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

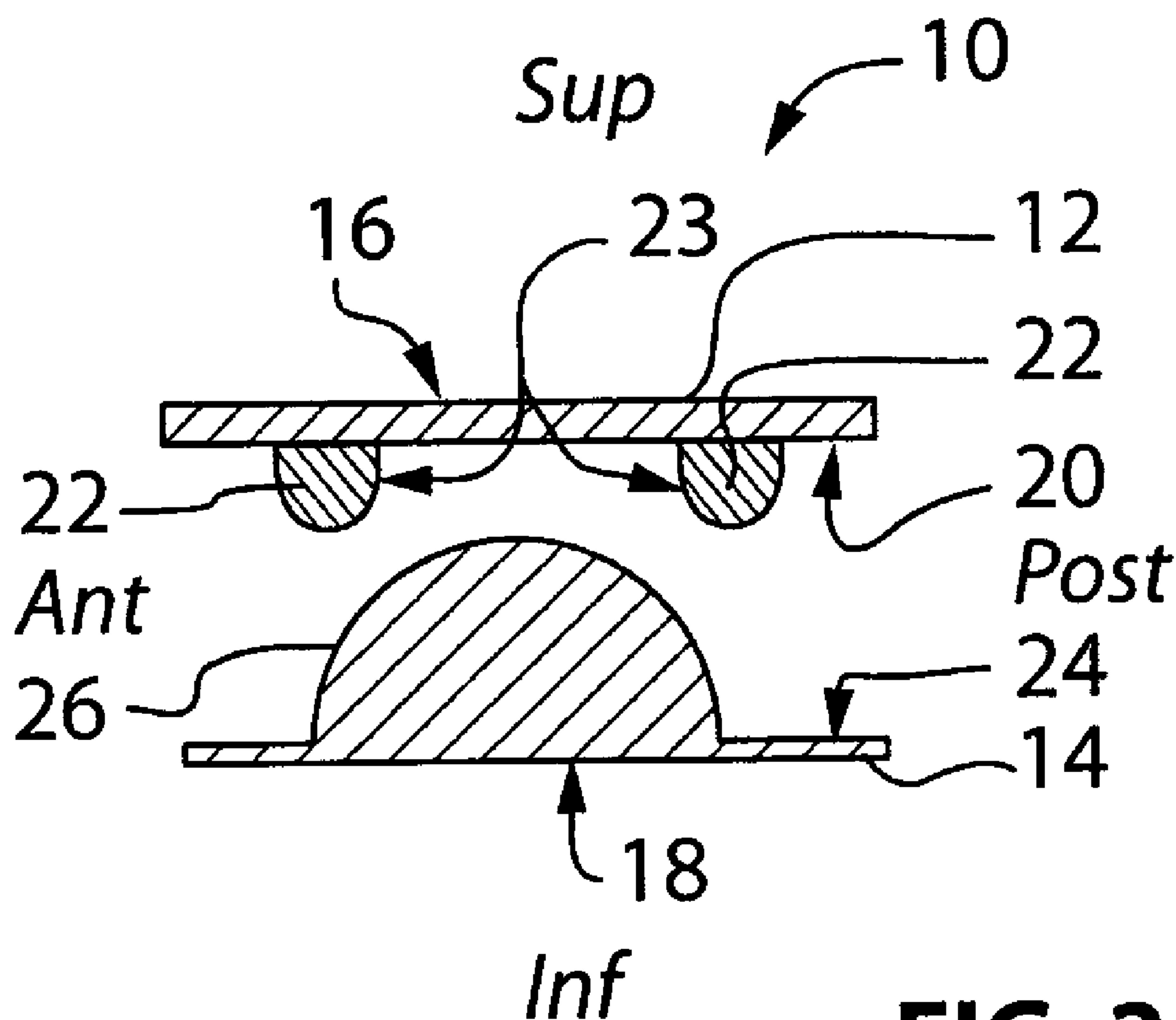


FIG. 2a

(57) Abrégé/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.

1 **ABSTRACT**

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

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

3 **CROSS REFERENCE TO PRIOR APPLICATIONS**

4 **[0001]** This application claims priority from US application number 61/067,545, filed February
5 28, 2008, the entire contents of which are incorporated herein by reference.

6 **FIELD OF THE INVENTION**

7 **[0002]** The present invention relates to the field of spinal implants and, more particularly, to
8 intervertebral disc prostheses, or artificial intervertebral discs.

9 **BACKGROUND OF THE INVENTION**

10 **[0003]** The spine is a complicated structure comprised of various anatomical components,
11 which, while being extremely flexible, provides structure and stability for the body. The spine is
12 made up of vertebrae, each having a ventral body of a generally cylindrical shape. Opposed
13 surfaces of adjacent vertebral bodies are connected together and separated by intervertebral discs
14 (or "discs"), comprised of a fibrocartilaginous material. The vertebral bodies are also connected to
15 each other by a complex arrangement of ligaments acting together to limit excessive movement and
16 to provide stability. A stable spine is important for preventing incapacitating pain, progressive
17 deformity and neurological compromise.

18 **[0004]** The anatomy of the spine allows motion (translation and rotation in a positive and
19 negative direction) to take place without much resistance but as the range of motion reaches the
20 physiological limits, the resistance to motion gradually increases to bring the motion to a gradual and
21 controlled stop.

22 **[0005]** Intervertebral discs are highly functional and complex structures. They contain a
23 hydrophilic protein substance that is able to attract water thereby increasing its volume. The protein,
24 also called the nucleus pulposus, is surrounded and contained by a ligamentous structure called the
25 annulus fibrosis. The main function of the discs is load bearing (including load distribution and shock
26 absorption) and motion. Through their weight bearing function, the discs transmit loads from one
27 vertebral body to the next while providing a cushion between adjacent bodies. The discs allow
28 movement to occur between adjacent vertebral bodies but within a limited range thereby giving the
29 spine structure and stiffness.

1 **[0006]** Due to a number of factors such as age, injury, disease etc., it is often found that
2 intervertebral discs lose their dimensional stability and collapse, shrink, become displaced, or
3 otherwise damaged. It is common for diseased or damaged discs to be replaced with prostheses
4 and various versions of such prostheses, or implants, are known in the art. One of such implants
5 comprises a spacer that is inserted into the space occupied by the disc. However, such spacers
6 have been found to result in fusion of the adjacent vertebrae, thereby preventing relative movement
7 there-between. This often leads to the compressive forces between the vertebrae in question to be
8 translated to adjacent vertebrae, thereby resulting in further complications such as damage to
9 neighbouring discs and/or damage to facet joints and the like.

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

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

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

1 SUMMARY OF THE INVENTION

2 **[0010]** In one aspect, the present invention provides an artificial disc or implant comprising a
3 ball and ring combination, which generally combines the features of known ball and socket designs
4 but which includes at least some degree of versatility in terms of the type and degree of constraint
5 that can be built into the device. The implant of the invention also provides for variations in the type
6 of motion and center of rotation.

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

12 **[0012]** In another aspect, one or both of the aforementioned sections may include one or more
13 "stops" or restrictive structures for limiting the range of relative movement between the two sections.

14 **[0013]** Thus, in one aspect, the invention provides an artificial intervertebral disc for implantation
15 between adjacent superior and inferior vertebrae of a spine, the disc comprising:

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

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

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

25 BRIEF DESCRIPTION OF THE DRAWINGS

26 **[0014]** These and other features of the invention will become more apparent in the following
27 detailed description in which reference is made to the appended drawings wherein:

28 **[0015]** Figure 1 is a schematic illustration of the range of motion of vertebrae.

29 **[0016]** Figure 2a is a sagittal cross sectional view of the artificial intervertebral disc of the
30 invention according to one embodiment.

31 **[0017]** Figure 2b is a transverse cross sectional view of the disc of Figure 1.

1 **[0018]** Figure 3 is a front coronal cross sectional view of the artificial intervertebral disc of the
2 invention according to another embodiment.

3 **[0019]** Figures 4 to 8 are sagittal cross sectional views of the artificial intervertebral disc of the
4 invention according to other embodiments.

5 **[0020]** Figure 9 is a front coronal cross sectional view of the artificial intervertebral disc of the
6 invention according to another embodiment.

7 **[0021]** Figures 10 and 11 are sagittal cross sectional views of the artificial intervertebral disc of
8 the invention according to other embodiments.

9 **[0022]** Figures 11a, 12a and 13a are sagittal cross sectional views of the artificial intervertebral
10 disc of the invention according to other embodiments.

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

13 **[0024]** Figures 14 and 15 are sagittal cross sectional views of the artificial intervertebral disc of
14 the invention according to other embodiments.

15 **[0025]** Figures 16a, 17a and 18a are sagittal cross sectional views of the artificial intervertebral
16 disc of the invention according to other embodiments.

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

19 **DETAILED DESCRIPTION OF THE INVENTION**

20 **[0027]** In the following description, the terms "superior", "inferior", "anterior", "posterior" and
21 "lateral" will be used. These terms are meant to describe the orientation of the implants of the
22 invention when positioned in the spine and are not intended to limit the scope of the invention in any
23 way. Thus, "superior" refers to a top portion and "posterior" refers to that portion of the implant (or
24 other spinal components) facing the rear of the patient's body when the spine is in the upright
25 position. Similarly, the term "inferior" will be used to refer to the bottom portions of the implant while
26 "anterior" will be used to refer to those portions that face the front of the patient's body when the
27 spine is in the upright position. With respect to views shown in the accompanying figures, the term
28 "coronal" will be understood to indicate a plane extending between lateral ends thereby separating
29 the body into anterior and posterior portions. Similarly, the term "laterally" will be understood to
30 mean a position parallel to a coronal plane. The term "sagittal" will be understood to indicate a plane
31 extending anteroposterior thereby separating the body into lateral portions. The term "axial" will be

1 understood to indicate a plane separating the body into superior and inferior portions. It will be
2 appreciated that these positional and orientation terms are not intended to limit the invention to any
3 particular orientation but are used to facilitate the following description.

4 **[0028]** Figure 1 illustrates the complexity of vertebral movement by indicating the various
5 degrees of freedom associated with a spine. In the normal range of physiological motion, vertebrae
6 extend between a "neutral zone" and an "elastic zone". The neutral zone is a zone within the total
7 range of motion where ligaments supporting the spinal bony structures are relatively non-stressed;
8 that is, the ligaments offer relatively little resistance to movement. The elastic zone is encountered
9 when the movement occurs at or near the limit of the range of motion. In this zone, the visco-elastic
10 nature of the ligaments begins to provide resistance to the motion thereby limiting same. The
11 majority of "everyday" or typical movements occurs within the neutral zone and only occasionally
12 continues into the elastic zone. Motion contained within the neutral zone does not stress soft tissue
13 structures whereas motion into the elastic zone will cause various degrees of elastic responses.
14 Therefore, a goal in the field of spinal prosthetic implants in particular, is to provide a prosthesis that
15 restricts motion of the vertebrae adjacent thereto to the neutral zone. Such restriction minimises
16 stresses to adjacent osseous and soft tissue structures. For example, such limitation of movement
17 will reduce facet joint degeneration.

18 **[0029]** In general terms, the present invention provides artificial discs or implants for replacing
19 intervertebral discs that are damaged or otherwise dysfunctional. The implants of the present
20 invention are designed to allow various degrees of motion between adjacent vertebral bodies, but
21 preferably within acceptable limits. In one embodiment, the invention is designed to permit relative
22 movement between the vertebrae adjacent to the artificial disc of the invention, such movement
23 including various degrees of freedom but preferably limited to a specified range. In one
24 embodiment, the artificial disc, or prosthesis, of the invention is provided with one or more "soft"
25 and/or "hard" stops to limit motion between the adjacent vertebrae. In particular, the artificial disc of
26 the invention provides for rotation, flexion, extension and lateral motions that are similar to normal
27 movements in the neutral and elastic zones (i.e. the movements associated with a normal or intact
28 disc). In addition, the device of the invention also allows various combinations of such motions, or
29 coupled motions. For example, the disc of the invention can be subjected to flexion and translation,
30 or lateral flexion and lateral translation, or flexion and rotation. Various other motions will be
31 apparent to persons skilled in the art given the present disclosure.

32 **[0030]** Figure 2a illustrates an artificial intervertebral disc 10 according to an embodiment of the
33 invention. As shown, the disc 10 includes a superior shell 12 and an inferior shell 14. Each of the
34 shells 12 and 14 comprise a bone contacting surface for placement against the bony structures of

1 vertically adjacent vertebral bodies in a region where the natural intervertebral disc has been
2 excised. As discussed above, such discectomy may be necessary in cases where the natural disc
3 is damaged or diseased. The superior shell 12 includes a superior surface 16 for placement against
4 the inferior surface of one vertebrae while the inferior shell 14 includes an inferior surface 18 for
5 placement against the superior surface of an adjacent and vertically lower vertebrae. It will be
6 understood that the terms "upper" and "lower" are used in conjunction with a spine in the upright
7 position. Although the term "shell" is used herein, it will be understood that such term is not intended
8 to limit the present invention to any shape or configuration. Other terms that may apply to the shells
9 would be plate etc. The term "shell" will be understood by persons skilled in the art to apply to the
10 structures shown and/or described herein as well as any equivalent structures.

11 **[0031]** In the embodiment shown in Figure 2a, the inferior surface 20 of the superior shell 12
12 includes a ring 22 attached thereto. In the embodiment shown, the ring 22 may comprise a
13 downward depending convex or generally toroidal structure. The ring 22 may be affixed to the
14 superior shell 12 or may be formed integrally therewith.

15 **[0032]** Figure 2b illustrates the ring 22 of Figure 2a. In the embodiment shown, the ring 22
16 comprises a generally ovoid structure with a longer anteroposterior length and a shorter lateral
17 length. In other embodiments, the ring 22 may have a circular or any other shape as may be
18 needed in view of the following discussion of the purpose of the ring.

19 **[0033]** Figure 2a also illustrates the superior surface 24 of the inferior shell 14, which is provided
20 with a convex structure, or "ball" 26, generally extending in the superior (or upward) direction.
21 Although the term "ball" is used herein, it will be apparent to persons skilled in the art that this term is
22 not intended to refer to a full or partial spherical structure. In one embodiment, as shown in Figure
23 2a, the ball 26 may comprise a hemispherical structure. In other embodiments, the ball 26 may
24 comprise an ovoid or other shape in plan view.

25 **[0034]** When implanting the artificial disc 10 into a intervertebral disc space, the two shells 12
26 and 14 are first aligned with inferior surface of the superior shell 12 facing the superior surface of the
27 inferior shell 14. In this alignment, the ball 26 and ring 22 are engaged with the ball 26 being
28 positioned within the lumen of the ring 22. In this orientation, the disc 10 is then inserted within the
29 intervertebral space, between the adjacent vertebral bodies. In this position, the outer surfaces of
30 the shells 12 and 14 are in contact with the respective vertebral bodies. Once so implanted, the
31 normal compressive force exerted by one vertebrae against the other will serve to maintain the disc
32 10 in position. It will be understood, that any other artificial means may be used to prevent
33 dislodging of the disc. For example, the outer surfaces of the shells may be provided with an
34 adhesive or bone cement etc. to ensure proper positioning.

1 **[0035]** Once in position, the superior surface of the ball 26 would contact the inferior surface 20
2 of the superior plate 12. This contact provides the desired separation between the adjacent
3 vertebral bodies relative movement between the ball 26 and the surface 20 provides the essential
4 articulation between the vertebral bodies. Further, the ring 22 serves to constrain the relative
5 movement between the ball 26 and the inferior surface 20. That is, the ring 22 limits the amount of
6 movement of the ball over the surface 20 to a defined articulation region. The surface 23 of the ring
7 22 that contacts the ball 26 is referred to herein as the articulation surface of the ring. It will be
8 understood that the ring 22 is dimensioned to be of sufficient height (as measured inferiorly from the
9 inferior surface of the superior shell) to provide the required limit, or "stop", for the ball 26. In a
10 typical application, the ring 22 would have a height of 1 to 5 mm. However, it will be understood that
11 various other sizes may be used or needed depending, for example, on the associated anatomy.
12 The invention is not limited to any specific dimensions as may be mentioned herein, and may be
13 modified to fit within any disc space of the human spine, i.e. the cervical, thoracic, or lumbar regions.
14 Further as mentioned above and as discussed further below, the ring 22 can be sized to limit or
15 constrain various movements of the ball 26 including translation, lateral bending, flexion, extension
16 and any coupled movements involving one or more of such specific movements. This flexibility in
17 design will therefore allow the artificial disc of the invention to function similarly to naturally occurring
18 discs while also allowing correction or prevention of any malformations.

19 **[0036]** In one embodiment, as shown in Figure 2a, the ring 22 is sized so that the smallest
20 length in its lumen is larger than the diameter of the ball 26. This arrangement allows the ball 26 to
21 contact the surface 20 and also allows some degree of travel of the ball before being limited by the
22 ring 22. As mentioned above, in one embodiment, the ring 22 is dimensioned to have an ovoid
23 shape (as shown in Figure 2b). This would, therefore, allow the ball 26 to travel in one direction
24 more than the other. In the example discussed above, the ring 22 is provided with a longer
25 anteroposterior length than a lateral length. This therefore allows further travel of the ball 26 in the
26 anteroposterior direction. In turn, this translates to a vertebral joint that allows greater flexion and
27 extension as compared to lateral flexion. It will also be understood that by allowing movement of the
28 ball 26 in these directions, it is possible to allow for coupled movement such as flexion in conjunction
29 with lateral flexion.

30 **[0037]** As indicated above, in one embodiment, the ball may be hemispheric in cross section but
31 the shape may be varied in size in any direction. Thus, the ball 26 may comprise a hemisphere or a
32 convex shape that is elongated in the anteroposterior and/or lateral directions. In general, the ball
33 26 may comprise any convex shape that provides the desired amount and type of intervertebral
34 movements. This variability in structure of the ball 26 would allow for a variety of different

1 movements to occur within the physical constraints of the ring 22. As discussed further below,
2 further motion constraints may be provided on the ball 26 itself.

3 **[0038]** Although Figure 2a shows the ball 26 being located centrally on the superior surface 24
4 of the inferior shell 14, it will be understood that this is not intended as a limitation. In other
5 embodiments, the ball 26 may be positioned at any variety of locations on the surface 24 depending
6 on the desired movement. As will be appreciated, varying the position of the ball 26 over the surface
7 24 would result in a variation in the center of rotation of the disc 10. For example, in one
8 embodiment the ball may be positioned posteriorly on the inferior shell 14. By varying the position of
9 the ball 26 with respect to the inferior shell 14, it is possible to provide the disc 10 with a variety of
10 movement, or articulation options.

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

20 **[0040]** An example of such hard stops is illustrated in Figure 3, wherein elements similar to
21 those described above are identified with the same reference numeral but with the letter "a" added
22 for clarity. As shown, hard stops 28 may be positioned laterally on either side of a ball 26a to limit
23 lateral flexion. That is, the hard stops 28 provide a barrier for lateral (i.e. coronal) movement of the
24 ring 22a over the surface of the ball 26. The stops 28 shown in Figure 3 may be of any length to
25 serve the aforementioned purpose.

26 **[0041]** In another embodiment, the hard stops 28 may be located anteriorly to limit flexion in the
27 anteroposterior direction and in still another embodiment, they would be located posteriorly. Any
28 combination could be used to provide hard stops to constrain motion. The stops could be any
29 manner of shapes from rectangular with rounded edges to domes and of variable height. It will be
30 understood that in one embodiment, hard stops 28 may be provided to restrict movement in all
31 directions if such limited movement is required. The "bumpers" 28 may be of various shapes for
32 example linear or curved. Similarly, it will be understood that in other embodiments, no such hard
33 stops may be needed.

1 **[0042]** Another embodiment of the above mentioned hard stop function is shown in Figure 4,
2 wherein elements similar to those described above are identified with the same reference numeral
3 but with the letter "b" added for clarity. As shown in Figure 4, instead of the "bumpers" 28 provided
4 on the inferior shell 14 as shown in Figure 3, one edge, in the illustrated case, the anterior edge, of
5 the ball 26b may be provided with a hard stop, which, in the embodiment shown, is formed as a
6 raised extension 30 on the ball. As shown, the extension 30 includes a superior surface having a
7 concave portion 32 adjacent the ball 26b, which serves as a "soft stop", as discussed further below.
8 The concave portion 32 extends from the anterior edge of the ball 26b, at a height between the
9 lowermost and uppermost height of the ball 26b, and curves upward towards the anterior end of the
10 disc 10b. Anterior of the concave portion 32 the extension 30 includes an edge 34, which acts a
11 hard stop. The arrangement shown in Figure 4 may be used in situations where flexion of the spine
12 at the region of the implant, is to be limited. As will be understood, during flexion, the anterior edge
13 of the ring 22b will traverse anteriorly over the superior surface of the ball 26b and first encounter the
14 concave portion 32. The concave portion 32, due to its upwardly curved surface, acts to slowly
15 restrict the movement of the ring 22b, thereby acting as a soft stop for the flexion movement. As
16 movement of the anterior edge of the ring 22b continues, the edge 34 is encountered and further
17 movement is prevented. Thus, the edge 34 serves as a hard stop for the flexion movement as well
18 as limiting any tendency for the device to take on an abnormal or perhaps undesired alignment.

19 **[0043]** In another embodiment, hard stops may be placed laterally on either side of the ball 26 to
20 a height only a few mm below the maximum height of the ball to limit lateral flexion.

21 **[0044]** Another embodiment of the invention is shown in Figure 13a and 13b (collectively
22 referred to as Figure 13), wherein elements similar to those described above are identified with the
23 same reference numeral but with the letter "c" added for clarity. In this embodiment, a hard stop 36
24 is provided on the superior surface 24c of the inferior shell 14c wherein such hard stop is positioned
25 immediately adjacent to the ball 26c or may be formed as part of the ball 26c. The hard stop 36 is
26 similar in function to that shown in Figure 3 but, is positioned only at the anterior edge of the ball
27 26c. As with the hard stop shown in Figure 4, the hard stop 36 of Figure 13 serves to limit flexion
28 and prevent abnormal or perhaps undesired alignment. In this case, the hard stop 36 does not offer
29 a gradual reduction to the flexion motion. As such, the arrangement shown in Figure 13 may be
30 used in cases where it is desired to limit flexion and correct and/or limit kyphosis.

31 **[0045]** In a similar manner, a further embodiment of the invention would have the hard stop 36
32 (or the extension 30 of Figure 4) located posteriorly on the inferior shell 14 so as to limit extension.
33 In a further embodiment, a combination of such hard stops could be located in any direction or even
34 circumferentially with respect to the ball and used to constrain motion in any or all directions. Thus,
35 the stops associated with the ball may be varied in many ways to limit motion in one or more planes.

1 The stops could be of any shape such as rectangular or convex such as dome-shaped. The stops
2 may be of the same or different materials amongst themselves, or of similar or different materials
3 compared to the shells. Further, the stops may be provided with rounded edges or any other
4 required shape. In addition, the stops may be of any height as will be understood by persons skilled
5 in the art. In yet another embodiment, the disc 10 may include no stops associated with the ball 26,
6 thereby allowing the ring to articulate over a maximum surface area of the ball.

7 **[0046]** Another embodiment of the invention is illustrated in Figure 5, wherein elements similar
8 to those described above are identified with the same reference numeral but with the letter "d" added
9 for clarity. As shown in Figure 5, the superior shell 12d may be provided with a well 38, which
10 comprises a concave region that is adapted to receive a portion of the ball 26d. As will be
11 understood, the well 38 would serve as a location means for positioning the ball 26d and/or as a
12 further means of constraining the ball. In conjunction with the ring 22d, the provision of the well 38
13 would increase the surface area contacted by the ball 26d for the purpose of constraining its
14 movement. As such, it will be understood that the well 38 would further serve to reduce the wear
15 effects on the ring 22d. Although the well 38 in Figure 5 is shown as being somewhat
16 complementary in shape to the ball 26d, it will be understood that such complementarity is not a
17 limitation of the invention. That is, the well 38 may be of various shapes and sizes to provide a
18 variety of constraint options.

19 **[0047]** Another embodiment of the invention is shown in Figure 6, wherein elements similar to
20 those described above are identified with the same reference numeral but with the letter "e" added
21 for clarity. Figure 6 illustrates an embodiment wherein the disc 10e is provided with a means of
22 absorbing axial forces, that is, forces that are transmitted axially along the spine. To provide such
23 force absorption, the disc 10e may be provided with one or more resilient elements one or both of
24 the inferior and superior shells, 12e and 14e, respectively. In the embodiment shown in Figure 6,
25 the ball 26e is separated from the superior surface 24e of the inferior shell 14e by a nucleus 40. The
26 nucleus 40 may comprise any known resilient material such as hydrogel, silicone, rubber etc. or may
27 comprise a mechanical device such as a spring etc. As will be understood, as an axial force is
28 applied to the disc 10e, the nucleus 40 would absorb some of such force, thereby offering some
29 cushioning and preventing or minimising pressure between the ball 26e and the ring 22e and/or the
30 superior shell 12e. In one embodiment, as shown in Figure 6, the ball 26e may be partially hollow to
31 accommodate a greater volume of the nucleus 40. In such arrangement, the nucleus 40 would
32 include a raised portion or section adapted to be located within the hollow ball 26e. Such a structure
33 may be advantageous for positively locating the ball 26e with respect to the inferior shell 14e. That
34 is, as with the embodiment shown in Figure 6, the nucleus 40, having a protruding portion extending
35 away from the inferior shell 14e, may be secured to the superior surface 24e of the inferior shell 14e.

1 The ball 26e, having a central cavity adapted to receive the protruding portion of the nucleus 40,
2 would be positioned over the nucleus 40 such that the protruding portion is inserted into the cavity of
3 the ball. In such case, the ball 26e would not need to be secured or attached directly to the inferior
4 shell 14e since the nucleus would serve to prevent or limit any relative movement between the ball
5 and the inferior shell 14e. In this way, the ball 26e may be described as "floating" on the nucleus 40.

6 **[0048]** A further embodiment of a resilient force absorbing means is illustrated in Figure 10,
7 wherein elements similar to those described above are identified with the same reference numeral
8 but with the letter "f" added for clarity. In Figure 10, the ball 26f of the disc 10f is secured to the
9 superior surface 24f of the inferior shell 14f as described previously. In this case, a spring 42 is
10 provided, which bears against the inferior surface 18f of the shell 14f. It will be understood that the
11 opposite side of the spring 42 may bear against the bony portion or portions of the adjacent vertebra
12 or against any surface or structure (such as a plate or the like) attached to such vertebra. The
13 spring 42 would function in a manner similar to the nucleus 40 described above. However, as
14 shown in Figure 10, a further advantage may be realised with the arrangement shown. Specifically,
15 since the spring may be positioned only against one edge of the disc 10f, the disc may be provided
16 with a pre-set positioning to align the adjacent vertebrae in any desired manner. For example, in the
17 embodiment shown in Figure 10, the spring 42 is located at the anterior edge of the disc 10f thereby
18 causing the superiorly adjacent vertebra (not shown) to be angled posteriorly. As will be understood,
19 such an arrangement, in addition to providing the aforementioned cushioning function, will also serve
20 to correct or prevent kyphosis. In the above description of Figure 10, the spring 42 has been
21 described as being located between the inferior shell 14f and the inferiorly adjacent vertebra.
22 However, in another embodiment, the spring 42 may be equally positioned between the ball 26f and
23 the inferior shell 14f while achieving the same function. In addition although the term "spring" is
24 used to describe element 42, it will be understood that any similarly functioning device may be used
25 with the disc 10f. For example, the spring 42 may comprise a mechanical device such as a coil
26 spring or a leaf spring. Alternatively, the spring 42 may comprise a wedge shaped or similarly
27 angulated resilient nucleus. Although Figure 10 illustrates the inferior shell 14f angled posteriorly, it
28 will be understood that such angulation may also be in the anterior direction in situations where
29 kyphosis is required or to be encouraged (such as a region where lordosis is to be prevented or
30 corrected such as the thoracic spine).

31 **[0049]** Another position adjusting means is illustrated in Figure 7, wherein elements similar to
32 those described above are identified with the same reference numeral but with the letter "g" added
33 for clarity. In Figure 7, the disc 10g has an inferior shell 14g which is provided with an angled
34 superior surface 24g with respect to the superior shell 12g. Due to such angulation, the ball 26g is
35 similarly angularly disposed in relation to the superior shell 12g and the ring 22g. As will be

1 understood, such a structure serves to prevent or correct kyphosis as described above in relation to
2 Figure 10. However, unlike Figure 10, the disc 10g of Figure 7 does not necessarily include a force
3 absorbing device. To achieve the desired angulation in the inferior shell 14g, the inferior shell may
4 be formed as a wedge, as depicted in Figure 7. Alternatively, the inferior shell may be formed in two
5 segments thereby separating the inferior surface 18g and the superior surface 24g by means of a
6 separating element (not shown). It will be understood that such separating element may comprise a
7 spring such as described above with reference to Figure 10. In such case, the disc 10g of Figure 7
8 would also include a force absorbing means as well. It will also be understood that the ball 26g of
9 Figure 7 may include a nucleus as described above with respect to Figure 6, thereby also providing
10 the disc 10g of Figure 7 with a means of absorbing axial forces. Although Figure 7 illustrates the
11 inferior shell 14g angled posteriorly, it will be understood that such angulation may also be in the
12 anterior direction in situations where kyphosis is required or to be encouraged (such as a region
13 where lordosis is to be prevented or corrected such as, for example, in the thoracic spine).

14 **[0050]** Much of the above discussion has focussed on variations that may be implemented to
15 the inferior shell 14 and/or the ball 26 of the invention. However, in a similar manner, the superior
16 shell 12 and/or the ring 22 may also be varied to achieve a variety of positions and functions. For
17 example, in one embodiment, the ring may be formed in various sizes and shapes. These would
18 include variations in the height of the limiting edge of the ring 22 and variations in its shape,
19 including circular, ovoid and rectangular forms etc. For example, by varying the shape of the ring
20 22, it will be understood that the shape and area for articulation with the ball would also be varied
21 thereby allowing the ball's constraint of motion to be tailored as needed. Similarly, the location of the
22 ring 22 may also be varied on the superior shell 12 so as to match the position of the ball 26. In
23 addition, the superior shell 12 may be provided with one or more "stops", such as hard stops and/or
24 soft stops, similar to those described above, for constraining or limiting the relative movements
25 between the superior and inferior shells. Such stops may comprise separate elements attached to
26 the superior shell or may form part of the ring 22 itself. For example, in one embodiment, the stops
27 may comprise raised edges of the ring. Further examples and aspects of the invention are
28 discussed further below.

29 **[0051]** An embodiment of the invention showing variations in the superior shell are illustrated in
30 Figures 11a and 11b (collectively referred to as Figure 11), wherein elements similar to those
31 described above are identified with the same reference numeral but with the letter "h" added for
32 clarity. In Figure 11, the ring 22h is sized to be larger than the ball 26h. In this embodiment, it will
33 be understood that articulation of the disc 10h involves contact mainly between the inferior surface
34 20h of the superior shell 12h. In other words, the ball 26h would be capable of translation movement
35 over a portion of the inferior surface 20h without hindrance by the ring 22h. Such translation

1 movement may comprise, for example, movement within the neutral zone. However, the ring 22h
2 would serve to constrain the ball 26h from travelling beyond such region, thereby acting as a “hard
3 stop”.

4 **[0052]** A variant of the ring 22h described above is illustrated in Figures 12a and 12b
5 (collectively referred to as Figure 12), wherein elements similar to those described above are
6 identified with the same reference numeral but with the letter “j” added for clarity. In this
7 embodiment, the disc 10j, is provided with ring 22j on the superior shell 12j that is narrower in size
8 and designed to be in contact with at least a portion of the ball 26j during all movement, i.e.
9 articulation of the disc 10j. As will be understood, such an arrangement would assist in minimising
10 wear on the inferior surface 20j of the superior shell 12j caused by constant contact with the ball 26j.
11 In addition, such an arrangement would limit lateral flexion while allowing for a full range of flexion
12 and extension

13 **[0053]** Figure 12b illustrates a further feature of the ring 22j, namely a larger anteroposterior
14 dimension as compared to a lateral dimension. As will be understood, such an arrangement serves
15 to allow the ball 26j a greater degree of freedom in movement in the sagittal plane and a restricted
16 amount of movement in the coronal plane. In another embodiment, the ring 22j may be elongated in
17 the coronal plane thereby achieving the opposite effect. Thus, it will be understood that any
18 combination of movements can be tailored by adjusting the dimensions of the ring 22.

19 **[0054]** Further embodiments of the invention are illustrated in Figures 14 and 15, wherein
20 elements similar to those described above are identified with the same reference numeral but with
21 the letter “m” or “n” added, respectively, for clarity. In the embodiments discussed above, the ring 22
22 has been described as having a convex outer surface, particularly the articulating surface, that is the
23 surface contacting the ball 26. However, as shown in Figures 14 and 15, the ring 22m and 22n,
24 respectively, may alternatively include a concave articulating surface thereby changing the
25 interaction between the ring and the ball. In both cases, the rings 22m and 22n have an articulation
26 surface contacting the ball 22m and 22n, respectively, that is concave in shape. Such concavity
27 may be provided around the entire perimeter of the ring or only on certain locations. Similarly, the
28 degree of curvature provided on the ring may be varied. For example, as shown in the two
29 embodiments illustrated, Figure 14 depicts a ring 22m that includes an articulation surface having a
30 greater degree of curvature than that of ring 22n shown in Figure 15. The concave articulation
31 surface of the ring would allow movements such as flexion, extension, lateral bending or any
32 combination thereof to be controlled by varying the degree of curvature provided. That is, the
33 concave articulation surface would also allow for a graduated resistance to the movement of the ball
34 thereby, for example, allowing for initial easy movement within the neutral zone but greater or
35 increasingly greater resistance to movement in the elastic zone. Such resistance will be understood

1 as a resistance provided against the ball. In another embodiment, the degree of curvature provided
2 on the ring may be varied as between locations. For example, a greater degree of curvature may be
3 provided at the lateral regions than in the anterior and posterior regions. This would, therefore,
4 provide greater resistance to lateral bending than to flexion or extension. In another embodiment,
5 the curvature of the ring can be varied to, for example, inhibit flexion by increasing the degree of
6 curvature at the anterior edge of the ring. In another embodiment, the ring may be provided with
7 both a constant or variably curved articulation surface as well as a non-circular shape. For example,
8 the ring may comprise a oval geometry with a large axis generally parallel to the sagittal plane. The
9 anterior and posterior articulation surfaces of such a ring may include a lesser degree of curvature
10 than the lateral articulation surfaces. Further discussion of such variability is provided below with
11 respect to Figures 16 to 18.

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

25 **[0056]** Figures 16a, 17a and 18a illustrate other embodiments of the invention. Where elements
26 similar to those described above are identified, the same reference numerals are used but with the
27 letters "r", "t" and "u" added, respectively, for clarity. Figures 16a, 17a and 18a are shown with an
28 inferior shell 14, ball 26 and stop 36 provided at the anterior edge of the ball 26, in a manner similar
29 to that described above with reference to Figure 13. As described above, although the stop 36 is
30 shown as being provided on the anterior edge of the ball 26, such stop may in fact be located in any
31 position depending on the need and in more than one location if necessary. It will be assumed that
32 this structure of the inferior shell is not intended to limit the embodiments illustrated in Figures 16a
33 to 18a.

34 **[0057]** Figure 16a illustrates a superior shell 12r that is similar to that shown in Figures 14 and
35 15. That is, the superior shell 12r includes a ring 22r that is provided on a generally flat inferior

1 surface 20r of the superior shell 12r. The ring 22r of this embodiment includes an articulation
2 surface 23r that is concavely curved for the purposes discussed in reference to Figures 14 and 15.
3 Figure 17a illustrates a variation of the disc of Figure 16a. In Figure 17a, the disc 10t includes a
4 superior shell 12t having a concavely curved inferior surface 20t. That is, the outer edges of the
5 inferior surface 20t are curved inferiorly. As with Figure 16a, the ring 22t also includes a concavely
6 curved articulation surface 23t. Similarly, Figure 18a illustrates a variation wherein the disc 10u
7 includes a superior shell 12u having a convexly curved inferior surface 20u. As with Figure 16a, the
8 ring 22u also includes a concavely curved articulation surface 23u.

9 **[0058]** As shown in Figures 16a to 18a, as the inferior surface 20 is curved, the ring 22 is also
10 allowed to assume a similar curvature. Such overall curvature of the ring 22 along with the curvature
11 of the articulation surface 23 will be understood to assist in directing and controlling the amount and
12 degree of constraint offered for movement of the ball 26. For example, as shown in Figure 17a, the
13 curvature of the inferior surface 20t is shown as being concave in the sagittal plane. Thus, this
14 orientation would serve to gradually resist movement of the ball in the anteroposterior directions, i.e.
15 during flexion and extension. As discussed above, the optional stop 26t (or stops, in the situation
16 where more than one stop is provided) would pose a hard stop to prevent movement in a given
17 direction. Similarly, a concave curvature of the inferior surface 20t in the coronal plane would inhibit
18 lateral bending.

19 **[0059]** In the case of Figure 18a, it will be understood that the convex curvature would serve to
20 assist motion. As a corollary to the above discussion, it will be understood that the convex curvature
21 of the inferior surface 20u shown in Figure 18a may be in either the sagittal or coronal planes.
22 Moreover, the concave or convex curvature of the inferior surface 20 discussed in reference to
23 Figures 17a and 18a will be understood to be provided in one or more directions. In one
24 embodiment, for example, such surface may be partially spherical, thereby providing a respectively
25 curved surface in all directions.

26 **[0060]** Figures 16b, 17b and 18b illustrate the rings 22r, 22t and 22u depicted, respectively, in
27 Figs 16a to 18a.

28 **[0061]** Although Figures 16a to 18a illustrate the ring 22 having a convexly curved articulation
29 surface 23, it will be understood that such surface may also be convexly curved as discussed above
30 in relation to other embodiments.

31 **[0062]** The structural components of the disc of the invention, in particular the ball and ring, may
32 be formed of from any medically suitable material such as titanium, titanium alloys, nickel, nickel
33 alloys, stainless steel, nickel-titanium alloys (such as Nitinol™), cobalt-chrome alloys, polyurethane,
34 porcelain, plastic and/or thermoplastic polymers (such as PEEK™), silicone, rubber, carbothane or

1 any combination thereof. In addition, it will be understood that the ball and ring may be made from
2 materials that are the same or different from the remainder of the respective shells. For example,
3 the ball may be made of titanium while the ring and both shells may be made of PEEK™. Various
4 other materials and combinations of materials will be known to persons skilled in the art.

5 **[0063]** As will be understood, and as explained above, the present invention may be adapted in
6 various ways to meet any number of desired motion characteristics. That is, the shape, position,
7 and size of the ball and/or ring may be chosen for various intervertebral joints of the spine and may
8 be tailored for providing or restricting the degree and direction of motion. Various features and
9 embodiments of the invention have been described and/or shown herein. It will be understood by
10 persons skilled in the art that various combinations of such features and embodiments can be used
11 depending on the need and requirements of the artificial disc. Further, although the figures illustrate
12 various embodiments for the purposes of describing embodiments of the present, the relative or
13 absolute dimensions shown are not intended to limit the scope of the invention in any way.

14 **[0064]** It will be apparent to persons skilled in the art that although the above discussion has
15 focussed on the superior shell being provided with the ring and the inferior shell being provided with
16 the ball, the reverse may also be used. That is, in other embodiments, the superior shell may
17 include the ball and the inferior shell may include the ring.

18 **[0065]** It will be apparent to persons skilled in the art that any bone contacting surfaces of the
19 discs discussed above (such as the external surfaces of the shells) may be provided with a texture,
20 treatment or coating to encourage or enhance bone ingrowth and/or adhesion to the adjacent bony
21 structure. For example, such surfaces may be provided with a roughened or grooved texture and/or
22 may be coated with a bone growth enhancing agent.

23 **[0066]** In addition, although the present invention has been described with reference to
24 intervertebral joints, the present invention may equally be used in other joints such as, for example,
25 knee joints.

26
27 **[0067]** Although the invention has been described with reference to certain specific
28 embodiments, various modifications thereof will be apparent to those skilled in the art without
29 departing from the purpose and scope of the invention as outlined in the claims appended hereto.
30 Any examples provided herein are included solely for the purpose of illustrating the invention and are
31 not intended to limit the invention in any way. Any drawings provided herein are solely for the
32 purpose of illustrating various aspects of the invention and are not intended to be drawn to scale or

1 to limit the invention in any way. The disclosures of all prior art recited herein are incorporated
2 herein by reference in their entirety.

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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.

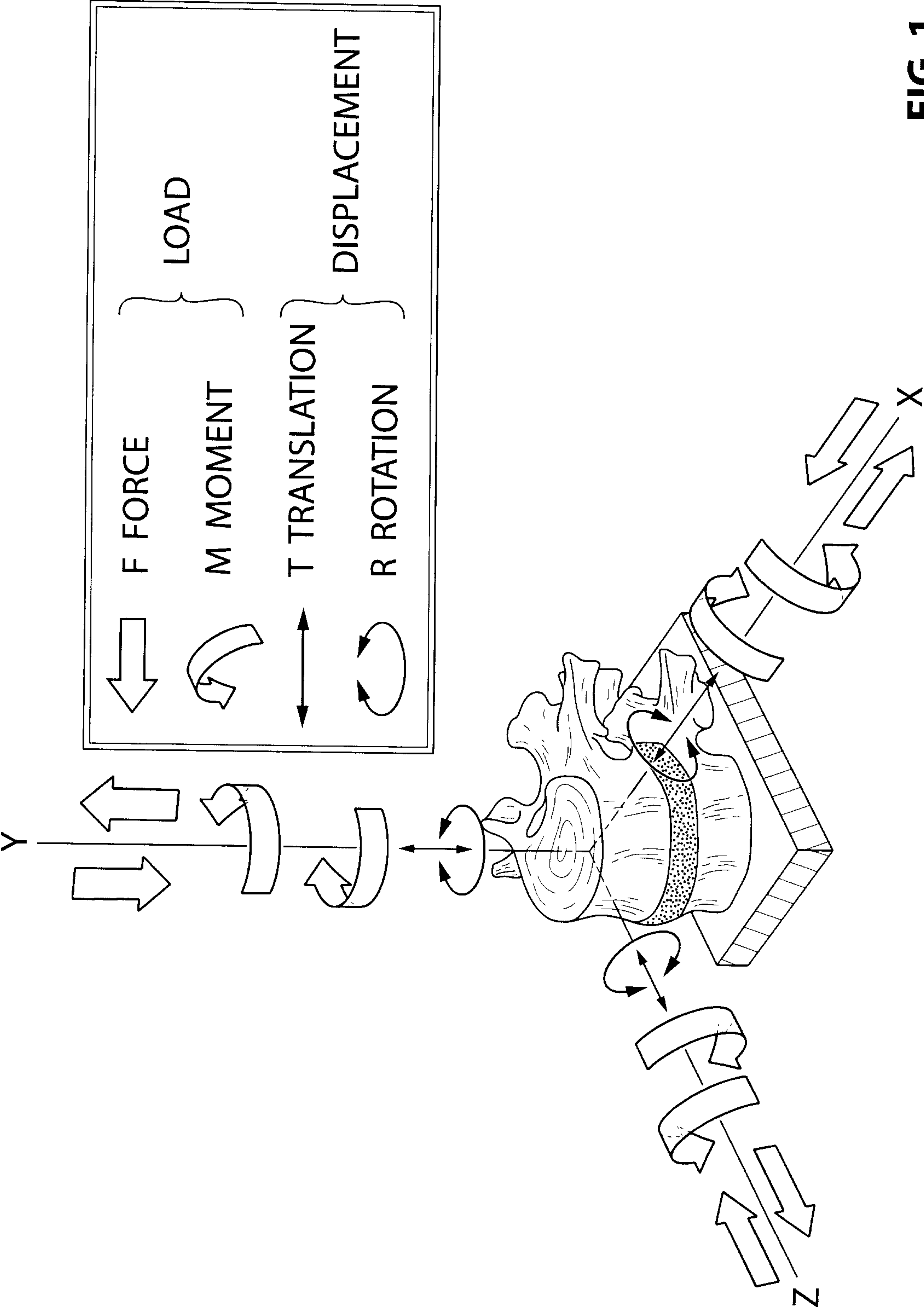
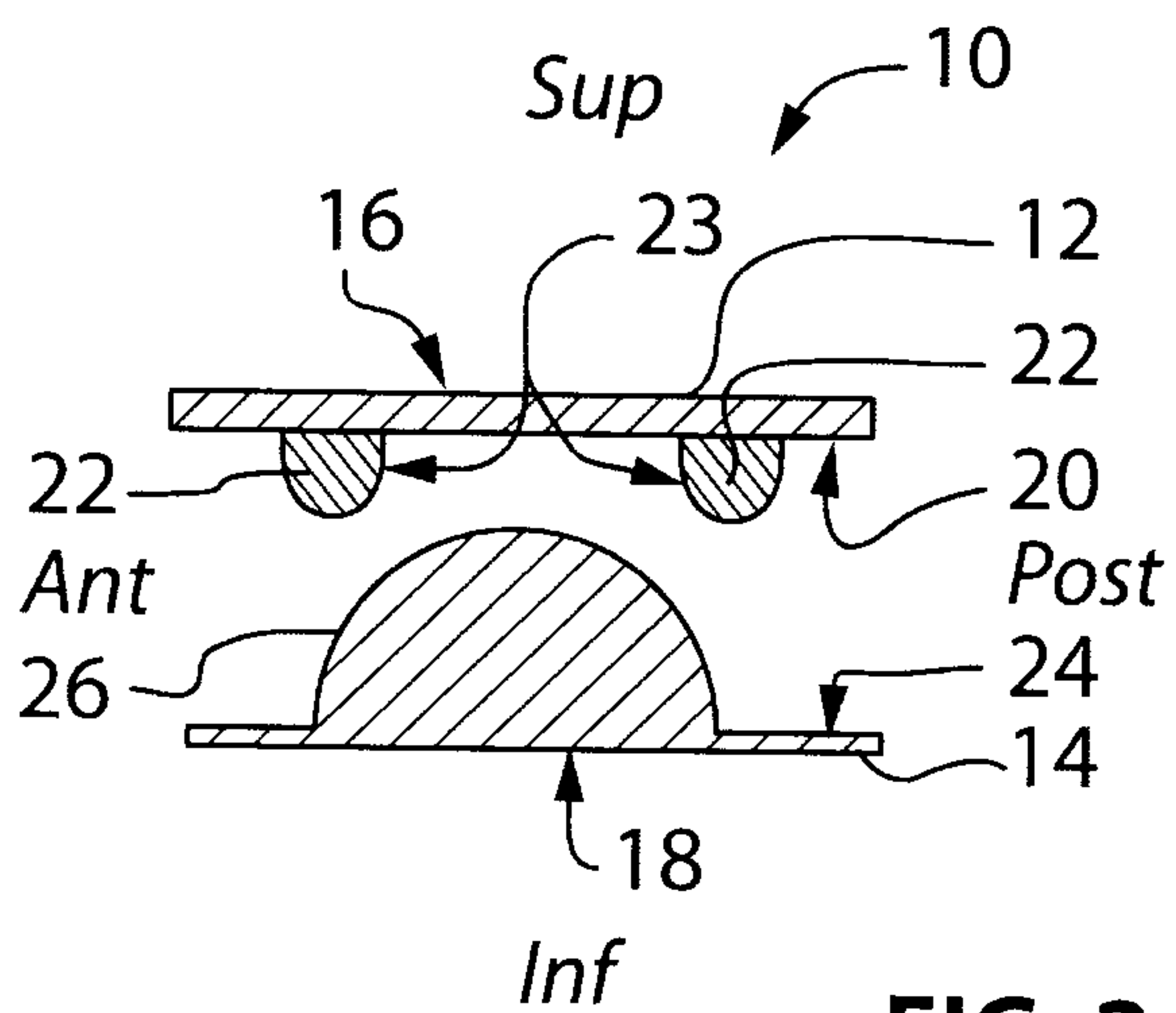
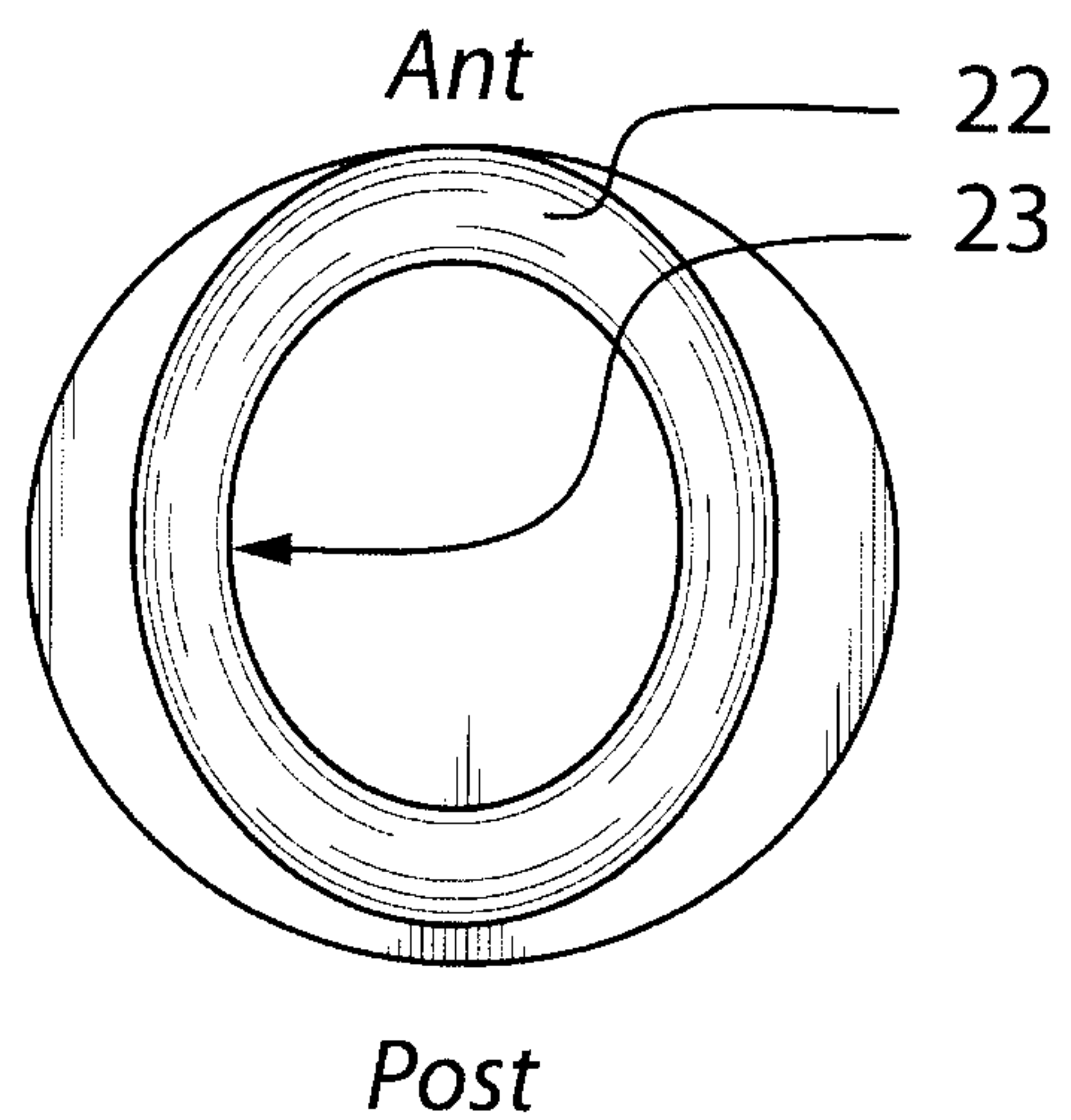
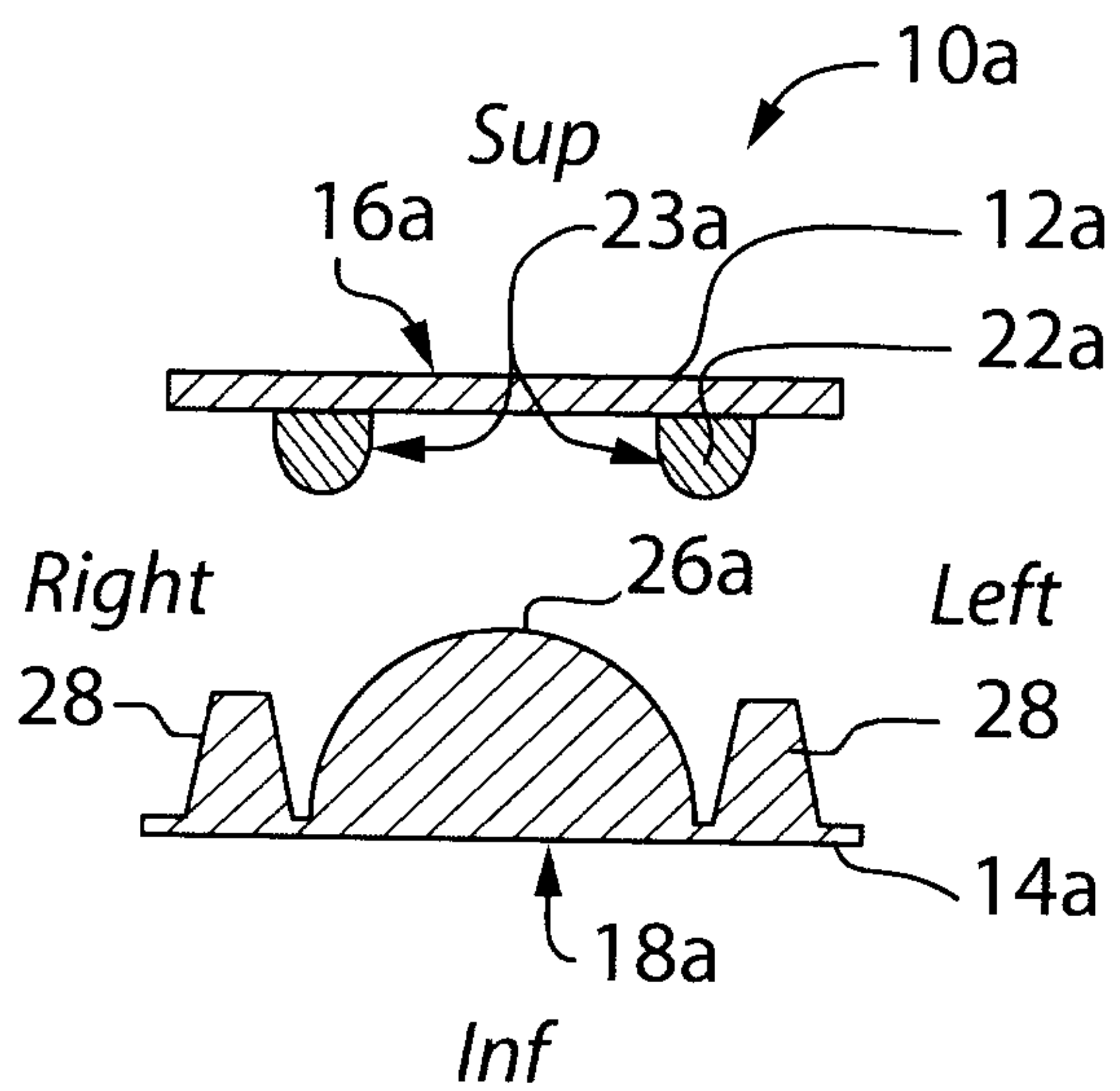
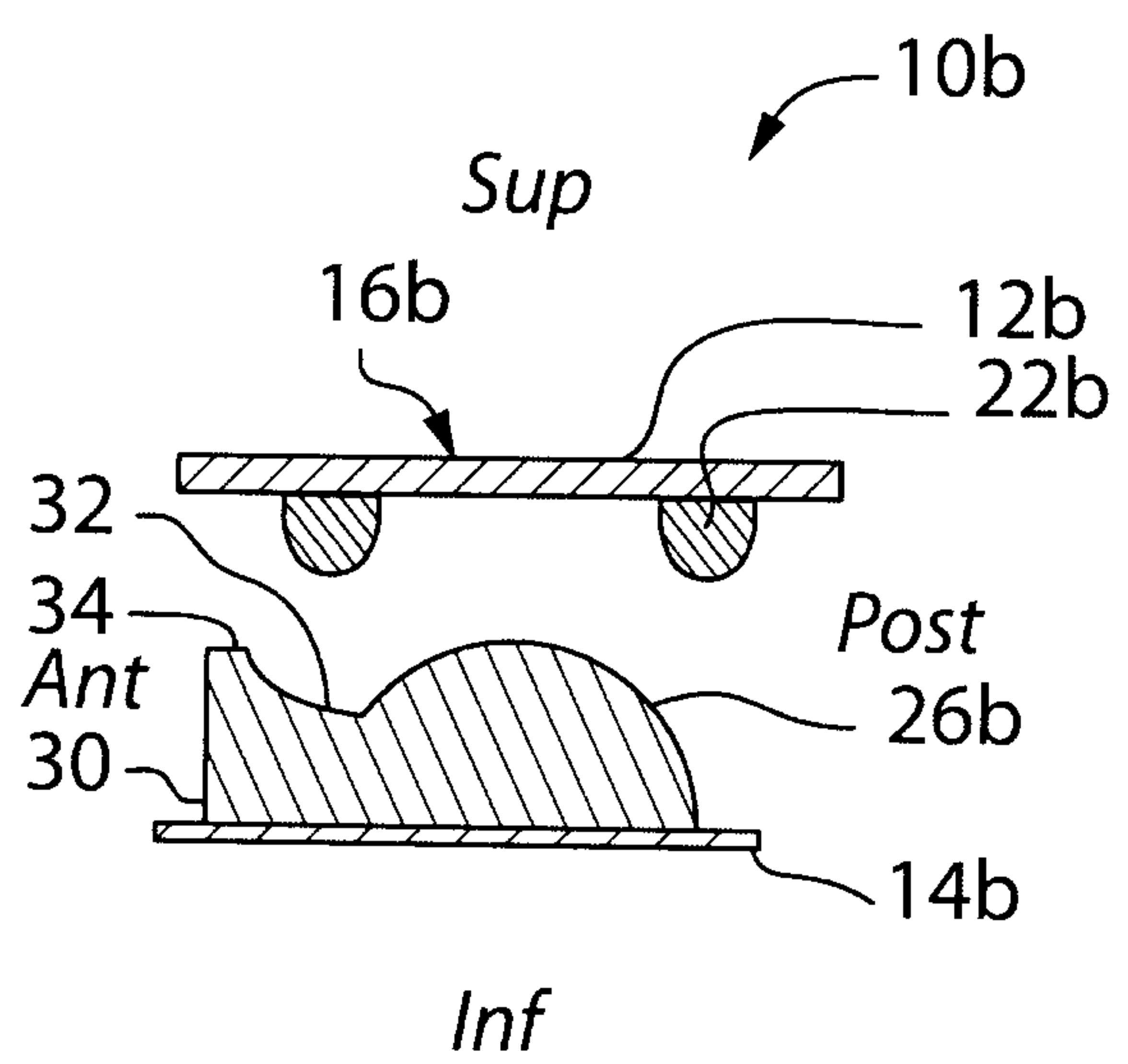
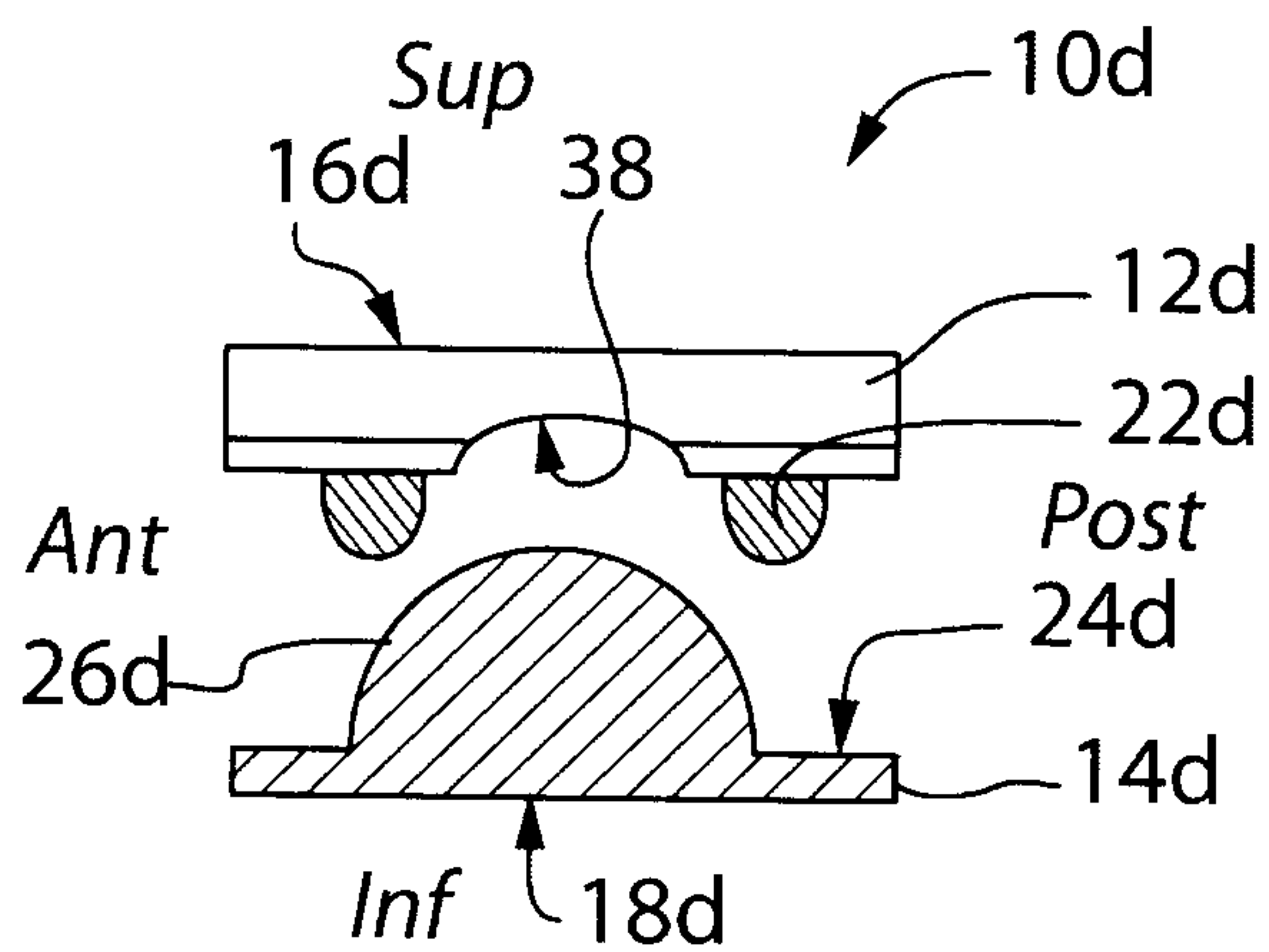
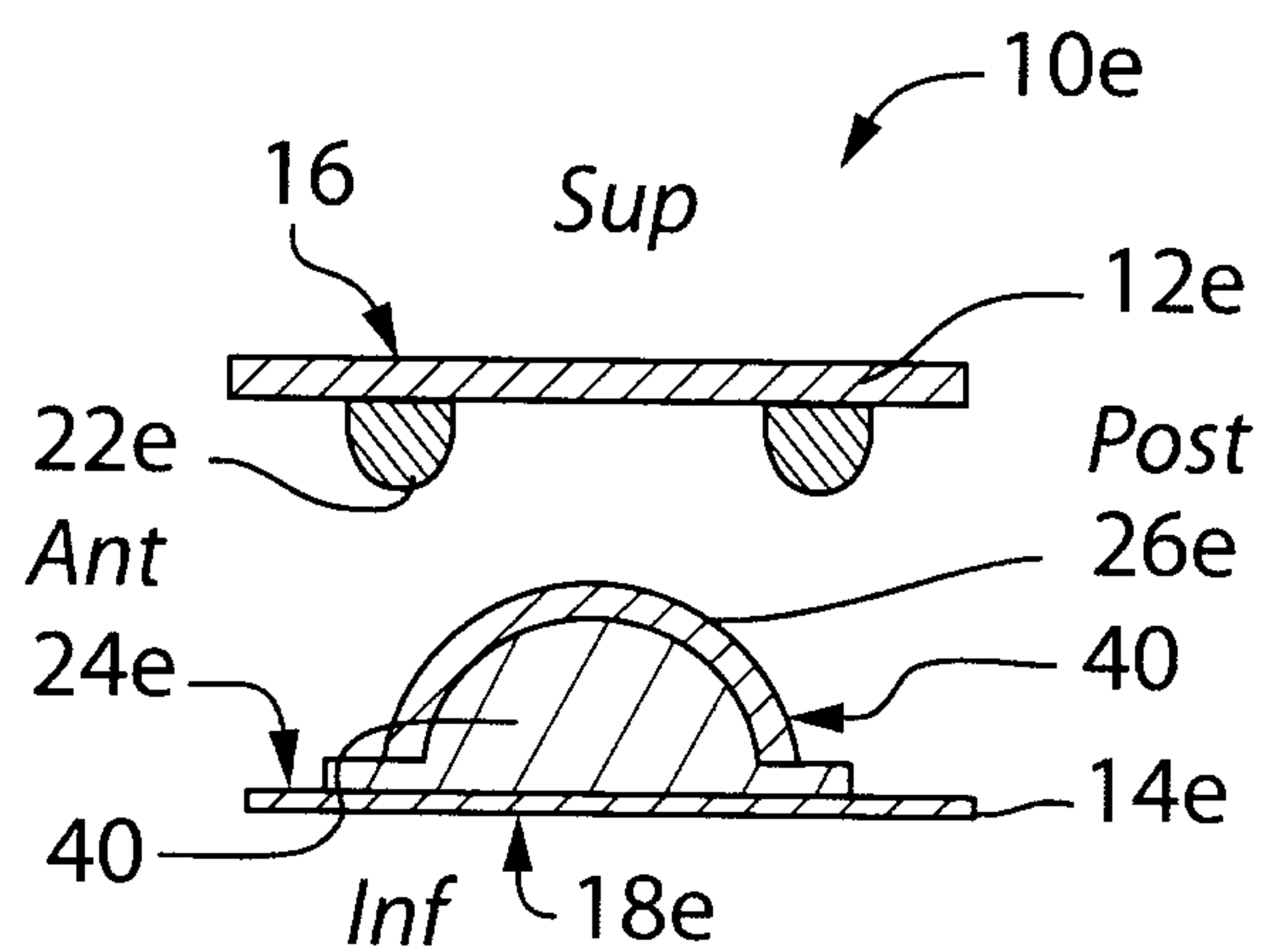
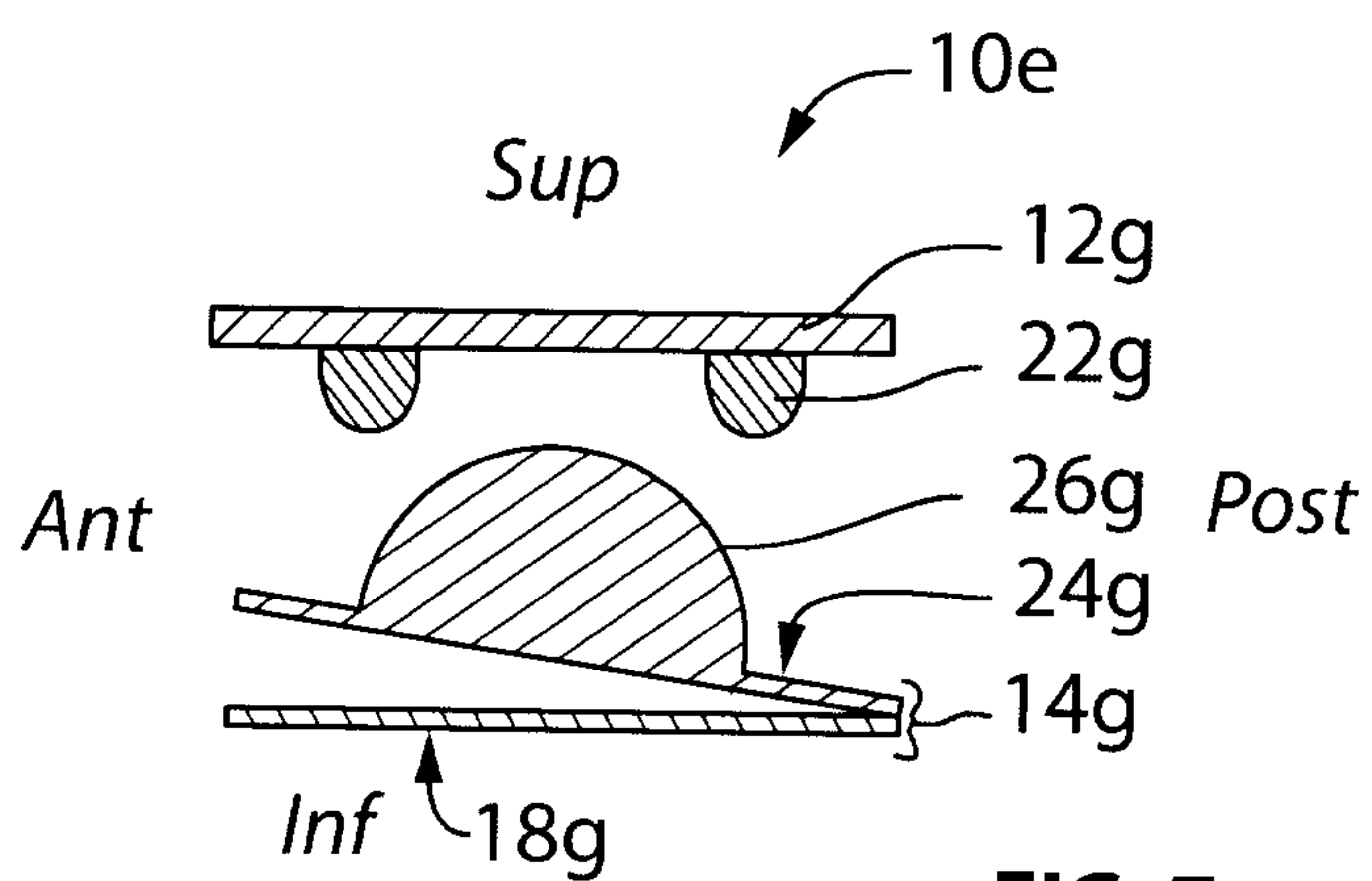


FIG. 1

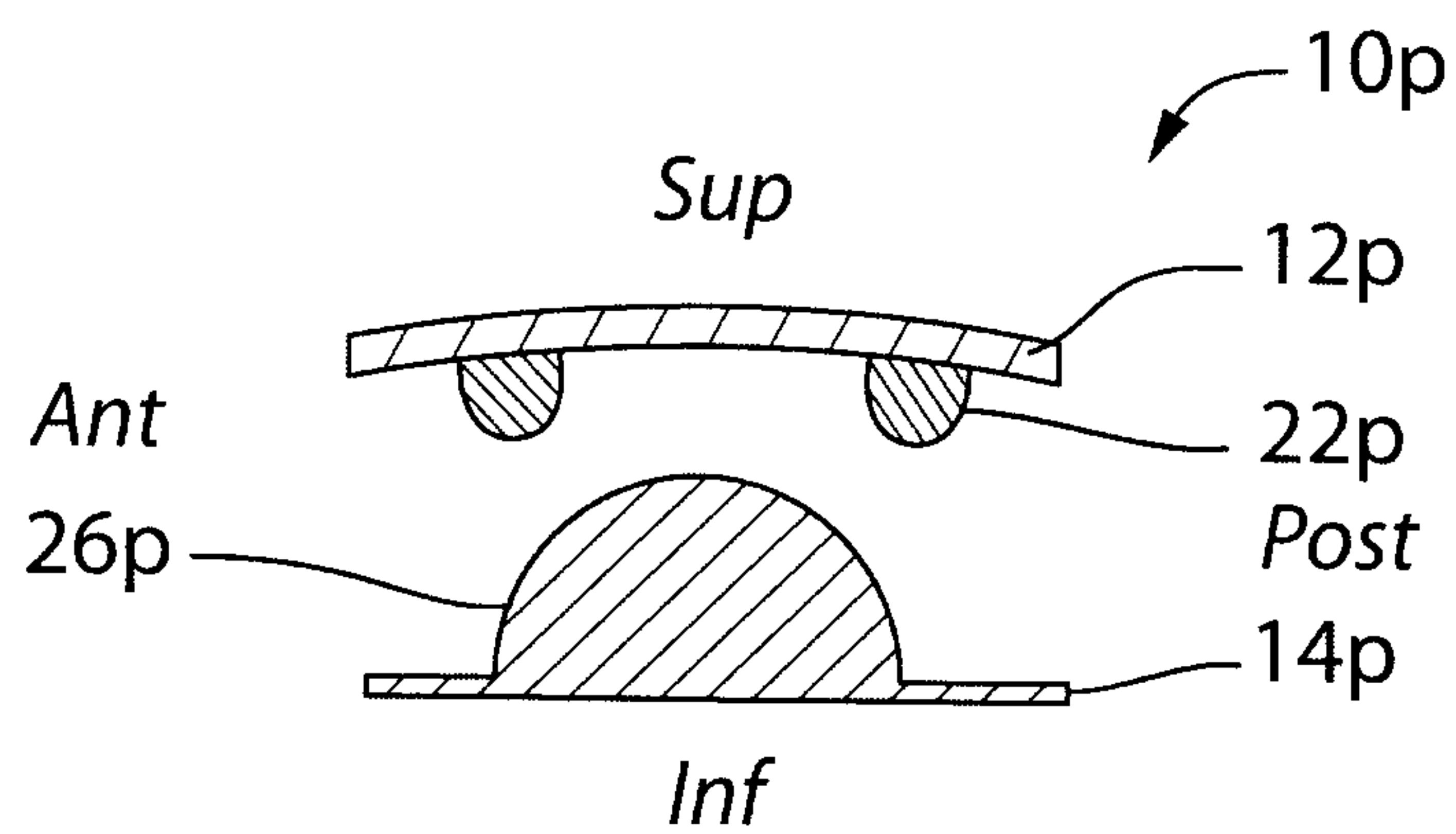
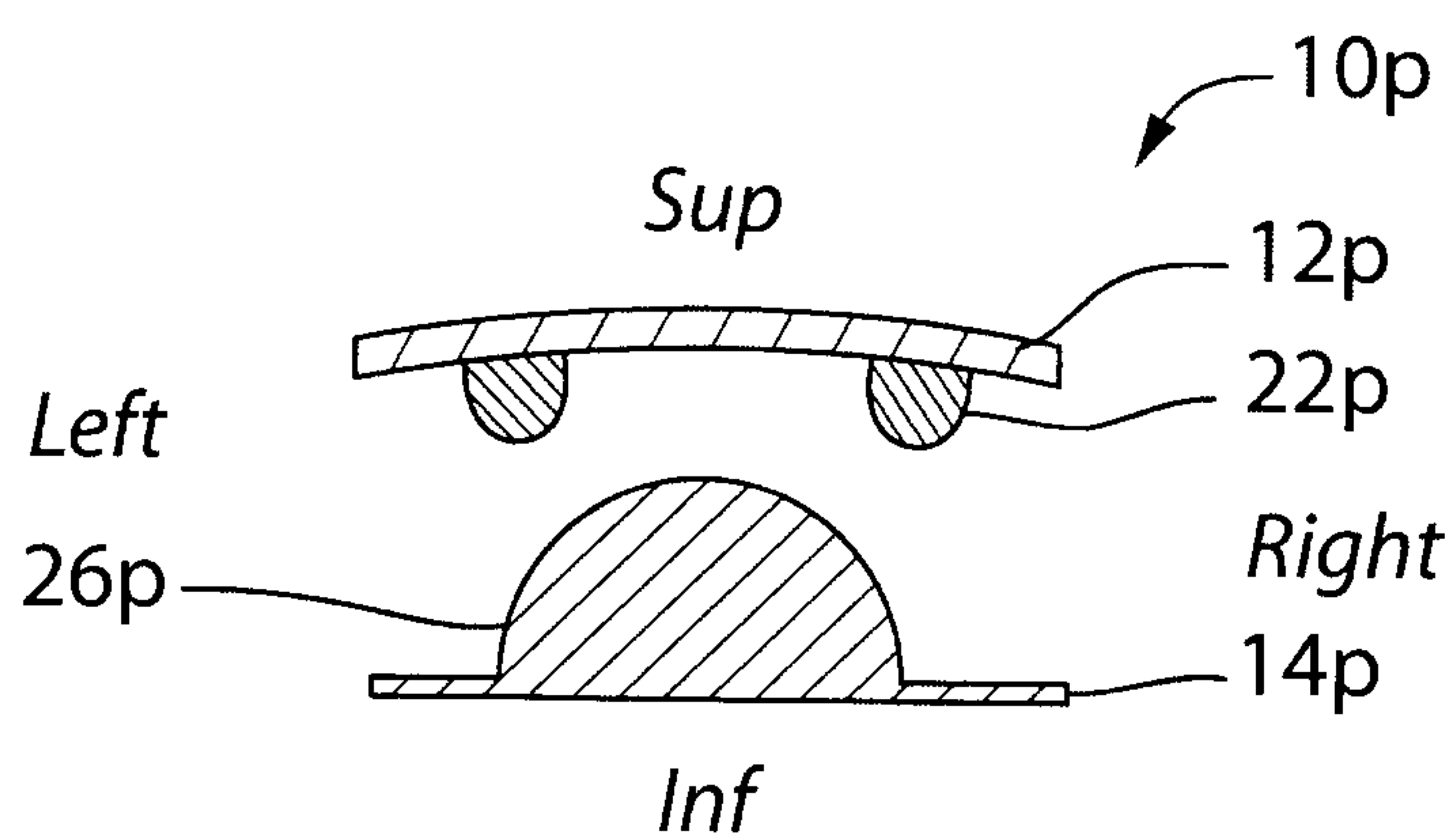
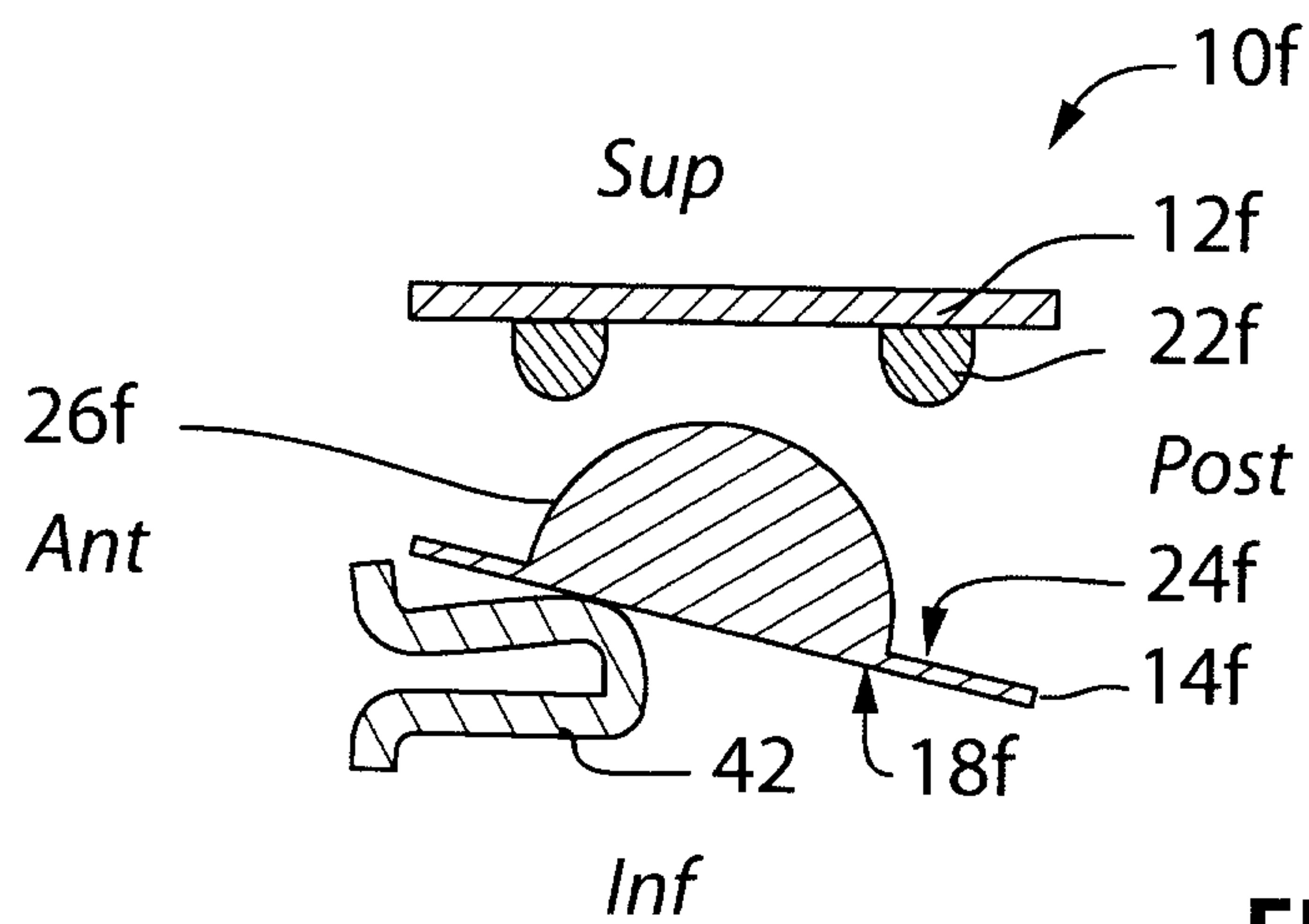
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**FIG. 2a****FIG. 2b****FIG. 3****FIG. 4**

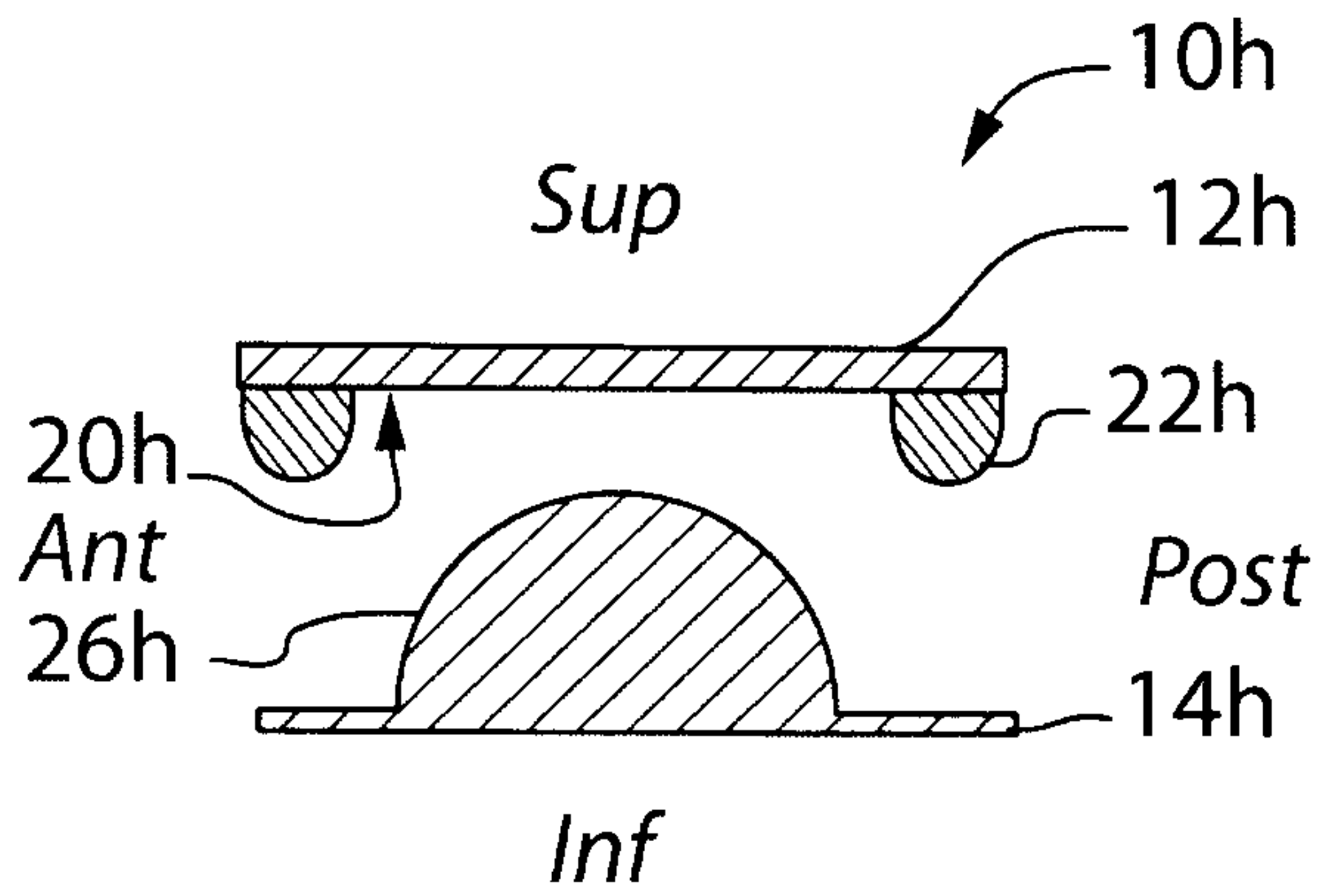
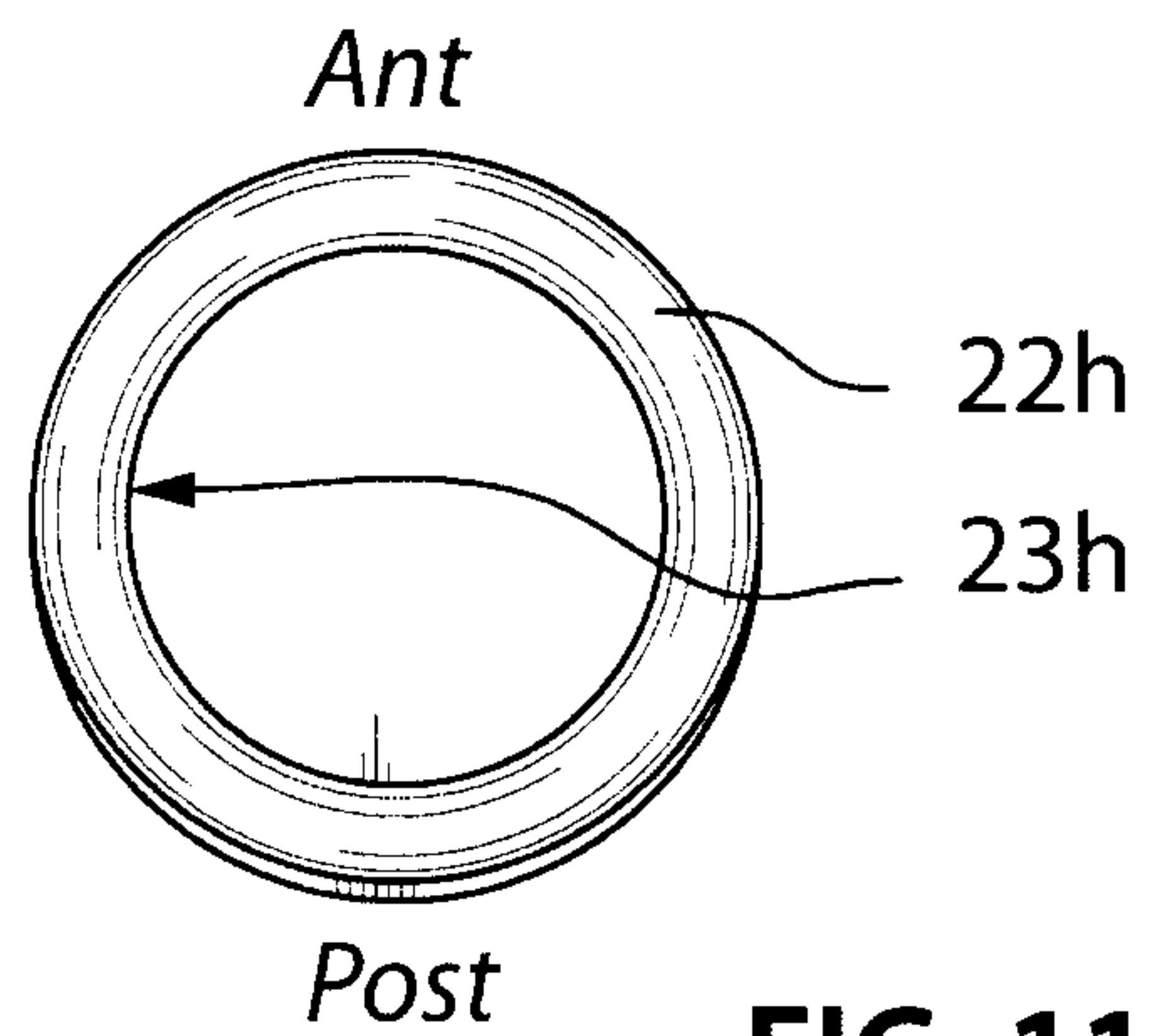
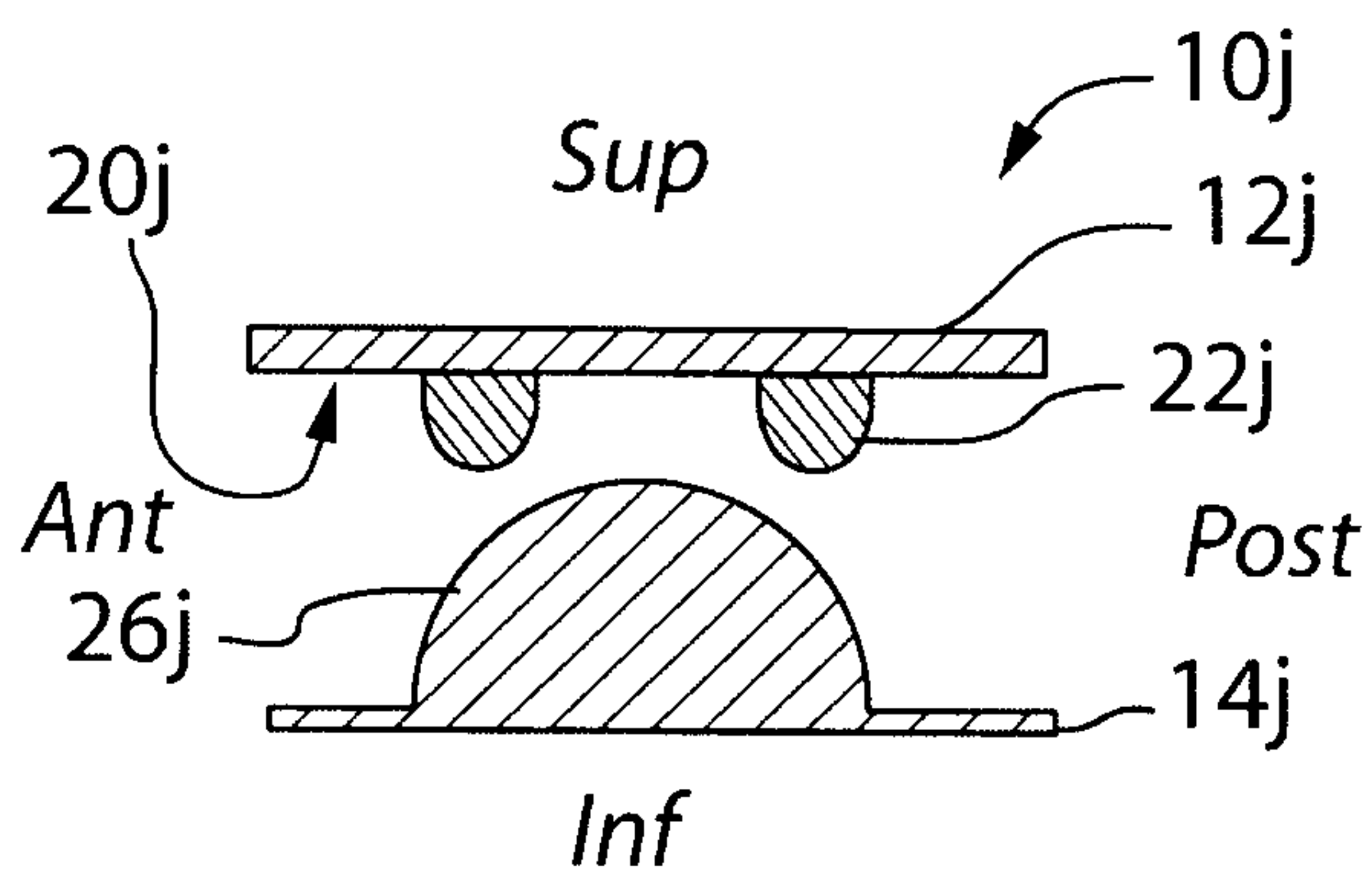
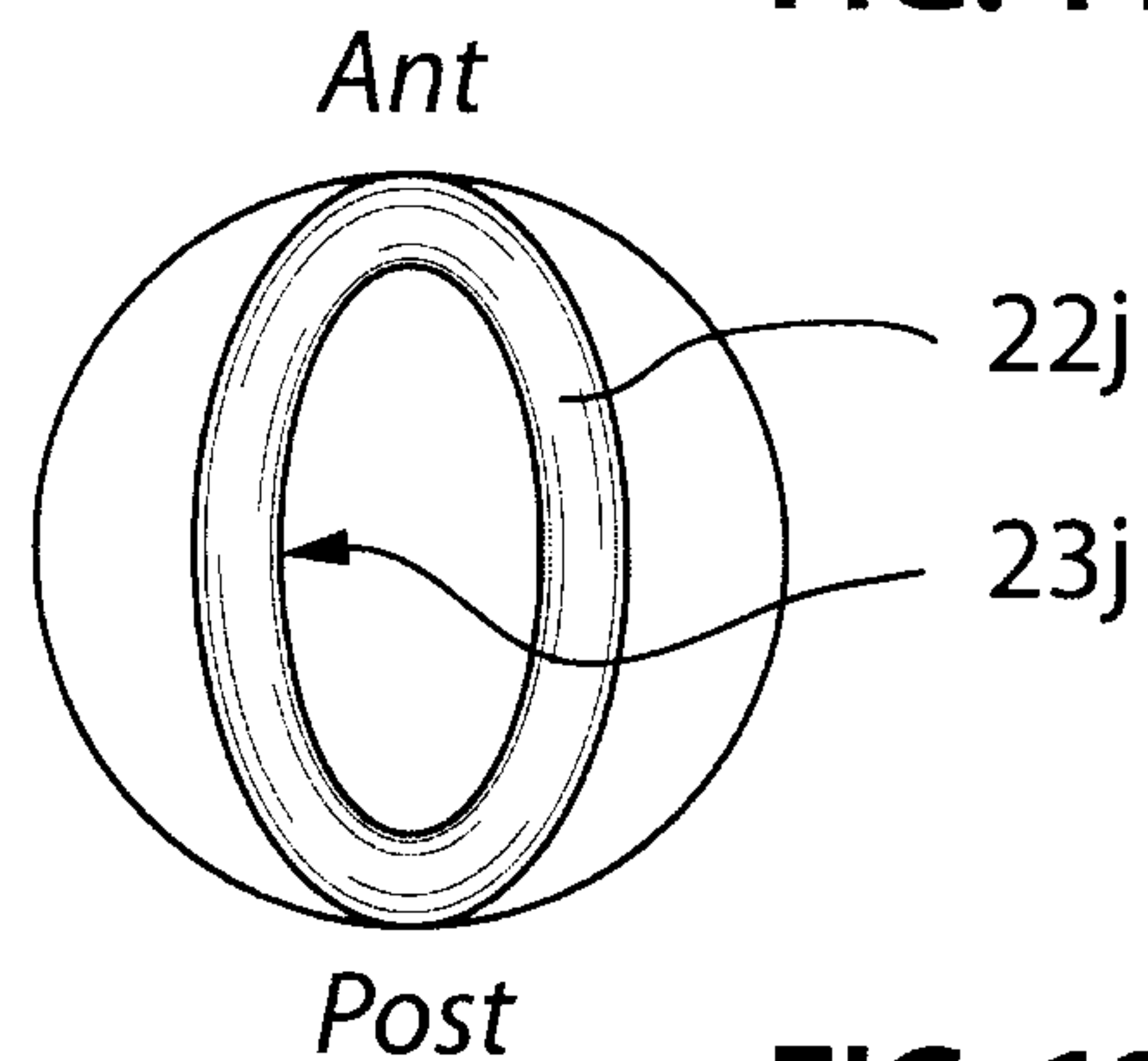
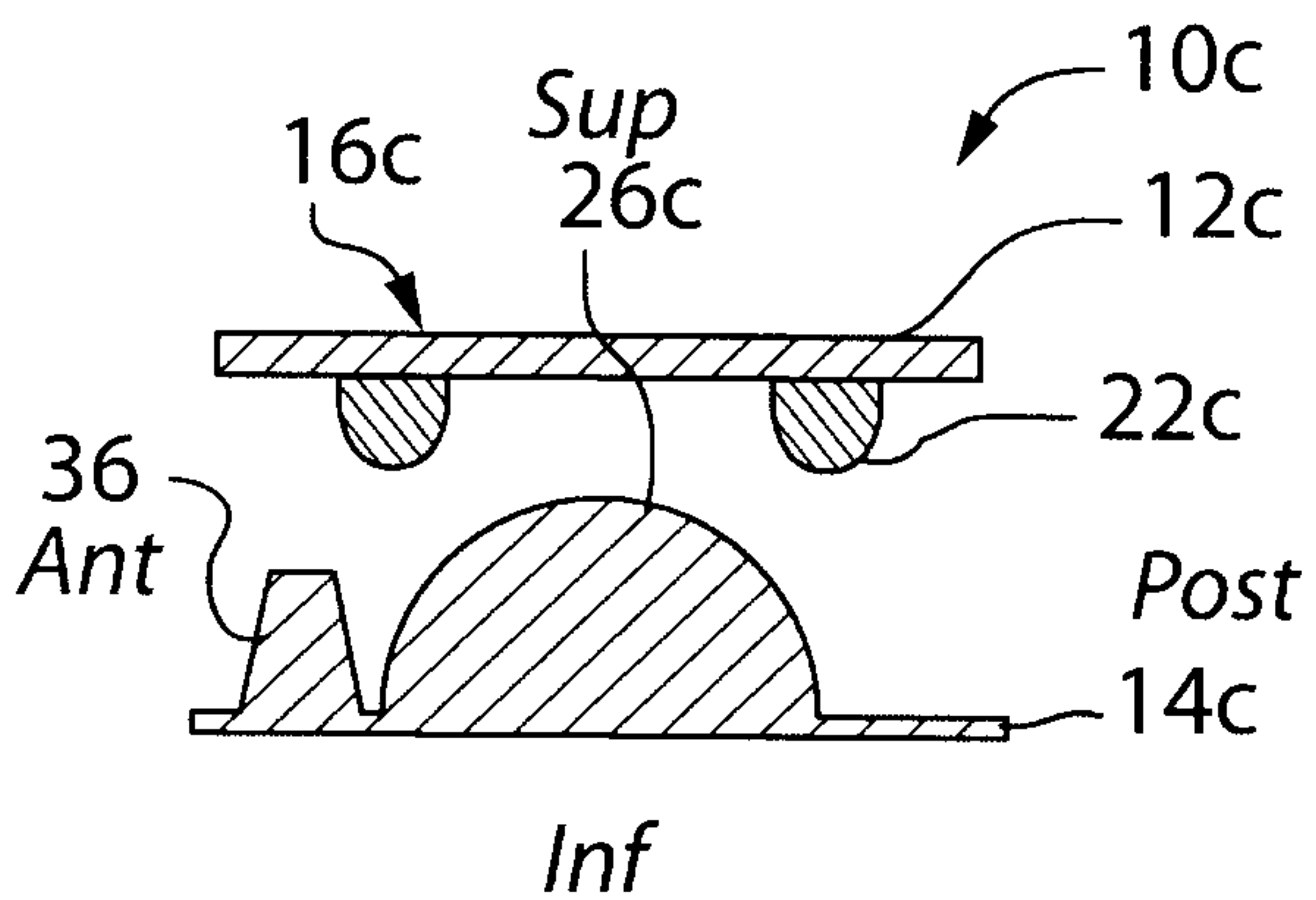
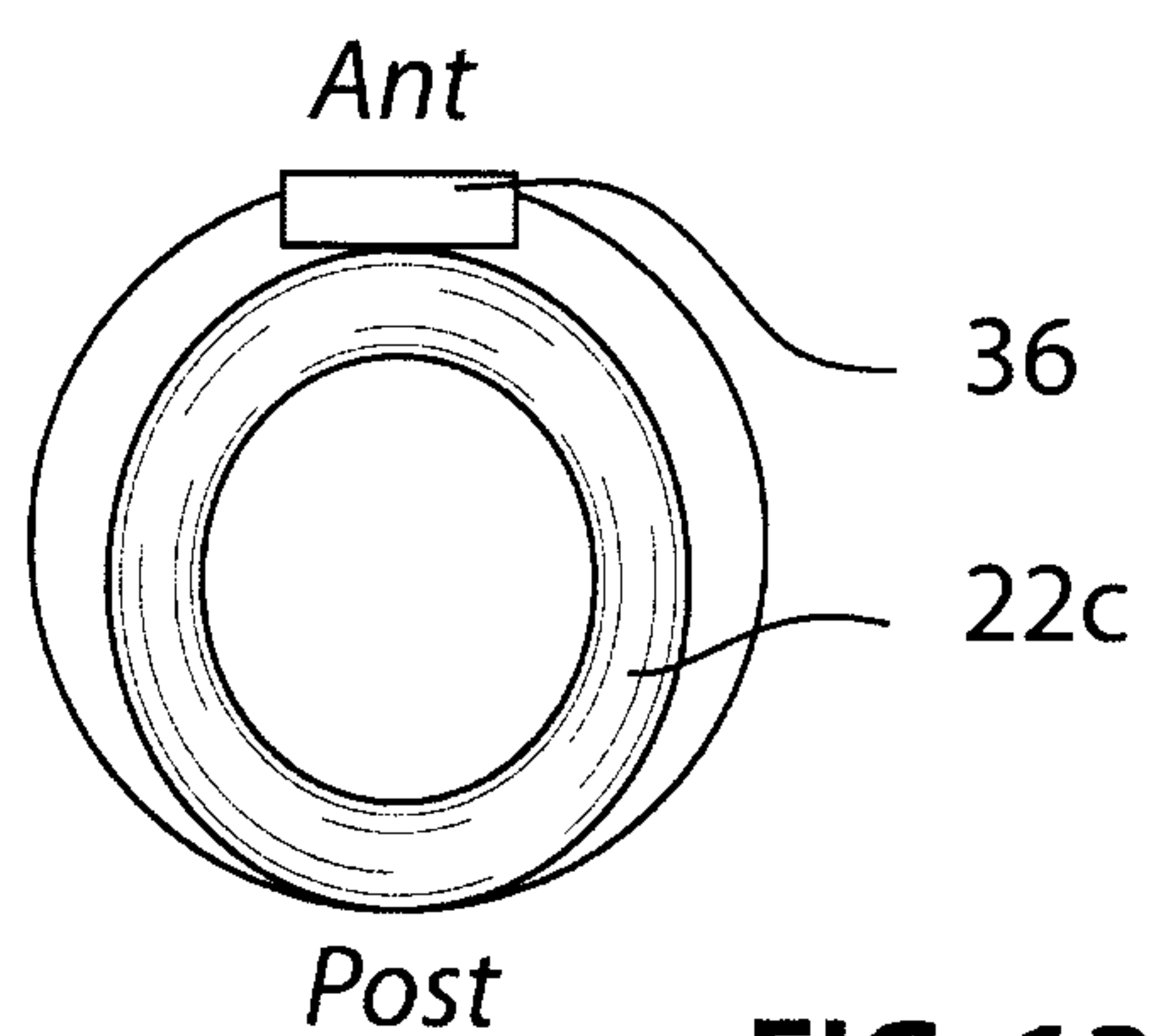
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**FIG. 5****FIG. 6****FIG. 7**

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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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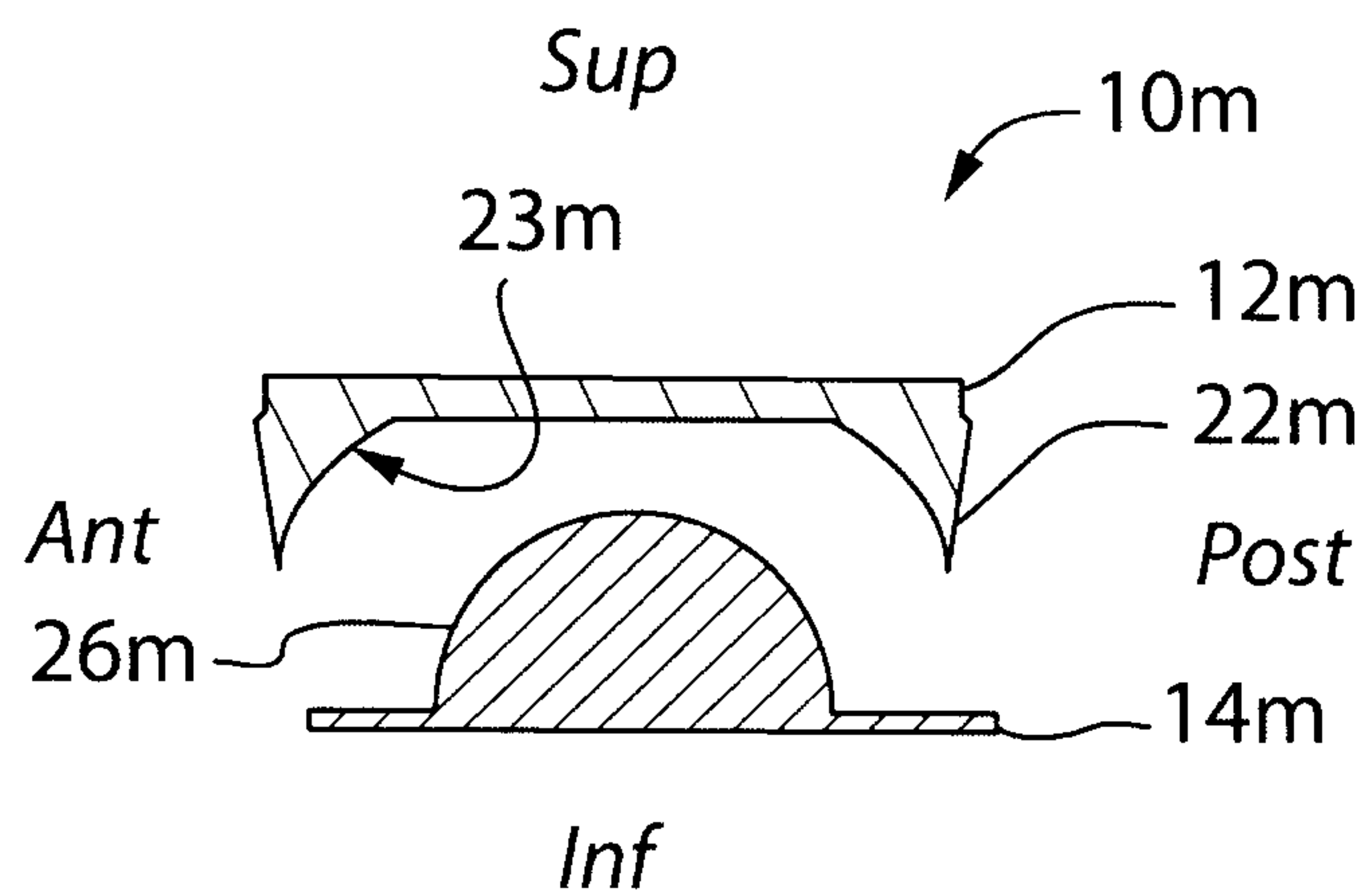


FIG. 14

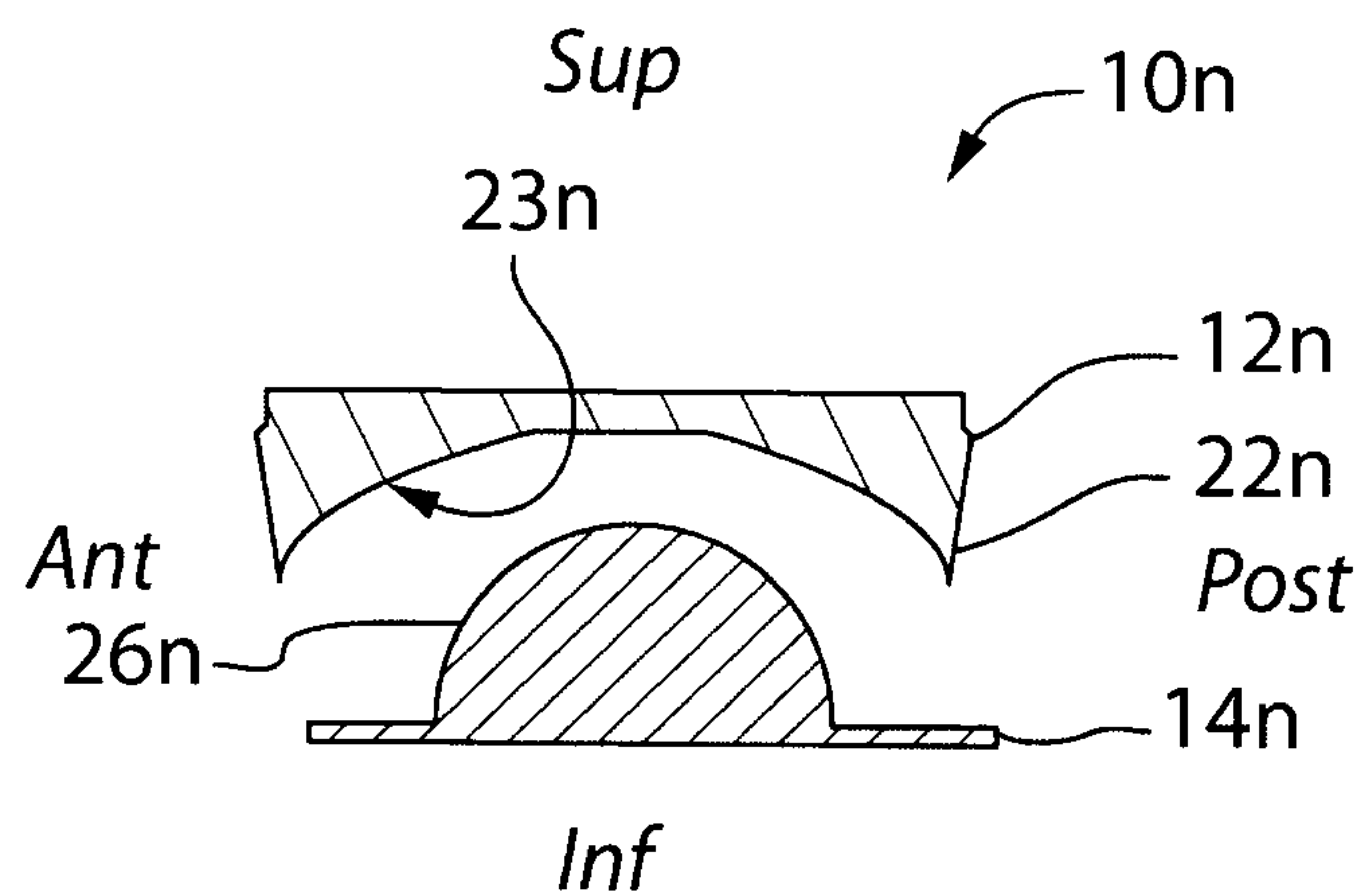
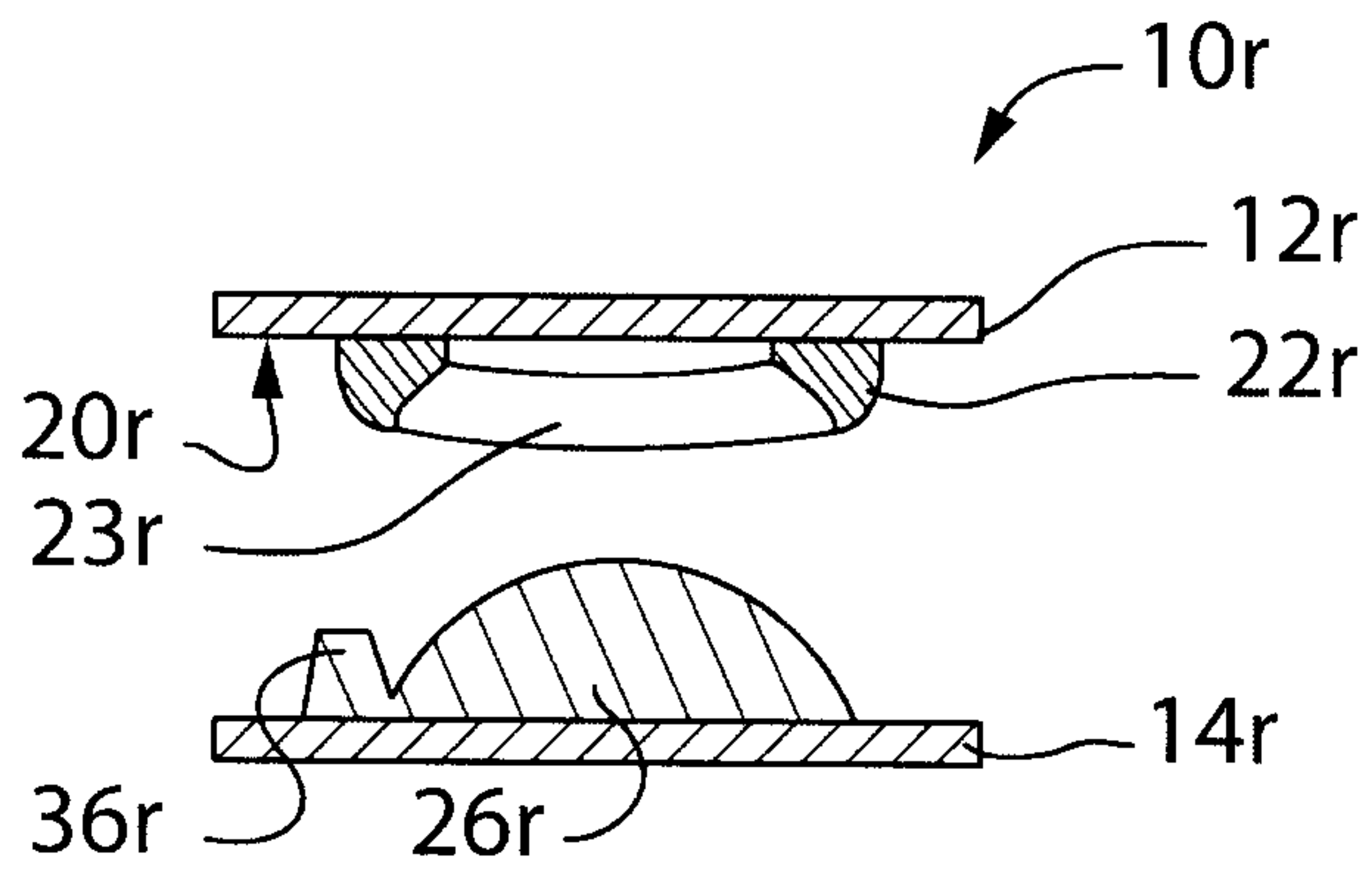
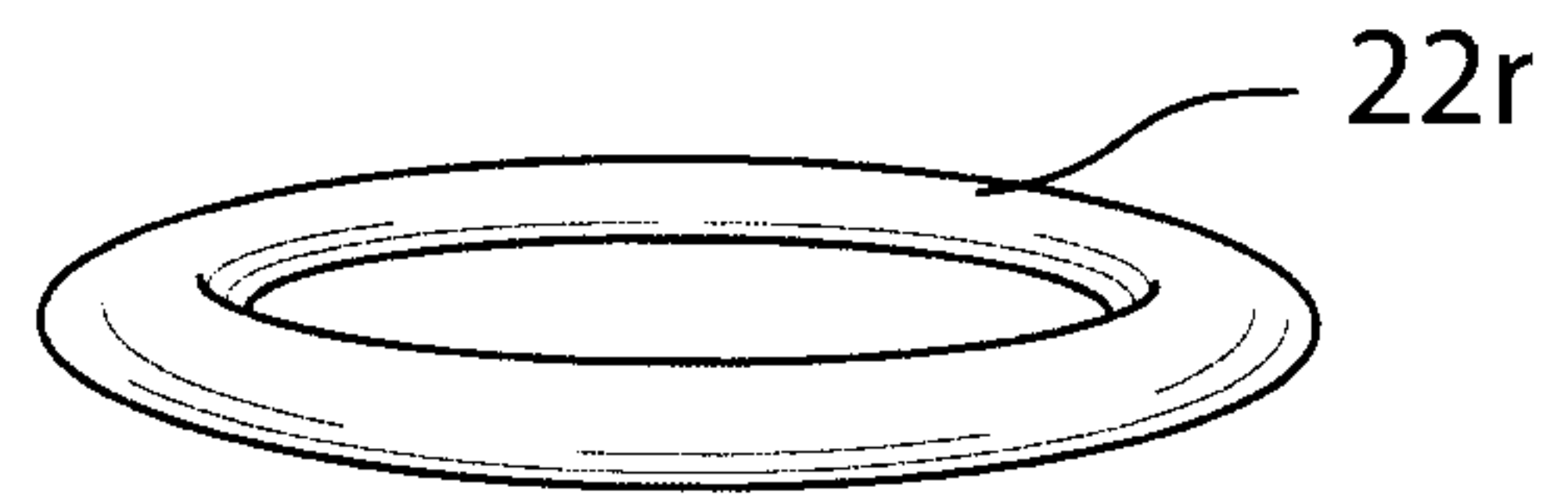
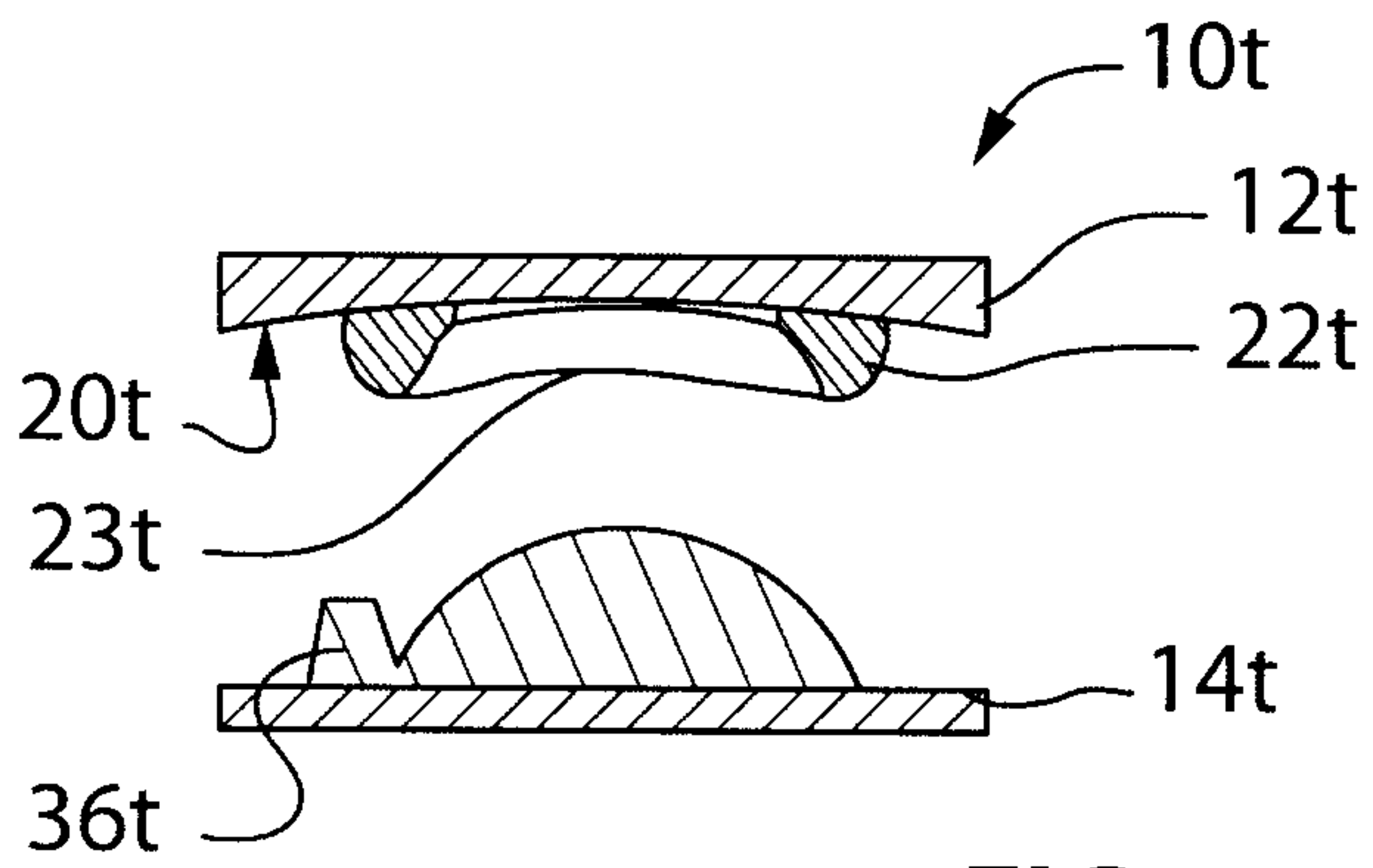
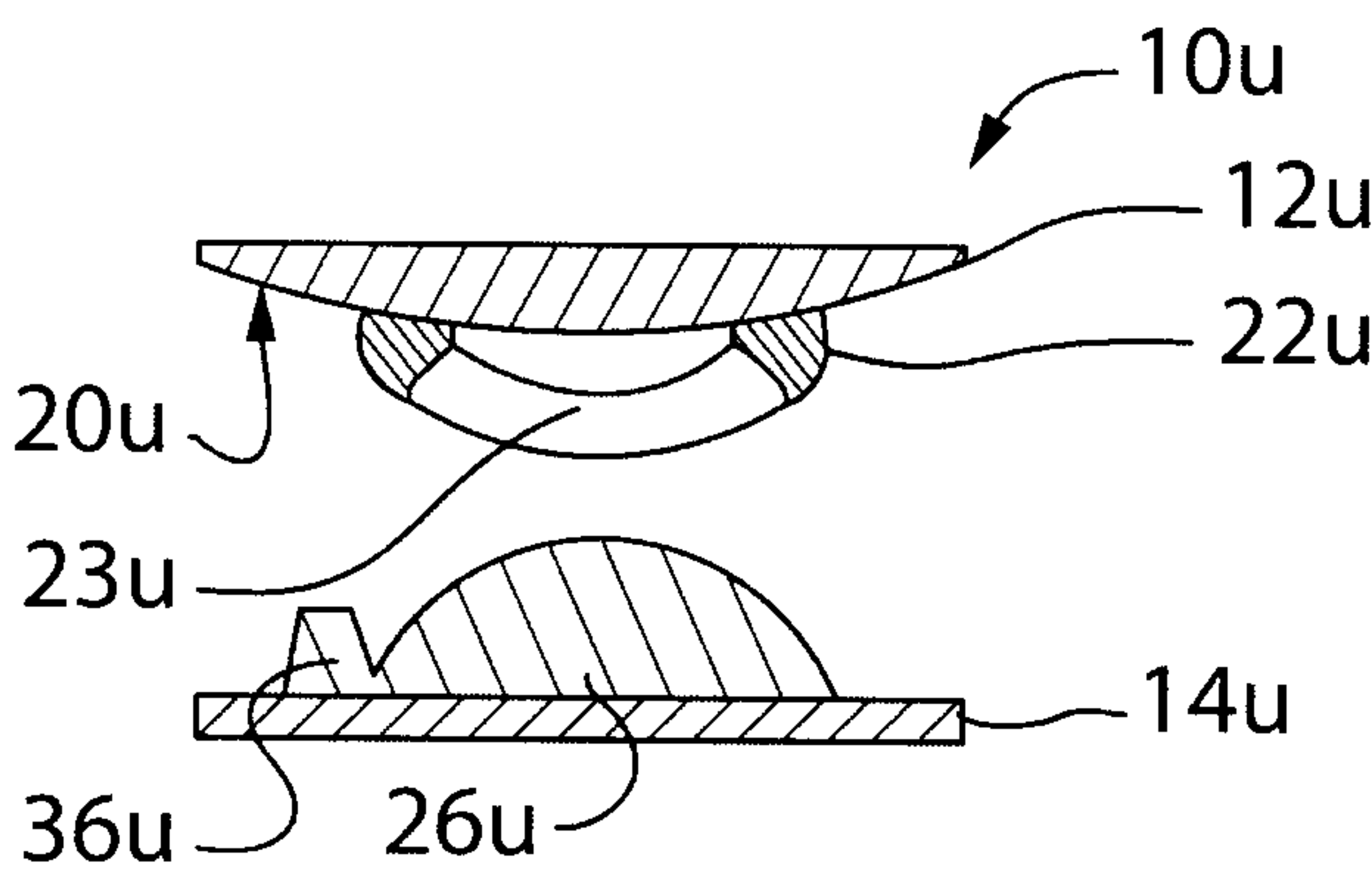


FIG. 15

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**FIG. 16a****FIG. 16b****FIG. 17a****FIG. 17b****FIG. 18a****FIG. 18b**

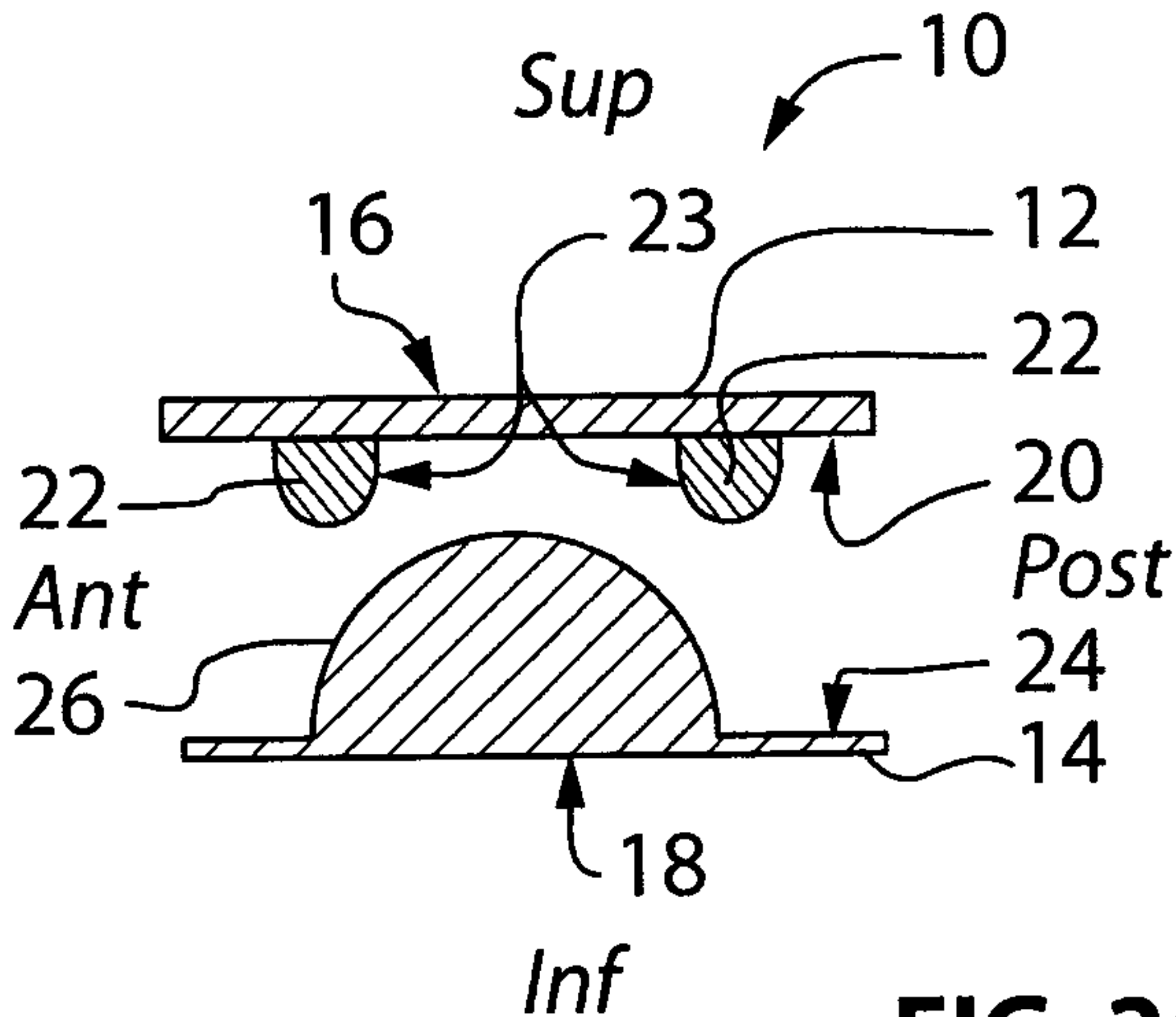


FIG. 2a