(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
6 August 2009 (06.08.2009)

PCT

(10) International Publication Number
WO 2009/097347 A1

(51) International Patent Classification:
A61F 2/12 (2006.01)

(21) International Application Number:
PCT/US2009/032259

(22) International Filing Date: 28 January 2009 (28.01.2009)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

12/024,843	1 February 2008 (01.02.2008)	US
12/024,826	1 February 2008 (01.02.2008)	US
12/024,835	1 February 2008 (01.02.2008)	US
12/024,846	1 February 2008 (01.02.2008)	US

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(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),

[Continued on next page]

(54) Title: BREAST IMPLANT WITH INTERNAL FLOW DAMPENING

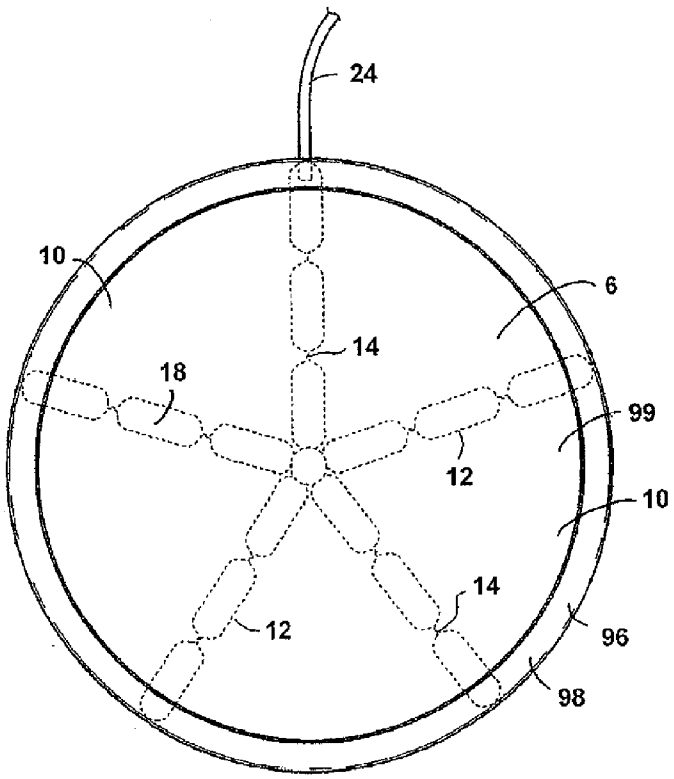


FIG 2

(57) Abstract: An implantable prosthesis (2) is provided having a membrane (4) which holds a flowable substance. The membrane (4) is separated into a first chamber and a second chamber with the first and second chambers being fluidly coupled via an orifice (14). The orifice (14) has a size which may be adjusted by the user after implanting the prosthesis (2) into the patient.

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European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*

BREAST IMPLANT WITH INTERNAL FLOW DAMPENING

BACKGROUND OF THE INVENTION

[0001] The present invention is directed to an implantable prosthesis which may be used anywhere in the body such as the breast.

[0002] An implant provides support for the surrounding body tissue and occupies voids created by the removal of tissue to preserve the normal outward appearance and feel of the body. Prosthetic devices have also been used to enhance or augment the appearance of body parts.

[0003] Breast prostheses have long been used for breast augmentation and for reconstruction such as following a mastectomy. The prostheses are available in numerous sizes and shapes including teardrop, round and low profile. Usually, breast prostheses are implanted via a small inframammary or pari-aerolar incision into a pocket dissected deep into the patient's own breast tissue in front of the pectoral muscle. In certain situations, the prosthesis may be placed behind the various chest muscles.

[0004] Some prosthetic devices have utilized an outer shell or envelope which is filled with a flowable substance such as silicone gel or saline. These prior art devices have tactile properties similar to normal tissue but suffer from certain disadvantages. Saline filled prosthetic devices can lack the proper appearance and tactile properties of normal tissue. Saline displaces relatively quickly and can create a fluid wave in the implant which presents an unnatural look and an audible sound. Saline filled implants also lack form stability which may result in the implant folding over itself or visible wrinkling.

[0005] The object of the present invention is to overcome some of the drawbacks of the prior art implants. The object of the present invention is to construct a surgically implantable prosthetic device which may be filled with saline and/or other fluids and which has desirable tactile appearance and other characteristics.

SUMMARY OF THE INVENTION

[0006] The implantable prosthesis of the present invention includes a membrane and an open cell structure contained within the membrane. The open cell

structure dampens fluid motion within the membrane to reduce some of the problems with prior art devices as described above.

[0007] In one aspect of the invention, the implantable prosthesis has an orifice of adjustable size. The orifice provides fluid communication between a first chamber and a second chamber in the membrane. The size of the orifice may be adjusted after implantation of the prosthesis using a control element.

[0008] In another aspect of the present invention, an implantable prosthesis is provided which has a tension element extending between two locations on the membrane. The tension on the tension element may be altered before or after introduction of the prosthesis into the patient. The tension element may extend through a seal which permits tensioning of the tension element while preventing the flowable substance from leaking out of the membrane.

[0009] In a further aspect of the present invention, the open-cell structure may have a plurality of voids which are substantially larger than the cells of the open-cell structure. The voids may be symmetrically positioned relative to an axis of symmetry in the membrane.

[0010] In still another aspect of the present invention, the open cell structure may have a natural, unbiased shape which is larger than the membrane. The open cell structure is compressed and positioned within the membrane so that the membrane holds the open cell structure in a collapsed shape.

[0011] The open cell structure may also include a channel extending along an outer surface of the open cell structure and adjacent to the inner surface of the membrane. The channel enhances fluid flow in this region and, in particular, in the area between the membrane and the open cell structure. The channels may be oriented radially with respect to an apex of the membrane, circumferentially or in any other suitable manner.

[0012] A plurality of spacers may also be used between the open cell structure and the membrane. The spacers provide an area between the membrane and the open cell structure which enhances fluid flow in the area between the membrane and open cell structure. The spacers may be attached to the external surface of the open cell structure or to the inner surface of the membrane.

[0013] The open cell structure may be selectively attached to the membrane at discrete locations which are separated by areas where the open cell structure is free to slide against the inner surface of the membrane. The attachments may be along the

anterior wall and/or posterior wall so that portions of the anterior and/or posterior wall are free of attachments to the open cell structure. The attachments may be along a continuous strip of the membrane which, for example, forms a loops that encircles the apex of the membrane.

[0014] The implantable prosthesis of the present invention includes a membrane and an open cell structure contained within the membrane. The open cell structure dampens fluid motion within the membrane to reduce some of the problems with prior art devices as described above.

[0015] In one aspect of the invention, the implantable prosthesis has an orifice of adjustable size. The orifice provides fluid communication between a first chamber and a second chamber in the membrane. The size of the orifice may be adjusted after implantation of the prosthesis using a control element.

[0016] In another aspect of the present invention, an implantable prosthesis is provided which has a tension element extending between two locations on the membrane. The tension on the tension element may be altered before or after introduction of the prosthesis into the patient. The tension element may extend through a seal which permits tensioning of the tension element while preventing the flowable substance from leaking out of the membrane.

[0017] In a further aspect of the present invention, the open-cell structure may have a plurality of voids which are substantially larger than the cells of the open-cell structure. The voids may be symmetrically positioned relative to an axis of symmetry in the membrane.

[0018] In still another aspect of the present invention, the open cell structure may have a natural, unbiased shape which is larger than the membrane. The open cell structure is compressed and positioned within the membrane so that the membrane holds the open cell structure in a collapsed shape.

[0019] The open cell structure may also include a channel extending along an outer surface of the open cell structure and adjacent to the inner surface of the membrane. The channel enhances fluid flow in this region and, in particular, in the area between the membrane and the open cell structure. The channels may be oriented radially with respect to an apex of the membrane, circumferentially or in any other suitable manner.

[0020] A plurality of spacers may also be used between the open cell structure and the membrane. The spacers provide an area between the membrane and the open cell

structure which enhances fluid flow in the area between the membrane and open cell structure. The spacers may be attached to the external surface of the open cell structure or to the inner surface of the membrane.

[0021] The open cell structure may be selectively attached to the membrane at discrete locations which are separated by areas where the open cell structure is free to slide against the inner surface of the membrane. The attachments may be along the anterior wall and/or posterior wall so that portions of the anterior and/or posterior wall are free of attachments to the open cell structure. The attachments may be along a continuous strip of the membrane which, for example, forms a loops that encircles the apex of the membrane.

[0022] The implantable prosthesis of the present invention includes a membrane and an open cell structure contained within the membrane. The open cell structure dampens fluid motion within the membrane to reduce some of the problems with prior art devices as described above.

[0023] In one aspect of the invention, the implantable prosthesis has an orifice of adjustable size. The orifice provides fluid communication between a first chamber and a second chamber in the membrane. The size of the orifice may be adjusted after implantation of the prosthesis using a control element.

[0024] In another aspect of the present invention, an implantable prosthesis is provided which has a tension element extending between two locations on the membrane. The tension on the tension element may be altered before or after introduction of the prosthesis into the patient. The tension element may extend through a seal which permits tensioning of the tension element while preventing the flowable substance from leaking out of the membrane.

[0025] In a further aspect of the present invention, the open-cell structure may have a plurality of voids which are substantially larger than the cells of the open-cell structure. The voids may be symmetrically positioned relative to an axis of symmetry in the membrane.

[0026] In still another aspect of the present invention, the open cell structure may have a natural, unbiased shape which is larger than the membrane. The open cell structure is compressed and positioned within the membrane so that the membrane holds the open cell structure in a collapsed shape.

[0027] The open cell structure may also include a channel extending along an outer surface of the open cell structure and adjacent to the inner surface of the membrane. The channel enhances fluid flow in this region and, in particular, in the area between the membrane and the open cell structure. The channels may be oriented radially with respect to an apex of the membrane, circumferentially or in any other suitable manner.

[0028] A plurality of spacers may also be used between the open cell structure and the membrane. The spacers provide an area between the membrane and the open cell structure which enhances fluid flow in the area between the membrane and open cell structure. The spacers may be attached to the external surface of the open cell structure or to the inner surface of the membrane.

[0029] The open cell structure may be selectively attached to the membrane at discrete locations which are separated by areas where the open cell structure is free to slide against the inner surface of the membrane. The attachments may be along the anterior wall and/or posterior wall so that portions of the anterior and/or posterior wall are free of attachments to the open cell structure. The attachments may be along a continuous strip of the membrane which, for example, forms a loops that encircles the apex of the membrane

[0030] The implantable prosthesis of the present invention includes a membrane and an open cell structure contained within the membrane. The open cell structure dampens fluid motion within the membrane to reduce some of the problems with prior art devices as described above.

[0031] In one aspect of the invention, the implantable prosthesis has an orifice of adjustable size. The orifice provides fluid communication between a first chamber and a second chamber in the membrane. The size of the orifice may be adjusted after implantation of the prosthesis using a control element.

[0032] In another aspect of the present invention, an implantable prosthesis is provided which has a tension element extending between two locations on the membrane. The tension on the tension element may be altered before or after introduction of the prosthesis into the patient. The tension element may extend through a seal which permits tensioning of the tension element while preventing the flowable substance from leaking out of the membrane.

[0033] In a further aspect of the present invention, the open-cell structure may have a plurality of voids which are substantially larger than the cells of the open-cell

structure. The voids may be symmetrically positioned relative to an axis of symmetry in the membrane.

[0034] In still another aspect of the present invention, the open cell structure may have a natural, unbiased shape which is larger than the membrane. The open cell structure is compressed and positioned within the membrane so that the membrane holds the open cell structure in a collapsed shape.

[0035] The open cell structure may also include a channel extending along an outer surface of the open cell structure and adjacent to the inner surface of the membrane. The channel enhances fluid flow in this region and, in particular, in the area between the membrane and the open cell structure. The channels may be oriented radially with respect to an apex of the membrane, circumferentially or in any other suitable manner.

[0036] A plurality of spacers may also be used between the open cell structure and the membrane. The spacers provide an area between the membrane and the open cell structure which enhances fluid flow in the area between the membrane and open cell structure. The spacers may be attached to the external surface of the open cell structure or to the inner surface of the membrane.

[0037] The open cell structure may be selectively attached to the membrane at discrete locations which are separated by areas where the open cell structure is free to slide against the inner surface of the membrane. The attachments may be along the anterior wall and/or posterior wall so that portions of the anterior and/or posterior wall are free of attachments to the open cell structure. The attachments may be along a continuous strip of the membrane which, for example, forms a loops that encircles the apex of the membrane.

[0038] These and other features of the present invention will become apparent from the following description of the preferred embodiments.

BRIEF DESCRIPTION OF THE DRAWINGS

[0039] Fig. 1 shows an implantable prosthesis.

[0040] Fig. 2 is a top view of the implantable prosthesis of Fig. 1.

[0041] Fig. 3 shows an internal wall having an orifice.

[0042] Fig. 4 shows the internal wall in an expanded shape which reduces the size of the orifice.

[0043] Fig. 5 shows the internal wall separated from the rest of the prosthesis.

[0044] Fig. 6 shows the internal wall expanded to collapse the orifice.

[0045] Fig. 7 shows another implantable prosthesis having tension elements which may be selectively tensioned by the user.

[0046] Fig. 8 shows a plan view of the prosthesis of Fig. 7.

[0047] Fig. 9 shows another implantable prosthesis having tension members.

[0048] Fig. 10 shows a plan view of the prosthesis of Fig. 9.

[0049] Fig. 11 shows another implantable prosthesis having a chamber which may be filled or evacuated.

[0050] Fig. 12 shows the chamber of Fig. 11 expanded.

[0051] Fig. 13 is a plan view of the implantable prosthesis of Fig. 12.

[0052] Fig. 14 shows another implantable prosthesis.

[0053] Fig. 15 is a plan view of the implantable prosthesis of Fig. 14.

[0054] Fig. 16 shows an open cell structure.

[0055] Fig. 17 shows a membrane which is smaller than the open cell structure of Fig. 16.

[0056] Fig. 18 shows another implantable prosthesis.

[0057] Fig. 19 is a plan view of the implantable prosthesis of Fig. 18.

[0058] Fig. 20 shows still another implantable prosthesis having radially oriented channels.

[0059] Fig. 21 is a plan view of the implantable prosthesis of Fig. 20.

[0060] Fig. 22 shows another implantable prosthesis having circumferential channels.

[0061] Fig. 23 is a plan view of the implantable prosthesis of Fig. 22.

[0062] Fig. 24 shows still another implantable prosthesis with a circumferential channel.

[0063] Fig. 25 is a plan view of the implantable prosthesis of Fig. 24.

[0064] Fig. 26 shows another implantable prosthesis with a selective number of discrete attachments along the posterior and anterior walls.

[0065] Fig. 27 is a plan view of the prosthesis of Fig. 26.

[0066] Fig. 28 shows an implantable prosthesis which is attached to the membrane along two circular strips.

[0067] Fig. 29 is a plan view of the prosthesis of Fig. 28.

[0068] Fig. 30 shows a plurality of spacers positioned between the membrane and the open cell structure.

[0069] Fig. 31 shows another embodiment having a plurality of spacers.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

[0070] Referring to Figs. 1-6, an implantable prosthesis 2 is shown. The prosthesis 2 includes a membrane 4 which may be made formed in any suitable manner. The membrane 4 contains a flowable substance 6 such as silicone gel, saline or any other suitable substance. The flowable substance 6 may also include elements (not shown), such as beads or spheres, which are suspended in the flowable substance 6 without departing from the scope of the invention. Any of the embodiments disclosed herein may incorporate features, structures and materials disclosed in U.S. Patent Application Serial No. 11/316,215 to Michael Lesh, entitled Tissue Augmentation Device filed December 22, 2005, the disclosure of which is incorporated in its entirety herein by reference. The present application is related to U.S. Patent App. Nos. 12/024,835; 12/024,826; 12/024,846; and 12/024,843, all filed on February 1, 2008 and incorporated by reference in their entireties.

[0071] The membrane 4 is divided into a number of chambers 10 separated by walls 12. The walls 12 each have one or more orifices 14 which have a size which may be adjusted. Changing the size of the orifices 14 in the walls 12 alters the flow characteristics of the prosthesis 2 in that a smaller orifice 14 will provide a slower flow rate of the flowable substance 6 between the chambers 10. The chambers 10 may also be filled with a substance which further reduces the flow rate of fluid such as an open-cell structure which may be a matrix of material, a sponge, a foam or any other suitable open-cell structure which reduces the flow rate of fluid within the membrane 4 as described below in connection with other preferred embodiments.

[0072] The walls 12 include an inflatable element 18 which is inflated or deflated to change the size of the orifice 14. The inflatable element 18 may be formed by bonding two sheets of material 22 together to form the wall 12. The sheets 22 are bonded together around the orifices 14 and a hole is cut to form the orifice 14. Inflation of the space between the sheets 22 causes the inflatable element to expand thereby reducing the size of the orifice 14. A control element 24 is releasably coupled to the membrane 4 and

is configured to extend out of the patient after the membrane 4 has been implanted into the patient. The control element 24 permits the user to change the size of the orifice 14 after introducing the prosthesis 2 into the patient. The control element 24 has a lumen coupled to a source of fluid (not shown) and may be provided with a releasable connection to the membrane 4 in any suitable manner. Although the control element 24 is configured to hydraulically alter the size of the orifice 14, the control element 24 may accomplish the change in orifice 14 size using any other method such as mechanical or electrical. For example, the size of the orifice 14 could be modified using a suture which cinches the orifice 14 to reduce the size of the orifice 14.

[0073] Referring to Figs. 7 and 8, another implantable prosthesis 30 is shown. The prosthesis 30 includes a membrane 32 which holds the flowable substance 6. The membrane 32 may be filled with an open-cell structure 34 as described above. The prosthesis 30 also includes one or more tension elements 36 which extend between two portions of the wall of the membrane 32 to help maintain a more stable shape. The tension elements 36 may extend through a valve 38 in the prosthesis 30 which permits the tension element 36 to slide therethrough while still maintaining a fluid tight seal. The tension element 36 is coupled to a control element 40 which may simply be a portion of the tension element 36 which extends out of the prosthesis 30. The tension elements 36 may extend from a posterior wall 42 to an anterior wall 44 of the membrane 32 but may, of course, be coupled to other parts of the membrane 32 as well.

[0074] The control element 40 is configured to extend out of the patient when the prosthesis 30 is implanted so that the user may adjust tension on the tension element 36 after implantation. Tension may be applied to one or more of the tension elements 36 to create a desirable texture and feel to the prosthesis 30. After the desired tension has been applied, the control element 40 may be removed by simply cutting the control element 40 or releasing the control element 40 using any other suitable method. A locking element 43 is coupled to the membrane 32 which automatically secures the tension element 36 after tension has been increased with the control element 40. The control element 40 may, of course, be manipulated prior to implantation of the prosthesis 30.

[0075] Referring to Figs. 9 and 10, still another implantable prosthesis 50 is shown. The prosthesis 50 includes a membrane 52 which holds the flowable substance 6. The membrane 52 may also contain an open-cell structure 56 which dampens fluid motion

although the invention may be practiced without the open-cell structure 56. A plurality of tension members 58 extend through the open-cell structure 56 and are attached to the membrane 52 at both ends. The membrane 52 may have a round posterior wall 60 which is symmetrical about an axis of symmetry 62. The tension members 58 may extend from one side of the membrane 52 to a diametrically opposed side of the membrane 52. The tension members 58 may also be symmetrically arranged relative to the axis of symmetry 62 and may be coupled together at a junction 64 so that tension is distributed among the tension members 58.

[0076] Referring to Figs. 11-13, yet another implantable prosthesis 70 is shown. The prosthesis 70 includes a membrane 72 having a first chamber 74, a second chamber 76 and a third chamber 78. The chambers 74, 76, 78 may be filled with an open-cell structure 80. The second chamber 76 is fluidly isolated from the first and third chambers 74, 78 and may be filled using a removable fill line 82. The second chamber 76 may be filled or evacuated as desired before or after the prosthesis 70 has been implanted into a patient. The second chamber 76 is positioned between the first and third chambers 74, 78 and may generally lie in a plane but may be oriented in any other suitable manner. The first and third chambers 74. 78 may be fluidly isolated from one another or may be fluidly coupled together.

[0077] Referring to Figs. 14 and 15, another implantable prosthesis 84 is shown. The prosthesis includes a membrane 86 filled with the flowable substance 6. The prosthesis 84 also includes an open-cell structure 90 which dampens fluid motion and helps to maintain a desired shape. The open-cell structure 90 includes a plurality of voids 92 which are substantially larger than an average cell size in the open-cell structure 90. The membrane 86 may be symmetrical about an axis of symmetry 91 which is centrally located relative to a round posterior wall 94. The round posterior wall 94 and symmetrical shape permit the user to implant the device without requiring a particular orientation when implanted. The voids 92 are preferably symmetrically positioned relative to the axis of symmetry 91. The voids 92 may be elongate channels 96 cut into the open-cell structure 90 which extend from the posterior wall 94 to an anterior wall 95 of the prosthesis 84.

[0078] Referring again to Figs. 1 and 9, a cover 96 may be used to cover a portion of an outer surface 99 of the membrane 4 and may be used with any of the implants described herein. The cover 96 may be a strip 98 of expanded PTFE which

extends over, and essentially parallel to, an area commonly referred to as the waist 100. The waist 100 is generally defined as a radially outer portion of the membrane 52 when the membrane 52 is supported by the posterior wall 60 as shown in Fig. 9. The cover 96 is positioned so that at least 80% of the ePTFE is positioned no more than 1 cm from the waist 100. Positioning the ePTFE cover 96 in this manner provides the advantages of ePTFE, such as the promotion of in-growth, without the high cost of covering the entire implant with ePTFE as has been suggested by some prior art devices. Of course, numerous aspects of the present invention may be practiced without the cover 96 or with the cover 96 extending around the entire outer surface or a substantial portion thereof without departing from those aspects of the invention.

[0079] The cover 96 may be applied to the membrane 52 in the following manner when using the strip 98 of ePTFE. The membrane 52 is held at two spaced-apart locations 103, 105 along the waist 100 and the membrane 52 is stretched to increase the space between these locations. The membrane 52 may be held by a curved work element which supports the curved shape of the membrane when the membrane 52 is stretched. The strip 98 is then attached to the membrane at both locations 103, 105 and the membrane 52 is then released to release tension on the membrane 52. This process may be repeated until the entire waist 100 is covered by the strip 98. In one embodiment, the strip 98 is attached at 6-10 locations around the periphery of the waist 100.

[0080] Referring now to Figs. 16 and 17, still another aspect of the present invention is shown. An open cell structure 102 is provided which has a natural, unbiased shape which is larger than membrane 104. The open cell structure 102 is compressed within the membrane 104 which holds the open cell structure 102 in a compressed state. The open cell structure 102 may occupy a volume when in the natural unbiased shape which is 5% to 20% larger than the volume of the membrane 104.

[0081] The open cell structure 102 may be larger than the membrane 104 in all dimensions or may be selectively larger in one or more dimensions. For example, the open cell structure 100 may have a height H which is 5% to 20% larger than a maximum dimension between an anterior wall 106 and a posterior wall 108. The open cell structure 102 may also have a width W which is 5% to 20% larger than a maximum outer dimension or diameter of the posterior wall 108.

[0082] Referring now to Figs. 18-25, an implantable prosthesis 109 is shown which has a membrane 110 and an open cell structure 114 with channels 122 formed in an

outer surface 124 of the open cell structure 114. The membrane 110 includes a posterior wall 116 and an anterior wall 118 having an apex 120. The channels 122 may be positioned adjacent to an inner surface 126 of the membrane 110 so that the flowable substance can flow in a more unrestricted manner in the channels 122 than in the open cell structure 114. The channels 122 may extend radially relative to the apex 120 of the membrane 112 (Figs. 18-21). The channels 120 may intersect one another at the inner surface 126 of the membrane 112 below the apex 120 (Figs. 20 and 21) or may be non-intersecting (Fig. 18 and 19). Referring to Figs. 22 and 23, the channel 122 may also extend circumferentially about the outer surface 124 of the open cell structure 114. The channel 122 may also be positioned adjacent to a waist 128 of the membrane which is a radially outer portion of the membrane 110 near the posterior wall 116 as described above. The channel 122 may also extend around the apex 120 of the membrane 110 at a position nearer to the apex 120 than to the waist 128 as shown in Figs. 24 and 25.

[0083] Referring now to Figs. 26-29, open cell structure 130 may be attached to membrane 132 at a selective number of locations which are separated by portions of the open cell structure 130 which are free to move relative to an inner surface 134 of the membrane 132. Figs. 26 and 27 shows the open cell structure 130 attached to the membrane 132 at four spaced apart locations on anterior wall 136 and posterior wall 138. Figs. 28 and 29 show the open cell structure 130 attached to the membrane 132 along a strip 140 on the anterior wall 136 and along a strip 142 on the posterior wall 138. The strip 136 on the anterior wall 136 may form a closed loop that encircles the apex of the membrane.

[0084] Referring now to Figs. 30 and 31, spacers 144 may also be provided between open cell structure 146 and the membrane 148. The spacers 144 create an area between the membrane 148 and the open cell structure 146 so that the flowable substance may flow in a less restricted manner in this area as compared to within the open cell structure 146. The spacers 144 may be attached to the membrane 148 or to the open cell structure 146 and may be integrally formed with either part. When attached to the open cell structure 146, the spacers 144 are free to slide against an inner surface 150 of the membrane 148. The spacers 144 may be sized and positioned so that less than 20% of an outer surface 152 of the open cell structure 146 is covered by the spacers 144. Stated another way, at least 80% of the outer surface 152 of the open cell structure 146 is free to move relative to the inner surface 150 of the membrane 148. The spacers 144 may be

arranged in a radially oriented fashion (Fig. 30) or in a circumferential pattern (Fig. 31) or any other suitable configuration without departing from the scope of the invention.

[0085] The present invention has been described in connection with various preferred embodiments and it is understood that modifications and alterations of these embodiments may be accomplished while remaining within the scope of the invention as defined by the claims. For example, the implants may be anatomical implants rather than symmetrical implants without departing from the scope of various aspects of the invention. Furthermore, the various aspects of the invention have been described independently but may, of course, be practiced together and such combinations are expressly incorporated. For example, the spacers 144 of Figs. 30 and 31 could be used in combination with the tension elements 36 of Figs. of 7 and 8.

WHAT IS CLAIMED IS:

1. An implantable prosthesis, comprising:

a soft, flexible outer membrane;

a flowable substance contained within the membrane;

an open cell structure positioned inside the membrane, the open cell structure being filled with the flowable substance so that the open cell structure dampens motion of the flowable substance within the membrane.

2. The implantable prosthesis of claim 1, wherein the membrane includes a first chamber and a second chamber and a flow restricting orifice which fluidly couples the first chamber to the second chamber.

3. The implantable prosthesis of claim 2, wherein an adjustable flow restricting orifice which fluidly couples the first chamber to the second chamber, the adjustable flow restricting orifice having a control element which permits the user to change a size of the orifice thereby altering a flow resistance between the first and second chambers.

4. The implantable prosthesis of claim 2, wherein the control element is configured to extend out of the patient when the membrane has been implanted into a patient so that the size of the orifice may be altered after the membrane has been implanted into the patient.

5. The implantable prosthesis, of claim 1, further comprising: a tension element coupled to the membrane at a first location and a second location; and a control element coupled to the tension element, the control element being configured to increase tension on the tension element so that the tension element draws the first and second locations toward one another.

6. The prosthesis of claim 5, wherein the control element is configured to extend out of the patient when the membrane has been implanted into a patient so that tension on the tension element may be altered after the membrane has been implanted into the patient.

7. The prosthesis of claim 5, wherein the membrane has a posterior wall and an anterior wall; and the first location being on the posterior wall and the second location being on the anterior wall.

8. The prosthesis of claim 5, further comprising a plurality of tension elements extending within the membrane, each of the tension elements being configured

to be tensioned independently by the user after introduction of the membrane into the patient.

9. The implantable prosthesis of claim 1, further comprising a plurality of elastic tension elements extending through the open-cell structure coupled to the membrane, each tension element having a first end and a second end which are both attached to the membrane.

10. The implantable prosthesis of claim 9, wherein the membrane has a round posterior wall; and the plurality of tension elements extend from one side of the membrane to a diametrically opposed side relative to the circular posterior wall.

11. The implantable prosthesis of claim 10, wherein the plurality of tension elements are coupled together at a junction which is between the first and second ends of the tension elements.

12. The implantable prosthesis of claim 1, further comprising a plurality of voids in the open-cell structure which are substantially larger than the cells of the open-cell structure.

13. The prosthesis of claim 12, wherein the plurality of voids are organized in a symmetrical pattern relative to the axis of symmetry.

14. The prosthesis of claim 12, wherein the plurality of voids are elongate channels which extend through the open-cell structure.

15. The implantable prosthesis of claim 1, further comprising a cover material;

the membrane having an outer surface, a posterior wall, an anterior wall and a waist, the waist being an outer ring which is positioned between the anterior wall and the posterior wall when the membrane is supported by the posterior wall;

the cover material extending over the membrane and being made of expanded PTFE, wherein at least 80 percent of the expanded ePTFE which covers the membrane is positioned no more than one centimeter from the waist of the membrane.

16. The prosthesis of claim 15, wherein the outer surface of the membrane is exposed to tissue when implanted into the patient except for the portion of the outer surface covered by the cover material.

17. The prosthesis claim 15, wherein the cover material is a strip of expanded PTFE which wraps around the membrane in a direction which is parallel to the waist so that the strip covers the outer surface of the membrane along the waist.

18. The implantable prosthesis of claim 1, wherein the open cell structure has a natural, unbiased shape which is larger than the membrane, the membrane holding the open cell structure in a compressed state which is smaller than the natural unbiased shape.

19. The implantable prosthesis of claim 1, wherein the membrane includes an inner surface which is exposed to the flowable substance; and the open cell structure includes a channel extending along an outer surface of the open cell structure adjacent to the inner surface of the membrane.

20. The implantable prosthesis of claim 19, wherein the membrane includes a posterior wall and an anterior wall, the anterior wall having an apex; and the open cell structure includes a plurality of channels which intersect at along the inner surface of the membrane below the apex.

21. The implantable prosthesis of claim 20, wherein the membrane includes a posterior wall and an anterior wall, the anterior wall having an apex; and the open cell structure includes a plurality of channels which extend radially relative to the apex of the membrane.

22. The implantable prosthesis of claim 20, wherein the plurality of channels in the open cell structure do not intersect one another.

23. The implantable prosthesis of claim 19, wherein the channel in the open cell structure extends circumferentially about an external surface of the open cell structure.

24. The implantable prosthesis of claim 1 wherein the membrane has a posterior wall, an anterior wall and an inner surface which is exposed to the flowable substance; and the open cell structure being selectively attached to the membrane at discrete locations.

25. The implantable prosthesis of claim 24, wherein the open cell structure is selectively attached at a plurality of locations separated by portions of the open cell structure which are free to move relative to the inner surface of the membrane.

26. The implantable prosthesis of claim 24, wherein the open cell structure is attached to the posterior wall of the membrane at a plurality of locations separated by portions of the open cell structure which are free to move relative to the inner surface of the membrane along the posterior wall.

27. The implantable prosthesis of claim 24, wherein the open cell structure is attached to the anterior wall of the membrane at a plurality of locations separated by

portions of the open cell structure which are free to move relative to the inner surface of the membrane along the anterior wall.

28. The implantable prosthesis of claim 25, wherein the open cell structure is selectively attached to the membrane along a strip of the inner surface of the membrane.

29. The implantable prosthesis of claim 1, further comprising a plurality of spacing elements positioned between the membrane and the open cell structure, the spacing elements forming a space between the membrane and the open cell structure to promote flow of the flowable substance in the space between the membrane and the open cell structure.

30. The implantable prosthesis of claim 29, wherein the membrane has an inner surface which is the open cell structure has an outer surface; and the plurality of spacing elements cover less than 20% of the outer surface of the open cell structure so that at least 80% of the outer surface is exposed and free to move relative to an inner surface of the membrane.

31. An implantable prosthesis, comprising:

a soft, flexible outer membrane, the membrane having a first chamber and a second chamber;

a flowable substance contained within the membrane;

an adjustable flow restricting orifice which fluidly couples the first chamber to the second chamber, the adjustable flow restricting orifice having a control element which permits the user to change a size of the orifice thereby altering a flow resistance between the first and second chambers.

32. The prosthesis of claim 31, wherein the orifice includes an inflatable structure and the control element is configured to deliver a fluid to the inflatable structure.

33. The prosthesis of claim 32, wherein the membrane has a posterior wall and an anterior wall; the orifice being positioned on an interconnecting wall which extends between the posterior wall and the anterior wall of the membrane thereby separating the first and second chambers.

34. The prosthesis of claim 31, further comprising a plurality of orifices, wherein the size of each of the orifices may be adjusted with the control element.

35. The prosthesis of claim 31, wherein the control element is configured to extend out of the patient when the membrane has been implanted into a patient so that the size of the orifice may be altered after the membrane has been implanted into the patient.

36. An implantable prosthesis, comprising:

a soft, flexible outer membrane;

a flowable substance contained within the membrane;

a tension element coupled to the membrane at a first location and a second location; and

a control element coupled to the tension element, the control element being configured to increase tension on the tension element so that the tension element draws the first and second locations toward one another.

37. The prosthesis of claim 36, wherein the control element is configured to extend out of the patient when the membrane has been implanted into a patient so that tension on the tension element may be altered after the membrane has been implanted into the patient.

38. The prosthesis of claim 36, wherein the membrane has a posterior wall and an anterior wall; and the first location being on the posterior wall and the second location being on the anterior wall.

39. The prosthesis of claim 36, further comprising a locking element coupled to the membrane and configured to maintain tension on the tension element after the control element has increased tension on the tension element.

40. The prosthesis of claim 36, further comprising a plurality of tension elements extending within the membrane, each of the tension elements being configured to be tensioned independently by the user after introduction of the membrane into the patient.

41. An implantable prosthesis, comprising:

a soft, flexible outer membrane having a posterior wall and an anterior wall;

a flowable substance contained within the membrane;

an open-cell structure having a plurality of cells contained within the membrane, the flowable substance being contained in the plurality of cells of the open-cell structure;

a plurality of elastic tension elements extending through the open-cell structure coupled to the membrane, each tension element having a first end and a second end which are both attached to the membrane.

42. The prosthesis of claim 41, wherein the membrane has a round posterior wall; and the plurality of tension elements extend from one side of the membrane to a diametrically opposed side relative to the circular posterior wall.

43. The prosthesis of claim 41, wherein the plurality of tension elements are coupled together at a junction which is between the first and second ends of the tension elements.

44. An implantable prosthesis, comprising:

a soft, flexible outer membrane having a first chamber and a second chamber which are not fluidly coupled to one another;

a first flowable substance contained within the first chamber of the membrane;

a second flowable substance contained within the second chamber of the membrane; and

a removable fill tube coupled to the second chamber to alter the amount of the second flowable substance in the second chamber, the removable fill tube permitting a user to fill the second chamber after the membrane has been implanted in a patient; and

an open-cell structure having a plurality of cells contained within the first chamber of the membrane, the first flowable substance being contained in the plurality of cells of the open-cell structure.

45. The implantable prosthesis of claim 44, wherein the membrane has a third chamber which also contains an open-cell structure; the second chamber being positioned between the first and third chambers.

46. An implantable prosthesis, comprising:

a soft, flexible outer membrane having a round posterior wall and an axis of symmetry, the membrane being symmetrical about the axis of symmetry;

a flowable substance contained within the membrane;

an open-cell structure having a plurality of cells contained within the membrane, the first flowable substance being contained in the plurality of cells of the open-cell structure; and

a plurality of voids in the open-cell structure which are substantially larger than the cells of the open-cell structure.

47. The prosthesis of claim 46, wherein the plurality of voids are organized in a symmetrical pattern relative to the axis of symmetry.

48. The prosthesis of claim 46, wherein the plurality of voids are positioned in a circular pattern around the axis of symmetry.

49. The prosthesis of claim 46, wherein the plurality of voids are elongate channels which extend through the open-cell structure.

50. An implantable prosthesis, comprising:

a membrane containing a flowable substance; and

an open cell structure positioned inside the membrane, the open cell structure being filled with the flowable substance so that the open cell structure dampens motion of the flowable substance within the membrane.

51. The implantable prosthesis of claim 50, wherein the membrane includes an inner surface which is exposed to the flowable substance; the open cell structure includes a channel extending along an outer surface of the open cell structure adjacent to the inner surface of the membrane.

52. The implantable prosthesis of claim 51, wherein the membrane includes a posterior wall and an anterior wall, the anterior wall having an apex; and the open cell structure includes a plurality of channels which intersect at the inner surface of the membrane below the apex.

53. The implantable prosthesis of claim 51, wherein the membrane includes a posterior wall and an anterior wall, the anterior wall having an apex; and the open cell structure includes a plurality of channels which extend radially relative to the apex of the membrane.

54. The implantable prosthesis of claim 53, wherein the plurality of channels in the open cell structure do not intersect one another.

55. The implantable prosthesis of claim 51, wherein the channel in the open cell structure extends circumferentially about an external surface of the open cell structure.

56. The implantable prosthesis of claim 55, wherein the membrane includes an inner surface, a posterior wall, an anterior wall and a waist, the waist being an outer ring of the membrane which is positioned between the anterior wall and the posterior wall when the membrane is supported by the posterior wall; and the channel in the open cell

structure extends circumferentially around the open cell structure adjacent to the inner surface of the membrane adjacent to the waist of the membrane.

57. The implantable prosthesis of claim 55, wherein the membrane includes an inner surface, a posterior wall, an anterior wall and a waist, the waist being an outer ring of the membrane which is positioned between the anterior wall and the posterior wall when the membrane is supported by the posterior wall, the anterior wall having an apex; and the channel extending around the apex at a position nearer to the apex than to the waist.

58. An implantable prosthesis, comprising:

a membrane containing a flowable substance, the membrane having a posterior wall and an anterior wall and an inner surface which is exposed to the flowable substance; and

an open cell structure positioned inside the membrane, the open cell structure being filled with the flowable substance so that the open cell structure dampens motion of the flowable substance within the membrane, the open cell structure being selectively attached to the membrane at discrete locations.

59. The implantable prosthesis of claim 58, wherein the open cell structure is selectively attached at a plurality of locations separated by portions of the open cell structure which are free to move relative to the inner surface of the membrane.

60. The implantable prosthesis of claim 59, wherein the open cell structure is attached to the posterior wall of the membrane at a plurality of locations separated by portions of the open cell structure which are free to move relative to the inner surface of the membrane along the posterior wall.

61. The implantable prosthesis of claim 59, wherein the open cell structure is attached to the anterior wall of the membrane at a plurality of locations separated by portions of the open cell structure which are free to move relative to the inner surface of the membrane along the anterior wall.

62. The implantable prosthesis of claim 59, wherein the open cell structure is selectively attached to the membrane along a strip of the inner surface of the membrane.

63. The implantable prosthesis of claim 62, wherein the open cell structure is selectively attached to the membrane so that the strip forms a loop.

64. The implantable prosthesis of claim 63, wherein the membrane has an apex in the anterior wall; the open cell structure is attached to the membrane in a loop which encircles the apex of the membrane.

65. An implantable prosthesis, comprising:

a membrane containing a flowable substance, the membrane having a posterior wall and an anterior wall and an inner surface which is exposed to the flowable substance; and

an open cell structure positioned inside the membrane, the open cell structure being filled with the flowable substance so that the open cell structure dampens motion of the flowable substance within the membrane; and

a plurality of spacing elements positioned between the membrane and the open cell structure, the spacing elements forming a space between the membrane and the open cell structure to promote flow of the flowable substance in the space between the membrane and the open cell structure.

66. The implantable prosthesis of claim 65, wherein the open cell structure has an outer surface; and the plurality of spacing elements cover less than 20% of the outer surface of the open cell structure.

67. The implantable prosthesis of claim 65, wherein the open cell structure has an outer surface; and the plurality of spacing elements are attached to the outer surface of the open cell structure and extend outwardly from the outer surface of the open cell structure, the plurality of spacing elements being free to slide against the interior surface of the membrane.

68. The implantable prosthesis of claim 65, wherein the open cell structure has an outer surface, wherein at least 80% of the outer surface of the open cell structure is free of attachments to the membrane.

69. An implantable prosthesis having an ePTFE cover, comprising:

a membrane containing a flowable substance, the membrane having an outer surface, a posterior wall, an anterior wall and a waist, the waist being an outer ring which is positioned between the anterior wall and the posterior wall when the membrane is supported by the posterior wall;

a cover material extending over the membrane, the cover material being made of expanded PTFE, wherein at least 80 percent of the expanded ePTFE

which covers the membrane is positioned no more than one centimeter from the waist of the membrane.

70. The prosthesis of claim 69, wherein the outer surface of the membrane is exposed to tissue when implanted into the patient except for the portion of the outer surface covered by the cover material.

71. The prosthesis claim 69, wherein the cover material is a strip of expanded PTFE which wraps around the membrane in a direction which is parallel to the waist so that the strip covers the outer surface of the membrane along the waist.

72. A method of attaching an ePTFE cover to a membrane, comprising the steps of:

providing a membrane filled with a flowable substance, the membrane having an outer surface, a posterior wall, an anterior wall and a waist;

holding the membrane at a first location along the waist and a second location along the waist;

stretching the membrane by moving the first and second locations away from one another;

attaching a piece of ePTFE to the membrane during the stretching step, the piece of ePTFE being attached to the membrane at the first location and at the second location.

73. The method of claim 72, wherein the attaching step is carried out so that at least 80 percent of the expanded ePTFE which covers the membrane is positioned no more than one centimeter from the waist of the membrane.

74. A method of forming an implantable prosthesis, comprising the steps of:

providing a membrane and an open cell structure, the open cell structure having a natural, unbiased shape which is larger than the membrane;

compressing the open cell structure and positioning the open cell structure inside the membrane so that the membrane holds the open cell structure in a collapsed shape which is smaller than the natural unbiased shape; and

filling the membrane with a flowable substance, the open cell structure being filled with the flowable substance which dampens motion of the flowable substance within the membrane.

75. The method of claim 74, wherein the providing step is carried out with the membrane having a posterior wall and an anterior wall, the open cell structure having a

shape with a height which is 5% to 20% larger than a maximum dimension between the anterior and posterior walls of the membrane.

76. The method of claim 74, wherein the providing step is carried out with the open cell structure occupying a volume when in the natural unbiased shape which is 5% to 20% larger than a volume of the membrane.

77. The method of claim 74, wherein the providing step is carried out with the membrane having a posterior wall and an an anterior wall, the open cell structure having a shape with a width which is 5% to 20% larger than a maximum dimension of the posterior wall.

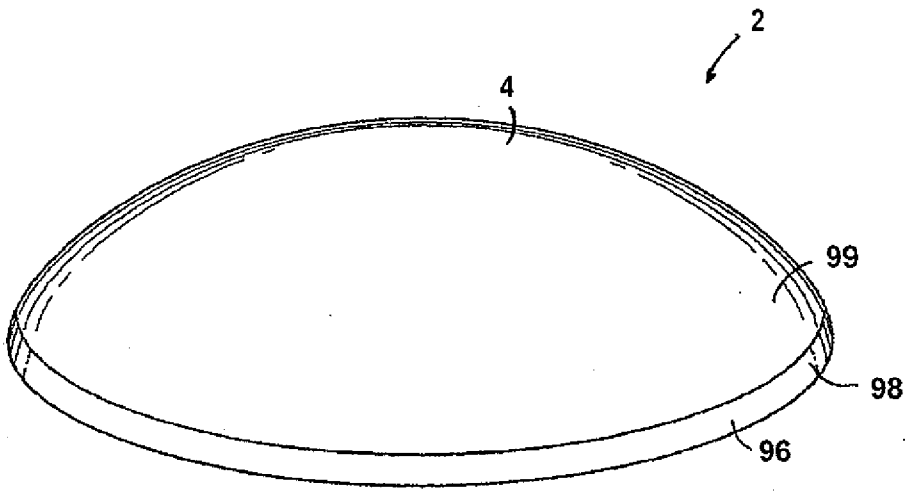


FIG 1

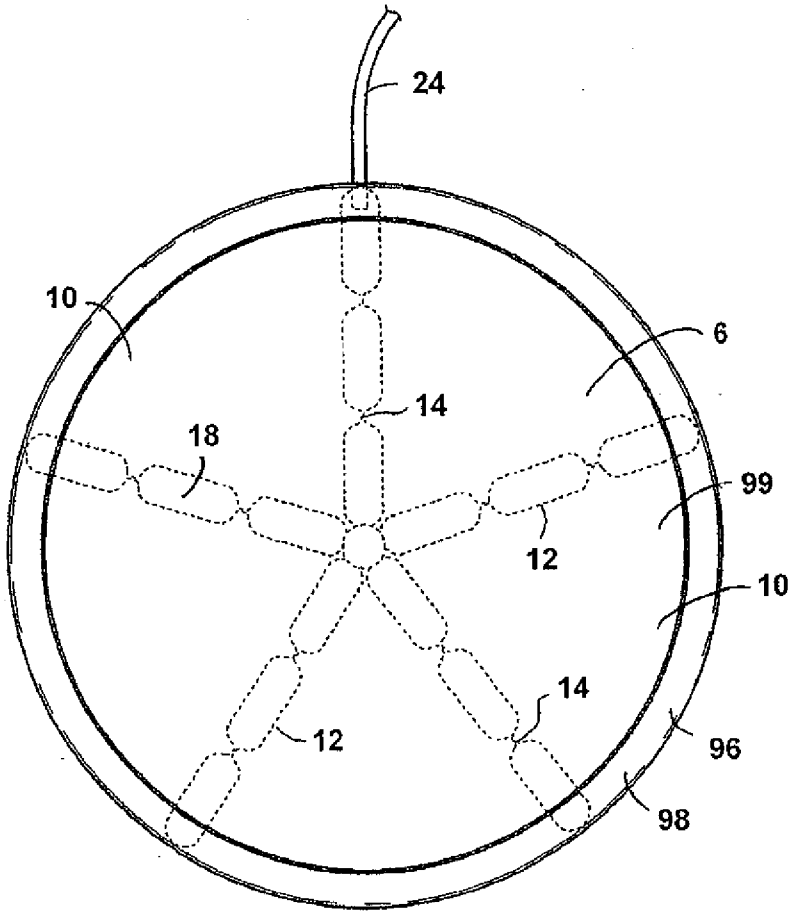


FIG 2

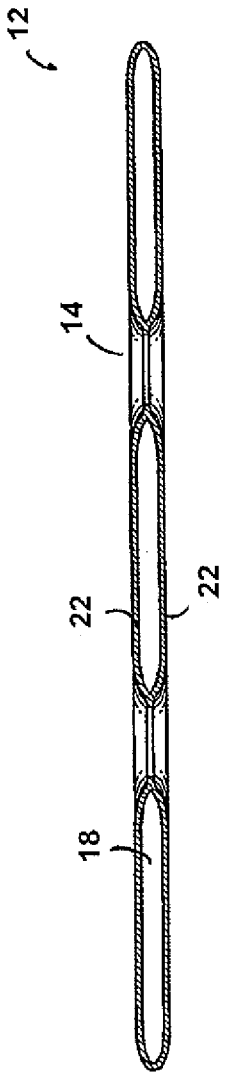


FIG 3

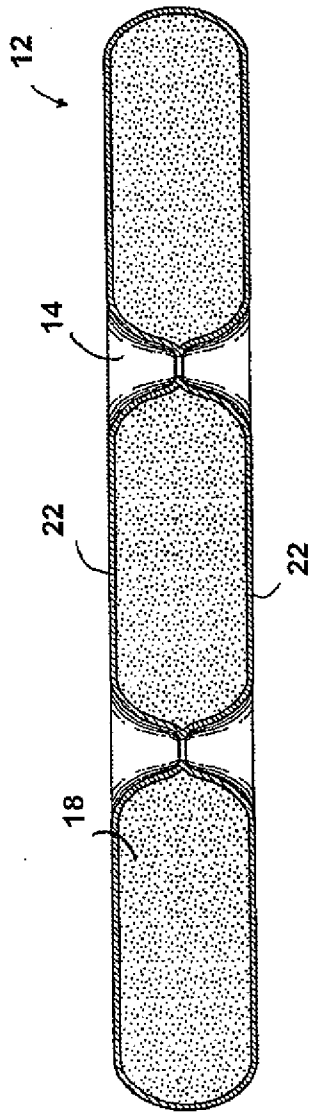


FIG 4

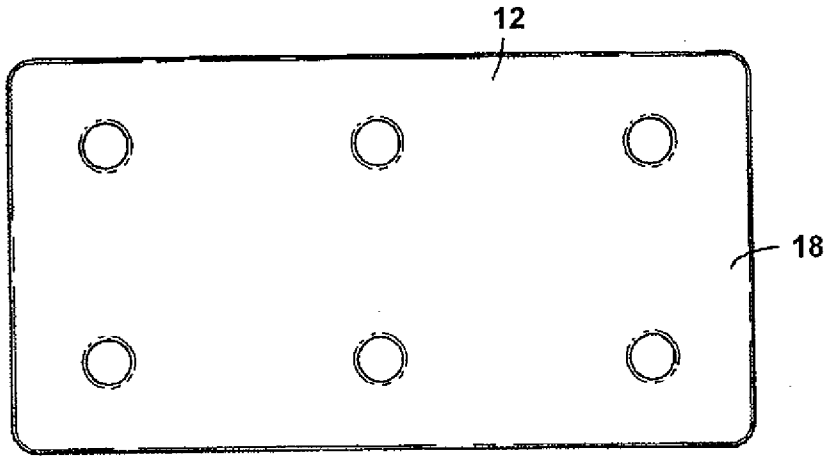


FIG 5

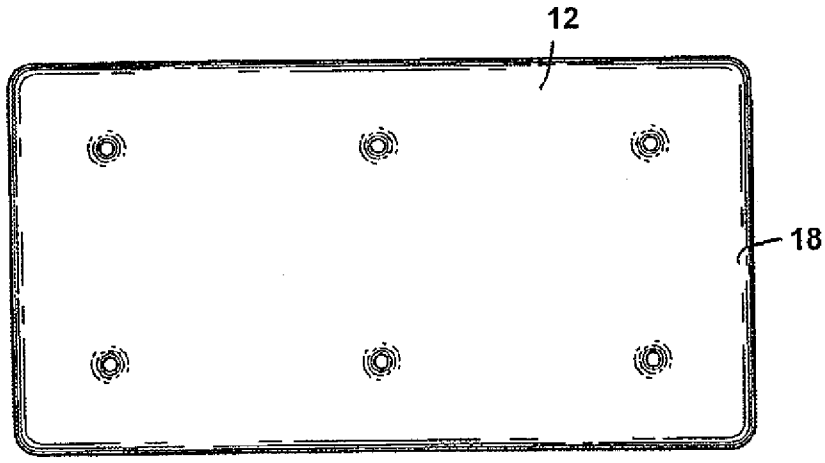


FIG 6

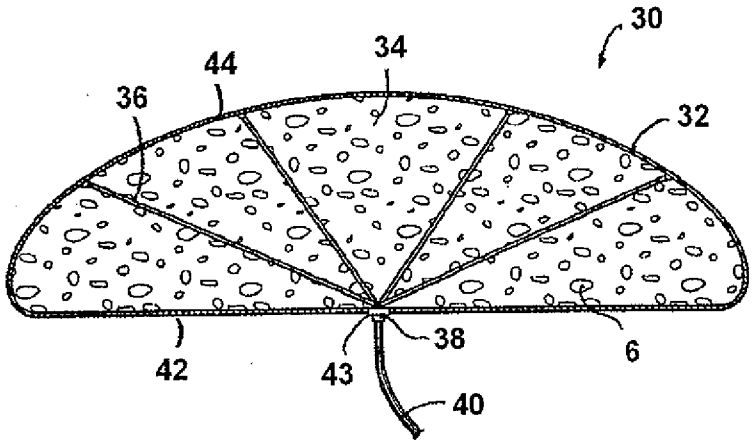


FIG 7

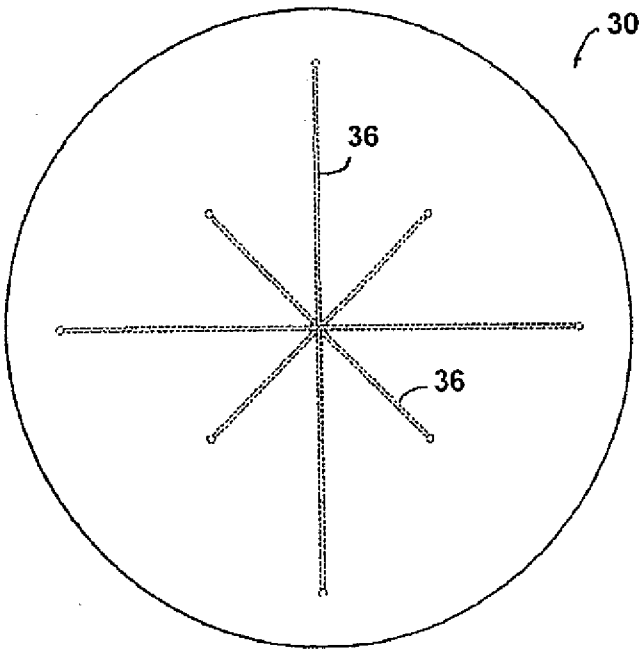


FIG 8

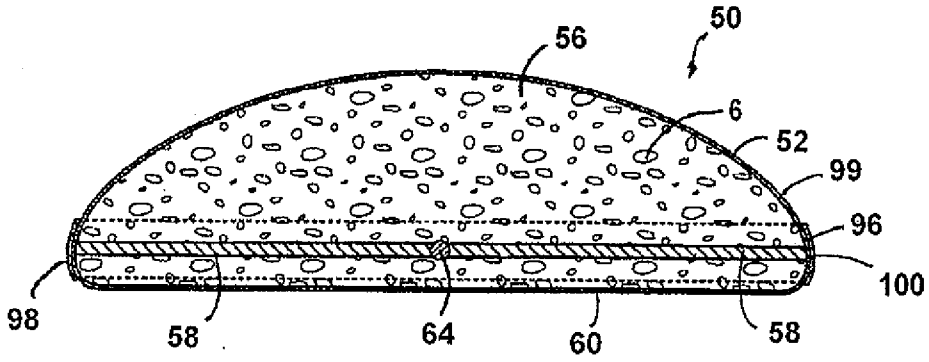


FIG 9

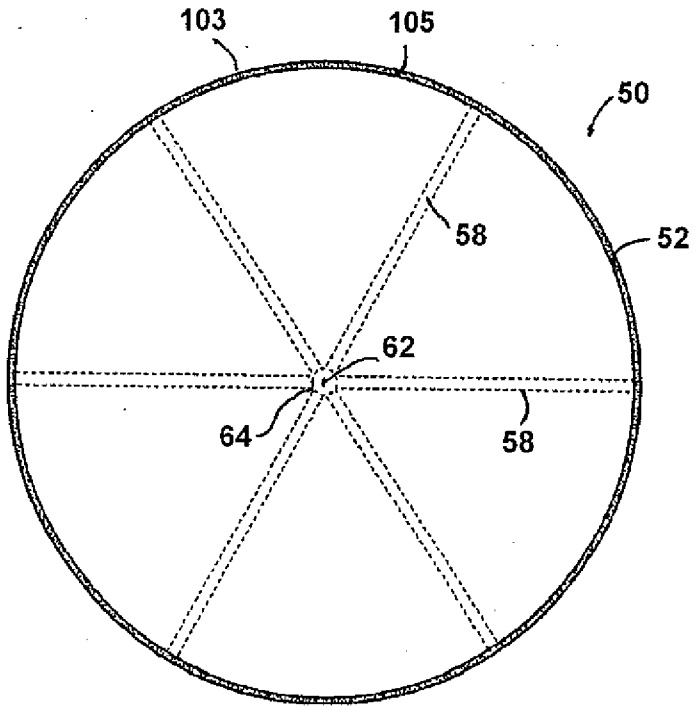


FIG 10

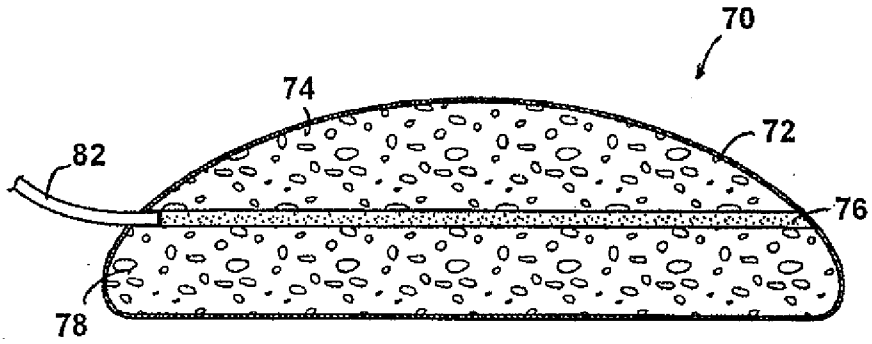


FIG 11

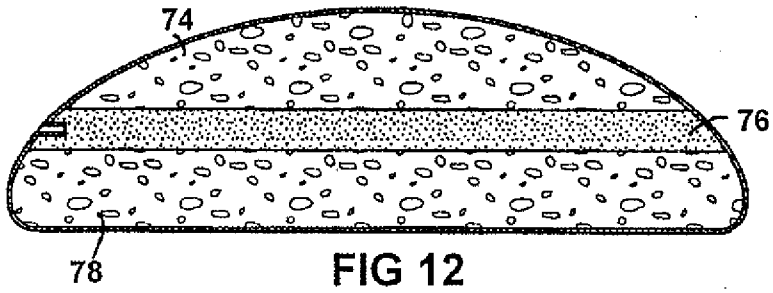


FIG 12

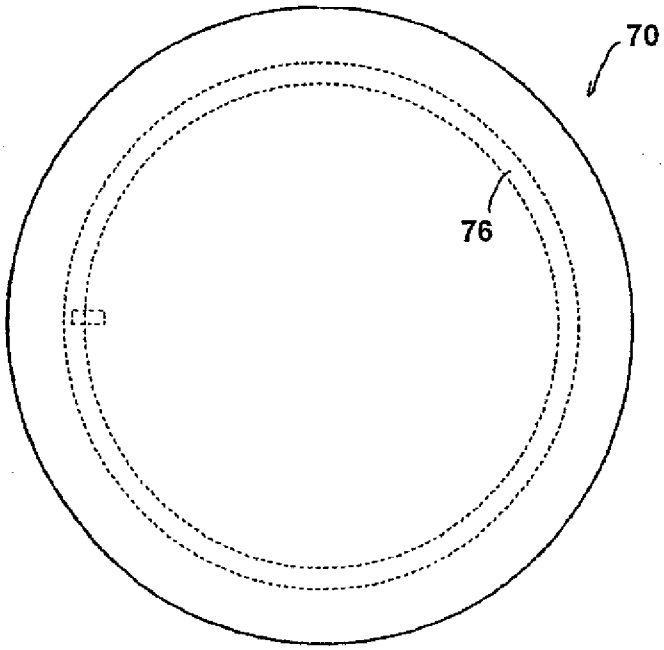


FIG 13

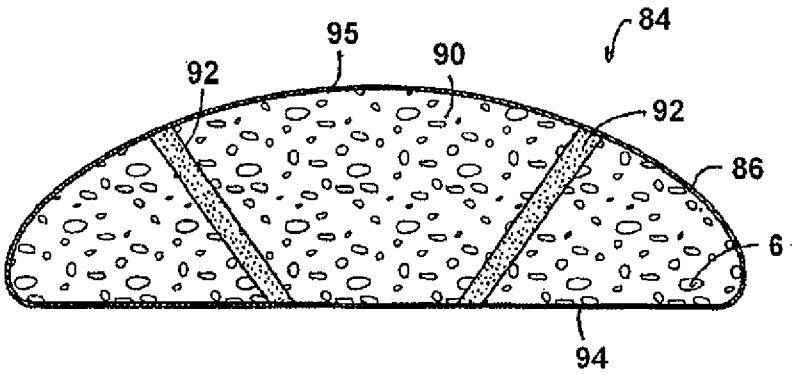


FIG 14

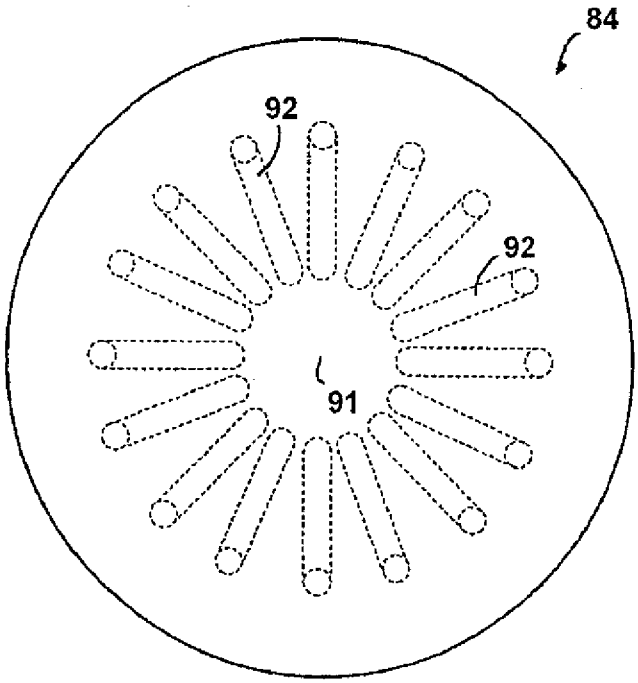


FIG 15

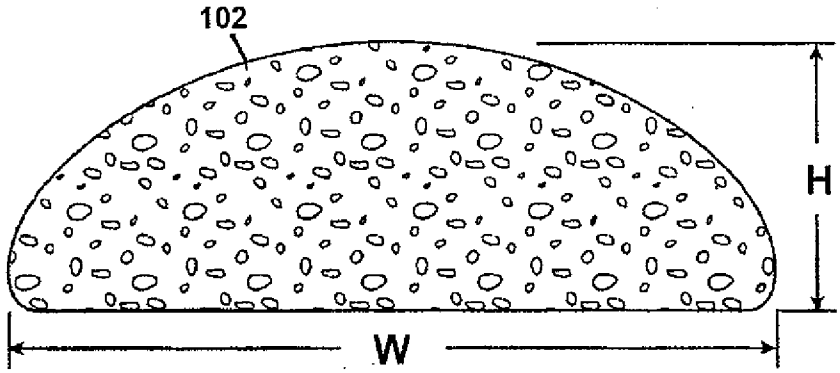


FIG 16

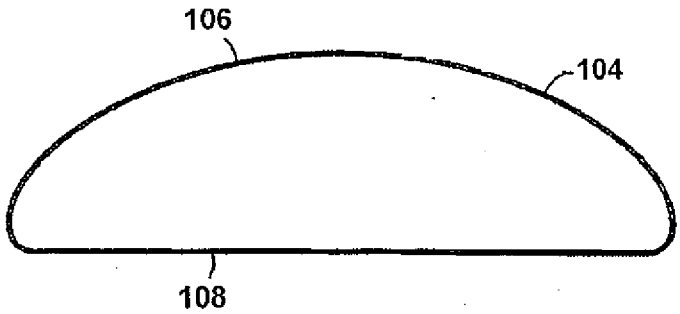


FIG 17

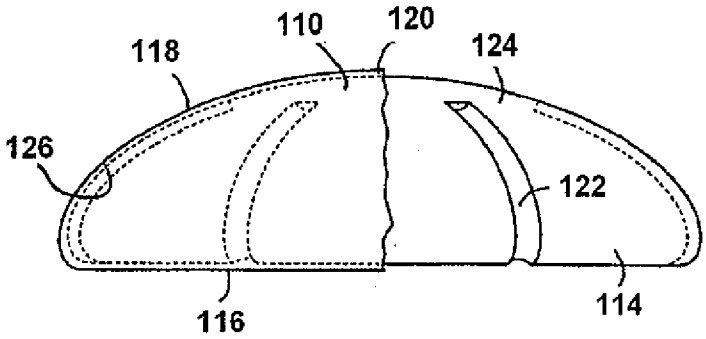


FIG 18

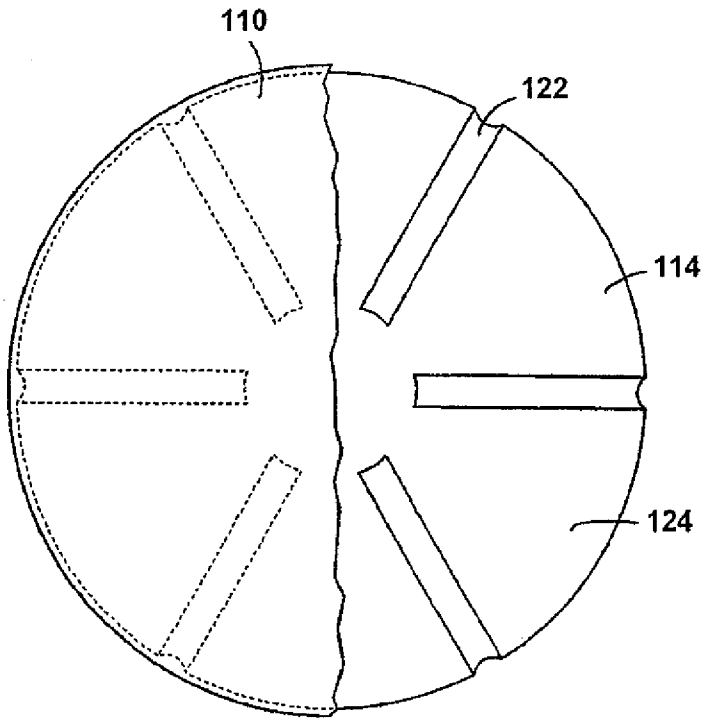


FIG 19

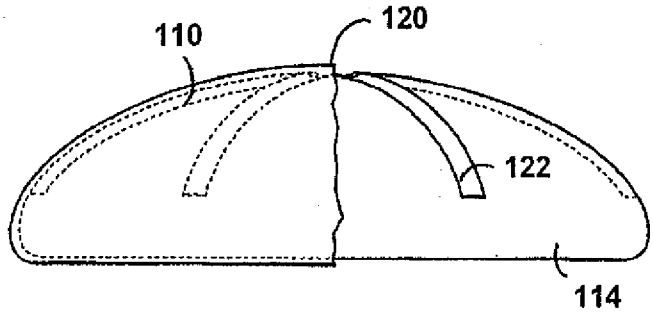


FIG 20

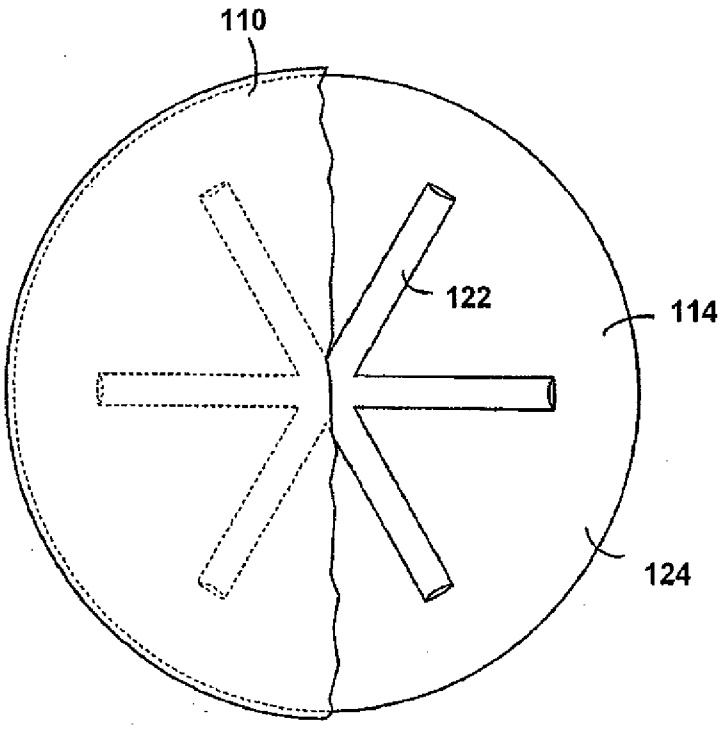


FIG 21

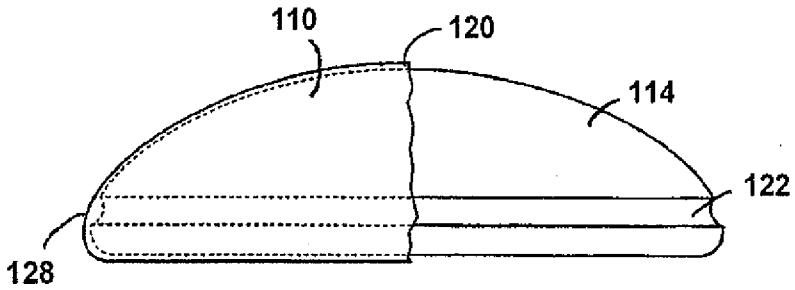


FIG 22

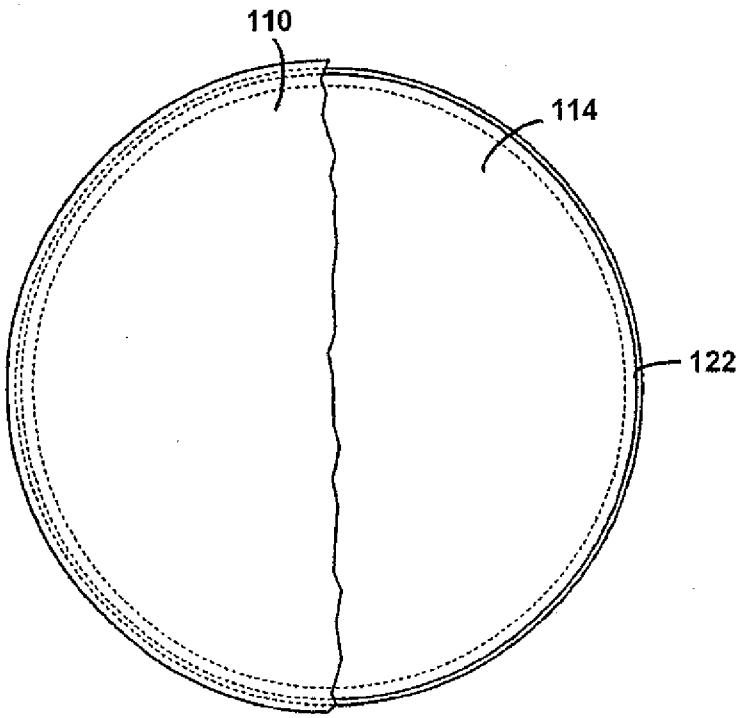


FIG 23

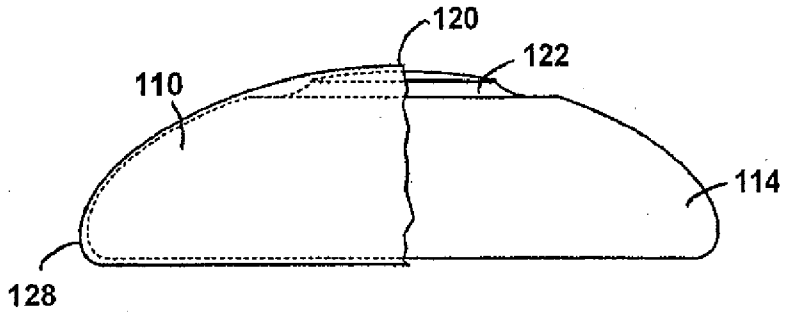


FIG 24

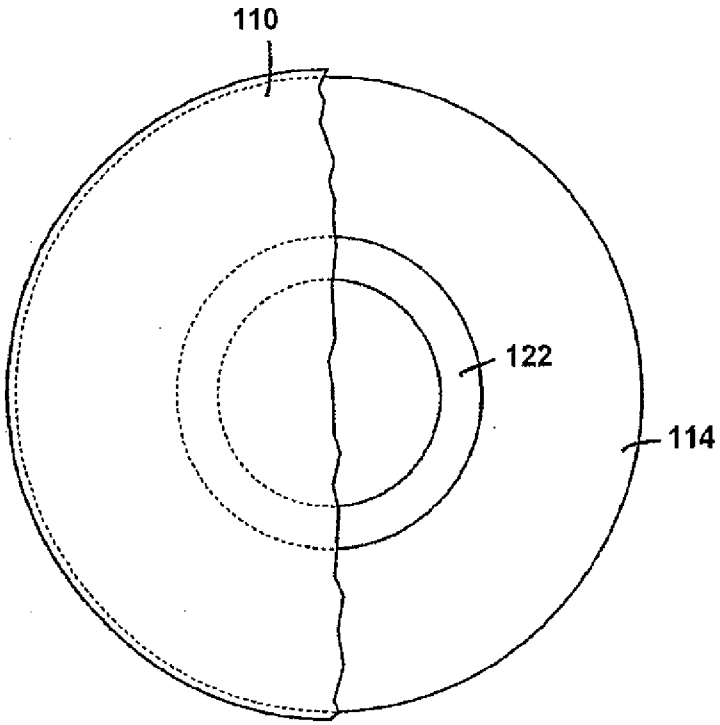


FIG 25

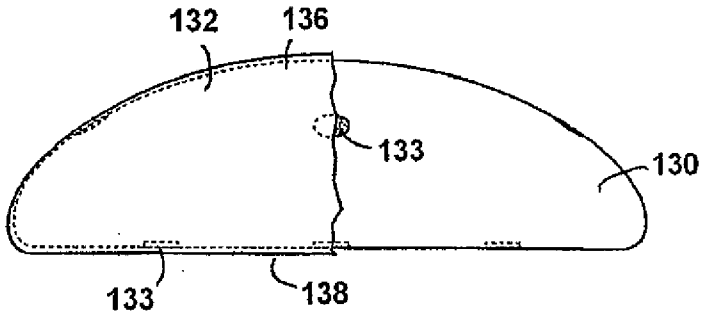


FIG 26

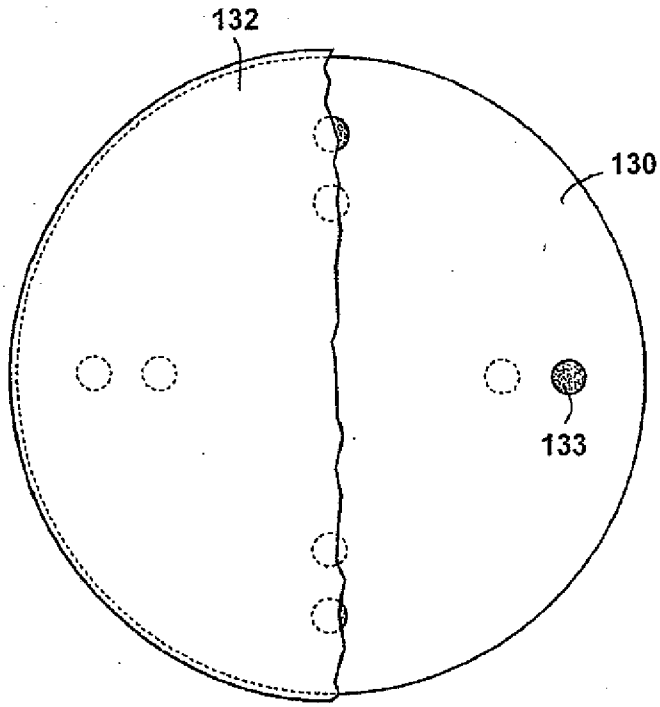


FIG 27

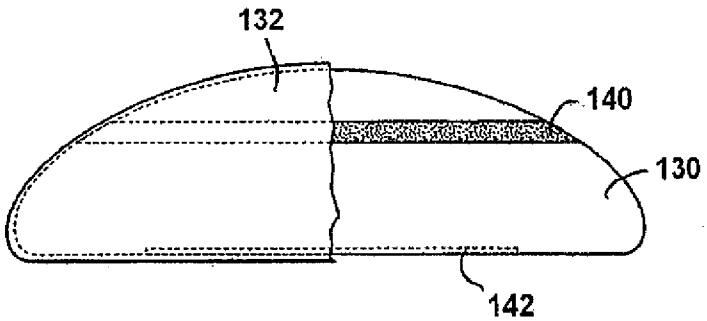


FIG 28

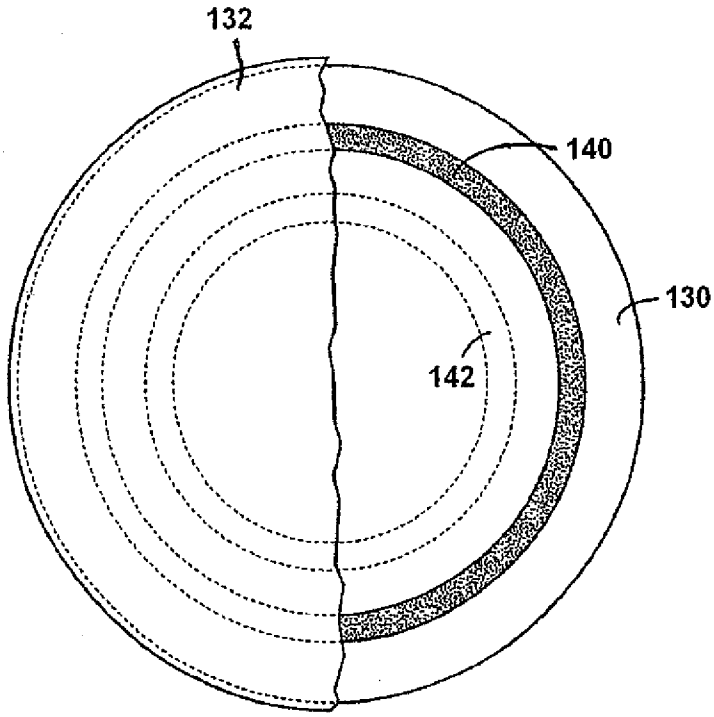


FIG 29

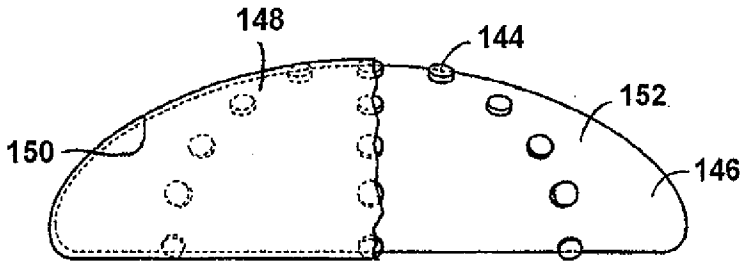


FIG 30

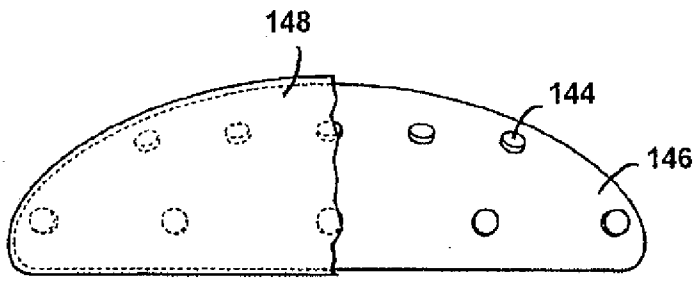


FIG 31

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2009/032259

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61F 2/12 (2009.01)
USPC - 623/8
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 2/12 (2009.01)
USPC - 623/7, 8, 13.13, 38, 45

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)
PatBase

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 2003/0074084 A1 (NAKAO) 17 April 2003 (17.04.2003) entire document	1-13, 18, 31-43, 46-48, 50, 58, 74-77 --- 14-17, 19-30, 44, 45, 49, 51-57, 59-71
Y	US 5,545,217 A (OFFRAY et al) 13 August 1996 (13.08.1996) entire document	14, 44, 45, 49
Y	EP 0 322 194 A1 (LEDERGERBER) 28 June 1989 (28.06.1989) entire document	15-17, 69-73
Y	US 6,802,861 B1 (HAMAS) 12 October 2004 (12.10.2004) entire document	19-23, 51-57
Y	US 4,531,244 A (HAMAS) 30 July 1985 (30.07.1985) entire document	24-30, 59-68
Y	US 2004/0249457 A1 (SMITH et al) 09 December 2004 (09.12.2004) entire document	72, 73

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

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Date of the actual completion of the international search	Date of mailing of the international search report
05 March 2009	16 MAR 2009
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

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