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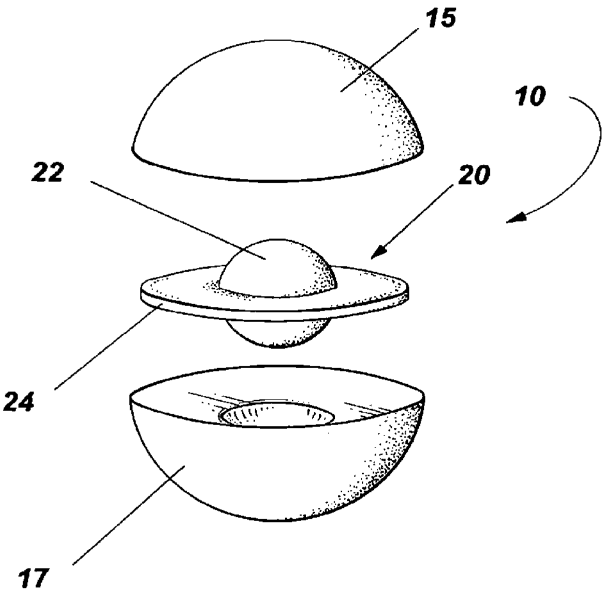

FIG. 1

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(57) Abstract: A multi-material spinal interbody device includes an inner dampener of compressible material in combination with a rigid outer material. The rigidity of the outer periphery of curved surfaces of the device, such as in an eliipsoid shape, provide support as a replacement to the nucleus propulsus, with the inner dampener providing for absorption of spinal forces.

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SPINAL INTERBODY DEVICE

Technical Field

The present invention relates to fusion and non-fusion spinal interbody devices.

Background Art

Spinal interbody devices such as the Fernstrom ball developed by Dr. Ulf Fernstrom, the Harmon Spinal Sphere of the Austenal Company (New York, NY) and the more recent Satellite Spinal System of Medtronic Sofamar Danek (Memphis, TN) have attempted stabilization in a disc interspace with an insertable solid sphere. Because of the rigidity and lack of compression of such solid spheres, undesirable subsidence of the device may result leading to possible nerve agitation and further corrective surgery.

Nucleus propulsus replacement has also been attempted with non-rigid hydrogels, such as disclosed in U.S. Pat. No. 7,214,245 to Marcolongo et al. Such hydrogels, however, are prone to migration and escape from the interbody space.

Accordingly, a need exists for a compressible spinal interbody device that avoids the problems of interbody devices that are either too rigid or too yielding.

Disclosure of Invention

In embodiments, the present invention answers this need by providing an interbody device with both rigid and compressible components for both supporting and absorbing axial loads while limiting subsidence and endplate erosion. The compressible components include material of greater compressibility than material of rigid components.

In one embodiment, rigid material may include, but not limited to, biocompatible materials such as polyetheretherketone (PEEK), titanium, stainless steel and cobalt chromium alone or in combination with other materials. In further embodiments, the compressible material may include, but not limited to, biocompatible materials such as elastomers, ultra high molecular weight polyethylene (UHMWPE), polycarbonate urethane (Sulene-PCU), polyethylene terephtalate (Sulene_PET), hydrogels (including with a polyethylene jacket), polyvinyl alcohol hydrogel (Aquarelle) and polycarbonate urethane elastomer (Newcleus) alone or in combination with other materials.

In embodiments of the invention, an interbody device includes top and bottom shells of a first material and an inner dampener of second dampening material. In some embodiments a plurality of shell components, such as quadrant shell pieces may be coupled with an inner dampener material. In one embodiment, the interbody device may be formed by a plurality of rigid material pieces interspersed with compressible material.

In alternative embodiments, an inner dampener may comprise a mechanical spring and like compressible components of various materials.

In one embodiment, an interbody device of the invention may be an ellipsoid, including but not limited to a sphere, oblate spheroid, prolate spheroid and scalene ellipsoids. In other embodiments of the invention an interbody device may compromise a partial ellipsoid, partial polyhedrons and other shapes configured to include top and bottom curved surface portions for contacting vertebral bodies.

In some embodiments, an interbody device includes an inner dampener having an ellipsoidal compressible core portion and a compressible equatorial planar surface portion extending outwardly from the core. In further embodiments the inner dampener includes an ellipsoidal compressible core portion and a compressible equatorial planar surface portion extending outwardly from the core.

In embodiments of the invention, compressible and rigid materials may be combined through coupling means including, but not limited to, overmolding (including injection molding), press-fitting, adhesives, mechanical fastening and the like.

In embodiments of the invention, an interbody device of the present invention may be adapted for interbody fusion procedures to provide improved stabilization, stress-shielding and maintenance of placement in the interbody space. In other embodiments of the present invention an interbody device of the present invention may be adapted for interbody non-fusion procedures to provide dynamic stabilization, stress-shielding, reduced movement, reduced likelihood of escape and reduced subsidence.

Brief Description of the Drawings

FIG. 1 is an exploded perspective view of a multi-component spherical interbody device in one embodiment of the present invention.

FIG. 2 is a basic plan view of a top outer shell component of a spherical interbody device in one embodiment of the present invention.

FIG. 3 is a basic plan view of an inner dampener component of a spherical interbody device in one embodiment of the present invention.

FIG. 4 is a basic plan view of a spherical interbody device in one embodiment of the present invention.

FIG. 5 is a cross-sectional plan view along Section A-A of FIG. 4 in one embodiment of the present invention.

FIG. 6 is a front perspective view of a multi-component non-spherical ellipsoid interbody device in one embodiment of the present invention.

FIG. 7 is a front perspective view of a multi-component non-spherical ellipsoid interbody device depicted in the intervertebral space in one embodiment of the present invention.

FIG. 8 is a basic cross-section plan view of a top plan view of a an interbody device including outer shell quadrants and an inner damper in one embodiment of the present invention.

FIG. 9 is a basic schematic view of a retracting grasper apparatus and interbody device in one embodiment of the present invention.

Best Modes for Carrying Out the Invention

The present invention provides an apparatus for disc nucleus replacement to promote the support and absorption of axial loads while limiting subsidence and endplate erosion in both vertebral fusion and non-fusion spinal treatments. In non-fusion embodiments, the combination of rigid and compressible components with curved surface portions adapted for placement and contacting the vertebral bodies may further promote motion preservation and dynamic stabilization.

Although a spinal interbody device of the present invention is described herein in ellipsoid embodiments, including spheres and spheroids, it will be appreciated that various shapes including curved surface portions may be provided in other embodiments.

Referring to FIGS. 1-5, an interbody device 10 in one embodiment of the invention is a spherical shape. The device 10 includes a top outer shell 15, a bottom outer shell 17 and an inner dampener 20. The outer shells 15 and 17 may comprise sphere portions adapted to couple to inner dampener 20. In some embodiments the top outer shell 15 and bottom outer shell 17 may be identical in size and shape. In other embodiments the shells 15 and 17 may be differently size or shaped. The outer shells may comprise relatively rigid biocompatible materials, including, but not limited to, PEEK or carbon fiber reinforced PEEK, titanium, stainless steel, cobalt chromium and the like, either alone or in combination with these or other materials.

The inner dampener 20 in one embodiment includes a dampener core 22. The dampener core may be provided in ellipsoidal or other shapes adapted for compressibility. In some embodiments, the inner dampener comprises a dampener core 22 and a planar equatorial projection 24 extending outward from dampener core 22. The inner dampener 20 may comprise compressible material including, but not limited to, polyethylene, polycarbonate urethane (Sulene), polyethylene terephtalate (Sulene), HP-100 silicone elastomer, hydrogel with a polyethylene jacket, polyvinyl alcohol hydrogel (Aquarelle), polycarbonate urethane elastomer (Newcleus) or other elastomers, polymers or rubber-like substances, either alone or in combination with these or other materials.

With particular reference to FIG. 1, in one embodiment of the invention the outer shells 15 and 17 may include a concave inner portion adapted for coupling to an ellipsoid-shaped, including spherical, dampener core 22 of the inner dampener 20. The dampener equatorial planar projection 24 extends outward between the non-concave periphery portions of the outer shells 15 and 17.

With further reference to FIGS 2-5, in embodiments the interbody device 10 may have diameters of various sizes, including ranging from about 6 to about 18 mm, although such sizes may be adapted to the particular patient or purpose. In one embodiment, the interbody devices has a spherical diameter of about 11 mm. In such embodiment, the inner dampener core 22 has a spherical diameter of about 5 mm and each of the outer shells 15 and 17 have a radius measure to the inner dampener core 22 of about 3 mm. In such embodiment the inner dampener equatorial planar projection 25 has a thickness of about 2 mm. In some embodiments of the invention, a kit may be provide including a range of sizes and/or shapes of the interbody device 10.

FIG. 6 shows a non-limiting alternative embodiment in which the interbody device 10 is provided in a non-spherical ellipsoid shape, such as an oblate spheroid or egg/ovular shape with a larger equatorial diameter and height. In other embodiments of the invention, prolate spheroids and scalene ellipsoid shapes may adapted for use in the present invention.

With further reference to FIG. 7, an interbody device 10 is shown implanted in an annular disc 50 with top and bottom curved surface portions abutting the vertebral bodies. The interbody device 10 may move within the biconvexity of the endplates of the adjacent vertebral bodies and the inner dampener 20 also allows for axial compression. In embodiments of the invention, the interbody device 10 migrates near the internal axis of rotation and becomes a substitute for the nucleus propulsus.

With reference to FIG. 8, in another embodiment of the invention the interbody device 10 may comprise a plurality of outer shells, such as outer shell quadrants 18 to provide a larger inner dampener 20. As shown in the embodiment depicted in FIG. 8, a plurality of equatorial planar projections may also be provided.

In other embodiments of the present invention, an inner dampener material may be interspersed or molded with rigid materials to also achieve the advantages of sufficient interbody support with compressibility.

In various embodiments of the present invention an interbody device 10 may be constructed as one piece or assembled as a unit. In some embodiments of the invention, overmolding processes, including but not limited to injection and/or insert molding, may be used to couple an inner dampener 20 and outer shell materials. In other embodiments, press-fitting, adhesives, mechanical fastening and like coupling means may be used. In alternative embodiments, a mechanical spring or similarly compressible apparatus may be provided in place of or complimentary to an inner dampener 20 or compressible material.

In one embodiment, outer shells 15 and 17 may be molded and include PEEK and the shells inserted at room temperature into a second mold. The second mold holds the two PEEK-containing outer shell parts interstitially and a damper material or materials, such as but not limited to elastomers, UHMW PE and the like, are inserted into the cavity between the outer shells. The molten damper material adheres at the molecular level with the PEEK during such process. In one embodiment, the inner cavity space between the PEEK outer shell parts may includes a torturous path within the inner cavity so that when the damper material is inserted in liquid form, it will flow into the paths, solidify and then become strongly bonded.

In one embodiment, surgically implanting the interbody device 10 could occur from a posterior approach. The device 10 may be implanted using a TLIF (transforaminal lumbar interbody fusion) or unilateral PLIF (posterior lumbar interbody fusion) technique that is common for surgeons performing fusions with interbody devices today. The interbody device 10 would also have the ability to be implanted in an ALIF or XLIF approach. In other embodiments, microdiscectomy, hemilaminectomy or laminotomy techniques may also be used. In the posterior approach, instead of removing as much disc as possible and performing an arthrodesis, enough disc is removed to place the device slightly posterior and midline in the intervertebral space and have the outer shells or curved surfaces of the device 10 rest on the endplates of the vertebral bodies.

Referring to FIG. 9, in one embodiment an interbody device grasping and positioning tool 100 may be provided for implanting the interbody device 10. Such tool may include a first arm 105 with curved contour to the shape of the interbody device 10. An opposite arm 110 may be provided for also supporting the device 10. In such embodiments, the curved grasping arm 105 permits positioning of the interbody device 10 with reduced risk of interfering with nerves or similar undesirable surgical contact of other positioning tools. One or both arms 105 and 110 may be retractable when the interbody device 10 is properly positioned. In alternative embodiments, arms 105 and 110 may be replaced by other retractable means, such as a partial scoop-shaped element contoured to the interbody device 10 and the like. In certain embodiment a grasping/positioning tool may be provided in a kit with one or more interbody devices 10, including both grasping/positioning tools and interbody devices 10 of various sizes and shapes.

While the invention has been described with reference to structures and methods in some embodiments of the invention, the invention is not intended to be limited thereto, but extends to modifications and improvements with the scope or equivalence of the claims.

Claims

What is claimed is:

1. An interbody device comprising a first curved vertebral body contact surface, a second curved vertebral body contact surface opposite the first vertebral body contact surface and a compressible inner dampener coupling the vertebral contact surfaces.

2. The interbody device of claim 1, wherein said inner dampener includes at least one material of a greater compressibility than one or more materials in the first and second vertebral contact surfaces.

3. The interbody device of claim 2, further comprising an ellipsoidal shape.

4. The interbody device of claim 3, wherein said ellipsoidal shape is selected from the group consisting of an oblate spheroid, prolate spheroid and scalene ellipsoid.

5. The interbody device of claim 4, wherein the inner dampener includes an ellipsoidal compressible core portion and a compressible equatorial planar surface portion extending outwardly from the core.

6. The interbody device of claim 3, wherein said ellipsoid shape is a sphere.

7. The interbody device of claim 6, wherein the inner dampener includes an ellipsoidal compressible core portion and a compressible equatorial planar surface portion extending outwardly from the core.

8. The interbody device of claim 3, wherein the inner dampener includes an ellipsoidal compressible core portion and a compressible equatorial planar surface portion extending outwardly from the core.

9. The interbody device of claim 1, wherein the inner dampener includes an ellipsoidal compressible core portion and a compressible equatorial planar surface portion extending outwardly from the core.

10. The interbody device of claim 2, wherein the first and second curved vertebral contact surfaces each include polyetheretherketone molded to the at least one material of the inner dampener having greater compressibility than polyetheretherketone.

11. The interbody device of claim 3, wherein the first and second curved vertebral contact surfaces each include polyetheretherketone molded to the at least one material of the inner dampener having greater compressibility than polyetheretherketone.

12. The interbody device of claim 11, further comprising a partial ellipsoid top outer shell including the first curved vertebral contact surface and a partial ellipsoid bottom

outer shell including the second curved vertebral contact surface, wherein the top and bottom outer shells are separated by the inner dampener.

13. The interbody device of claim 1, further comprising a partial ellipsoid top outer shell including the first curved vertebral contact surface and a partial ellipsoid bottom outer shell including the second curved vertebral contact surface, wherein the top and bottom outer shells are separated and coupled by the inner dampener.

14. The interbody device of claim 8, further comprising a partial ellipsoid top outer shell including the first curved vertebral contact surface and a partial ellipsoid bottom outer shell including the second curved vertebral contact surface, wherein the top and bottom outer shells are separated and coupled by the inner dampener.

15. The interbody device of claim 14, wherein each of the top and bottom shells include an inner concave portion configured to secure the ellipsoidal compressible core portion of the inner dampener and wherein the compressible equatorial planar surface portion of the inner dampener extends and couples between the non-concave periphery of each of the top and bottom shells.

16. An interbody device comprising two or more materials of different compressibility molded into an ellipsoidal shape having at least opposite curved surfaces adapted for contacting vertebral bodies.

17. The interbody device of claim 16, comprising two or more outer shells including a first resilient material and an inner dampener of a second compressible material.

18. The interbody device of claim 17, wherein the first resilient material is polyetheretherketone and the second compressible material is an elastomer.

19. The interbody device of claim 17, wherein the first resilient material is polyetheretherketone and the second compressible material is polyethylene.

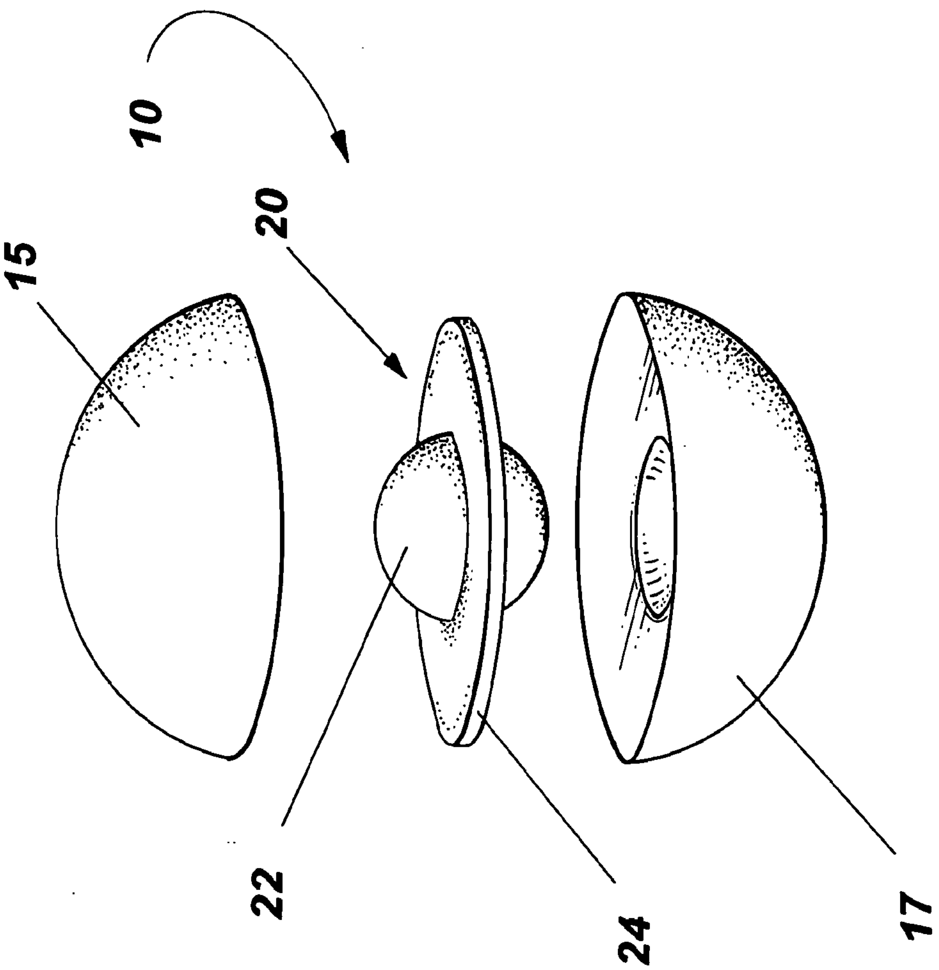
20. The interbody device of claim 16, wherein the ellipsoidal shape is a sphere.

21. The interbody device of claim 16, wherein said ellipsoidal shape is selected from the group consisting of an oblate spheroid, prolate spheroid and scalene ellipsoid.

22. The interbody device of claim 18, wherein the ellipsoidal shape is a sphere.

23. The interbody device of claim 18, wherein said ellipsoidal shape is selected from the group consisting of an oblate spheroid, prolate spheroid and scalene ellipsoid.

FIG. 1



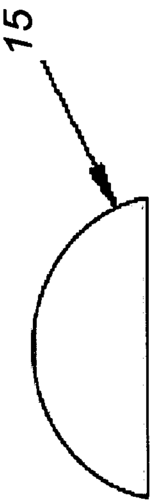


FIG. 2

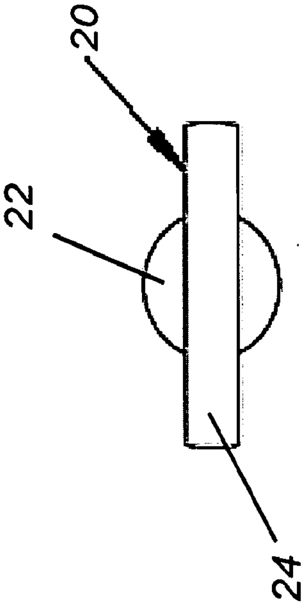


FIG. 3

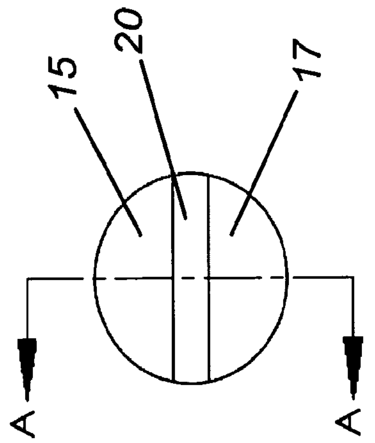


FIG. 4

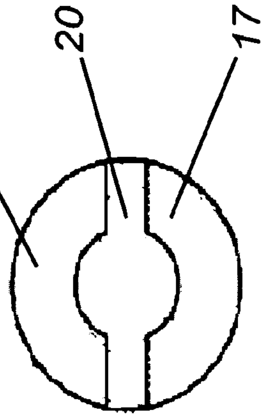


FIG. 5

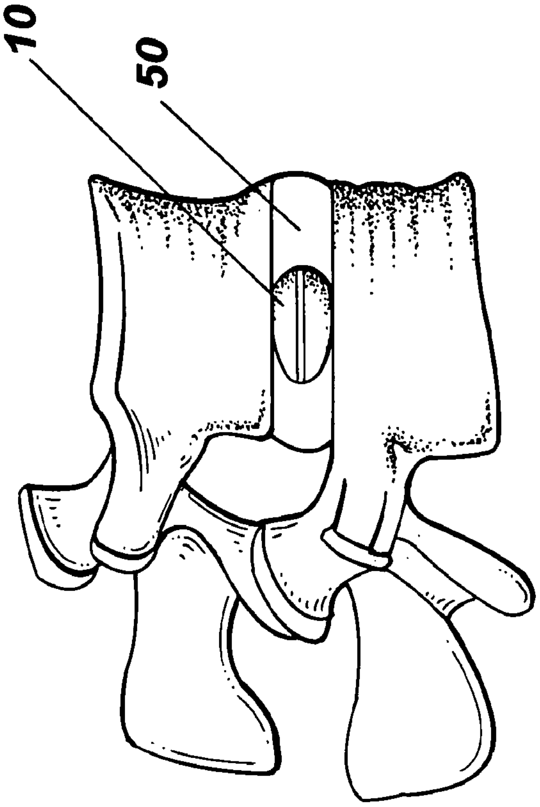


FIG. 7

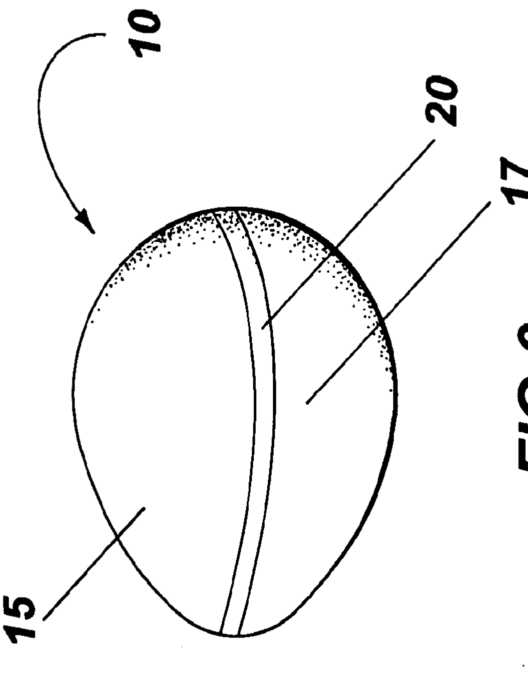


FIG.6

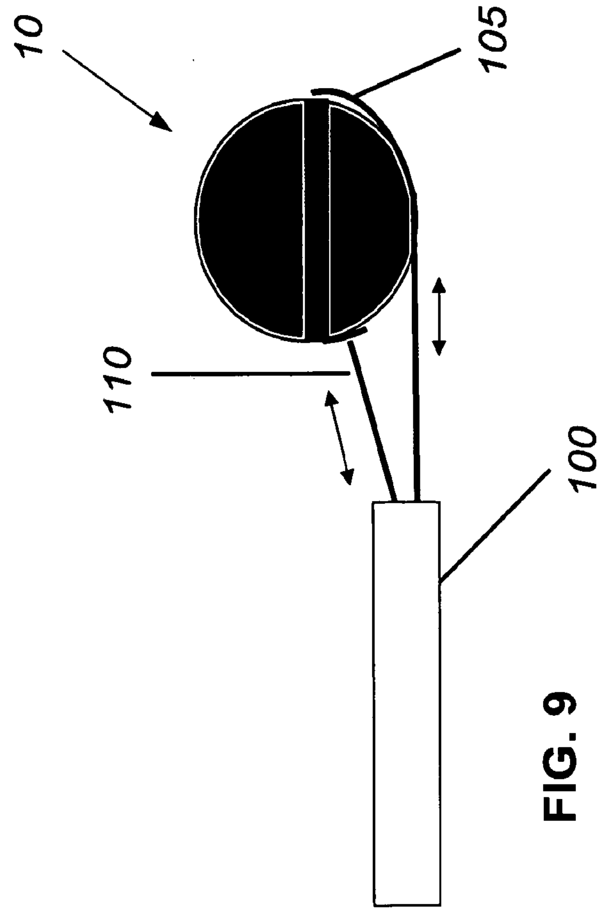


FIG. 9

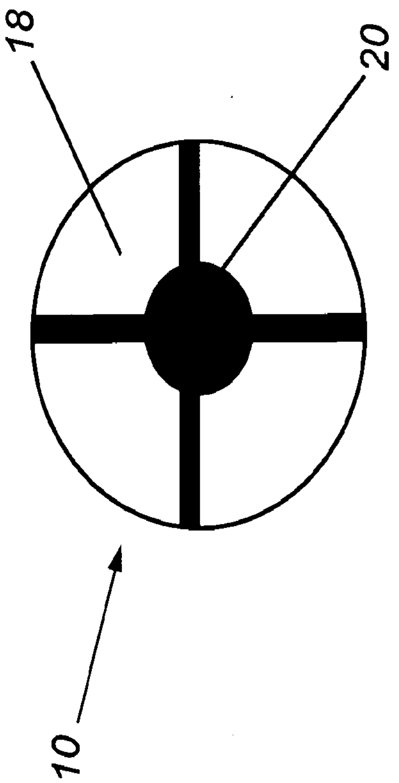


FIG. 8

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 08/66169

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61F 2/44 (2008.04)
USPC - 623/17.16
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: A61F 2/44 (2008.04)
USPC: 623/17.16

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
IPC: A61F 2/02, 2/30; A61F 2/44 (2008.04)
USPC 623/16.11, 17.11, 17.16 (text searched-see terms below)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PubWest: PGPB, USPT, USOC, EPAB, and JPAB; Google Scholar
Search terns: spine, spinal, vertebr$4, invertebr$4, spher$4, round, circle, curv$3, concav$2, convex, ball adj2 socket, ellips$3, core, central, elast$5, deform$4, peek, polyetheretherketone, and polyethylene

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X ----- Y	US 7,025,787 B2 (BRYAN et al.) 11 April 2006 (11.04.2006), entire patent, more specifically, Fig 1 and 7, col 3, ln 33 to col 6, ln 13, col 8, ln 41-54, and col 9, ln 56 to col 10, ln 17, col 10, ln 18-26, col 13, ln 36-39, and col 17, ln 11-13	1-9, 13-17, 20, and 21 ----- 10-12, 18, 19, 22, and 23
Y	US 2004/0010316 A1 (WILLIAM et al.) 15 January 2004 (15.01.2004), para[0065] and [0074]	10-12, 18, 19, 22, and 23
A	US 2007/0088441 A1 (DUGGAL et al.) 19 April 2007 (19.04.2007), entire patent	1-23

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

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

Date of the actual completion of the international search	Date of mailing of the international search report
03 October 2008 (03.10.2008)	09 OCT 2008

Name and mailing address of the ISA/US	Authorized officer:
Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774