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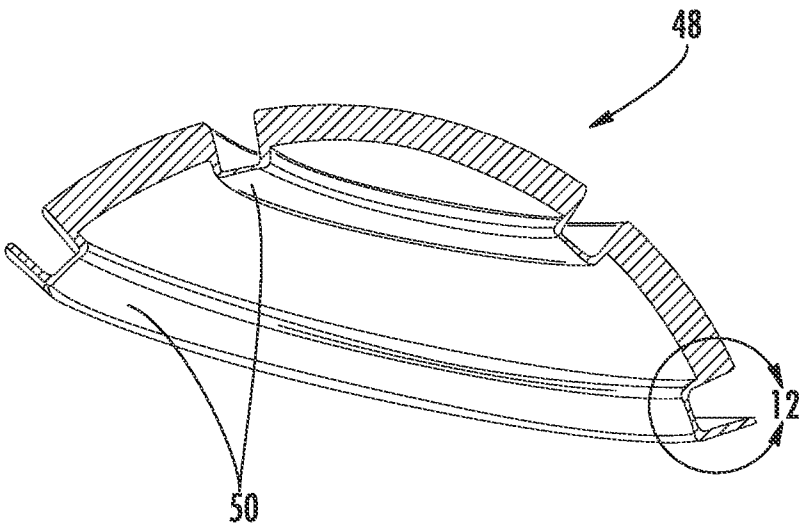
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(54) Title: MEDICAL IMPLANTS



(57) Abstract: A medical implant includes a first member adapted to be implanted to bond and having a substantially rigid first contact surface; and a second member adapted to be implanted to bone and having a substantially rigid second contact surface which bears against the first contact surface so as to transfer load from one member to the other while allowing relative motion between the two members; At least one of the first and second contact surfaces is adapted to have resilient properties when placed under load.

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MEDICAL IMPLANTS

BACKGROUND OF THE INVENTION

[0001] This invention relates generally to medical implants, and more particularly to medical implants having wear resistant geometries and wear resistant thin films thereon.

[0002] Medical implants, such as knee, hip, and spine orthopedic replacement joints and other joints and implants have previously consisted primarily of a hard metal motion element that engages a polymer contact pad. This has usually been a high density high wear resistant polymer, for example Ultra-High Molecular Weight Polyethylene (UHMWPE), or other resilient material. The problem with this type of configuration is the polymer eventually begins to degrade due to the caustic nature of blood, the high impact load, and high load cycle. As the resilient member degrades, pieces of polymer may be liberated into the joint area, often causing accelerated wear, implant damage, and tissue inflammation and harm.

[0003] It is desirable to employ a design using a hard member on a hard member e.g. metals or ceramics), thus eliminating the polymer. Such a design is expected to have a longer service life. Extended implant life is important as it is now often required to revise or replace implants. Implant replacement is undesirable from a cost, inconvenience, patient health, and resource consumption standpoint.

[0004] Implant using two hard elements of conventional design will be, however, subject to rapid wear. First, a joint having one hard, rigid element on another will not be perfectly shaped to a nominal geometry. Such imperfections will result in points of high stress, thus causing localized wear. Furthermore, two hard elements would lack the resilient nature of a natural joint. Cartilage has a definite resilient property, absorbing shock and distributing periodic elevated loads. This in turn extends the life of a natural joint and reduces stress on neighboring support bone and tissue. If two rigid members are used, this ability to absorb the shock of an active lifestyle could be diminished. The rigid members would transmit the excessive shock to the implant to

bone interface. Some cyclical load in these areas stimulates bone growth and strength; however, excessive loads or shock stress or impulse loading the bone-to-implant interface will result in localized bone mass loss, inflammation, and reduced support.

BRIEF SUMMARY OF THE INVENTION

[0005] These and other shortcomings of the prior art are addressed by the present invention, which according to one aspect provides a medical implant, including: a first member adapted to be implanted to bone and having a substantially rigid first contact surface; and a second member adapted to be implanted to bone and having a substantially rigid second contact surface which bears against the first contact surface so as to transfer load from one member to the other while allowing relative motion between the two members. At least one of the first and second contact surfaces is adapted to have resilient properties when placed under load.

[0006] According to another aspect of the invention, a medical implant includes: a first member adapted to be implanted to bone and having a substantially rigid, convex-curved first contact surface; and a second member adapted to be implanted to bone and having a substantially rigid, concave-curved second contact surface riding against the first contact surface. The second contact is adapted to bend elastically in at least one plane when placed under a preselected operating load.

BRIEF DESCRIPTION OF THE DRAWINGS

[0007] The invention may be best understood by reference to the following description taken in conjunction with the accompanying drawing figures in which:

[0008] Figure 1 is a side view of a lower portion of a hip implant constructed in accordance with the present invention;

[0009] Figure 2 is a schematic side view of a thin film treatment apparatus for use with the present invention;

[0010] Figure 3 is an enlarged view of a trabecular metal structure;

[0011] Figure 4 is a perspective view of a hip implant;

[0012] Figure 5 is a perspective view of a portion of a knee implant;

[0013] Figure 6 is a cross-sectional view of a portion of a resilient contact member constructed in accordance with the present invention;

[0014] Figure 7 is an enlarged view of the contact member of Figure 7 in contact with a mating joint member;

[0015] Figure 8 is a side view of a resilient contact member in contact with a mating joint member;

[0016] Figures 9A and 9B are side and perspective views, respectively, of a joint with mating members;

[0017] Figures 10A and 10B are overall and detailed cross-sectional views of the joint of Figures 9A and 9B;

[0018] Figure 11 is a cross-sectional view of a cup for an implant according to an alternate embodiment of the invention;

[0019] Figure 12 is an enlarged view of a portion of the cup of Figure 11;

[0020] Figure 13 is a perspective view of a segmented implant constructed according to the present invention;

[0021] Figure 14 is an enlarged view of a portion of Figure 13;

[0022] Figures 15A through 15C are various views of the implant of Figure 13;

[0023] Figures 16A through 16F are various views of another segmented implant constructed according to the present invention;

[0024] Figure 17 is a cross-sectional view of an implant joint including a flexible seal;

[0025] Figure 18 is an enlarged view of a portion of Figure 17;

[0026] Figure 19 is a perspective view of a finite element model of a joint member; and

[0027] Figure 20 is a perspective view of a finite element model of another joint member.

DETAILED DESCRIPTION OF THE INVENTION

[0028] Referring to the drawings wherein identical reference numerals denote the same elements throughout the various views, Figure 1 depicts an exemplary lower member 10 of a hip implant constructed in accordance with the present invention. The lower member 10 is generally metallic and includes an elongated body 12 and a ball end 14. Although a hip implant is used as an example, the present invention is equally applicable to other types of implants

[0029] The surface of the ball end 14, or portions thereof, has a thin film 16 of a carbon-based material deposited thereon, referred to as a diamond-like carbon (DLC) material. This thin film material is essentially pure carbon, has a noncrystalline microstructure, and exhibits a flexural capability of approximately 8% or better. The carbon structure and bond layer enable the thin film 16 to endure significant vibration and deformation without cracking or detaching from the substrate or delaminating. Such thin films may be obtained from BioMedFlex LLC, Huntersville, NC, 28078.

[0030] The thin film 16 is applied in multiple layers, for example about 3 to about 30 layers may be used. The use of multilayers prevents residual stress build up in the individual layers and in the total film thickness This is in contrast to typical prior art thin films which have residual stress present and are brittle, limiting their ability to bear a localized load. The total thickness of the thin film 16 may be in the range of about 0.5 to about 6 μm. No post coating annealing or mechanical polishing is required, and the thin film 16 has a high adhesion strength, for example about 8500 lb/in^2 or greater.

[0031] Figure 2 illustrates a thin film apparatus 18 for applying the thin film 16 to the lower member 10. The thin film apparatus 18 is a chemical vapor deposition

(CVD) apparatus of a known type. It includes a processing chamber 20 which receives the workpiece, a hydrocarbon gas source 22, an RF field generator 24 of a known type, and a vacuum pump 26.

[0032] The thin film process proceeds as follows. First, the untreated lower member 10 is plasma cleaned in a known manner to eliminate any foreign material or contaminants from the surface thereof. The thin film 16 is then deposited over the exterior of the ball end 14 using a plasma assisted chemical vapor deposition (CVD) process. Since the thin film process is CVD, it does not require a direct line-of-sight to achieve a satisfactory thin film. Once the thin film cycle is complete, the lower member 10 is removed from the chamber 20.

[0033] It is also possible to construct the thin film 16 by alternating layers of metal doped DLC with layers of amorphous hydrogenated diamond like carbon. Examples of suitable materials for the multilayers include: amorphous hydrogenated carbon, silicon doped amorphous hydrogenated carbon, boron doped amorphous hydrogenated carbon, nitrogen doped amorphous hydrogenated carbon, boron nitride doped amorphous hydrogenated carbon, or other metal doped amorphous hydrogenated carbon.

[0034] The thin film 16 does not require an intermediate film or coating layer (such as TiN). It has a high electrical resistivity and high thermal conductivity. The thin film 16 may be doped with one or more metallic, semi-metallic or other elements to produce a balance of high hardness without sacrificing typical DLC coefficients of reduced friction, adhesion layer strength, and overall bond strength.

[0035] The thin film 16 has several beneficial effects to the surface on which it is applied. The thin film is conformal and more uniform than physical vapor deposition methods. It creates a non-porous, chemically inert, protective boundary layer. It improves the ability to withstand a localized (Hertzian) load while still providing exceptional wear resistance and high adhesion. It provides unique flexural property that allows the thin film 16 (and underlying substrate) to flex under load. This combination of flexural nature and high wear resistance makes the thin film 16 a

solution for a variety of applications such as: gears (spiral bevel, hypoid, helical, spur, worm, etc.); medical implants; knees, hips, finger joint, spine, etc.; medical instruments; cams (and cam shafts) lifters (e.g. flat tappet); valves (automotive and industrial); curvic couplings; hurth couplings; bearings (e.g. gothic arch and planar and roller surface); shafts (especially shaft faces or shoulders); and other similar applications.

[0036] The thin film 16 has the ability to withstand scuffing and galling. It has a high hardness, low friction, and resists chemical wear. The thin film 16 enhances (fortifies) and protects the substrate surface to better preserve the exterior (exposed area) of the substrate to reduce the effects of micro surface damage (cracks and spalling); an initial wear indicator and mechanism. The high Hertzian contact stress tolerance makes it possible to actually maintain a hard carbon thin film 16 were prior art DLCs would fail (due to cracking and adhesion layer failure)

[0037] Superfinishing of the thin film 16 is possible. This would produce an even better surface finish on a processed surface than originally existed on the bare substrate; even if the original substrate was finished to a sub micron (<1 micro-inch Ra) surface finish.

[0038] The resilient hard carbon thin film 16 described above may be used on implants having osseointegration surfaces, which are surfaces designed to be infiltrated by bone growth to improve the connection between the implant and the bone. Osseointegration surfaces may be made from materials such as trabecular metal, textured metal, or sintered or extruded implant integration textures. Trabecular metal is an open metal structure with a high porosity (e.g. about 80%). An example of a trabecular metal structure is shown in Figure 3.

[0039] The thin film 16 may be applied to any osseointegration surface. Figures 4-6 illustrate various examples of implants having osseointegration surfaces "S", including a hip joint shank 28, a hip joint cup 30, and a knee joint 32. The thin film 16 may also be applied to other implants, such as plates and fasteners used for reconstructive procedures The thin film 16 may be doped to facilitate

osseointegration, for example with titanium or fluorine. The thin film 16 may be a single layer of DLC material or a multilayer material as described above. If desired, a non-doped thin film may be used to create a wear resistant surface while discouraging bone integration. For example, in the hip joint lower member 10 of Figure 2, the ball end 14 may be coated with a non-doped thin film 16 as described above.

[0040] In order to utilize the superior characteristics of the thin films described above, a specialized implant contact interface (implant geometry) may be used. In this geometry, an implanted joint would include two typically hard (i.e. metal or ceramic) members; however, at least one of the members is formed such that it has the characteristics of a resilient member, such as: the ability to absorb an impact load; the ability to absorb high cycle loading (high endurance limit); the ability to be self cleaning; and the ability to function as a hydrodynamic and/or hydrostatic bearing. One or both of these contact interface members may have thin film applied. If thin film is applied to two mating surfaces, it may be desirable to use two different compositions to improve the wear resistance and component compatibility. It may also be desired to apply thin film to one surface and a different surface treatment or coating to the mating surface.

[0041] Generally, the contact resilient member is flexible enough to allow elastic deformation and avoid localized load increases, but not so flexible as to risk plastic deformation, cracking and failure. In particular, the resilient member is designed such that the stress levels therein will be below the high-cycle fatigue endurance limit. As an example, the resilient member might be only about 10% to about 20% as stiff as a comparable solid member. It is also possible to construct the resilient member geometry with a variable stiffness, i.e. having a low effective spring rate for small deflections and a higher rate as the deflections increase, to avoid failure under sudden heavy loads.

[0042] Figure 6 illustrates an exemplary contact member 34 including a basic resilient interface geometry. The contact member 34 is representative of a portion of a medical implant and is made of one or more metals or ceramics (for example, partially stabilized Zirconia). It is coated with a thin film (not shown) as described

above. The geometry includes a lead in shape, Z1 and Z2, a contact shape, Z3 and Z4, a lead out shape, Z5 and Z6, and a relieved shape, Z7. It may be desired to vary the cross-sectional thickness to achieve a desired mechanical stiffness to substrate resilience characteristic. The presence of the relieved region Z7 introduces flexibility into the contact member 34, reduces the potential for concentrated point contact with a mating curved member, and provides a reservoir for a working fluid.

[0043] The Z7 region may be local to the contact member 34 or may be one of several. In any case, it may contain a means of providing fluid pressure to the internal contact cavity to produce a hydrostatic interface. A passive (powered by the regular motion of the patient) or active (powered by micro components and a dedicated subsystem) pumping means and optional filtration may be employed to provide the desired fluid interaction.

[0044] A hydrodynamic interface is desirable as, by definition, it means the contact member 34 is not actually touching the mating joint member. The lead-in and lead-out shapes Z1, Z2, Z5, Z6 are configured to generate a shear stress in the working fluid so as to create the fluid "wedge" of a hydrodynamic support. However, in this type of arrangement, there is a point where the two bearing surfaces are resting on each other in the absence of fluid shear between the two members of the joint or implant. This is what causes what is called stick-slip (the transition from static to dynamic friction then to hydrodynamic motion). The resilient nature of the thin film 16, allows a design which has reduced wear even when the contact member 34 flexes or is in a static friction regime.

[0045] Figure 7 shows a closer view of the contact member 34. It may be desirable to make the contact radius (Z3 and Z4) larger or smaller, depending on the application requirement and flexural requirement. For example, Figure 8 illustrates the contact member 34 in contact with a mating joint member 38 having a substantially larger radius than the contact member 34. The radius ratio between the two joint members is not particularly critical, so long as one of the members exhibits the resilient properties described herein.

[0046] Another way to achieve a resilient member is to employ a design that uses contacting surfaces with similar geometric relationships but sandwiches a resilient media between two semi-rigid elements. For example, Figures 9A-9B and 10A-10B illustrate a joint assembly with a cup 40 and a mating ball 42, both of generally rigid metals or ceramics. One or more ring-like rigid (i.e. metal or ceramic) contact pads 44 are attached to the cup 40, with a resilient material (e.g. polymer) 46 sandwiched between the two. In this case a polymer may be desirable as it is subjected to a distributed load versus the opportunity for localized wearing and degradation. The cup surface, including the contact pads 44, are coated with a thin film as described above.

[0047] Figures 11 and 12 illustrate a coated cup 48 of metal or ceramic with two integrally-formed contact rings 50. More contact rings may be added if needed. As shown in Figure 12, the volume behind the contact rings 50 may be relieved. This relieved area 52 may be shaped so as to produce a desired balance between resilience and stiffness. A varying cross-section geometry defined by varying inner and outer spline shapes may be desired. In other words, a constant thickness is not required. A material such as a gel or non-Newtonian fluid (not shown) may be disposed in the relieved area 52 to modify the stiffness and damping characteristics of the contact rings 50 as needed for a particular application. The cup 48 could be used as a stand-alone portion of a joint, or it could be positioned as a liner within a conventional liner. The contact ring 50 is shown under load in Figure 19, which depicts contour lines of highest compressive stress at "C1". This is the portion of the contact ring 50 that would be expected to undergo bending first. The bearing interface portion of the resilient contact member could be constructed as a bridge cross-section supported on both sides as shown or as a cantilevered cross-section depending on the desired static and dynamic characteristics.

[0048] Figures 13-16 show a joint member 54 having a segmented shape. The generally rectangular shape (in plan view) is illustrative and could be modified to suit a specific requirement. Contours C1 and C2 and C3 and C4 can be shaped as needed to yield the desired contact area and profile and contour coverage. Contact profile P1 can be modified to suit the load and resilience characteristic desired for the specific application. The joint member 54 may be solid in the center zone or open. The contact

surface can have shaped grooves (for example in the profile P1) positioned to allow particles to move off the load bearing contact surface and eventually move back into the joint for absorption back into the body. The joint member 54 is shown under load in Figure 20, which depicts an area of highest compressive stress at "C2". This is the portion of the joint member 54 that would be expected to undergo bending first.

[0049] Figures 17 and 18 illustrate an implant 56 of rigid material which includes a wiper seal 58. The wiper seal 58 keeps particles out of the contact area (seal void) 60 of the implant 58, and working fluid (natural or synthetic) in. The seal geometry is intended to be representative and a variety of seal characteristics may be employed; such as a single lip seal, a double or multiple lip seal, a pad or wiper seal made from a variety of material options. Different seal mounting options may be used; lobe in shaped groove as shown in Figures 17 and 18, a retaining ring or clamp, adhesion substance. The seal may also be incorporated into the contact face of the interface zone.

[0050] It may be desirable to create a return passage 62 from the seal void region 60 back into the internal zone 64 in order to stabilize the pressure between the two and to allow for retention of the Internal zone fluid if desired. This is especially relevant when the hydrostatic configuration is considered.

[0051] It is noted that it may be desirable to surface treat either or both interfaces of any of the above-described joints with a laser, shot peen, burnishing, or water shock process, to reduce wear. The benefit could be as much from surface annealing and microstructure and microfracture elimination as smoothing itself.

[0052] The foregoing has described medical implants with wear-resistant geometries and coatings. While specific embodiments of the present invention have been described, it will be apparent to those skilled in the art that various modifications thereto can be made without departing from the spirit and scope of the invention. Accordingly, the foregoing description of the preferred embodiment of the invention and the best mode for practicing the invention are provided for the purpose of illustration only and not for the purpose of limitation.

WHAT IS CLAIMED IS:

1. A medical implant, comprising:

a first member adapted to be implanted to bone and having a substantially rigid first contact surface;

a second member adapted to be implanted to bone and having a substantially rigid second contact surface which bears against the first contact surface so as to transfer load from one member to the other while allowing relative motion between the two members;

wherein at least one of the first and second contact surfaces is adapted to have resilient properties when placed under load.

2. The medical implant of claim 1 wherein a resilient thin film is disposed on at least one of the contact surfaces, the thin film consisting essentially of carbon in a non-crystalline microstructure.

3. The medical implant of claim 1 wherein the contact surfaces are ceramic, metallic, or a combination thereof.

4. The medical implant of claim 1, wherein the first and second contact surfaces contacting have geometrically similar shapes, and where a resilient material is carried by a selected one of the contact surfaces and sandwiched between the contact surfaces.

5. The medical implant of claim 4, wherein at least one rigid contact pad, having a surface area substantially less than that of either the first and second contact surfaces, is attached to a selected one of the first and second contact surfaces, and a resilient material is sandwiched between the contact pad and the selected contact surface.

6. The medical implant of claim 4 in which the resilient material is a polymer.

7. The medical implant of claim 4, wherein the first and second contact surfaces each form a portion of a sphere.

8. The medical implant of claim 1, wherein a selected one of the first and second contact surfaces includes at least one integrally-formed contact ring protruding therefrom.

9. The medical implant of claim 8, wherein a volume behind the at least one contact ring is hollow.

10. The medical implant of claim 9 wherein a fluid is disposed in the volume behind the at least one contact ring.

11. The medical implant of claim 8 wherein the contact ring includes a relieved, concave portion.

12. The medical implant of claim 1 wherein a selected one of the contact surfaces comprises a relieved concave shape bounded by protruding portions.

13. The medical implant of claim 1 wherein a selected one of the first and second contact surfaces carries a resilient wiper seal which bears against the other one of the contact surfaces.

14. The medical implant of claim 1 wherein a selected one of the first and second contact surfaces carries a resilient wiper seal which bears against the other one of the contact surfaces.

15. A medical implant, comprising:

a first member adapted to be implanted to bone and having a substantially rigid, convex-curved first contact surface;

a second member adapted to be implanted to bone and having a substantially rigid, concave-curved second contact surface riding against the first contact surface;

wherein the second contact is adapted to bend elastically in at least one plane when placed under a preselected operating load.

16. The medical implant of claim 15 wherein a resilient thin film is disposed on at least one of the contact surfaces, the thin film consisting essentially of carbon in a non-crystalline microstructure.

17. The medical implant of claim 15 wherein the contact surfaces are ceramic, metallic, or a combination thereof.

18. The medical implant of claim 15, wherein a resilient material is carried by the second contact surface, and sandwiched between the contact surfaces.

19. The medical implant of claim 18, wherein at least one rigid contact pad, having a surface area substantially less than that of either the first and second contact surfaces, is attached to the second contact surface, and a resilient material is sandwiched between the contact pad and the selected contact surface.

20. The medical implant of claim 18 in which the resilient material is a polymer.

21. The medical implant of claim 15, wherein the second contact surface includes at least one integrally-formed contact ring protruding therefrom.

22. The medical implant of claim 21, wherein a volume behind the at least one contact ring is hollow.

23. The medical implant of claim 22 wherein a fluid is disposed in the volume behind the at least one contact ring.

24. The medical implant of claim 21 wherein the contact ring includes a relieved, concave portion.

25. The medical implant of claim 15 wherein the second contact surface comprises a relieved concave shape bounded by protruding portions.

26. The medical implant of claim 15 wherein a selected one of the first and second contact surfaces carries a resilient wiper seal which bears against the other one of the contact surfaces.

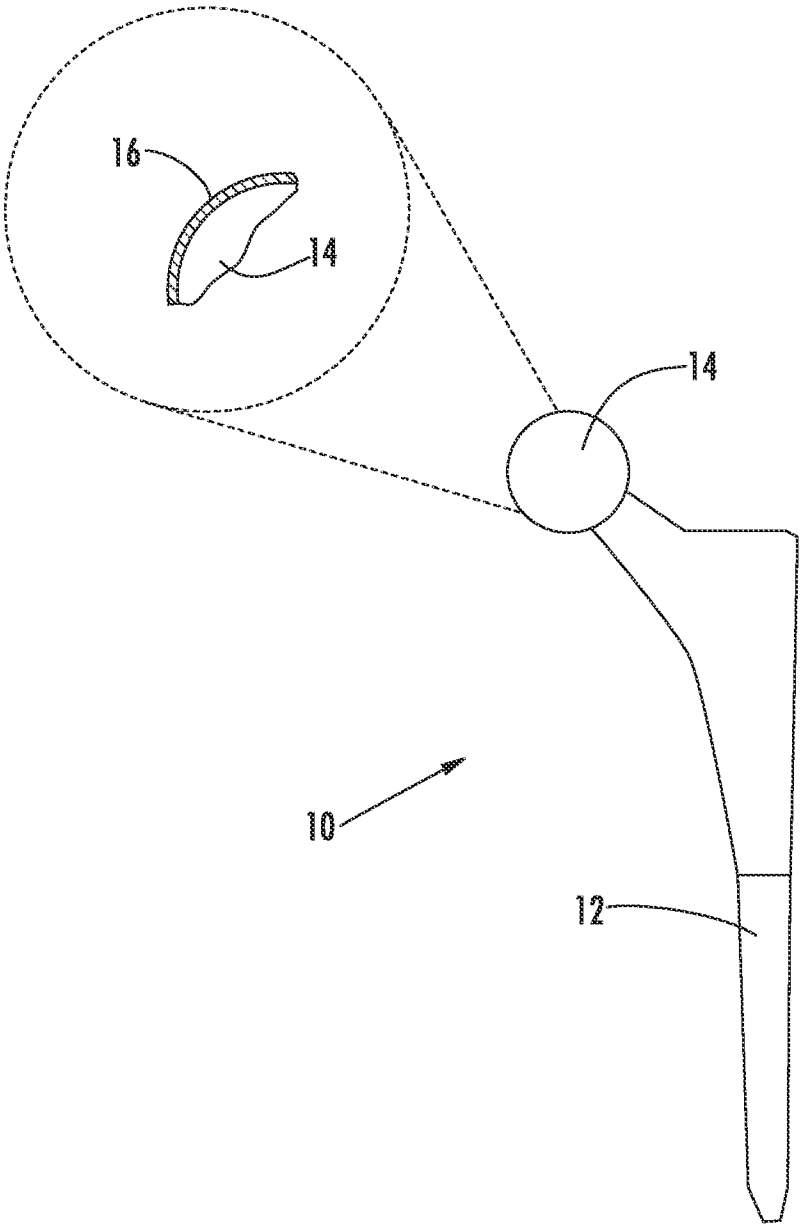


FIG. 1

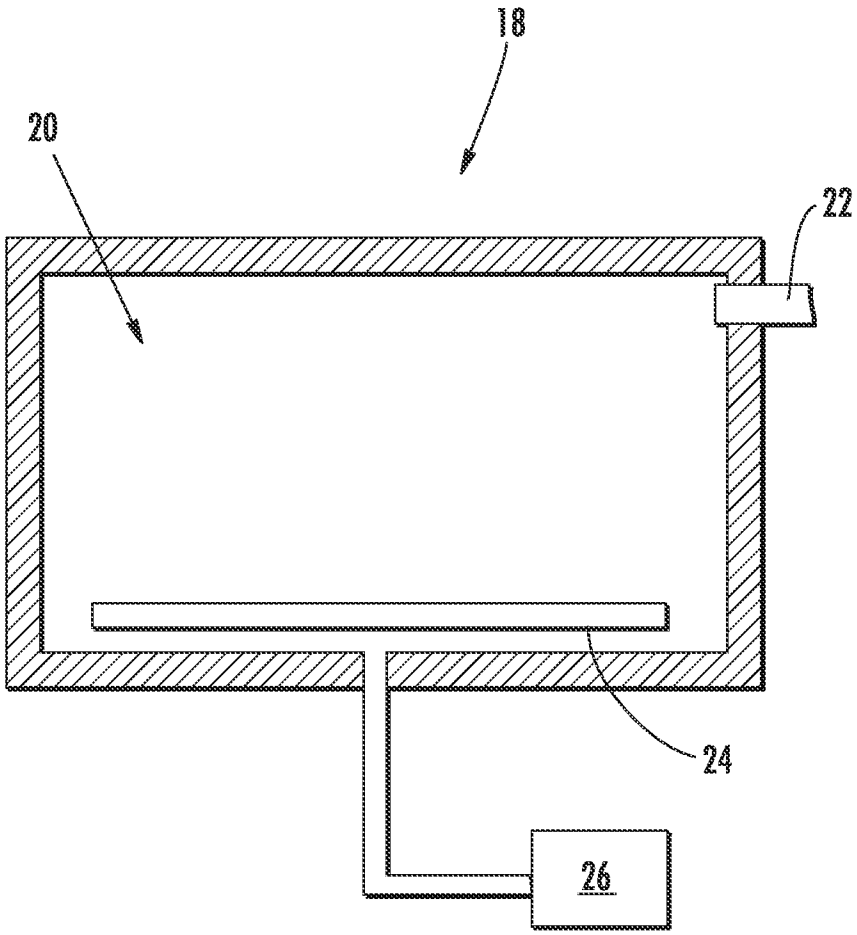


FIG. 2

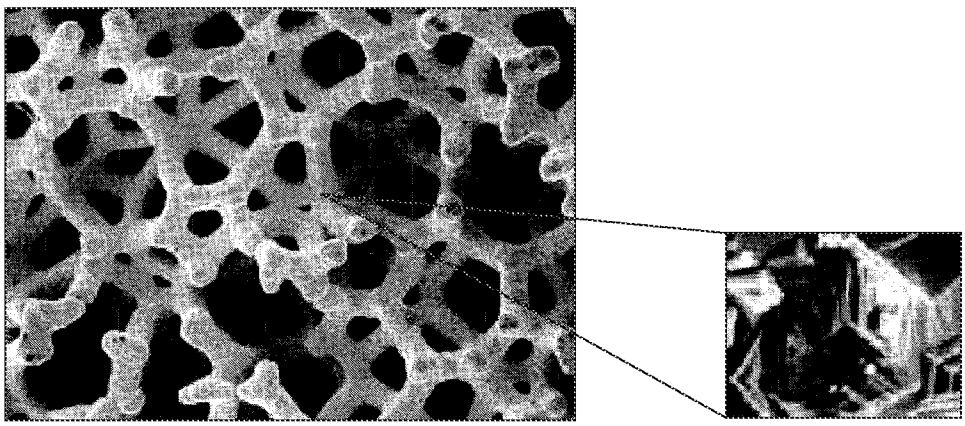


FIG. 3

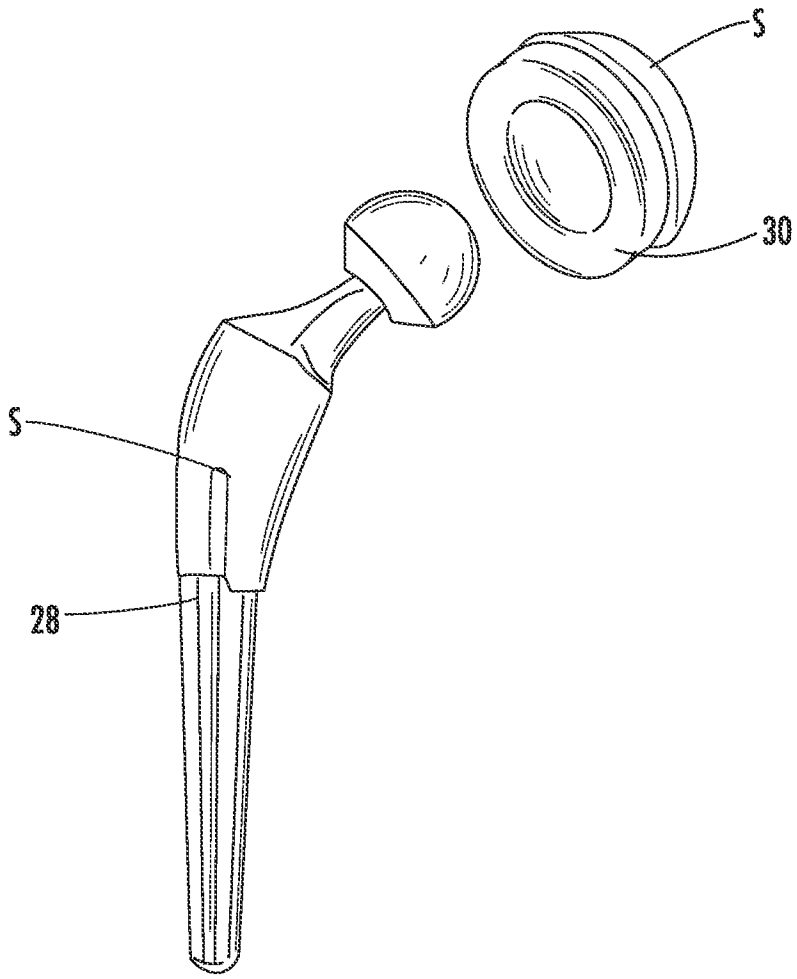


FIG. 4

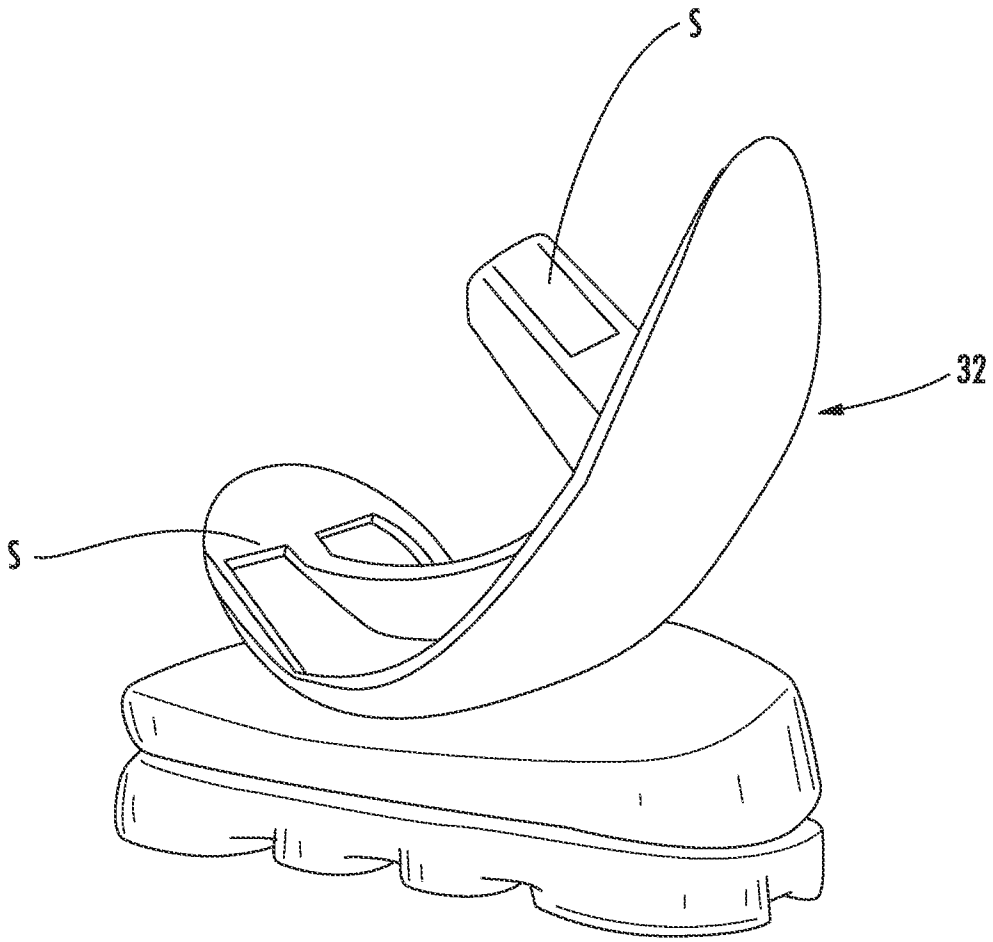


FIG. 5

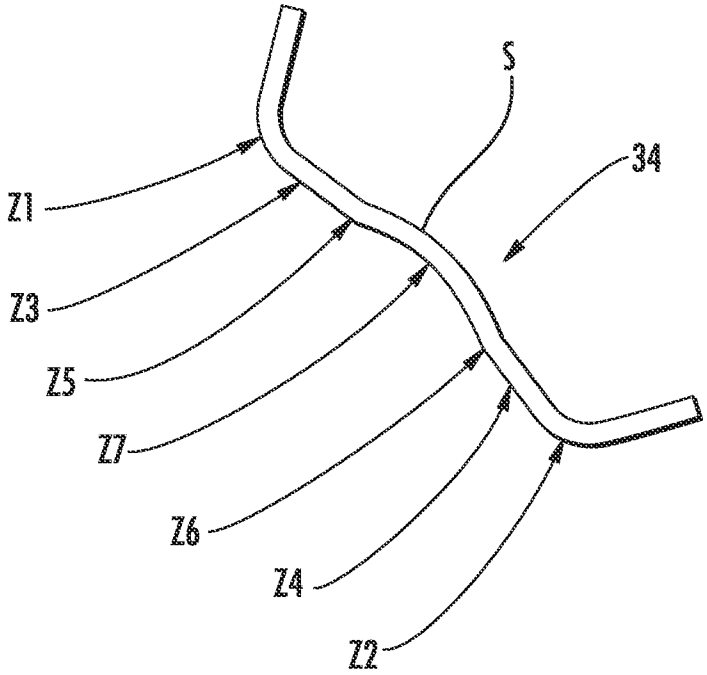


FIG. 6

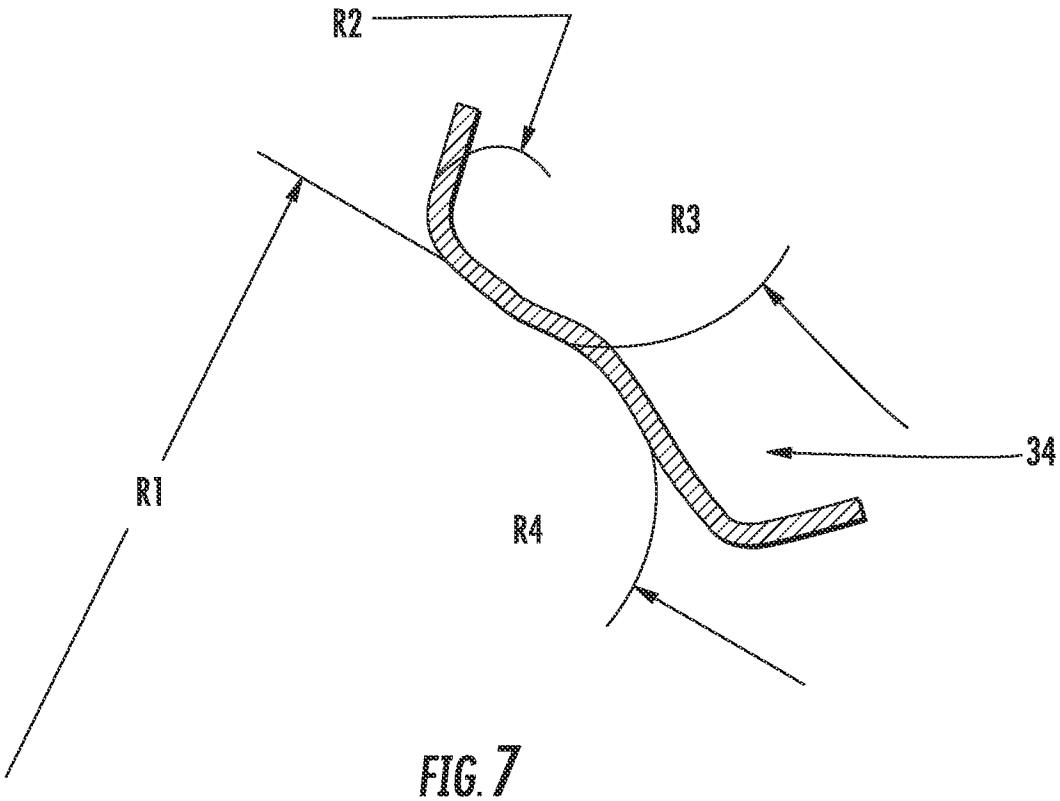


FIG. 7

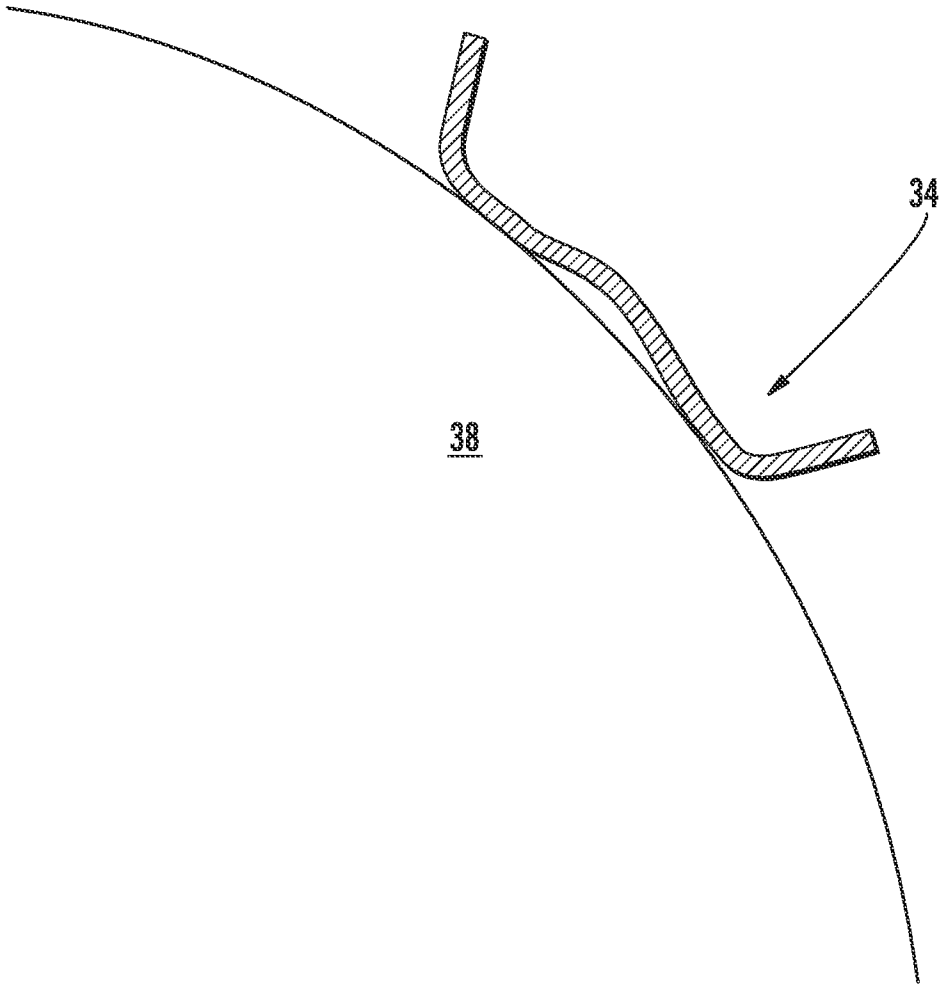


FIG. 8

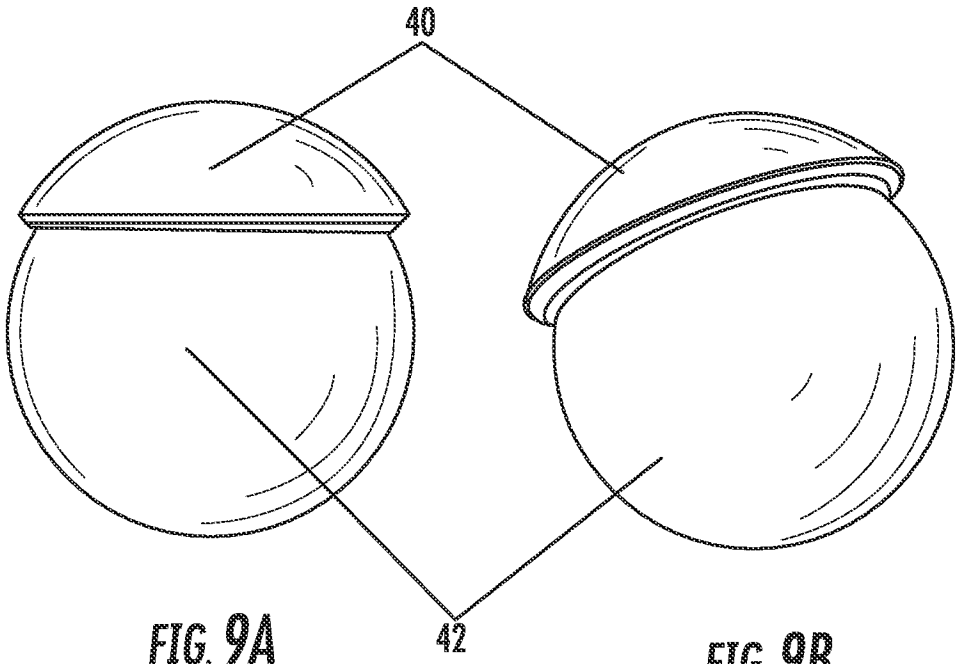


FIG. 9A

FIG. 9B

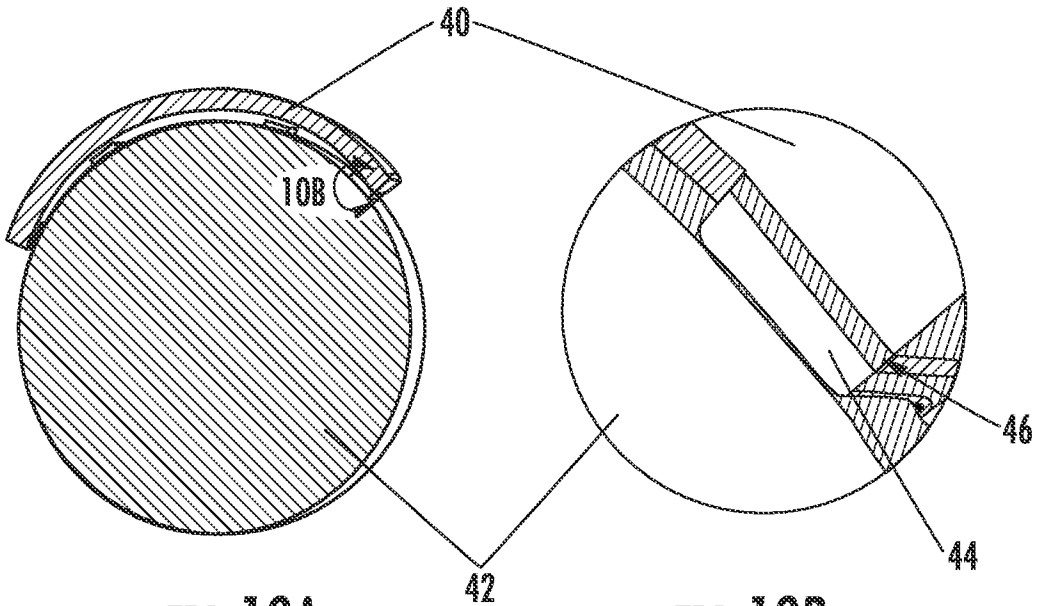


FIG. 10A

FIG. 10B

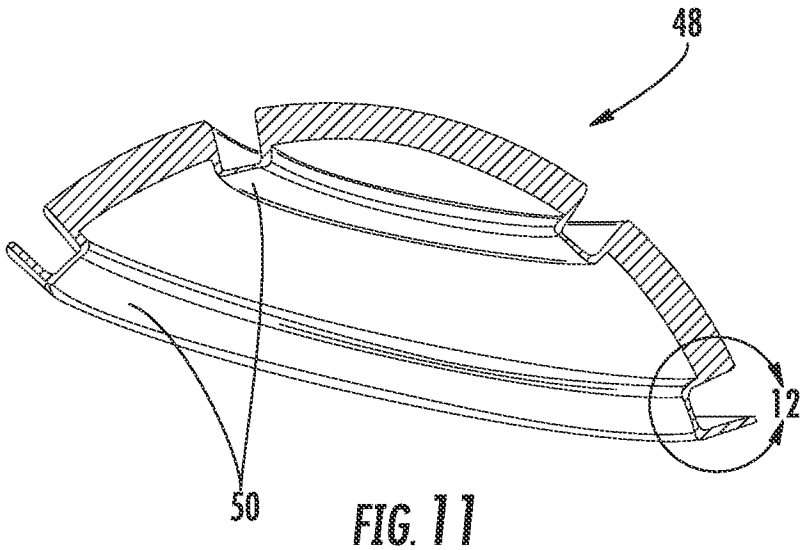


FIG. 11

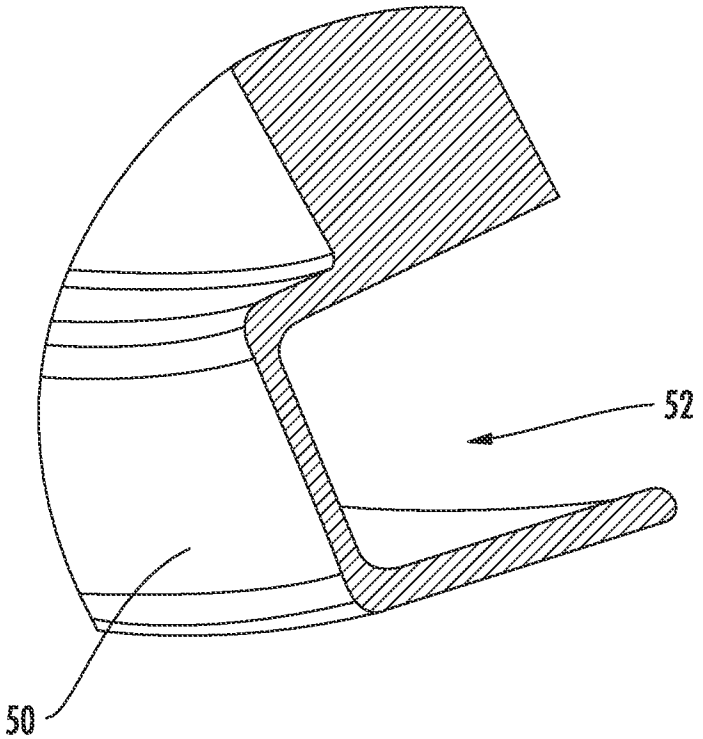


FIG. 12

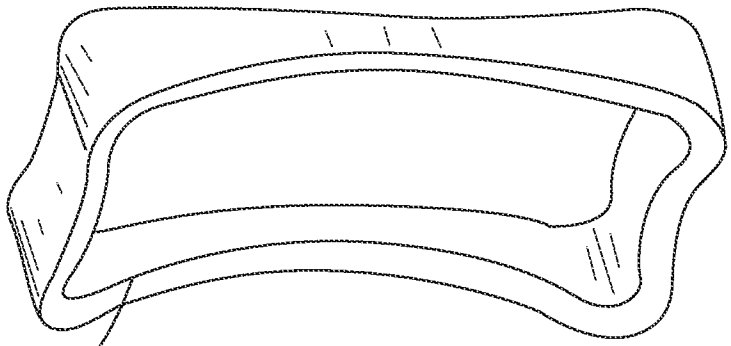


FIG. 13

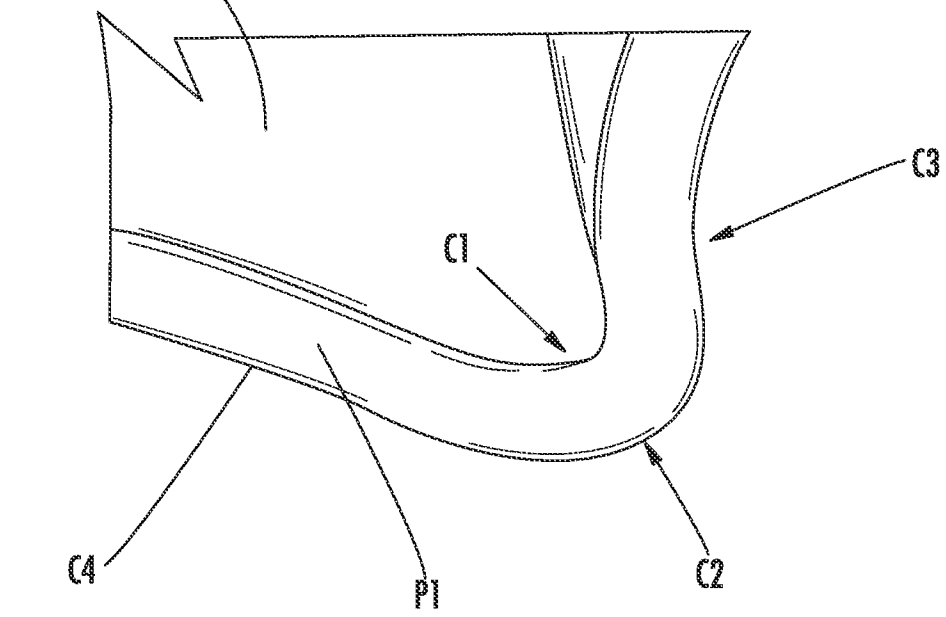


FIG. 14

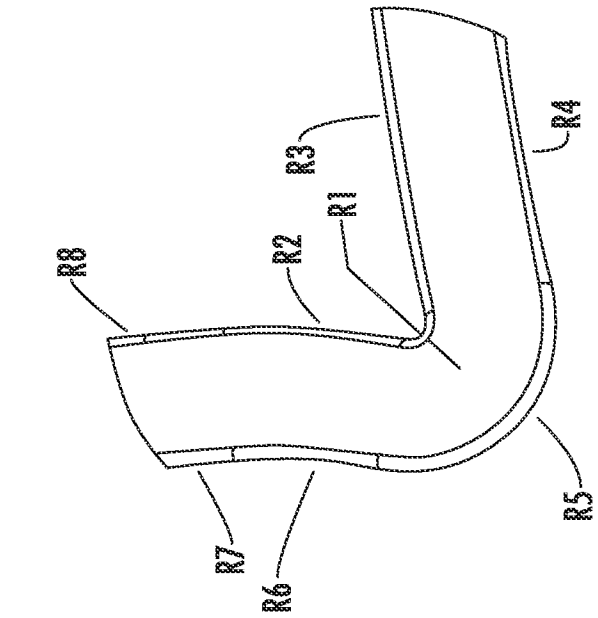


FIG. 15B

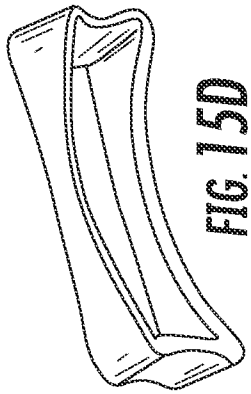
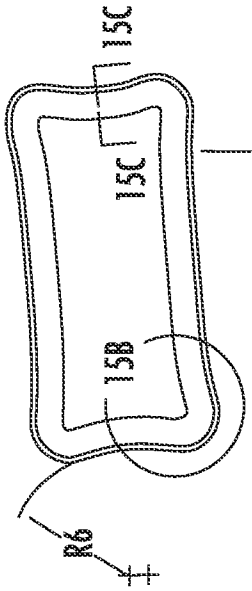


FIG. 15D



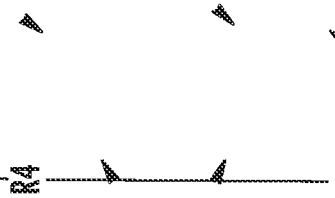


FIG. 15A

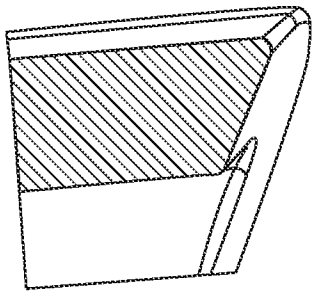


FIG. 15C

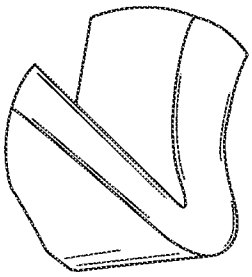


FIG. 16C

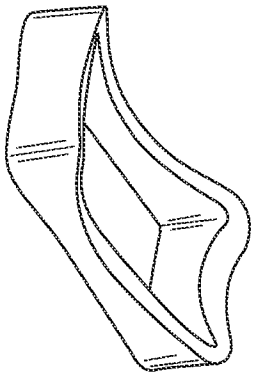


FIG. 16F

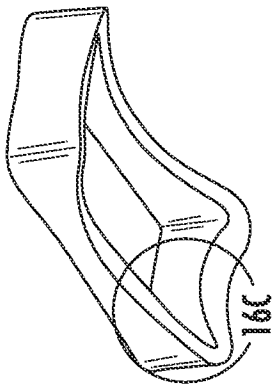


FIG. 16B

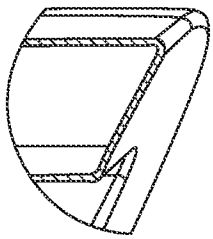


FIG. 16E

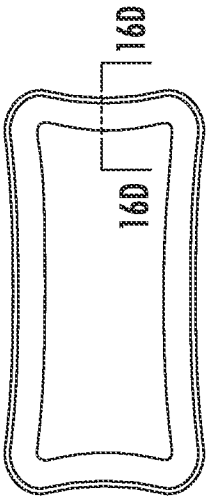


FIG. 16A

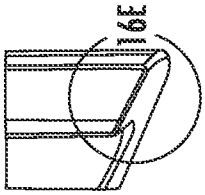


FIG. 16D

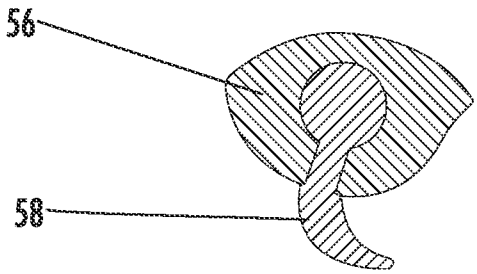


FIG. 17

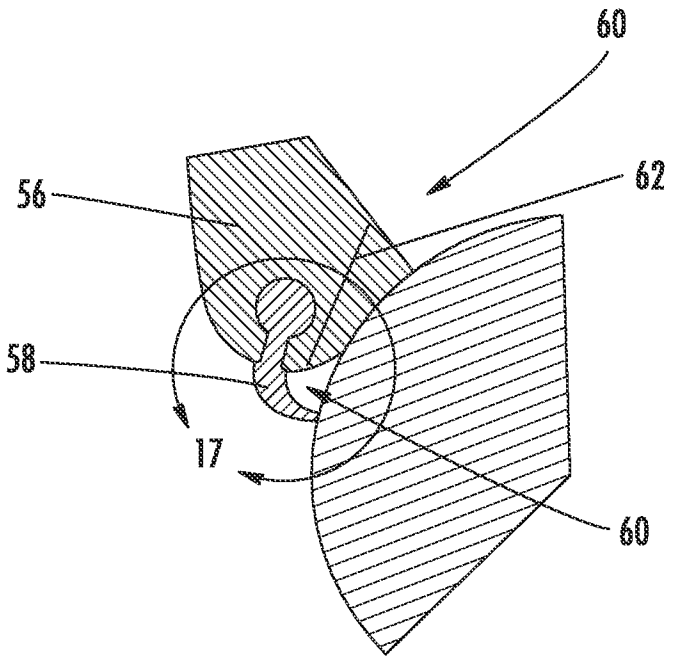


FIG. 18

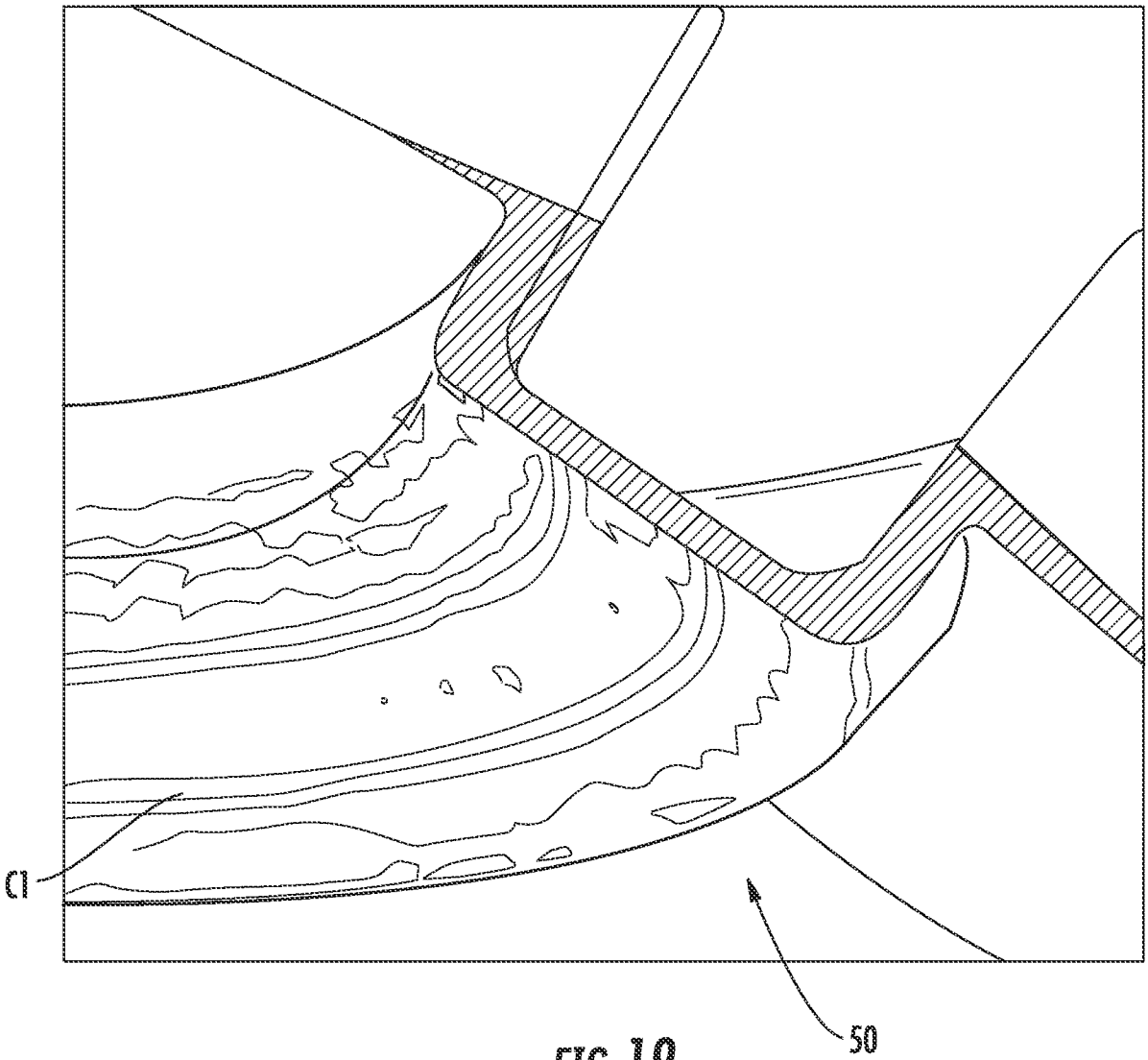


FIG. 19

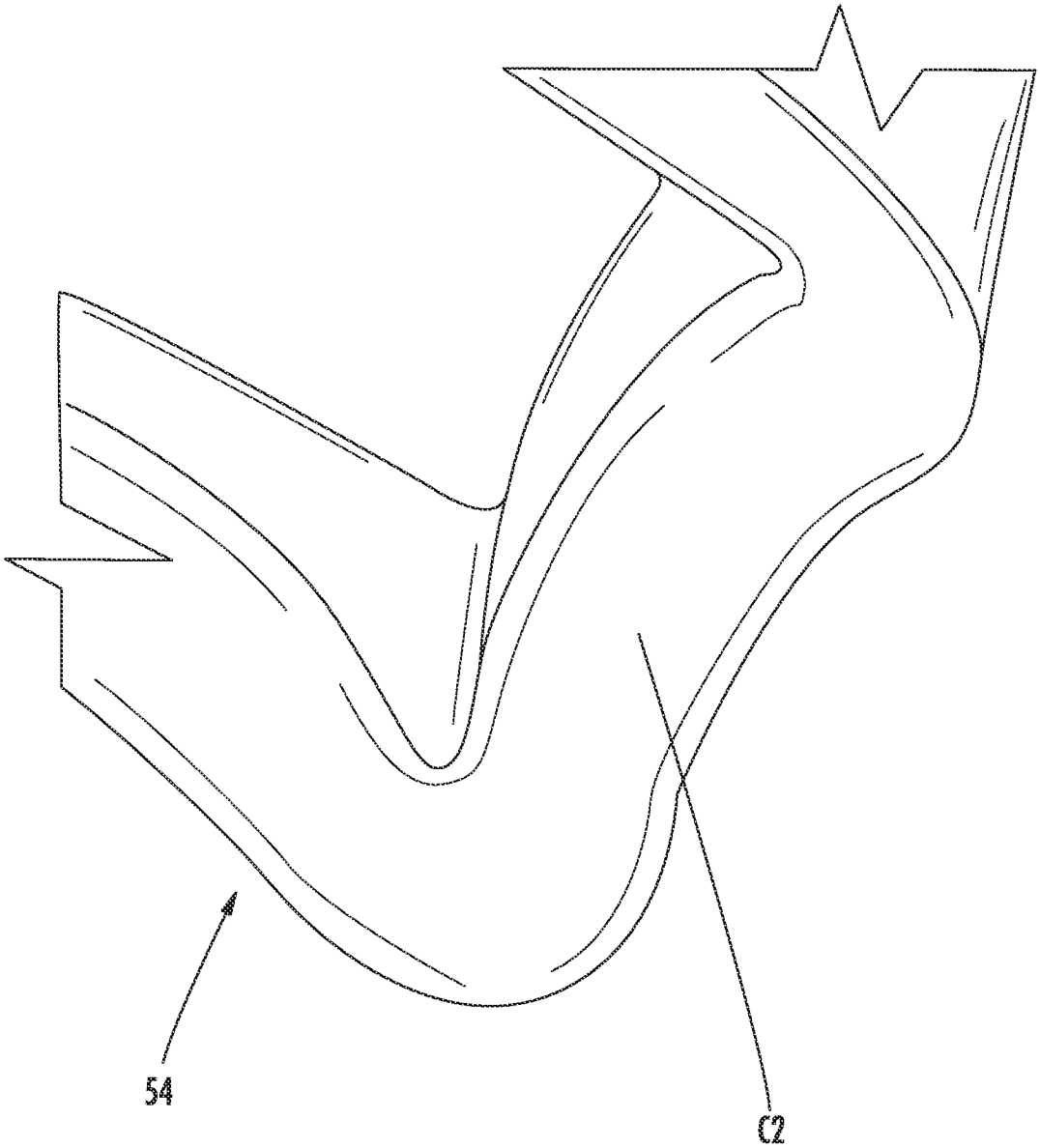


FIG. 20

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2007/083965

A. CLASSIFICATION OF SUBJECT MATTER

A61F 2/28(2006.01)i, A61F 2/30(2006.01)i

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 8: A61F 2/28, A61F 2/ 30, A61F 2/32, A61F 2/34, A61F 2/40

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

eKIPASS(KIPO internal), USPTO, ScienceDirect (implant, resilient, artificial, joint, and similar terms)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	WO 03/049649 A1 (KIM, S.) 19 JUNE 2003 See Claims 1-23, Figs. 2-5.	1,3,4,7,12,15,17,18,25 2, 6, 16, 20
Y	EP 1,508,315 A2 (STEINBERG, A.) 23 FEBRUARY 2005 See Abstract, paragraphs [0065] - [0069].	2, 6, 16, 20
A	US 7,108,719 B2 (HORBER, W.) 19 SEPTEMBER 2006 See Claim 8.	1-26
A	US 5,061,288 A (UNILINK INC.) 29 OCTOBER 1991 See Claims 12 & 18, Fig. 1.	1-26
A	US 5,549,695 A (SULZER MEDIZINALTECHNIC AG.) 27 AUGUST 1996 See Abstract, Claim 4.	1-26

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

☒ See patent family annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
06 MARCH 2008 (06.03.2008)	**06 MARCH 2008 (06.03.2008)**

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JEONG, JAE CHEOL

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/US2007/083965

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