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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
4 February 2016 (04.02.2016)

WIPO | PCT

(10) International Publication Number
WO 2016/019351 A1

(51) International Patent Classification:
A61F 2/16 (2006.01)

(21) International Application Number:
PCT/US2015/043315

(22) International Filing Date:
31 July 2015 (31.07.2015)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
62/031,324 31 July 2014 (31.07.2014) US

(71) Applicant: **ONEFOCUS VISION, LLC** [US/US]; 8358 Santuary Lane, Fernandina Beach, FL 32034 (US).

(72) Inventors; and
(71) Applicants : **CHRIST, Marie, Dvorak** [US/US]; 8358 Sanctuary Lane, Fernandina Beach, FL 32034 (US). **CHRIST, Richard** [US/US]; 8358 Sanctuary Lane, Fernandina Beach, FL 32034 (US).

(72) Inventors: **WAITE, Steve**; 8358 Sanctuary Lane, Fernandina Beach, FL 32034 (US). **GUPTA, Amitava**; 8358 Sanctuary Lane, Fernandina Beach, FL 32034 (US). **PAYOR, Rick**; 3015 Scarlett Oak Court, Cumming, GA 30041 (US).

(74) Agents: **SHIMMICK, John** et al.; Wilson Sonsini Goodrich & Rosati, 650 Page Mill Road, Palo Alto, CA 94304-1050 (US).

(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, BN, BR, BW, BY, BZ, CA, CH, CL, 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, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, 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,

[Continued on next page]

(54) Title: SACRIFICIAL MOLDING PROCESS FOR AN ACCOMODATING CONTACT LENS

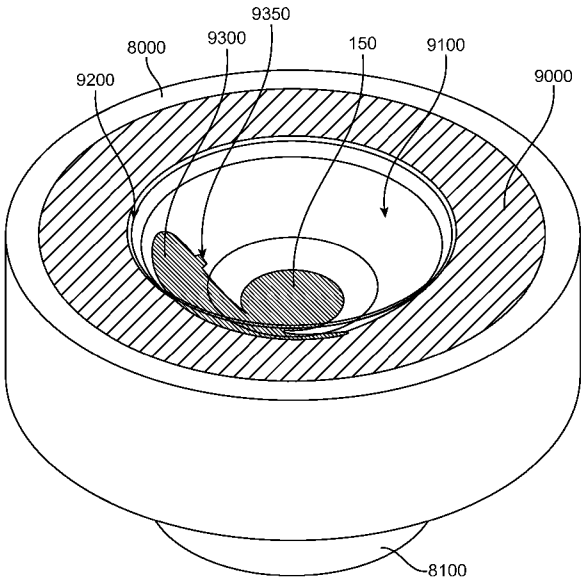


FIG. 17

(57) Abstract: A method to manufacture an accommodating contacting lens is provided. A soft contact lens material precursor is placed into a container and cured. The cured contact lens material is machined to form an intermediate surface over which an accommodating lens module is placed. Further precursor is placed onto the intermediate surface and surrounding the lens module. This further precursor is cured. Afterwards, the surface of the cured precursor or soft contact lens material is machined to form a first surface of the accommodating contact lens. Then, the opposite surface is machined to form a second surface of the accommodating contact lens, thereby forming the accommodating contact lens with the module disposed in the interior. The first and second surfaces may be a posterior and anterior surface, respectively, of the accommodating contact lens.

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GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, 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, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

SACRIFICIAL MOLDING PROCESS FOR AN ACCOMMODATING CONTACT LENS

CROSS-REFERENCE

[0001] The present application claims priority to U.S. Application Serial No. 62/031,324, filed July 31, 2014, entitled "Sacrificial Molding Process for an Accommodating Contact Lens" (attorney docket no. 44910-707.101), the entire disclosure of which is incorporated herein by reference.

[0002] This subject matter of the present application is related to the following patent applications: PCT/US2014/013427, filed on 28 January 2014, entitled "Accommodating Soft Contact Lens" (attorney docket no. 44910-703.601); U.S. Application Serial No. 61/757,457, filed on January 28, 2013, entitled "An Accommodating Soft Contact Lens" (attorney docket no. 44910-703.102); PCT/US2014/013859, filed on January 30, 2014, entitled "Manufacturing Process of an Accommodating Contact Lens" (attorney docket no. 44910-704.601); U.S. Application Serial No. 61/758,416, filed on January 30, 2013, entitled "Manufacturing Process of an Accommodating Soft Contact Lens" (attorney docket no. 44910-704.101); U.S. Application Serial No. 61/857,462, filed July 23, 2013, entitled "Manufacturing Process of an Accommodating Soft Contact Lens II" (attorney docket no. 44910-704.102); PCT/US2014/071988, filed on December 22, 2014, entitled "Fluidic Module For Accommodating Soft Contact Lens" (attorney docket no. 44910-705.601); U.S. Application Serial No. 61/919,691, filed on December 20, 2013, entitled "Fluidic Meniscus Module for Accommodating Soft Contact Lens" (attorney docket no. 44910-705.101); U.S. Provisional Application Serial No. 62/031,290, filed on July 31, 2014, entitled "Fluidic Meniscus Module for Accommodating Soft Contact Lens" (attorney docket no. 44910-705.102); and U.S. Provisional Application Ser. No. 62/031,305, filed on July 31, 2014, entitled "Control Device Responsive to Lid Fissure Width" (attorney docket no. 44910-706.101), the entire disclosures of which are incorporated herein by reference.

BACKGROUND

[0003] The present invention relates generally to the treatment presbyopia.

[0004] As the eye ages, the lens of the eye become less capable of moving to provide variable optical power, a condition referred to a presbyopia. In young subjects, the lens of the eye can accommodate viewing at various distances, so that the user can be both near and far object with clear focus. However as the eye ages, the lens of the eye becomes less

capable of accommodating both near and far vision and subjects with good far vision may benefit from glasses to read close objects.

[0005] Prior methods and apparatus of treating presbyopia provide less than ideal treatment in at least some respects. Prior treatments of presbyopia include bifocal spectacles, progressive addition lenses, and multifocal contact lenses, as well as reading glasses and accommodating intraocular lenses. At least some subjects are spectacle intolerant, and spectacles can be difficult to wear in at least some situations. Multi focal lenses can degrade vision at both near and far vision at least partially in at least some instances. Intraocular lenses require surgery and can be more invasive that would be ideal in at least some instances.

[0006] Although multifocal contact lenses have been proposed, such lenses produce less than ideal results in at least some instances. Multifocal contact lenses may have two or more optical zones of different optical power. In at least some instances, one of these zones of different optical power can transmit light to the eye that is out of focus on the retina and degrades vision of the subject. Although contact lenses that translate on the cornea have been proposed in order to provide variable focus, such lenses can be somewhat difficult for subjects to use and provide less than ideal results in at least some instances. Examples of multifocal contact lenses are described in Patent Nos.: US 7,517,084; US 7,322,695; US 7,503,652; US 6,092,899; and US 7,810,925, for example.

[0007] Although accommodating contact lenses have been previously proposed, the prior accommodating contact lenses can be less than ideal in at least some instances. For example, the optical properties of the prior accommodating contact lenses can be less than ideal. For example, the shape of the central shape changing region of the prior accommodating contact lenses can be somewhat distorted when the eye accommodates, and the accommodating optical zone can be somewhat smaller than would be ideal. Also, the optical zones the prior lenses can be shaped somewhat irregularly and may provide less than ideal changes in optical power. Also, the materials of the prior accommodating contact lenses can be less than ideally suited for combination with known contact lens materials, and the extent to which prior accommodating contact lenses can be worn on the eye is less than ideal in at least some instances. Accommodating contact lenses are described in WO 91/10154; US 7,699,462; US 7,694,464; and USP 7,452,075, for example.

[0008] In addition to the deficiencies noted above, work in relation to embodiments also suggests that the prior accommodating contact lenses are less than ideally suited for manufacturing, and that at least some of the prior accommodating contact lenses may be

difficult to produce in large volumes in at least some instances. The prior methods and apparatus for manufacturing contact lenses can be less than ideally suited to provide contact lenses having different materials. In at least some instances, the prior methods and apparatus of manufacturing contact lenses with different materials can provide less than ideal integration into a contact lens, for example. In at least some instances, the dissimilar materials can have different amounts of shrinkage and expansion during the manufacturing process, which can cause different layers of material to induce distortions to the contact lens and in some instances separate, for example delaminate, in at least some instances. Also, the prior methods and apparatus can be less than ideally suited for positioning components composed of different materials within contact lenses. For example, pre-positioning a component in a contact lens mold and manufacturing the component can be more difficult than would be ideal in at least some instances.

[0009] Work in relation to embodiments suggests that the formulations of the precursor material for the accommodating contact lenses can provide less than ideal integration with the embedded accommodation module, and that the prior materials for such contact lenses can be less than ideal. For example, dissimilar materials can be less than ideally coupled together in at least some instances. Adhesion of the dissimilar lens materials can be less than ideal. Work in relation to embodiments suggest that a non-hydrogel material coupled to a hydrogel material can provide less than ideal contact, and the curing process can be related to imperfections such as pooling, less than ideal adhesion, or bubbles, for example.

[0010] In light of the above, it would be desirable to provide improved methods and apparatus for manufacturing contact lenses. Ideally, such methods and apparatus would provide an improved accommodating contact lens, facilitate manufacturing of the accommodating contact lens, provide improved positioning of components composed of dissimilar materials within the lens, provide improved coupling of components within the lens, provide quality near vision, intermediate and far vision, be compatible with known safe contact lens materials, and be readily manufactured. At least some of these objectives are met with the embodiments as disclosed herein.

SUMMARY

[0011] Embodiments of the present invention provide improved methods and apparatus for manufacturing accommodating contact lenses and improved accommodating contact lenses and methods of use. Although specific reference is made to contact lenses, the embodiments

disclosed herein can be used in one or more of many fields such as astronomy, machine vision, and digital cameras.

[0012] In many embodiments, one or more surfaces of a contact lens is machined to an optical surface with components of the accommodating contact lens embedded in a contact lens covering material. The machined surface may comprise one or more of an anterior surface or a posterior surface of the accommodating contact lens. In many embodiments, a pre-configured self supporting module is covered in a soft contact lens material, in order to provide seamless integration of the module within the contact lens body comprising the module and the contact lens covering material. In many embodiments, the module is embedded in the contact lens covering material coating the module and shaped to provide optical correction of the user. In many embodiments, the module is placed in a mold and the covering material cured around the module to form a contact lens body. While the mold can be provided in one or more of many ways, in many embodiments the mold comprises a sacrificial mold that can be machined away to form an optical surface of the accommodating contact lens.

[0013] The covering material can be soft when placed on the eye, and one or more of stiff, firm or rigid during one or more manufacturing steps and prior to placement on the eye. The covering material can comprise one or more of many polymer precursor materials such as a monomer. In many embodiments, the covering material comprises a diluent combined with the precursor material prior to curing that inhibits a change in volume when replaced with water during hydration. The methods and apparatus disclosed herein can fixedly embed the module in the contact lens body material, such that the module remains fixed in the covering material during steps of the manufacturing process and when hydrated and placed on the eye. This fixing of the module in the contact lens material allows the contact lens to be machined to optical tolerances in order to treat refractive error of the eye and in at least some embodiments one or more aberrations of the eye such as spherical aberration and coma.

[0014] In many embodiments, and accommodating contact lens module is provided for use with an accommodating contact lens. Components of the accommodating contact lens module can be manufactured and assembled with low distortion optics to provide improved vision, and the module may comprise a self-supporting free standing module capable of being grasped by one of the components and placed in a mold without distorting the optical components of the module when placed. In many embodiments, the module is compatible with soft contact lens materials, such as hydrogels and silicones, and compatible with soft contact lens manufacturing processes such as molding of hydrogels and silicones.

[0015] The module may comprise one or more of many components that can be placed in the mold together. The module may comprise one or more of an optical chamber, a support structure extending around the optical chamber, one or more eyelid engaging chambers, one or more extensions extending between the one or more eyelid engaging chambers and the optical chamber, or one or more anchors. Each of these components can be placed in the mold for encapsulation in order to provide accurate optical correction of the eye of the subject, for both far vision and near vision. In many embodiments, the module is inspected prior to placement in the mold. In many embodiments, the optical properties of the module such as optical power and change in optical power are determined prior to placement in the mold in order to provide a functional accommodating contact lens to the eye of the subject.

[0016] The components can be assembled and connected in one or more of many ways such as by welding such as laser welding or an adhesive to seal the module which may be hermetically sealed. In many embodiments, the module comprises a plurality of eyelid engaging chambers arranged for cumulative far vision, intermediate vision and near vision correction, respectively, with additional add power as the eyelid successively engages the plurality of chambers. The chambers of the module can be filled with fluid prior to placing the module in the mold, and the module can be pressurized prior to placement in the mold. The fluid can remain pressurized when the accommodating contact lens has been removed from the mold, packaged, and placed on the eye in order to increase responsiveness and inhibit hysteresis of the accommodating contact lens. In many embodiments, module comprises one or more membranes to inhibit leakage of the fluid, and the fluid is placed in the module to inhibit bubble formation, such as with degassing of the fluid prior to placement in the sealed module and orientation of the module when fluid is drawn into the module.

[0017] In many embodiments, module is encapsulated within the mold in order to inhibit optical properties of the module and correct vision of the eye. The mold may comprise a convexly curved male portion corresponding to a base curvature of the cornea of the eye and a concavely curved optically corrective female potion having a concave surface profile corresponding to a refractive error of the eye. The module can be encapsulated within the mold to form the anterior and posterior surfaces of the accommodating contact lens with shape profiles for the optical correction of the eye and for fitting the contact lens on the cornea of the eye, respectively. In many embodiments, the accommodating contact lens module comprises an optically transparent material having an index of refraction similar to the soft contact lens material such that light can be transmitted through module without introducing perceptible visual artifacts.

[0018] The module can be encapsulated in the contact lens material in one or more of many ways. In many embodiments, a precursor material is placed on the module to provide a layer of the precursor material on the module. The layer of precursor material on the module can ensure that at least a thin layer of the soft contact lens material encapsulates the module. In many embodiments, the module is wettable by the precursor material to provide the layer on the module. The surface of the module can be treated so as to comprise the wettable surface, such as with a plasma treatment to form hydroxyl groups on the surface of the module. The precursor material may comprise one or more of a monomer, a partially cured monomer, an oligomer, or a pre-polymer. In many embodiments, the module is placed in the mold with the precursor material, and the precursor material comprises an amount of viscosity sufficient to form a layer having a thickness suitable for encapsulation. In many embodiments, the precursor material is partially cured to provide the viscosity in order to form the layer with the thickness. The module may comprise a density greater than the precursor material, such that the module settles in the precursor material with the layer extending between the module and the mold. The precursor material can be cured with the layer extending between one or more surfaces of the module and the mold order to encapsulate the module and provide the encapsulating contact lens material with the thickness when worn on the eye. In many embodiments, the layer comprises a thickness sufficient to inhibit tearing of the layer away from the one or more components of the module. In many embodiments, the soft contact lens comprises an anterior layer comprising an anterior thickness on an anterior an anterior side extending between the anterior surface of the module and the anterior surface of the lens, and a posterior layer comprising a posterior thickness on posterior side extending between the posterior surface of the module and the posterior surface of the lens, in which the anterior layer is thinner than the posterior layer in order to facilitate anterior movement of the anterior membrane of the optical chamber. In many embodiments, the anterior thickness is determined at least in part by the viscosity of the precursor material, such that the precursor material can be provided with a viscosity in order to form the soft contact lens material with an appropriate anterior thickness.

[0019] The module can be placed in the mold in one or more of many ways. In many embodiments, the mold comprises a concavely curved lower female portion oriented upward in order to receive the precursor material and the module, and a convexly curved upper male portion oriented downward to fit with the female portion when the module and precursor material have been placed. In many embodiments, an anterior surface of the module is oriented downward toward the concave surface of the mold, with an anterior layer of

precursor material extending between the anterior surface of the module and the concave surface of the mold. The convex surface of the male portion of the mold can be advanced toward the concave surface of the female portion into mating engagement with the female portion in order to form the posterior surface of the accommodating contact lens when the precursor material has cured.

[0020] Aspects of the present disclosure may provide a method of manufacturing an accommodating contact lens. An accommodating contact lens module and a soft contact lens material may be provided. The accommodating contact lens module may be encapsulated in the soft contact lens material. One or more of an anterior or posterior surface of the soft contact lens material having the contact lens module encapsulated therein may be machined to form an optical correction zone for a subject.

[0021] The accommodating contact lens module may comprise a free standing module. The module may comprises an index of refraction similar to an index of refraction of the soft contact lens material in order to transmit light refracted by the anterior and posterior surfaces of the optical correction zone through at least a portion of the module and inhibit optical artifacts.

[0022] The accommodating contact lens module may comprises a free standing module comprising one or more of an optical chamber, a support structure, one or more eyelid engaging chambers, one or more extensions extending between the optical chamber and the one or more chambers, or an anchor. The accommodating contact lens module may comprise the free standing module comprising the optical chamber, the support structure, the one or more eyelid engaging chambers, and the one or more extensions extending between the optical chamber and the one or more chambers and the anchor. The free standing module may be configured such that the optical chamber, the support structure, the one or more eyelid engaging chambers, the one or more extensions extending between the optical chamber and the one or more chambers and the anchor are connected to each other prior to placement in the mold such that the module comprises a self-supporting module capable of being lifted and placed in the mold by grasping the one or more of the optical chamber, the one or more eyelid engaging chambers, the one or more extensions extending between the optical chamber, the one or more chambers, or the anchor. The module may be grasped by an end effector of a robot.

[0023] The module may comprise the optical chamber and the one or more eyelid engaging chambers. The optical chamber may comprise an anterior membrane having an anterior thickness and a posterior membrane having a posterior thickness. The posterior thickness

may be greater than the anterior thickness. The one or more eyelid engaging chambers may comprise an anterior membrane having an anterior membrane thickness greater than a posterior membrane thickness of the one or more chambers. The anterior surface of the anterior membrane of the optical chamber may comprise a convex curvature. A posterior surface of the posterior membrane of the one or more chambers may comprise a convex surface. The module may comprise the anchor and the anchor may comprise a flange comprising a plurality of openings which may be placed in the mold.

[0024] An optically transmissive coupling fluid may have been placed in the accommodation module prior to encapsulating the module. The fluid may be pressurized within the module when the module has been placed in the mold.

[0025] An optical chamber of the module may comprise an optical power when placed in the mold. The optical power may be inhibited by the soft contact lens material with the module encapsulated within the contact lens material. The optical chamber may comprise an optically transmissive coupling fluid. The optical chamber may comprise a convexly curved anterior surface of an anterior membrane when the module has been placed in the mold. The anterior membrane may comprise an elastic deflection. The elastic deflection may pressurize the optically transmissive coupling fluid when the module has been placed in the mold.

[0026] The soft contact lens material may comprise one or more of a hydrogel, silicone, siloxane, silicone hydrogel, galyfilcon A, senofilcon A, Comfilcon A, Enfilcon A, polyacrylate, or polyhydroxyethylmethacrylate (pHEMA).

[0027] To provide the soft contact lens material, a first casting cup may be filled with a precursor of the contact lens material. The first casting cup may comprise one or more of a polymer, thermoplastic, polymethyl methacrylate (PMMA), polyethylene, polypropylene, polyvinyl chloride, polytetraflouroethylene, polycarbonate, or bisphenol A. The soft contact lens material may further be provided by curing the precursor of the contact lens material to provide a first soft contact lens material portion of the soft contact lens material in the first casting cup. A surface of the first contact lens material portion may be machined, such as with a diamond turner, to form an intermediate surface. The intermediate surface may have a concave configuration. The surface of the first contact lens material portion may be machined by engaging a rod to the first casting cup and actuating the attached rod such as by rotation.

[0028] To encapsulate the accommodating contact lens module in the soft contact lens material, the accommodating contact lens module and the precursor of the soft contact lens material may be placed onto the intermediate surface. The precursor of the contact lens

material on the intermediate surface may be cured to form a second contact lens material portion of the contact lens material. To place the precursor of the soft contact lens material on the intermediate surface, the first casting cup may be engaged with a second casting cup. A mold may be thus formed between the first and second casting cups and the precursor may be introduced into the mold.

[0029] One or more of the anterior or posterior surface of the contact lens material having the accommodating contact lens module encapsulated therein may be machined such as by machining a surface of the second contact lens material portion (e.g., with a diamond turner) to form a first surface of the optical correction zone. To form a second surface of the optical correction zone, the machining rod may be disengaged from the first casting cup and the first soft contact lens material portion may be machined (e.g., with a diamond turner) to form a second surface of the optical correction zone. To machine the first contact lens material portion here, the one or more of the first or second casting cups may be engaged. The first surface of the optical correction zone may comprise a posterior surface and the second surface of the optical correction zone may comprise an anterior surface and vice versa. To complete the accommodating contact lens, the first and second casting cups may be machined or dissolved away leaving only the contact lens.

[0030] Aspects of the present disclosure provide methods, apparatus and compositions for manufacturing a hydrogel material. In many embodiments a polymeric material precursor is combined with a first diluent and a second diluent, cured to form a polymeric material, then placed in water to remove the diluents. The first and second diluents may modulate the polymerization reaction to reduce shrinkage during curing, and can also reduce water expansion of the cured polymeric material upon exchange of the diluent with water.

[0031] In many embodiments, exchanging the diluents with water softens the polymeric material to form a hydrogel.

[0032] In many embodiments, the first and second diluent are provided such that the molar volume of the combined diluents is equal to or close to the molar volume of water, in order to inhibit the expansion of the cured monomer when the diluent is replaced with water.

[0033] In many embodiments, the first diluent comprises a high molecular weight component with relatively high density and viscosity, and the second diluent comprises a low molecular weight component with relatively low density and viscosity. The high density and viscosity of the first diluent may reduce cure shrinkage. The low density of viscosity of the second diluent may inhibit expansion of the cured polymer upon replacement of the diluent with water. The first diluent may comprise one or more of many high molecular weight

substances such as one or more of many polyethylene glycol molecules having a molecular weight in the range 600 – 4,500 Da, and the first diluent may comprise a composition of a plurality of high molecular weight molecules having a molecular weight in the range of 600-4500 Da. The second diluent may comprise one or more of isopropyl alcohol, ethanol, methanol, or a glycerol solution. The first diluent may comprise one or more of a polyol, polyether diol, polyethylene glycol, polypropylene glycol, and poly(tetramethylene ether) glycol.

[0034] In many embodiments, the precursor material combined with the diluent solution may be cured by heating the precursor, or by exposing the precursor to UV radiation.

[0035] In many embodiments, the precursor material comprises hydrophilic monomer components, cross-linker components, and photo-initiator components.

BRIEF DESCRIPTION OF THE DRAWINGS

[0036] The novel features of the invention are set forth with particularity in the appended claims. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

[0037] Figure 1 shows a top view of the fluidic module embedded in a contact lens upon primary gaze, in which the fluidic module comprises a central chamber and several peripheral chambers, interconnected via micro-channels;

[0038] Figures 2A to 2C show design of the fluidic module and chambers, in accordance with embodiments;

[0039] Figure 3 shows a top view of the fluidic module, comprising a central chamber and several peripheral chambers, interconnected via micro-channels, upon downward gaze, in accordance with embodiments;

[0040] Figure 4 shows a flow chart of assembly of the fluidic module, in accordance with embodiments;

[0041] Figure 5 shows filling and sealing of the fluidic module, in accordance with embodiments;

[0042] Figure 6 shows a process of molding and forming a soft contact lens made of a hydrophilic monomer or a silicone hydrogel modified to add the inclusion of a fluidic module, fabricated as shown in Figure 5, in accordance with embodiments;

[0043] Figure 7 shows a schematic of a mold surface for forming an accommodating contact lens, in accordance with embodiments;

[0044] Figure 8 shows the mold surface of Figure 6 in use with a cup to form a mold for forming the accommodating contact lens, in accordance with embodiments;

[0045] Figure 9 shows an intermediate lens formed with the mold of Figure 7, in accordance with embodiments;

[0046] Figure 10 shows an accommodating lens module placed over the intermediate lens of Figure 8, in accordance with embodiments;

[0047] Figure 11 shows the intermediate lens and accommodating lens module of Figure 9 in use with a second cup to form a mold for completing the accommodating contact lens, in accordance with embodiments;

[0048] Figure 12 shows the completed accommodating contact lens over the mold surface of Figure 6, in accordance with embodiments;

[0049] Figure 13 shows a process of molding and forming a soft contact lens comprising a fluidic module, fabricated as shown in Figures 7-12, in accordance with embodiments;

[0050] Figure 14 shows a perspective view of a casting cup, in accordance with embodiments;

[0051] Figure 15 shows a perspective view of the casting cup of Figure 14 filled with a cured monomer formulation, in accordance with embodiments;

[0052] Figure 16 shows a side, sectional view of the casting cup of Figure 15 with a machined intermediate surface of the cured monomer formulation, in accordance with embodiments;

[0053] Figure 17 shows a perspective view of the casting cup of Figure 16 with an accommodating lens module placed into the intermediate surface, in accordance with embodiments;

[0054] Figure 18 shows a perspective view of the casting cup of Figure 17 with a second layer of cured monomer formulation placed over the intermediate surface and the module , in accordance with embodiments;

[0055] Figure 19 shows a perspective view of a concave lens surface formed on the cured monomer formulation in the casting cup of Figure 18, in accordance with embodiments;

[0056] Figure 20 shows a perspective, sectional view of the casting cup of Figure 18 attached to a block, in accordance with embodiments;

[0057] Figure 21 shows a side, sectional view of the casting cup and attached block of Figure 20, in accordance with embodiments;

[0058] Figure 22 shows a perspective view of the machined convex lens surface on the cured monomer formulation in the casting cup of Figure 21, in accordance with embodiments;

[0059] Figure 23 shows a perspective view of the accommodating contact lens formed from the process of Figures 14 to 22, in accordance with embodiments;

[0060] Figure 24 shows a process of molding and forming a soft contact lens comprising a fluidic module, fabricated as shown in Figures 14-23, in accordance with embodiments; and

[0061] Figure 25 shows a table of some exemplary materials that the monomer formulation may comprise, in accordance with embodiments.

DETAILED DESCRIPTION

[0062] A better understanding of the features and advantages of the present disclosure will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of embodiments of the present disclosure are utilized, and the accompanying drawings.

[0063] Although the detailed description contains many specifics, these should not be construed as limiting the scope of the disclosure but merely as illustrating different examples and aspects of the present disclosure. It should be appreciated that the scope of the disclosure includes other embodiments not discussed in detail above. other modifications, changes and variations which will be apparent to those skilled in the art may be made in the arrangement, operation and details of the method and apparatus of the present disclosure provided herein without departing from the spirit and scope of the invention as described herein.

[0064] The inventors have developed solutions to the problems of the prior art and disclose herein an improved design comprising a fluidic module that may be embedded into a soft contact lens for correction of presbyopia.

[0065] The embodiments disclosed herein can be combined in one or more of many ways to provide improved accommodation of a contact lens.

[0066] As used herein like characters identify like elements.

[0067] As used herein the words “top” or “upper” encompass the anterior surface, away from the corneal surface, and the words “bottom” or “lower” encompass the posterior surface, closest to the corneal surface.

[0068] As used herein the letter “C” after a number in the context of temperature encompasses degrees Celsius and Centigrade, as will be readily understood by a person of ordinary skill in the art.

[0069] As used herein a dash "-" can be used to express a range of values, as will be readily understood by a person of ordinary skill in the art.

[0070] As used herein, the same index refraction encompasses an index of refraction close enough to another index of refraction to inhibit visual artifacts that might otherwise be perceptible to the user.

[0071] As used herein, similar index refraction encompasses an index of refraction close enough to another index of refraction to inhibit visual artifacts.

[0072] As used herein, the term "process" is used interchangeably with the term "method".

[0073] As used herein, a "soft" contact lens material encompasses a material that is soft when placed on the eye, although the material can be one or more of stiff, firm, or rigid, during one or more manufacturing steps prior to placement on the eye.

[0074] The module and manufacturing process described herein are well suited for combination with many known prior contact lenses and manufacturing processes, such that the accommodating soft contact lenses can be produced in large quantities, and are compatible with many known prior contact lens configurations and shapes. The anterior surface of the accommodating contact lens can be configured to correct refractive error of the eye such as sphere, cylinder and axis, and can be configured to correct aberrations of the eye, such as spherical aberration and coma, for example. The posterior surface of the accommodating contact lens can be configured to fit the eye with one or more of many shapes such as one or more spherical curvature profile, an elliptical profile, or a plurality of curvatures, as may be appropriate to fit one or more structures the eye such as the cornea, for example.

[0075] In many embodiments, the module comprises a stiffness greater than the soft contact lens material. The stiffness of the module can be configured in one or more of many beneficial ways to provide low distortion optics and to inhibit tearing of the contact lens material encapsulating the module, for example when the contact lens is deflected. The stiffness of the module can range from slightly stiffer than the soft contact lens material such as a hydrogel, to substantially stiffer than the encapsulating contact lens material. Although the module may comprise one or more components comprising stiffness to add rigidity, in many embodiments the module comprises both stiffness to provide low distortion optics and sufficient compliance so as to bend with encapsulating contact lens material in order to inhibit tearing of the encapsulating material away from the module.

Microfluidic Module

[0076] Figure 1 shows a top view of a fluidic module 150, comprising a central chamber 160 and several peripheral chambers 180, interconnected via micro-channels 172, upon primary gaze, in accordance with embodiments.

[0077] In many embodiments, the design comprises a single, hermetically sealed fluidic module that comprises one or more separate chambers, interconnected by means of micro-channels, embedded in a soft contact lens, as shown in Figure 1.

[0078] In many embodiments, the central chamber 160 is cylinder shaped with edges that are relatively stiff, its faces being covered by a relatively flexible distensible membrane. The top and bottom faces can be circular in shape.

[0079] The central chamber is connected to each of the peripheral chambers by means of a micro-channel.

[0080] Figures 2A-2C show examples of fluidic modules and chambers, in accordance with embodiments.

[0081] The shape of the peripheral chambers are also cylindrical, and their top and bottom faces are circular or elongated, as shown in Figures 2A-2C.

[0082] The fluidic module can be located inside the soft contact lens 100 such that the geometrical center of the lens optic is co-linear with the geometrical center of the central chamber of the fluidic module.

[0083] The fluidic module can be filled with a biocompatible fluid 190, preferably of the same refractive index as the material of the soft contact lens, in the range of 1.44 to 1.55 or about 1.40 to about 1.55, for example.

[0084] The viscosity of the fluid can be in the range 0.2-2.0 centistokes at 37C, or in the range of about 0.2 to 5.0 centistokes at 37 C.

[0085] The fluid 190 is preferably a siloxane, a fluorocarbon, an ester, an ether or a hydrocarbon, or combinations thereof, for example.

[0086] The membrane is biocompatible, and has an index preferably substantially the same as the fluid and the contact lens itself, in the range 1.44 - 1.55, or within the range from 1.40 to 1.55, for example.

[0087] The membrane may be of the same thickness throughout, or it may have a thickness profile, contoured to control its rigidity or flexibility along the dimensions of the membrane.

[0088] The membrane is preferably a fluorocarbon, a polyester, a polyurethane, a polyether, a polyimide, a polyamide, an acrylate or methacrylate ester, or a copolymer bearing these functionalities.

[0089] The module may comprise on or more of many optically transmissive materials, such as one or more of a plastic, a polymer, a thermo plastic, a fluoropolymer a non-reactive thermoplastic fluoropolymer, or polyvinylidene difluoride (hereinafter "PVDF"), for example.

[0090] The micro-channels are fabricated from a biocompatible material, and may be a fluorocarbon, a polyester, a polyimide, a polyamide, an epoxide, an acrylate or methacrylate ester, or a hydrocarbon such as polypropylene or polyethylene.

[0091] The walls of the central chamber of the module may either be composed of the same material as the membrane on the two sides, or it may be made of a different material.

[0092] The fluidic module 150 can be embedded in the soft contact lens 100 such that the module is close to the anterior (convex) surface of the lens.

[0093] Preferably there is a thin layer of contact lens material above the fluidic module, its thickness being in the range of 5-10 microns.

[0094] Being close to the surface of the contact lens, a change in curvature of the fluidic module (caused by inflation or deflation through fluid transfer between the central and peripheral chambers) causes a corresponding change in the anterior curvature of the soft contact lens.

[0095] The diameter 161 of the central chamber 160 can be at least about 3 mm, for example within a range from about 3.0 to 5.0 mm, such as a range from about 3.0 to about 4.5 mm, for example within a range from about 4.0 - 4.5 mm, while the length of the edge can be about 10-40 microns.

[0096] The thickness of the membranes 162, 166, comprising the top and the bottom surfaces of the central chamber can be in the range 5-20 microns.

[0097] The thickness of the membrane comprising the edge 164 can be in the range 10-50 microns.

[0098] The peripheral chambers 180 have a total area of 5.0 — 8.0 mm^2 and a thickness of 10-30 microns each.

[0099] The total volume of the sealed module can be in the range of 0.15- 0.80 mm^3, or 0.15 -0.80 microliter, or from about 0.15 to about 2.50 mm^3 (about 0.15 to about 2.50 microliter), for example.

[00100] Each micro-channel can be about 10-30 microns in internal diameter and about 2-5 mm long, or from about 1 to about 5 mm long, for example.

[00101] The micro-channels may be designed to have an uniform internal diameter or it may have micro-indentations oriented to impede flow in one direction in preference to the other.

[00102] The purpose of these indentations can be to modulate the response time of the onset and removal of the additional plus power after the down-gaze.

[00103] Figure 3 shows a top view of the fluidic module, comprising a central chamber and several peripheral chambers, interconnected via micro-channels, upon downward gaze, in accordance with embodiments.

[00104] The mechanism of action involves movement of the scleral sphere caused by down-gaze typically occurring when the wearer attempts to read or perform a near vision task.

[00105] The eyeball moves down by about 20 degrees - 60 degrees, depending on the level of down-gaze, causing the corneal surface to rotate down by about 2.0 mm - 6.0 mm

[00106] The peripheral chambers slide under the lower eyelid and can be compressed, as shown in Figure 3.

[00107] A 2.0 mm downward movement of the lens positioned on the cornea will cause partial (30-60%) compression, while a 4.0 mm or greater eye movement will cause the entire peripheral chamber to be compressed.

[00108] In many embodiments eyelid caused compression will be able to expel a fraction (20% - 60%) of the fluid in the peripheral chamber(s) when the totality of peripheral chambers move under the lower eyelid.

[00109] The fluid moves travels through the micro-channels connected at the distal end to the central chamber, and increases the hydrostatic pressure in the central chamber.

[00110] The hydrostatic pressure being equal in all directions, causes a spherical inflation of the membrane on the top and bottom faces.

[00111] This inflation may be preferentially directed to the top surface by using a thicker membrane at the top surface, rendering it stiffer than the membrane covering the bottom surface of the central chamber.

[00112] In some embodiments, the hydrostatic pressure may be equal in all directions, and consequently causes a spherical inflation of the membrane on the top and bottom faces.

[00113] In many embodiments, the relative extent of inflation of the top and the bottom faces can be adjusted by adjusting the thickness of the membranes covering the top and bottom faces and providing an accommodating module having an appropriate thickness of each of the top and bottom membranes.

[00114] Similarly, the edge can be rendered less distensible by using a relatively thick walled membrane for its fabrication.

[00115] In many embodiments, a 2.0D increase in power can be achieved by a 5.0 - 7.0 micron sag height change of the anterior (top) surface of the central chamber, when the

central chamber is within a range from about 3.0 mm to about 5.0 mm, for example about 4.0 mm in diameter. Alternatively or in combination, a 2.0D increase in power can be achieved by a 5.0 - 15.0 micron sag height change of the anterior (top) surface of the central chamber, when the central chamber is within a range from about 3.0 mm to about 5.0 mm, for example about 4.0 mm in diameter.

[00116] This change in curvature can be effected by injection of fluid of volume equal to 0.10 - 0.15 microliters. Alternatively or in combination, the change in curvature can be effected by injection of fluid of volume within a range from about 0.07 to about 0.21 microliters, for example.

[00117] In many embodiments, the total volume of fluid to be expelled from the peripheral chambers to the central chamber due to eyelid pressure can be within a range from about 0.10 to about 0.30 microliters. Alternatively or in combination, the total volume of fluid to be expelled from the peripheral chambers to the central chamber due to eyelid pressure can be within a range from about 0.07 to about 0.30 microliters.

[00118] As shown in Figures 1-3, the central optical chamber 160 comprising the reservoir is connected to the one or more eyelid engaging chambers with one or more extensions 170 comprising one or more channels 172. The one or more eyelid engaging chambers 180 may comprise a plurality of eyelid engaging chambers, such as chamber A, chamber B, chamber C and chamber D. A plurality of extensions comprising a plurality of channels connects the plurality of chambers to the central optical chamber. The micro-channels extend between the central optical chamber and each of the plurality of chambers.

[00119] The plurality of eyelid engaging chambers can be arranged in one or more of many ways. For example, the eyelid engaging chambers can be arranged to engage the eyelid sequentially, simultaneously, incrementally, or in combinations thereof, for example.

[00120] The plurality of eyelid engaging chambers can be arranged to provide incremental amounts of optical power to the central optical chamber upon increasing engagement of the lower eyelid with the plurality of chambers. In many embodiments, a first eyelid engaging chamber such as chamber B or chamber C engages the eyelid before a second eyelid engaging chamber such as chamber A or chamber D. Engagement of the first eyelid engaging chamber can urge a first amount of fluid into the central optical chamber to provide a first amount of optical power. Engagement of the second eyelid engaging chamber can urge a second amount of fluid into the central optical chamber to provide a second amount of optical power greater than the first amount of optical power. The first amount of fluid from the first eyelid engaging chamber can be combined with the second amount of fluid from the

second eyelid engaging chamber to provide the second amount of optical power greater than the first amount of optical power, for example. In many embodiments, the first amount of fluid can be combined with the second amount of fluid within the central optical chamber to provide the increased optical power.

[00121] In many embodiments, the first chamber comprises a first plurality of chambers, and the second chamber comprises a second plurality of chambers, for example. Chambers B and C may comprise a first plurality of chambers, each contributing an amount of optical power within a range from about 0.25 Diopters to about 0.75 Diopters, for example. Chambers A and D may comprise a second plurality of chambers, each contributing an amount of optical power within a range from about 0.25 Diopters to about 0.75 Diopters, for example. For example each of chambers A, B, C and D may provide about 0.5 Diopters of correction, and engagement of chambers B and C provides about 1 D of additional optical power with a first position of the lens in relation to the eyelid, and engagement of chambers A, B, C and D provides about 2 D of additional optical power with a second position of the eyelid in relation to the lens.

MANUFACTURING OF THE FLUIDIC MODULE

[00122] Figure 4 shows a flow chart of assembly of the fluidic module.

[00123] The manufacturing process 400 of this fluidic module 150 involves forming the central and the peripheral chambers as well as the micro-channels separately, then joining them in order to form the whole module, as shown in Figure 1.

[00124] Preferably, the peripheral chambers are formed by casting, injection molding or blow molding.

[00125] Thermoplastics, preferably partially crystalline thermoplastics such as polycarbonate, polypropylene, polyethylene, polyethers, polyamides, polyimides, polyfluorocarbons such as polyvinylidene difluoride (hereinafter "PVDF"), polyvinylidene fluoride, for example commercially available Tyvek™ or Kynar™, may be used to injection mold or blow mold the chambers.

[00126] These materials have superior toughness, and many of them are biocompatible.

[00127] In many embodiments, the following steps are used for fabrication of the central optical chamber 160.

[00128] In many embodiments, the edge wall is formed first at a step 440, using a mandrel or a cylindrical mold to wrap around a thin film cut to shape at a step 442. For example, a piece of a thermoplastic cut into a strip 6.3-6.5 mm long, 20 microns wide and 5 microns in

thickness is cut from a roll of this material, using a water jet or a picosecond pulsed laser, for example.

[00129] In many embodiments, this strip 444 is wrapped around a rigid mandrel of diameter 4.0 mm, and it's the free edges that overlap over a distance of 0.1-0.3 mm are sealed by a heat sealing or laser welding process at a step 446.

[00130] The mandrel may be made of a stiff, for example relatively rigid material, capable of withstanding relatively high temperatures, and should have a relatively low thermal expansion coefficient such as a high melting plastic, e.g., an aromatic polyimide, a ceramic or a metal.

[00131] In many embodiments, the cylindrical shape is removed from the mandrel after the edges have been joined, for example.

[00132] In many embodiments, the shape is placed on a flat, rigid substrate over a flat end piece made of a thermoplastic or thermoset material whose diameter is matched to the diameter of the cylinder.

[00133] In many embodiments, the edge is sealed by a laser welding or a heat sealing process, preferably acting through the rigid substrate or platform supporting the end piece.

[00134] The platform also functions as a heat sink and minimizes heat diffusion up into the wall or across the surface of the end piece.

[00135] Precise control of temperature rise away from the joint can be helpful in order to minimize heat distortion.

[00136] In many embodiments, once the end piece has been sealed to the edge of the cylinder, the piece is inverted, placed over a second end piece, then the sealing process is repeated.

[00137] In many embodiments, the micro-channels 170 are fabricated at a step 450 from thin sheets of a thermoplastic such as polyethylene, polypropylene, polyvinylidene difluoride (PVDF), Tedar™, Kynar™, Viton™, or other heat sealable or weldable materials, for example.

[00138] In many embodiments, the preferred process at a step is similar to the one used to fabricate the edge member of the central chamber 160, as described above.

[00139] At a step 452 strips 454 can be cut as described herein.

[00140] At a step 456 the strips of material can be sealed as described herein to form the extensions 170 comprising the channels as described herein.

[00141] At a step 410, the top surface of the central optical chamber 150 is made. At a step 412 PVDF sheet is cut as described herein to make the circular membrane 414. At a step 416,

the circular membrane 414 is sealed on the upper rim of the extension to form upper membrane 162 of the central optical chamber.

[00142] At a step 420, the bottom surface of the central optical chamber 150 is made. At a step 422 PVDF sheet is cut as described herein to make the circular membrane 424. At a step 426, the circular membrane 424 is sealed as described herein on the upper rim of the support to form upper membrane 162 of the central optical chamber.

[00143] At a step 430, the peripheral chamber is formed by blow molding. At a step 432 the peripheral chamber is provided for assembly and may be sealed as described herein.

[00144] At a step 460 components of the module are assembled to form the module 150.

[00145] The components assembled in order to manufacture module 150 comprise a top surface of the central chamber 418, a bottom surface of the central chamber 428, a peripheral chamber 434, walls of the central chamber 448 and the micro-channel 458.

[00146] In many embodiments, the tubes forming the micro-channels 458 are next sealed on to the edges of the central chamber 448 and the peripheral chamber 180, as shown in Figure 1.

[00147] In many embodiments, the process provides an initial step sealing the tubes edgewise onto the wall of the edges, so that a fluid tight seal is formed 360 degrees around the circumference of the micro-channels.

[00148] In many embodiments, a metal insert is then used to penetrate the wall of the edges of the central chamber and the peripheral chamber(s) in order to open a fluid path. This path is fully enlarged so that is equal to the internal diameter of the micro-channel.

[00149] In many embodiments, an inlet and an outlet port are then affixed to the wall of the peripheral chamber(s), using a process similar to the one used above.

[00150] In many embodiments, the inlet and outlet ports are tubes similar in diameter, wall thickness and length as the micro-channels, and micro-channel pieces fabricated as above may be used as inlet and outlet ports.

[00151] In many embodiments, preferably, the inlet port is attached to the peripheral chamber and the outlet port is attached to the central chamber.

[00152] Figure 5 shows a method 500 of filling and sealing of the fluidic module. In many embodiments, the assembled module is then filled with fluid, as follows.

[00153] The fluid 190 to be used to fill the module is degassed by placing it in a closed container with an opening, closing the opening with a valve, cooling the fluid down to a temperature at which the fluid freezes or to -100C whichever is greater, then pulling vacuum through this opening so as to expel all air from the space above the fluid in the container.

[00154] The vacuum is shut off, the fluid is warmed to room temperature, then it is cooled again, before reapplying vacuum.

[00155] This process is repeated until a pressure gauge, connected to the fluid container registers no change in pressure upon application of vacuum to the container containing the fluid at a low temperature.

[00156] In many embodiments, a consideration is not to apply vacuum to the container when the fluid is at room temperature, in order to avoid evaporative losses of the fluid.

[00157] A gas tight syringe is inserted into the container, a quantity of fluid is drawn into the syringe, the tip of the syringe inserted into the inlet port affixed to the peripheral chamber.

[00158] An outlet tube, preferably made of metal is affixed to the outlet port.

[00159] The module is positioned such that the fluid inlet port is at the bottom and the outlet port is at the top.

[00160] Vacuum is pulled through the outlet tube, as the syringe is driven to inject fluid through the inlet tube.

[00161] Fluid injection is topped when the module is filled with fluid, and the fluid level reaches the outlet tube.

[00162] The inlet and the outlet tubes are then sealed off close to the edge of the wall of the chambers, leaving approximately 0.05 to 0.1 mm clearance.

[00163] The sealing process may involve application of heat, or a laser beam, for example.

[00164] The foregoing is given as an example, in accordance with embodiments, and is not intended to limit the described manufacturing and assembly process in any way.

EMBEDDING THE MICROFLUIDIC MODULE IN A SOFT CONTACT LENS BODY

[00165] Figure 6 shows a method 600 of encapsulating a module 150 within contact lens material 110 to form an accommodating contact lens. While the method 600 can be performed in one or more of many ways, in many embodiments method 600 comprises modification of conventional process of molding and forming a soft contact lens made of a hydrophilic monomer or a silicone hydrogel to add the inclusion of a fluidic module, fabricated as shown in Figure 5 and as described herein, in accordance with embodiments;

[00166] In many embodiments, after assembly, the fluidic module passes through an inspection station at a step 645 that may be automated for high volume production that comprises a vision system to check dimensions and seal integrity and an optical probe to test the optical properties of the central chamber, when the peripheral chamber is compressed.

[00167] In many embodiments, the module is then placed in a tray designed for a pick and place robot at a step 610, and delivered to the contact lens manufacturing line that may be automated for high volume production.

[00168] At a step 620, a degassed monomer can be provided.

[00169] At a step 630, molds are provided.

[00170] At a step 632, bottom molds are placed in trays.

[00171] At a step 634, bottom molds are placed on an automated track.

[00172] At a step 636, bottom molds are placed with monomer.

[00173] At a step 612, the module 150 is picked up and placed with a monomer.

[00174] At a step 640, top molds are placed in trays.

[00175] At a step 642, the top molds placed in the trays are picked up and placed with a robot.

[00176] At a step 638, bottom molds with monomer and module in place receive the top molds.

[00177] At a step 650, the assembly is molded on the track.

[00178] At a step 652, UV radiation or heat is applied to mold the assembly on the track.

[00179] At a step 654, the assembly is placed in a demolding bath.

[00180] At a step 656, the accommodating contact lenses are inspected with a vision system. In many embodiments, the optical properties of the module such as optical power and change in optical power are determined prior to placement in the mold in order to provide a functional accommodating contact lens to the eye of the subject.

[00181] At a step 658, the accommodating contact lenses are packaged.

[00182] At a step 659, the molds are cleaned and returned to inventory.

[00183] In many embodiments, the contact lens is typically made of a hydrophilic monomer or a silicone hydrogel material as described herein.

[00184] The lens may be formed, by way of example only, by cast polymerizing a monomer mixture comprising the monomer, an ultraviolet or thermal polymerization initiator and other additives such as a UV blocking agent or an antioxidant, for example.

[00185] In many embodiments, the cast molding process is generally performed by creating a cavity formed by two molds, filling this cavity (mold cavity) with a layer of the monomer formulation, then applying energy, that may be ultraviolet radiation, heat, ultrasonic energy, microwave energy, or the like to trigger the polymerization process by activating the polymerization initiator.

[00186] In many embodiments, the monomer formulation is cured by application of energy in the form of UV radiation, since a UV curing process allows better control of cure temperature and completes the cure in a shorter time.

[00187] In many embodiments, the UV radiation that is applied to initiate the curing process is in the range of 300 nm to 500 nm.

[00188] More preferably, the wavelength range is 310 nm to 450 nm.

[00189] In many embodiments, the tray comprising multiple mold assemblies, each consisting of a lower mold, a layer of monomer, the fluidic module immersed in monomer, and a top mold, is moved at a slow uniform speed along a track through a tunnel illuminated with UV radiation, provided from a bank of UV light sources placed either under and/or over the track

[00190] In many embodiments, typically, the UV radiation induced cure process is completed within 30-600 seconds.

[00191] In embodiments using UV curing process, the mold through which UV radiation is transmitted is transparent to UV in the wavelength range to activate the UV initiator, typically 310 nm to 450 nm.

[00192] Cure process initiated by other types of energy, e.g., heat may be provided with a substantially longer cure period.

[00193] In many embodiments, the monomer is cured as in a conventional line, although it is possible that the cure time may have to be increased in order to allow of the UV blocking properties of the fluidic module.

[00194] The UV radiation may be applied from the top and the bottom in order to fully cure the monomer, forming the contact lens.

[00195] In many embodiments, the steps involving loading of the top and bottom molds in trays that move along separate paths, the delivery of the monomer into the bowl of the second mold, the placement of the upper mold into the layer of the monomer allowing it to spread and form a continuous layer of desired thickness are all automated in a high volume production line.

[00196] Figure 6 shows how the conventional process of molding and forming a soft contact lens made of a hydrophilic monomer or a silicone hydrogel may be modified to add the inclusion of a fluidic module, fabricated as shown in Figure 5.

[00197] In many embodiments, the sealed module is added by means of a pick and place robot to the lower mold after the monomer has been injected, so that the optical center of the central chamber is aligned with the optical center of the mold.

[00198] In many embodiments, the monomer comprises, for example consists of, hydrophilic components capable of undergoing radical induced addition polymerization, such as acrylates and methacrylates, as well as certain allyl, vinyl or styrenic compounds.

[00199] A vision system may be used to check the alignment of the fluidic module delivered into the pool of the monomer in the lower mold.

[00200] Although reference is made to a monomer, a person of ordinary skill in the art will recognize that one or more of many precursor components can be used to form the polymer in accordance with the teachings described herein, such as one or more of a monomer, an oligomer, a pre-polymer, or a composition comprising mixtures of reactive polymers with un-reacted monomers, for example.

[00201] One or more of the steps of Fig. 6 is suitable for combination in accordance with embodiments disclosed herein.

[00202] In manufacturing an accommodating soft contact lens (ACL) incorporating a fluidic module embedded at or near the optical center of the lens, the seamless integration of the module in the lens body is generally desired. For example, if the ACL is formed by cast molding a relatively hydrophilic monomer formulation in a mold cavity in which the module is pre-positioned at the correct location before the mold cavity is sealed and curing commences, it may be helpful to ensure that the cure induced shrinkage forces do not cause the fluidic module to be deformed. The hydration process that follows the curing step may also cause the module to collapse at certain points, which may lead the fluid to pool at other parts of the module, or make it lose adhesion to the lens material, which may cause formation of bubbles at the interface of the module membrane and the lens body.

[00203] It is therefore desirable to provide a more controlled encapsulation process of the fluidic module into the lens body. It is also desirable to provide a positioning and fixing process for the module into the lens body such that the module is not displaced during subsequent processing steps.

[00204] As used herein, the word "cup" refers to a mold without an optical surface, as commonly used in the contact lens manufacturing industry. A cup, as used herein, denotes a container having a floor and walls, that is used to contain a fluid monomer. A cup may comprise a material that is transparent to radiation used to cure the monomer, or is able to withstand the curing temperature for several hours, for example up to 48 hours.

[00205] Figures 7-13 illustrate a molding and machining process which when used in tandem can form the ACL with an embedded module.

[00206] Figure 7 shows a polystyrene (PS) mold 2000 that may be used to form a semi-finished button. The PS mold 2000 may form the concave surface 1000 of the ACL. The PS mold 2000 may be used to cast a semi-finished button from the monomer formulation by attaching a cup 3000 to the PS mold 2000 as shown in Figure 8, thereby forming a mold cavity 3500 and curing the monomer formulation inside this cavity. The button may be referred to as semi-finished because one of its surfaces may be molded to the final finish, while the other surface is machined in subsequent steps. The PS mold 2000 may have a fixture that can be used to attach the anterior cup 3000 for a second molding step as shown in Figure 8. This cup 3000 may be removed after the casting process is complete.

[00207] The polystyrene mold 2000 may form the concave surface 1000 of the lens. As shown in Figure 9, the semi-finished button 5000 may be diamond turned to form the intermediate surface 4000. The PS mold 2000 may comprise an adapter element 2100 centered at the base of the mold; the adapter element 2100 can be used for capturing the part into the collet of the lathe or the mill. The center line of the rod feature or adapter element 2100 at the back of the PS mold 2000 (see Figure 7) may form the geometrical center of the ACL.

[00208] After the intermediate surface 4000 has been formed, the part may then be transferred to a precision milling machine to create a bed 4100 for the fluidic module 150 as shown in Figure 10. The module 150 can be made to adhere to the intermediate surface 4000 by using a drop of the monomer formulation that is partially cured as an adhesive.

[00209] A second cup 6000 may now attached to the PS mold 2000, forming a molding cavity 6500 between the intermediate surface 4000 and the inner surface 6100 of the second cup. This space can be filled with the monomer mixture, vacuum can be applied to remove bubbles, and the monomer can be cured to form a second semi-finished form of the button 5000, as shown in Figure 11.

[00210] The casting cup can then be removed, and the cured polymer 110 can be precision machined in order to form the final lens 100 and its anterior surface 7000 as shown in Figure 12. The machining process may form the optical zone for optical power and optical center, the peripheral zone for stabilization, and the edge for comfort and fit. The lens may then be hydrated before being inspected and packaged prior to sterilization.

[00211] Figure 13 shows a process 1300 of molding and forming a soft contact lens comprising a fluidic module, fabricated as shown in Figures 7-12, in accordance with embodiments. In step 1310, a polystyrene mold having a concave surface is provided. In step 1315, a first cup is attached to the mold, and a monomer formulation is added to the

mold cavity and cured to form the intermediate surface of the ACL. In step 1320, the intermediate surface is machined to create a bed for the fluidic module, and the module is adhered onto the bed. In step 1325, a second cup is attached to the mold, and the monomer formulation is added to the mold cavity and cured to form the semi-finished anterior surface of the ACL. In step 1330, the semi-finished anterior surface is machined to form the finished anterior surface. In step 1335, the ACL is removed from the mold, extracted in water to remove diluent, then hydrated in water or physiological saline. In step 1340, the ACL is inspected, packaged, and sterilized.

[00212] Figure 13 shows a method of molding and forming a soft contact lens in accordance with some embodiments. A person of ordinary skill in the art will recognize many adaptations and variations in accordance with the embodiments disclosed herein. For example some of the steps can be deleted; additional steps can be performed; the order of the steps can be changed; some of the steps comprise sub-steps; some of the steps can be repeated and some of the steps may comprise one or more steps of other methods as disclosed herein.

[00213] Figures 14-23 illustrate another molding and machining process which when used in tandem can form the ACL with an embedded module.

[00214] In the process of Figures 14-23, the two lens surfaces may be formed by a precision machining process. The process may begin with a casting of a button formed by curing the monomer formulation in a non-optical mold (called a casting cup), which may be made of a thermoplastic such as polymethyl methacrylate (PMMA). Figure 14 shows an empty casting cup 8000. This cup may comprise an adapter element 8100 (e.g., on the bottom surface opposite the cavity of the casting cup) to capture the part by a collet of a precision lathe or a mill.

[00215] Figure 15 shows the casting cup 8000 with the cured monomer formulation 110 forming a button 9000. As shown in Figure 16, the button 9000 can be machined down to form an intermediate surface 9100 that may function as a substrate for the fluidic module. A protrusion 9200, in the form of a protruding rim, may be machined at the edge of the intermediate surface, so as to provide an edge to the lens. For example, the protrusion may be a rim with a diameter of about 14 mm, defining the edge of a correspondingly sized contact lens. The protrusion can provide a reference point for proper alignment throughout the manufacturing process, by allowing the edge of the lens to remain visible. For example, the protrusion can help the fluidic module to be properly centered when being placed.

[00216] The intermediate surface 9100 may be further milled in order to create a bed 9300 for the module 150, as shown in Figure 17. The bed provides for precise alignment, by making it difficult for the seated module to move outside of the bed throughout the manufacturing process. The machined bed may further comprise a side tab 9350, which can provide a reference for determining the correct side alignment of the module during placement. The bed can be moistened with a drop of an adhesive that matches the refractive index of the monomer formulation. For example, the monomer formulation itself may be partially cured, for example by exposure to UV radiation for a few seconds, then placed on the bed of the module. The module can be placed over the adhesive onto the bed to ensure adhesion to the intermediate surface as shown in Figure 17. The module may be positioned manually, by centering the module under an operating microscope, adjusting the angle as appropriate.

[00217] The cup 8000 may then be attached to a second casting cup, and additional monomer formulation may be injected into the mold cavity formed by the two cups. The cured monomer formulation 110 can form a button 9000 with an embedded fluidic module 150, as shown in Figure 18.

[00218] The second cup can be removed, and the first casting cup 8000 may then be mounted on a collet of a precision diamond turning machine, holding it using the end rod or adapter element 8100. The surface of the button 9000 can be machined to form the first finished, concave surface 9400 of the lens as shown in Figure 19.

[00219] The casting cup 8000 containing the semi-finished button 9000 may then be attached to a block 8500 having a domed protrusion 8510 to engage the concave, first finished surface 9400 of the lens, as shown in Figures 20 and 21. The concave surface of the lens may be blocked using an adhesive 8520 such as water soluble wax or other blocking agent, then engaged with the domed protrusion of the block, preferably with the block 8500 and the first casting cup 8000 centered to within 10 microns.

[00220] The block 8500 also comprises an adapter element 8600 that can be used for capturing the part into the collet of the lathe or the mill. Once attached to the casting cup 8000 containing the semi-finished button 9000, the block can then be mounted on a precision lathe, to cut away the PMMA cup 8000 and form the second or the convex (anterior) surface 9500 of the lens as shown in Figure 22.

[00221] The machining process may form the optical zone 200 for optical power and optical center, the peripheral zone 210 for stabilization, and the edge 220 for comfort and fit.

The machining process may provide the generation of non-radially symmetric features as when creating a toric surface or stabilization mechanisms on the lens surface.

[00222] The lens 100, now comprising two finished surfaces 9400 and 9500 as shown in Figure 22, is then deblocked to remove from the block 8500 and to remove the blocking agent 8520, for example by using water to dissolve the blocking wax. The final lens 100, as shown in Figure 23, is then extracted typically for several hours to remove the diluent, and replaced in water or physiological saline.

[00223] The lens can then be inspected and packaged for sterilization.

[00224] Figure 24 shows a process 2400 of molding and forming a soft contact lens comprising a fluidic module, fabricated as shown in Figures 14-23, in accordance with embodiments. In step 2410, a casting cup having an adapter element is provided. In step 2415, the cup is filled with a monomer formulation and cured to form a button. In step 2420, the button is machined to create an intermediate surface, comprising a bed for the fluidic module and a protruding rim that defines the edge of the lens. In step 2425, the module is attached to the intermediate surface by adhering the module to the bed. In step 2430, a second cup is attached to the casting cup, and the mold cavity is filled with a monomer formulation and cured to form a button with the embedded fluidic module. In step 2435, the button surface is machined to form the concave (posterior) surface of the lens. In step 2440, the casting cup containing the button is attached to a block at the concave surface of the lens, where the concave surface of the lens is blocked with a blocking agent. In step 2445, the casting cup and the cured monomer formulation button is machined away to form the convex (anterior) surface of the lens. In step 2450, the accommodating soft contact lens (ACL) with the embedded fluidic module is removed from the block, extracted in water to remove the diluent, and hydrated in water or physiological saline. In step 2455, the ACL is inspected, packaged, and sterilized.

[00225] Figure 24 shows a method of molding and forming a soft contact lens in accordance with some embodiments. A person of ordinary skill in the art will recognize many adaptations and variations in accordance with the embodiments disclosed herein. For example some of the steps can be deleted; additional steps can be performed; the order of the steps can be changed; some of the steps comprise sub-steps; some of the steps can be repeated and some of the steps may comprise one or more steps of other methods as disclosed herein.

FORMULATING THE SOFT CONTACT LENS MATERIAL PRECURSOR

[00226] As described herein, in manufacturing an accommodating soft contact lens (ACL) incorporating a fluidic module embedded at or near the optical center of the lens, the seamless integration of the module in the lens body is generally desired. For example, if the ACL is formed by cast molding a relatively hydrophilic monomer formulation in a mold cavity in which the module is pre-positioned at the correct location before the mold cavity is sealed and curing commences, it may be helpful to ensure that the cure induced shrinkage forces do not cause the fluidic module to be deformed. The hydration process that follows the curing step may also configured to inhibit changes in the volume of the cured contact lens covering material.. In many embodiments, a lens material is provided that may be formed from a monomer formulation that is designed to provide good integration with the embedded fluidic module.

[00227] In many embodiments, the monomer formulation is chosen to have physical and chemical properties desirable for use as a soft contact lens. For example, the formulation can compromise a monomer that is optically transparent and have a refractive index in the range 1.41-1.43 measured at 536 nm. The monomer formulation can form a lens that, when hydrated, is wettable, as measured by a contact angle of 60 degrees or less. Preferably, the monomer has good oxygen permeability, measured as Dk/I in the range 30-50 barrers. The monomer may have a glass transition temperature in the range 0-20°C, and the modulus of the polymer may be in the range 0.3-1.5 MPa. In many embodiments, the monomer formulation is chosen to have physical and chemical properties that match at least some of the properties of the material comprising the module.

[00228] In many embodiments, the formulation may have reduced shrinkage during curing, such that the curing of the soft contact lens material does not cause the deformation of the fluidic module. For example, the formulation may comprise a monomer that is curable to form the lens at a temperature not exceeding 50°C, and has a water content in the range 25-50%. Preferably, the monomer has a cure shrinkage less than or equal to 5% by volume.

[00229] In many embodiments, the formulation is designed to have reduced water expansion when the soft contact lens is hydrated with water or saline subsequent to the formation of the lens. For example, the monomer can be premixed with a diluent, chosen such that the diluent can be replaced by water subsequent to the formation of the lens without causing a significant change in volume of the lens. Preferably, the water expansion of the formed lens upon replacement of the diluent is water is less than 5% by volume.

[00230] A diluent for the monomer formulation may comprise a mix of two or more components, chosen to reduce cure shrinkage and water expansion of the cured monomer. While the diluent does not chemically participate in the curing reaction, it affects the rates of the reactions by altering the mole fractions of each reactive constituent and the overall viscosity of the material. The diluent may comprise a high molecular weight component with relatively high density and viscosity, such as polyethylene glycol, and a low molecular weight component with relatively low density and viscosity, such as isopropanol. High molecular weight components in the diluent can help to inhibit cure shrinkage, by increasing the viscosity of the diluent. Low molecular weight components in the diluent can help improve the hydration of the contact lens when placed in water, and can help improve diluent extraction from the cured monomer, thereby improving the biocompatibility of the contact lens. Preferably, the mix of components is selected such that the molar volume of the diluent is equal to or close to the molar volume of water, in order to minimize the expansion of the cured monomer when the diluent is replaced with water.

[00231] In many embodiments, the monomer formulation comprises a mixture of hydrophilic acrylates and methacrylates, a photochemical polymerization initiator, and a diluent, selected so as to have a high but controlled rate of initiation and polymerization. This monomer formulation may have a final glass transition temperature of the polymerization product of less than 25°C, so that the cure process can be completed at or near room temperature and provides a cure or post-cure temperature no higher than 50°C.

[00232] Figure 25 shows a table of some exemplary materials that the monomer formulation may comprise, in accordance with embodiments. The formulation may comprise one or more of many components, including mono-functional monomers, multi-functional monomers, cross-linkers, diluents, and photo-initiators. For example, a formulation may compromise a mixture of hydroxyethyl methacrylate (10-30% w/w) and methoxyethyl methacrylate (10-20% w/w), with a smaller proportion of a more hydrophilic monomer such as polyoxymethylene diacrylate or glycerol monomethacrylate (0-15% w/w), a highly hydrophilic monomer with a slower curing rate such as N-vinyl pyrollidone (0-15% w/w), a cross-linker such as trimethylolpropane triacrylate or trimethylol propane trimethacrylate, or ethylene glycol dimethacrylate or N,N' diethyl bisacrylamide (1-5% w/w), a photo-initiator such as diethoxy acetophenone or diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (1-3% w/w), and a diluent such as polyethylene glycol of molecular weight 600-4,500 Da (20-35% w/w).

[00233] To prepare the monomer formulation for manufacturing a contact lens, monomer components may first be purified to remove polymerization inhibitors, by one of many methods well-known in the art such as fractional distillation, spinning band distillation, and preparative liquid chromatography. The formulation comprising the mixed monomers may then be degassed to remove dissolved oxygen, then molded to shape the body of the contact lens as described herein. Subsequently, the monomer formulation may be cured by one of many known methods, such as photo-curing by exposure to ultraviolet radiation at a modest temperature. The formed contact lens may be extracted to remove the diluent, then replaced in water or physiological saline for sterilization and distribution.

[00234] While preferred embodiments of the present invention have been shown and described herein, it will be obvious to those skilled in the art that such embodiments are provided by way of example only. Numerous variations, changes, and substitutions will now occur to those skilled in the art without departing from the invention. It should be understood that various alternatives to the embodiments of the invention described herein may be employed in practicing the invention. It is intended that the following claims define the scope of the invention and that methods and structures within the scope of these claims and their equivalents be covered thereby.

CLAIMS

WHAT IS CLAIMED IS:

1. A method of manufacturing an accommodating contact lens, the method comprising:

providing an accommodating contact lens module and a contact lens covering material;

encapsulating the accommodating contact lens module in the contact lens covering material; and

machining one or more of an anterior or posterior surface of the soft contact lens covering material having the contact lens module encapsulated therein to form an optical correction zone for a subject.

2. A method as in claim 1, wherein the accommodating contact lens module comprises a free standing module prior to being covered with the contact lens covering material.

3. A method as in claim 1, wherein the module comprises an index of refraction similar to an index of refraction of the contact lens covering material in order to transmit light refracted by the anterior and posterior surfaces of the optical correction zone through at least a portion of the module and inhibit optical artifacts.

4. A method as in claim 1, wherein the accommodating contact lens module comprises a free standing module comprising one or more of an optical chamber, a support structure, one or more eyelid engaging chambers, one or more extensions extending between the optical chamber and the one or more chambers, or an anchor.

5. A method as in claim 4, wherein the accommodating contact lens module comprises the free standing module comprising the optical chamber, the support structure, the one or more eyelid engaging chambers, the one or more extensions extending between the optical chamber and the one or more chambers and the anchor, and wherein the free standing module is configured such that the optical chamber, the support structure, the one or more eyelid engaging chambers, the one or more extensions extending between the optical chamber and the one or more chambers and the anchor are connected to each other prior to placement in the mold such that the module comprises a self-supporting module capable of being lifted and placed in the mold by grasping the one or more of the optical chamber, the one or more eyelid engaging chambers, the one or more extensions extending between the optical chamber, the one or more chambers, or the anchor.

6. A method as in claim 5, wherein the module is grasped by an end effector of a robot.

7. A method as in claim 4, wherein the module comprises the optical chamber and the one or more eyelid engaging chambers and wherein the optical chamber comprises an anterior membrane having an anterior thickness and a posterior membrane having a posterior thickness, the posterior thickness greater than the anterior thickness, and wherein the one or more eyelid engaging chambers comprises an anterior membrane having an anterior membrane thickness greater than a posterior membrane thickness of the one or more chambers .

8. A method as in claim 7, wherein an anterior surface of the anterior membrane of the optical chamber comprises a convex curvature and a posterior surface of the posterior membrane of the one or more chambers comprises a convex surface.

9. A method as in claim 4, wherein module comprises the anchor and the anchor comprises a flange comprising a plurality of openings and wherein the plurality of openings is placed in the mold.

10. A method as in any one of claims 1, 4, or 5, wherein an optically transmissive coupling fluid has been placed in the accommodation module prior to encapsulating the module.

11. A method as in claim 10, wherein the fluid is pressurized within the module when the module has been placed in the mold.

12. A method as in claim 1, wherein an optical chamber of the module comprises an optical power when placed in the mold and wherein the optical power is inhibited by the contact lens covering material with the module encapsulated within the contact lens covering material.

13. A method as in claim 12, the optical chamber comprises an optically transmissive coupling fluid and the optical chamber comprises a convexly curved anterior surface of an anterior membrane when the module has been placed in the mold.

14. A method as in claim 13, the anterior membrane comprises an elastic deflection and wherein the elastic deflection pressurizes the optically transmissive coupling fluid when the module has been placed in the mold.

15. A method as in claim 1, wherein the contact lens covering material comprises one or more of a hydrogel, silicone, siloxane, silicone hydrogel, galyfilcon A, senofilcon A, Comfilcon A, Enfilcon A, polyacrylate, or polyhydroxyethylmethacrylate (pHEMA).

16. A method as in claim 1, wherein providing the contact lens covering material comprises filling a first casting cup with a precursor of the contact lens covering material.

17. A method as in claim 16, wherein the first casting cup comprises one or more of a polymer, thermoplastic, polymethyl methacrylate (PMMA), polyethylene, polypropylene, polyvinyl chloride, polytetraflouroethylene, polycarbonate, or bisphenol A.

18. A method as in claim 16, wherein providing the contact lens covering material further comprises curing the precursor of the contact lens covering material to provide a first contact lens covering material portion of the contact lens covering material in the first casting cup.

19. A method as in claim 18, further comprising machining a surface of the first contact lens covering material portion to form an intermediate surface.

20. A method as in claim 19, wherein the surface of the first contact lens covering material portion is machined with a diamond turner.

21. A method as in claim 19, wherein the intermediate surface has a concave configuration.

22. A method as in claim 19, wherein machining the surface of the first contact lens covering material portion comprises engaging a rod coupled to the first casting cup.

23. A method as in claim 22, wherein machining the surface of the first contact lens covering material portion further comprises actuating the attached rod.

24. A method as in claim 22, wherein encapsulating the accommodating contact lens module in the contact lens covering material comprises placing the accommodating contact lens module and the precursor of the contact lens covering material onto the intermediate surface.

25. A method as in claim 24, further comprising curing the precursor of the contact lens covering material on the intermediate surface to form a second contact lens covering material portion of the contact lens covering material.

26. A method as in claim 25, wherein placing the precursor of the contact lens covering material comprises engaging the casting cup with a second casting cup, and

wherein machining one or more of the anterior or posterior surface of the contact lens covering material having the accommodating contact lens module encapsulated therein comprises machining a surface of the second contact lens covering material portion to form a first surface of the optical correction zone.

27. A method as in claim 26, wherein the surface of the second contact lens covering material portion is machined with a diamond turner.

28. A method as in claim 26, further comprising disengaging the rod from the first casting cup and machining the first contact lens covering material portion to form a second surface of the optical correction zone.

29. A method as in claim 28, wherein machining the first contact lens covering material portion comprises engaging one or more of the first or second casting cups.

30. A method as in claim 28, wherein the second surface of the first contact lens covering material portion is machined with a diamond turner.

31. A method as in claim 28, wherein the second surface of the optical correction zone comprises an anterior surface.

32. A method as in claim 26, wherein the first surface of the optical correction zone comprises a posterior surface.

33. A method of manufacturing a hydrogel, the method comprising:

combining a polymeric material precursor with a first diluent and a second diluent;

curing the bathed precursor to form a polymeric material portion such that cure shrinkage of the polymeric material portion is reduced by the first and second diluents; and

providing water to the polymeric material portion such that the first and second diluents in the polymeric material portion are exchanged with the water to form the hydrogel, wherein water expansion of the polymeric material portion is inhibited with the first and second diluents.

34. A method as in claim 33, wherein exchanging the first and second diluents with the water softens the polymeric material.

35. A method as in claim 33, wherein combining the precursor of the polymeric material in the first and second diluents comprises mixing the precursor of the polymeric material with a combination of the first and second diluents, the combination comprising a molarity substantially equimolar with a molarity of the water.

36. A method as in claim 33, wherein the first and second diluents in the polymeric material portion are exchanged with the water such that the exchanged first and second diluents and the exchanged water are substantially equimolar.

37. A method as in claim 33, wherein the first diluent comprises a high molecular weight diluent and the second diluent comprises a low molecular weight diluent.

38. A method as in claim 37, wherein the high molecular weight diluent comprises a high molecular weight (MW) compound with a MW of at least about 600 Da and the low molecular weight diluent comprises a low MW compound with a MW of less than 100 Da.

39. A method as in claim 33, wherein the first diluent comprises a high density diluent and the second diluent comprises a low density diluent.

40. A method as in claim 39, wherein the high density diluent has a density of greater than 0.8 g/cc and the low density diluent has a density of less than 0.8 g/cc.

41. A method as in claim 33, wherein the first diluent comprises a high viscosity diluent and the second diluent comprises a low viscosity diluent.

42. A method as in claim 41, wherein the high viscosity diluent has a viscosity of greater than 50 centiStokes (cSts) and the low viscosity diluent has a viscosity of less than 50 cSts.

43. A method as in claim 33, wherein the first diluent comprises one or more of polyethylene glycol (PEG) with molecular weights in the range 600-4,500 Da.

44. A method as in claim 33, wherein the second diluent comprises one or more of an alcohol, isopropyl alcohol, ethanol, methanol, or a glycerol solution.

45. A method as in claim 33, wherein curing the bathed precursor to form the polymeric material portion comprises heating the bathed precursor.

46. A method as in claim 33, wherein curing the bathed precursor comprises exposing the bathed precursor with UV radiation.

47. A method as in claim 33, wherein curing the bathed precursor comprises photocuring the bathed precursor.

48. A method as in claim 33, wherein the precursor comprises a photochemical polymerization initiator.

49. A method as in claim 33, wherein the precursor comprises a monomer.

50. A method as in claim 49, wherein the monomer comprises hydrophilic components.

51. A method as in claim 49, wherein molecular structure of the hydrophilic components comprises one or more of acrylates, methacrylates, vinyl, allyl, or other olefinic groups capable of undergoing addition polymerization.

52. A method as in claim 33, wherein the precursor comprises a cross-linker.

53. A method as in claim 52, wherein the cross-linker comprises one or more of triacrylates or tetraacrylates.

54. An accommodating contact lens, comprising:

an optically transparent body comprising an anterior surface and a posterior surface shaped to correct vision of the patient;

an accommodation module contained within the body;

wherein one or more of the anterior surface or the posterior surface comprises a surface machined to correct vision of the patient.

55. An accommodating contact lens as in claim 54, wherein the one or more surfaces comprises structure of the machining process.

56. A method of manufacturing a contact lens, the method comprising:

Placing a contact lens module in a mold;

Providing a polymeric material comprising a low molecular weight diluent and a high molecular weight diluent;

Curing the polymeric material to form one or more optical surfaces of the contact lens with one or more surfaces of the mold.

57. A method as in claim 56, wherein the one or more surfaces of the mold forms one or more of an anterior optical surface or a posterior optical surface of the contact lens.

58. A method as in claim 57, wherein the mold forms the anterior optical surface and the posterior optical surface of the contact lens.

59. A composition, the composition comprising:

A polymeric material; and

A plurality of diluents contained within the polymeric material, wherein the polymeric material comprises a stiff material.

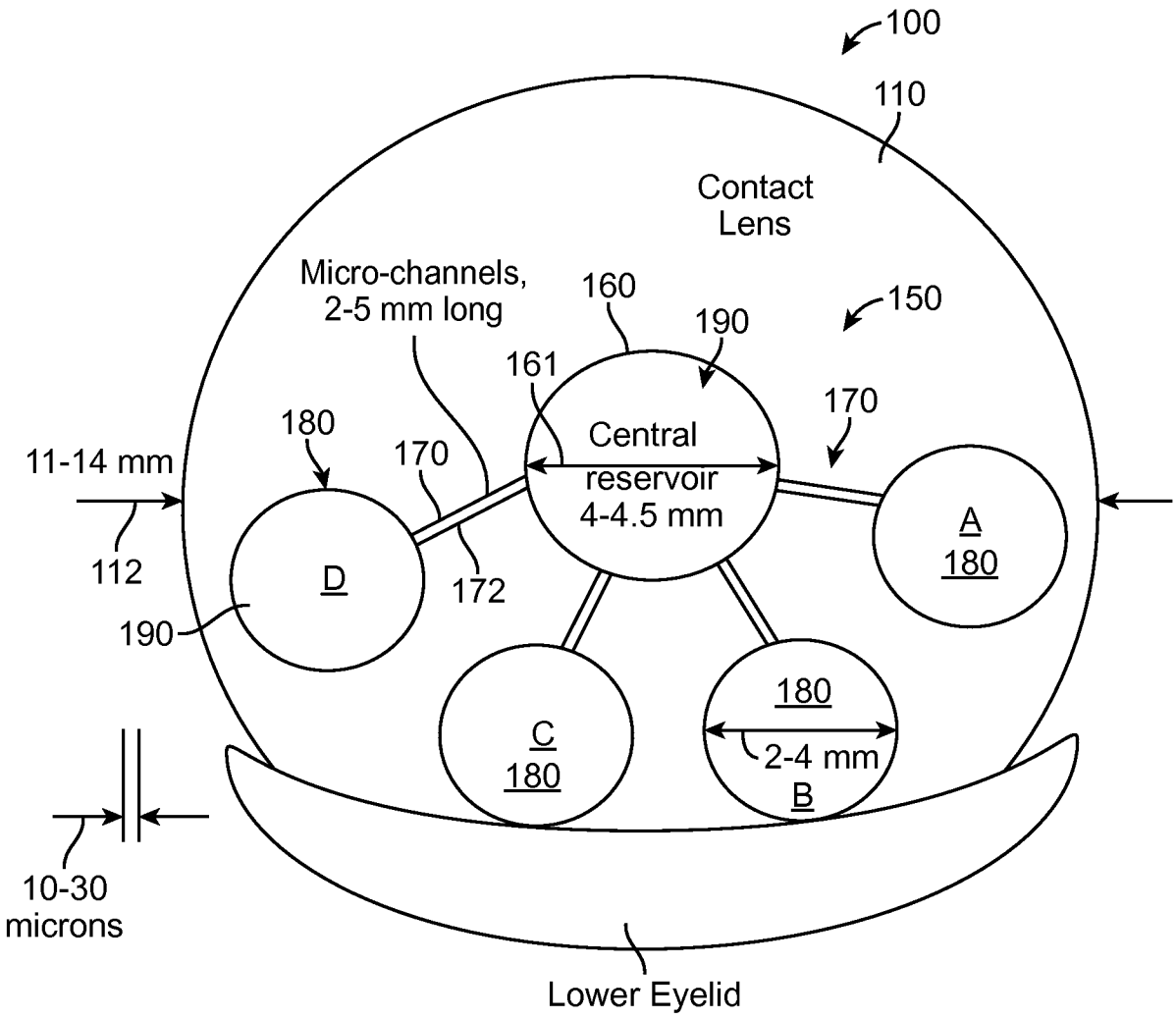

100
110
Contact
Lens
Micro-channels,
2-5 mm long
160
190
150
161
170
180
170
Central
reservoir
4-4.5 mm
11-14 mm
112
D
172
A
180
190
C
180
180
2-4 mm
B
10-30
microns
Lower Eyelid

FIG. 1

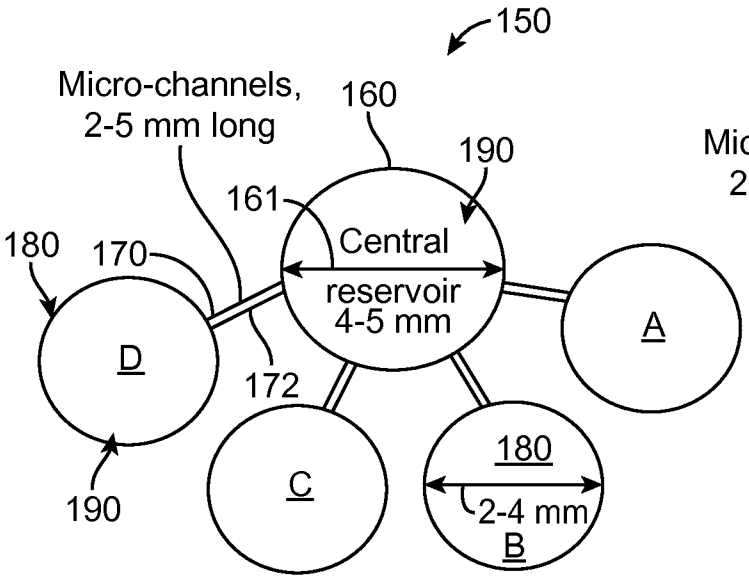


FIG. 2A

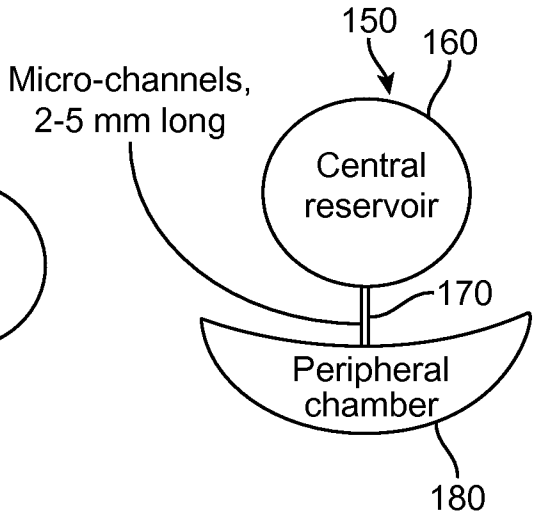


FIG. 2B

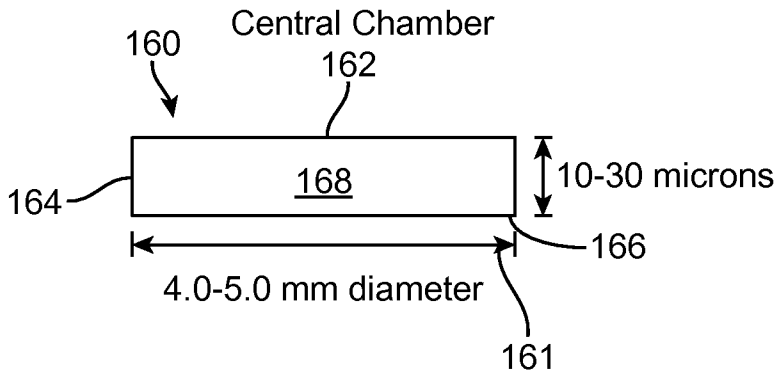


FIG. 2C

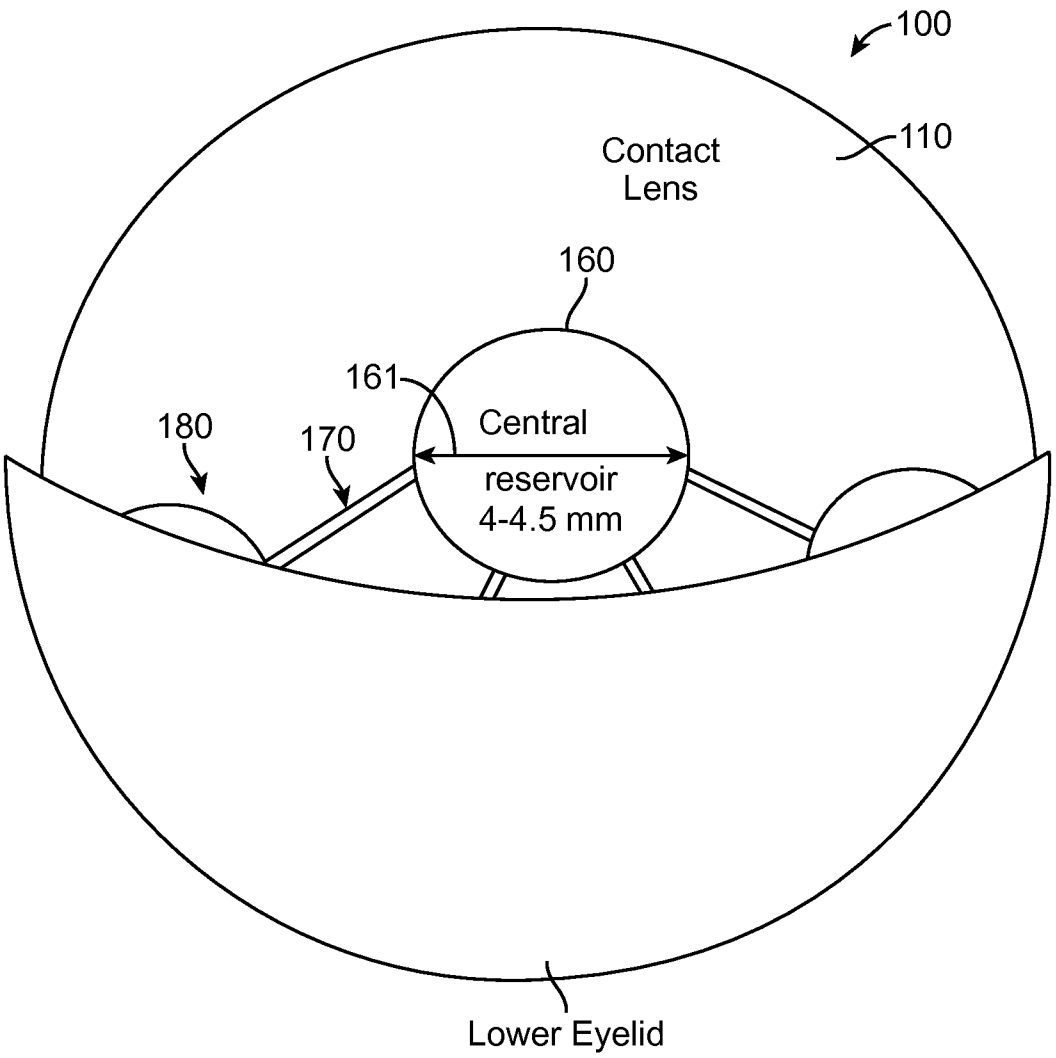

100
110
Contact
Lens
160
161
180
170
Central
reservoir
4-4.5 mm
Lower Eyelid

FIG. 3

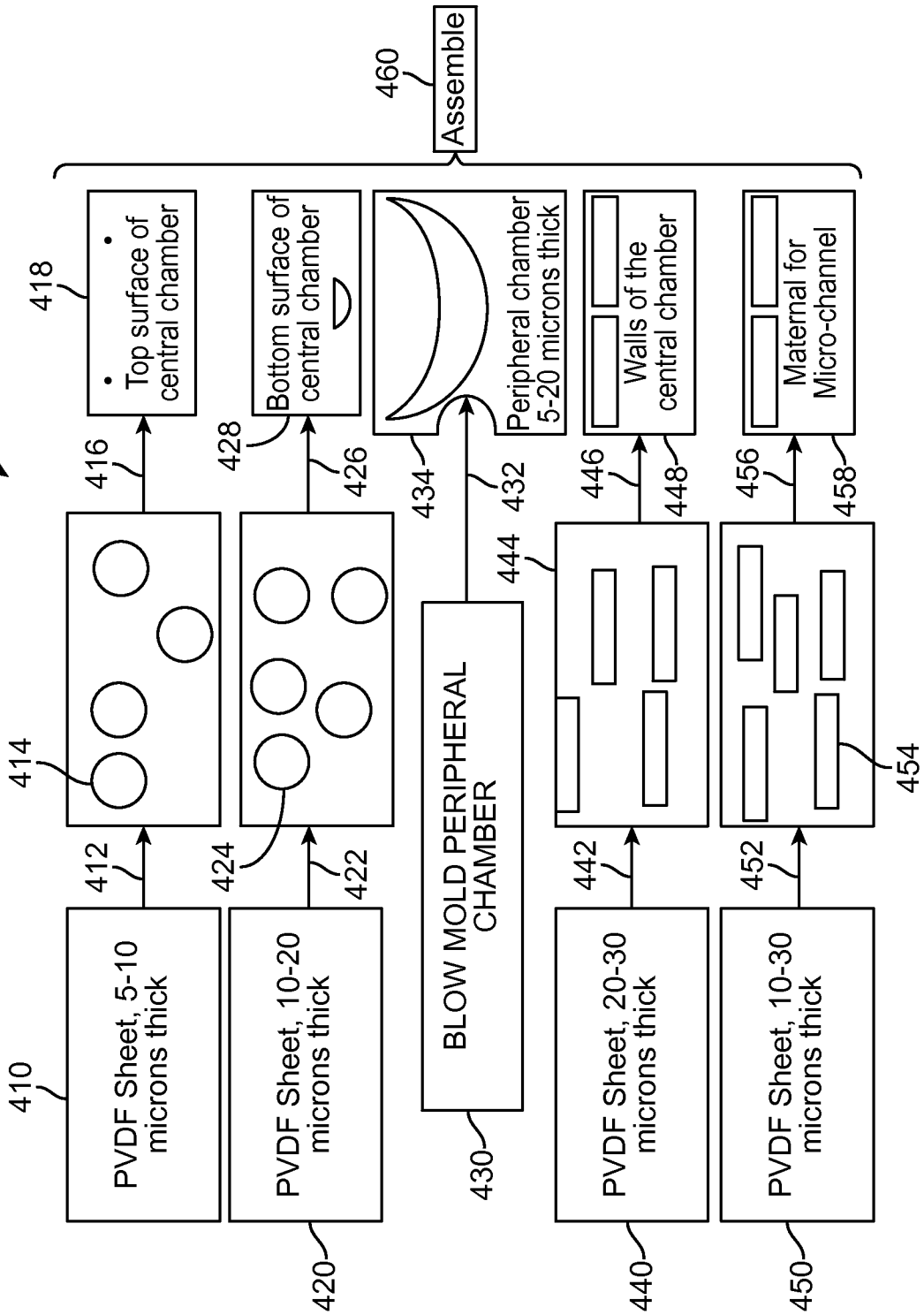

400
410
PVDF Sheet, 5-10 microns thick
412
414
416
418
Top surface of central chamber
420
PVDF Sheet, 10-20 microns thick
422
424
426
428
Bottom surface of central chamber
430
BLOW MOLD PERIPHERAL CHAMBER
432
434
Peripheral chamber 5-20 microns thick
440
PVDF Sheet, 20-30 microns thick
442
444
446
Walls of the central chamber
448
450
PVDF Sheet, 10-30 microns thick
452
454
456
Maternal for Micro-channel
458
460
Assemble

FIG. 4

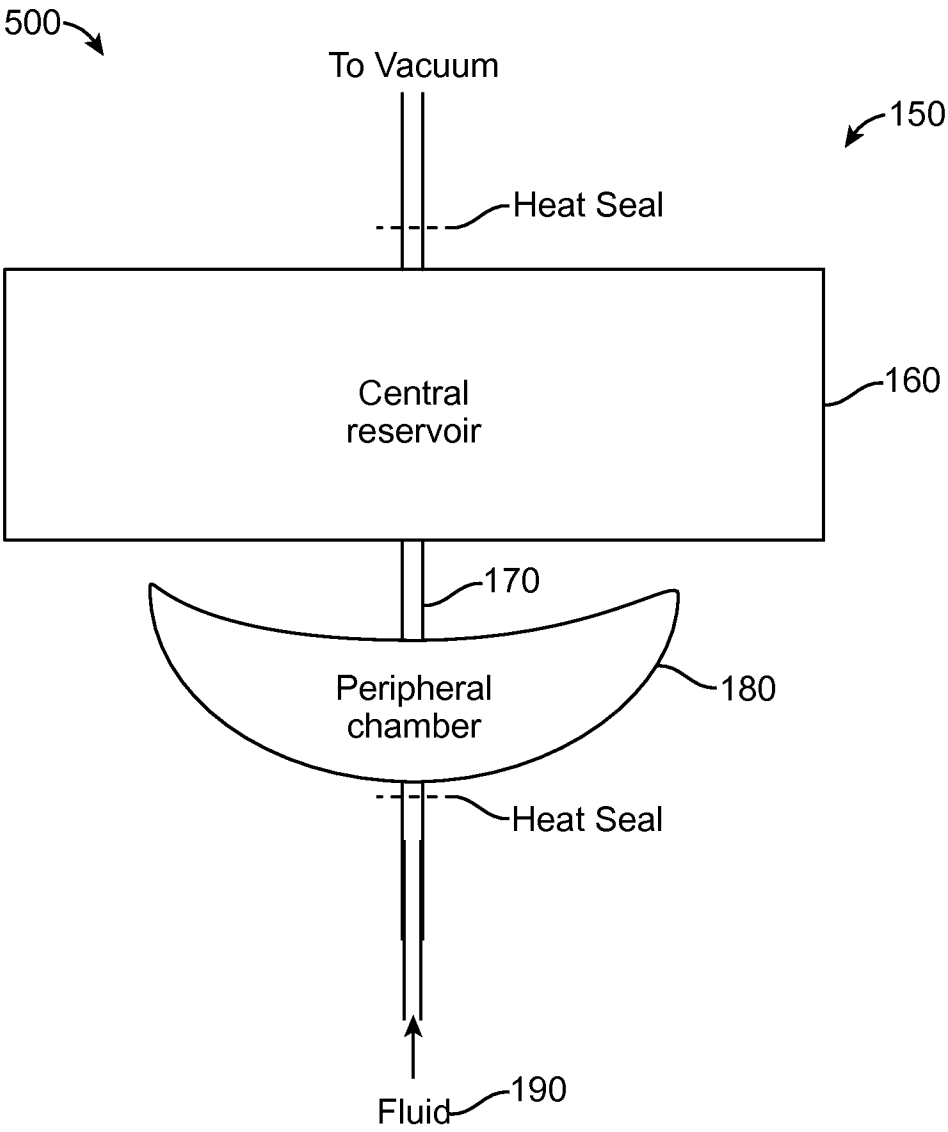

500
To Vacuum
150
Heat Seal
Central
reservoir
160
170
Peripheral
chamber
180
Heat Seal
Fluid
190

FIG. 5

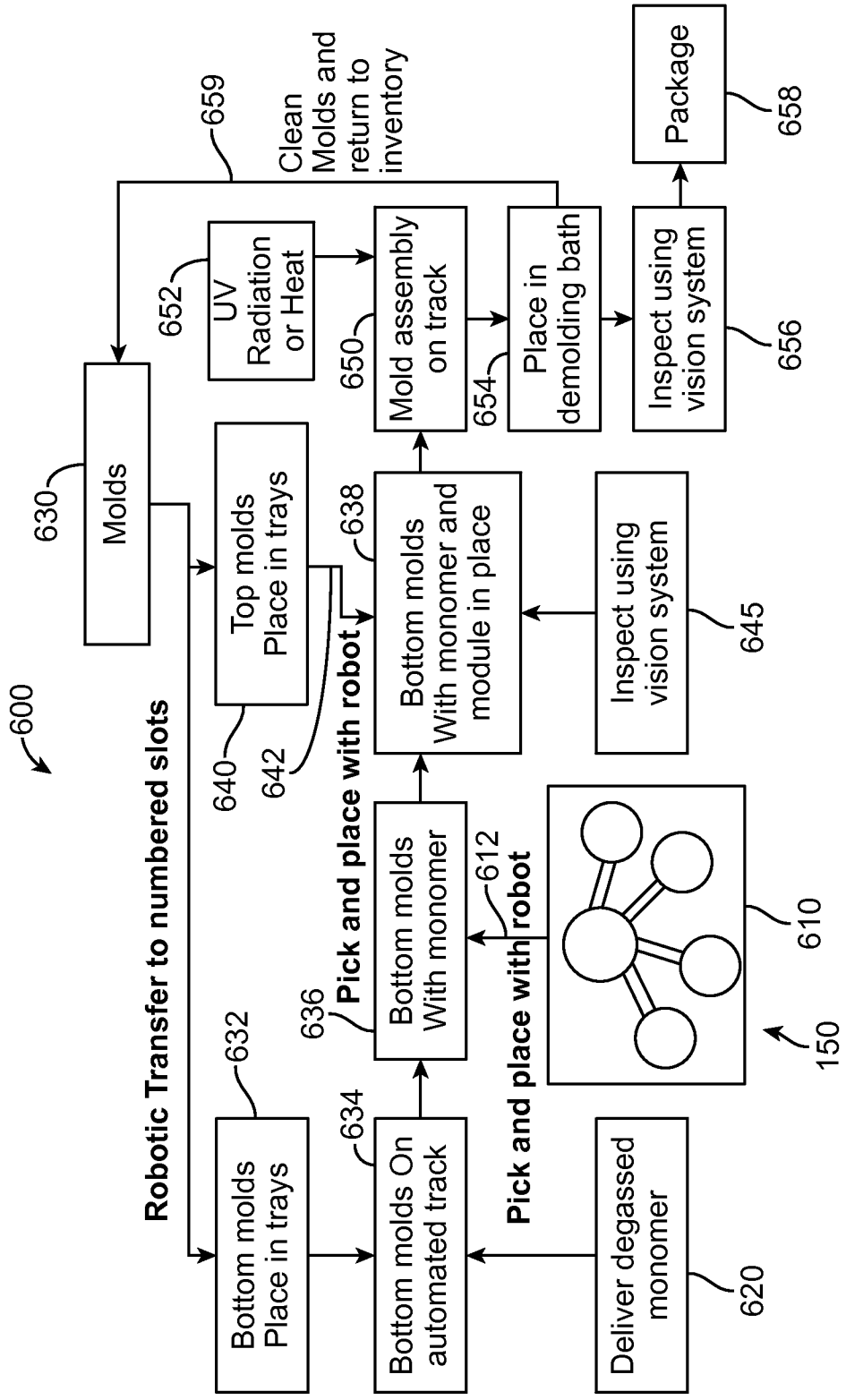

600
Deliver degassed monomer
620
Bottom molds On automated track
634
Bottom molds Place in trays
632
Robotic Transfer to numbered slots
Pick and place with robot
636
Bottom molds With monomer
612
Pick and place with robot
610
150
Bottom molds With monomer and module in place
638
Inspect using vision system
645
Top molds Place in trays
640
642
Pick and place with robot
Molds
630
UV Radiation or Heat
652
Mold assembly on track
650
Place in demolding bath
654
Inspect using vision system
656
Package
658
Clean Molds and return to inventory
659

FIG. 6

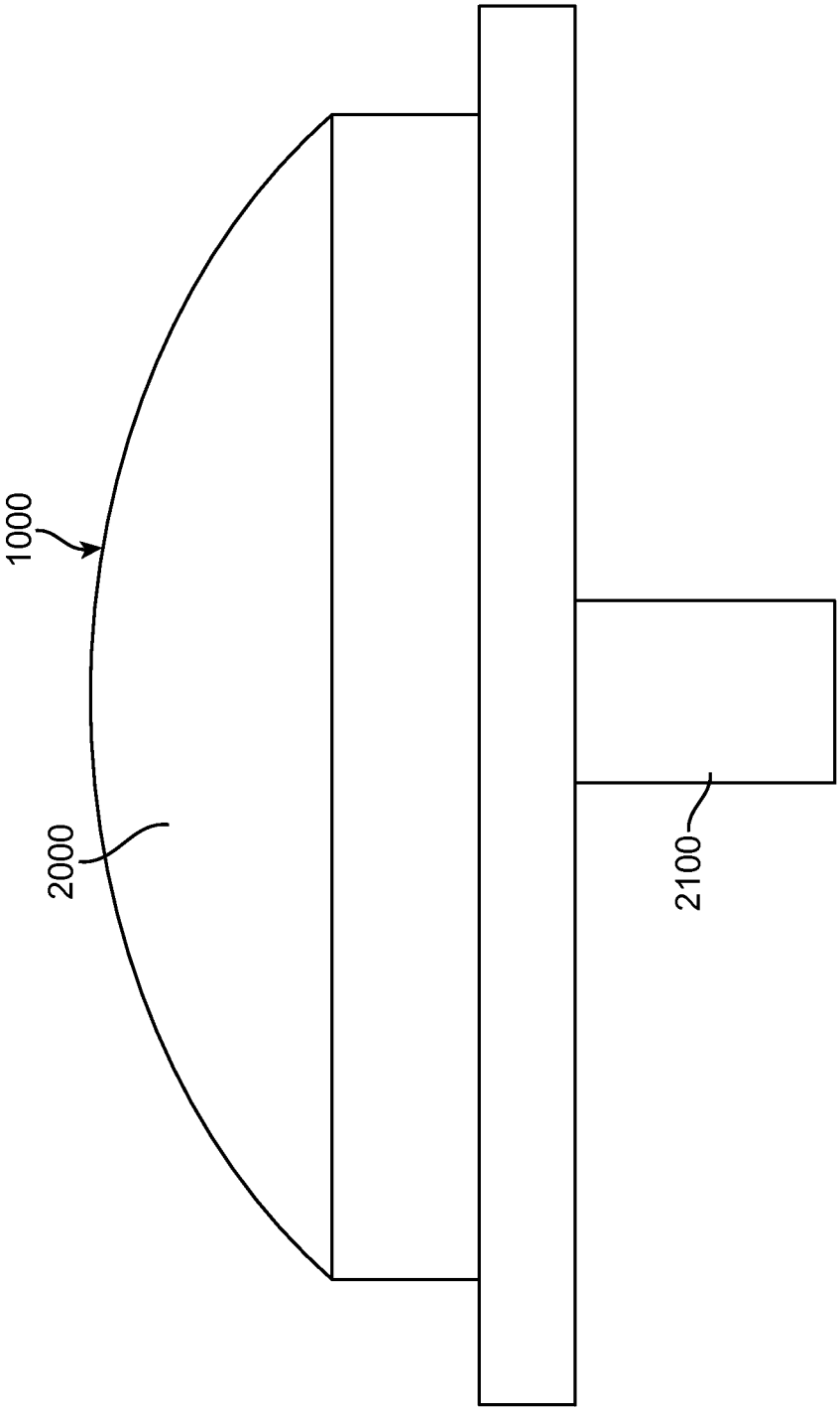


FIG. 7

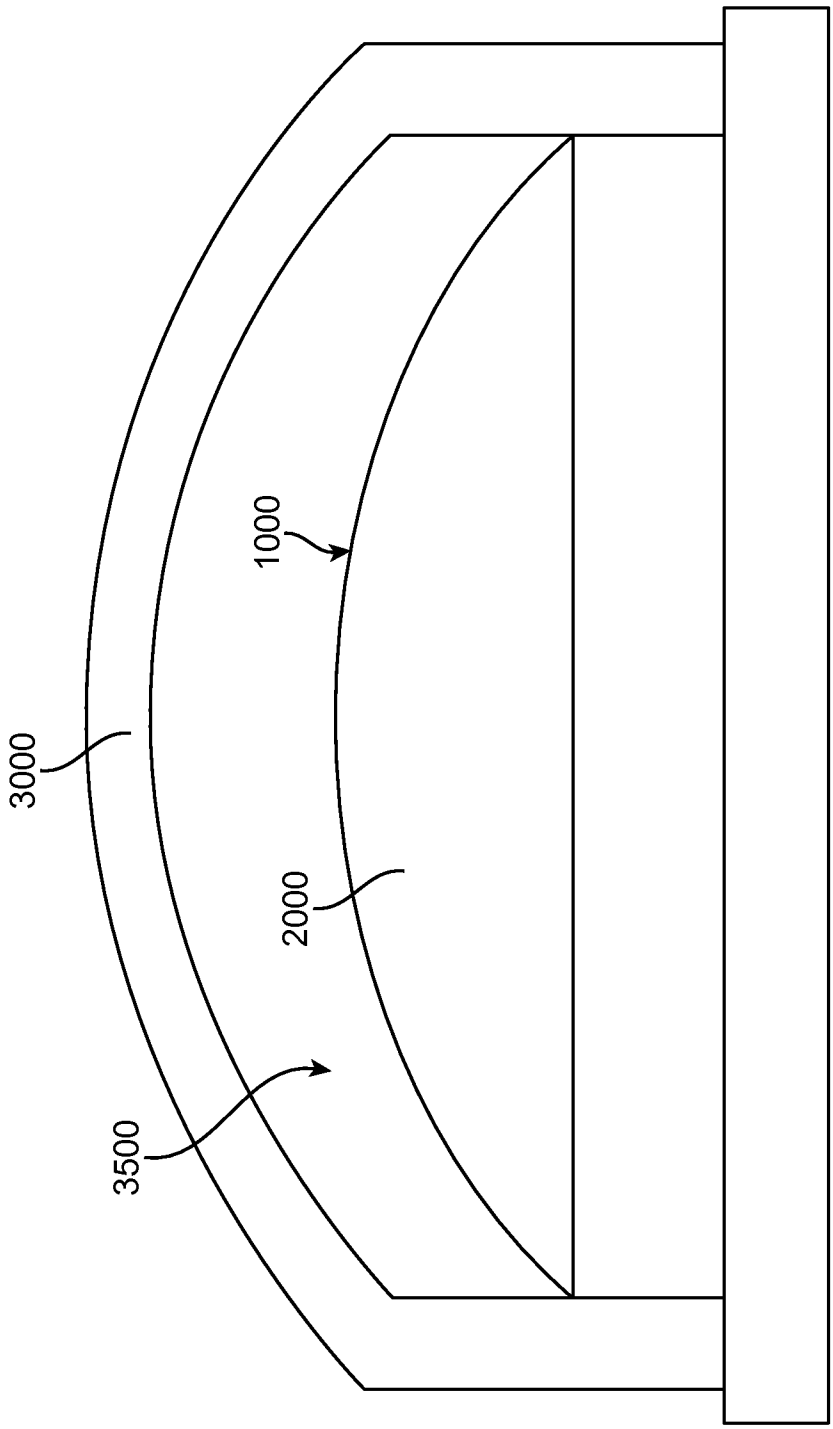


FIG. 8

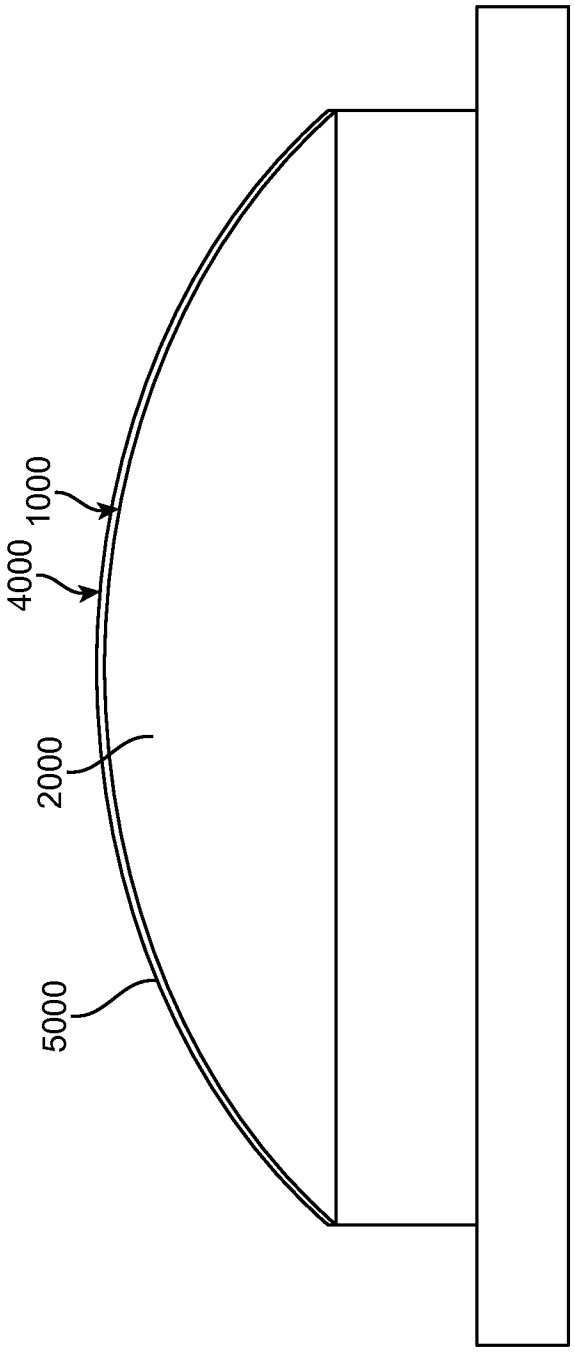


FIG. 9

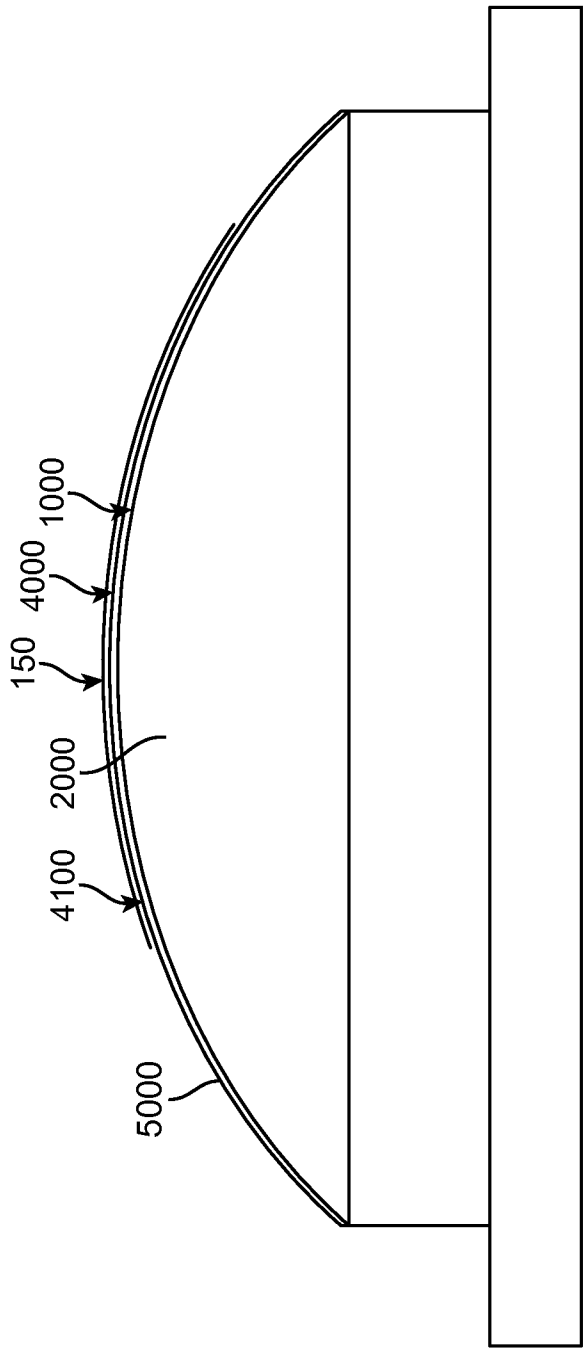


FIG. 10

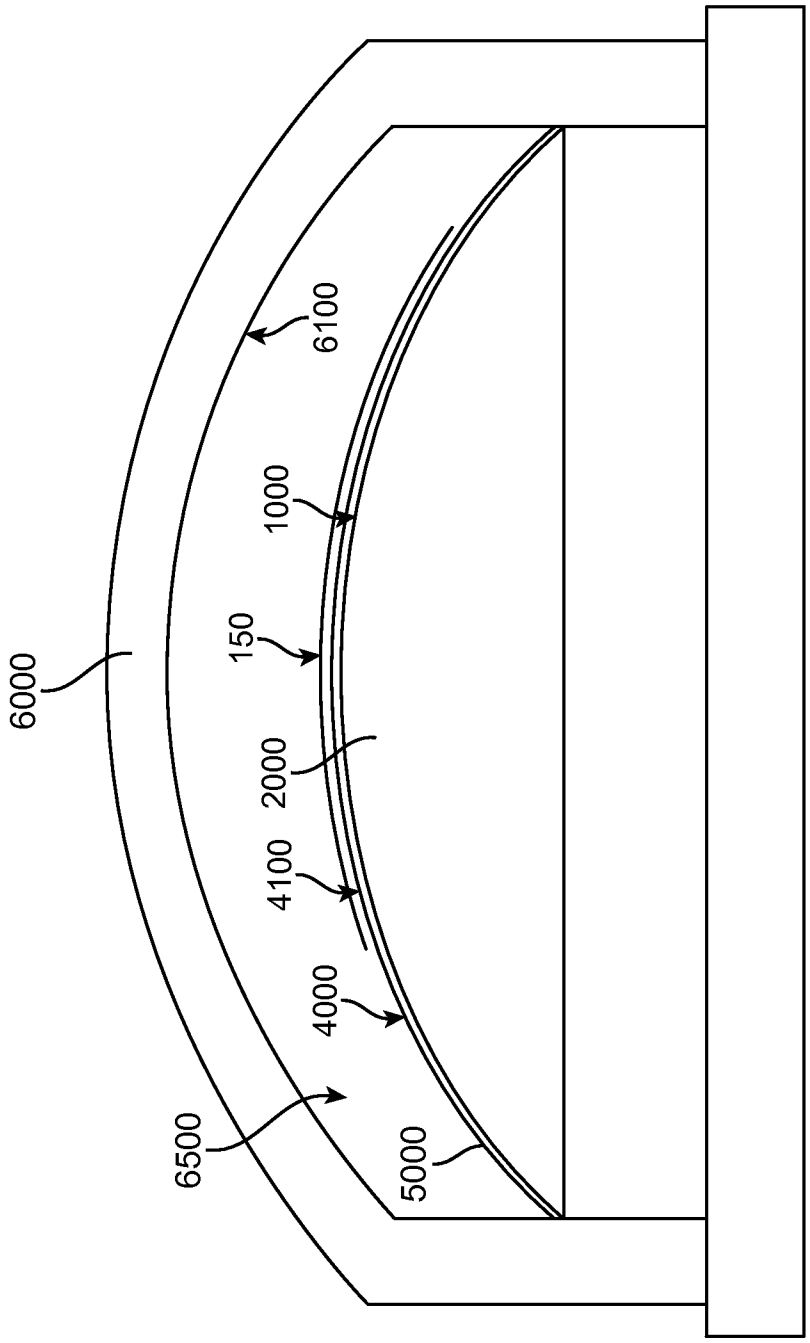


FIG. 11

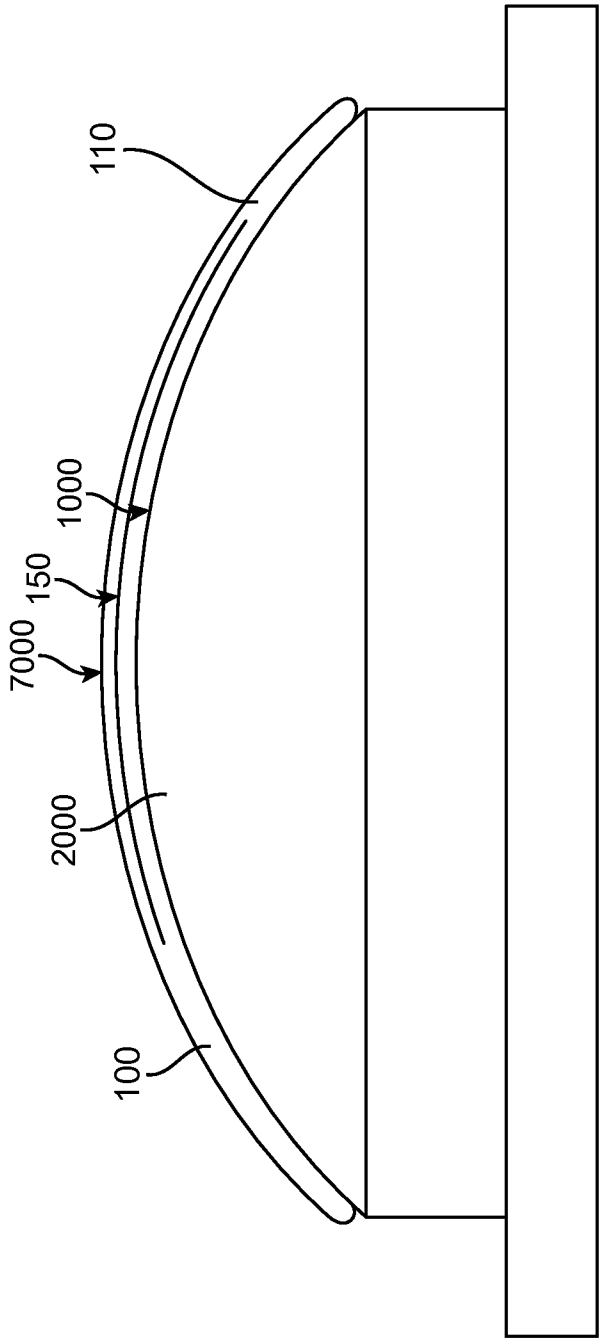


FIG. 12

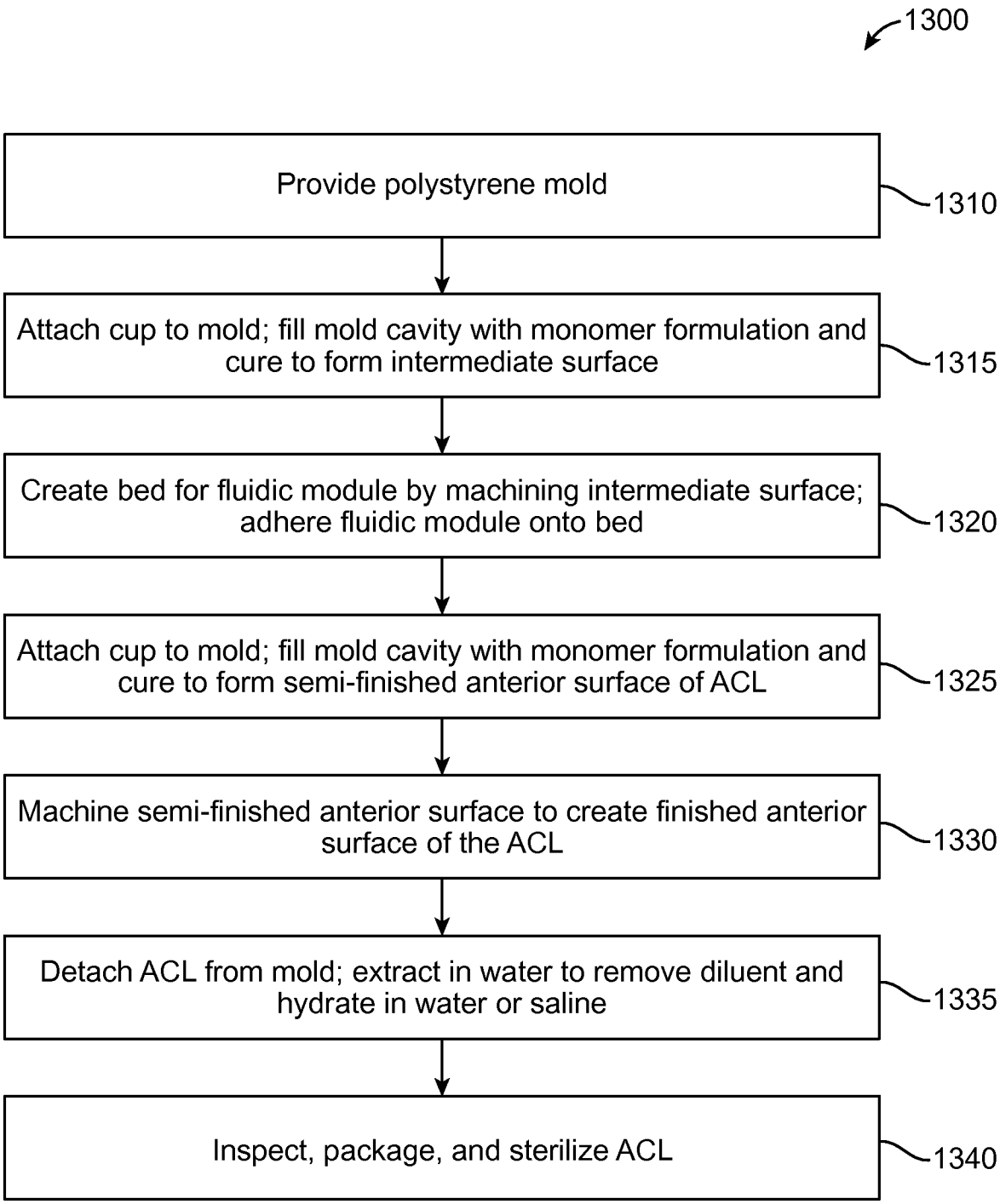

1300
Provide polystyrene mold
1310
Attach cup to mold; fill mold cavity with monomer formulation and cure to form intermediate surface
1315
Create bed for fluidic module by machining intermediate surface; adhere fluidic module onto bed
1320
Attach cup to mold; fill mold cavity with monomer formulation and cure to form semi-finished anterior surface of ACL
1325
Machine semi-finished anterior surface to create finished anterior surface of the ACL
1330
Detach ACL from mold; extract in water to remove diluent and hydrate in water or saline
1335
Inspect, package, and sterilize ACL
1340

FIG. 13

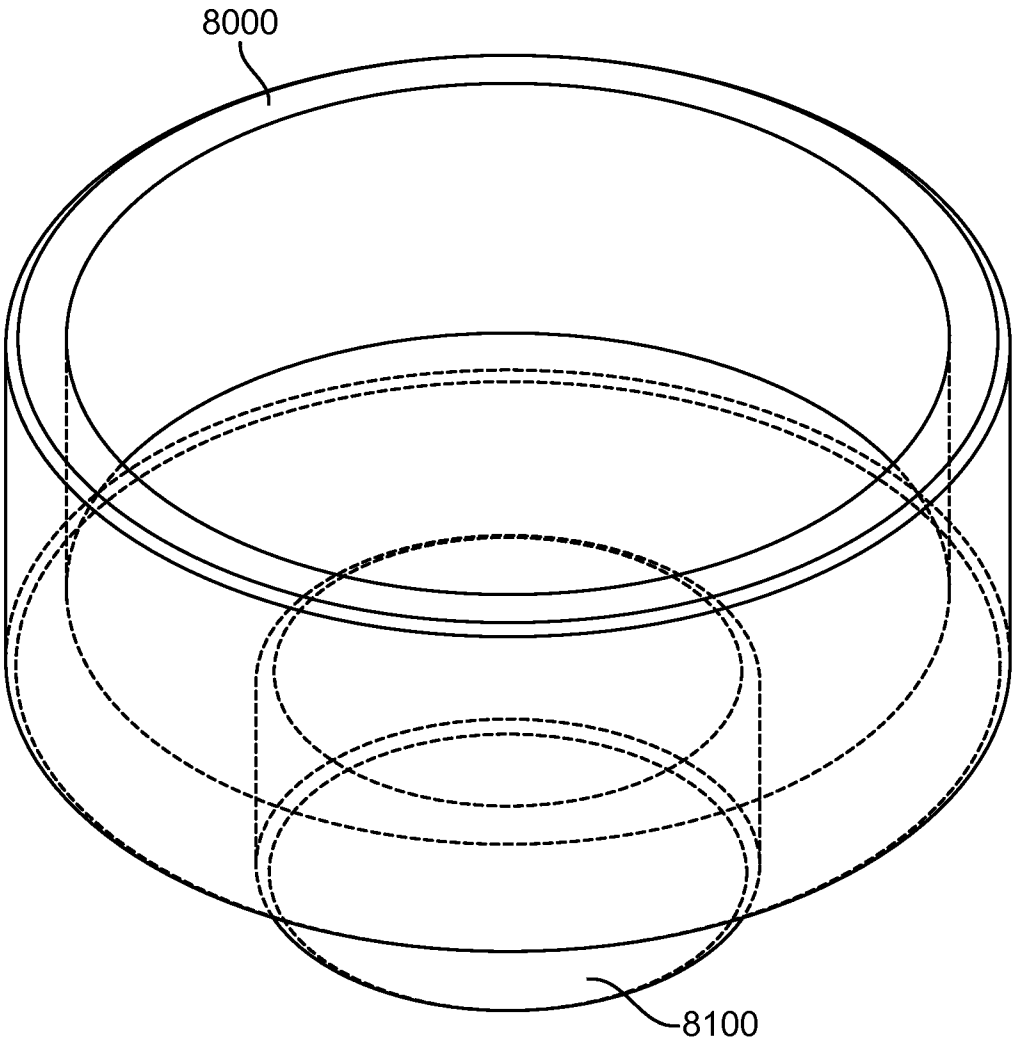


FIG. 14

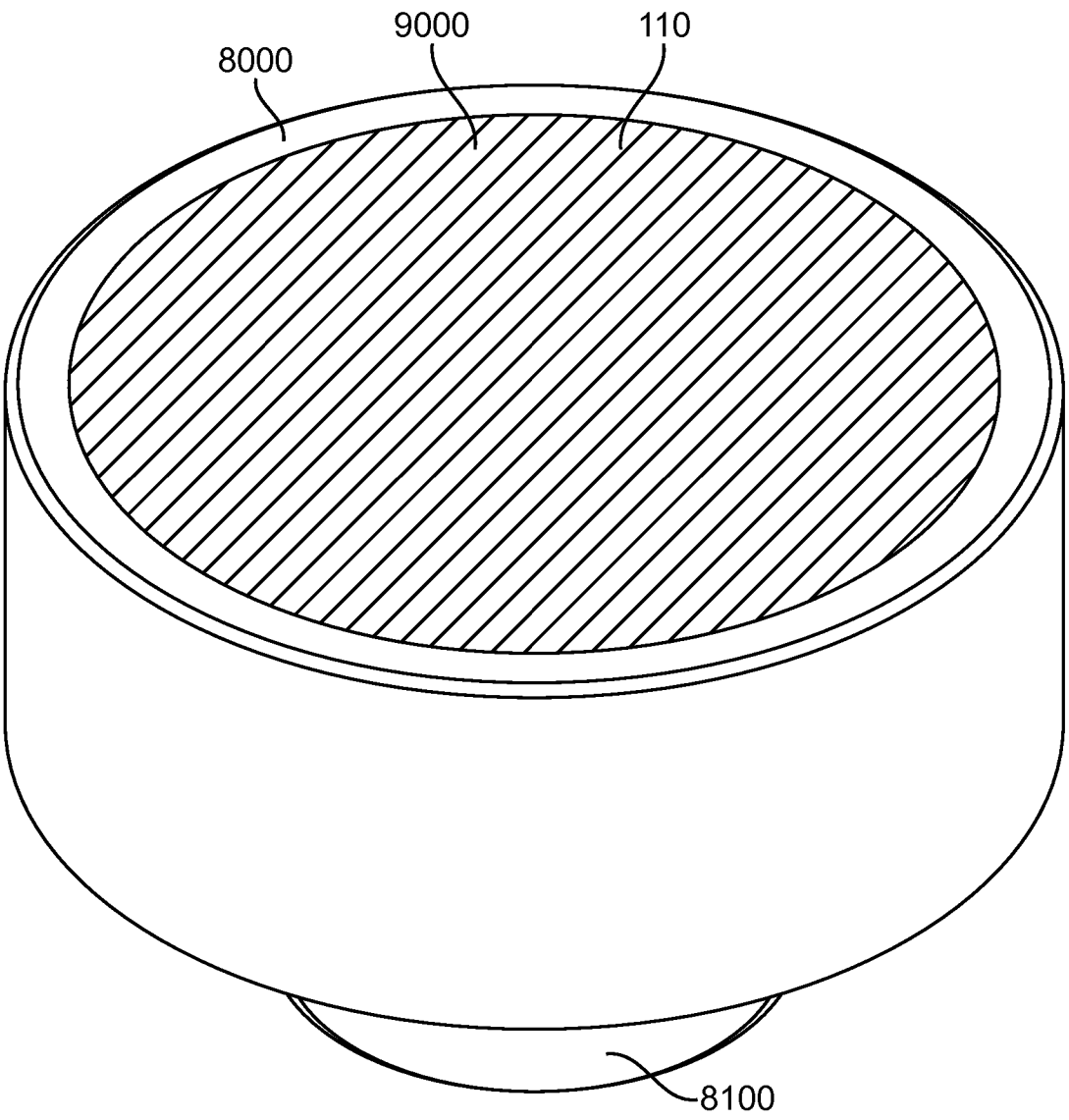


FIG. 15

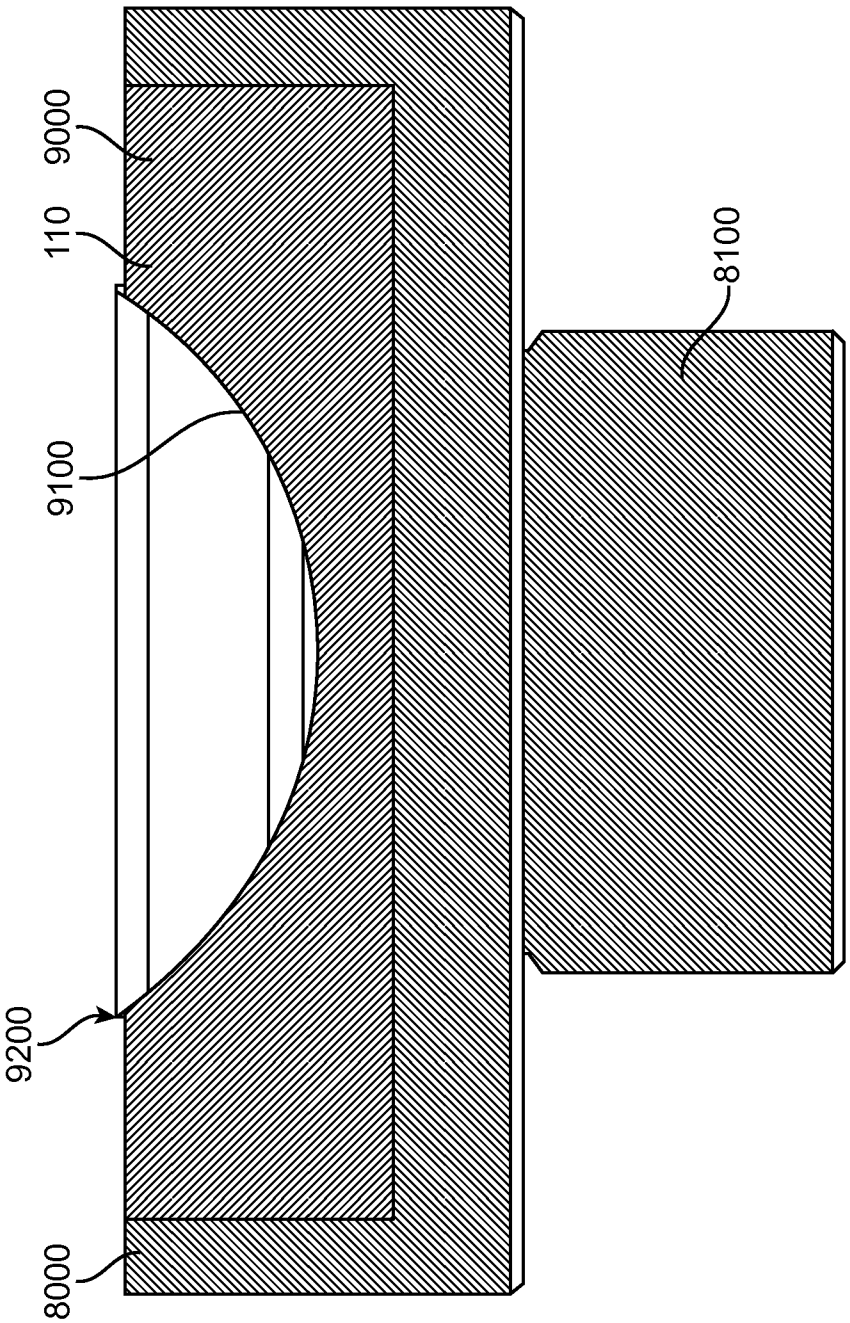


FIG. 16

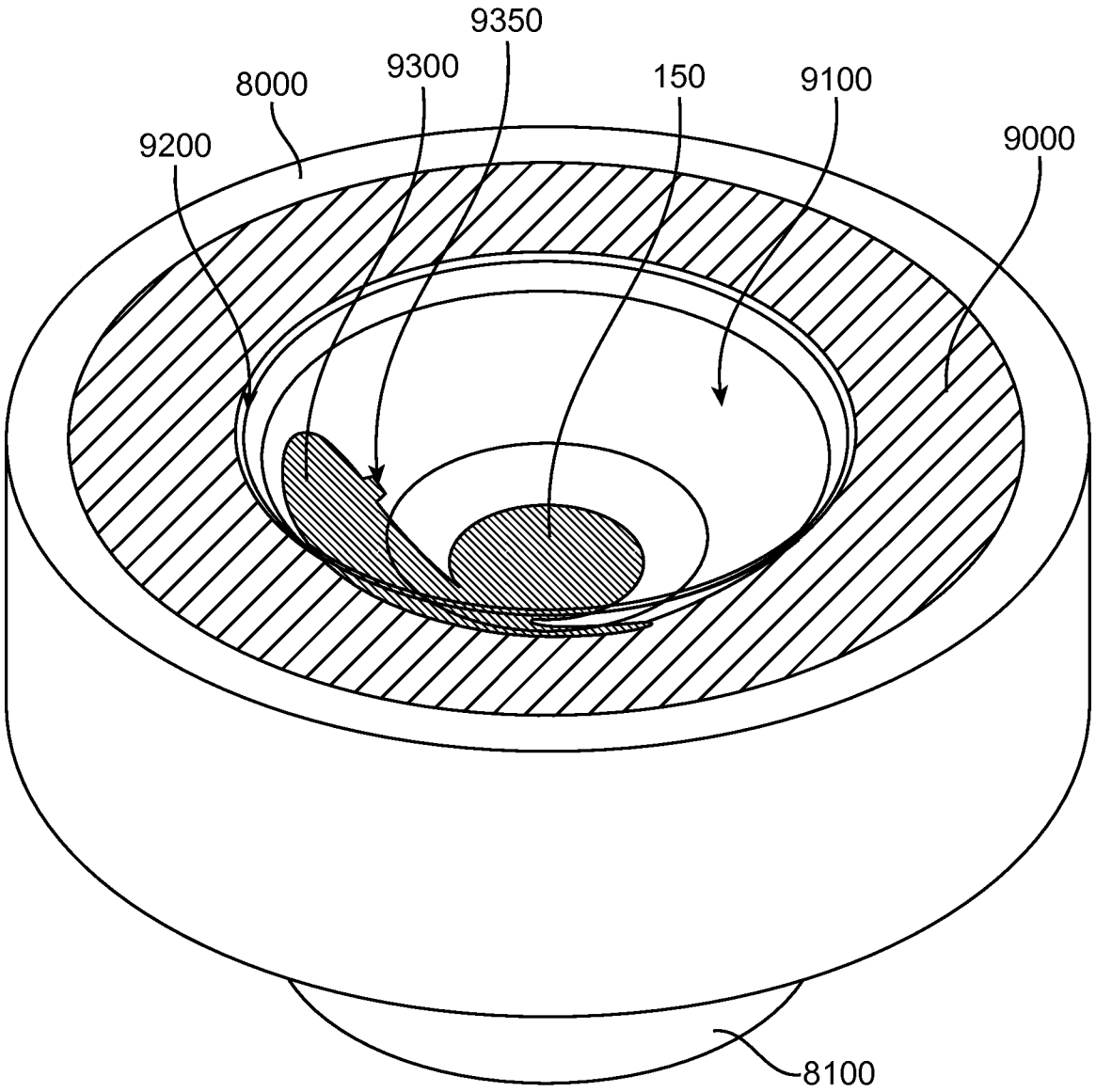


FIG. 17

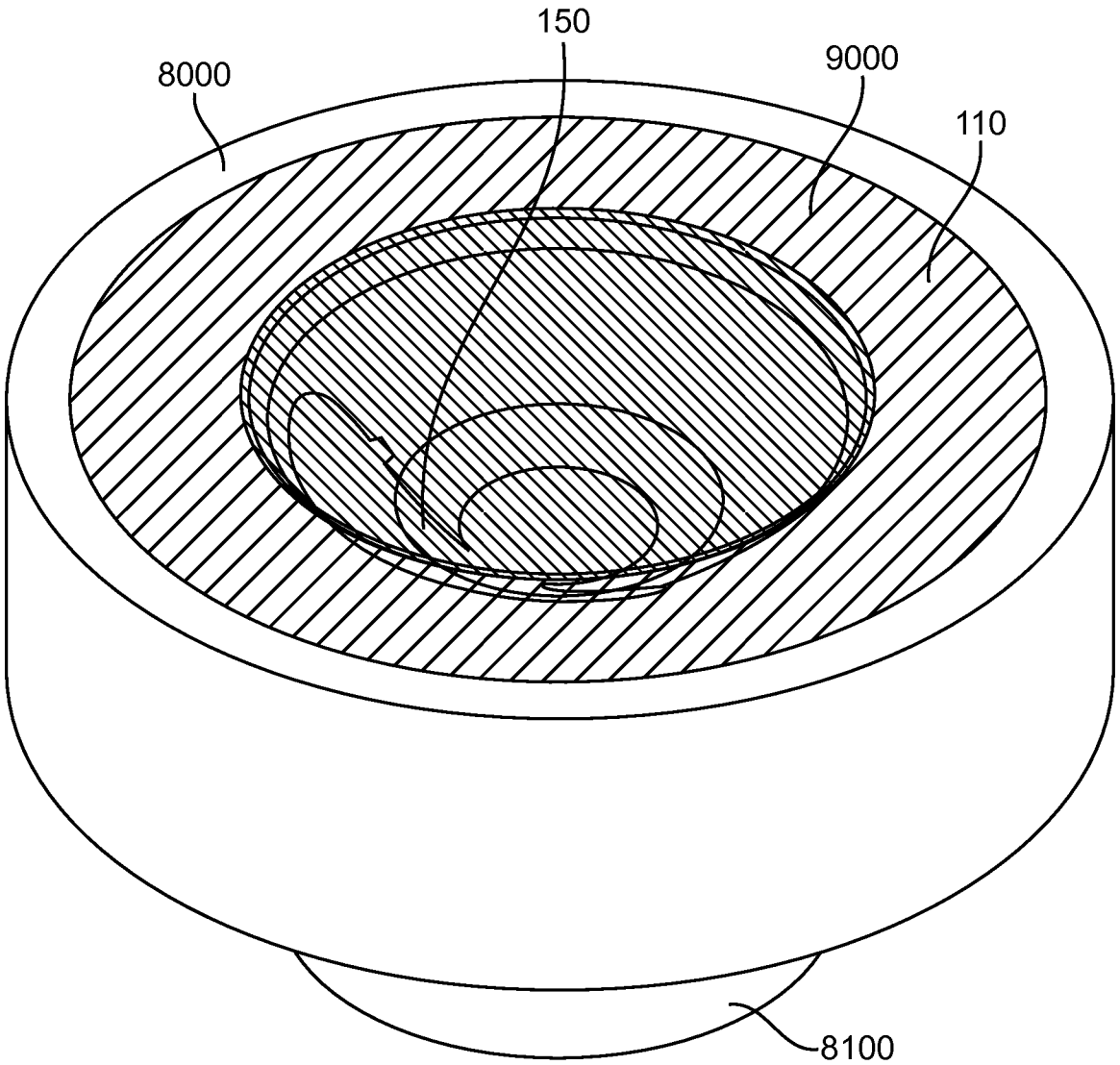


FIG. 18

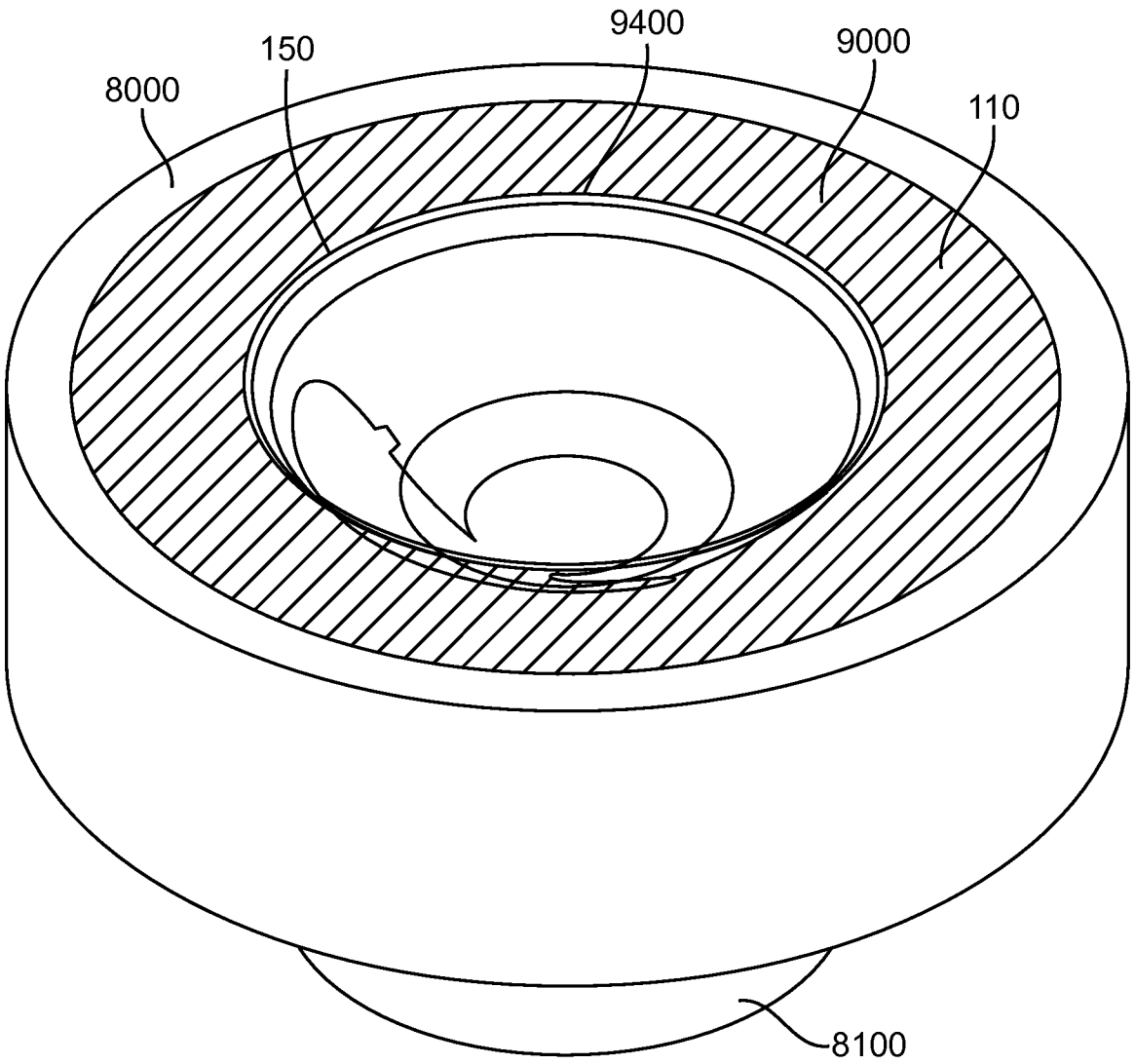


FIG. 19

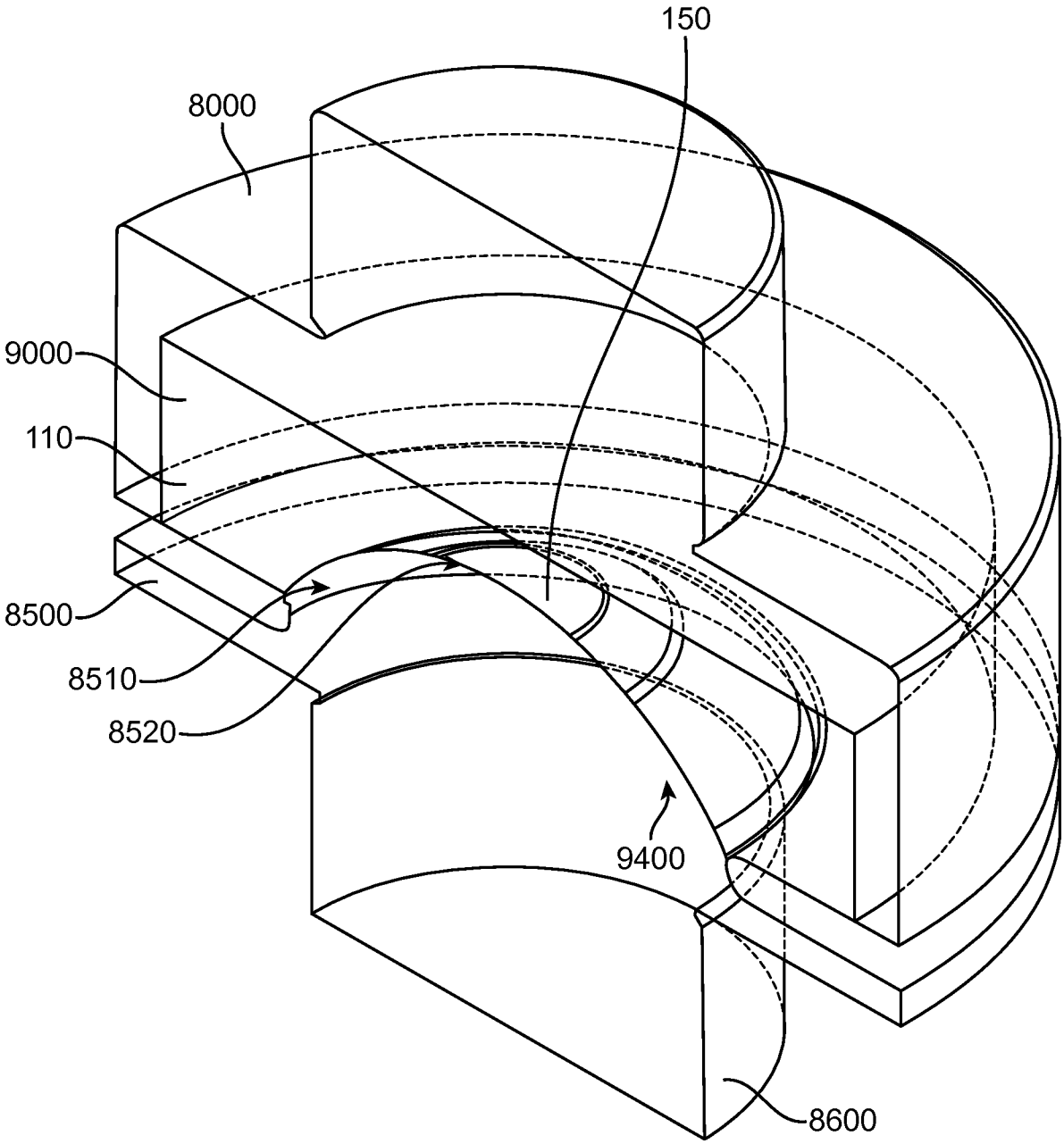


FIG. 20

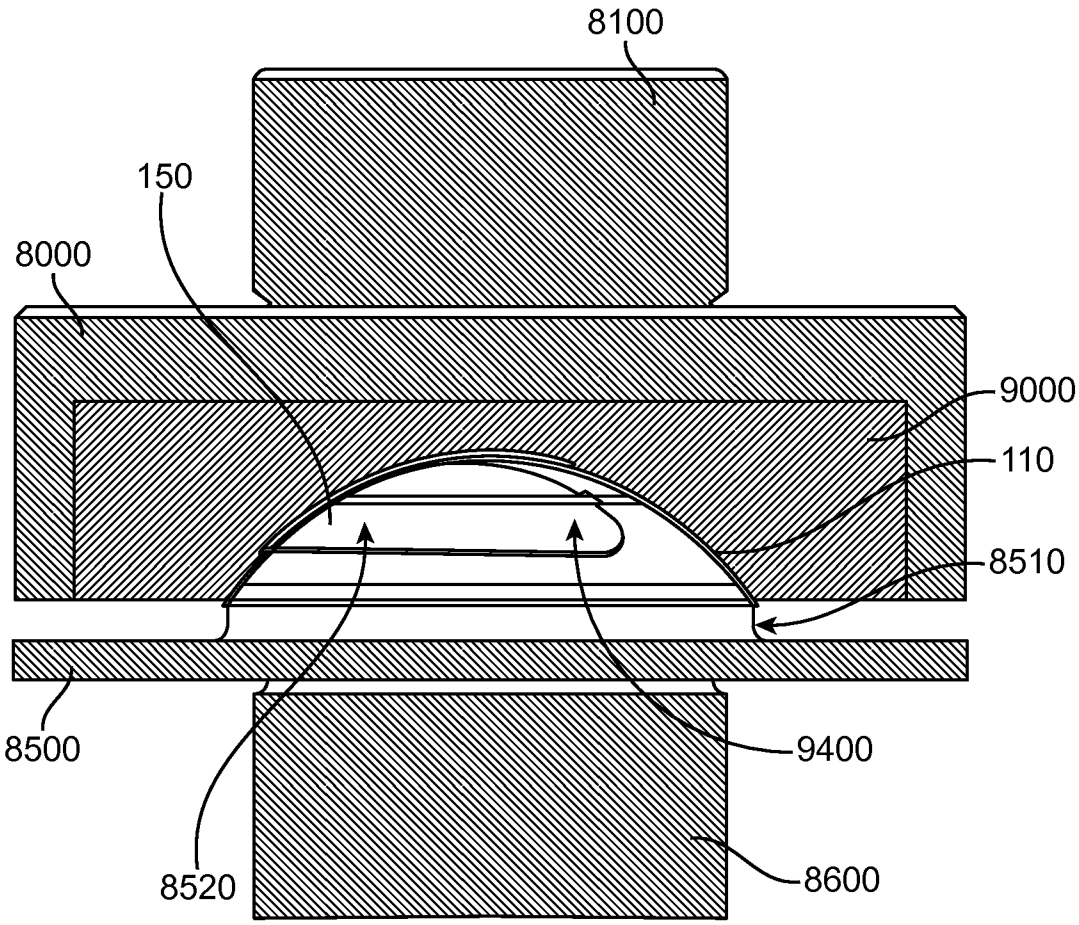


FIG. 21

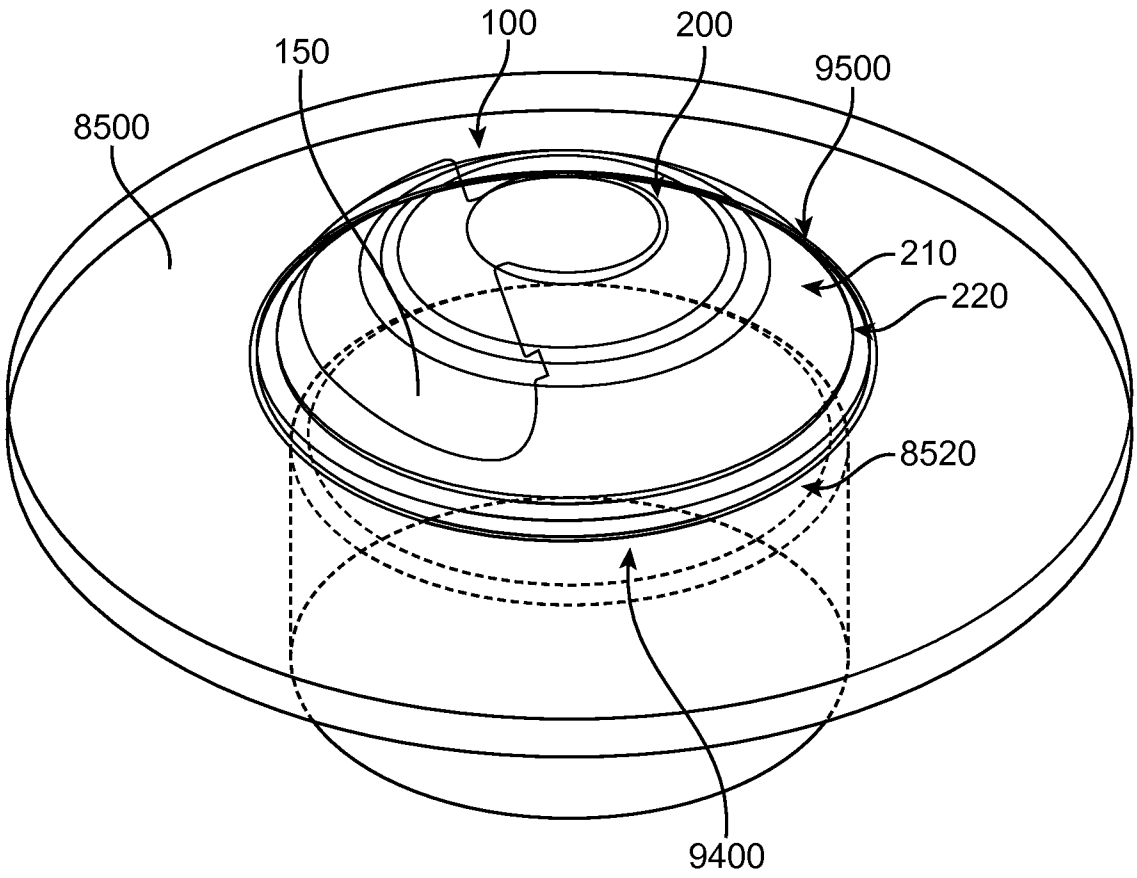


FIG. 22

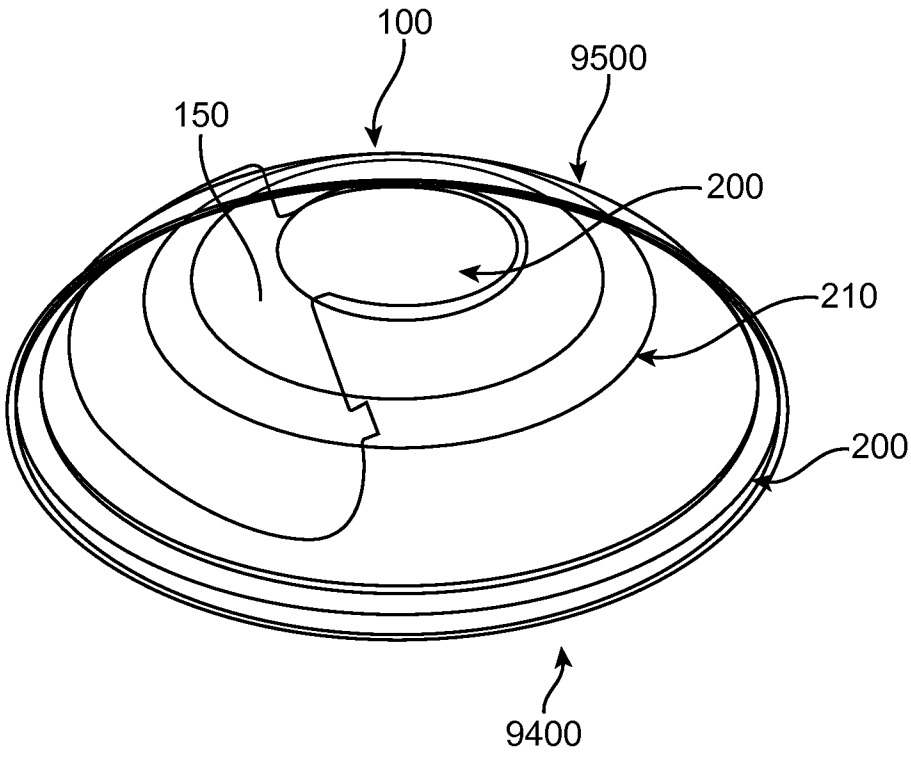


FIG. 23

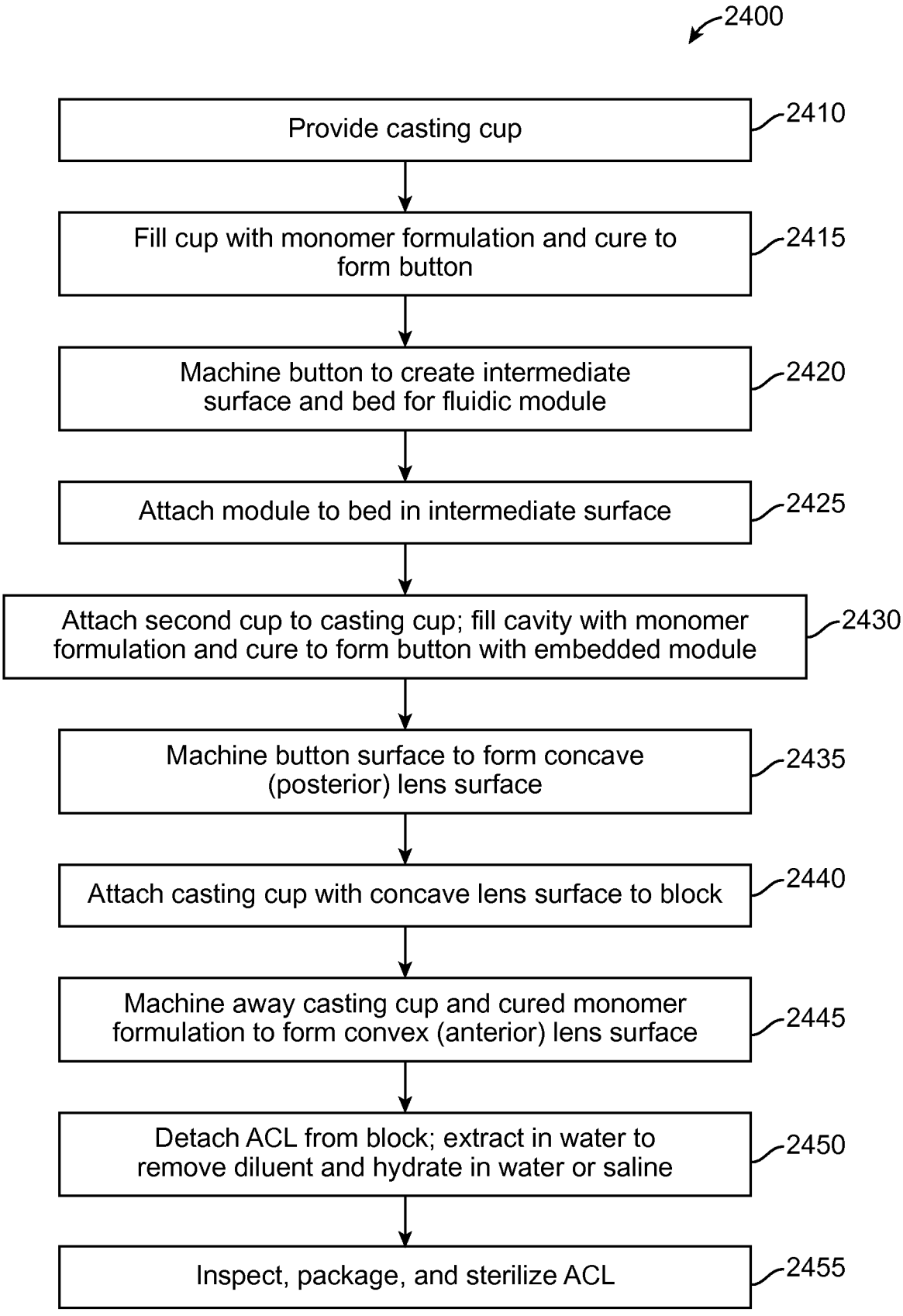

2400
Provide casting cup
2410
Fill cup with monomer formulation and cure to form button
2415
Machine button to create intermediate surface and bed for fluidic module
2420
Attach module to bed in intermediate surface
2425
Attach second cup to casting cup; fill cavity with monomer formulation and cure to form button with embedded module
2430
Machine button surface to form concave (posterior) lens surface
2435
Attach casting cup with concave lens surface to block
2440
Machine away casting cup and cured monomer formulation to form convex (anterior) lens surface
2445
Detach ACL from block; extract in water to remove diluent and hydrate in water or saline
2450
Inspect, package, and sterilize ACL
2455

FIG. 24

Monofunctional Monomers	Multifunctional Monomers	Cross linkers	Diluents	Photo-intiators
Hydroxy ethyl methacrylate	Ethylene glycol dimethacrylate	Trimethoxy propane triacrylate	Deionized water	Diphenyl(2,4,6-trimethylbenzoyl) phosphineoxide
Glyceryl monomethacrylate	Polyethylene glycol diacrylate (400)	Pentaerythritol Tetraacrylate	Methanol	Dimethoxy acetopheonone
Methoxyethyl methacrylate	Propoxylated neopentyl glycol diacrylate		Isopropanol	4-hydroxy benzophenone
N-Vinyl pyrollidone	Polyethylene glycol diacrylate (600)		Polyethylene glycol (600)	
Dimethyl acrylamide			Polyethylene glycol (3,500)	

FIG. 25

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2015/043315

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61F 2/16 (2015.01)
CPC - A61F 2/1618 (2015.11)
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 2/16; B29D 11/00; G02B 3/12, 3/14 (2015.01)
CPC - A61F 2/1618, 2/1624; B29D 11/00028, 11/00038; G02B 3/12, 3/142015.11) (keyword delimited)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC -351/159.34, 159.68; 623/6.13, 6.14, 6.27

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PatBase, Google Patents, Google Patent/Scholar, Google.
Search terms used:accommodate, encapsulate, robot, lens, eyelid, chambers, engaging, transparent, body, machined, surface, contact, method of manufacturing, module

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2012/0268712 A1 (EGAN et al) 25 October 2012 (25.10.2012) entire document	1-4,7,10,15,54,55
A	US 7,551,357 B2 (HUANG) 23 June 2009 (23.06.2009) entire document	1-32,54,55
A	US 2008/0231801 A1 (IULIANO) 25 September 2008 (25.09.2008) entire document	1-32,54,55
A	CA 2 899 432 A1 (ONEFOCUS TECHNOLOGY) 31 July 2014 (31.07.2014) entire document	1-32,54,55

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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

Date of the actual completion of the international search	Date of mailing of the international search report
05 November 2015	11 DEC 2015
Name and mailing address of the ISA/ Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer Blaine Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2015/043315

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

See extra sheet.

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-32, 54, 55

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

International application No.
PCT/US2015/043315

CONTINUED FROM BOX NO. III:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I, claims 1-32, 54 and 55 are drawn to a method of manufacturing an accommodating contact lens.

Group II, claims 33-53 and 59 are drawn to a method of manufacturing a hydrogel.

Group III, claims 56-58 are drawn to a method of manufacturing a contact lens.

The inventions listed as Groups I - III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical features of Group I, providing an accommodating contact lens module and a contact lens covering material; encapsulating the accommodating contact lens module in the contact lens covering material; and machining one or more of an anterior or posterior surface of the soft contact lens covering material having the contact lens module encapsulated therein to form an optical correction zone for a subject, are not present in Groups II or III; the special technical features of Group II, curing the bathed precursor to form a polymeric material portion such that cure shrinkage of the polymeric material portion is reduced by the first and second diluents; and providing water to the polymeric material portion such that the first and second diluents in the polymeric material portion are exchanged with the water to form the hydrogel, are not present in Groups I or III; and, the special technical features of Group III, placing a contact lens module in a mold; providing a polymeric material comprising a low molecular weight diluent and a high molecular weight diluent; curing the polymeric material to form one or more optical surfaces of the contact lens with one or more surfaces of the mold, are not present in Groups I or II.

Groups I and III share the technical features of a method of manufacturing a contact lens. However, this shared technical feature does not represent a contribution over the prior art. Specifically, US 5,160,463 A to Evans et al. teaches a method of manufacturing a contact lens (Abstract).

Groups II and III share the technical features of providing and curing a polymeric material comprising a first diluent and a second diluent. However, these shared technical features do not represent a contribution over the prior art. Specifically, US 4,701,288 A to Cook et al. teaches a hybrid contact lens and other composite polymeric article (Abstract) comprising a polymeric material (21) comprising a first diluent (part of a liquid diluent) and a second diluent (part of a solid diluent; col. 4, lines 23-64; col. 7, lines 25-60). Cook et al., further teaches curing a polymeric material to manufacture a hybrid contact lens (polymerization by any method, including heating, catalysis, crosslinking, irradiation or combinations thereof; col. 4, lines 10-22).

Since none of the special technical features of the Groups I - III inventions are found in more than one of the inventions, unity is lacking.