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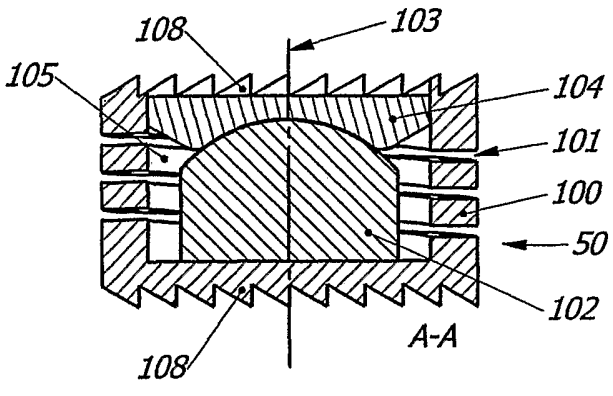
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(54) Title: INTERVERTEBRAL DISC REPLACEMENT PROSTHESIS



(57) Abstract: An intervertebral disc prosthesis (50) that comprises a deformable flexure (100) with an axial cavity (105), the axial cavity (105) extending along the axis of the flexure (100); a slit (101) defined in the perimeter surface of the flexure (100) to provide flexibility to the disc member, the slit (101) having a slit thickness. The slit (101) may be in the form of a coil to impart a spring-like appearance and function. The intervertebral disc prosthesis (50) further comprises a lower disc support (102) housed in the axial cavity and an upper disc support (104) housed in the axial cavity; with the lower and upper disk supports (102, 104) communicating with one another to provide support to the disc. The lower or upper disc support (102, 104) may alternatively be incorporated into the flexure.

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INTERVERTEBRAL DISC REPLACEMENT PROSTHESIS

FIELD OF THE INVENTION

This invention relates, generally, to the field of intervertebral disc replacement prosthesis.

BACKGROUND OF THE INVENTION AND DESCRIPTION OF RELATED ART

Degenerative disc disease is a common condition of the intervertebral disc (IVD) of the spine characterized by disc height collapse with or without disc herniation, osteophyte formation, foramenal stenosis, facet hypertrophy, synovial cyst, and other symptoms. Any or a combination of these findings can lead to pain or neurological deficit. Many of the symptoms of degenerative disc disease may be alleviated by decompression of the neural structures and immobilization of the involved spinal segments. Immobilization is typically achieved in the long term by removal of the disc and placement of bone graft. Temporary immobilization to encourage incorporation of the bone graft can be achieved with placement of rigid hardware such as screws and rods.

While immobilization and a successful fusion may relieve the pain associated with nerve impingement, the long-term consequences of eliminating the motion of the IVD show a tendency toward increased risk of failure of the adjacent discs. The lack of motion at the fusion site places increased biomechanical demands on the adjacent discs causing them to degenerate prematurely.

Replacement prostheses have been suggested for degenerative disc disease to allow motion at the operative disc level. However these devices are devoid of stiffness and stability and rely on the remaining spinal elements, such as the ligaments, muscles and remaining IVD tissue, namely the annulus fibrosis, for stability. For example, United States Patent Numbers 5,556,431 to Buttner-Janz, 5,507,846 to Bullivant and 5,888,226 to Chaim, all of which are incorporated herein by reference, describe prostheses that comprise ball and socket type joints. These inventions rely on stretching the annulus fibrosis to put the prosthesis into compression to gain stiffness. But there is risk of altering the spine's biomechanics by increasing the disc height past the normal range and risk of damage to the annulus fibrosis. If the disc space is not stretched enough an unstable spinal segment could result, possibly leading to pain and further injury. Furthermore, all of these prior art disc replacement prostheses consist of several parts that are not connected. Implantation entails insertion of several separate pieces that must be properly aligned during surgery. The surgery is often performed with a minimal incision offering limited access to the insertion site. Perfect alignment after insertion could be difficult.

Other prostheses have been suggested (for example, see Unites States Patents 6,136,031 to Middleton, 5,320,644 to Baumgartner, 5,827,328 to Buttermann and 5,676,702 to Ratron, all of which are incorporated herein by reference) which have their own inherent stiffness, but do not take into account that axial loads placed on the spine during activity are generally much larger than bending loads. Therefore, these prostheses would either bottom out under axial loads and offer no response to bending loads, or be stiff enough to support the axial loads and thereby too stiff to flex under bending loads.

What is needed is an intervertebral disc prosthesis that assists in alleviating the symptoms of degenerative disc disease without sacrificing normal spinal mechanics.

SUMMARY OF THE INVENTION

An object of the present invention is to provide an intervertebral disc prosthesis that assists in alleviating the symptoms of degenerative disc disease without sacrificing normal spinal biomechanics, and therefore not compromising the health of adjacent discs.

Another object of the present invention is to provide an intervertebral disc prosthesis that performs effectively and efficiently within a patient's spine over a long period of time.

Furthermore, another object of the present invention is a prosthesis that is easily implanted and mimics both the motion and the stiffness of a normal disc.

Embodiments of this invention include a prosthesis that is comprised of a flexible element enclosing supports, or bearing surfaces that resemble a ball-and-socket joint. In all embodiments, alignment of the bearing surfaces may be achieved during manufacture, not during surgery. Therefore, implantation involves placement of a single unit. The implant has the ability to mimic the motion of a normal healthy disc and also to approximate the stiffness of the disc material that it is replacing. These embodiments may be sized to accommodate a range of disc space geometries for the cervical, thoracic or lumbar spine.

A preferred embodiment of the present invention is an implantable intervertebral disc replacement prosthesis that comprises a deformable flexure with an axial cavity, the axial cavity extending along the axis of the flexure and a slit defined

in the perimeter surface of the flexure to provide flexibility to the disc member, the slit having a slit thickness. This embodiment further comprises a lower disc support housed in the axial cavity and an upper disc support housed in the axial cavity; with the lower and upper disk supports communicating with one another to provide support to the disc.

Alternatively, either the upper or lower disc support means may be incorporated into the flexure in the form of a concave axial cavity or a convex protuberance.

These and other embodiments will be apparent from the disclosure and claims.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a posterior view of a preferred embodiment of the present invention.

Figure 2 is a lateral, cross-sectional view of a preferred embodiment taken along line A-A of Figure 1.

Figure 3 is an exploded view of the preferred embodiment depicted in Figures 1 & 2.

Figure 4 is a diagram demonstrating the method of finding the instantaneous axis of rotation of a vertebra in motion relative to a fixed point.

Figure 5 is a lateral cross-sectional view of a normal spinal motion segment.

Figure 6 is a lateral cross-sectional view of a spinal motion segment showing placement of an embodiment of the invention in the disc space.

Figure 7 is a lateral view of an alternative embodiment of the present invention with slits or cuts that terminate in perimeter openings

Figure 8 is an isometric view of the alternative embodiment shown in Figure 7. **Figure 9** is an isometric view of an alternative embodiment of the present invention with an oval shape

Figure 10 is a cross-sectional view of an alternative embodiment of the present invention with a fixed axis.

Figure 11 is a cross-sectional view of an alternative embodiment of the present invention with a shifted axis.

Figure 12 is a cross-sectional view of an alternative embodiment of the present invention with an angulated flexure.

Figure 13 is a cross-sectional view of an alternative embodiment of the present invention with a lower seat.

Figure 14 is a cross-sectional view of an alternative embodiment of the present invention where the flexure incorporates an upper disc support means.

Figure 15 is a cross-sectional view of an alternative embodiment of the present invention with a wire spring.

Figure 16 is a cross-sectional view of an alternative embodiment of the present invention where the flexure incorporates a lower disc support means.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

A preferred embodiment of the invention is shown in Figures 1, 2 & 3. The disc replacement prosthesis of the present invention is an implantable intervertebral

disc replacement prosthesis **50** containing a flexure **100** which has an axis **103**. The flexure **100** is formed from a solid piece of material in which a blind hole is bored defining an axial cavity **105** which extends along the axis **103**. In this embodiment, a helical slit **101** is cut in the perimeter surface, with the axis of the helix approximately coincident with axis **103** of disc member **50**, so that the perimeter surface resembles a helical coil or spring.

The disc replacement of the present embodiment further comprises a lower disc support **102** housed in the axial cavity **105**, and an upper disc support **104** housed in the axial cavity **105**, with the lower and upper disc supports communicating with one another to provide support to the disc. The lower and upper disc supports also act as bearing elements, and may communicate in a ball-and-socket type arrangement. These elements (i.e. the lower and upper disc supports) communicate to act as a transferor of axial compression loads. Lower disc support **102** may or may not be rigidly attached to flexure **100.** Upper disc support **104** may be rigidly attached to the flexure **100** by press-fit, retaining ring, pins, welds or some other means, and also forms the upper surface of the disc member

All embodiments of the present invention are to be made from a surgically implantable biocompatible material. The preferred material for the flexure **100** should possess high fatigue strength such as titanium, titanium alloy, or stainless steel. The material for the upper and lower disc supports **104** and **102** should possess excellent wear resistance and compressive strength. Ceramics, titanium, titanium alloy, stainless steel, cobalt chrome, composites, or polymers should preferably be used for these elements. Alternatively, a biocompatible material with a wear reducing coating

could be used. For example, a titanium nitride coating may be used on the supports or the flexure.

Attachment of the disc member **50** to the adjacent vertebrae should involve both immediate and long-term fixation. Immediate fixation can be achieved with a mechanical bone attachment means. For example, the upper and/or lower surfaces may include mechanical elements such as teeth **108**. Also, The entire superior and inferior surfaces, including teeth **108** can be coated with a bone ingrowth inducing osteoconductive substance such as sintered beads or sintered wires or an osteoinductive coating such as hydroxyapatite for long-term fixation. Osteoinductive and osteoconductive coatings have been used extensively in joint replacement for many years and have been proven to be effective.

The flexure **100** allows the disc member **50** to react to bending loads by flexing. The geometry of helical slit **101** can determine the stiffness of flexure **100** and therefore the stiffness of disc member **50**. For example, to produce a more flexible implant the thickness of helical slit **101** can be increased so that less material of flexure **100** remains. Also the number of coils will determine the stiffness of the flexure. The spring action of flexure **100** will allow rotation and will have an inherent torsional stiffness that is also determined by the geometry of helical slit **101**. The range of motion of disc member **50** is determined by the point at which flexure **100** bottoms out (the point at which a bending load causes adjacent coils to come into contact). The range of motion is determined by the space between the coils, which is equivalent to the thickness of helical slit **101** multiplied by the number of coils. Therefore helical slit **101** can be tailored to match the mechanical and kinematical characteristics of a normal disc at any level in the spine.

The instantaneous axis of rotation (IAR) is a parameter that characterizes how one body rotates with respect to another body (or a fixed point) in planar motion. Normal spinal motion can be characterized as planar (2D) for pure flexion-extension. Figure 4 demonstrates the general method of determining the IAR of the motion of a body from two positions. Translation vectors $\mathbf{A_1}$, $\mathbf{A_2}$ and $\mathbf{B_1}$, $\mathbf{B_2}$ are drawn from points before the motion to corresponding points after the motion. The intersection of the perpendicular bisectors of these translation vectors is the IAR of the motion.

The preferred embodiment of the present invention incorporates a mobile IAR. The ball-and-socket arrangement of the preferred embodiment of Figures 1, 2, & 3 may comprise a lower disc support **102** having a convex surface, and an upper disc support **104** having a surface suitable for receiving and communicating with the convex surface of lower disc support **102**. The convex surface of lower disc support **102** may vary. For instance, it may range from a partial hemisphere to a full hemisphere or it may be an elongated element with a rounded or partially rounded end. Motion at the interface between lower disc support **102** (as seen in Figure 2) and upper disc support **104** has an IAR at the center of the radius of the bearing surface of lower disc support **102**. However, this embodiment also allows translation between lower disc support **102** and flexure **100**. The combination of rotation and translation allows a range of possible IAR's.

Figure 5 is a cross-sectional view of a motion segment including a superior vertebra **200**, IVD **204** and an inferior vertebra **202**. The IAR for adjacent vertebrae in the normal lumbar spine has been shown to be located on or near the superior endplate of the inferior vertebra **202** of a motion segment, as shown. Figure 6 shows the same cross-section of the spine as Figure 5, but with placement of disc member

50. In order to prevent unnatural loading of the facet joints **206**, the correct IAR must be maintained. The mobile IAR described above may allow correct IAR of motion between superior vertebra **200** and inferior vertebra **202** after implantation of disc element **50**.

Figures 7 and 8 show an alternative embodiment where approximately horizontal perimeter slits **152** have been cut into flexure **150** instead of a helical-type slit. Preferably, the slit is substantially at a right angle to the axis of the disc member. The orientation of the slits is such that at least one slit is opened and at least one slit is closed under the action of bending loads imposed at any plane through the axis of the disc member. In the embodiment depicted in the drawings, each slit terminates in a hole or a perimeter opening **154**, with a diameter that is larger than the thickness of the slit to reduce stress concentration. Preferably, the perimeter opening is circular-shaped. The depth, thickness and number of the perimeter slits **152** as well as the size of perimeter opening **154** determine the stiffness of the disc member. The thickness and number of perimeter slits **152** determine the range of motion of the prosthesis.

Disc **50** can be made into a variety of shapes, as long as the spirit of the invention is not adversely affected. That is, the disc prosthesis of the present invention may have a surface (such as, for example, the upper surface or the lower surface) that is flat, convex in shape or is otherwise shaped to fit the cavity of a vertebral endplate. Furthermore, from a top (superior-to-inferior) view, disc member **50** may be of a variety of shapes: for example circular, kidney-shaped, or oval-shaped. Figure 9 shows an alternative embodiment of a disc **51** of the invention in which flexure **160** is oval shaped. Teeth **168** and upper disc support **164** are similar to those described above.

Multiple alternative embodiments are also shown. A cross sectional view of an alternative embodiment of a disc **52** of the invention is shown in Figure 10 that has a fixed IAR at the center of the radius of hemispherical lower disc support **205**. The flexure **100** and the upper disc support **104** are also shown. Figure 11 shows a cross sectional view of an alternative embodiment of a disc **54** of the invention in which the IAR has been shifted down and left, demonstrating that the IAR can be tailored to match the IAR of a healthy disc simply by altering the radius of curvature and the center of the radius of curvature of partial hemispherical lower disc support **305**. Upper disc support **304** has been made to communicate with partial hemispherical disc support **305**. The flexure **100** is also shown.

Figure 12 shows angulated disc member **56** with angulated flexure **400** and augmented lower disc support **405** and augmented upper disc support **404**. The angle θ incorporated into angulated disc member **56** is meant to maintain the natural lordosis of the lumbar or cervical spine or the natural kyphosis of the thoracic spine. This angle could be matched to any lordosis or kyphosis of a disc level being replaced.

Figure 13 shows a disc **58** of the present invention with the addition of a lower seat member **510** communicated with the axial cavity of flexure **100**. In the case that a metal material is used for flexure **100** and a harder ceramic material is used for shortened lower disc support **505**, lower seat member **510** could also be made of ceramic so that all elements experiencing sliding contact would gain the advantage of low wear ceramic on ceramic contact. The upper disc support **104** is also shown.

Another alternative embodiment of the disc **60** of the present invention is pictured in Figure 14. A concave recess is created in flexure **600** which is meant to

communicate with a flanged lower disc support **605**. In this way, the upper disc support is incorporated into flexure **600**. Flexure **600** may be rigidly attached to flange **610** of flanged lower disc support **605** by weld, pins, retaining ring or some other means.

Another alternative embodiment of the disc **60** is pictured in Figure 15. A spring element **700** is a conventional helical spring made by forming a wire into a helix. Flanged upper disc support **704** and flanged lower disc support **705** are made to communicate with each other and to communicate with spring **700**. Spring **700** may be rigidly attached to either or both flanged upper disc support **704** or flanged lower disc support **705**.

Another alternative embodiment if the disc **64** of the present invention is pictured in Figure 16. Flexure **800** incorporates a protuberance **805** which serves as a lower disc support. Upper disc support **104** is made to communicate with protuberance **805**. Therefore, the lower disc support is incorporated into flexure **800**.

The disc prosthesis of the present invention may be inserted into the spine using standard medical procedures. For example, see Benzel, Spine Surgery: Techniques, Complication Avoidance, and Management, 1999, the contents of which are incorporated herein by reference. Particularly see Benzel, at Section 11, pages 142-192. Additionally, when inserting the disc prostheses of the present invention, the prosthesis may be inserted so that the lower disc support is superior to (from a top view) to the upper disc support. In other words, the disc prosthesis of the present invention mat be used such that, when looking at the spine, the upper disc support as described herein is on the bottom and the lower disc support is on top.

All cited patents and publications referred to in this application are herein expressly incorporated herein by reference.

This invention thus being described, it will be obvious that the same may be varied in many ways. Such variations are not to be regarded as a departure from the spirit and scope of the present invention, and all such modifications as would be obvious to one of ordinary skill in the art are intended to be included within the scope of the following claims.

I claim:

1. An implantable intervertebral disc replacement prosthesis, comprising:

an upper surface and a lower surface;

a deformable flexure with a perimeter surface and an axial cavity, the axial cavity extending along the axis of the flexure;

a slit defined in the perimeter surface of the flexure to provide flexibility to the flexure, the slit having a slit thickness;

a lower disc support housed in the axial cavity; and

an upper disc support housed in the axial cavity;

wherein the lower and upper disk supports communicating with one another to provide support to the disc.

2. The implantable intervertebral disc replacement prosthesis of claim 1, wherein the disc permits flexion-extension, axial rotation and lateral bending for a wearer of the disc by deformation of the disc.

3. The implantable intervertebral disc replacement prosthesis of claim 1, whereby the lower and upper disc supports communicate to act as a transferor of axial compression load.

4. The implantable intervertebral disc replacement of claim 1, wherein the slit is helical to the axis of the disc.

5. The implantable intervertebral disc replacement prosthesis of claim 1, wherein the slit is transverse to the axis of the disc.

6. The implantable intervertebral disc replacement of claim 5, wherein the slit has a first end and a second end, with each end terminating in a perimeter opening larger than the slit thickness.

7. The implantable intervertebral disc replacement of claim 6, wherein the perimeter opening is circular-shaped.

8. The implantable intervertebral disc replacement of claim 1, wherein the disc comprises in the range of two to five slits, including said first mentioned slit.

9. The implantable intervertebral disc of claim 1, wherein the lower and the upper disc supports communicate in a ball-and-socket-type arrangement.

10. The implantable intervertebral disc replacement prosthesis of claim 1, wherein the lower disc support has a convex surface, and the upper disc support has a surface suitable for receiving and communicating with the convex surface of the lower disc support.

11. The implantable intervertebral disc replacement prosthesis of claim 1, wherein the lower disc support has a concave surface, and the upper disc support has a surface

suitable for receiving and communicating with the concave surface of the lower disc support.

12. The implantable intervertebral disc replacement prosthesis of claim 1, wherein the disc is shaped to fit a cavity between two vertebrae.

13. The implantable intervertebral disc replacement prosthesis of claim 1, wherein at least one of the upper surface or the lower surface is convex.

14. The implantable intervertebral disc replacement prosthesis of claim 1, wherein at least one of the upper surface or the lower surface is substantially flat.

15. The implantable intervertebral disc replacement prosthesis of claim 1, wherein the disc is kidney-shaped.

16. The implantable intervertebral disc replacement prosthesis of claim 1, wherein the disc is made from surgically implantable ceramic, metal, composite, or polymer materials.

17. The implantable intervertebral disc replacement prosthesis of claim 1, wherein said upper and lower disc supports have a coating that comprises a titanium nitride material.

18. The implantable intervertebral disc replacement prosthesis of claim 1, wherein the prosthesis further comprises a bone fixation promotion surface on at least one of the upper surface and the lower surface.

19. The implantable intervertebral disc replacement prosthesis of claim 18, wherein at least one of the upper surface or the lower surface comprises teeth.

20. The implantable intervertebral disc replacement prosthesis of claim 18, wherein the bone fixation promotion surface comprises an osteoconductive or an osteoinductive material.

21. The implantable intervertebral disc replacement prosthesis of claim 20, wherein the coating is hydroxyapatite.

22. An implantable intervertebral disc replacement prosthesis, comprising:

an upper surface and a lower surface;

a deformable flexure with a perimeter surface that defines an axial cavity, the axial cavity extending along the axis of the flexure;

a slit defined in the perimeter surface of the flexure to provide flexibility to the flexure, the slit having a slit thickness; and

a lower disc support housed in the axial cavity;

wherein the lower disc support is received by and communicates with the axial cavity of the flexure to provide support to the disc.

23. The implantable intervertebral disc replacement prosthesis of claim 22, wherein the disc permits flexion-extension, axial rotation and lateral bending for a wearer of the prosthesis by deformation of the disc.

24. The implantable intervertebral disc replacement prosthesis of claim 22, whereby the lower disc support and the axial cavity of the flexure communicate to act as a transferor of axial compression load.

25. The implantable intervertebral disc replacement of claim 22, wherein the slit is helical to the axis of the disc.

26. The implantable intervertebral disc replacement prosthesis of claim 22, wherein the slit is transverse to the axis of the disc.

27. The implantable intervertebral disc replacement of claim 26, wherein the slit has a first end and a second end, with each end terminating in a perimeter opening larger than the slit thickness.

28. The implantable intervertebral disc replacement of claim 27, wherein the perimeter opening is circular-shaped.

29. The implantable intervertebral disc replacement of claim 22, wherein the disc member comprises in the range of two to five slits, including said first mentioned slit.

30. The implantable intervertebral disc of claim 22, wherein the lower disc support and the axial cavity of the flexure communicate in a ball-and-socket-type arrangement.

31. The implantable intervertebral disc replacement prosthesis of claim 22, wherein the lower disc support has a convex surface, and the axial cavity of the flexure has a surface suitable for receiving and communicating with the convex surface of the lower disc support.

32. The implantable intervertebral disc replacement prosthesis of claim 22, wherein the lower disc support has a concave surface, and the axial cavity of the flexure has a protuberance suitable for receiving and communicating with the concave surface of the lower disc support.

33. The implantable intervertebral disc replacement prosthesis of claim 22, wherein the prosthesis is shaped to fit a cavity between two vertebrae.

34. The implantable intervertebral disc replacement prosthesis of claim 22, wherein at least one of the upper surface or the lower surface is convex.

35. The implantable intervertebral disc replacement prosthesis of claim 22, wherein at least one of the upper surface or the lower surface is substantially flat.

36. The implantable intervertebral disc replacement prosthesis of claim 22, wherein the prosthesis is kidney-shaped.

37. The implantable intervertebral disc replacement prosthesis of claim 22, wherein the prosthesis is made from a surgically implantable ceramic, metal, composite, or polymer.

38. The implantable intervertebral disc replacement prosthesis of claim 22, wherein at least one of said axial cavity or lower disc support has a coating that comprises a titanium nitride material.

39. The implantable intervertebral disc replacement prosthesis of claim 22, wherein the prosthesis further comprises a bone fixation promotion surface on at least one of the upper surface and the lower surface.

40. The implantable intervertebral disc replacement prosthesis of claim 39, wherein at least one of the upper surface or the lower surface comprises teeth.

41. The implantable intervertebral disc replacement prosthesis of claim 40, wherein the bone fixation promotion surface comprises an osteoconductive or an osteoinductive material.

42. The implantable intervertebral disc replacement prosthesis of claim 41, wherein the coating is hydroxyapatite.

43. The implantable intervertebral disc replacement prosthesis of claim 22, wherein the lower disc support substantially fills the axial cavity.

44. An implantable intervertebral disc replacement prosthesis, comprising:

a deformable helical spring member that defines an axial cavity, the axial cavity extending along the axis of the spring member;

a lower disc support housed in the axial cavity; and

an upper disc support housed in the axial cavity;

wherein the lower and upper disc supports communicate with each other to provide support to the disc

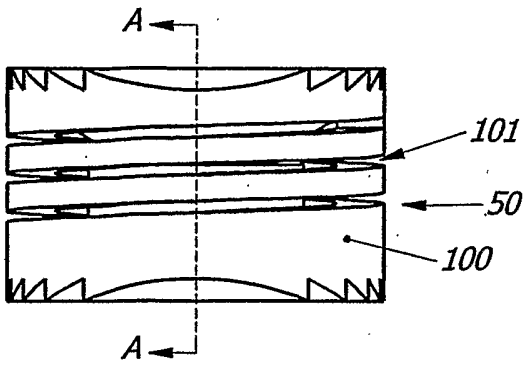


Fig. 1

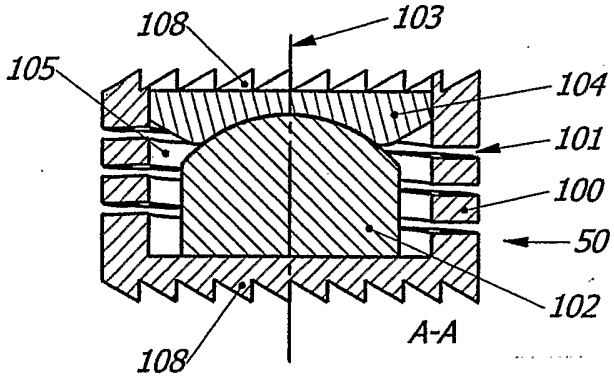


Fig. 2

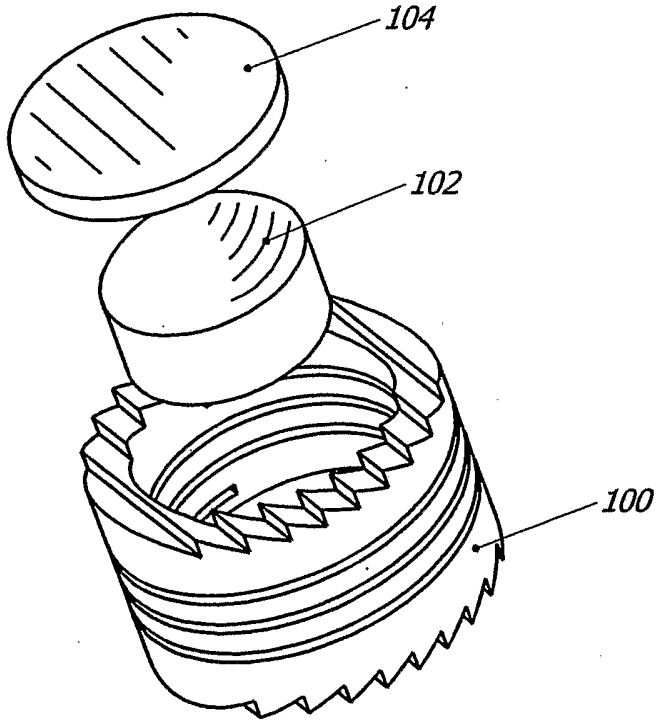


Fig. 3

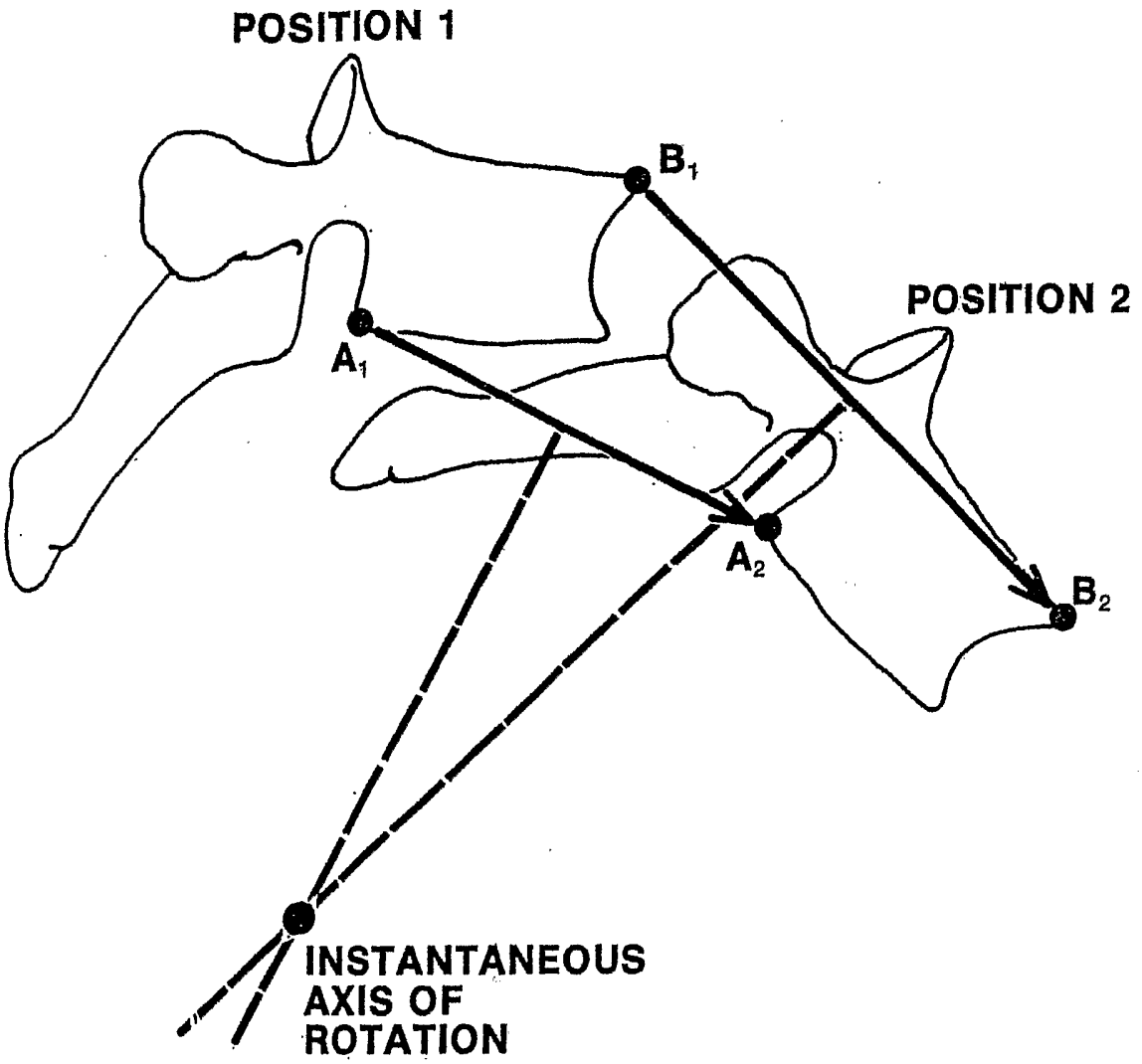

POSITION 1
B1
POSITION 2
A1
A2
B2
INSTANTANEOUS
AXIS OF
ROTATION

Fig. 4

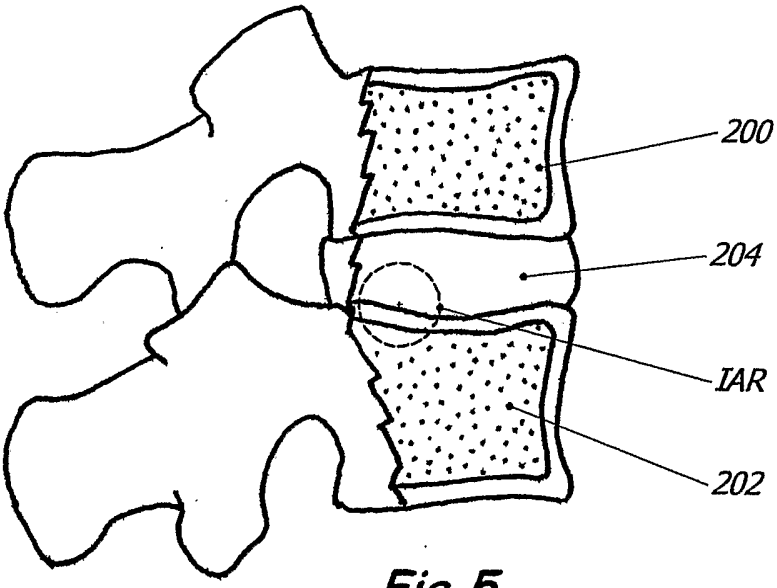


Fig. 5

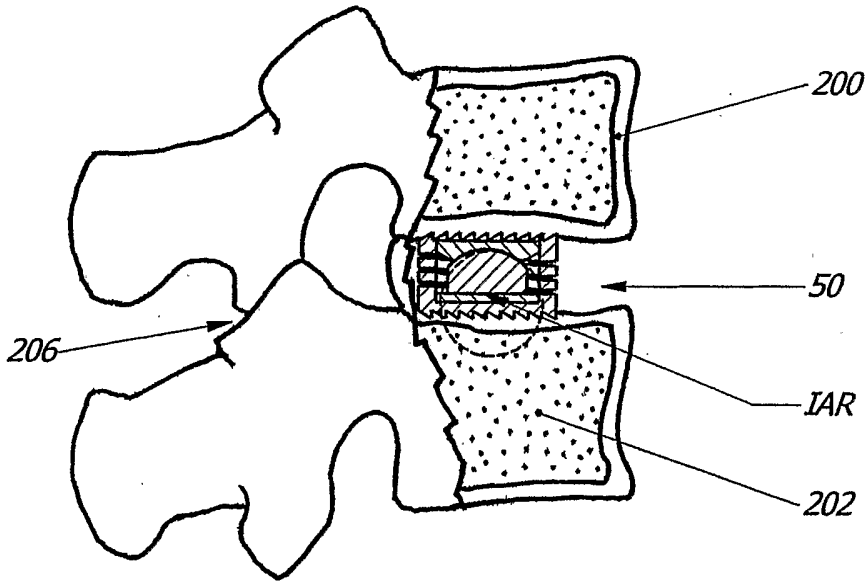


Fig. 6

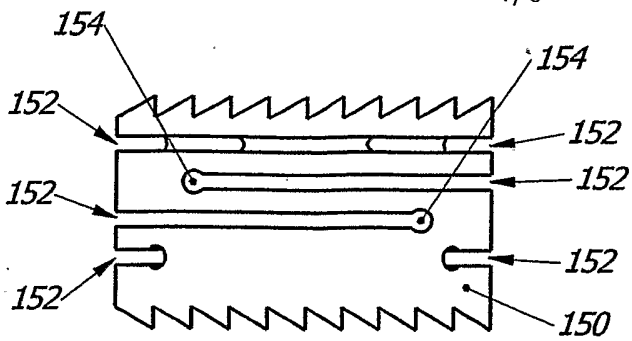


Fig. 7

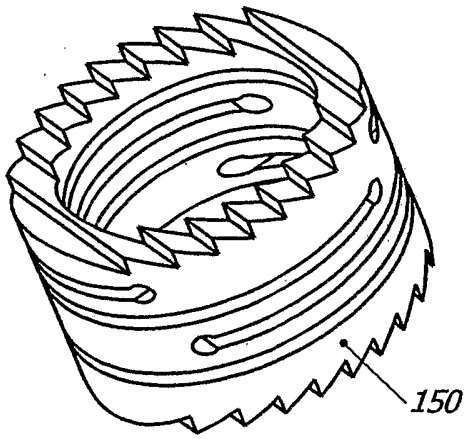


Fig. 8

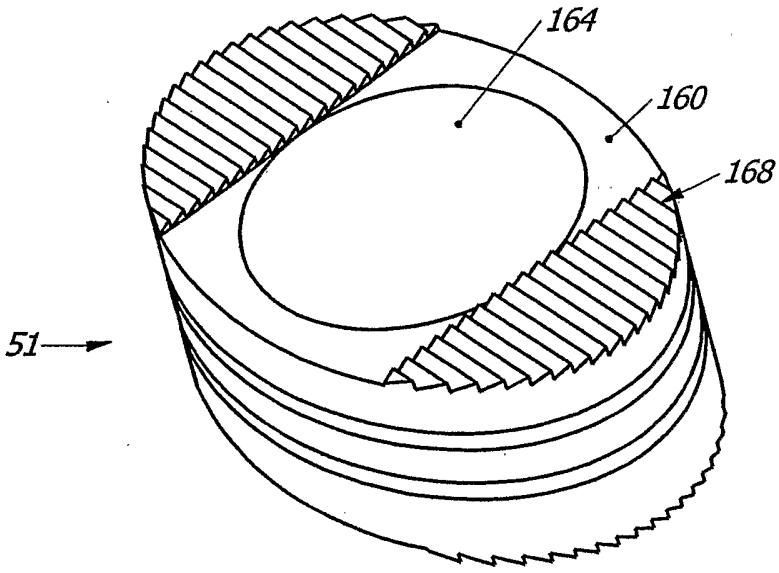


Fig. 9

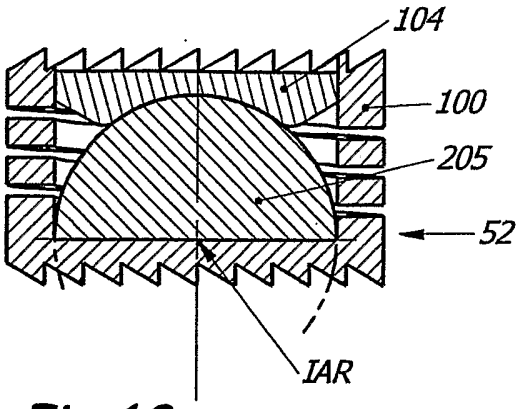


Fig. 10

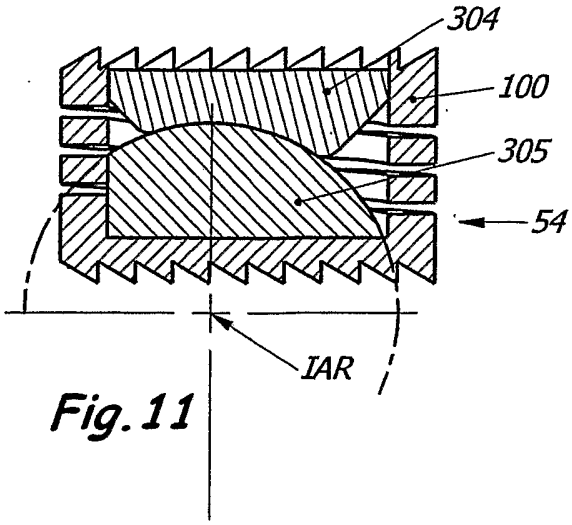


Fig. 11

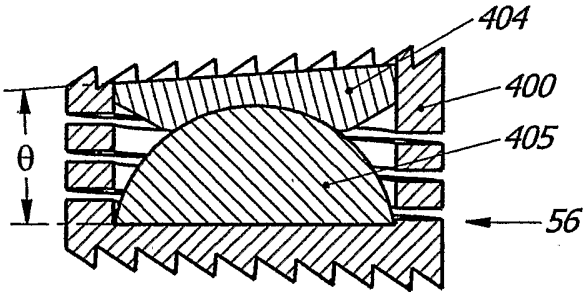


Fig. 12

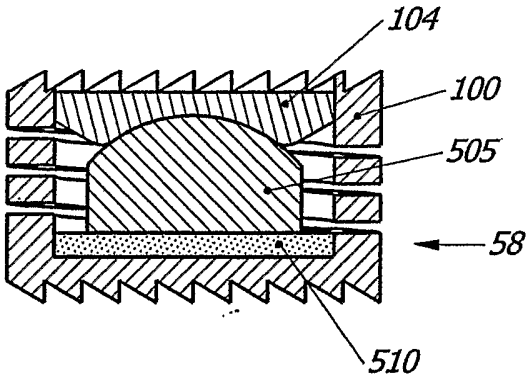


Fig. 13

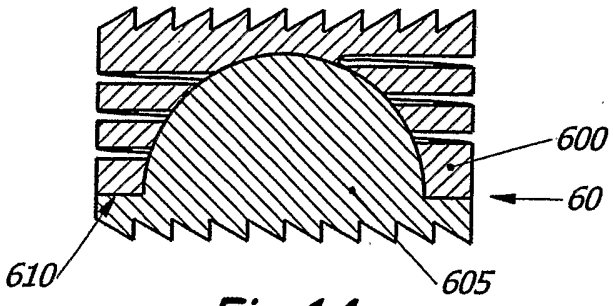


Fig. 14

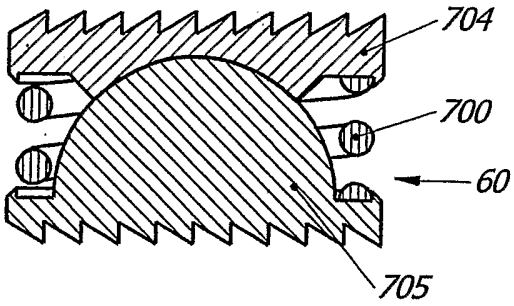


Fig. 15

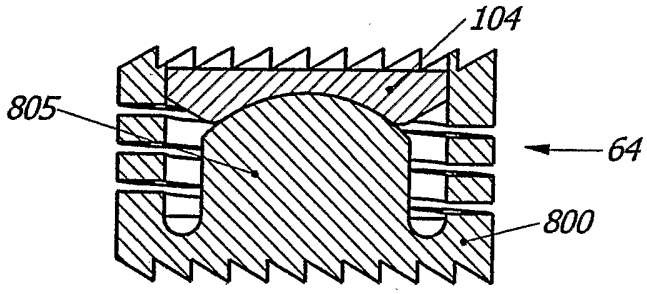


Fig. 16

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 03/30175

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 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)
IPC 7 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 6 296 664 B1 (MIDDLETON LANCE M) 2 October 2001 (2001-10-02) figures 4-6,10 column 3, line 54 -column 5, line 30	1-5,8, 10, 12-16, 22-26, 29,31, 33-37,44
Y		6,7,9, 11, 17-21, 27,28, 30,32, 38,39, 41,42

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
29 January 2004	05/02/2004

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Stach, R

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 03/30175

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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A		2,3,10, 12-16, 22-24, 31,33-37

Y	US 6 579 321 B1 (DAWSON JOHN M ET AL) 17 June 2003 (2003-06-17) figures 2-9 column 3, line 51 -column 4, line 35 column 5, line 25 - line 67	6,7,19, 27,28
A		1,2,4,5, 8,9, 11-16, 18,22, 23,25, 26,29, 30, 32-37,39

Y	EP 0 985 384 A (BUECHEL PAPPAS TRUST) 15 March 2000 (2000-03-15) claim 4	17,38

A	FR 2 734 148 A (BIOMAT) 22 November 1996 (1996-11-22)	

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