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(54) Title: INTERVERTEBRAL DISC PROSTHESIS HAVING BALL AND RING STRUCTURE

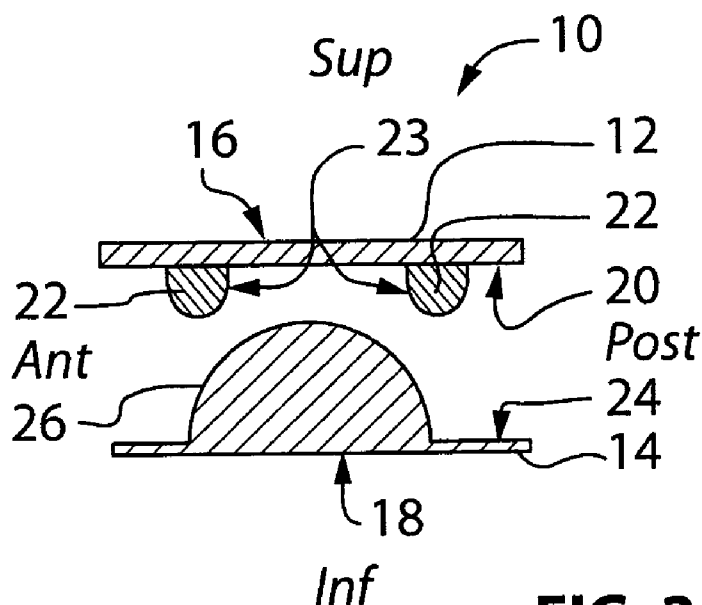


FIG. 2a

(57) Abstract: An artificial intervertebral disc comprises two opposing shells having opposing inner surfaces and oppositely directed outer surfaces. The outer surfaces adapted for locating against adjacent vertebrae. The inner surface of one shell including a ball and the inner surface of the other shell including a cooperating ring adapted to restrict articulation of the ball within a defined region.



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**INTERVERTEBRAL DISC PROSTHESIS
HAVING BALL AND RING STRUCTURE**

CROSS REFERENCE TO PRIOR APPLICATIONS

[0001] This application claims priority from US application number 60/067,545, filed February 28, 2008, the entire contents of which are incorporated herein by reference.

FIELD OF THE INVENTION

[0002] The present invention relates to the field of spinal implants and, more particularly, to intervertebral disc prostheses, or artificial intervertebral discs.

BACKGROUND OF THE INVENTION

[0003] The spine is a complicated structure comprised of various anatomical components, which, while being extremely flexible, provides structure and stability for the body. The spine is made up of vertebrae, each having a ventral body of a generally cylindrical shape. Opposed surfaces of adjacent vertebral bodies are connected together and separated by intervertebral discs (or "discs"), comprised of a fibrocartilaginous material. The vertebral bodies are also connected to each other by a complex arrangement of ligaments acting together to limit excessive movement and to provide stability. A stable spine is important for preventing incapacitating pain, progressive deformity and neurological compromise.

[0004] The anatomy of the spine allows motion (translation and rotation in a positive and negative direction) to take place without much resistance but as the range of motion reaches the physiological limits, the resistance to motion gradually increases to bring the motion to a gradual and controlled stop.

[0005] Intervertebral discs are highly functional and complex structures. They contain a hydrophilic protein substance that is able to attract water thereby increasing its volume. The protein, also called the nucleus pulposus, is surrounded and contained by a ligamentous structure called the annulus fibrosis. The main function of the discs is load bearing (including load distribution and shock absorption) and motion. Through their weight bearing function, the discs transmit loads from one vertebral body to the next while providing a cushion between adjacent bodies. The discs allow movement to occur between adjacent vertebral bodies but within a limited range thereby giving the spine structure and stiffness.

[0006] Due to a number of factors such as age, injury, disease etc., it is often found that intervertebral discs lose their dimensional stability and collapse, shrink, become displaced, or

1 otherwise damaged. It is common for diseased or damaged discs to be replaced with prostheses
2 and various versions of such prostheses, or implants, are known in the art. One of such implants
3 comprises a spacer that is inserted into the space occupied by the disc. However, such spacers
4 have been found to result in fusion of the adjacent vertebrae, thereby preventing relative
5 movement there-between. This often leads to the compressive forces between the vertebrae in
6 question to be translated to adjacent vertebrae, thereby resulting in further complications such as
7 damage to neighbouring discs and/or damage to facet joints and the like.

8 **[0007]** More recently, disc replacement implants that allow various degrees of movement
9 between adjacent vertebrae have been proposed. Examples of some prior art implants are
10 provided in the following US patents: no. 5,562,738 (Boyd et al.); no. 6,179,874 (Cauthen); and
11 no. 6,572,653 (Simonson).

12 **[0008]** Unfortunately, the disc replacement, or implant, solutions taught in the prior art are
13 generally deficient in that they do not take into consideration the unique and physiological
14 function of the spine. For example, many of the known artificial disc implants are unconstrained
15 with respect to the normal physiological range of motion of the spine in the majority of motion
16 planes. Although some of the prior art devices provide a restricted range of motion, such
17 restrictions are often outside of the normal physiological range of motion; thereby rendering such
18 devices functionally unconstrained. Further, the known unconstrained implants rely on the
19 normal, and in many cases diseased structures such as degenerated facets, to limit excessive
20 motion. This often leads to early or further facet joint degeneration and other collateral damage
21 to spinal components.

22 **[0009]** In addition, many of the artificial discs known in the art, such as US patent nos.
23 5,562,738 (mentioned above) and 5,542,773, and US patent application publication nos.
24 2005/0149189 and 2005/0256581, generally comprise a ball and socket joint that is implanted
25 between adjacent vertebral bodies. One of the issues associated with such devices is the
26 difficulty in designing constraints to motion. Quite often, such constraints are provided by the soft
27 tissue adjacent to the implant, thereby resulting in a limited degree of constraint and/or damage
28 to such tissue structures. Where constraints are provided, typical ball and socket implants are
29 not easily adapted to for providing various types and degrees of constraint as may be required
30 depending on the need.

31 SUMMARY OF THE INVENTION

32 **[0010]** In one aspect, the present invention provides an artificial disc or implant comprising a
33 ball and ring combination, which generally combines the features of known ball and socket
34 designs but which includes at least some degree of versatility in terms of the type and degree of

1 constraint that can be built into the device. The implant of the invention also provides for
2 variations in the type of motion and center of rotation.

3 **[0011]** In one aspect, the invention comprises an artificial disc having two main sections or
4 components, each being adapted to be positioned against opposed vertebral body surfaces of
5 adjacent vertebrae. One of the two sections including a "ball" structure comprising a convex
6 bearing surface. The other of the sections including a "ring" structure comprising a ring adapted
7 to receive and constrain at least a portion of the convex surface.

8 **[0012]** In another aspect, one or both of the aforementioned sections may include one or
9 more "stops" or restrictive structures for limiting the range of relative movement between the two
10 sections.

11 **[0013]** Thus, in one aspect, the invention provides an artificial intervertebral disc for
12 implantation between adjacent superior and inferior vertebrae of a spine, the disc comprising:

13 - first and second cooperating shells, each of said shells having opposed inner surfaces
14 and oppositely directed outer surfaces, the outer surfaces being adapted for placement against
15 said vertebrae;

16 - the inner surface of the first shell including a convex protrusion;

17 - the inner surface of the second shell including an articulation surface and a motion
18 constraining ring adapted to receive said convex protrusion when said first and second shells are
19 combined, wherein, when in use, the articulation surface of the second shell contacts and bears
20 against said convex protrusion, and said ring constrains relative movement between the convex
21 protrusion and the second shell.

22 BRIEF DESCRIPTION OF THE DRAWINGS

23 **[0014]** These and other features of the invention will become more apparent in the following
24 detailed description in which reference is made to the appended drawings wherein:

25 **[0015]** Figure 1 is a schematic illustration of the range of motion of vertebrae.

26 **[0016]** Figure 2a is a sagittal cross sectional view of the artificial intervertebral disc of the
27 invention according to one embodiment.

28 **[0017]** Figure 2b is a transverse cross sectional view of the disc of Figure 1.

29 **[0018]** Figure 3 is a front coronal cross sectional view of the artificial intervertebral disc of
30 the invention according to another embodiment.

31 **[0019]** Figures 4 to 8 are sagittal cross sectional views of the artificial intervertebral disc of
32 the invention according to other embodiments.

[0020] Figure 9 is a front coronal cross sectional view of the artificial intervertebral disc of the invention according to another embodiment.

[0021] Figures 10 and 11 are sagittal cross sectional views of the artificial intervertebral disc of the invention according to other embodiments.

[0022] Figures 11a, 12a and 13a are sagittal cross sectional views of the artificial intervertebral disc of the invention according to other embodiments.

[0023] Figures 11b, 12b and 13b are transverse cross sectional views of the artificial intervertebral discs of Figures 11a, 12a and 13a, respectively.

[0024] Figures 14 and 15 are sagittal cross sectional views of the artificial intervertebral disc of the invention according to other embodiments.

[0025] Figures 16a, 17a and 18a are sagittal cross sectional views of the artificial intervertebral disc of the invention according to other embodiments.

[0026] Figures 16b, 17b and 18b are side perspective views of the rings of the discs shown in Figures 16a, 17a and 18a, respectively.

DETAILED DESCRIPTION OF THE INVENTION

[0027] In the following description, the terms "superior", "inferior", "anterior", "posterior" and "lateral" will be used. These terms are meant to describe the orientation of the implants of the invention when positioned in the spine and are not intended to limit the scope of the invention in any way. Thus, "superior" refers to a top portion and "posterior" refers to that portion of the implant (or other spinal components) facing the rear of the patient's body when the spine is in the upright position. Similarly, the term "inferior" will be used to refer to the bottom portions of the implant while "anterior" will be used to refer to those portions that face the front of the patient's body when the spine is in the upright position. With respect to views shown in the accompanying figures, the term "coronal" will be understood to indicate a plane extending between lateral ends thereby separating the body into anterior and posterior portions. Similarly, the term "laterally" will be understood to mean a position parallel to a coronal plane. The term "sagittal" will be understood to indicate a plane extending anteroposterior thereby separating the body into lateral portions. The term "axial" will be understood to indicate a plane separating the body into superior and inferior portions. It will be appreciated that these positional and orientation terms are not intended to limit the invention to any particular orientation but are used to facilitate the following description.

[0028] Figure 1 illustrates the complexity of vertebral movement by indicating the various degrees of freedom associated with a spine. In the normal range of physiological motion,

vertebrae extend between a "neutral zone" and an "elastic zone". The neutral zone is a zone within the total range of motion where ligaments supporting the spinal bony structures are relatively non-stressed; that is, the ligaments offer relatively little resistance to movement. The elastic zone is encountered when the movement occurs at or near the limit of the range of motion. In this zone, the visco-elastic nature of the ligaments begins to provide resistance to the motion thereby limiting same. The majority of "everyday" or typical movements occurs within the neutral zone and only occasionally continues into the elastic zone. Motion contained within the neutral zone does not stress soft tissue structures whereas motion into the elastic zone will cause various degrees of elastic responses. Therefore, a goal in the field of spinal prosthetic implants in particular, is to provide a prosthesis that restricts motion of the vertebrae adjacent thereto to the neutral zone. Such restriction minimises stresses to adjacent osseous and soft tissue structures. For example, such limitation of movement will reduce facet joint degeneration.

[0029] In general terms, the present invention provides artificial discs or implants for replacing intervertebral discs that are damaged or otherwise dysfunctional. The implants of the present invention are designed to allow various degrees of motion between adjacent vertebral bodies, but preferably within acceptable limits. In one embodiment, the invention is designed to permit relative movement between the vertebrae adjacent to the artificial disc of the invention, such movement including various degrees of freedom but preferably limited to a specified range. In one embodiment, the artificial disc, or prosthesis, of the invention is provided with one or more "soft" and/or "hard" stops to limit motion between the adjacent vertebrae. In particular, the artificial disc of the invention provides for rotation, flexion, extension and lateral motions that are similar to normal movements in the neutral and elastic zones (i.e. the movements associated with a normal or intact disc). In addition, the device of the invention also allows various combinations of such motions, or coupled motions. For example, the disc of the invention can be subjected to flexion and translation, or lateral flexion and lateral translation, or flexion and rotation. Various other motions will be apparent to persons skilled in the art given the present disclosure.

[0030] Figure 2a illustrates an artificial intervertebral disc 10 according to an embodiment of the invention. As shown, the disc 10 includes a superior shell 12 and an inferior shell 14. Each of the shells 12 and 14 comprise a bone contacting surface for placement against the bony structures of vertically adjacent vertebral bodies in a region where the natural intervertebral disc has been excised. As discussed above, such discectomy may be necessary in cases where the natural disc is damaged or diseased. The superior shell 12 includes a superior surface 16 for placement against the inferior surface of one vertebrae while the inferior shell 14 includes an inferior surface 18 for placement against the superior surface of an adjacent and vertically lower vertebrae. It will be understood that the terms "upper" and "lower" are used in conjunction with a

1 spine in the upright position. Although the term "shell" is used herein, it will be understood that
2 such term is not intended to limit the present invention to any shape or configuration. Other
3 terms that may apply to the shells would be plate etc. The term "shell" will be understood by
4 persons skilled in the art to apply to the structures shown and/or described herein as well as any
5 equivalent structures.

6 **[0031]** In the embodiment shown in Figure 2a, the inferior surface 20 of the superior shell 12
7 includes a ring 22 attached thereto. In the embodiment shown, the ring 22 may comprise a
8 downward depending convex or generally toroidal structure. The ring 22 may be affixed to the
9 superior shell 12 or may be formed integrally therewith.

10 **[0032]** Figure 2b illustrates the ring 22 of Figure 2a. In the embodiment shown, the ring 22
11 comprises a generally ovoid structure with a longer anteroposterior length and a shorter lateral
12 length. In other embodiments, the ring 22 may have a circular or any other shape as may be
13 needed in view of the following discussion of the purpose of the ring.

14 **[0033]** Figure 2a also illustrates the superior surface 24 of the inferior shell 14, which is
15 provided with a convex structure, or "ball" 26, generally extending in the superior (or upward)
16 direction. Although the term "ball" is used herein, it will be apparent to persons skilled in the art
17 that this term is not intended to refer to a full or partial spherical structure. In one embodiment,
18 as shown in Figure 2a, the ball 26 may comprise a hemispherical structure. In other
19 embodiments, the ball 26 may comprise an ovoid or other shape in plan view.

20 **[0034]** When implanting the artificial disc 10 into a intervertebral disc space, the two shells
21 12 and 14 are first aligned with inferior surface of the superior shell 12 facing the superior surface
22 of the inferior shell 14. In this alignment, the ball 26 and ring 22 are engaged with the ball 26
23 being positioned within the lumen of the ring 22. In this orientation, the disc 10 is then inserted
24 within the intervertebral space, between the adjacent vertebral bodies. In this position, the outer
25 surfaces of the shells 12 and 14 are in contact with the respective vertebral bodies. Once so
26 implanted, the normal compressive force exerted by one vertebrae against the other will serve to
27 maintain the disc 10 in position. It will be understood, that any other artificial means may be
28 used to prevent dislodging of the disc. For example, the outer surfaces of the shells may be
29 provided with an adhesive or bone cement etc. to ensure proper positioning.

30 **[0035]** Once in position, the superior surface of the ball 26 would contact the inferior surface
31 20 of the superior plate 12. This contact provides the desired separation between the adjacent
32 vertebral bodies relative movement between the ball 26 and the surface 20 provides the
33 essential articulation between the vertebral bodies. Further, the ring 22 serves to constrain the
34 relative movement between the ball 26 and the inferior surface 20. That is, the ring 22 limits the
35 amount of movement of the ball over the surface 20 to a defined articulation region. The surface
36 23 of the ring 22 that contacts the ball 26 is referred to herein as the articulation surface of the

ring. It will be understood that the ring 22 is dimensioned to be of sufficient height (as measured inferiorly from the inferior surface of the superior shell) to provide the required limit, or "stop", for the ball 26. In a typical application, the ring 22 would have a height of 1 to 5 mm. However, it will be understood that various other sizes may be used or needed depending, for example, on the associated anatomy. The invention is not limited to any specific dimensions as may be mentioned herein, and may be modified to fit within any disc space of the human spine, i.e. the cervical, thoracic, or lumbar regions. Further as mentioned above and as discussed further below, the ring 22 can be sized to limit or constrain various movements of the ball 26 including translation, lateral bending, flexion, extension and any coupled movements involving one or more of such specific movements. This flexibility in design will therefore allow the artificial disc of the invention to function similarly to naturally occurring discs while also allowing correction or prevention of any malformations.

[0036] In one embodiment, as shown in Figure 2a, the ring 22 is sized so that the smallest length in its lumen is larger than the diameter of the ball 26. This arrangement allows the ball 26 to contact the surface 20 and also allows some degree of travel of the ball before being limited by the ring 22. As mentioned above, in one embodiment, the ring 22 is dimensioned to have an ovoid shape (as shown in Figure 2b). This would, therefore, allow the ball 26 to travel in one direction more than the other. In the example discussed above, the ring 22 is provided with a longer anteroposterior length than a lateral length. This therefore allows further travel of the ball 26 in the anteroposterior direction. In turn, this translates to a vertebral joint that allows greater flexion and extension as compared to lateral flexion. It will also be understood that by allowing movement of the ball 26 in these directions, it is possible to allow for coupled movement such as flexion in conjunction with lateral flexion.

[0037] As indicated above, in one embodiment, the ball may be hemispheric in cross section but the shape may be varied in size in any direction. Thus, the ball 26 may comprise a hemisphere or a convex shape that is elongated in the anteroposterior and/or lateral directions. In general, the ball 26 may comprise any convex shape that provides the desired amount and type of intervertebral movements. This variability in structure of the ball 26 would allow for a variety of different movements to occur within the physical constraints of the ring 22. As discussed further below, further motion constraints may be provided on the ball 26 itself.

[0038] Although Figure 2a shows the ball 26 being located centrally on the superior surface 24 of the inferior shell 14, it will be understood that this is not intended as a limitation. In other embodiments, the ball 26 may be positioned at any variety of locations on the surface 24 depending on the desired movement. As will be appreciated, varying the position of the ball 26 over the surface 24 would result in a variation in the center of rotation of the disc 10. For example, in one embodiment the ball may be positioned posteriorly on the inferior shell 14. By

1 varying the position of the ball 26 with respect to the inferior shell 14, it is possible to provide the
2 disc 10 with a variety of movement, or articulation options.

3 **[0039]** In other embodiments, the inferior shell 14 may be adapted to provide resistance to
4 the movement of the ring 22. In one embodiment, the inferior shell 14 may be provided with one
5 or more hard stops or bumpers to limit the movement of the ring 22 over the ball 26. The term
6 "hard stops" is understood to mean a physical motion limiter. In particular, a "hard stop" would
7 serve to limit motion so as not to exceed the aforementioned elastic zone. A "soft stop", on the
8 other hand would serve to commence limitation of motion once the elastic zone is entered.
9 According to an embodiment of the invention, such stops may be built into the shell around the
10 ball, at any distance, or may be formed as part of the ball itself. In one aspect, the hard stops
11 may be of a height that is only a few millimetres below the maximum height of the ball 26.

12 **[0040]** An example of such hard stops is illustrated in Figure 3, wherein elements similar to
13 those described above are identified with the same reference numeral but with the letter "a"
14 added for clarity. As shown, hard stops 28 may be positioned laterally on either side of a ball
15 26a to limit lateral flexion. That is, the hard stops 28 provide a barrier for lateral (i.e. coronal)
16 movement of the ring 22a over the surface of the ball 26. The stops 28 shown in Figure 3 may
17 be of any length to serve the aforementioned purpose.

18 **[0041]** In another embodiment, the hard stops 28 may be located anteriorly to limit flexion in
19 the anteroposterior direction and in still another embodiment, they would be located posteriorly.
20 Any combination could be used to provide hard stops to constrain motion. The stops could be
21 any manner of shapes from rectangular with rounded edges to domes and of variable height. It
22 will be understood that in one embodiment, hard stops 28 may be provided to restrict movement
23 in all directions if such limited movement is required. The "bumpers" 28 may be of various
24 shapes for example linear or curved. Similarly, it will be understood that in other embodiments,
25 no such hard stops may be needed.

26 **[0042]** Another embodiment of the above mentioned hard stop function is shown in Figure 4,
27 wherein elements similar to those described above are identified with the same reference
28 numeral but with the letter "b" added for clarity. As shown in Figure 4, instead of the "bumpers"
29 28 provided on the inferior shell 14 as shown in Figure 3, one edge, in the illustrated case, the
30 anterior edge, of the ball 26b may be provided with a hard stop, which, in the embodiment
31 shown, is formed as a raised extension 30 on the ball. As shown, the extension 30 includes a
32 superior surface having a concave portion 32 adjacent the ball 26b, which serves as a "soft stop",
33 as discussed further below. The concave portion 32 extends from the anterior edge of the ball
34 26b, at a height between the lowermost and uppermost height of the ball 26b, and curves upward
35 towards the anterior end of the disc 10b. Anterior of the concave portion 32 the extension 30
36 includes an edge 34, which acts a hard stop. The arrangement shown in Figure 4 may be used

1 in situations where flexion of the spine at the region of the implant, is to be limited. As will be
2 understood, during flexion, the anterior edge of the ring 22b will traverse anteriorly over the
3 superior surface of the ball 26b and first encounter the concave portion 32. The concave portion
4 32, due to its upwardly curved surface, acts to slowly restrict the movement of the ring 22b,
5 thereby acting as a soft stop for the flexion movement. As movement of the anterior edge of the
6 ring 22b continues, the edge 34 is encountered and further movement is prevented. Thus, the
7 edge 34 serves as a hard stop for the flexion movement as well as limiting any tendency for the
8 device to take on an abnormal or perhaps undesired alignment.

9 **[0043]** In another embodiment, hard stops may be placed laterally on either side of the ball
10 26 to a height only a few mm below the maximum height of the ball to limit lateral flexion.

11 **[0044]** Another embodiment of the invention is shown in Figure 13a and 13b (collectively
12 referred to as Figure 13), wherein elements similar to those described above are identified with
13 the same reference numeral but with the letter "c" added for clarity. In this embodiment, a hard
14 stop 36 is provided on the superior surface 24c of the inferior shell 14c wherein such hard stop is
15 positioned immediately adjacent to the ball 26c or may be formed as part of the ball 26c. The
16 hard stop 36 is similar in function to that shown in Figure 3 but, is positioned only at the anterior
17 edge of the ball 26c. As with the hard stop shown in Figure 4, the hard stop 36 of Figure 13
18 serves to limit flexion and prevent abnormal or perhaps undesired alignment. In this case, the
19 hard stop 36 does not offer a gradual reduction to the flexion motion. As such, the arrangement
20 shown in Figure 13 may be used in cases where it is desired to limit flexion and correct and/or
21 limit kyphosis.

22 **[0045]** In a similar manner, a further embodiment of the invention would have the hard stop
23 36 (or the extension 30 of Figure 4) located posteriorly on the inferior shell 14 so as to limit
24 extension. In a further embodiment, a combination of such hard stops could be located in any
25 direction or even circumferentially with respect to the ball and used to constrain motion in any or
26 all directions. Thus, the stops associated with the ball may be varied in many ways to limit
27 motion in one or more planes. The stops could be of any shape such as rectangular or convex
28 such as dome-shaped. The stops may be of the same or different materials amongst themselves,
29 or of similar or different materials compared to the shells. Further, the stops may be provided
30 with rounded edges or any other required shape. In addition, the stops may be of any height as
31 will be understood by persons skilled in the art. In yet another embodiment, the disc 10 may
32 include no stops associated with the ball 26, thereby allowing the ring to articulate over a
33 maximum surface area of the ball.

34 **[0046]** Another embodiment of the invention is illustrated in Figure 5, wherein elements
35 similar to those described above are identified with the same reference numeral but with the
36 letter "d" added for clarity. As shown in Figure 5, the superior shell 12d may be provided with a

well 38, which comprises a concave region that is adapted to receive a portion of the ball 26d. As will be understood, the well 38 would serve as a location means for positioning the ball 26d and/or as a further means of constraining the ball. In conjunction with the ring 22d, the provision of the well 38 would increase the surface area contacted by the ball 26d for the purpose of constraining its movement. As such, it will be understood that the well 38 would further serve to reduce the wear effects on the ring 22d. Although the well 38 in Figure 5 is shown as being somewhat complementary in shape to the ball 26d, it will be understood that such complementarity is not a limitation of the invention. That is, the well 38 may be of various shapes and sizes to provide a variety of constraint options.

[0047] Another embodiment of the invention is shown in Figure 6, wherein elements similar to those described above are identified with the same reference numeral but with the letter "e" added for clarity. Figure 6 illustrates an embodiment wherein the disc 10e is provided with a means of absorbing axial forces, that is, forces that are transmitted axially along the spine. To provide such force absorption, the disc 10e may be provided with one or more resilient elements one or both of the inferior and superior shells, 12e and 14e, respectively. In the embodiment shown in Figure 6, the ball 26e is separated from the superior surface 24e of the inferior shell 14e by a nucleus 40. The nucleus 40 may comprise any known resilient material such as hydrogel, silicone, rubber etc. or may comprise a mechanical device such as a spring etc. As will be understood, as an axial force is applied to the disc 10e, the nucleus 40 would absorb some of such force, thereby offering some cushioning and preventing or minimising pressure between the ball 26e and the ring 22e and/or the superior shell 12e. In one embodiment, as shown in Figure 6, the ball 26e may be partially hollow to accommodate a greater volume of the nucleus 40. In such arrangement, the nucleus 40 would include a raised portion or section adapted to be located within the hollow ball 26e. Such a structure may be advantageous for positively locating the ball 26e with respect to the inferior shell 14e. That is, as with the embodiment shown in Figure 6, the nucleus 40, having a protruding portion extending away from the inferior shell 14e, may be secured to the superior surface 24e of the inferior shell 14e. The ball 26e, having a central cavity adapted to receive the protruding portion of the nucleus 40, would be positioned over the nucleus 40 such that the protruding portion is inserted into the cavity of the ball. In such case, the ball 26e would not need to be secured or attached directly to the inferior shell 14e since the nucleus would serve to prevent or limit any relative movement between the ball and the inferior shell 14e. In this way, the ball 26e may be described as "floating" on the nucleus 40.

[0048] A further embodiment of a resilient force absorbing means is illustrated in Figure 10, wherein elements similar to those described above are identified with the same reference numeral but with the letter "f" added for clarity. In Figure 10, the ball 26f of the disc 10f is secured to the superior surface 24f of the inferior shell 14f as described previously. In this case, a spring 42 is provided, which bears against the inferior surface 18f of the shell 14f. It will be

understood that the opposite side of the spring 42 may bear against the bony portion or portions of the adjacent vertebra or against any surface or structure (such as a plate or the like) attached to such vertebra. The spring 42 would function in a manner similar to the nucleus 40 described above. However, as shown in Figure 10, a further advantage may be realised with the arrangement shown. Specifically, since the spring may be positioned only against one edge of the disc 10f, the disc may be provided with a pre-set positioning to align the adjacent vertebrae in any desired manner. For example, in the embodiment shown in Figure 10, the spring 42 is located at the anterior edge of the disc 10f thereby causing the superiorly adjacent vertebra (not shown) to be angled posteriorly. As will be understood, such an arrangement, in addition to providing the aforementioned cushioning function, will also serve to correct or prevent kyphosis. In the above description of Figure 10, the spring 42 has been described as being located between the inferior shell 14f and the inferiorly adjacent vertebra. However, in another embodiment, the spring 42 may be equally positioned between the ball 26f and the inferior shell 14f while achieving the same function. In addition although the term "spring" is used to describe element 42, it will be understood that any similarly functioning device may be used with the disc 10f. For example, the spring 42 may comprise a mechanical device such as a coil spring or a leaf spring. Alternatively, the spring 42 may comprise a wedge shaped or similarly angulated resilient nucleus. Although Figure 10 illustrates the inferior shell 14f angled posteriorly, it will be understood that such angulation may also be in the anterior direction in situations where kyphosis is required or to be encouraged (such as a region where lordosis is to be prevented or corrected such as the thoracic spine).

[0049] Another position adjusting means is illustrated in Figure 7, wherein elements similar to those described above are identified with the same reference numeral but with the letter "g" added for clarity. In Figure 7, the disc 10g has an inferior shell 14g which is provided with an angled superior surface 24g with respect to the superior shell 12g. Due to such angulation, the ball 26g is similarly angularly disposed in relation to the superior shell 12g and the ring 22g. As will be understood, such a structure serves to prevent or correct kyphosis as described above in relation to Figure 10. However, unlike Figure 10, the disc 10g of Figure 7 does not necessarily include a force absorbing device. To achieve the desired angulation in the inferior shell 14g, the inferior shell may be formed as a wedge, as depicted in Figure 7. Alternatively, the inferior shell may be formed in two segments thereby separating the inferior surface 18g and the superior surface 24g by means of a separating element (not shown). It will be understood that such separating element may comprise a spring such as described above with reference to Figure 10. In such case, the disc 10g of Figure 7 would also include a force absorbing means as well. It will also be understood that the ball 26g of Figure 7 may include a nucleus as described above with respect to Figure 6, thereby also providing the disc 10g of Figure 7 with a means of absorbing axial forces. Although Figure 7 illustrates the inferior shell 14g angled posteriorly, it will be

understood that such angulation may also be in the anterior direction in situations where kyphosis is required or to be encouraged (such as a region where lordosis is to be prevented or corrected such as, for example, in the thoracic spine).

[0050] Much of the above discussion has focussed on variations that may be implemented to the inferior shell 14 and/or the ball 26 of the invention. However, in a similar manner, the superior shell 12 and/or the ring 22 may also be varied to achieve a variety of positions and functions. For example, in one embodiment, the ring may be formed in various sizes and shapes. These would include variations in the height of the limiting edge of the ring 22 and variations in its shape, including circular, ovoid and rectangular forms etc. For example, by varying the shape of the ring 22, it will be understood that the shape and area for articulation with the ball would also be varied thereby allowing the ball's constraint of motion to be tailored as needed. Similarly, the location of the ring 22 may also be varied on the superior shell 12 so as to match the position of the ball 26. In addition, the superior shell 12 may be provided with one or more "stops", such as hard stops and/or soft stops, similar to those described above, for constraining or limiting the relative movements between the superior and inferior shells. Such stops may comprise separate elements attached to the superior shell or may form part of the ring 22 itself. For example, in one embodiment, the stops may comprise raised edges of the ring. Further examples and aspects of the invention are discussed further below.

[0051] An embodiment of the invention showing variations in the superior shell are illustrated in Figures 11a and 11b (collectively referred to as Figure 11), wherein elements similar to those described above are identified with the same reference numeral but with the letter "h" added for clarity. In Figure 11, the ring 22h is sized to be larger than the ball 26h. In this embodiment, it will be understood that articulation of the disc 10h involves contact mainly between the inferior surface 20h of the superior shell 12h. In other words, the ball 26h would be capable of translation movement over a portion of the inferior surface 20h without hindrance by the ring 22h. Such translation movement may comprise, for example, movement within the neutral zone. However, the ring 22h would serve to constrain the ball 26h from travelling beyond such region, thereby acting as a "hard stop".

[0052] A variant of the ring 22h described above is illustrated in Figures 12a and 12b (collectively referred to as Figure 12), wherein elements similar to those described above are identified with the same reference numeral but with the letter "j" added for clarity. In this embodiment, the disc 10j, is provided with ring 22j on the superior shell 12j that is narrower in size and designed to be in contact with at least a portion of the ball 26j during all movement, i.e. articulation of the disc 10j. As will be understood, such an arrangement would assist in minimising wear on the inferior surface 20j of the superior shell 12j caused by constant contact

1 with the ball 26j. In addition, such an arrangement would limit lateral flexion while allowing for a
2 full range of flexion and extension

3 **[0053]** Figure 12b illustrates a further feature of the ring 22j, namely a larger anteroposterior
4 dimension as compared to a lateral dimension. As will be understood, such an arrangement
5 serves to allow the ball 26j a greater degree of freedom in movement in the sagittal plane and a
6 restricted amount of movement in the coronal plane. In another embodiment, the ring 22j may be
7 elongated in the coronal plane thereby achieving the opposite effect. Thus, it will be understood
8 that any combination of movements can be tailored by adjusting the dimensions of the ring 22.

9 **[0054]** Further embodiments of the invention are illustrated in Figures 14 and 15, wherein
10 elements similar to those described above are identified with the same reference numeral but
11 with the letter "m" or "n" added, respectively, for clarity. In the embodiments discussed above,
12 the ring 22 has been described as having a convex outer surface, particularly the articulating
13 surface, that is the surface contacting the ball 26. However, as shown in Figures 14 and 15, the
14 ring 22m and 22n, respectively, may alternatively include a concave articulating surface thereby
15 changing the interaction between the ring and the ball. In both cases, the rings 22m and 22n
16 have an articulation surface contacting the ball 22m and 22n, respectively, that is concave in
17 shape. Such concavity may be provided around the entire perimeter of the ring or only on certain
18 locations. Similarly, the degree of curvature provided on the ring may be varied. For example,
19 as shown in the two embodiments illustrated, Figure 14 depicts a ring 22m that includes an
20 articulation surface having a greater degree of curvature than that of ring 22n shown in Figure
21 15. The concave articulation surface of the ring would allow movements such as flexion,
22 extension, lateral bending or any combination thereof to be controlled by varying the degree of
23 curvature provided. That is, the concave articulation surface would also allow for a graduated
24 resistance to the movement of the ball thereby, for example, allowing for initial easy movement
25 within the neutral zone but greater or increasingly greater resistance to movement in the elastic
26 zone. Such resistance will be understood as a resistance provided against the ball. In another
27 embodiment, the degree of curvature provided on the ring may be varied as between locations.
28 For example, a greater degree of curvature may be provided at the lateral regions than in the
29 anterior and posterior regions. This would, therefore, provide greater resistance to lateral
30 bending than to flexion or extension. In another embodiment, the curvature of the ring can be
31 varied to, for example, inhibit flexion by increasing the degree of curvature at the anterior edge of
32 the ring. In another embodiment, the ring may be provided with both a constant or variably
33 curved articulation surface as well as a non-circular shape. For example, the ring may comprise
34 a oval geometry with a large axis generally parallel to the sagittal plane. The anterior and
35 posterior articulation surfaces of such a ring may include a lesser degree of curvature than the
36 lateral articulation surfaces. Further discussion of such variability is provided below with respect
37 to Figures 16 to 18.

[0055] Figures 8 and 9 illustrate another embodiment of the invention. Where elements similar to those described above are identified, the same reference numerals are used but with the letter "p" added for clarity. As shown in Figures 8 and 9, the superior shell 12p is provided with a convex curvature wherein the outer edges thereof are curved inferiorly. It will be understood that the degree of curvature of the superior shell 12p may vary from the depicted in Figures 8 and 9. Such curvature of the superior shell 12p would serve to correspond with the natural curved shape of the endplate on the vertebra. It will be understood that although the superior shell is shown in Figures 8 and 9 as having such curvature, the inferior shell 14p may similarly be provided with such complementary curvature corresponding to curvatures in the adjacent end plate. As shown in Figures 8 and 9, the superior shell 12p would still include the ring 22p for constraining movement of the ball 26p. Such ring 22p may therefore also be designed to assume the curvature of the superior shell 12p. Thus, according to this embodiment, the ball 26p may be constrained to motion over the gently sloping curvature of the superior shell 12p, in either or both of the sagittal or coronal planes.

[0056] Figures 16a, 17a and 18a illustrate other embodiments of the invention. Where elements similar to those described above are identified, the same reference numerals are used but with the letters "r", "t" and "u" added, respectively, for clarity. Figures 16a, 17a and 18a are shown with an inferior shell 14, ball 26 and stop 36 provided at the anterior edge of the ball 26, in a manner similar to that described above with reference to Figure 13. As described above, although the stop 36 is shown as being provided on the anterior edge of the ball 26, such stop may in fact be located in any position depending on the need and in more than one location if necessary. It will be assumed that this structure of the inferior shell is not intended to limit the embodiments illustrated in Figures 16a to 18a.

[0057] Figure 16a illustrates a superior shell 12r that is similar to that shown in Figures 14 and 15. That is, the superior shell 12r includes a ring 22r that is provided on a generally flat inferior surface 20r of the superior shell 12r. The ring 22r of this embodiment includes an articulation surface 23r that is concavely curved for the purposes discussed in reference to Figures 14 and 15. Figure 17a illustrates a variation of the disc of Figure 16a. In Figure 17a, the disc 10t includes a superior shell 12t having a concavely curved inferior surface 20t. That is, the outer edges of the inferior surface 20t are curved inferiorly. As with Figure 16a, the ring 22t also includes a concavely curved articulation surface 23t. Similarly, Figure 18a illustrates a variation wherein the disc 10u includes a superior shell 12u having a convexly curved inferior surface 20u. As with Figure 16a, the ring 22u also includes a concavely curved articulation surface 23u.

[0058] As shown in Figures 16a to 18a, as the inferior surface 20 is curved, the ring 22 is also allowed to assume a similar curvature. Such overall curvature of the ring 22 along with the curvature of the articulation surface 23 will be understood to assist in directing and controlling the

1 amount and degree of constraint offered for movement of the ball 26. For example, as shown in
2 Figure 17a, the curvature of the inferior surface 20t is shown as being concave in the sagittal
3 plane. Thus, this orientation would serve to gradually resist movement of the ball in the
4 anteroposterior directions, i.e. during flexion and extension. As discussed above, the optional
5 stop 26t (or stops, in the situation where more than one stop is provided) would pose a hard stop
6 to prevent movement in a given direction. Similarly, a concave curvature of the inferior surface
7 20t in the coronal plane would inhibit lateral bending.

8 **[0059]** In the case of Figure 18a, it will be understood that the convex curvature would serve
9 to assist motion. As a corollary to the above discussion, it will be understood that the convex
10 curvature of the inferior surface 20u shown in Figure 18a may be in either the sagittal or coronal
11 planes. Moreover, the concave or convex curvature of the inferior surface 20 discussed in
12 reference to Figures 17a and 18a will be understood to be provided in one or more directions. In
13 one embodiment, for example, such surface may be partially spherical, thereby providing a
14 respectively curved surface in all directions.

15 **[0060]** Figures 16b, 17b and 18b illustrate the rings 22r, 22t and 22u depicted, respectively,
16 in Figs 16a to 18a.

17 **[0061]** Although Figures 16a to 18a illustrate the ring 22 having a convexly curved
18 articulation surface 23, it will be understood that such surface may also be convexly curved as
19 discussed above in relation to other embodiments.

20 **[0062]** The structural components of the disc of the invention, in particular the ball and ring,
21 may be formed of from any medically suitable material such as titanium, titanium alloys, nickel,
22 nickel alloys, stainless steel, nickel-titanium alloys (such as Nitinol™), cobalt-chrome alloys,
23 polyurethane, porcelain, plastic and/or thermoplastic polymers (such as PEEK™), silicone,
24 rubber, carbothane or any combination thereof. In addition, it will be understood that the ball and
25 ring may be made from materials that are the same or different from the remainder of the
26 respective shells. For example, the ball may be made of titanium while the ring and both shells
27 may be made of PEEK™. Various other materials and combinations of materials will be known
28 to persons skilled in the art.

29 **[0063]** As will be understood, and as explained above, the present invention may be
30 adapted in various ways to meet any number of desired motion characteristics. That is, the
31 shape, position, and size of the ball and/or ring may be chosen for various intervertebral joints of
32 the spine and may be tailored for providing or restricting the degree and direction of motion.
33 Various features and embodiments of the invention have been described and/or shown herein. It
34 will be understood by persons skilled in the art that various combinations of such features and
35 embodiments can be used depending on the need and requirements of the artificial disc.
36 Further, although the figures illustrate various embodiments for the purposes of describing

embodiments of the present, the relative or absolute dimensions shown are not intended to limit the scope of the invention in any way.

[0064] It will be apparent to persons skilled in the art that although the above discussion has focussed on the superior shell being provided with the ring and the inferior shell being provided with the ball, the reverse may also be used. That is, in other embodiments, the superior shell may include the ball and the inferior shell may include the ring.

[0065] It will be apparent to persons skilled in the art that any bone contacting surfaces of the discs discussed above (such as the external surfaces of the shells) may be provided with a texture, treatment or coating to encourage or enhance bone ingrowth and/or adhesion to the adjacent bony structure. For example, such surfaces may be provided with a roughened or grooved texture and/or may be coated with a bone growth enhancing agent.

[0066] In addition, although the present invention has been described with reference to intervertebral joints, the present invention may equally be used in other joints such as, for example, knee joints.

[0067] Although the invention has been described with reference to certain specific embodiments, various modifications thereof will be apparent to those skilled in the art without departing from the purpose and scope of the invention as outlined in the claims appended hereto. Any examples provided herein are included solely for the purpose of illustrating the invention and are not intended to limit the invention in any way. Any drawings provided herein are solely for the purpose of illustrating various aspects of the invention and are not intended to be drawn to scale or to limit the invention in any way. The disclosures of all prior art recited herein are incorporated herein by reference in their entirety.

WE CLAIM:

1. An artificial intervertebral disc for implantation between adjacent superior and inferior vertebrae of a spine, the disc comprising:
 - first and second cooperating shells, each of said shells having opposed inner surfaces and oppositely directed outer surfaces, the outer surfaces being adapted for placement against said vertebrae;
 - the inner surface of the first shell including a convex protrusion;
 - the inner surface of the second shell including an articulation surface and a motion constraining ring adapted to receive said convex protrusion when said first and second shells are combined, wherein, when in use, the articulation surface of the second shell contacts and bears against said convex protrusion, and said ring constrains relative movement between the convex protrusion and the second shell.
2. The artificial disc of claim 1 further including at least one motion limiting means provided on the first shell for limiting relative movement between the protrusion and the ring.
3. The artificial disc of claim 2 wherein said at least one motion limiting means comprises a barrier preventing further relative movement between the protrusion and the ring.
4. The artificial disc of claim 2 wherein said at least one motion limiting means comprises a gradually increasing motion resistor for relative movement between the protrusion and the ring.
5. The artificial disc of claim 1 wherein said ring is generally circular in shape.
6. The artificial disc of claim 1 wherein said ring is generally oval in shape.
7. The artificial disc of claim 1 wherein said ring includes a contact surface for contacting said convex protrusion when said artificial disc is in use, and wherein said contact surface is convexly shaped.
8. The artificial disc of claim 1 wherein said ring includes a contact surface for contacting said convex protrusion when said artificial disc is in use, and wherein said contact surface is concavely shaped.
9. The artificial disc of claim 1 wherein said first shell includes a force absorbing means for absorbing compressive forces urging together the first and second shells.

10. The artificial disc of claim 9 wherein said force absorbing means comprises a mechanical spring or a resilient material.
11. The artificial disc of claim 10 wherein said force absorbing means is provided between the first shell and the convex protrusion.
12. The artificial disc of claim 11 wherein said convex protrusion includes a cavity for housing at least a portion of said force absorbing means.
13. The artificial disc of claim 10 wherein said force absorbing means is provided between the first shell and outer surface of said first shell.
14. The artificial disc of claim 1 wherein said first shell includes an inner surface that is angularly arranged with respect to the second shell.
15. The artificial disc of claim 1 wherein the inner surface of said second shell is concavely shaped.
16. The artificial disc of claim 1 wherein the inner surface of said second shell is convexly shaped.

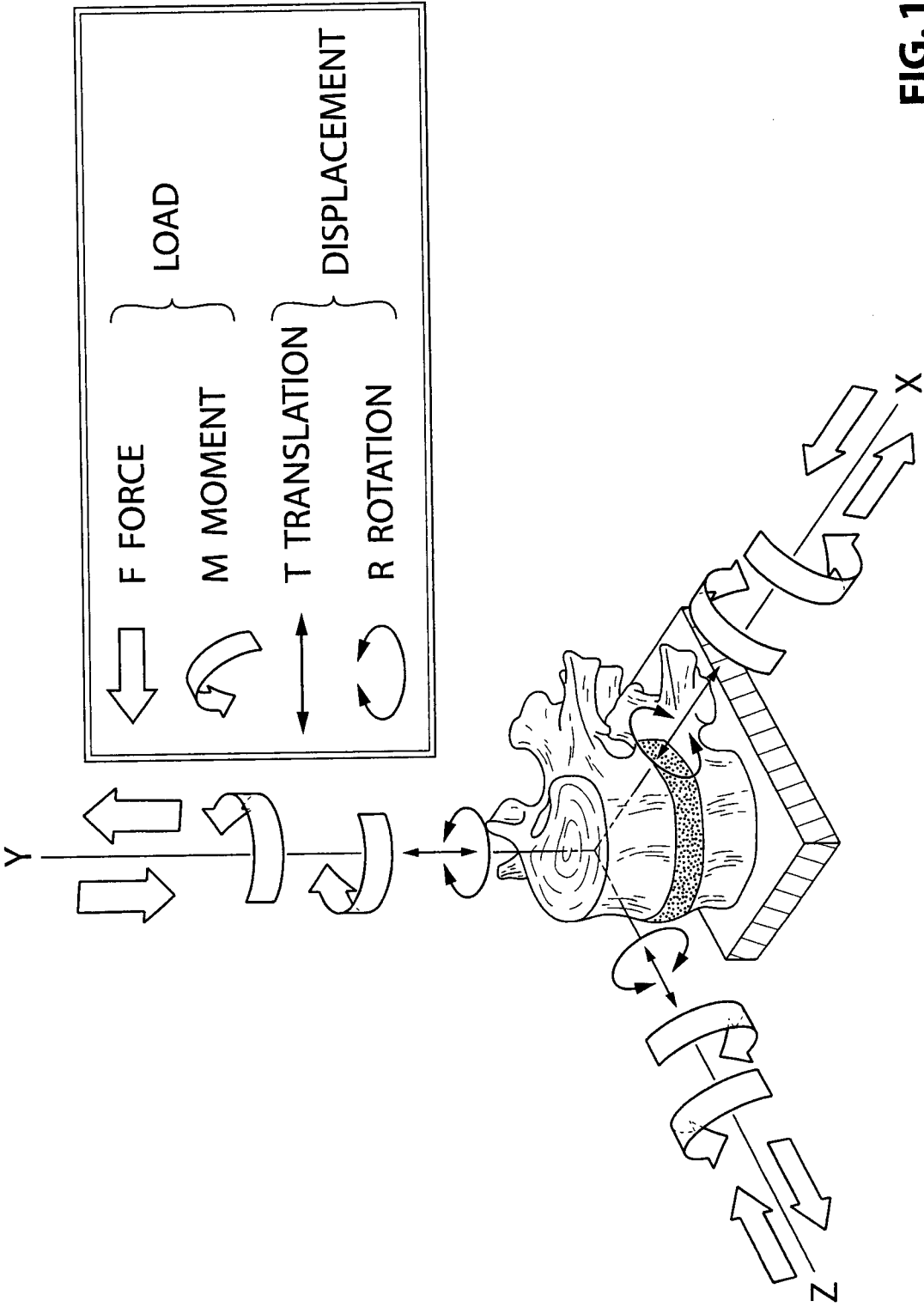


FIG. 1

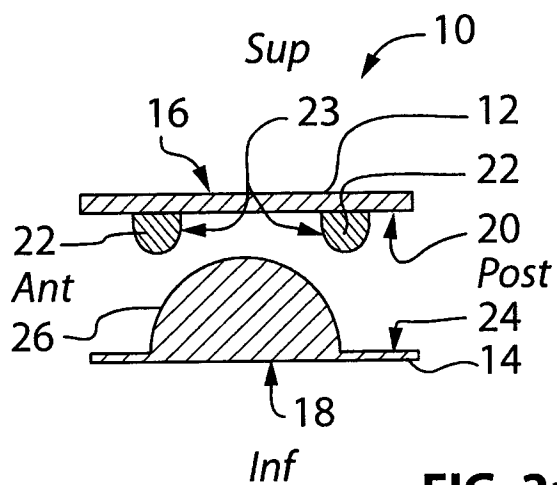


FIG. 2a

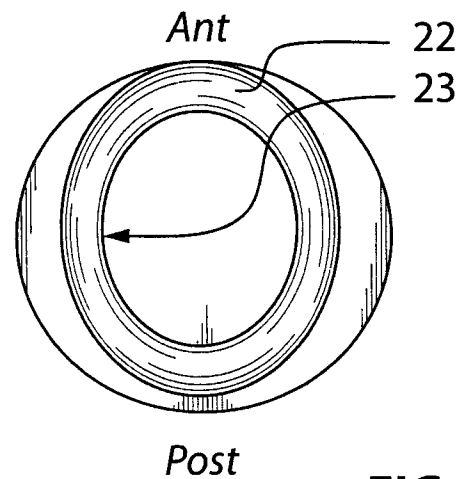


FIG. 2b

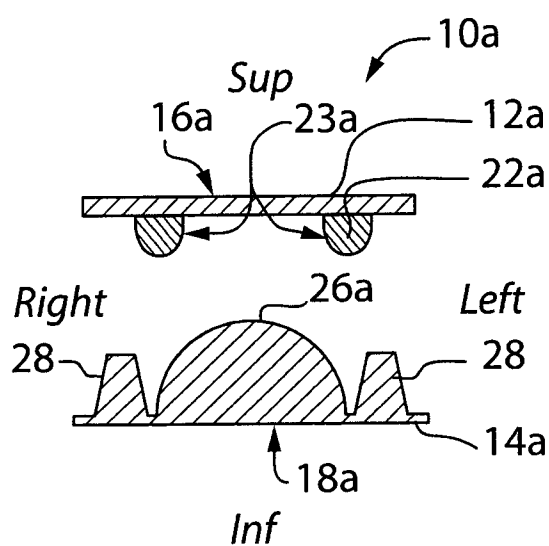


FIG. 3

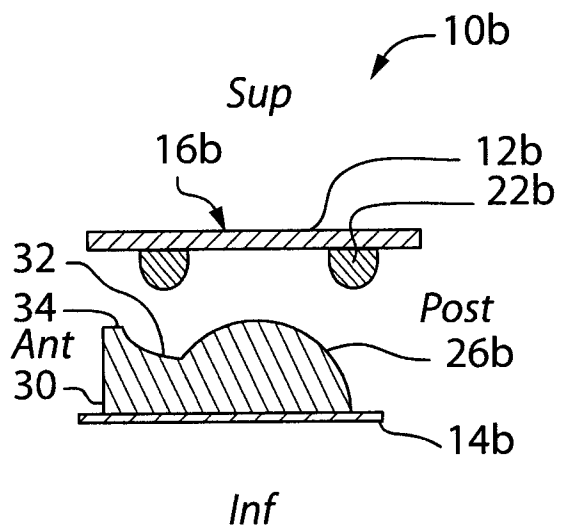


FIG. 4

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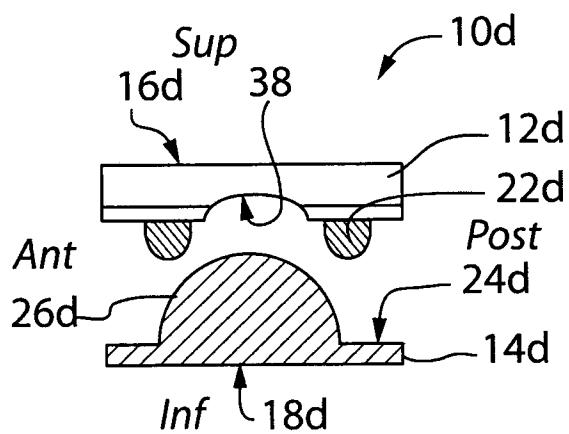


FIG. 5

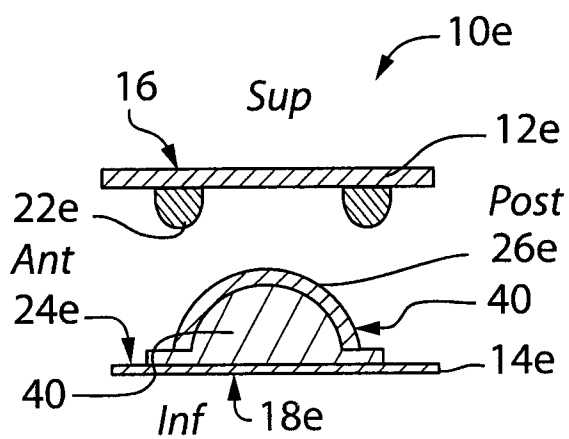


FIG. 6

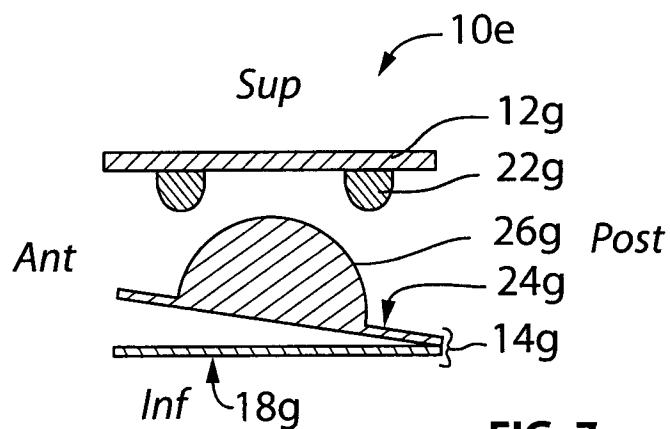


FIG. 7

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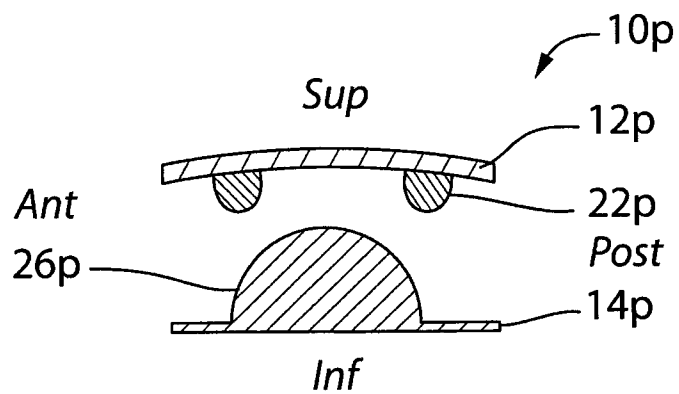


FIG. 8

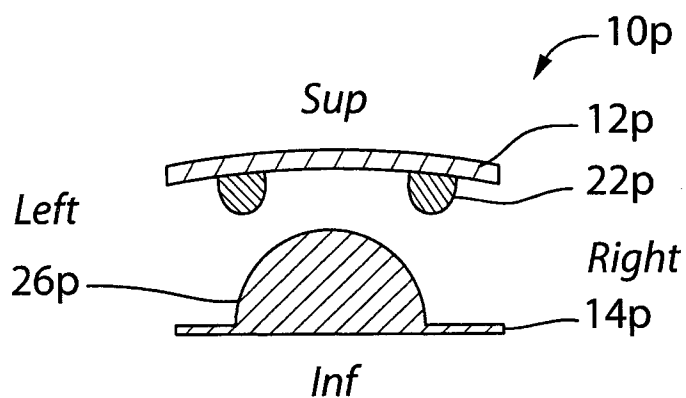


FIG. 9

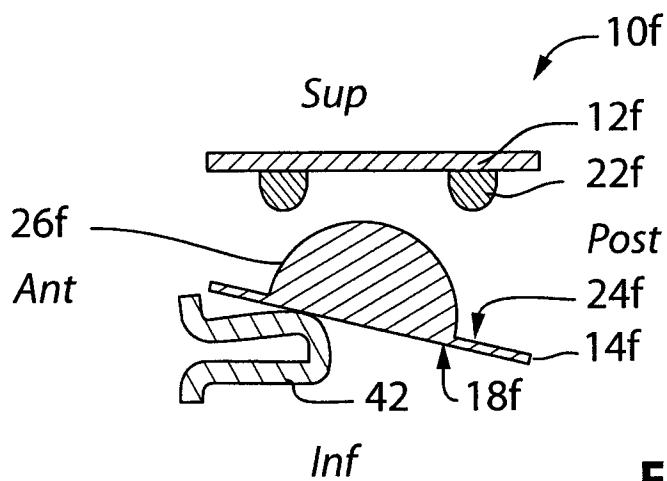


FIG. 10

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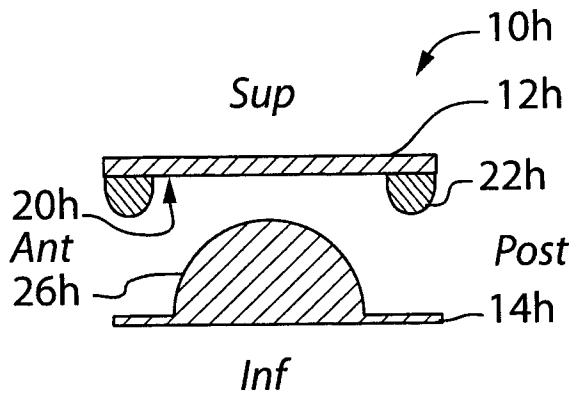


FIG. 11a

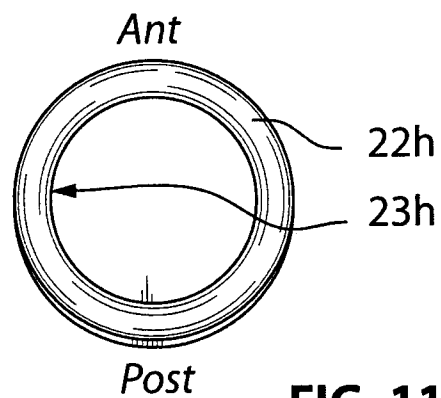


FIG. 11b

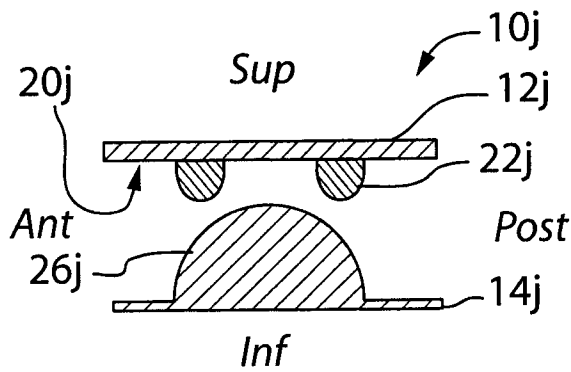


FIG. 12a

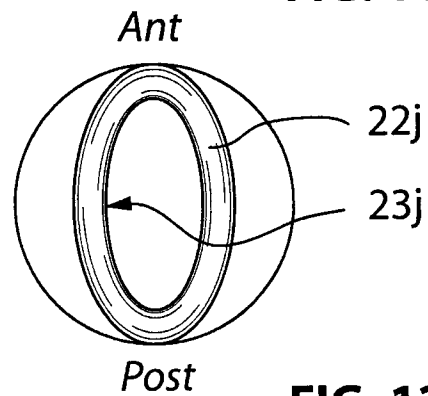


FIG. 12b

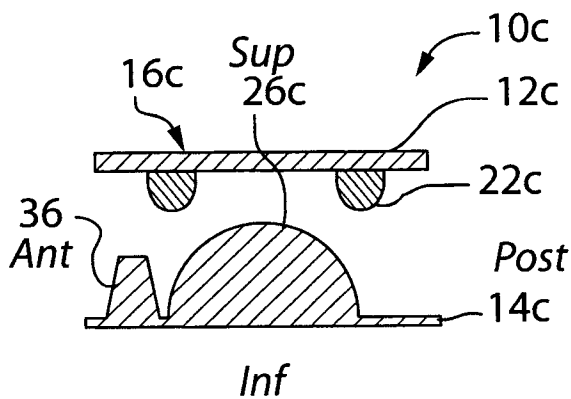


FIG. 13a

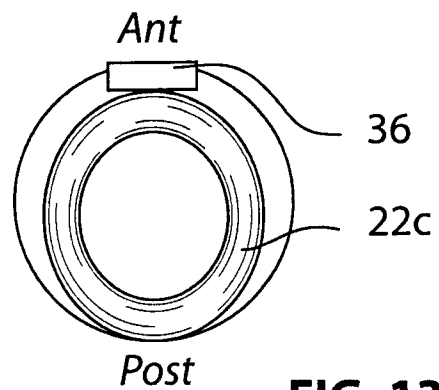
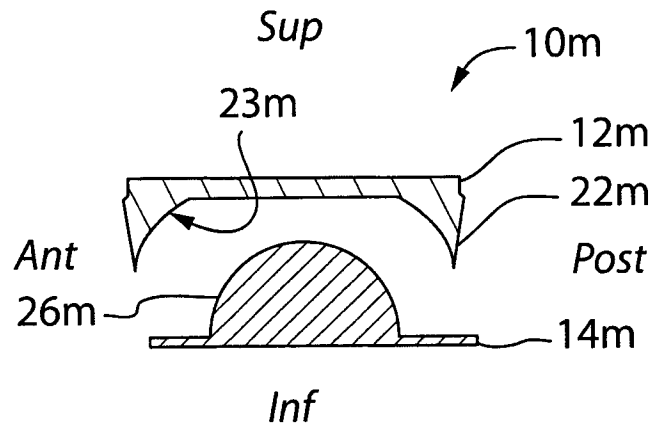
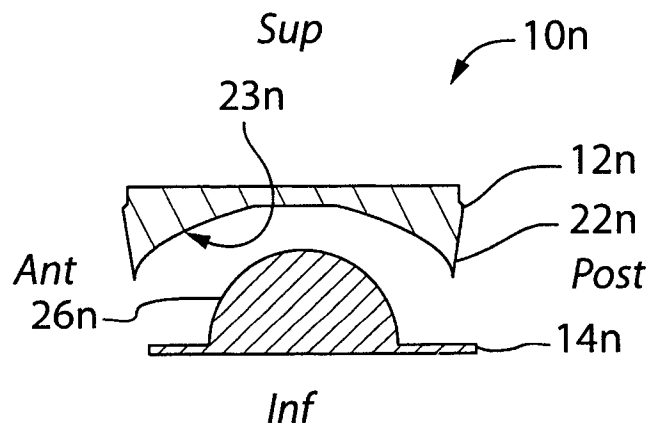


FIG. 13b

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**FIG. 14****FIG. 15**

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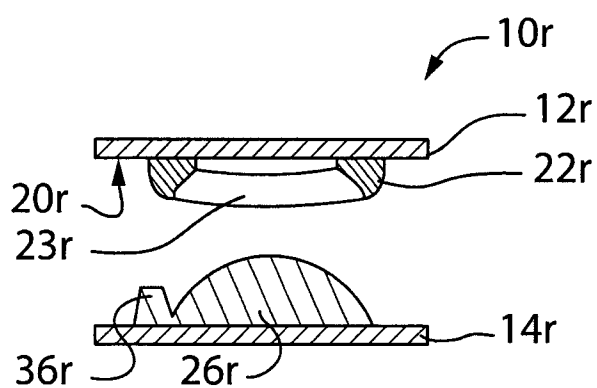


FIG. 16a



FIG. 16b

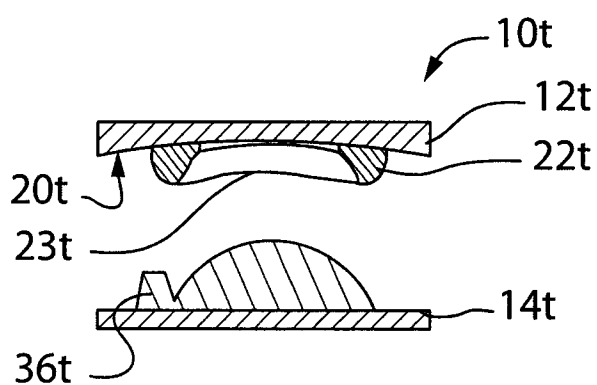


FIG. 17a



FIG. 17b

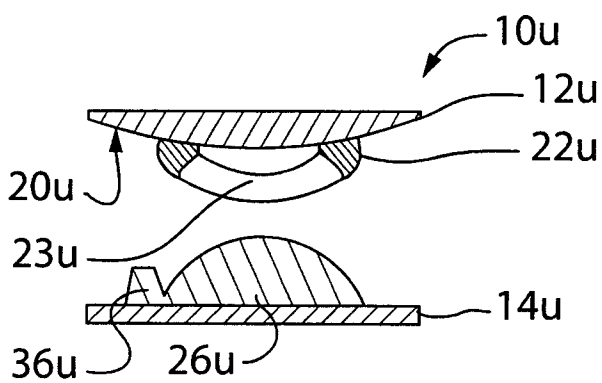


FIG. 18a



FIG. 18b

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CA2009/000233

A. CLASSIFICATION OF SUBJECT MATTER IPC: A61F 2/44 (2006.01) 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 USC: 623/17 Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic database(s) consulted during the international search (name of database(s) and, where practicable, search terms used) EPOQUE, Delphion, Canadian Patent database: intervertebral disc, articulation surface, convex, concave, motion limiting, motion restraining, ring, barrier		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2005/044151 (HENTRICH) 19.MAY.2005 (19.05.2005)	1-8, 14-16
Y	Entire document, Figures 7-10	9-13
Y	US 7314487 (RALPH et al.) 01.JAN.2008 (01.01.2008) Entire document	9-13
A	US 5899941 (NISHIJIMA et al.) 04.MAY.1999 (04.05.1999) Entire document	1
A	US 5683465 (SHINN et al.) 04.NOV.1997 (04.11.1997) Figure 7	1
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input checked="" type="checkbox"/> See patent family annex.		
* Special categories of cited documents : "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier 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 05 May 2009 (05-05-2009)	Date of mailing of the international search report 23 June 2009 (23-06-2009)	
Name and mailing address of the ISA/CA Canadian Intellectual Property Office Place du Portage I, C114 - 1st Floor, Box PCT 50 Victoria Street Gatineau, Quebec K1A 0C9 Facsimile No.: 001-819-953-2476	Authorized officer Hoan Huynh 819- 934-3467	

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/CA2009/000233

Patent Document Cited in Search Report	Publication Date	Patent Family Member(s)	Publication Date
WO 2005044151A1	19-05-2005	None	
US 7314487B2	01-01-2008	AT 426377T AU 2002322278B2 CA 2451359A1 EP 1414333A2 EP 1414333A4 EP 1414333B1 IL 159459D0 JP 4073867B2 JP 2004535239T US 6468310B1 US 6527806B2 US 6723127B2 US 6758861B2 US 7314486B2 US 2003014111A1 US 2003014112A1 US 2003040801A1 US 2004204763A1 US 2004236426A1 WO 03007780A2 WO 03007780A3	15-04-2009 22-03-2007 30-01-2003 06-05-2004 14-02-2007 25-03-2009 01-06-2004 09-04-2008 25-11-2004 22-10-2002 04-03-2003 20-04-2004 06-07-2004 01-01-2008 16-01-2003 16-01-2003 27-02-2003 14-10-2004 25-11-2004 30-01-2003 10-04-2003
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US 5683465A	04-11-1997	None	