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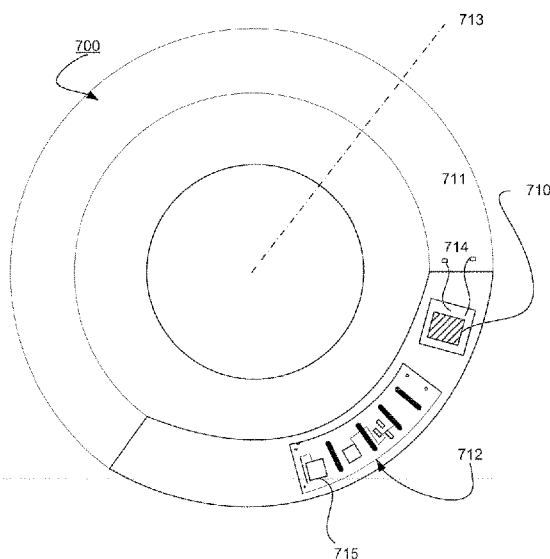
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(54) Title: ENERGIZED MEDIA FOR AN OPHTHALMIC DEVICE

(57) Abstract: This invention discloses methods and apparatus for providing a media insert with an energy source to an ophthalmic lens. The energy source is capable of powering a component included within the ophthalmic lens. In some embodiments, an ophthalmic lens is cast molded from a silicone hydrogel and the component includes an electro-optical lens portion.

FIG. 7



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ENERGIZED MEDIA FOR AN OPHTHALMIC DEVICE

RELATED APPLICATIONS

This application claims priority to Provisional Patent Application U.S. Ser. No.
5 61/101282 which was filed on September 30, 2008, and Patent Application U.S. Ser.
No. 12/565,407 which was filed on September 23, 2009, the contents of which are
relied upon and incorporated by reference.

FIELD OF USE

This invention describes an energized media insert for an ophthalmic device
10 and, more specifically, in some embodiments, the fabrication of an ophthalmic lens
with an energized media insert.

BACKGROUND

Traditionally an ophthalmic device, such as a contact lens, an intraocular lens
or a punctal plug included a biocompatible device with a corrective, cosmetic or
15 therapeutic quality. A contact lens, for example, can provide one or more of: vision
correcting functionality; cosmetic enhancement; and therapeutic effects. Each function
is provided by a physical characteristic of the lens. A design incorporating a refractive
quality into a lens can provide a vision corrective function. A pigment incorporated
into the lens can provide a cosmetic enhancement. An active agent incorporated into a
20 lens can provide a therapeutic functionality. Such physical characteristics are
accomplished without the lens entering into an energized state.

More recently, it has been theorized that active components may be
incorporated into a contact lens. Some components can include semiconductor
devices. Some examples have shown semiconductor devices embedded in a contact
25 lens placed upon animal eyes. However, such devices lack a free standing energizing
mechanism. Although wires may be run from a lens to a battery to power such
semiconductor devices, and it has been theorized that the devices may be wirelessly
powered, no mechanism for such wireless power has been available.

It is desirable therefore to have additional methods and apparatus conducive to the formation of ophthalmic lenses that are energized to an extent suitable for providing one or more of functionality into an ophthalmic lens and a controlled change in optical characteristic of an ophthalmic lens or other biomedical device.

5

SUMMARY

Accordingly, the present invention includes a media insert that can be energized and incorporated into an ophthalmic device, such as, for example a contact lens or a punctal plug. In addition, methods and apparatus for forming an ophthalmic lens, with an energized media insert are presented. In some embodiments, the media in
10 an energized state is capable of powering a component capable of drawing a current. Components may include, for example, one or more of: a variable optic lens element, a semiconductor device and an active or passive electronic device. Some embodiments can also include a cast molded silicone hydrogel contact lens with a rigid or formable energized insert contained within the ophthalmic lens in a biocompatible fashion.

15

The present invention therefore includes disclosure of an ophthalmic lens with an energized media portion, apparatus for forming an ophthalmic lens with an energized media portion and methods for the manufacturing the same. An energy source can be deposited onto a media insert and the insert can be placed in proximity to one, or both of, a first mold part and a second mold part. A reactive monomer mix is
20 placed between the first mold part and the second mold part. The first mold part is positioned proximate to the second mold part thereby forming a lens cavity with the energized media insert and at least some of the reactive monomer mix in the lens cavity; the reactive monomer mix is exposed to actinic radiation to form an ophthalmic lens. Lenses are formed via the control of actinic radiation to which the reactive
25 monomer mixture is exposed.

DESCRIPTION OF THE DRAWINGS

FIG. 1 illustrates a mold assembly apparatus according to some embodiments of the present invention.

FIG. 2A-2D illustrates various embodiments of a media insert which can be placed
30 within an ophthalmic lens.

FIG. 3 illustrates an apparatus for placing an Energy Source within an ophthalmic lens mold part.

Fig. 4 illustrates method steps according to some embodiments of the present invention.

- 5 Fig. 5 illustrates method steps according to some additional aspect of the present invention.

Fig. 6 illustrates a processor that may be used to implement some embodiments of the present invention.

Fig. 7 illustrates a depiction of an exemplary media insert.

- 10 Fig. 8 illustrates a cross section of an exemplary media insert.

DETAILED DESCRIPTION OF THE INVENTION

The present invention includes methods and apparatus for manufacturing an ophthalmic lens with an energized media insert. In addition, the present invention includes an ophthalmic lens with a media insert incorporated into the ophthalmic lens.

- 15 According to the present invention an energized lens 100 is formed with an embedded Media Insert and an Energy Source, such as an electrochemical cell or battery as the storage means for the energy and in some embodiments, encapsulation and isolation of the materials comprising the Energy Source from an environment into which an ophthalmic lens is placed.

- 20 In some embodiments, a Media Insert also includes a pattern of circuitry, components and Energy Sources. Various embodiments can include the Media Insert locating the pattern of circuitry, components and Energy Sources around a periphery of an optic zone through which a wearer of a lens would see, while other embodiments can include a pattern of circuitry, components and Energy Sources which are small
25 enough to not adversely affect the sight of a contact lens wearer and therefore the Media Insert can locate them within, or exterior to, an optical zone.

In general, according to some embodiments of the present invention, a Media Insert is embodied within an ophthalmic lens via automation which places an Energy Source a desired location relative to a mold part used to fashion the lens.

In some embodiments, an Energy Source is placed in electrical communication with a component which can be activated on command and draws electrical current from the Energy Source included within the ophthalmic lens. A component can include for example, a semiconductor device, an active or passive electrical device or
5 an electrically activated machine, including for example: Microelectromechanical systems (MEMS), nanoelectromechanical systems (NEMS), or micromachines. Subsequent to placing the Energy Source and component, a Reactive Mixture can be shaped by the mold part and polymerized to form the ophthalmic lens.

In the following sections detailed descriptions of embodiments of the invention
10 will be given. The description of both preferred and alternative embodiments are exemplary embodiments only, and it is understood that to those skilled in the art that variations, modifications and alterations may be apparent. It is therefore to be understood that said exemplary embodiments do not limit the scope of the underlying invention.

15

GLOSSARY

In this description and claims directed to the presented invention, various terms may be used for which the following definitions will apply:

Component: as used herein refers to a device capable of drawing electrical
20 current from an Energy Source to perform one or more of a change of logical state or physical state.

Energized: as used herein refers to the state of being able to supply electrical current to or to have electrical energy stored within.

Energy: as used herein refers to the capacity of a physical system to do work.
25 Many uses within this invention may relate to the said capacity being able to perform electrical actions in doing work.

Energy Source: as used herein refers to device capable of supplying Energy or placing a biomedical device in an Energized state.

Energy Harvesters: as used herein refers to device capable of extracting energy
30 from the environment and convert it to electrical energy.

Lens: refers to any ophthalmic device that resides in or on the eye. These devices can provide optical correction or may be cosmetic. For example, the term lens can refer to a contact lens, intraocular lens, overlay lens, ocular insert, optical insert or

other similar device through which vision is corrected or modified, or through which eye physiology is cosmetically enhanced (e.g. iris color) without impeding vision. In some embodiments, the preferred lenses of the invention are soft contact lenses and made from silicone elastomers or hydrogels.

5 Lens forming mixture or “Reactive Mixture” or “RMM”(reactive monomer mixture): as used herein refers to a monomer or prepolymer material which can be cured and crosslinked or crosslinked to form an ophthalmic lens. Various embodiments can include lens forming mixtures with one or more additives such as: UV blockers, tints, photoinitiators or catalysts, and other additives one might desire in
10 an ophthalmic lenses such as, contact or intraocular lenses.

 Lens Forming Surface: refers to a surface that is used to mold a lens. In some embodiments, any such surface can have an optical quality surface finish, which indicates that it is sufficiently smooth and formed so that a lens surface fashioned by the polymerization of a lens forming material in contact with the molding surface is
15 optically acceptable. Further, in some embodiments, the lens forming surface 103-104 can have a geometry that is necessary to impart to the lens surface the desired optical characteristics, including without limitation, spherical, aspherical and cylinder power, wave front aberration correction, corneal topography correction and the like as well as any combinations thereof.

20 Lithium Ion Cell: refers to an electrochemical cell where Lithium ions move through the cell to generate electrical energy. This electrochemical cell, typically called a battery, may be reenergized or recharged in its typical forms.

 Media Insert: as used herein refers to a formable or rigid substrate capable of supporting an Energy Source within an ophthalmic lens. In some embodiments, the
25 Media Insert also supports one or more components.

 Mold: refers to a rigid or semi-rigid object that may be used to form lenses from uncured formulations. Some preferred molds include two mold parts forming a front curve mold part and a back curve mold part.

 Optical Zone: as used herein refers to an area of an ophthalmic lens through
30 which a wearer of the ophthalmic lens sees.

 Power: as used herein refers to work done or energy transferred per unit of time.

 Rechargeable or Re-energizable: as used herein refers to a capability of being restored to a state with higher capacity to do work. Many uses within this invention

may relate to the capability of being restored with the ability to flow electrical current at a certain rate for a certain, reestablished time period.

Reenergize or Recharge: To restore to a state with higher capacity to do work. Many uses within this invention may relate to restoring a device to the capability to
5 flow electrical current at a certain rate for a certain, reestablished time period.

Released from a mold: means that a lens is either completely separated from the mold, or is only loosely attached so that it can be removed with mild agitation or pushed off with a swab.

Molds

10 Referring now to Fig. 1, a diagram of an exemplary mold device 100 for an ophthalmic lens is illustrated with a Media Insert 111. As used herein, the terms a mold device 100 includes a plastic formed to shape a cavity 105 into which a lens forming mixture can be dispensed such that upon reaction or cure of the lens forming mixture, an ophthalmic lens of a desired shape is produced. The molds and mold
15 assemblies 100 of this invention are made up of more than one "mold parts" or "mold pieces" 101-102. The mold parts 101-102 can be brought together such that a cavity 105 is formed between the mold parts 101-102 in which a lens can be formed. This combination of mold parts 101-102 is preferably temporary. Upon formation of the lens, the mold parts 101-102 can again be separated for removal of the lens.

20 At least one mold part 101-102 has at least a portion of its surface 103-104 in contact with the lens forming mixture such that upon reaction or cure of the lens forming mixture that surface 103-104 provides a desired shape and form to the portion of the lens with which it is in contact. The same is true of at least one other mold part 101-102.

25 Thus, for example, in a preferred embodiment a mold device 100 is formed from two parts 101-102, a female concave piece (front piece) 102 and a male convex piece (back piece) 101 with a cavity formed between them. The portion of the concave surface 104 which makes contact with lens forming mixture has the curvature of the front curve of an ophthalmic lens to be produced in the mold device 100 and is
30 sufficiently smooth and formed such that the surface of an ophthalmic lens formed by polymerization of the lens forming mixture which is in contact with the concave surface 104 is optically acceptable.

In some embodiments, the front mold piece 102 can also have an annular flange integral with and surrounding circular circumferential edge and extends from it in a plane normal to the axis and extending from the flange (not shown).

5 A lens forming surface can include a surface 103-104 with an optical quality surface finish, which indicates that it is sufficiently smooth and formed so that a lens surface fashioned by the polymerization of a lens forming material in contact with the molding surface is optically acceptable. Further, in some embodiments, the lens forming surface 103-104 can have a geometry that is necessary to impart to the lens surface the desired optical characteristics, including without limitation, spherical, 10 aspherical and cylinder power, wave front aberration correction, corneal topography correction and the like as well as any combinations thereof.

At 111, a Media Insert is illustrated onto which an Energy Source 109 and a Component 108 are mounted. The Media Insert 111 may be any receiving material onto which an Energy Source 109 may be placed, in some embodiments may also 15 include circuit paths, components and other aspects useful to place the Energy Source 109 in electrical communication with the Component 108 and enable the Component to draw an electrical current from the Energy Source 109.

In some embodiments, the Media Insert 111 includes a flexible substrate. Additional embodiments can include a Media Insert 111 that is rigid, such as a silicon 20 wafer. In some embodiments, a rigid insert may include an optical zone providing an optical property (such as those utilized for vision correction) and a non-optical zone portion. An Energy Source can be placed on one or both of the optic zone and non-optic zone of the insert. Still other embodiments can include an annular insert, either rigid or formable or some shape which circumvents an optic zone through which a user 25 sees.

Other embodiments include a Media Insert 111 formed of a clear coat of a material which be incorporated into a lens when the lens is formed. The clear coat can include for example a pigment as described below, a monomer or other biocompatible material.

30 Various embodiments also include placing an Energy Source 109 onto Media Insert 111 prior to placement of the Media Insert 111 into a mold portion used to form a lens. The Media Insert 111 may also include one or more components which will receive an electrical charge via the Energy Source 109.

In some embodiments, a lens with a Media Insert 111 can include a rigid center soft skirt design in which a central rigid optical element is in direct contact with the atmosphere and the corneal surface on respective an anterior and posterior surfaces, wherein the soft skirt of lens material (typically a hydrogel material) is attached to a periphery of the rigid optical element and the rigid optical element also acts as a Media Insert providing energy and functionality to the resulting ophthalmic lens.

Some additional embodiments include a Media Insert 111 that is a rigid lens insert fully encapsulated within a hydrogel matrix. A Media Insert 111 which is a rigid lens insert may be manufactured, for example using microinjection molding technology. Embodiments can include, for example, a poly(4-methylpent-1-ene copolymer resin with a diameter of between about 6mm to 10mm and a front surface radius of between about 6 mm and 10mm and a rear surface radius of between about 6 mm and 10 mm and a center thickness of between about 0.050mm and 0.5 mm. Some exemplary embodiments include an insert with diameter of about 8.9 mm and a front surface radius of about 7.9 mm and a rear surface radius of about 7,8 mm and a center thickness of about 0.100 mm and an edge profile of about 0.050 radius. One exemplary micromolding machine can include the Microsystem 50 five-ton system offered by Battenfield Inc.

The Media Insert can be placed in a mold part 101-102 utilized to form an ophthalmic lens.

Mold part 101-102 material can include, for example: a polyolefin of one or more of: polypropylene, polystyrene, polyethylene, polymethyl methacrylate, and modified polyolefins. Other molds can include a ceramic or metallic material.

Other mold materials that may be combined with one or more additives to form an ophthalmic lens mold include, for example, Ziegler-Natta polypropylene resins (sometimes referred to as znPP); a clarified random copolymers for clean molding as per FDA regulation 21 CFR (c) 3.2 ; a random copolymer (znPP) with ethylene group.

Still further, in some embodiments, the molds of the invention may contain polymers such as polypropylene, polyethylene, polystyrene, polymethyl methacrylate, modified polyolefins containing an alicyclic moiety in the main chain and cyclic polyolefins. This blend can be used on either or both mold halves, where it is preferred that this blend is used on the back curve and the front curve consists of the alicyclic copolymers.

In some preferred methods of making molds 100 according to the present invention, injection molding is utilized according to known techniques, however, embodiments can also include molds fashioned by other techniques including, for example: lathing, diamond turning, or laser cutting.

5 Typically, lenses are formed on at least one surface of both mold parts 101-102. However, in some embodiments, one surface of a lens may be formed from a mold part 101-102 and another surface of a lens can be formed using a lathing method, or other methods.

Lenses

10 Referring now to Fig. 2A-2D, exemplary designs of Media Inserts 211-214 are illustrated. Fig. 2A illustrates an annular Media Insert 211. Other Media Inserts may be of various shapes conducive to placement with an ophthalmic lens. Some preferred shapes include shapes with arcuate designs matching a portion of the overall shape of the ophthalmic lens. Fig. 2B illustrates a Media Insert 212 which includes an area of
15 about $\frac{1}{2}$ of an full annular design and also includes an arcuate area which may surround an optic zone of a lens into which the Media Insert 212 is placed. Similarly, Fig. 2C includes a Media insert 213 of about $\frac{1}{3}$ of an annular design. Fig. 2D illustrates an annular design 214 with multiple discrete portions 215-217 of the Media Insert 214. Discrete portions 215-217 can be useful to isolate various functions
20 attributed to the individual portions 215-217. For example, one discrete portion 215-217 may contain one or more Energy Sources and another discrete portion 215-217 may include components.

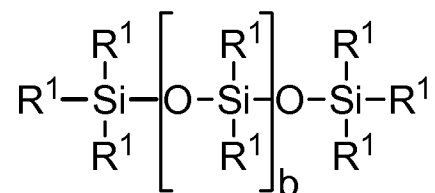
In some embodiments, a Media Insert 211-214 may have an optic zone that includes a variable optic powered by an Energy Source located on the Media Insert
25 211-214. The Media Insert 211-214 can also include circuitry to control the variable optic included in the optic zone 211-214. In this discussion, a variable optic can be considered a component.

An Energy Source can be in electrical communication with a component. The component can include any device which responds to an electrical charge with a
30 change in state, such as, for example: a semiconductor type chip; a passive electrical device; or an optical device such as a crystal lens.

In some specific embodiments, an Energy Source includes, for example: battery or other electrochemical cell; capacitor; ultracapacitor; supercapacitor; or other storage component. Some specific embodiments can include a lithium ion battery located on a Media Insert 211-214 on the periphery of an ophthalmic lens outside of the optic zone and chargeable via one or more of radio frequency and magnetic inductance into an Energy Source deposited via ink jetting.

In some embodiments, a preferred lens type can include a lens that includes a silicone containing component. A “silicone-containing component” is one that contains at least one [-Si-O-] unit in a monomer, macromer or prepolymer. Preferably, the total Si and attached O are present in the silicone-containing component in an amount greater than about 20 weight percent, and more preferably greater than 30 weight percent of the total molecular weight of the silicone-containing component. Useful silicone-containing components preferably comprise polymerizable functional groups such as acrylate, methacrylate, acrylamide, methacrylamide, vinyl, N-vinyl lactam, N-vinylamide, and styryl functional groups.

Suitable silicone containing components include compounds of Formula I



where

R^1 is independently selected from monovalent reactive groups, monovalent alkyl groups, or monovalent aryl groups, any of the foregoing which may further comprise functionality selected from hydroxy, amino, oxa, carboxy, alkyl carboxy, alkoxy, amido, carbamate, carbonate, halogen or combinations thereof; and monovalent siloxane chains comprising 1-100 Si-O repeat units which may further comprise functionality selected from alkyl, hydroxy, amino, oxa, carboxy, alkyl carboxy, alkoxy, amido, carbamate, halogen or combinations thereof;

where $b = 0$ to 500, where it is understood that when b is other than 0, b is a distribution having a mode equal to a stated value;

wherein at least one R^1 comprises a monovalent reactive group, and in some embodiments between one and 3 R^1 comprise monovalent reactive groups.

As used herein “monovalent reactive groups” are groups that can undergo free radical and/or cationic polymerization. Non-limiting examples of free radical reactive groups include (meth)acrylates, styryls, vinyls, vinyl ethers, C₁₋₆alkyl(meth)acrylates, (meth)acrylamides, C₁₋₆alkyl(meth)acrylamides, N-vinyl lactams, N-vinyl amides, C₂₋₁₂alkenyls, C₂₋₁₂alkenylphenyls, C₂₋₁₂alkenyl naphthyls, C₂₋₆alkenylphenyl C₁₋₆alkyls, O-vinyl carbamates and O-vinyl carbonates. Non-limiting examples of cationic reactive groups include vinyl ethers or epoxide groups and mixtures thereof. In one embodiment the free radical reactive groups comprises (meth)acrylate, acryloxy, (meth)acrylamide, and mixtures thereof.

Suitable monovalent alkyl and aryl groups include unsubstituted monovalent C₁ to C₁₆alkyl groups, C₆-C₁₄ aryl groups, such as substituted and unsubstituted methyl, ethyl, propyl, butyl, 2-hydroxypropyl, propoxypropyl, polyethyleneoxypropyl, combinations thereof and the like.

In one embodiment b is zero, one R¹ is a monovalent reactive group, and at least 3 R¹ are selected from monovalent alkyl groups having one to 16 carbon atoms, and in another embodiment from monovalent alkyl groups having one to 6 carbon atoms. Non-limiting examples of silicone components of this embodiment include 2-methyl-2-hydroxy-3-[3-[1,3,3,3-tetramethyl-1-[(trimethylsilyl)oxy]disiloxanyl]propoxy]propyl ester (“SiGMA”), 2-hydroxy-3-methacryloxypropyloxypropyl-tris(trimethylsiloxy)silane, 3-methacryloxypropyltris(trimethylsiloxy)silane (“TRIS”), 3-methacryloxypropylbis(trimethylsiloxy)methylsilane and 3-methacryloxypropylpentamethyl disiloxane.

In another embodiment, b is 2 to 20, 3 to 15 or in some embodiments 3 to 10; at least one terminal R¹ comprises a monovalent reactive group and the remaining R¹ are selected from monovalent alkyl groups having 1 to 16 carbon atoms, and in another embodiment from monovalent alkyl groups having 1 to 6 carbon atoms. In yet another embodiment, b is 3 to 15, one terminal R¹ comprises a monovalent reactive group, the other terminal R¹ comprises a monovalent alkyl group having 1 to 6 carbon atoms and the remaining R¹ comprise monovalent alkyl group having 1 to 3 carbon atoms. Non-limiting examples of silicone components of this embodiment include (mono-(2-hydroxy-3-methacryloxypropyl)-propyl ether terminated polydimethylsiloxane (400-

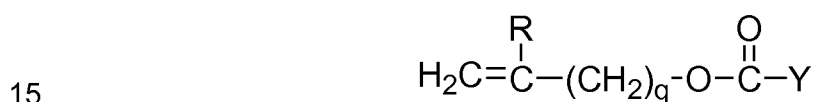
1000 MW)) ("OH-mPDMS"), monomethacryloxypropyl terminated mono-n-butyl terminated polydimethylsiloxanes (800-1000 MW), ("mPDMS").

In another embodiment b is 5 to 400 or from 10 to 300, both terminal R¹ comprise monovalent reactive groups and the remaining R¹ are independently selected
 5 from monovalent alkyl groups having 1 to 18 carbon atoms which may have ether linkages between carbon atoms and may further comprise halogen.

In one embodiment, where a silicone hydrogel lens is desired, the lens of the present invention will be made from a reactive mixture comprising at least about 20 and preferably between about 20 and 70%wt silicone containing components based on
 10 total weight of reactive monomer components from which the polymer is made.

In another embodiment, one to four R¹ comprises a vinyl carbonate or carbamate of the formula:

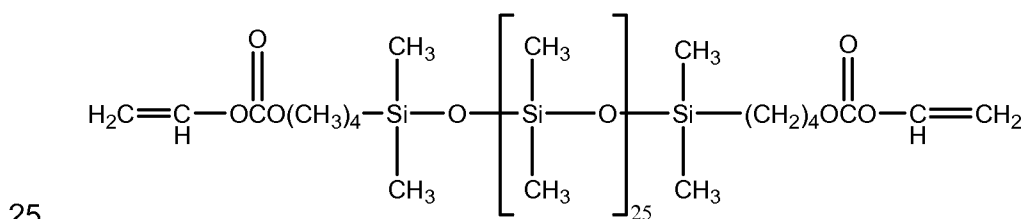
Formula II



wherein: Y denotes O-, S- or NH-;

R denotes, hydrogen or methyl; d is 1, 2, 3 or 4; and q is 0 or 1.

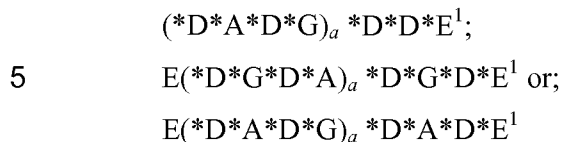
The silicone-containing vinyl carbonate or vinyl carbamate monomers
 20 specifically include: 1,3-bis[4-(vinylloxycarbonyloxy)but-1-yl]tetramethyl-disiloxane; 3-(vinylloxycarbonylthio) propyl-[tris (trimethylsiloxy)silane]; 3-[tris(trimethylsiloxy)silyl] propyl allyl carbamate; 3-[tris(trimethylsiloxy)silyl] propyl vinyl carbamate; trimethylsilylethyl vinyl carbonate; trimethylsilylmethyl vinyl carbonate, and



Where biomedical devices with modulus below about 200 are desired, only one R¹ shall comprise a monovalent reactive group and no more than two of the remaining R¹ groups will comprise monovalent siloxane groups.

Another class of silicone-containing components includes polyurethane macromers of the following formulae:

Formulae IV-VI



wherein:

D denotes an alkyl diradical, an alkyl cycloalkyl diradical, a cycloalkyl diradical, an aryl diradical or an alkylaryl diradical having 6 to 30 carbon atoms,

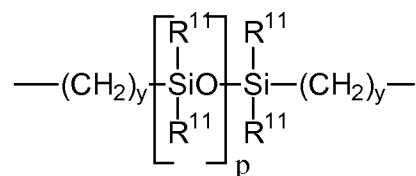
10 G denotes an alkyl diradical, a cycloalkyl diradical, an alkyl cycloalkyl diradical, an aryl diradical or an alkylaryl diradical having 1 to 40 carbon atoms and which may contain ether, thio or amine linkages in the main chain;

* denotes a urethane or ureido linkage;

$_a$ is at least 1;

15 A denotes a divalent polymeric radical of formula:

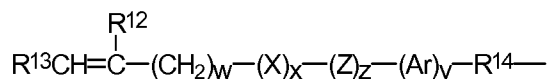
Formula VII



R^{11} independently denotes an alkyl or fluoro-substituted alkyl group having 1 to 10 carbon atoms which may contain ether linkages between carbon atoms; y is at least 1;

20 and p provides a moiety weight of 400 to 10,000; each of E and E^1 independently denotes a polymerizable unsaturated organic radical represented by formula:

Formula VIII



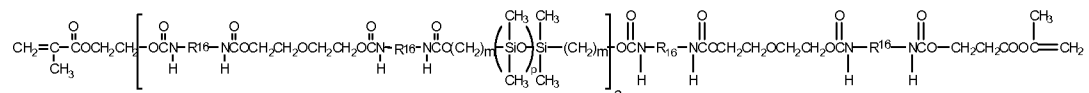
wherein: R^{12} is hydrogen or methyl; R^{13} is hydrogen, an alkyl radical having 1 to 6 carbon atoms, or a $\text{---CO---Y---R}^{15}$ radical wherein Y is ---O--- , Y---S--- or ---NH--- ;

25 R^{14} is a divalent radical having 1 to 12 carbon atoms; X denotes ---CO--- or ---OCO--- ;

Z denotes —O— or —NH—; Ar denotes an aromatic radical having 6 to 30 carbon atoms; w is 0 to 6; x is 0 or 1; y is 0 or 1; and z is 0 or 1.

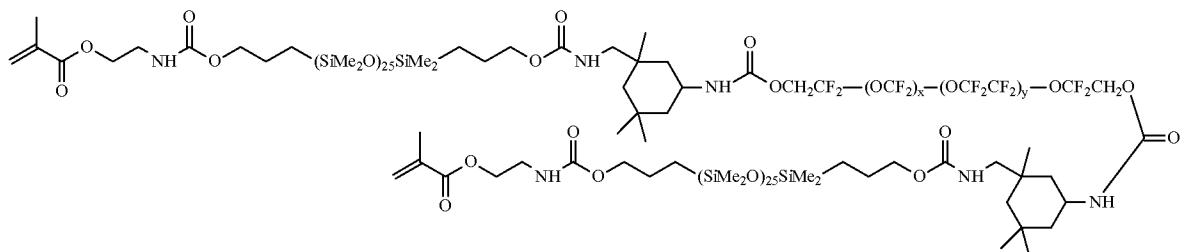
A preferred silicone-containing component is a polyurethane macromer represented by the following formula:

5 Formula IX



wherein R¹⁶ is a diradical of a diisocyanate after removal of the isocyanate group, such as the diradical of isophorone diisocyanate. Another suitable silicone containing macromer is compound of formula X (in which x + y is a number in the range of 10 to 30) formed by the reaction of fluoroether, hydroxy-terminated polydimethylsiloxane, isophorone diisocyanate and isocyanatoethylmethacrylate.

Formula X



Other silicone containing components suitable for use in this invention include
15 macromers containing polysiloxane, polyalkylene ether, diisocyanate, polyfluorinated
hydrocarbon, polyfluorinated ether and polysaccharide groups; polysiloxanes with a
polar fluorinated graft or side group having a hydrogen atom attached to a terminal
difluoro-substituted carbon atom; hydrophilic siloxanyl methacrylates containing ether
and siloxanyl linkages and crosslinkable monomers containing polyether and
20 polysiloxanyl groups. Any of the foregoing polysiloxanes can also be used as the
silicone containing component in this invention.

Processes

The following method steps are provided as examples of processes that may be
25 implemented according to some aspects of the present invention. It should be

understood that the order in which the method steps are presented is not meant to be limiting and other orders may be used to implement the invention. In addition, not all of the steps are required to implement the present invention and additional steps may be included in various embodiments of the present invention.

5 Referring now to Fig. 4, a flowchart illustrates exemplary steps that may be used to implement the present invention, at 401, an Energy Source is placed on to a Media Insert. The Media Insert may or may not also contain one or more components.

At 402, a reactive monomer mix can be deposited into a first mold part.

At 403, the Media Insert is placed into a cavity formed by the first mold part.

10 In some preferred embodiments, the Media Insert 111 is placed in the mold part 101-102 via mechanical placement. Mechanical placement can include, for example, a robot or other automation, such as those known in the industry to place surface mount components. Human placement of a Media Insert 111 is also within the scope of the present invention. Accordingly, any mechanical placement effective to place a Media
15 Insert 111 with an Energy Source 109 within a cast mold part such that the polymerization of a Reactive Mixture 110 contained by the mold part will include the Energy Source 109 in a resultant ophthalmic lens.

In some embodiments, a processor device, MEMS, NEMS or other component may also be mounted on the Media Insert and be in electrical communication with the
20 Energy Source.

At 404, the first mold part can be placed proximate to the second mold part to form a lens forming cavity with at least some of the reactive monomer mix and the Energy Source in the cavity. At 405, the reactive monomer mix within the cavity can be polymerized. Polymerization can be accomplished for example via exposure to one
25 or both of actinic radiation and heat. At 406, the lens is removed from the mold parts.

Although invention may be used to provide hard or soft contact lenses made of any known lens material, or material suitable for manufacturing such lenses, preferably, the lenses of the invention are soft contact lenses having water contents of about 0 to about 90 percent. More preferably, the lenses are made of monomers
30 containing hydroxy groups, carboxyl groups, or both or be made from silicone-containing polymers, such as siloxanes, hydrogels, silicone hydrogels, and combinations thereof. Material useful for forming the lenses of the invention may be made by reacting blends of macromers, monomers, and combinations thereof along

with additives such as polymerization initiators. Suitable materials include, without limitation, silicone hydrogels made from silicone macromers and hydrophilic monomers.

Referring now again to Fig 4, at 402, a reactive mixture is placed between a first
5 mold part and a second mold part and at 403, the Media Insert is positioned in contact with the reactive mixture. At 404, the first mold part is placed proximate to a second mold part to form a lens cavity with the reactive monomer mix and the media in the lens cavity.

At 405, the reactive mixture is polymerized, such as for example via exposure to
10 one or both of actinic radiation and heat. At 406, an ophthalmic device incorporating the Media Insert and Energy Source is removed from the mold parts used to form the ophthalmic device.

Referring now to Fig. 5, in another aspect of the present invention, a Media Insert incorporated into an ophthalmic device can be powered via an incorporated Energy
15 Source. At 501, a Media Insert is placed within an ophthalmic lens, as discussed above. At 502, the Media Insert is placed in electrical communication with a component incorporated into the Media Insert or otherwise included in the ophthalmic lens 105. Electrical communication can be accomplished, for example, via circuitry incorporated into the Media Insert or via pathways ink jetted or otherwise formed
20 directly upon lens material.

At 503, energy is directed to a component incorporated into the ophthalmic lens. The energy can be directed, for example, via electrical circuitry capable of conducting the electrical charge. At 504 the component performs some action based upon the energy directed to the component. The action can include a mechanical action
25 affecting the lens or some action processing information including one or more of: receiving, transmitting, storing and manipulating information. Preferred embodiments will include the information being processed and stored as digital values.

At 505, in some embodiments, information can be transmitted from a component incorporated into the lens.

Apparatus

Referring now to Fig. 3, automated apparatus 310 is illustrated with one or Media Insert 314 transfer interfaces 311. As illustrated, multiple mold parts, each with an associated Media Insert 314 are contained on a pallet 313 and presented to a media transfer interfaces 311. Embodiments, can include a single interface individually
5 placing Media Inserts 314, or multiple interfaces (not shown) simultaneously placing Media Inserts 314 in multiple mold parts, and in some embodiments, in each mold.

Another aspect of some embodiments includes apparatus to support the Media Insert 314 while the body of the ophthalmic lens is molded around these components.
10 In some embodiments the Energy Source may affixed to holding points in a lens mold (not illustrated). The holding points may be affixed with polymerized material of the same type that will be formed into the lens body.

Referring now to Fig. 6 a controller 600 is illustrated that may be used in some embodiments of the present invention. The controller 600 includes one or more
15 processors 610, which may include one or more processor components coupled to a communication device 620. In some embodiments, a controller 600 can be used to transmit energy to the Energy Source placed in the ophthalmic lens.

The processors 610 are coupled to a communication device configured to communicate energy via a communication channel. The communication device may
20 be used to electronically control one or more of: automation used in the placement of a media with an Energy Source into the ophthalmic lens mold part and the transfer of digital data to and from a component mounted on the media and placed within an ophthalmic lens mold part or to control a component incorporated into the ophthalmic lens.

25 The communication device 620 may also be used to communicate, for example, with one or more controller apparatus or manufacturing equipment components.

The processor 610 is also in communication with a storage device 630. The storage device 630 may comprise any appropriate information storage device, including combinations of magnetic storage devices (*e.g.*, magnetic tape and hard disk

drives), optical storage devices, and/or semiconductor memory devices such as Random Access Memory (RAM) devices and Read Only Memory (ROM) devices.

The storage device 630 can store a program 640 for controlling the processor 610. The processor 610 performs instructions of a software program 640, and thereby
5 operates in accordance with the present invention. For example, the processor 610 may receive information descriptive of Media Insert placement, component placement, and the like. The storage device 630 can also store ophthalmic related data in one or more databases 650 and 660. The database may include customized Media Insert designs, metrology data, and specific control sequences for controlling energy to and
10 from a Media Insert.

Referring to Fig. 7, a top down depiction of an exemplary embodiment of a Media Insert 700 is shown. In this depiction, an Energy Source 710 is shown in a periphery portion 711 of the Media Insert 700. The Energy Source 710 may include, for example, a thin film, rechargeable lithium ion battery. The Energy Source 710 may
15 be connected to contact points 714 to allow for interconnection. Wires may be wire bound to the contact points 714 and connect the Energy Source 710 to a photoelectric cell 715 which may be used to reenergize the battery Energy Source 710. Additional wires may connect the Energy Source 710 to a flexible circuit interconnect via wire bonded contact.

20 In some embodiments, the Media Insert 700 may include a flexible substrate. This flexible substrate may be formed into a shape approximating a typical lens form in a similar manner previously discussed. However to add additional flexibility, the Media Insert 700 may include additional shape features such as radial cuts along its length. Various electronic components 712 such as integrated circuits, discrete
25 components, passive components and such devices may also be included.

An optic zone 713 is also illustrated. The optic zone may be optically passive with no optical change, or it may have a predetermined optical characteristic, such as a predefined optical correction. Still other embodiments include an optical zone with a variable optic component that may be varied on command,

30 Referring now to Fig. 8, a cross sectional of a Media Insert 800 is illustrated. The Media Insert 800 can include an optic zone 830 as discussed above and also one or

more periphery portions 810-820. In preferred embodiments, the media insert and components will be placed within the periphery portions 810-820.

In some embodiments there may be manners of affecting the ophthalmic lens' appearance. Aesthetics of the thin film microbattery surface may be altered in various
5 manners which demonstrate a particular appearance when embedded in the electroactive contact lens or shaped hydrogel article. In some embodiments the thin film microbattery may be produced with aesthetically pleasing patterned and/or colored packaging materials which could serve to either give a muted appearance of the thin film microbattery or alternatively provide iris-like colored patterns, solid
10 and/or mixed color patterns, reflective designs, iridescent designs, metallic designs, or potentially any other artistic design or pattern. In other embodiments, the thin film battery may be partially obscured by other components within the lens, for example a photovoltaic chip mounted to the battery anterior surface, or alternatively placement of the battery behind all or a portion of a flexible circuit. In further embodiments, the thin
15 film battery may be strategically located such that either the upper or lower eyelid partially or wholly obscures the visibility of the battery. It may be apparent to one skilled in the art that there are numerous embodiments relating to appearance of an energized ophthalmic device and the methods to define them.

There may be numerous embodiments relating to the method of forming an
20 energized ophthalmic device of the various types that have been described. In one set of embodiments, the inventive art herein may include assembling subcomponents of a particular energized ophthalmic lens embodiment in separate steps. The "off-line" assembly of advantageously shaped thin film microbatteries, flexible circuits, interconnects, microelectronic components, and/or other electroactive components in
25 conjunction with a biocompatible, inert, conformal coating to provide an all-inclusive, embeddable singular package that can be simply incorporated into standard contact lens manufacturing processes. Flexible circuits may include those fabricated from copper clad polyimide film or other similar substrates. Conformal coatings may include, but are not limited to, parylene (grades N, C, D, HT, and any combinations
30 thereof), poly(p-xylylene), dielectric coatings, silicone conformal coatings, or any other advantageous biocompatible coatings.

Some embodiments of the present invention may be methods that are directed toward the geometric design of thin film microbatteries in geometries amenable to the embedment within and/or encapsulation by ophthalmic lens materials. Other embodiments may involve methods that incorporate thin film microbatteries in various materials such as, but not limited to, hydrogels, silicone hydrogels, rigid gas-permeable “RGP” contact lens materials, silicones, thermoplastic polymers, thermoplastic elastomers, thermosetting polymers, conformal dielectric/insulating coatings, and hermetic barrier coatings.

Other embodiments may involve methods for the strategic placement of an Energy Source within an ophthalmic lens geometry. Specifically, in some embodiments the Energy Source may be an opaque article. Since the Energy Source may not obstruct the transmission of light through the ophthalmic lens, methods of design in some embodiments may ensure that the central 5-8 mm of the contact lens may not be obstructed by any opaque portions of the Energy Source. It may be apparent to one skilled in the art that there may be many different embodiments relating to the design of various Energy Sources to interact favorably with the optically relevant portions of the ophthalmic lens.

In some embodiments the mass and density of the Energy Source may facilitate designs such that said Energy Source may also function either alone or in conjunction with other lens stabilization zones designed into the body of the ophthalmic lens to rotationally stabilize the lens while on eye. Such embodiments could be advantageous for a number of applications including, but not limited to, correction of astigmatism, improved on-eye comfort, or consistent/controlled location of other components within the energized ophthalmic lens.

In additional embodiments, the Energy Source may be placed a certain distance from the outer edge of the contact lens to enable advantageous design of the contact lens edge profile in order to provide good comfort while minimizing occurrence of adverse events. Examples of such adverse events to be avoided may include superior epithelial arcuate lesions or giant papillary conjunctivitis.

By way of non-limiting example in some embodiments, a cathode, electrolyte and anode features of embedded electrochemical cells may be formed by printed appropriate inks in shapes to define such cathode, electrolyte and anode regions. It

may be apparent that batteries thus formed could include both single use cells, based for example on manganese oxide and zinc chemistries, and rechargeable thin batteries based on lithium chemistry similar to the above mentioned thin film battery chemistry. It may be apparent to one skilled in the arts that a variety of different embodiments of the various features and methods of forming energized ophthalmic lenses may involve the use of printing techniques.

In addition, in some embodiments, energy harvesters may be included and placed in electrical communication in a fashion which enables the energy harvesters to charge one or more Energy Sources. Energy harvesters can include, for example: photovoltaic energy cells, thermoelectric cells or piezoelectric cells. Harvesters have a positive aspect in that they can absorb energy from the environment and then can provide electrical energy without an external wired connection. In some embodiments, harvesters may comprise an energy source in an energized ophthalmic lens. In other embodiments, however, the energy harvester may be combined with other sources that can store energy in an electrical form.

Other types of Energy Source include the use of capacitor type devices. It may be apparent, that capacitors may provide an energy density solution that is higher than energy harvesters but less than that of batteries.

Capacitors are a type of Energy Source that stores energy in an electrical form and therefore, may be one of the Energy Sources that can be combined with energy harvesters to create a wireless Energy Source that is capable of storage of energy. Generally capacitors have an advantage over batteries in that they have higher power density, in general, than batteries. There are many different types of capacitors ranging from standard electrical thin film capacitors, Mylar capacitors, electrolytic capacitors and relative newer and more advanced technologies of high-density nanoscale capacitors or supercapacitors.

In some additional embodiments, Energy Sources including electrochemical cells or batteries may define a relatively desirable operational point. Batteries have numerous advantageous characteristics. For example, batteries store energy in a form that is directly converted to electrical energy. Some batteries may be rechargeable or Re-energizable and therefore, represent another category of Energy Source that may be coupled to energy harvesters. Batteries generally are capable of relatively high energy

density, and the energy batteries store can perform functions with relatively higher energy requirements as compared with other miniaturized Energy Sources. In addition, the batteries can be assembled into forms that are flexible. For applications requiring high power capabilities, it may be apparent to one skilled in the art that a

5 Battery may also be coupled to Capacitors. There may be numerous embodiments that comprise a battery at least as part of an Energy Source in an energized ophthalmic lens.

Another type of embodiment can include a fuel cell as an Energy Source. Fuel cells generate electricity by consuming a chemical fuel source which then generates electricity and byproducts including heat energy. Fuel cell embodiments may be

10 possible using biologically available materials as the fuel source.

There are many different types of batteries which may be included in embodiments of energized ophthalmic lenses. For example, single use batteries may be formed from various cathode and anode materials. By way of non-limiting examples these materials may include one or more of: Zinc, carbon, Silver,

15 Manganese, Cobalt, Lithium and Silicon. Still other embodiments may derive from the use of batteries that are rechargeable. Such batteries may in turn be made of one or more of: Lithium Ion technology; Silver Technology; Magnesium technology; Niobium technology or other current providing material. It may be apparent to one skilled in the art that various current battery technologies for single use or rechargeable

20 battery systems may comprise the Energy Source in various embodiments of an energized ophthalmic lens.

In some embodiments, the physical and dimensional constraints of a contact lens environment may be conducive to thin film batteries. Thin film batteries may occupy the small volume of space consistent with human ophthalmic embodiments.

25 Furthermore, they may be formed upon a substrate that is flexible allowing for the body of both the ophthalmic lens and included battery with substrate to have freedom to flex.

In the case of thin film batteries, examples may include single charge and rechargeable forms. Rechargeable batteries afford the ability of extended usable

30 product lifetime and, therefore, higher energy consumption rates. Much development activity has focused on the technology to produce electrically energized ophthalmic

lenses with rechargeable thin film batteries; however, the inventive art is not limited to this subclass.

Rechargeable thin film batteries are commercially available, for example, Oak Ridge National Laboratory has produced various forms since the early 1990s. Current
5 commercial producers of such batteries include Excellatron Solid State, LLC (Atlanta, GA), Infinite Power Solutions (Littleton, CO), and Cymbet Corporation, (Elk River, MN). The technology is currently dominated by uses that include flat thin film batteries. Use of such batteries may comprise some embodiments of this inventive art; however, forming the thin film battery into a three dimensional shape, for example
10 with a spherical radius of curvature comprises desirable embodiments of the inventive art. Numerous shapes and forms of such a three dimensional battery embodiment are within the scope of the invention.

Conclusion

The present invention, as described above and as further defined by the claims
15 below, provides methods of providing energized Media Inserts and apparatus for implementing such methods, as well as ophthalmic lenses formed with the Media Inserts.

CLAIMS

1. A method of forming an ophthalmic lens, the method comprising:
5 placing media insert comprising an energy source and a current drawing component mounted to the media insert proximate to a first mold part;
depositing a reactive monomer mix into the first mold part;
positioning the media insert in contact with the reactive monomer mix;
positioning the first mold part proximate to a second mold part thereby
10 forming a lens cavity with the media insert and the energy source and the component and at least some of reactive monomer mix in the lens cavity; and
exposing the reactive monomer mix to actinic radiation.
- 15 2. The method of claim 1 wherein the media insert comprises an electrochemical cell.
3. The method of claim 2 wherein the media insert comprises an annular shape.
20
4. The method of claim 2 wherein the media insert comprises an arcuate shape.
- 25 5. The method of claim 2 wherein the media insert comprises a rigid insert and the method additionally comprises the step of fixing the energy source to the media insert.
- 30 6. The method of claim 1 wherein the rigid insert comprises multiple disparate portions.

7. The method of claim 5 wherein the energy source comprises a thin film electrochemical cell.
- 5 8. The method of claim 7 wherein the electrochemical cell comprises a lithium ion battery.
9. The method of claim 7 wherein the electrochemical cell comprises a
10 rechargeable material.
10. The method of claim 7 wherein the electrochemical cell comprises a cathode
comprising nano-scaled crystals.
15
- 11, The method of claim 10 wherein the nano-scaled crystals comprise lithium iron
phosphide.
- 20 12. The method of claim 5 additionally comprising injection molding the media
insert.
- 25 13. The method of claim 3 wherein the binder layer comprises a prepolymer.
14. The method of claim 1 wherein the media insert comprises a formable
substrate.
30

15. An method for manufacturing an ophthalmic lens, the method comprising:
operating first automation to place a media insert comprising an energy
source in one or both of: proximate to, or in contact with, a first mold part;
operating a second automation in logical communication with the first
5 automation to dispense a reactive monomer mix into the first mold part following the
placement of the media insert comprising an energy source in one or both of:
proximate to, or in contact with, a first mold part; and
operating a third automation to expose the reactive monomer mix within
the first mold part to actinic radiation.
10

16. The method for manufacturing an ophthalmic lens of claim 15 additionally
comprising the step of:
operating a fourth automation to place a second mold part proximate to
15 the first mold thereby creating a lens forming cavity with the media insert comprising
the energy source and at least some of the reactive monomer mix within the lens
forming cavity.

20 17. The method for manufacturing an ophthalmic lens of claim 16 additionally
comprising the steps of:
holding multiple first mold parts in a pallet; and
operating a fifth automation to move the pallet proximate to the source
of actinic radiation.
25

18. The method for manufacturing an ophthalmic lens of claim 17 additionally
comprising the steps of:
storing executable software code on a digital storage device in digital
30 communication with a processor, wherein the processor is in further communication
with the automation; and
executing the software code via the processor to control the automation
and cause the automation to perform the method steps included in claim 17.

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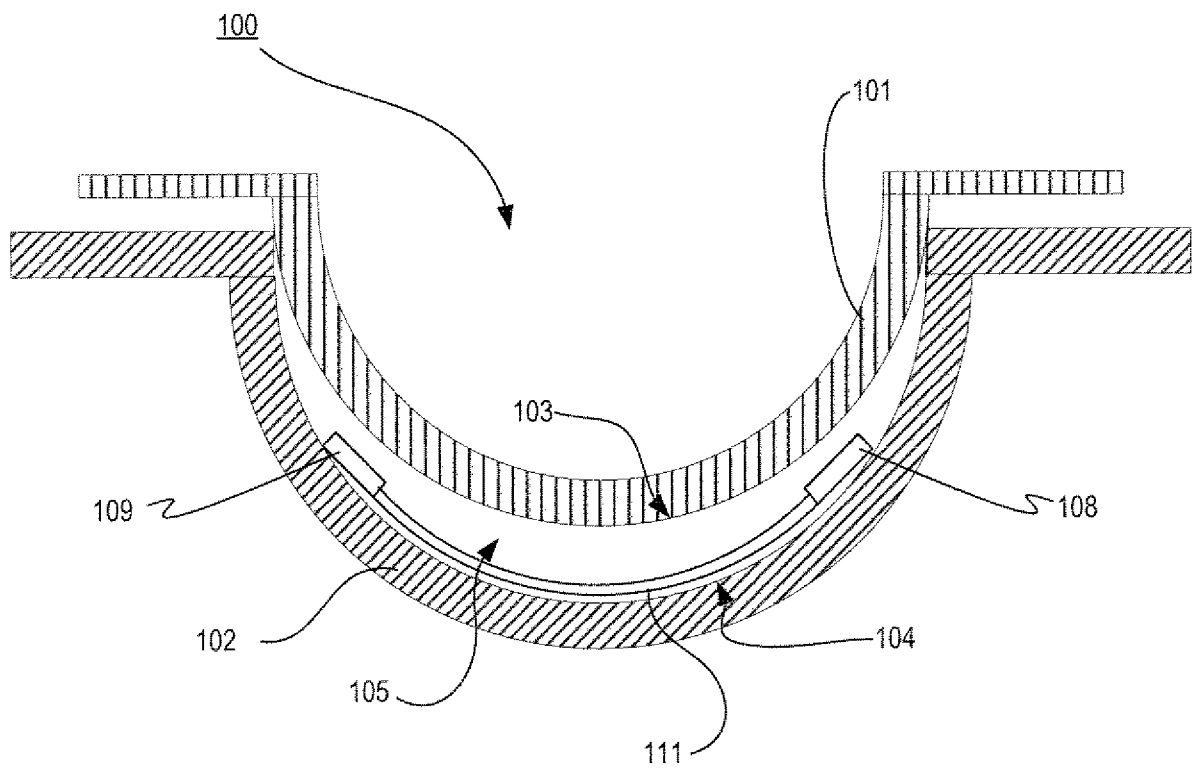


FIG. 1

FIG. 2A

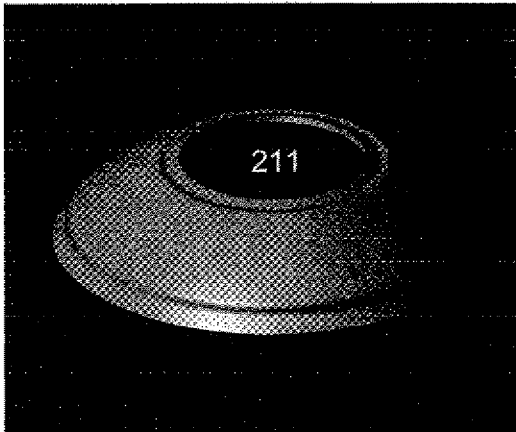


FIG. 2B

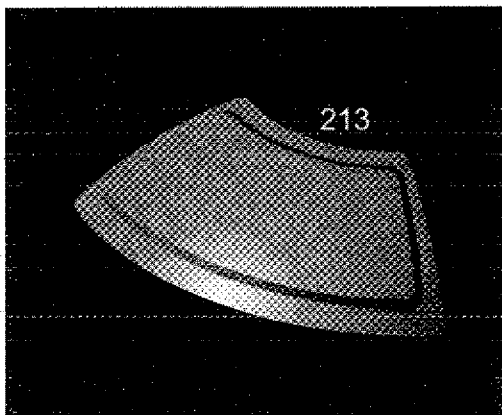
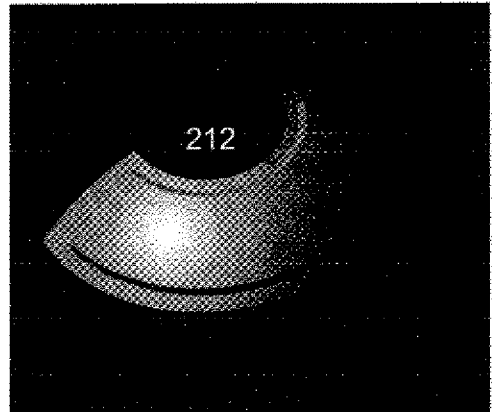


FIG. 2C

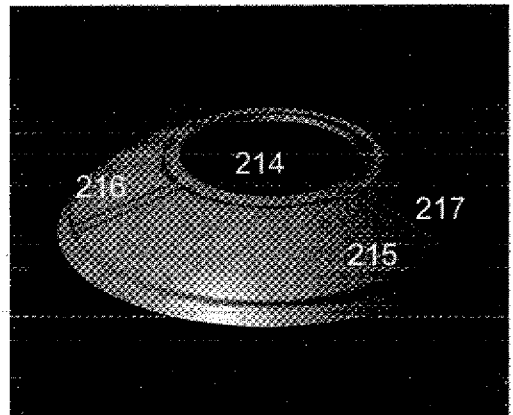


FIG. 2D

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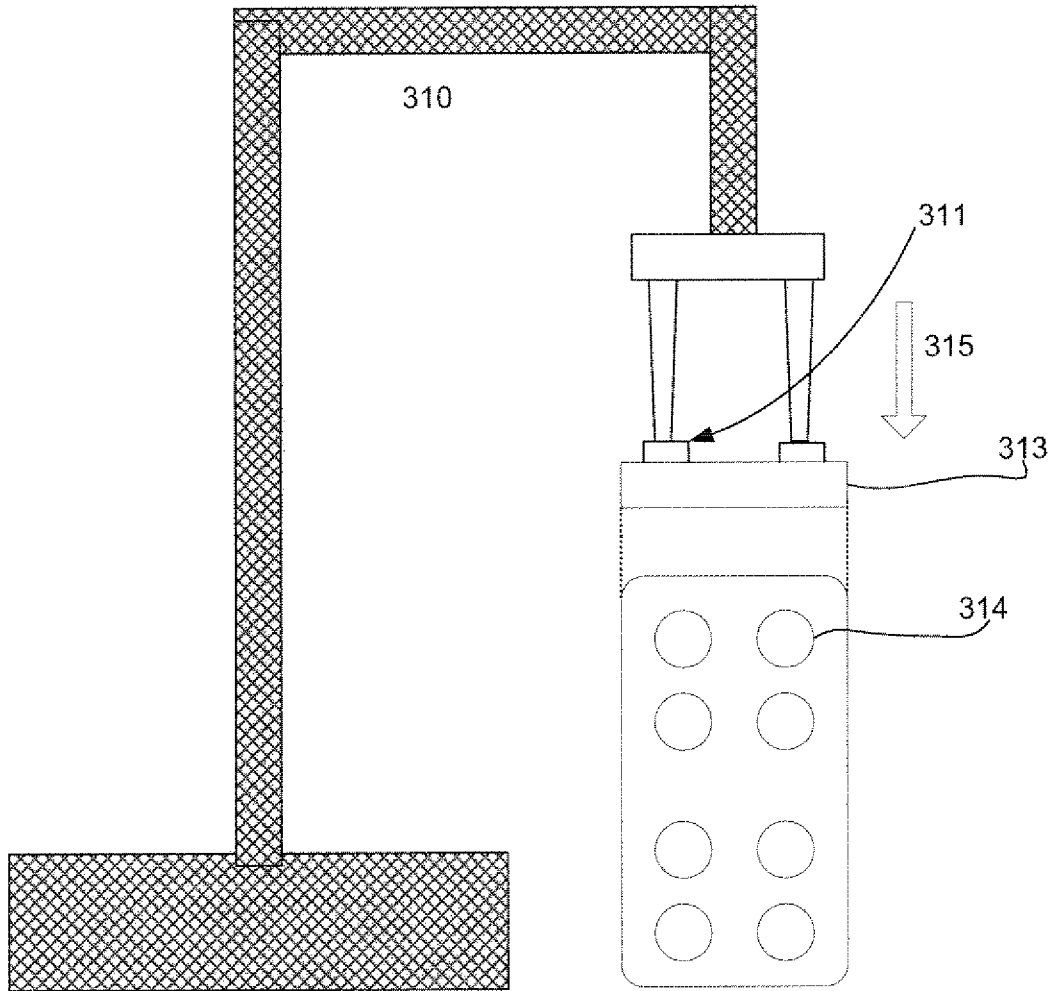


FIG. 3

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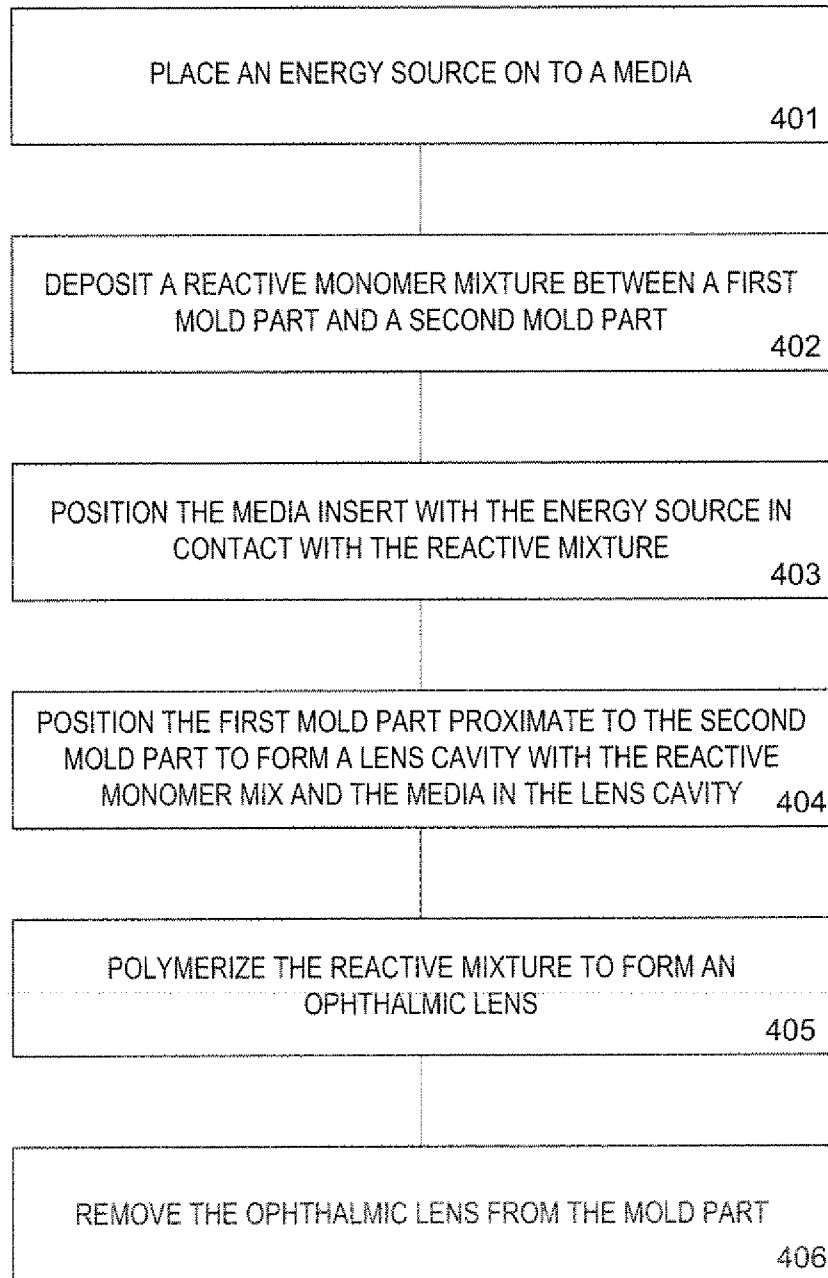


FIG. 4

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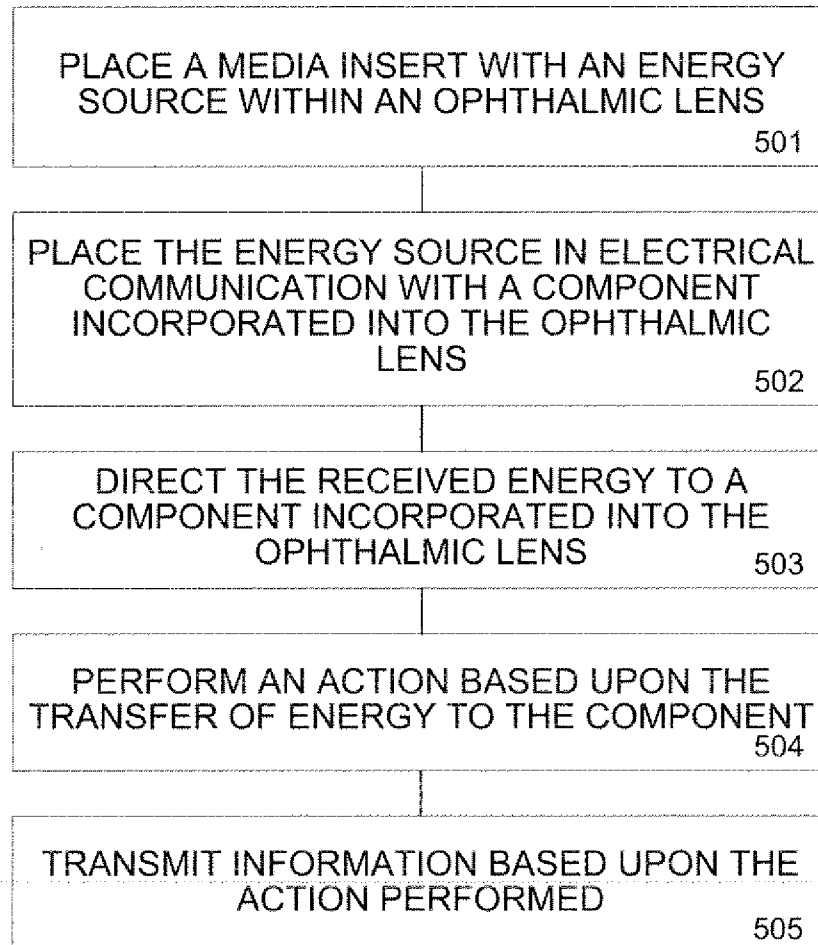


FIG. 5

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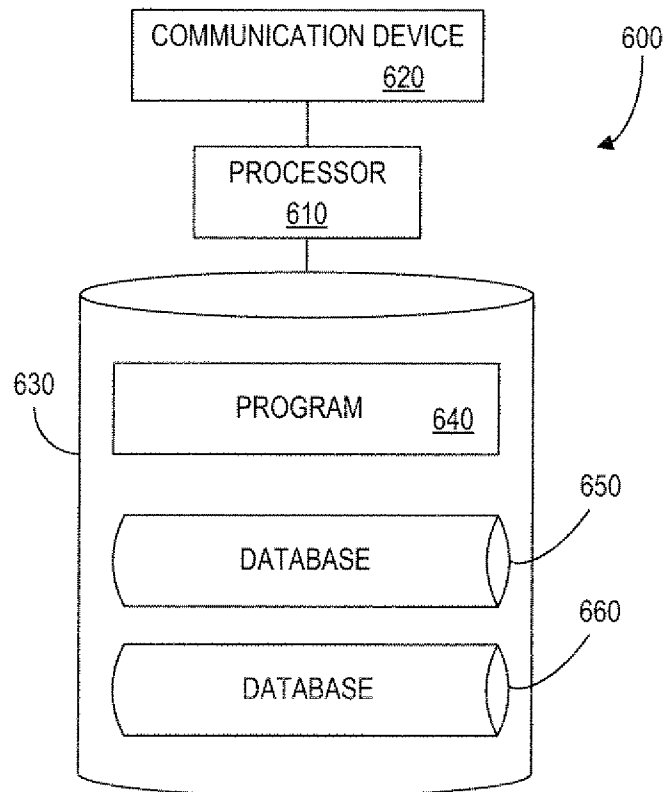


FIG. 6

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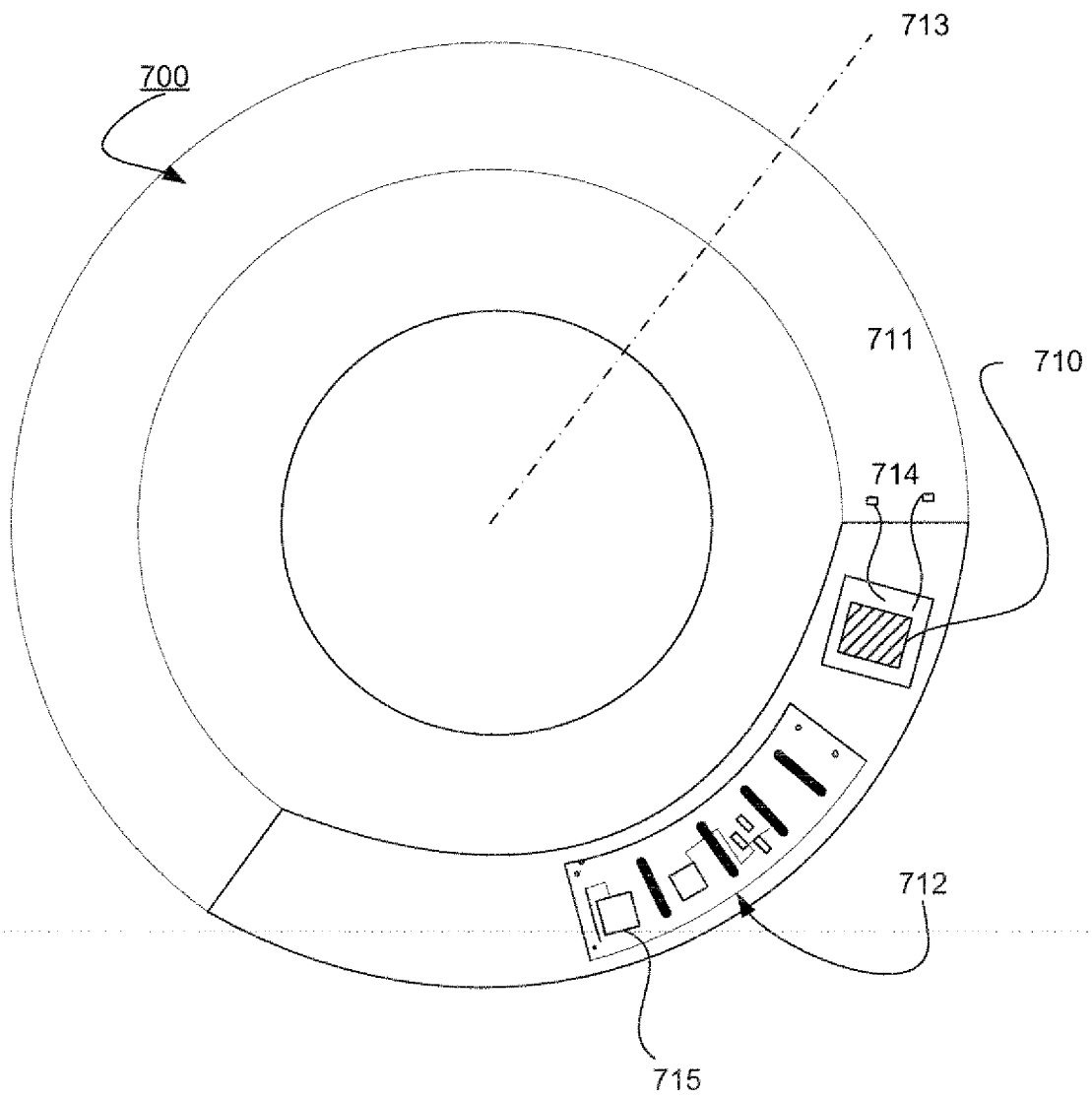


FIG. 7

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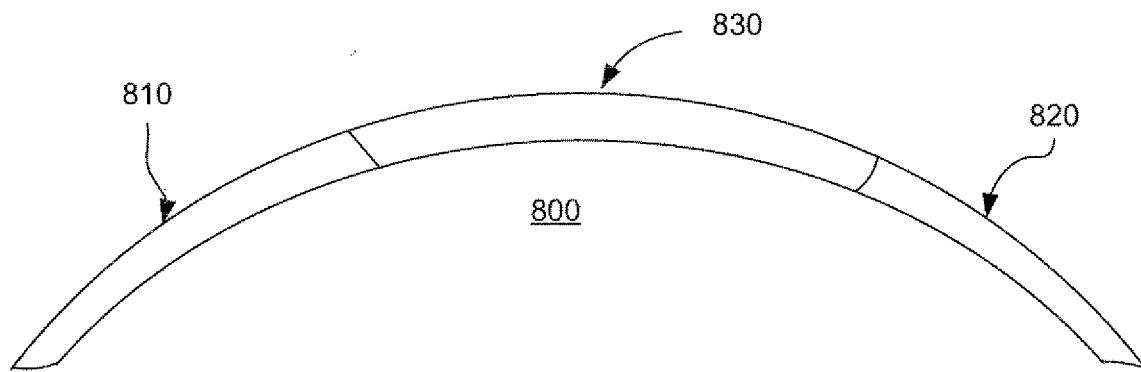


FIG. 8