which normally surrounds and constrains the softer cartilage cushion of the disc material). The surgeon then, in succession, inserts a series of intervertebral trial spacers of defined width. Each of the series of spacers is of a progressively wider thickness, resulting in the continual widening of the space until restoration of the proper disc height has been achieved. Proper disc height restoration

is determined by surgical experience, and by observation of the annulus. (Often, the tightening of the annulus indicates that the proper disc height has been reached, inasmuch as the annulus is much less likely to be distorted by the same disruption that caused the intervertebral disc to collapse in the first place.)

More particularly, with respect to the specific instruments disclosed herein, a series of solid trial spacer elements and an instrument for their insertion and removal is now provided. Each trial spacer is a generally cylindrical disc having a deep annular groove at its midpoint, which forms a central trunk and radial flanges at each end of the trunk. Stated alternatively, two cylindrical upper and lower halves of the disc are held in a closely coaxial spaced apart association by the central trunk, which forms a coaxial bridge between the upper and lower halves. The annular groove is particularly useful for holding the spacer using the spacer insertion instrument of the invention, described below, in that the holding end of the insertion instrument fits within the groove.

A variety of features of embodiments of the trial spacer elements are disclosed. In some embodiments, such as the first and second embodiments described below, support portions (the portions that are in contact with the adjacent vertebral bodies when the spacer is disposed between the bodies) of the top and bottom surfaces are parallel. Spacers having this feature are generally described herein as "constant thickness" trial spacers. In other embodiments, such as the third and fourth embodiments described below, the support portions are not parallel, providing an overall taper to the spacer at an angle. Spacers having this feature are generally described herein as "tapered thickness" trial spacers. The tapered thickness trial spacers are particularly useful for treating scoliosis, as described below.

Other features of embodiments of the trial spacer elements include beveled flanges and non-parallel annular groove walls. More specifically, in some embodiments, such as the second and fourth embodiments described below, the flanges are radially beveled in that an outer edge of the top surface of the disc is tapered toward an outer edge of the bottom surface of the disc. In other embodiments, such as the first and third embodiments described below, the flanges are not radially beveled in this manner. The radial beveling feature can be particularly useful for easing the insertion of the spacer in between collapsed vertebral bodies, as described below. Further, in some embodiments, such as the first and third embodiments described below, the walls of the annular groove are parallel, such that the floor of the groove is as wide as the opening of the groove. In other embodiments, such as the second and fourth embodiments described below, the walls of the annular groove are tapered toward one another with the increasing depth of the groove, such that the floor of the groove is narrower than the opening of the groove. Each type of annular groove is useful, depending on the particular surgical application and on the particular embodiment of the spacer insertion instrument that is used to insert the spacer.

Collections of trial spacer elements are provided by the invention. Preferably, each spacer in a particular set maintains the same diameter as the other spacers in the set. (it shall be understood that different collections of spacers may be provided such that the diameter of the selected collection of trial spacers is appropriate for the specific patient being treated. For example, the diameters of the trial spacers in a collection that is suitable for use with pediatric patients would be smaller than the diameters of the trial spacers in a collection that is suitable for use with adult patients.) Also

preferably, each spacer in a particular set has a predetermined depth that differs from the depth of the other spacers in the set. The predetermined depth is provided in that while each spacer in the set shares the same annular groove dimensions (so that each can be held by the same insertion instrument), each spacer has a different flange thickness (in sets where the spacers are constant thickness spacers). For sets of tapered thickness spacers, the predetermined maximum depth and predetermined minimum depth (the two depths providing the overall taper) are provided in that while each spacer in the set shares the same annular groove dimensions (so that each can be held by the same insertion instrument), each spacer has a different maximum flange thickness and a different minimum flange thickness. Preferably in sets of tapered thickness spacers, the overall taper angle is the same for each spacer in the set. The usefulness of providing sets of spacers similar in most respects except for the depth dimension will be described in greater detail below.

Referring now to FIGS. **1***a–c*, a first embodiment of an intervertebral trial spacer **100** of the invention is illustrated in side, top and side cutaway views, respectively. The spacer **100** is a cylindrical disc with an annular groove **102** that forms a central trunk **103** and radial flanges **104,106** at each end of the trunk **102**. In this embodiment, support portions **108,110** of the top and bottom surfaces **112,114** of the disc are parallel. Further in this embodiment, the walls **120,122** of the annular groove **102** are parallel, such that the floor **124** of the groove **102** is as wide as the opening **126** of the groove **102**. Further in this embodiment, the spacer **100** has a central bore **128**.

Referring now to FIG. **1***d*, a set of intervertebral spacers **100***a–l* of the invention are illustrated in a side view. Each spacer **100***a–l* is formed generally similarly to the intervertebral spacer **100** of FIGS. **1***a–c*, except that each spacer **100***a–l* has a predetermined depth (denoted by the preferred dimension identified adjacent each spacer) provided in that while each spacer **100***a–l* shares the same annular groove dimensions as the other spacers, each spacer **100***a–l* has a different flange thickness dimension. For example, the flanges **1041,1061** are thicker than the flanges **104***a*,**106***a*.

Referring now to FIGS. **2***a–c*, a second embodiment of an intervertebral spacer **200** of the invention is illustrated in side, top and side cutaway views, respectively. Similarly to the spacer **100**, the spacer **200** is a cylindrical disc with an annular groove **202** that forms a central trunk **203** and radial flanges **204,206** at each end of the trunk **202**. However, in this embodiment, the flanges **204,206** are radially tapered in that support portions **208,210** of the top and bottom surfaces **212,214** of the disc are parallel, while an outer edge **216** of the top surface **212** is tapered toward an outer edge **218** of the bottom surface **214**. Further in this embodiment, in contrast to the spacer **100**, the walls **220,222** of the annular groove **202** are tapered toward one another with the increasing depth of the groove **202**, such that the floor **224** of the groove **202** is more narrow than the opening **226** of the groove. Further in this embodiment, the spacer **200** has a central bore **228**.

Referring now to FIG. **2***d*, a set of intervertebral spacers **200***a–l* of the invention are illustrated in a side view. Each spacer **200***a–l* is formed generally similarly to the intervertebral spacer **200** of FIGS. **2***a–c*, except that each spacer **200***a–l* has a predetermined depth (denoted by the preferred dimension identified adjacent each spacer) provided in that while each spacer **200***a–l* shares the same annular groove dimensions as the other spacers, each spacer **200***a–l* has a different flange thickness dimension. For example, the flanges **2041,2061** are thicker than the flanges **204***a*,**206***a*.

With regard to the instrument for the insertion and removal of the trial spacer elements, a first embodiment (particularly useful for inserting constant thickness trial spacers) of a spacer insertion tool includes an elongated shaft and a handle at one end of the shaft. The distal end of the shaft includes semi-circular hook that is adapted to hold a trial spacer within an enclosure formed by the hook. The angle swept out by the hook is slightly greater than 180 degrees, but the inner diameter of the hook is only slightly larger than the central trunk of the trial spacer. Therefore, the trial spacer may be snapped into the enclosure, but maintains complete rotational freedom within its grasp. A loading tool may be provided to assist in the loading and unloading of the trial spacer from the trial spacer insertion instrument of this embodiment. This loading tool comprises a forked hook having two tines separated by a notch that engages the shaft of the insertion tool as the tines engage the flanges of the trial spacer, to force the trial spacer into the enclosure. Alternatively and/or additionally, the same device may be utilized to remove the spacer from the enclosure, by reversing the position of the forked hook relative to the insertion tool and the spacer.

Referring now to FIG. **5***a*, a first embodiment of a spacer insertion tool **500** of the invention is illustrated in a side view. The insertion tool **500** includes an elongated shaft **502** and a handle **503** at one end of the shaft **502**. At the other end of the shaft **502**, the insertion tool **500** includes a semi-circular hook **504** that is adapted to hold an intervertebral spacer of the invention within an enclosure **506** of the hook **504**. The central trunk of the spacer can be snapped into the enclosure **506** of the hook **504** so that the extent of the hook **504** fits loosely within the annular groove of the spacer and is flanked by the flanges of the spacer. The central trunk of the spacer can also be snapped out of the enclosure **506**.

In this regard, the hook **504** has an opening **508** that temporarily expands when the central trunk of the spacer is forced through the opening **508**. That is, the outer diameter of the central trunk is greater than the width of the opening **508**, so that the central trunk cannot pass through the opening **508** without force. The application of a force sufficient to cause the opening **508** to expand when confronted with the central trunk causes the central trunk to pass through the opening **508**. After the central trunk has cleared the opening **508**, the opening **508** will contract. The temporary expansion in this embodiment is provided by the hook **504** being formed of a material having a low elasticity and the hook **504** being provided with a stress notch **510** on the extent (preferably located opposite the opening **508** for maximum efficiency) to ease the expansion.

Once the spacer is loaded into the enclosure, the opening **508**, having contracted back to its resting width, prevents the central trunk from exiting the enclosure radially through the opening, because, as stated above, the outer diameter of the central trunk is greater than the width of the opening **508**. Further, by flanking the extent of the hook **504**, the flanges of the spacer prevent the spacer from exiting the enclosure laterally. The hook **504** therefore holds the spacer loosely in the enclosure so that the spacer can rotate about the cylindrical axis of the central trunk while being held by the hook **504**.

Referring now to FIG. **5***b*, a cutaway view of the insertion tool **500** of FIG. **5***a* holding the spacer **100** of FIGS. **1***a–c* shows the extent of the hook **504** in cross-section and fitting within the annular groove of the spacer. It can be seen that to enable the spacer **100** to be loosely held in the enclosure, the width of the extent is smaller than the width of the annular groove, and the depth of the extent is less than the