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(57) Abstract: Ophthalmic device molds made from a first portion of a molding surface formed from a first polymer and a second portion of the molding surface formed from a second polymer are described. When combined, the first portion and the second portion of the molding surface form an entire molding surface suitable for molding an entire surface, such as an anterior surface or a posterior surface of an ophthalmic device. Methods of manufacturing ophthalmic devices using these molds, including contact lenses, are also described.



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## OPHTHALMIC DEVICE MOLDS AND RELATED METHODS

### FIELD

[0001] The present disclosure relates to ophthalmic device molds formed from a first portion comprising a vinyl alcohol copolymer and a second portion comprising a second polymer, and methods of manufacturing ophthalmic devices using these molds.

### BACKGROUND

[0002] In cast molding methods of producing ophthalmic devices, such as ocular inserts and contact lenses, separate mold members are typically used to form each surface of the device. Often a pair of mold members, one of which forms the entire anterior device surface and another of which forms the entire posterior device surface are typically combined to form a device-shaped cavity, and a reaction mixture or polymerizable composition is cured in the device-shaped cavity. After placing the polymerizable composition in a first mold member, the first mold member and a second mold member are placed together or coupled together to form a mold assembly with an ophthalmic device-shaped cavity therebetween. The mold assembly is then cured to polymerize the polymerizable composition, forming the polymeric ophthalmic device in the device-shaped cavity of the mold assembly.

[0003] Commonly, a complete mold member, including its entire molding surface, is produced by injection molding a thermoplastic polymer into a mold-shaped cavity. Lathing of mold members in order to form an entire molding surface has also been described. However, the lens design features which can be reproducibly formed in the molding surfaces while still achieving the necessary optical quality molding surfaces can be somewhat limited when the molding surfaces must be formed either by injection molding or lathing. For example, preparing metal molding cavities having intricate patterns engraved into them can be very difficult and expensive, particularly when a large number of metal molding cavities in a large number of lens powers may be required for commercial-scale production. The cost of lathing individual mold

members can be prohibitively expensive and time-consuming, particularly at commercial scales. And even when it is possible or economically feasible to prepare such molding surfaces, it may be difficult if not impossible to release a cured polymeric device body from an intricate molding surface without damaging the device body. Thus, there is a need for new low-cost molding surfaces which allow intricate or complicated surfaces to be cast-molded on ophthalmic device bodies, while readily allowing the cast-molded surfaces to be released from the molding surfaces, and for methods of preparing and using these molding surfaces in the manufacture of ophthalmic devices.

[0004] All publications, including patents, published patent applications, scientific or trade publications and the like, cited in this specification are hereby incorporated herein in their entirety.

#### SUMMARY

[0005] The present disclosure is directed to a method of manufacturing an ophthalmic device, comprising:

- (a) placing a polymerizable composition comprising at least one hydrophilic monomer in direct contact with an entire molding surface configured to cast mold an anterior or posterior surface of an ophthalmic device; and
- (b) curing the polymerizable composition in direct contact with the entire molding surface to form a polymerized reaction product comprising a polymeric ophthalmic device body,

wherein a first polymer is used to form a first portion of said molding surface configured to mold the entire anterior or posterior surface of an ophthalmic device, a second polymer is used to form a distinct second portion of said molding surface configured to mold the entire anterior or posterior surface of an ophthalmic device and, when combined, the distinct first and second portions form the entire said molding surface configured to mold the entire anterior or posterior surface of an ophthalmic device.

[0006] In one example, the first polymer can comprise or consist of at least one polar polymer. The first polymer can comprise or consist of at least one vinyl alcohol copolymer. The first polymer can comprise or consist of at least one vinyl alcohol copolymer which is not an ethylene-vinyl alcohol copolymer. The first polymer can

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comprise or consist of a water-soluble polymer. The first polymer can comprise or consist of at least one water-soluble vinyl alcohol copolymer. The first polymer can comprise or consist of at least one thermoplastic polymer.

The first polymer can comprise or consist of at least one thermoplastic vinyl alcohol copolymer. The first polymer can comprise or consist of NICHIGO G-POLYMER™ (Nippon Gohsei, Osaka, Japan).

[0007] The second polymer can comprise or consist of at least one polar polymer. The second polymer can comprise or consist of at least one non-polar polymer. The second polymer can comprise or consist of at least one ethylene-vinyl alcohol copolymer. The second polymer can comprise or consist of at least one polymer which is not a water-soluble polymer. The second polymer can comprise or consist of at least one thermoplastic polymer. The second polymer can comprise or consist of polypropylene.

[0008] The step of using the first polymer to form the first portion of the molding surface can comprise or consist of injection molding the first polymer. The injection molding the first polymer can use a process setting selected from the group consisting of: melt temperature from about 180°C to about 250°C, barrel temperature from about 180°C to about 250°C, throat temperature from about 30°C to about 70°C, mold tool temperature from about 30°C to about 95°C, holding time from about 1 second to about 5 seconds, injection speed from about 50 mm/second to about 250 mm/second, plasticizing speed from about 100 mm/second to about 300 mm/second, injection pressure from about 50 Bar to about 180 Bar, holding pressure from about 10 Bar to about 200 Bar, back pressure from about 5 Bar to about 25 Bar, and any combination thereof. In one example, at least two of the above process settings can be used. In another example, at least three of the above process settings can be used. In yet another example, at least four of the above process settings can be used.

[0009] The step of using the first polymer to form the first portion of the molding surface can comprise or consist of lathing the first polymer. The step of using the second polymer to form the second portion of the molding surface can comprise or consist of injection molding the second polymer. The step of using the second polymer copolymer to form the second portion of the molding surface can comprise or consist of lathing the second polymer.

[0010] The step of using the first polymer to form the first portion of the molding surface can comprise or consist of forming a matrix of the first polymer. The method can further comprise the step of combining the matrix and the second portion of the molding surface to

form the entire molding surface prior to the step of placing the polymerizable composition comprising in direct contact with the entire molding surface.

[0011] The step of using the first polymer to form the first portion of the molding surface can comprise or consist of applying the first polymer directly onto a pre-formed molding surface formed of the second polymer. The applying the first polymer directly onto a pre-formed molding surface can comprise or consist of casting the vinyl alcohol into a pre-formed mold member comprising the second portion of the molding surface formed of the second polymer.

[0012] The method can further comprise the step of affixing the first portion and the second portion to each other to form the entire molding surface.

[0013] The method can further comprise the step of releasing the polymeric ophthalmic device body from both the first portion of the molding surface and the second portion of the molding surface. In one example, the polymeric ophthalmic device body can be released from the second portion of the molding surface before the device body is released from the first portion of the molding surface. The method can further comprise releasing the polymeric ophthalmic device body from at least the second portion of the molding surface using a process which does not involve contacting the device body or the second portion of the molding surface with a liquid. The method can further comprise releasing the polymeric ophthalmic device body from at least the first portion of the molding surface by contacting the device body and the first portion of the molding surface with a liquid. The contacting the first portion of the molding surface with the liquid can result in the liquid at least partially dissolving the first portion of the molding surface.

[0014] The polymerizable composition can comprise at least one silicon-containing monomer, and the polymeric ophthalmic device body can comprise a silicone hydrogel ophthalmic device body.

[0015] The entire molding surface can comprise an entire molding surface configured to mold a posterior surface of a contact lens, and the polymeric ophthalmic device body can comprise a polymeric contact lens body. The first portion of the molding surface can be configured to form all of or a part of a peripheral zone of a contact lens surface. The first

portion of the molding surface can be configured to form at least one channel in a peripheral zone of a contact lens surface.

[0016] In one example, the first portion of the molding surface can be configured to form at least one channel on a surface of the device. In other words, the entire channel can be part of an outer surface of the device, such that the channel itself is part of the outer surface of the device. In another example, the first portion of the molding surface can be configured to form at least one channel extending from at least one surface of the device into a body of the device. In other words, in this example, a portion of the channel can form an outer surface of the device, while another portion of the channel can be within and surrounded by the body of the lens. In one example, such a channel can extend from a first outer surface of the device into the lens body without having a second outlet to a lens surface. In another example, such a channel can extend from a first outer surface of the device into the device body and then back out of the device body at a second opening on a surface of the device. In this example, the first opening can be a different opening than the second opening. Additionally, the first opening can be on a first device surface, and the second opening can be on the same device surface as the first opening, or can be on a different surface of the device.

[0017] The present disclosure is also directed to an ophthalmic contact lens mold member that includes a molding surface configured to form an entire anterior or posterior surface of a contact lens, the molding surface comprising:

- (a) a first portion formed of a first polymer, wherein the first portion is configured to cast mold a first region of the surface of the contact lens; and
- (b) a distinct second portion formed of a second polymer, wherein the second portion is configured to cast mold a second region of the surface of the contact lens, wherein the distinct first and second portions of the molding surface are combined to form a single molding surface, and wherein the combination of the distinct first and second portions is configured to form the entire molding surface to cast mold said entire anterior or posterior surface of the contact lens.

[0018] Any and all features described herein and any combination of such features are included within the scope of the present application provided that the features of any such



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combination are not mutually inconsistent. In addition, any feature or combination of features may be specifically excluded from any example of the present disclosure.

**BRIEF DESCRIPTION OF THE DRAWINGS**

[0019] FIG. 1 is a flow chart illustrating steps of a method for producing an ophthalmic device.

[0020] FIG. 2 is a flow chart illustrating certain inputs and outputs of the method of FIG. 1.

[0021] FIG. 3 is a drawing illustrating several matrices which can be prepared and used as a portion of a molding surface as described herein.

[0022] FIG. 4 is a drawing two matrices including non-molding regions to allow the matrices to be attached to a mold member.

## DETAILED DESCRIPTION

[0023] New ophthalmic device molds have been discovered. These ophthalmic device molds can be used to cast mold polymeric ophthalmic device bodies, including ocular insert bodies and contact lens bodies. These molds can comprise one or more molding surfaces, where each molding surface comprises a first portion of the molding surface formed from a first polymer, and a second portion of the molding surface formed from a second polymer. Together, the first portion and the second portion form the entire molding surface, i.e., the molding surface is configured to form an entire surface of an ophthalmic device, such as, for example, an entire anterior surface of a contact lens or an entire posterior surface of a contact lens. As used herein, a molding surface is understood to refer to the portion of a mold member which is configured to form single surface, such as a posterior or anterior surface, of a device. When a molding surface is used to form an ophthalmic device, the quality of the surface is sufficient to form a surface on the device which is of acceptable quality for placement in the eye. For example, a molding surface used to form a surface of a contact lens is of sufficient quality to form a device acceptable for placement in the eye, and may also, if used to form a vision correction zone, be of sufficient quality to form a vision-correcting lens.

[0024] When used to cast mold an ophthalmic device, the first portion and the second portion are combined to form a single, complete molding surface. Combining the first portion and the second portion can comprise physically placing a pre-formed first portion and a pre-formed second portion in physical contact with each other, or can comprising forming the first portion in contact with a pre-formed second portion. However, forming the entire molding

surface does not comprise forming a mixture of the first and second polymers and using the polymer mixture to form the entire molding surface. Instead, distinct first and second portions are combined to form the entire molding surface, and once the first and second portions have been combined to form the entire molding surface, distinct first and second portions remain. Thus, when the first portion and the second portion of the molding surface are combined to form an entire molding surface, the first portion and the second portion are physically adjacent to each other and in close enough contact with each other such that the entire molding surface can be used to cast mold a liquid polymerizable composition without the composition flowing between the first portion and the second portion at the interface between the first portion and the second portion.

**[0025]** In the process of using the entire molding surface to cast mold a surface of an ophthalmic device, a polymerizable composition is placed on the molding surface. When placed on the molding surface, the polymerizable composition is in direct contact with both the first portion of the molding surface and the second portion of the molding surface. As is often done in cast molding, a first mold member comprising the molding surface formed from the first portion and the second portion can be combined with a second mold member such that a device-shaped cavity is formed between the molding surface of the first mold member and the molding surface of the second mold member. As used herein, a mold assembly is understood to refer to the combination of a first mold member and a second mold member. The second mold member can be a mold member as described herein, or can be a conventional mold member, i.e., a mold member having a unitary molding surface which is not formed by combining two or more separate portions of different polymers.

**[0026]** Once the polymerizable composition has been placed in direct contact with the molding surfaces of both the first mold member and the second mold member of the mold assembly, the mold assembly can be reacted to polymerize the polymerizable composition to form a polymeric device body. During the curing process, the polymerizable composition and the resulting polymeric device body remain in direct contact with the molding surfaces of both the first mold member and the second mold member.

**[0027]** When used to cast mold an ophthalmic device surface, the first portion of the molding surface molds a first region of the surface, and the second portion of the molding

surface molds a second region of the surface. For example, the first region of the lens molded by the first portion of the molding surface can comprise or consist of a peripheral zone (i.e., a non-vision correcting zone) on an anterior or posterior surface of a contact lens, and the second region of the lens molded by the second portion of the molding surface can comprise or consist of an optic zone (i.e., a vision correcting zone) on an anterior or posterior surface of a contact lens.

**[0028]** The first polymer used to form the first portion of the molding surface can comprise or consist of at least one vinyl alcohol copolymer. As used herein, a vinyl alcohol copolymer is a polymer comprising at least one unit of a vinyl alcohol functional group and units of a functional group which is not a vinyl alcohol. This is distinct from a vinyl alcohol homopolymer, which is a polymer comprising only repeating units of a vinyl alcohol functional group, i.e., poly(vinyl alcohol) (PVOH), or a modified form of PVOH such as a form of PVOH which has been physically combined (i.e., not reacted or co-polymerized) with ingredients such as plasticizers which modify the properties of the PVOH, such as, for example, the melting temperature to allow the PVOH to be injection molded.

**[0029]** The first polymer can comprise or consist of a water-soluble polymer such as, for example, a water-soluble vinyl alcohol copolymer. As used herein, a water-soluble vinyl alcohol copolymer is understood to be a vinyl alcohol copolymer which is visibly soluble in water or an aqueous solution at room temperature (e.g., about 20-25 degrees C). For example, a vinyl alcohol copolymer can be a copolymer for which 50 grams or more of the copolymer are visibly fully soluble in 1 liter of deionized water at 20 degrees C (i.e., the copolymer is soluble at a level of at least 5% wt/wt in water) as determined using a standard shake flask method as known to persons of ordinary skill in the art. In another example, the vinyl alcohol copolymer can be a copolymer for which 100 grams or more of the copolymer are visibly soluble in 1 liter of deionized water at 20 degrees C. In another example, the vinyl alcohol copolymer can be a copolymer for which 150 grams or more of the copolymer are visibly soluble in 1 liter of deionized water at 20 degrees C. In yet another example, the vinyl alcohol copolymer can be a copolymer for which 200 grams or more of the copolymer are visibly soluble in 1 liter of deionized water at 20 degrees C.

**[0030]** The first polymer can rapidly dissolve in water or an aqueous solution. In one example, when agitated in 1 liter of deionized water at 30 degrees C, a sample of the first polymer can dissolve at least 40% (wt/wt) in 20 minutes or less. In another example, when agitated in 1 liter of deionized water at 30 degrees C, a sample of the first polymer can dissolve at least 50% (wt/wt) in 20 minutes or less. In yet another example, when agitated in 1 liter of deionized water at 30 degrees C, a sample of the first polymer can dissolve at least 60% (wt/wt) in 20 minutes or less.

**[0031]** In one example, the first polymer can be a polymer, such as, for example, a vinyl alcohol copolymer, which, when solubilized, has a low level of insoluble (i.e., undissolved and undissolvable) solids present in the solution. For example, when a sample of the first polymer is placed in water or an aqueous solution, following complete dissolution of the soluble portion of the copolymer, only a small portion of solid polymer material remains. For example, less than about 20% of the amount of polymer by weight, or less than about 15% of the polymer by weight, or less than about 10% by weight, or less than about 8% by weight, or less than about 6% of the amount of polymer by weight, or less than about 5% of the amount of polymer by weight can remain as insoluble solids.

**[0032]** In one example, the first polymer can be a polymer which, when solubilized, has a low level of insoluble solids present in solution, can dissolve in water at a temperature from about 30 degrees C to about 80 degrees C in less than or equal to 20 minutes to form a 3% (wt/wt) solution of the vinyl alcohol copolymer in water, the solution having a level of insoluble solids of about 10% (wt/wt) or less (i.e., 10% by weight of the sample of copolymer added to the water remains present as insoluble solids present in the solution). In another example, the first polymer can dissolve in water at a temperature from about 30 degrees C to about 80 degrees C in less than or equal to 20 minutes to form a 6% (wt/wt) solution of the first polymer in water, the solution having a level of insoluble solids of about 6% (wt/wt) or less. In yet another example, the first polymer can dissolve in water at a temperature from about 30 degrees C to about 80 degrees C in less than or equal to 20 minutes to form a 10% (wt/wt) solution of the first polymer in water, the solution having a level of insoluble solids of about 15% (wt/wt) or less.

[0033] The solutions of the first polymer formed by dissolving the first portion of the molding surface in a liquid may not present manufacturing difficulties such as, for example, excessive foaming, gelation of the liquid, or the liquid becoming cloudy due to undissolved or precipitated copolymer. For example, the first polymer of the present disclosure can be a polymer such as, for example, a vinyl alcohol copolymer, which forms physically stable aqueous solutions. An aqueous solution of the first polymer may not gel in solution for over 3 hours, 6 hours, 12 hours, 24 hours, or 48 hours after formation of the solution. An aqueous solution of the first polymer can have a viscosity which varies less than about 20%, less than about 15%, or less than about 10% when stored at a temperature of about 90°C or less over a period of at least 12 hours. In another example, a solution of first polymer can be highly resistant to precipitating when subjected to high shear. The solution of the first polymer can retain its initial haze level following mixing in a high shear mixer at 1000 rpm for 30 minutes at 10°C. In another example, the solution of the first polymer can have a haze level less than  $\pm 15\%$ , or less than  $\pm 10\%$ , or less than  $\pm 5\%$  of its initial haze level following mixing in a high shear mixer at 1000 rpm for 30 minutes at 10°C. The aqueous solution of the first polymer may not foam significantly, i.e., the solution may not foam at a level which becomes disruptive during a “wet” demolding or delensing process.

[0034] When formed into a dry film, the first polymer can have a low rate of oxygen transmittance. For example, the rate of oxygen transmittance through a dry film formed of the polymer can be less than 2.0 cc  $20\mu\text{m}^2$  day atm, or less than 1.5 cc  $20\mu\text{m}^2$  day atm, or less than 1.0 cc  $20\mu\text{m}^2$  day atm, or less than 0.5 cc  $20\mu\text{m}^2$  day atm, or less than 0.2 cc  $20\mu\text{m}^2$  day atm as determined for a dry sample at 20 degrees C. In another example, the rate of oxygen transmittance can be less than 0.005 cc  $20\mu\text{m}^2$  day, or less than 0.004 cc  $20\mu\text{m}^2$  day, or less than 0.003 cc  $20\mu\text{m}^2$  day. When a first polymer with a low rate of oxygen transmittance is used to form a molding surface of a mold member used to cast mold an ophthalmic device, due to the low level of oxygen transmittance of the molding surface, it may be possible to cure the ophthalmic device in an oxygen-containing atmosphere without the presence of oxygen in the atmosphere disrupting the curing process. Thus, in one example, the methods of manufacturing of the present disclosure can be methods using molding surfaces formed of the first polymer having a low rate of oxygen transmission and can involve curing the polymerizable

composition in the presence of an oxygen-containing or oxygen-rich atmosphere to form the polymeric ophthalmic device, although it is also possible to cure the polymerizable composition in the presence of a low oxygen or essentially oxygen-free atmosphere, such as, for example, an atmosphere rich in nitrogen gas or another inert gas.

**[0035]** The first polymer can be biodegradable. For example, the first polymer can have a level of biodegradability of at least 40%, or at least 50%, or at least 60%, after a standing time of about 30 days as determined using test method ISO 14851 with a sample of about 600 ml, about 300 ml of standard testing solution, and a temperature of about 25 degrees C.

**[0036]** The first polymer can be relatively transparent to visible light. When the transparency of the solid, dry polymer is measured as percent haze, the percent haze of the polymer can be less than 30%, or less than 27%, or less than 24%, or less than 22%, or less than 20%, or less than 18%.

**[0037]** The first polymer can have a relatively low level of UV light transmittance. The UV light transmittance through the first portion of the molding surface formed of the polymer can be less than 15% (i.e., more than 85% of the UV light is not transmitted). The UV light transmittance through the first portion of the molding surface can be less than 10%, or less than 5%, or less than 3%. When molding surfaces formed of the polymer having low UV light transmittance are used in a curing process involving the use of UV light, the level of UV light transmitted into the device-forming cavity may need to be high, and thus a high level of incident UV light may need to be applied to the exterior (back) of the molding surface. For example, more than 500  $\mu$ W, or more than 750  $\mu$ W, or more than 1000  $\mu$ W, or more than 1200  $\mu$ W, or more than 1500  $\mu$ W of UV light can be applied to the exterior of the molding surface during the curing process. As many UV light bulbs are known to function best when operating at higher levels, providing such high incident light levels may allow the UV bulbs to operate more efficiently, increasing bulb life.

**[0038]** The first polymer, while having good aqueous solubility, can be practically insoluble in one or more organic solvents. The term "organic solvent" refers to an organic substance which has the ability to solvate or dissolve at least one material. In one example, the organic solvent can be used to dissolve the first polymer. Examples of organic solvents include, without limitation, alcohols, e.g., alkanols, such as ethanol, isopropanol and the like, chloroform, butyl

acetate, tripropylene glycol methyl ether, dipropylene glycol methyl ether acetate, and the like and mixtures thereof. For example, the first polymer can be practically insoluble in ethyl acetate, or can be practically insoluble in benzene, or can be practically insoluble in toluene, or can be practically insoluble in ethyl acetate, benzene and toluene.

**[0039]** The first polymer can be a thermoplastic polymer copolymer, i.e., a polymer that becomes liquid or malleable when heated and freezes to a glassy state when sufficiently cooled, and which can be repeatedly re-melted and re-molded.

**[0040]** The first polymer be a polymer can rapidly dissolve in water or an aqueous solution; or can be a polymer which, when solubilized, has a low level of insoluble solids present in the solution; or can be a polymer which forms solutions which are not prone to excessive foaming; or can be a polymer which forms solutions having stable viscosities; or can be a polymer which forms solutions that do not precipitate excessively when subjected to high shear conditions; or can be a polymer which, when formed into a dry film, has a low rate of oxygen transmittance; or can be a polymer that is biodegradable; or can be a polymer that is relatively transparent to visible light in solid form; or can be a polymer with a relatively low level of transmittance of UV light; or can be a polymer that is a thermoplastic; or can be any combination thereof.

**[0041]** The first polymer can be a polar polymer. For example, the first polymer can have a polarity from about 1% to about 70%, or from about 1% to about 50%, or from about 1% to about 10%, or from about 10% to about 45%, or from about 20% to about 40%, or from about 30% to about 45%, or from about 20% to about 30%.

**[0042]** The average polarity of the polymer can be determined based on the Owens-Wendt-Rabel-Kaelbel model, where the contact angle of the thermoplastic polymer is determined using a number of different liquids of known polarities. The Owens-Wendt-Rabel-Kaelbel equation can be written in the form of a linear equation, where  $y$  is calculated based on the observed contact angle of each of the different liquids with the polymer ( $\theta$ ) and  $x$  is calculated based on the known polar ( $\sigma_L^P$ ) and disperse ( $\sigma_L^D$ ) components of the total surface energy ( $\sigma_L^T$ ) of each of the different liquids. The data points from the different liquids ( $x,y$ ) can be plotted, and the linear regression of the plot can then be used to determine the slope ( $m$ ) and y-intercept ( $b$ ). The calculated slope and y-intercept can then be used to calculate the polar ( $\sigma_S^P$ ) and disperse ( $\sigma_S^D$ )



components of the total surface energy of the polar thermoplastic polymer ( $\sigma_s^T$ , where  $\sigma_s^T = \sigma_s^P + \sigma_s^D$ ).

**[0043]** The Owens-Wendt-Rabel-Kaelble Equation in the form of a linear equation:

$$\frac{\sigma_L (\cos \theta + 1)}{2\sqrt{\sigma_L^D}} = \frac{\sqrt{\sigma_S^P} \sqrt{\sigma_L^P}}{\sqrt{\sigma_L^D}} + \sqrt{\sigma_S^D}$$

where  $Y = \frac{\sigma_L (\cos \theta + 1)}{2\sqrt{\sigma_L^D}}$ ,  $m = \sqrt{\sigma_S^P}$ ,  $x = \frac{\sqrt{\sigma_L^P}}{\sqrt{\sigma_L^D}}$ , and  $b = \sqrt{\sigma_S^D}$

**[0044]** Examples of the liquids with different polarities which can be used to determine average polarity of the polymer include, but are not limited to, deionized water, diiodomethane, dimethyl sulfoxide (DMSO), and formamide. In selecting the liquids with different polarities, ideally, a number of liquids having a range of polarities based on the liquid's polar component ( $\sigma_L^P$ ) of total surface energy would be selected, rather than selecting a number of liquids with different total surface energies ( $\sigma_L^T$ ). Using this method, the average polarity of the polymer is calculated by dividing the calculated polar component ( $\sigma_s^P$ ) of total surface energy for the polymer by its calculated total surface energy ( $\sigma_s^T$ ) and multiplying by 100 to obtain the percent polarity.

**[0045]** In one particular example, the first polymer can be NICHIGO G-POLYMER™ manufactured by Nippon Gohsei, Osaka, Japan.

**[0046]** The first polymer can comprise a vinyl alcohol copolymer with high vinyl alcohol content, or with low vinyl alcohol content, i.e., the majority of the units present in the vinyl alcohol copolymer can be units of a type of vinyl alcohol, or a minority of the units present in the vinyl alcohol copolymer can be units of a type of vinyl alcohol, respectively. The vinyl alcohol copolymer can be a vinyl alcohol copolymer having a vinyl alcohol unit content greater than or equal to about 95%, greater than or equal to about 90%, greater than or equal to about 85%, greater than or equal to about 80%, greater than or equal to about 75%, greater than or equal to about 70%, greater than or equal to about 65%, greater than or equal to about 60%, greater than or equal to about 55%, greater than or equal to about 50%, greater than or equal to about 45%, greater than or equal to about 40%, greater than or equal to about 35%, greater than

or equal to about 30%, greater than or equal to about 25%, greater than or equal to about 20%, greater than or equal to about 15%, greater than or equal to about 10%, greater than or equal to about 5%, or less than or equal to about 5%. The percentage of vinyl alcohol units in the polymer chain can be expressed as on a weight percent basis, or a molar percent basis.

[0047] The first polymer can be a vinyl alcohol copolymer other than an ethylene-vinyl alcohol copolymer (i.e., the vinyl alcohol copolymer is not comprised of units of ethylene). The vinyl alcohol copolymer can be a vinyl alcohol copolymer essentially free of ethylene units.

[0048] One or more of the first polymers disclosed herein can be used to form the first portion of the molding surface used to cast mold an ophthalmic device. For example, the first portion of the molding surface of a mold member can be formed by injection molding the first polymer, by machining the first polymer, or by both injection molding and machining the first polymer. The machining can comprise lathing, or ablating, or both lathing and ablating the vinyl alcohol copolymer to form all or a portion of a molding surface.

[0049] Various polymers known to those of ordinary skill in the art can be used as the second polymer of the present disclosure. The second polymer can comprise or consist of a polar polymer. Examples of polar polymers include poly(vinyl alcohol) homopolymers (PVOH) or ethylene-vinyl alcohol copolymers (EVOH), or can comprise polybutylene terephthalate (PBT), or any combination thereof. The second polymer can comprise or consist of a non-polar polymer. Examples of non-polar polymer include polypropylene, or polystyrene, or polyethylene, or any combination thereof. The second polymer can comprise or consist of a thermoplastic. The second polymer can comprise or consist of a thermoplastic having a melting point at least 20 degrees C, or at least 50 degrees higher than the first polymer. The second polymer can comprise or consist of a polymer which is not water-soluble, or which is essentially insoluble in water.

[0050] The first portion of the molding surface formed of the first polymer can be part of a first mold member comprising an entire molding surface configured to mold an entire anterior surface of an ophthalmic device. The first portion of the molding surface formed of the first polymer can be part of a second mold member comprising an entire molding surface configured to mold an entire posterior surface of an ophthalmic device. The first mold member and the second mold member can be configured to form an ophthalmic device-shaped cavity

therebetween when the first mold member and the second mold member are combined as a mold assembly.

**[0051]** As used herein, an ophthalmic device can comprise an ocular insert. An ocular insert is a polymeric device which is, during wear, placed in contact with the conjunctiva or with an anterior ocular surface, or the punctum, or any combination thereof. The anterior ocular surface contacted by the ocular insert during wear can comprise the cornea, or the sclera, or both. In one example, the ocular insert can comprise a punctual plug. An ocular insert may or may not be a transparent device, and may or may not include an optic zone providing vision correction. Optionally, the ocular insert can comprise a drug-delivery device, a diagnostic device, or both. When the ocular insert comprises a drug-delivery device, the drug delivery device can be configured to provide controlled release of a drug over a pre-determined period of time such as, for example, 2 hours, or 12 hours, or 24 hours, or one week, or one month, or more than one month.

**[0052]** The first portion of the molding surface formed of the first polymer can be a first portion of a molding surface of a mold member comprising an entire molding surface configured to mold an entire anterior surface of an ocular insert. The first portion of the molding surface formed of the first polymer can be part of a second mold member comprising an entire molding surface configured to mold an entire posterior surface of an ocular insert. The first mold member and the second mold member can be configured to form an ocular insert-shaped cavity therebetween when the first mold member and the second mold member are combined as a mold assembly.

**[0053]** As used herein, contact lenses are understood to be polymeric devices configured to be placed or disposed on a cornea of an animal or human eye. Generally, contact lenses comprise a convex anterior surface, and a concave posterior surface which may contact the cornea during wear. Contact lenses can be cosmetic lenses or vision correction lenses or both cosmetic and vision correction lenses. Vision correction lenses include a transparent vision correction optic zone. The vision correction optic zone can be surrounded by a non-vision correction peripheral zone which may also be transparent or may include a region intended to mask, enhance or change eye color or appearance. Cosmetic lenses are lenses intended to mask,

enhance or change eye color or appearance, and may or may not be transparent and may or may not include a vision correction optic zone.

**[0054]** The first portion of the molding surface formed of the first polymer can be a first portion of a molding surface of a first mold member, the entire molding surface comprising a concave molding surface configured to mold an entire anterior surface of a contact lens. The first portion of the molding surface formed of the first polymer can be a first portion of a molding surface of a second mold member, the entire molding surface comprising a convex molding surface configured to mold an entire posterior surface of a contact lens. The first mold member and the second mold member can be configured to form a contact lens-shaped cavity therebetween when the first mold member and the second mold member are combined as a mold assembly.

**[0055]** The first portion of the molding surface which is formed of the first polymer can comprise a first portion of a molding surface of a mold member, or a first portion of a molding surface of a mold assembly. Similarly, the second portion of the molding surface which is formed of the second polymer can comprise a second portion of a molding surface of a mold member, or a second portion of a molding surface of a mold assembly. When the first and second portions comprise first and second portions of a molding surface of a mold assembly, it is to be understood that both the first portion and the second portion of the molding surface are present in at least one entire molding surface of the mold assembly. In one example, both the first portion and the second portion of the molding surface can be present in each of the entire molding surface of the mold assembly.

**[0056]** In another example, the first portion of the molding surface formed of the first polymer can comprise a portion of an entire molding surface of a single-piece mold member (i.e., a unitary mold member used to mold both an anterior surface and a posterior surface of the ophthalmic device). In such an example, the entire molding surface will also comprise the second portion of the molding surface formed of the second polymer. The single-piece mold member can be a mold member formed in one piece with the device-forming cavity being integral to the mold member. In other words, the device-shaped cavity can be a hollow area integral to the mold member and is not be formed by assembling multiple mold members. The single-piece mold member can be configured such that, after it is formed, at least one port is

present in the mold member to allow injection of monomer into the mold. The single-piece mold member can be configured such that, after it is formed, at least one vent is present in the mold member to allow excess monomer to flow out of the mold member during or following injection of monomer into the mold. The single-piece mold member can be formed using techniques such as, for example lost core molding or gas assisted injection molding, which are known to those of ordinary skill in the art. The use of a single-piece mold member can reduce the amount of monomer required to form the ophthalmic device, and, when formed from the water-soluble copolymer, can reduce the physical manipulation required to release the polymeric ophthalmic device from the single-piece mold member as compared to a mold assembly formed from a plurality of mold members, as the single-piece mold member can be dissolved in water to release the polymeric device body, reducing the opportunity for damage to occur to the device as compared to mechanical methods of releasing the device. Additionally, use of a single-piece mold member may allow the manufacture of ophthalmic devices having unusual geometries which would be more difficult to form using a plurality of mold members.

**[0057]** The process of cast molding contact lens bodies, including silicone hydrogel contact lens bodies, typically begins with the preparation of a pair of mold members (i.e., a first mold member and a second mold member). The mold members can be produced by injection molding a thermoplastic polymer mold material into mold shaped cavities, by lathing the polymer mold material to form the entire mold member, or by a combination of injection molding and lathing, for example, injection molding to form the basic shape of the mold member and then lathing all or part of the lens forming region of the mold member. For example, a first portion of the device-forming molding surface can comprise an injection molded lens-forming molding surface, and a second portion of the device-forming molding surface can comprise a machined device-forming molding surface. In one such example, the first portion of the lens-forming molding surface can comprises a portion of the lens-forming molding surface molding a peripheral zone and edge of a contact lens, and a second portion of the lens-forming molding surface can comprise a portion of the lens-forming molding surface molding an optic zone of a contact lens.

**[0058]** Typically, when cast molding ophthalmic devices having optical zones, two mold members are combined to form a mold assembly. The two mold members are sized and

structured to be assembled together to define a device-shaped cavity therebetween. In the one example, for molding a contact lens, each of the two mold members can comprise either an optical quality concave lens forming molding surface used to mold an anterior surface of a lens, or a convex optical quality lens forming molding surface used to mold a posterior surface of a lens. For the purposes of this disclosure, the mold member with a concave molding surface is referred to as a first mold member or a female mold member, and the mold member with a convex molding surface is referred to as a second mold member or a male mold member. The first and second mold members can be structured to form a lens-shaped cavity therebetween when assembled with each other to form a mold assembly. Alternative mold member configurations, such as, for example, mold assemblies comprising more than two mold members or mold members that are shaped or structured differently than described above, can be used with the vinyl alcohol copolymers described herein. Additionally, the mold members can be configured to comprise more than one lens forming region. For example, a single mold member can be configured to comprise a region configured to mold an anterior lens surface as well as a posterior lens surface, i.e., to act as either a female or male mold member.

**[0059]** It is to be understood that the first polymer of the first portion of the molding surface is a different polymer than the second polymer of the second portion of the molding surface. The first polymer can be different from the second polymer on the basis that the first polymer and the second polymer are polymers comprising units of different monomers, or are polymers having different average molecular weights, or are polymers having different molecular weight distributions, or any combination thereof.

**[0060]** The first polymer can be used to form a first portion of at least one molding surface of a mold member or a mold assembly or a single-piece mold (i.e., at least one molding surface of at least one mold) for molding polymeric ophthalmic device bodies. The second polymer can be used to form a second portion of at least one molding surface of a mold member or a mold assembly or a single-piece mold (i.e., at least one molding surface of at least one mold) for molding polymeric ophthalmic device bodies. The portion of the at least one molding surface of the at least one mold can be produced by conventional injection molding procedures known to persons of ordinary skill in the art. For example, a quantity of the first polymer or the second polymer can be heated to form a molten thermoplastic polymer. The molten

thermoplastic polymer can be dispensed into a mold cavity in the shape of an ophthalmic device mold, including a portion of a molding surface or an entire molding surface. In one example, the mold cavity can include at least a portion of one or two optical quality contact lens forming molding surfaces. The molding surfaces used to form the optical quality lens-forming molding surfaces of the mold can be provided as components of one or more removable inserts located in a plate or other housing, or can be machined as part of the molding cavity.

[0061] In one example, the process settings used to injection mold the first polymer of the present disclosure content can include:

Melt temperature from about 160°C to about 250°C

Barrel temperature from about 160°C to about 250°C

Throat temperature from about 30°C to about 70°C

Mold tool temperature from about 30°C to about 95°C

Holding time from about 1 second to about 5 seconds

Injection speed from about 50 mm/second to about 250 mm/second

Plasticizing speed from about 100 mm/second to about 300 mm/second

Injection pressure from about 50 bar to about 180 bar

Holding pressure from about 10 bar to about 200 bar

Back pressure from about 5 bar to about 25 bar.

[0062] For example, at least two of these process settings can be used to injection mold the first polymer. In another example, three, four, five, six, seven, eight, nine, ten, or all of these process settings can be used to injection mold the first polymer. In one example, the melt temperature can be from about 160°C to about 220°C, and the barrel temperature from about 160°C to about 220°C. In another example, the melt temperature can be from about 180°C to about 250°C, and the barrel temperature from about 180°C to about 250°C.

[0063] The at least one molding surface of the at least one mold can be produced by a combination of injection molding and machining, for example, lathing or ablating, where the basic shape of the mold is prepared by injection molding, and all or a portion of the device-forming molding surface is prepared by removing a portion of the mold, for example by machining a portion of the mold, such as, for example, all or a part of the region of the mold used to mold an optical zone of an ophthalmic device. In other words, in accordance with the

present disclosure, the device-forming molding surfaces of the at least one mold can be formed completely by injection molding, can be formed completely by machining, or can be formed by injection molding to form a mold r, a portion of the device-forming molding surface of which is subsequently machined to form the final device-forming molding surface of the mold. Thus, in one example, injection molding the at least one of the first mold member and the second mold member can comprise forming a non-molding portion of at least one of the first mold member and the second mold member by injection molding, and forming a device-forming molding surface of the at least one of the first mold member and the second mold member by machining or lathing or ablating or any combination thereof the non-molding portion of the mold member.

**[0064]** The first polymer can be used to form at least a first portion of the device-forming molding surface of a mold, where at least a second portion of the device forming molding surface of the mold is formed of the second polymer. In one example, at least some of the non-molding regions of the mold (i.e., regions of the mold which are not used to form a surface of a device body) can also be formed of the second polymer. In one example, the second portion of the device forming molding surface, or a non-molding portion of the mold, or both can be formed of a second polymer which is essentially insoluble in water or aqueous solutions, such as, for example a metal or polymeric material such as polypropylene. In one example, the non-molding portion can comprise a frame or support for an entire device-forming molding surface comprising the first polymer and the second polymer. The first portion of the device-forming molding surface can be formed using various methods, such as, for example, injection molding or film casting. Similarly, the second portion of the device-forming molding surface can be formed using various methods, such as, for example, injection molding or film casting.

**[0065]** Regardless of the method used to form the portions of the molding surface of the mold, the mold can be used to mold cosmetic contact lenses having a printed design on one of their surfaces. These cosmetic contact lenses may or may not have a vision-correction zone. Prior to placing the polymerizable composition in direct contact with the entire molding surface, a design of any sort can be placed on one or more of the molding surfaces of one or more of the mold members to be used to form the lens. The design printed on the mold can be configured to mask the appearance of the eye, change the appearance of the eye, such as, for



example, change the appearance of the color of the eye, or enhance the appearance of the eye, such as is done, for example, by a limbal ring.

**[0066]** The design can be printed onto any molding surface of the mold member, a concave surface or a convex surface. The design can be printed onto the molding surface of the mold using any printing method, such as, for example, using ink-jet printing, using a cliché method, and the like.

**[0067]** The ink or pigment printed onto the molding surface can be a water-based ink or pigment vehicle, or can be an organic solvent-based ink or pigment vehicle.

**[0068]** In one example, due to the use of a first polymer such as, for example, a vinyl alcohol copolymer to form the first portion of the molding surface onto which the design is printed, a surface treatment such as, for example, a plasma treatment may not need to be applied to the molding surface in order for the design to be printed with good reproducibility onto the molding surface, although a surface treatment can also be applied. In one example, the ink or pigment vehicle applied to the molding surface of the mold member does not bead up when applied to the molding surface. When the polymerizable composition is placed in contact with the printed molding surface and subsequently cured, demolded and delensed, the printing becomes integrated into the polymeric lens body and remains with the lens body following the demolding and delensing.

**[0069]** When two or more mold members are used to mold the device, a volume of polymerizable composition is placed in direct contact with the molding surface of one of the mold members before the mold members are combined to form the mold assembly. Typically this is accomplished by placing a predetermined quantity of the polymerizable composition onto one of the molding surfaces, such as, for example, placing the polymerizable composition into a concave molding surface of a first mold member. The mold assembly is then assembled by placing another mold member in contact with the first mold member having the polymerizable composition, such as, for example, by placing a convex molding surface of a second mold member in contact with the first mold member such that a device-shaped cavity is formed between the first and second mold members, the device-shaped cavity containing the polymerizable composition. If used, a connection is then formed between the first and second mold members by whatever means is being used in order to maintain the molding surfaces of

the mold members in proper alignment during the curing process. Typically, the connection is formed between non-molding portions of the mold members (i.e., not between the molding surfaces of the mold members).

**[0070]** When two or more mold members are combined as a mold assembly, the process of assembling the mold members into a mold assembly can further comprise the step of forming a connection between the mold members or affixing the mold members to each other. The mold members can be permanently affixed to each other, or can be temporarily affixed to each other. The first mold member and the second mold member can be structured to be easily separated after being assembled together, preferably without causing substantial damage to the polymeric ophthalmic device body produced in the lens shaped cavity.

**[0071]** In one example, the mold members can be configured to form a mechanical connection based on the shape of elements of the mold members. For example, the mold members can be configured to form an interference fit when pressure is applied to one or both of the mold members. In another example, the mold members can both be threaded so as to form a connection by engaging the interconnecting threads between the mold members. Other examples of mechanical connections can include bores and protrusions between the mold members, or other locking structures.

**[0072]** In another example, the mold members can be affixed to each other using an adhesive substance placed between the mold members. The adhesive substance can comprise or consist of a thermoplastic material. The thermoplastic material can comprise or consist of the same thermoplastic material used to form at least one of the mold members to be affixed to each other. For example, a non-molding portion of one or both of the thermoplastic mold members can be deformed or melted in order to affix the mold members to each other.

**[0073]** In one example, a non-molding portion of one or both of the mold members can be heated in order to melt a portion of one or both of the mold members to form a weld between the mold members in order to adhere the mold members to each other. The weld formed between the mold members can comprise a single weld located in a single non-molding location between the mold members, for example, a single weld in a single spot in a peripheral region surrounding the device-shaped cavity. The weld formed between the mold members can comprise a plurality of welds, each located in a single non-molding location between the mold

member, for example, 2 or 3 or 4 or 5 or more individual welds each formed in a single spot in a peripheral region, where the plurality of welds are positioned around the perimeter of the device-shaped cavity. The plurality of welds can be equidistant from each other around the perimeter of the device-shaped cavity, or can be positioned in a non-symmetric pattern. The weld formed between the mold members can comprise a single weld located around the entire perimeter of the lens forming cavity. In such an example, although the thickness of the melted thermoplastic may vary across different portions of the weld, a single continuous weld is present between the mold members in an area which completely encircles the perimeter of the device-shaped cavity formed between the mold members.

[0074] In another example, a portion of a solvent capable of dissolving one or both of the mold members can be applied to one or both of the mold members in order to dissolve a non-molding portion of one or both of the mold members in order to meld a surface of one mold member to a surface of the other mold member. As the dissolved mold material re-solidifies, the melded material can act to affix the mold members to each other. The solvent can comprise or consist of water or an aqueous solution. The amount of solvent applied can be a very small portion of the solvent such as, for example, a few microliters. The solvent can be dropped onto a surface to be joined, can be sprayed onto a surface to be joined, can be stamped onto a surface to be joined, etc. For example, one or all of the mold members, prior to being placed together to form the mold assembly, can be contacted by a stamp wetted with the solvent. The stamp can be shaped to conform to the shape of the surface to be joined. For example, the stamp can be ring-shaped such that, when it contacts a non-molding region of one of the mold members surrounding the device-shaped region of the mold member, only the non-molding region of the mold member which is intended to be jointed to the other mold member is wetted. While the solvent is still wet, the mold members can be placed in contact and melded together. Optionally, pressure can be applied to the mold assembly to assist in the process of affixing the mold members to each other. The pressure can be applied for a period of time until the mold members have fully melded to each other. Optionally, heat or air can be applied to assist in melding the mold members and drying the solvent in order to reduce the amount of time for the meld to form and the melded material to re-solidify, firmly affixing the mold members to each other to form the mold assembly

**[0075]** In the example where a solvent is used to dissolve a portion of a mold member and form a meld between the mold members, the melded material can be located in a single non-molding location between the mold members, for example, a single spot in a peripheral region surrounding the device-shaped cavity. The melded material can be located in a plurality of non-molding locations between the mold member, for example, 2 or 3 or 4 or 5 or more individual spots in a peripheral region, where the plurality of locations are positioned around the perimeter of the device-shaped cavity. The plurality of locations can be equidistant from each other around the perimeter of the device-shaped cavity, or can be positioned in a non-symmetric pattern. The region of melded material formed between the mold members can be a single continuous region located around the entire perimeter of the device-shaped cavity. In such an example, although the thickness of the melded thermoplastic may vary across different portions of the adhered region, a single continuous region of melded material can be present between the mold members and can completely encircle the perimeter of the device-shaped cavity formed between the mold members.

**[0076]** In another example, an adhesive substance such as a form of glue, contact cement or sealant can be used to form a bond between the mold members. In yet another example, the mold members can be joined using an additional element such as a clip, clamp or bracket. Regardless of the type of connection used between the mold members, the connection is intended to keep the mold members in alignment during the curing process, and can be capable of being released before the demolding process or as part of the demolding process.

**[0077]** When at least one of the molding surfaces or mold members of the mold assembly is formed from a water-soluble material, such as, for example, a water-soluble vinyl alcohol copolymer, the mold members of the mold assembly can be connected in such a manner that the mold members cannot be released from each other except by at least partially dissolving at least one of the mold members of the mold assembly. In other words, the mold assembly, once formed, can be a non-opening mold assembly wherein the polymeric device body is released by dissolving all or part of the mold members comprising the mold assembly.

**[0078]** The single-piece mold member or the mold assembly having the polymerizable composition in the device-shaped cavity is then cured. Curing the polymerizable composition in the device-shaped cavity forms a polymerized reaction product in the shape of the device-

shaped cavity, i.e., a polymeric device body. Curing typically comprises application of a form of electromagnetic radiation to the mold assembly including the polymerizable composition in order to cause polymerization of the polymerizable composition in the device-shaped cavity of the mold assembly. The form of electromagnetic radiation can comprise thermal radiation, microwave radiation, visible light, ultraviolet (UV) light, etc. Any combination of two or more forms of electromagnetic radiation, as well as two or more levels of one or more forms of electromagnetic radiation, can be used to cure the mold assemblies. The method of curing is usually matched to the type of initiator used in the polymerizable composition, i.e., a polymerizable composition comprising a UV initiator is usually cured using UV light, and a polymerizable composition comprising a thermal initiator is usually cured using thermal radiation, and usually at a temperature above the initiation temperature of the thermal initiator. Regardless of the method of curing that is used, the temperature during the curing process can be maintained at a temperature below the melting point of the first polymer or the second polymer or both the first polymer and the second polymer, or below the glass transition temperature of the first polymer or the second polymer or both the first polymer and the second polymer. The curing process typically involves curing the single-piece mold or mold assembly until the polymerizable composition has polymerized sufficiently such that the polymeric device body will retain the shape of the device-shaped cavity following demolding and delensing. As such, the curing process may not result in complete reaction of all the polymerizable components of the polymerizable composition.

[0079] In one example, microwave radiation can be used to cure the polymerizable composition in a single-piece mold member or in a mold assembly formed using a molding surface comprising at least one vinyl alcohol copolymer. Use of microwave radiation to cure the polymerizable composition in a molding surface comprising the vinyl alcohol copolymer can reduce the amount of time required to cure the composition as compared to the use of UV light or thermal radiation (i.e., a heated oven). For example, the time required to cure the polymerizable composition in a molding surface comprising the vinyl alcohol copolymer using microwave radiation can be less than or equal to 30 minutes, or less than or equal to 20 minutes, or less than or equal to 15 minutes, or less than or equal to 10 minutes. In another example, the polymerizable composition can comprise a thermal initiator such as, for example, 2,2'-

azobiz(isobutyronitrile) (AIBN, VAZO®-64), and the polymerizable composition can be cured using microwave radiation. In another example, the polymerizable composition can comprise a Comfilcon A polymerizable composition containing a thermal initiator such as, for example, AIBN, and the polymerizable composition can be cured using microwave radiation. In yet another example, the polymerizable composition can be cured using microwave radiation, and the polymeric device body can be wet demolded, or wet delensed, or both wet demolded and wet delensed from the molding surface comprising the vinyl alcohol copolymer. The wet demolding, or wet delensing, or both wet demolding and delensing can result in the molding surface comprising the vinyl alcohol copolymer at least partially dissolving. In a particular example, the yield of polymeric device bodies from a manufacturing process involving using molding surfaces comprising the vinyl alcohol copolymer, curing using microwave radiation, and wet demolding and delensing can be higher than the yield of the same polymeric device bodies manufactured using the same process but using molding surfaces formed entirely from a different material such as, for example, polypropylene, or EVOH.

**[0080]** When least a first portion of one of the device-forming molding surfaces is formed of a material comprising or consisting of a vinyl alcohol copolymer, during the process of curing the polymerizable composition to form the polymeric device body, the polymerizable composition is in direct contact with the vinyl alcohol copolymer, and at least one portion of a surface of the resulting ophthalmic device body is thus formed in direct contact with the vinyl alcohol copolymer. When the vinyl alcohol copolymer is a water-soluble vinyl alcohol copolymer, the process of releasing the polymeric ophthalmic device from the single-piece mold member can comprise contacting the single-piece mold member with water or an aqueous solution and dissolving at least a portion of the single-piece mold member.

**[0081]** As used herein, “demolding” refers to the process of separating the molding surfaces of the mold assembly following curing of the polymerizable composition. As a result of the demolding process, the molding surfaces are separated from each other, and the device body remains in contact with, or attached to, or adhered to one and only one of the molding surfaces used to cast mold the device body. When the first molding surface to be released from the polymeric device body is a molding surface comprising a first portion of a first polymer and a second portion of a second polymer, separate demolding processes may be required to demold

the first portion of the molding surface and the second portion of the molding surface. These separate demolding processes can be dry demolding processes or wet demolding processes.

**[0082]** Dry demolding processes involve the use of mechanical processes to separate the molding surface or portion of the molding surface of the mold assembly after curing. In dry demolding processes, the mold assembly including the polymeric device body is not contacted with a liquid, such as an organic solvent, water or an aqueous solution during the demolding process, and typically the mold assembly including the polymeric device body has not been exposed to a liquid prior to the dry demolding process. Following a dry demolding process, the polymeric device body remains in contact with one, and only one, of the entire molding surfaces used to mold the device body. In other words, when the first molding surface to be demolded comprises a first portion and a second portion, the demolding process may require demolding both the first portion and the second portion of the first molding surface simultaneously or sequentially. When the first portion and the second portion of the first molding surface are demolded sequentially, following demolding of the first portion of the molding surface, the second portion of the first molding surface, along with the second molding surface, may remain in contact with the polymeric device body. Similarly, when the first portion and the second portion of the first molding surface are demolded sequentially, following demolding of the second portion of the molding surface, the first portion of the first molding surface, along with the second molding surface, may remain in contact with the polymeric device body following the demolding step.

**[0083]** In one example, a dry demolding process may include squeezing one or more of the molding surfaces or mold members to deform the molding surface(s) or mold member(s) and to separate the molding surfaces, leaving the polymeric device body in contact with one of the molding surfaces or one portion of the molding surface. If the mold members of the mold assembly are held together at least in part by an interference fit between the mold members, a dry demolding process may include applying pressure to one or more of the molding surfaces or mold members in order to push the molding surfaces or mold members away from each other to break the interference fit. If the mold members of the mold assembly are held together at least in part by a weld between the molding surfaces or mold members, dry demolding may include cutting through or breaking apart the welded material.

**[0084]** Wet demolding processes involve application of a liquid to separate the entire molding surfaces or portions of the molding surfaces of the mold assembly after curing. In wet demolding processes, the mold assembly including the polymeric device body is contacted with a liquid, such as an organic solvent, water or an aqueous solution, during the demolding process. Following a wet demolding process, the polymeric device body can remain in contact with one, and only one, of the entire molding surfaces used to mold the device body, or can be released from a portion of a first molding surface used to mold the device body, or can be released from portions of the first and second molding surfaces used to mold the device body, or can be released from the entire molding surfaces of both the first and second molding surfaces used to mold the device body. Wet demolding processes may additionally involve the use of mechanical methods of separating the molding surfaces or portions of molding surfaces in addition to application of liquid to the mold assembly, including squeezing one or more of the molding surfaces or mold members to deform the molding surfaces, applying pressure to one or more of the molding surfaces or mold members in order to push the molding surfaces or mold members away from each other to break an interference fit, or cutting through welds or an adhesive holding the mold assemblies together. When an additional mechanical separation step is used, it is typically done after first applying the liquid to the mold assembly, such as, for example, dipping or immersing the mold assembly in a liquid.

**[0085]** As part of a wet or dry demolding process, it may be desired to have the device body remain in contact with a particular entire molding surface or portion of a molding surface, such as either the molding surface or a portion of the molding surface of the first or the second mold member, following the demolding process. In order to help the device body remain in contact with the desired molding surface or portion of the molding surface, heat can be applied to the first or second molding surface or mold member, for example, by blowing heated air on the back of the molding surface or mold member. Alternatively, the first or second molding surface or mold member can be chilled, for example by blowing chilled air on the back of the molding surface or mold member or applying a chilled liquid to one of the molding surfaces or mold members. An application of pressure to either the first or second molding surface or mold member before demolding or concurrently with the demolding process can also help the device body to remain in contact with a particular molding surface or mold member (i.e., the first or



second molding surface or mold member) following the demolding process. In one example, when it is desired to have the polymeric device body remain in contact with the second molding surface or mold member at the end of the demolding process, heat can be applied to the back of the first molding surface or mold member immediately before or during the demolding process. The heat can be applied at a temperature below the melting point of the molding surface or mold member. The heat can be applied for a short amount of time such as, for example, less than or equal to 15 seconds, or less than or equal to 10 seconds, or less than or equal to 5 seconds.

**[0086]** “Delensing” refers to the process of releasing the device body from the one molding surface or portion of a molding surface with which the device body remains in contact after an entire surface of the device body has been released from the entire first molding surface of the mold assembly. As used herein, “delensing” may refer to a process involving any ophthalmic device body, including an ocular insert body or a contact lens body.

**[0087]** Dry delensing processes involve the use of mechanical processes to release the device body from the one remaining entire molding surface or portion of the one remaining molding surface with which the device body is in contact following the demolding step. In dry delensing processes, the device body and the one remaining entire molding surface or portion of a molding surface with which the device body is in contact are not contacted by a liquid, such as an organic solvent, water or an aqueous solution, as part of the delensing process. While it is possible that a wet demolding process (involving application of a liquid to a mold assembly including a polymeric device body) may be used prior to a dry delensing process, it is more common to use a dry demolding process prior to a dry delensing process. When a dry demolding process and a dry delensing process are used together, the device body has not been exposed to a liquid, for example an organic solvent, water or an aqueous solution, until after the device body has been released from both entire molding surfaces of the mold assembly (i.e., released from the first and second portions of both the first and second molding surfaces). In one example, a dry delensing process may involve the use of a vacuum apparatus to lift the polymeric device body from the one remaining entire molding surface or portion of a molding surface with which it was in contact following the demolding step. A dry delensing process may also involve squeezing the one remaining entire molding surface or portion of a molding

surface to at least partially break the bond between the one entire molding surface or one portion of a molding surface and the lens body. A dry delensing process may involve blowing air between the edge of the device body and the entire molding surface or portion of the molding surface to at least partially break the bond between the device body and the molding surface. A dry delensing process may involve inserting a prying tool between the edge of the device body and the molding surface to at least partially break the bond between the device body and the molding surface.

**[0088]** Following dry demolding and dry delensing, the polymeric device bodies may be washed (e.g., rinsed or extracted or hydrated or any combination thereof) either in an organic solvent-based liquid, or in a liquid essentially free of an organic solvent. Alternatively, following dry demolding and dry delensing, the polymeric device body can be placed directly into a package with a packaging solution, sealed, and sterilized.

**[0089]** Wet delensing processes involve the application of a liquid such as an organic solvent, water or an aqueous solution to release the device body from the one remaining entire molding surface or portion of a molding surface with which the device body is in contact following the demolding step. After or concurrently with application of the liquid, a wet delensing process can further comprise using a vacuum apparatus to lift the polymeric device body from the one remaining molding surface with which it was in contact following the demolding step. Optionally, a wet delensing process may also include using mechanical means to assist in releasing the device body, such as, for example, squeezing the one remaining molding surface to at least partially break the bond between the one molding surface, blowing air between the edge of the device body and the molding surface, or inserting a prying tool between the edge of the device body and the molding surface to at least partially break the bond between the device body and the molding surface.

**[0090]** In one example, when dry demolding and dry delensing processes followed by a washing process using a liquid free of an organic solvent are used, or when wet demolding, wet delensing and washing processes using a liquid free of an organic solvent are used, the resulting device body will not have been exposed to an organic solvent during the manufacturing process. When such a device body which has not been exposed to an organic solvent is subsequently placed into a contact lens package with a packaging solution, sealed and

sterilized, the resulting device product will not have been exposed to an organic solvent during its manufacturing process.

**[0091]** In the example where the first polymer is a water-soluble polymer such as, for example, a water-soluble vinyl alcohol copolymer, due to this solubility, when using one or more molding surfaces comprising a portion of the molding surface formed of a water-soluble polymer, it is possible to use wet demolding processes, wet delensing processes, or both wet delensing and demolding processes involving application of an aqueous liquid to at least partially dissolve the portions of the molding surface formed of the water-soluble polymer. In one example of such a process, the mold assembly, mold member(s) or molding surface(s) including the polymeric device body can be transferred to a tray before application of the liquid. The tray can comprise separate recesses sized and structured to contain the device bodies after the portion(s) of the molding surface(s) are dissolved by the liquid. For example, when the all of the molding surfaces of a mold assembly used to mold the device body comprise first portions of the molding surfaces formed of a water-soluble polymer, after curing, the mold assembly including the polymeric device body can be transferred to the tray. In another example, when the first portion of one entire molding surface of the mold assembly is formed of a water-soluble polymer and the second portion of the molding surface and non-molding portions of the mold assembly are formed of materials insoluble in the liquid, the second portion of the molding surface and the non-molding portions of the mold assembly can be separated from the first portion of the molding surface and the device body, and the first portion of the molding surface which remain adhered to the polymeric device body can be transferred to the tray. In another example, when the first portion of at least one molding surface of the mold assembly are formed from a water-soluble polymer and the second portion of at least one molding surface of the mold assembly and non-molding portions of the mold assembly are formed of one or more materials insoluble in the liquid, the entire molding assembly, including the second portions of the molding surfaces and the non-molding portions formed of insoluble materials, can be placed in the tray, and the soluble portions of the molding surfaces can be allowed to dissolve, releasing the device body from the mold assembly. The portions of the molding surfaces and non-molding portions of the mold assembly formed of the insoluble material, as well as the device body, can then be removed from the tray. In yet another example,

after demolding, a first molding surface formed of a water-soluble polymer and the attached polymeric device body can be transferred to the tray.

**[0092]** The liquid applied in the wet demolding process, the wet delensing process, or both the wet demolding and delensing process can comprise water or an aqueous solution. In one example, the aqueous solution can comprise an aqueous solution of a processing aid which increases the rate of dissolution of the first polymer. In another example, the processing aid can be a compound that assists in washing the polymeric device bodies or that assists in the removal of an extractable material from the polymeric device bodies. In yet another example, the processing aid can be a compound that helps protect the device body from damage or deformation during processing, such as, for example, a surfactant, including Tween 80.

**[0093]** The term “surfactant” refers to a substance which has the ability to reduce the surface tension of water, for example, water or an aqueous solution in which the substance is present. By reducing the surface tension of the water, a surfactant facilitates the water containing the surfactant, when in contact with a polymeric device body which has not previously been subjected to extraction processing with an organic solvent, to more intimately contact the device body and/or more effectively wash or remove at least one material present in the device body from the device body relative to the water without the surfactant or surfactant component. Generally, a surfactant does not act directly on the at least one material to solvate or dissolve the at least one material. Examples of surfactants include, without limitation, zwitterionic surfactants including forms of betaine, non-ionic surfactants including forms of polysorbate such as polysorbate 80, forms of poloxamers or poloxamines, fluorinated surfactants, and the like and mixtures thereof. In one example, one or more surfactants can be incorporated into the polymerizable compositions described herein, in washing liquids described herein, in the packaging solutions described herein, and any combination thereof.

**[0094]** The process of applying the liquid to dissolve the first portion of the molding surface(s) can include processes which increase the rate of dissolution of the polymer, or which reduce the foaming or gelation of the solution following dissolution of the polymer.

**[0095]** In one example, the size or volume of the entire molding surface or a first portion of a molding surface can be reduced prior to applying the liquid to dissolve the first polymer, such

as, for example, by cutting off or machining away or ablating a portion of the molding surface or portion of a molding surface.

**[0096]** In another example, before, or during or following or any combination thereof, the step of applying the liquid, the temperature of the liquid can be controlled, for example, in order to maintain the liquid at a temperature which increases the rate of dissolution of the first polymer, or at a temperature at which the viscosity of the first polymer solution remains relatively stable.

**[0097]** In yet another example, the first polymer can be dissolved using a process or apparatus which cycles fresh solvent over the molding surface(s), or mold member(s), or mold assembly comprising the first polymer, such as, for example, a Soxhlet apparatus.

**[0098]** During or following the step of applying the liquid, the liquid or the molding surface(s) or mold member(s) or mold assembly comprising the first polymer can be agitated, for example, to increase the rate of dissolution of the first polymer.

**[0099]** During or following the step of applying the liquid, ultrasonic energy can be applied to the liquid, the mold assembly, the mold member(s), or the molding surface(s) comprising the first polymer. In another example, the ultrasonic energy can be applied to the liquid and to a mold assembly, mold member(s), or molding surface(s) comprising the first polymer contained in a tray.

**[00100]** The liquid applied to the molding surface(s), or mold member(s), or mold assembly comprising the first polymer can be applied as part of a wet demolding process, or applied to a device body and an entire molding surface or portion of a molding surface as part of a wet delensing process. The temperature of the liquid can be about 90°C or less, about 80°C or less, about 70°C or less, about 60°C or less, about 50°C or less, about 40°C or less, or about 30°C or less.

**[00101]** The application of the liquid can result in complete dissolution of the portion of the molding surface(s) or molding member(s) or mold assembly comprising the first polymer in about 240 minutes or less, or in about 180 minutes or less, or in about 120 minutes or less, or in about 90 minutes or less, or in about 60 minutes or less, or in about 30 minutes or less, or in about 20 minutes or less. Alternatively, application of the liquid can result in partial dissolution of the portion of the molding surface(s) or mold member(s) or mold assembly comprising the

first polymer, wherein the partial dissolution is sufficient to separate the molding surfaces of the mold assembly (i.e., to demold the mold assembly), to release the device body from one entire molding surface or portion of a molding surface (i.e., to delens the device body), or both demold and delens (i.e., completely release the device body from all the molding surfaces used for form it). For example, the application of liquid can result in greater than 10%, 25%, 50%, 75%, or 90% by weight or volume of the portion of the molding surface(s) comprising the first polymer being dissolved.

[00102] As previously discussed, in some examples, by using a vinyl alcohol copolymer disclosed herein as the first polymer, demolding, delensing or both demolding and delensing processes involving dissolution of the vinyl alcohol copolymer are not severely impacted by some of the problems experienced when dissolving other water-soluble polymers in aqueous solutions. For example, PVOH, when dissolved in aqueous solutions, can create a large amount of foam, gelation of the solution, a cloudy solution, or any combination of these problems. As the presence of foam, gels or a cloudy solution can be disruptive to mechanical processing and manufacturing steps, additional measures and expenses are required to control or eliminate these problems. Solutions of the vinyl alcohol copolymers described herein that are produced as part of a wet demolding, delensing or both demolding and delensing process involving dissolution of molding surfaces comprising the vinyl alcohol copolymer in water or aqueous solutions do not produce large volumes of foam, even when the liquid and the molding surfaces are agitated. Further, the solutions do not gel easily, making it possible to conduct the demolding, delensing or both demolding and delensing processes in large tanks or baths where a single volume of liquid is applied to a plurality of lenses and molding surfaces. As the solution does not gel under these conditions, it is possible to easily empty the solution from the tank or bath and re-fill the tank or bath with fresh or recycled liquid. As the solution of the vinyl alcohol copolymer in the liquid remains clear, it is possible to observe the device bodies and the mold members either manually or using an automated system to determine whether or not the device body has been released from the molding surface(s), or whether or not the molding surface(s) have dissolved. As the solution of the vinyl alcohol copolymer can have a higher specific gravity than the solvent alone, the solution of the copolymer may sink to the bottom of a tank during a dissolution process. The tank used during the dissolution process can be fitted

with a drain and a valve at the bottom of the tank in order to remove all or a portion of the copolymer solution from the tank during or following the dissolution process. The tank used during the dissolution process can be configured to be funnel shaped, in order to direct the heavier copolymer solution to the bottom-most portion of the tank during or following the dissolution process.

**[00103]** Following removal of the vinyl alcohol copolymer solution formed as part of the manufacturing process, the vinyl alcohol copolymer solution can be recycled or reclaimed. The recycling or reclaiming process can use the reclaimed vinyl alcohol copolymer to re-form ophthalmic mold members, or can use the reclaimed copolymer for another purpose. For example, the solvent used to dissolve the copolymer can be evaporated off, resulting in a solid reclaimed copolymer or a more concentrated copolymer solution.

**[00104]** Following release of the polymeric ophthalmic device body from the mold assembly, e.g., from all the molding surfaces used to cast mold the device body, in one example, the first polymer may no longer be present on a surface of the polymeric device body. In other words, once the device body has been released from the at least one molding surface comprising the first polymer, a layer of the first polymer may not remain on a surface of the device body. The release of the device body from the at least one molding surface can comprise a dry demolding step or a dry delensing step or a wet demolding step or a wet delensing step. Following release of the device body from the at least one molding surface comprising the first polymer, a portion of the first polymer may remain present in solution, and the device body can be present in the solution. However, when the device body is present in the solution, the solubilized portion of the first polymer may not be chemically or physically attached or bonded to a surface of the device body, and thus in this example the first polymer can be rinsed from the surface of the device body using a solution free of the first polymer. When the solubilized first polymer can be rinsed from a surface of the device body in this manner, it is understood that the portion of solubilized first polymer which may have been in contact with a device body surface while the device body was present in the solution does not constitute a "layer" of the first polymer as used herein.

**[00105]** Depending upon the type of device body and the demolding/delensing processes used, following demolding and delensing, the device body may be subjected to one or more

washing steps, including washing steps in an organic solvent, an aqueous solution of an organic solvent, water, or an aqueous solution essentially free of an organic solvent. The washing step can be used to clean dirt or debris from the device bodies, to extract materials from the device bodies, or to hydrate the device bodies. For example, a washing step can be used to remove diluents from the device body, to remove unreacted or partially reacted monomers from the device body, or to increase wettability of the device body.

**[00106]** In one example, the washing solution can comprise an organic solvent or an aqueous solution of an organic solvent. The organic solvent can comprise a volatile organic solvent such as, for example, a volatile alcohol. Examples of volatile alcohols can include lower alcohols, such as forms of methanol, ethanol, propanol, etc.

**[00107]** As previously discussed, the term “organic solvent” refers to an organic substance having the ability to solvate or dissolve at least one material. The organic solvent can be used to dissolve unreacted materials, diluents and the like, present in a polymeric device body which has not previously been subjected to extraction processing. In one example, the material is a material that is not soluble or does not dissolve in water or an aqueous solution. In another example, the material is a material that is not as soluble or does not dissolve as much in water or an aqueous solution, i.e., the material has increased solvation in the organic solvent as compared to water or an aqueous solution. Thus, the organic solvent in contact with such an unextracted device body is effective to solvate or dissolve at least one material present in the device body, or to increase the solvation or dissolve to a greater extent the at least one material present in the device body to reduce the concentration of the at least one material in the device body, or to reduce the concentration of the at least one material in the device body as compared to a device body treated with water or an aqueous solution. The organic solvent may be used without dilution, that is 100% organic solvent, or may be used in a composition including less than 100% organic solvent, for example and without limitation, an aqueous solution including an organic solvent. In general, an organic solvent acts, for example, directly acts, on the at least one material to solvate or dissolve the at least one material.

**[00108]** In another example, the washing solution can comprise water or an aqueous solution essentially free of an organic solvent. The aqueous solution essentially free of an organic solvent used to wash the present lenses can include aqueous salt solutions, buffer solutions,



surfactant solutions, wetting agent solutions, comfort agent solutions, any combination thereof, and the like. In one example, one or more polymeric wetting agents or comfort agents can be used to wash the present device bodies, or in a packaging solution used with the present device bodies. However, it is understood that the present device bodies can have ophthalmically acceptably wettable surfaces when washed or packaged in an aqueous solution that does not contain any polymeric wetting agents or comfort agents. Thus, while the polymeric wetting agents or comfort agents may be used to increase the wettability of such devices, their wettability is not dependent solely upon the use of such agents.

**[00109]** Following release of the device body from all the molding surfaces and, if used, one or more optional washing steps, the device body can be placed into a blister package along with a portion of packaging solution. In one example, the blister package can comprise a hydrophobic polymer. The blister package can then be sealed and sterilized, for example, by autoclaving the package under conditions suitable for sterilizing the package. Alternatively, when a water-soluble polymer is used to form the first portion of one or more molding surface(s), it is possible to place the device body and the portions of the molding surface(s) formed of the water-soluble polymer directly into the blister package with a portion of solution (without the need to demold, delens or both demold and delens the device body from the portions of the molding surface(s) formed of the water-soluble polymer before placing it in the blister package), and have the portions of the molding surface(s) or mold assembly formed of the water-soluble polymer dissolve in the solution during or after the manufacturing process. The solution placed in the package and used to dissolve the water-soluble polymer can comprise a packaging solution, or can comprise a solution which is subsequently removed from the package and replaced with a packaging solution prior to sealing and sterilizing the package.

**[00110]** A device can be used to increase the volume of solution used to dissolve the portions of the molding surface(s) formed of the water-soluble polymer such as the device described in PCT Application No. PCT/US11/28197, which is hereby incorporated by reference in its entirety. Alternatively, the device body and molding surface(s) can be placed in the blister package with a portion of washing solution which is replaced by packaging solution before the blister package is sealed. Again, a device as described in PCT Application No. PCT/US11/28197 can be used for this purpose.

**[00111]** The portion(s) of the molding surface(s) formed of the water-soluble polymer can dissolve in the portion of solution before the blister package is sealed, after the blister package is sealed, before the blister package is autoclaved, or after the blister package is autoclaved. For example, before sealing the blister package, after sealing the blister package, before autoclaving the blister package, or after autoclaving the blister package, less than about 15%, less than about 10%, less than about 5%, or less than about 1% by weight of the water-soluble polymer added to the blister package can remain undissolved in the blister package.

**[00112]** In the examples where the portion(s) of the molding surface(s) formed of the water-soluble polymer are dissolved in the packaging solution sealed in the blister package with the lens body, the water-soluble polymer can comprise an ophthalmically acceptable ingredient present in the packaging solution. In one example, the water-soluble polymer, when dissolved in the packaging solution, can further serve as a wetting agent, a comfort agent, as an agent that prevents the lens body from sticking to the blister package, or any combination thereof.

**[00113]** The molding surfaces described herein can be used to cast mold various types of polymerizable compositions. The polymerizable composition can comprise at least one hydrophilic monomer. The polymerizable composition can further comprise at least one crosslinker, or at least one initiator, or at least one tinting agent, or at least one UV blocker, or any combination thereof. The at least one initiator can comprise at least one UV initiator or at least one thermal initiator. In one example, the hydrophilic monomer can comprise a silicone-free monomer such as, for example, 2-hydroxyethyl methacrylate (HEMA). In another example, the polymerizable composition can further comprise at least one silicon-containing monomer. In yet another example, the polymerizable composition can be a polymerizable composition which, when polymerized, forms a hydrogel polymeric ophthalmic device body.

**[00114]** As used herein, the term "hydrogel" refers to a polymeric material, typically a network or matrix of polymer chains, capable of swelling in water or becoming swollen with water. A hydrogel can also be understood to be a material that retains water in an equilibrium state. The network or matrix may or may not be cross-linked. Hydrogels refer to polymeric materials, including ophthalmic devices, ocular inserts and contact lenses that are water swellable or are water swelled. Thus, a hydrogel may be (i) unhydrated and water swellable, or (ii) partially hydrated and swollen with water, or (iii) fully hydrated and swollen with water.

The hydrogel may be a silicone hydrogel, a silicone-free hydrogel, or an essentially silicone-free hydrogel.

**[00115]** The term "silicone hydrogel" or "silicone hydrogel material" refers to a particular hydrogel that includes a silicon (Si)-containing component. For example, a silicone hydrogel is typically prepared by combining a silicon-containing monomer with conventional hydrophilic hydrogel precursors. A silicone hydrogel ophthalmic device is an ophthalmic device, including a vision correcting contact lens, which comprises a silicone hydrogel material.

**[00116]** The polymerizable composition can be a polymerizable composition capable of forming a silicone hydrogel polymer when polymerized. The silicone hydrogel polymerizable composition can comprise a) at least one silicon-containing monomer and b) at least one hydrophilic monomer. In the silicone hydrogel polymerizable composition, the at least one hydrophilic monomer can comprise a hydrophilic monomer with an N-vinyl group. The at least one hydrophilic monomer can comprise a vinyl amide. The at least one silicon-containing monomer of the silicone hydrogel polymerizable composition can be a silicon-containing monomer having a molecular weight greater than 3,000 daltons. The at least one silicon-containing monomer can comprise at least two silicon-containing monomers, each having different numbers of polymerizable groups and different molecular weights. Optionally, the silicone hydrogel polymerizable composition can further comprise a diluent such as, for example, a form of silicone oil. In a particular example, the silicone hydrogel polymerizable composition can comprise a Comfilcon A polymerizable composition, and the polymerized reaction product can be a Comfilcon A polymeric lens body.

**[00117]** When the polymerizable composition comprises a silicon-containing monomer, the composition can further comprise at least one compatible crosslinking agent. In particular examples, the silicone-containing component may act as both a crosslinker and as a silicone-containing component. With respect to polymerizable compositions as discussed herein, "compatible" components refers to components which, when present in a polymerizable composition prior to polymerization, form a single phase that is stable for a duration of time adequate to allow manufacture of a polymeric lens body from the composition. For some components, a range of concentrations may be found to be compatible. Additionally, when the polymerizable composition is used to form a contact lens, "compatible" components are

components which, when polymerized to form a polymeric lens body, produce a lens that has adequate physical characteristics to be used as a contact lens (e.g., adequate transparency, modulus, tensile strength, etc.)

**[00118]** "Molecular weight" in the context of a polymer described herein refers to the nominal average molecular mass of a polymer, typically determined by size exclusion chromatography, light scattering techniques, or intrinsic viscosity determination in 1,2,4-trichlorobenzene. Molecular weight in the context of a polymer can be expressed as either a number-average molecular weight or a weight-average molecular weight, and in the case of vendor-supplied materials, will depend upon the supplier. Typically, the basis of any such molecular weight determinations can be readily provided by the supplier if not provided in the packaging material. Typically, references herein to molecular weights of monomers, including macromers and pre-polymers, or of polymers herein refer to the number average molecular weight. Both molecular weight determinations, number-average and weight-average, can be measured using gel permeation chromatographic or other liquid chromatographic techniques. Other methods for measuring molecular weight values can also be used, such as the use of end-group analysis or the measurement of colligative properties (e.g., freezing-point depression, boiling-point elevation, or osmotic pressure) to determine number-average molecular weight or the use of light scattering techniques, ultracentrifugation or viscometry to determine weight-average molecular weight.

**[00119]** The hydrophilicity or hydrophobicity of a substance can be determined using conventional techniques, such as, for example, based on the substance's aqueous solubility. For purposes of the present disclosure, a hydrophilic substance is a substance that is visibly soluble in an aqueous solution at room temperature (e.g. about 20-25 degrees C). For example, a hydrophilic monomer can be understood to be any monomer for which 50 grams or more of the monomer are visibly fully soluble in 1 liter of water at 20 degrees C (i.e., the monomer is soluble at a level of at least 5% wt/wt in water) as determined using a standard shake flask method as known to persons of ordinary skill in the art. A hydrophobic substance, as used herein, is a monomer that is visibly insoluble in an aqueous solution at room temperature, such that separate, visually identifiable phases are present in the aqueous solution, or such that the aqueous solution appears cloudy and separates into two distinct phases over time after sitting at

room temperature. For example, a hydrophobic monomer can be understood to be any monomer for which 50 grams of the monomer are not visibly fully soluble in 1 liter of water at 20 degrees C (i.e., the monomer is soluble at a level of less than 5% wt/wt in water).

**[00120]** A "monomer" refers to a polymerizable compound, regardless of the molecular weight of the compound. Thus, a monomer can be a low molecular weight monomer, a macromer, or a pre-polymer as described below.

**[00121]** A "low molecular weight monomer" refers to a relatively low molecular weight compound, for example a compound with an average molecular weight less than 700 Daltons that is polymerizable. In one example, a low molecular weight monomer can comprise a single unit of a molecule containing one or more functional groups capable of polymerizing to combine with other molecules to form a polymer, the other molecules being of the same structure or different structures as the low molecular weight monomer.

**[00122]** A "macromer" refers to medium and high molecular weight compounds or polymers, which can contain one or more functional groups capable of polymerization or further polymerization. For example, a macromer can be a compound or polymer with an average molecular weight of from about 700 Daltons to about 2,000 Daltons.

**[00123]** A "prepolymer" refers to a polymerizable or crosslinkable higher molecular weight compound. A prepolymer, as used herein can contain one or more functional groups. In one example, a prepolymer can be a series of monomers or macromers bonded together such that the overall molecule remains polymerizable or crosslinkable. For example, a prepolymer can be a compound with an average molecular weight greater than about 2,000 Daltons.

**[00124]** A "polymer" refers to a material formed by polymerizing one or more monomers, macromers, prepolymers or mixtures thereof. As used herein, a polymer is understood to refer to a molecule that is not capable of being polymerized, but is capable of being crosslinked to other polymers, for example, to other polymers present in a polymerizable composition or during the reaction of monomers, macromers and/or prepolymers to form other polymers in a polymerizable composition.

**[00125]** A "network" of a hydrophilic polymer typically means that crosslinks are formed between polymer chains by covalent bonds or by physical bonds, e.g. hydrogen bonds. A network can include two or more polymeric components, and can include an interpenetrating

network (IPN) in which one polymer is physically entangled with a second polymer such that there are few, if any, covalent bonds between them, but the polymers cannot be separated from each other without destroying the network.

**[00126]** An "interpenetrating network" or "IPN" refers to a combination of two or more different polymers, in network form, of which at least one is synthesized (e.g., polymerized) and/or cross-linked in the presence of the other without or substantially without any covalent bonds between them. An IPN can be composed of two kinds of chains forming two separate networks, but in juxtaposition or interpenetrating. Examples of IPNs include sequential IPNs, simultaneous IPNs, and homo-IPNs.

**[00127]** A "pseudo-IPN" refers to a polymeric reaction product where at least one of the different polymers is cross-linked while at least one other polymer is non-crosslinked (e.g. linear or branched), wherein the non-cross-linked polymer is distributed in and held by the cross-linked polymer on a molecular scale such that the non-cross-linked polymer is substantially unextractable from the network.

**[00128]** Hydrophilic Monomers. Hydrophilic monomers, including silicon-free hydrophilic monomers, are included in the polymerizable compositions used to make the present silicone hydrogels. The silicon-free hydrophilic monomers exclude hydrophilic compounds that contain one or more silicon atoms. Hydrophilic monomers can be used in combination with silicon-containing monomers, macromers or prepolymers in the polymerizable compositions to form silicone hydrogels. In silicone hydrogels, hydrophilic monomer components include those that are capable of providing at least about 10% (w/w), or even at least about 25% (w/w) water content to the resulting hydrated lens when combined with the other polymerizable composition components. For silicone hydrogels, the total hydrophilic monomers can be from about 25% (w/w) to about 75% (w/w), or from about 35% (w/w) to about 65% (w/w), or from about 40% (w/w) to about 60% (w/w), of the polymerizable composition.

**[00129]** Monomers that may be included as the hydrophilic monomers typically possess at least one polymerizable double bond, at least one hydrophilic functional group, or both. Examples of polymerizable double bonds include, for example, vinyl, acrylic, methacrylic, acrylamido, methacrylamido, fumaric, maleic, styryl, isopropenylphenyl, O-vinylcarbonate, O-vinylcarbamate, allylic, O-vinylacetyl and N-vinyl lactam and N-vinylamido double bonds. In

one example, the hydrophilic monomers are vinyl-containing (e.g., an acrylic containing monomer or a non-acrylic vinyl containing monomer). Such hydrophilic monomers may themselves be used as crosslinking agents.

**[00130]** Hydrophilic vinyl-containing monomers that may be incorporated into the materials of the present lenses include, without limitation, the following: N-vinyl lactams (e.g. N-vinyl pyrrolidone (NVP)), N-vinyl-N-methyl acetamide (VMA), N-vinyl-N-ethyl acetamide, N-vinyl-N-ethyl formamide, N-vinyl formamide, N-2-hydroxyethyl vinyl carbamate, N-carboxy- $\beta$ -alanine N-vinyl ester and the like and mixtures thereof. One example of a vinyl-containing monomer is N-vinyl-N-methyl acetamide (VMA). The structure of VMA corresponds to  $\text{CH}_3\text{C}(\text{O})\text{N}(\text{CH}_3)\text{--CH=CH}_2$ . Hydrophilic monomers which may be incorporated into the polymerizable composition also include hydrophilic monomers such as N,N-dimethyl acrylamide (DMA), 2-hydroxyethyl acrylate, glycerol methacrylate, 2-hydroxyethyl methacrylamide, N-vinylpyrrolidone (NVP), and polyethyleneglycol monomethacrylate. In certain examples, hydrophilic monomers including DMA, NVP and mixtures thereof are employed.

**[00131]** In accordance with the present disclosure, a cross-linking agent is understood to be a monomer having more than one polymerizable functional group as part of its molecular structure, such as two or three or four polymerizable functional groups, i.e., a multifunctional monomer such as a bifunctional or trifunctional or tetrafunctional monomer. One or more non-silicon cross-linking agents that can be used in the polymerizable compositions disclosed herein include, for example, without limitation, allyl (meth)acrylate, or lower alkylene glycol di(meth)acrylate, or poly(lower alkylene) glycol di(meth)acrylate, or lower alkylene di(meth)acrylate, or divinyl ether, or divinyl sulfone, or di- and trivinylbenzene, or trimethylolpropane tri(meth)acrylate, or pentaerythritol tetra(meth)acrylate, or bisphenol A di(meth)acrylate, or methylenebis(meth)acrylamide, or triallyl phthalate, or diallyl phthalate, or ethylene glycol dimethacrylate (EGDMA), or triethylene glycol dimethacrylate (TEGDMA), or triethylene glycol divinyl ether (TEGDVE), or trimethylene glycol dimethacrylate (TMGDMA), or any combination thereof. In one example, the cross-linking agent can have a molecular weight less than 1500 daltons, or less than 1000 daltons, or less than 500 daltons, or less than 200 daltons. Typically, the crosslinking agents are present in the polymerizable

silicone hydrogel composition in relatively small total amounts in the polymerizable composition, such as in an amount ranging from about 0.1% (w/w) to about 10% (w/w), or from about 0.5% (w/w) to about 5% (w/w), or from about 0.75% (w/w) to about 1.5% (w/w), by weight of the polymerizable composition.

**[00132]** In some examples, one or more of the monomers may comprise crosslinking functionality (i.e., the monomer may be multi-functional). In such cases, the use of an additional crosslinker in addition to the monomer, macromer or prepolymer with crosslinking functionality is optional, and the monomer, macromer or prepolymer with crosslinking functionality may be present in the polymerizable silicone hydrogel composition in a larger amount, such as, for example, at least about 3% (w/w), at least about 5% (w/w), at least about 10% (w/w), or at least about 20% (w/w).

**[00133]** Useful silicon-containing components comprise polymerizable functional groups such as vinyl, acrylate, methacrylate, acrylamide, methacrylamide, N-vinyl lactam, N-vinylamide, and styryl functional groups. The polymerizable compositions as described herein can be based on a silicon-containing monomer, including a silicon-containing low molecular weight monomer, or a silicon-containing macromer, or a silicone-containing prepolymer, or any combination thereof, and a hydrophilic monomer or co-monomer, and a crosslinking agent. In one example, the polymerizable composition of the present disclosure can comprise at least two silicon-containing monomers, each having a different molecular weight. Examples of silicon-containing components that may be useful in the present polymerizable compositions can be found in U.S. Pat. Nos. 3,808,178, 4,120,570, 4,136,250, 4,139,513, 4,153,641, 4,740,533, 5,034,461, 5,496,871, 5,959,117, 5,998,498, 5,981,675, and 5,998,498; U.S. Pat. Application Publication Nos. 2007/0066706, 2007/0296914, 2008/0048350, 2008/0269429, and 2009/0234089; and Japanese patent application publication number 2008-202060A, all of which are incorporated in their entireties herein by reference.

**[00134]** The polymerizable compositions for use as described herein may include one or more hydrophobic monomers, including silicon-free hydrophobic monomers. Examples of such silicon-free hydrophobic monomers include, without limitation, acrylic and methacrylic acids and derivatives thereof, including methylmethacrylate. Any combination of two or more hydrophobic monomers may be employed.



**[00135]** Illustrative acrylic monomers which can be used in the polymerizable composition include N,N-dimethylacrylamide (DMA), 2-hydroxyethyl acrylate, glycerol methacrylate, 2-hydroxyethyl methacrylate (HEMA), methacrylic acid, acrylic acid, methylmethacrylate (MMA), ethylene glycol methyl ether methacrylate (EGMA), and any mixtures thereof. In one example, the total acrylic monomer content is in an amount ranging from about 5% (w/w) to about 50% (w/w) of the polymerizable composition used to prepare a silicone hydrogel lens product, and can be present in an amount ranging from about 10% (w/w) to about 40% (w/w), or from about 15% (w/w) to about 30% (w/w), of the polymerizable composition.

**[00136]** Additional Hydrogel Components. The polymerizable compositions used in the lenses and in the methods described herein can also include additional components, e.g., one or more initiators, such as one or more thermal initiators, one or more ultraviolet (UV) initiators, visible light initiators, any combination thereof, and the like, one or more UV absorber agents or compounds, or UV radiation or energy absorber, tinting agent, pigments, release agents, antimicrobial compounds, and/or other additives. The term "additive" in the context of the present disclosure refers to a compound or any chemical agent provided in the present hydrogel contact lens polymerizable compositions or the polymerized hydrogel contact lens products, but which is not necessary for the manufacture of a hydrogel contact lens.

**[00137]** The polymerizable compositions may comprise one or more initiator compounds, i.e., a compound capable of initiating polymerization of a polymerizable composition. Thermal initiators, i.e., initiators having a "kick-off" temperature, can be used. For instance, exemplary thermal initiators that can be employed in the present polymerizable compositions include 2,2'-azobiz(isobutyronitrile) (AIBN, VAZO®-64), 2,2'-azobis(2,4-dimethylpentanenitrile) (VAZO®-52), 2,2'-Azobis(2-methylbutyronitrile) (VAZO®-67), and 1,1'-azobis(cyclohexanecarbonitrile) (VAZO®-88). For VAZO® thermal initiators, the grade number (i.e., 64, 52, 67, 88, etc.) is the Celsius temperature at which the half-life of the initiator in solution is 10 hours. All of the VAZO® thermal initiators described herein are available from DuPont (Wilmington, Del., USA). Additional thermal initiators, including nitrites as well as other types of initiators, are available from Sigma Aldrich. Ophthalmically compatible silicone hydrogel contact lenses can be obtained from polymerizable compositions that comprise from

about 0.05% (w/w) to about 0.8% (w/w), or from about 0.1% (w/w) to about 0.6% (w/w), of VAZO®-64 or other thermal initiator.

**[00138]** The polymerizable compositions may also comprise a demolding aid, that is to say, one or more ingredients effective in making more facile removal of the cured contact lenses from their molds. Exemplary demolding aids include hydrophilic silicones, polyalkylene oxides, and any combination thereof. The polymerizable compositions may additionally comprise a diluent selected from the group consisting of hexanol, ethoxyethanol, isopropanol (IPA), propanol, decanol and any combination thereof. Diluents, if employed, are typically present in amounts ranging from about 10% (w/w) to about 30% (w/w). Compositions having relatively higher concentrations of diluents tend to, but do not necessarily, have lower ionoflux values, reduced modulus, and increased elongation, as well as water break up times (WBUTs) greater than 20 seconds. Additional materials suitable for use in making hydrogel contact lenses are described in U.S. Pat. No. 6,867,245, the disclosure of which is incorporated in its entirety herein by reference. In certain examples however, the polymerizable composition is diluent-free.

**[00139]** In a particular example of a polymerizable composition, the composition comprises a first monomer having a first reactivity ratio, and a second monomer having a second reactivity ratio that is less than the first reactivity ratio. As understood by persons of ordinary skill in the art, a reactivity ratio can be defined as the ratio of the reaction rate constant of each propagating species adding its own monomer to the rate constant for its addition of other monomer. Such compositions may also include at least one cross-linking agent having a reactivity ratio similar to the first reactivity ratio or to the second ratio. Such compositions may also include at least two crosslinking agents, the first crosslinking agent having a reactivity ratio similar to the first reactivity ratio, and the second crosslinking agent having a reactivity ratio similar to the second reactivity ratio. In certain examples, the lens precursor compositions may include one or more removable additives. For example, the polymerizable compositions may include one or more compatibilizers, demolding aids, delensing aids, wettability enhancers, and ionoflux reducers which are removable.

**[00140]** Silicone hydrogel contact lenses are based on polymerizable lens formulations that include silicon-containing monomers, including low molecular weight monomers, macromers,

prepolymers or any combination thereof, and at least one hydrophilic monomer, as previously described. Some examples of silicone hydrogel contact lens materials include materials having the following USANs: aquafilcon A or aquafilcon B, balafilcon A, comfilcon A, enfilcon A, galyfilcon A, lenefilcon A, lotrafilcon A, lotrafilcon B, senofilcon A, narafilecon A, and filcon II 3. In one example, the lens body with ophthalmically acceptably wettable anterior and posterior surfaces without application of a surface treatment to the lens body, or without the presence of an interpenetrating polymeric network (IPN) of a polymeric wetting agent in the lens body is a comfilcon A silicone hydrogel contact lens body.

[00141] Ophthalmic devices comprise bodies that have surfaces, such as an anterior surface and a posterior surface. As used herein, an ophthalmically acceptably wettable ophthalmic device is a device having surfaces that are all ophthalmically acceptably wettable. Wettability refers to the hydrophilicity of one or more surfaces of a device. As used herein, a surface of a device can be considered to be ophthalmically acceptably wettable if the device receives a score of 3 or above in a wettability assay conducted as follows. An ophthalmic device is dipped into distilled water, removed from the water, and the length of time that it takes for the water film to recede from the device surface is determined (e.g., water break up time (WBUT)). The assay grades devices on a linear scale of 1-10, where a score of 10 refers to a device in which a drop takes 20 seconds or more to fall from the device. A device having a WBUT of more than 5 seconds, such as at least 10 seconds or more desirably at least about 15 seconds, can be a device having ophthalmically acceptably wettable surfaces. Wettability can also be determined by measuring a contact angle on one or both device surfaces. The contact angle can be a dynamic or static contact angle, a sessile drop contact angle, a pendant drop contact angle, or a captive bubble contact angle. Lower contact angles generally refer to increased wettability of a device surface. For example, an ophthalmically acceptably wettable surface of a device can have a contact angle less than about 120 degrees. However, in certain examples, the devices can have a contact angle no greater than 90 degrees, and in further examples, the device can have an advancing contact angle less than about 80 degrees.

[00142] The ophthalmic devices cast molded using the molding surfaces disclosed herein can have ophthalmically acceptably wettable surfaces when fully hydrated, and may not require application of a surface treatment or the presence of an IPN or pseudo-IPN of a polymeric

wetting agent in the device body in order for the lens to have ophthalmically acceptably wettable surfaces. However, application of a surface treatment to the device or the presence of an IPN or pseudo-IPN of a polymeric wetting agent in the device body can be used to further increase the wettability of the device surfaces above a level that is considered ophthalmically acceptably wettable.

**[00143]** An "ophthalmically compatible silicone hydrogel device" refers to a silicone hydrogel ophthalmic device, such as a contact lens, that can be worn on a person's eye without the person experiencing or reporting substantial discomfort, including ocular irritation and the like. When the device is a contact lens, such lenses often have an oxygen permeability, a surface wettability, a modulus, a water content, an ionoflux, a design, and any combination thereof, which permit the lenses to be comfortably worn on a patient's eye for extended periods of time, such as for at least a day, at least a week, at least two weeks, or about a month without requiring removal of the lens from the eye. Typically, ophthalmically compatible silicone hydrogel devices do not cause or are not associated with significant corneal swelling, corneal dehydration ("dry eye"), superior-epithelial arcuate lesions ("SEALs"), or other significant discomfort. Ophthalmically compatible silicone hydrogel contact lenses meet clinical acceptability requirements for daily wear or extended wear contact lenses.

**[00144]** Ophthalmically compatible silicone hydrogel devices have ophthalmically acceptably wettable surfaces, although a device with ophthalmically acceptably wettable surfaces may not necessarily be ophthalmically compatible. A silicone hydrogel contact device having an "ophthalmically acceptably wettable surface" can be understood to refer to a silicone hydrogel device that does not adversely affect the tear film of a device wearer's eye to a degree that results in the device wearer experiencing or reporting discomfort associated with placing or wearing the silicone hydrogel device on an eye.

**[00145]** A method of manufacturing ophthalmic devices, for example, silicone hydrogel contact lenses, is illustrated in FIG. 1. In accordance with the present disclosure, all of the steps illustrated in FIG. 1, or a subset of the steps illustrated in FIG. 1 can comprise a method of manufacturing contact lenses. Items which serve as inputs, outputs or both inputs and outputs of the steps of FIG. 1 are illustrated in FIG. 2.

[00146] FIG. 1 includes a step 102 of providing a first polymer. The first polymer is illustrated in FIG. 2 as element 202.

[00147] Step 104 of FIG. 1 illustrates the step of using the first polymer to form a first portion of a molding surface of at least one of a first mold member and a second mold member. Element 204 of FIG. 2 illustrates the resulting first portion of the molding surface(s) comprising or consisting of the first polymer.

[00148] In one example, the step of using the first polymer to form the first portion of the molding surface can comprise forming a matrix of the first polymer. The matrix can comprise a net-like matrix of the first polymer. The net-like matrix can be formed into a sheet which can be cut and placed in contact with the second portion of the molding surface to form the first portion of the molding surface, or the matrix can be formed directly into a shape corresponding to the shape of the first portion of the molding surface. For example, the matrix can be formed into a shape corresponding to the shape of a peripheral zone of a contact lens. FIG. 3 illustrates three different possible matrix designs 3A, 3B and 3C which correspond to the shape of a peripheral zone of a contact lens. In 3A, 3B and 3C, the dark lines represent areas formed from the first polymer. One of ordinary skill in the art will recognize that there are numerous methods of forming such matrices, such as, for example, injection molding.

[00149] FIG. 1 also includes a step 106 of providing a second polymer. The second polymer is illustrated in FIG. 2 as element 206.

[00150] Step 108 of FIG. 1 illustrates the step of using the second polymer to form a second portion of the molding surface of the at least one of a first mold member and a second mold member. Element 208 of FIG. 2 illustrates the resulting first portion of the molding surface(s) comprising or consisting of the first polymer.

[00151] Step 110 of FIG. 1 illustrates the step of combining the first portion of the molding surface and the second portion of the molding surface to form an entire molding surface. The entire molding surface is illustrated in FIG. 2 as element 210. When the first portion of the molding surface formed of the first polymer comprises a matrix of the first polymer such as a matrix illustrated in FIG. 3, the step of using the second polymer to form the second portion of the molding surface can be a step of forming a conventional contact lens mold member having a conventional molding surface, i.e., a molding surface configured to mold an entire lens surface,

and the step of combining the first portion and the second portion can comprise the step of affixing a matrix formed from a first polymer onto the molding surface formed from the second molding member. When the matrix is affixed to the molding surface, the matrix of the first polymer will be on top of and in direct contact with portions of the molding surface formed of the second polymer, and thus the matrix of the first polymer will “block” portions of the molding surface formed of the second polymer. When this combined molding surface is used to cast mold an ophthalmic device, the polymerizable composition will contact the second polymer of the molding surface only in those areas not “blocked” by the first polymer matrix, and thus the composition will be in direct contact with both the first portion of the molding surface formed by the first polymer matrix, and the second portion of the molding surface formed by the second polymer.

**[00152]** In one example, the steps of forming the first portion or second portion of the molding surface and combining the first portion and the second portion can comprise the same step. For example, the second portion of the molding surface can be prepared by injection molding the second polymer to form a mold member comprising the second portion of the molding surface, and subsequently the first polymer can be used to form the second portion of the molding surface, for example by depositing the first polymer directly onto the molding surface formed of the second polymer, or by molding the first polymer in a mold comprising the second mold member. The first portion of the molding surface can be configured to form at least one channel on a surface of the device. In other words, the entire channel can be part of an outer surface of the device, such that the channel itself is part of the outer surface of the device.

**[00153]** In one example, when a matrix of the first polymer is used, only a part of the matrix can be used as a first portion of the molding surface, while another part of the matrix can be used to form a structure within a body of a device (i.e., the other part of the matrix is not used to form a structure at a surface of the device). For example, the first portion of the molding surface can be configured to form at least one channel extending from at least one surface of the device into a body of the device. In other words, in this example, the matrix formed of the first polymer can be used to form a channel which begins at an outer surface of the device and the matrix can also be used to form a channel which is within and surrounded by the body of the device and in communication with the channel extending from the at least one surface of the

device. In one example, such a channel can extend from a first outer surface of the device into the device body without having a second outlet to a device surface (i.e., the channel can have just one opening, the opening from the first outer surface being the only opening, and the channel can extend into, but not back out of, the body of the device). In another example, such a channel can extend from a first outer surface of the device into the device body and then back out to a second opening on a surface of the device. In this example, the first opening can be a different opening than the second opening. Additionally, the first opening can be on a first device surface, and the second opening can be on the same device surface as the first opening, or can be on a different surface of the device. In other words, the first opening can be on the anterior surface of the device, and the second opening can be on the anterior surface or on the posterior surface of the device.

**[00154]** For example, only the outer perimeter of the matrices illustrated in FIG. 3 (300A, 300B and 300C) may be in placed in direct contact with the portion of the molding surface formed of the second polymer, and so only the outer perimeters (300A, 300B, 300C) of the matrices would comprise the first portion of the molding surface. When the polymerizable composition is placed in contact with this molding surface, only the outer perimeters (300A, 300B and 300C) would be used to mold an outer surface of the device (for example, a portion of an edge of a contact lens), while the remaining parts of the matrices would be surrounded by the polymerizable composition. Following curing, only the outer perimeters (300A, 300B, 300C) would be present on an outer surface of the resulting device body, while the remaining parts of the matrices would be surrounded by the polymeric device body. If the first polymer used to form the matrices consisted of a water-soluble polymer, the mold assembly, demolded lens body, or the partially delensed lens body could be contacted by water or an aqueous solution to dissolve the first polymer. Dissolving the first polymer could result in dissolution of the entire matrix of the first polymer, including the both the part of the matrix present on an outer surface of the device as well as the part of the matrix present in the device body, thereby producing a device body having channels present within the device body.

**[00155]** In another example, the step of combining the first portion and the second portion can comprise attaching a matrix of the first polymer to mold member formed of the second polymer. FIG. 4 illustrates two different matrices having two different non-molding regions

which can be used to affix the matrix to a mold member. The matrix 4A has a plurality of loops 401 formed of the first polymer in a non-molding region of the matrix which can be placed over a post on a non-molding region of a mold member formed of the second polymer in order to affix the matrix comprising the first portion of the molding surface to a second portion of a molding surface to form an entire molding surface. The matrix 4B has a ring of the first polymer 402 in a non-molding region of the matrix which can be used to affix the matrix to a mold member comprising the second portion of the molding surface. For example, an adhesive can be placed on the non-molding ring of the matrix to affix the matrix to a mold member, or a weld can be formed between the non-molding ring of the matrix and a non-molding region of a mold member formed of the second polymer in order to affix the first portion of the molding surface to the second portion of the molding surface and form an entire molding surface.

[00156] FIG. 1 also includes a step 112 of placing a polymerizable composition in direct contact with the entire molding surface 210. In reference to the present disclosure, the polymerizable composition can be understood to be a polymerizable composition, such as, for example, a silicon-containing polymerizable composition capable of forming a silicone hydrogel polymer when polymerized. The polymerizable composition is illustrated in FIG. 2 as element 212. The polymerizable composition may be understood to be a pre-polymerized or pre-cured composition suitable for polymerization.

[00157] Typically, the polymerizable composition is not polymerized before curing or polymerization of the composition. However, polymerizable compositions may be partially polymerized before undergoing a curing process. In some examples, the polymerizable composition may comprise a polymer component which becomes crosslinked with other components of the polymerizable composition during the curing process. The polymeric component can be wetting agent or comfort agent. Alternatively, the polymeric component can be a polymeric component which is not a polymeric wetting or comfort agent, which does not form an interpenetrating polymeric network or pseudo-IPN in the lens body, or which is neither a polymeric wetting or comfort agent and does not form an IPN or pseudo-IPN in the lens body.

[00158] The present polymerizable compositions can be provided in containers, dispensing devices, or mold members prior to a curing or polymerization procedure, as described herein. Referring back to FIG. 1, in step 112, the polymerizable composition is placed on a device-



forming molding surface (i.e., an entire molding surface used to mold an entire surface of an ophthalmic device such as a lens surface) of a female mold member or of a male mold. The female mold member can be understood to be a first mold member or an anterior mold member, and the male mold member can be understood to be a second mold member or a posterior mold member. For example, the female mold member comprises a molding surface that defines the anterior or front surface of a lens produced from the lens mold. The second mold member may be understood to be a male mold member or a posterior mold member. For example, the second mold member includes a molding surface that defines the posterior surface of a device such as a lens produced in the mold member (e.g., the second or male mold member can have a convex lens forming molding surface).

[00159] To form a mold assembly, the first mold member is placed in contact with a second mold member, forming a device-shaped cavity in the space between the molding surface of the first mold member and the molding surface of the second mold member. The method illustrated in FIG. 1 includes a step 114 of forming a contact lens mold assembly by placing two contact lens mold members in contact with each other to form a lens-shaped cavity therebetween. For example, with reference to FIG. 2, following execution of step 114, the polymerizable silicone hydrogel composition 212 is located in the contact lens-shaped cavity of the mold assembly 214.

[00160] At step 116, the method illustrated in FIG. 1 includes curing the polymerizable composition to form a polymeric device body which is contained in a mold assembly, as illustrated in FIG. 2 as element 216. At this point in the process, the polymeric lens body has not been exposed to a liquid. In one example the polymeric lens body can be a polymerized silicone hydrogel contact lens body. During curing, the components of the polymerizable composition polymerize to form a polymeric lens body. Thus, the curing may also be understood to be a polymerizing step. The curing 116 can include exposing the polymerizable lens precursor composition to a form of electromagnetic radiation effective in polymerizing the components of the lens precursor composition. For example, the curing 116 can include exposing the polymerizable composition to polymerizing amounts of heat, microwave radiation or ultraviolet (UV) light, among other forms of electromagnetic radiation. The curing 116 can also include curing the compositions in an oxygen-free or nearly oxygen-free environment. For

example, the curing 116 can occur in the presence of nitrogen or other inert gases. The curing 116 can be effective to fully polymerize the polymerizable composition, or can polymerize the polymerizable composition to a level such that the lens body when processed (e.g., demolded, delensed, washed, packaged, sterilized, etc.) is capable of retaining its molded shape adequately to serve as a contact lens.

**[00161]** A polymeric device body which has not been exposed to a liquid can be present at various stages in the manufacturing process, depending upon the types of demolding and delensing processes used, and whether or not one or more optional washing steps are performed. For example, a polymeric lens body which has not been exposed to a liquid can be a polymeric lens body prior to undergoing a wet demolding process, or a wet delensing process, or a wet demolding and delensing process, or an optional washing process, or any combination thereof. For example, the washing process can be a cleaning process to remove dust or debris, or an extraction process to remove a portion or substantially all of one or more extractable components from the polymeric lens body, or a hydration process to partially or fully hydrate the hydrogel lens body, or any combination thereof. For example, the polymeric lens body which has not been contacted by a liquid can comprise a lens body present in a lens shaped cavity of a mold assembly or of two molding surfaces after a curing process, or can comprise a lens body in contact with one and only one mold member following a dry demolding process, or can comprise a contact lens body in a tray or other device following dry delensing and dry delensing processes. The polymeric lens body which has not been exposed to a liquid can include a lens forming component, such as a silicon-containing polymeric network or matrix in the shape of a lens, and a removable component that can be removed from the lens body following polymerization. The removable component can be understood to include unreacted monomers, oligomers, partially reacted monomers, or other agents which have not become covalently attached or otherwise immobilized relative to the lens-forming component. The removable component can also be understood to include one or more additives, including diluents, that can be removed from the polymerized lens product during a cleaning, extraction, or hydration procedure, as discussed herein. Thus, materials of the removable component can include linear uncross-linked or slightly cross-linked or branched polymers of extractable

materials that are not cross-linked to or otherwise immobilized relative to the polymer backbone, network, or matrix of the lens body.

**[00162]** After curing the polymerizable compositions, the method illustrated in FIG. 1 can optionally include a step 118 of separating the polymeric device body from the mold members of the mold assembly. As illustrated in FIG. 2, the output of step 118 is a polymeric device body which has been released from all the molding surfaces used to form it 218. In one example, the process of separating the polymeric lens body from the mold member can comprise a demolding process resulting in the polymeric lens body remaining in contact with one, and only one, entire molding surface of the molding surfaces used to form the polymeric lens body. Following the demolding process, the polymeric lens body is located on, or remains in contact with, just one of the molding surfaces of the mold assembly. The one and only one mold member with which the polymeric lens body remains in contact following demolding can be the molding surface comprising the first portion of the molding surface 204 formed using the first polymer 202, or can be a different molding surface. When the step 118 of separating the polymeric lens body from the molding surfaces comprises a demolding process, the step of separating can further include a delensing step releasing the polymeric lens body from the one and only one entire molding surface or portion of a molding surface with which it remained in contact following the demolding process. The polymeric lens body can be delensed from the entire molding surface or a portion of the molding surface of the male mold member or from the entire molding surface or a portion of the molding surface of the female mold member, depending on which mold member the polymeric lens body remains in contact with following the demolding process. Alternatively, the step 118 can comprise a combination demolding and delensing process, where the lens body is released simultaneously from all of the molding surfaces used to form it. When at least one of the molding surfaces used to form the lens body comprises a water-soluble polymer, the separating process can involve applying a liquid to the lens body and the molding surface (in the form of a mold assembly, a single mold member, a pair of molding surfaces an entire molding surface or a portion of a molding surface, the molding surface(s) being either in contact with, or separated from, the non-molding portion(s) of the mold member(s) to at least partially dissolve the water-soluble polymer and thereby

release the lens body from the molding surface(s). The liquid used in a wet separation process can comprise water or an aqueous solution.

**[00163]** The method illustrated in FIG. 1 can optionally include a step 120 of washing the device body. The washing step can comprise contacting a polymeric lens body with a liquid, for example an organic solvent, an organic solvent solution, water or an aqueous solution free of an organic solvent, to clean dust or debris from the lens body, or to extract the lens body to remove extractable materials from the lens body, or to fully or partially hydrate the lens body, or any combination thereof. In one example, the washing step 120 can comprise a washing step to remove or dilute the liquid used during a wet demolding process, a wet delensing process, or both. The washing step 120 results in a cleaned, extracted or hydrated lens body 220, as shown in FIG. 2. The washing step 120 can optionally be conducted on a mold assembly including a polymeric lens body, a polymeric lens body remaining in contact with one molding surface, a polymeric lens body which has been fully released from all the molding surfaces used to form it, and can be conducted repeatedly as part of the manufacturing process.

**[00164]** The washing step 120 can optionally include a step of hydrating the polymeric device body. The hydrating step can include contacting a polymeric lens body or one or more batches of such polymeric lens bodies with water or an aqueous solution to form a hydrated lens product, such as, for example, a silicone hydrogel contact lens. The hydration step can fully or partially hydrate the lens body. In one example, the polymeric lens body which is hydrated in the hydration step is a delensed polymeric lens body which has not been contacted by a liquid prior to the hydration step, or can comprise a polymeric lens body which has previously been contacted by a liquid. When the optional washing step 120 includes a hydration step, the resulting output comprises a washed, hydrated polymeric device body 220.

**[00165]** After the separating step 118, and the optional washing step 120, the method illustrated in FIG. 1 can optionally include a step 122 of packaging the device body to produce a packaged ophthalmic device product 222. For example, a lens body can be placed in a blister pack, vial or other suitable container along with a volume of a packaging liquid, such as a saline solution, including buffered saline solutions. In one example, the washing step 120 and packaging step 122 can be conducted simultaneously by placing a polymeric lens body, including a polymeric lens body which has not previously been contacted by a liquid, in a

blister package or container with a portion of packaging liquid which serves as both a packaging solution and a washing solution. In another example, the separating and packaging step can be conducted simultaneously by placing a polymeric lens body in contact with a mold assembly, two molding surfaces of a mold assembly, a mold member, or a molding surface in a blister package or container with a portion of packaging liquid which serves to release the lens body by dissolving the vinyl alcohol copolymer mold member(s) or molding surface(s). When the optional packaging step 122 is included in the method, the resulting output is a packaged polymeric device body 222, as illustrated in FIG. 2.

**[00166]** Optionally, the method illustrated in FIG. 1 can further comprise one or more inspection steps 124. In the example illustrated in FIG. 1, the inspection step is conducted following the packaging step, before the package is sealed and sterilized, although the one or more inspection steps can be conducted at any point in the process, either before curing or after curing, on a dry device body or a wet device body. For example, an inspection can be performed on one or more mold members to determine the acceptability of the molding surfaces, can be performed on a mold member following placing of the polymerizable composition to detect the presence of bubbles in the polymerizable composition, on a dry lens following curing to determine the acceptability of the dry lens body, or on a wet lens body following separating, washing or packaging to determine the acceptability of the wet lens body. The result of optional inspection step(s) 124 as illustrated in FIG. 1 is a packaged inspected device body 224, but in other processes can comprise an inspected mold member, an inspected polymerizable composition in a mold member, an inspected dry lens body, or an inspected wet lens body.

Following the step 124 of inspecting the packaged device body, the blister pack or container containing the packaged, inspected device body 224 can be sealed, and subsequently sterilized, as shown in optional step 126 of FIG. 1, to produce a sterilized package comprising an ophthalmic device product such as, for example, a contact lens. The packaged device body can be exposed to sterilizing amounts of radiation, including heat such as by autoclaving, gamma radiation, e-beam radiation, ultraviolet radiation, and the like. Depending upon the previous process steps used, the sterilization process can also serve to partially or fully extract, fully hydrate, or both extract and hydrate the packaged device body, or to dissolve the mold

member(s) or molding surface(s) comprising the vinyl alcohol copolymer. The result of step 126 is a packaged ophthalmic device product 226 as illustrated in FIG. 2.

**[00167]** Comprises/comprising and grammatical variations thereof when used in this specification are to be taken to specify the presence of stated features, integers, steps or components or groups thereof, but do not preclude the presence or addition of one or more other features, integers, steps, components or groups thereof.

## CLAIMS

1. A method of manufacturing an ophthalmic device, comprising:
  - (a) placing a polymerizable composition comprising at least one hydrophilic monomer in direct contact with an entire molding surface configured to cast mold an anterior or posterior surface of an ophthalmic device; and
  - (b) curing the polymerizable composition in direct contact with the entire molding surface to form a polymerized reaction product comprising a polymeric ophthalmic device body,

wherein a first polymer is used to form a first portion of said molding surface configured to mold the entire anterior or posterior surface of an ophthalmic device, a second polymer is used to form a distinct second portion of said molding surface configured to mold the entire anterior or posterior surface of an ophthalmic device and, when combined, the distinct first and second portions form the entire said molding surface configured to mold the entire anterior or posterior surface of an ophthalmic device.

2. The method of claim 1, wherein the first polymer comprises at least one vinyl alcohol copolymer which is not an ethylene-vinyl alcohol copolymer.
3. The method of any one of claims 1-2, wherein the first polymer comprises NICHIGO G-POLYMER™.

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4. The method of any one of claims 1-3, wherein the second polymer comprises polypropylene.
5. The method of any one of claims 1-4, wherein the step of using the first polymer to form the first portion of the molding surface comprises injection molding the first polymer.
6. The method of claim 5, wherein the step of injection molding the first polymer uses a process setting selected from the group consisting of: melt temperature from about 180°C to about 250°C, barrel temperature from about 180°C to about 250°C, throat temperature from about 30°C to about 70°C, mold tool temperature from about 30°C to about 95°C, holding time from about 1 second to about 5 seconds, injection speed from about 50 mm/second to about 250 mm/second, plasticizing speed from about 100 mm/second to about 300 mm/second, injection pressure from about 50 Bar to about 180 Bar, holding pressure from about 10 Bar to about 200 Bar, back pressure from about 5 Bar to about 25 Bar, and any combination thereof.
7. The method of any one of claims 1-6, wherein the step of using the first polymer to form the first portion of the molding surface comprises lathing the first polymer.
8. The method of any one of claims 1-7, wherein the step of using the first polymer to form the first portion of the molding surface comprises forming a matrix of the first polymer.
9. The method of claim 8, wherein the method further comprises the step of combining the matrix and the second portion of the molding surface to form the entire molding



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surface prior to the step of placing the polymerizable composition comprising in direct contact with the entire molding surface.

10. The method of any one of claims 1-9, wherein the step of using the first polymer to form the first portion of the molding surface comprises applying the first polymer directly onto a pre-formed molding surface formed of the second polymer.

11. The method of claim 10, wherein the applying the first polymer directly onto a pre-formed molding surface comprises casting the vinyl alcohol into a pre-formed mold member comprising the second portion of the molding surface formed of the second polymer.

12. The method of any one of claims 1-11, wherein the method further comprises the step of releasing the polymeric ophthalmic device body from both the first portion of the molding surface and the second portion of the molding surface, and the polymeric ophthalmic device body is released from the second portion of the molding surface before the device body is released from the first portion of the molding surface.

13. The method of any one of claims 1-12, wherein the method further comprises releasing the polymeric ophthalmic device body from at least the second portion of the molding surface using a process which does not involve contacting the device body or the second portion of the molding surface with a liquid.

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14. The method of any one of claims 1-13, wherein the method further comprises releasing the polymeric ophthalmic device body from at least the first portion of the molding surface by contacting the device body and the first portion of the molding surface with a liquid.
15. The method of claim 14, wherein the contacting the first portion of the molding surface with the liquid results in the liquid at least partially dissolving the first portion of the molding surface.
16. The method of any one of claims 1-15, wherein the polymerizable composition comprises at least one silicon-containing monomer, and the polymeric ophthalmic device body comprises a silicone hydrogel ophthalmic device body.
17. The method of any one of claims 1-16, wherein the entire molding surface comprises an entire molding surface configured to mold a posterior surface of a contact lens, and the polymeric ophthalmic device body comprises a polymeric contact lens body.
18. The method of any one of claims 1-17, wherein the first portion of the molding surface is configured to form at least one channel on a surface of the device.
19. The method of any one of claims 1-17, wherein the first portion of the molding surface is configured to form at least one channel extending from at least one surface of the device into a body of the device.

20. An ophthalmic contact lens mold member that includes a molding surface configured to form an entire anterior or posterior surface of a contact lens, the molding surface comprising:

(a) a first portion formed of a first polymer, wherein the first portion is configured to cast mold a first region of the surface of the contact lens; and

(b) a distinct second portion formed of a second polymer, wherein the second portion is configured to cast mold a second region of the surface of the contact lens, wherein the distinct first and second portions of the molding surface are combined to form a single molding surface, and wherein the combination of the distinct first and second portions is configured to form the entire molding surface to cast mold said entire anterior or posterior surface of the contact lens.

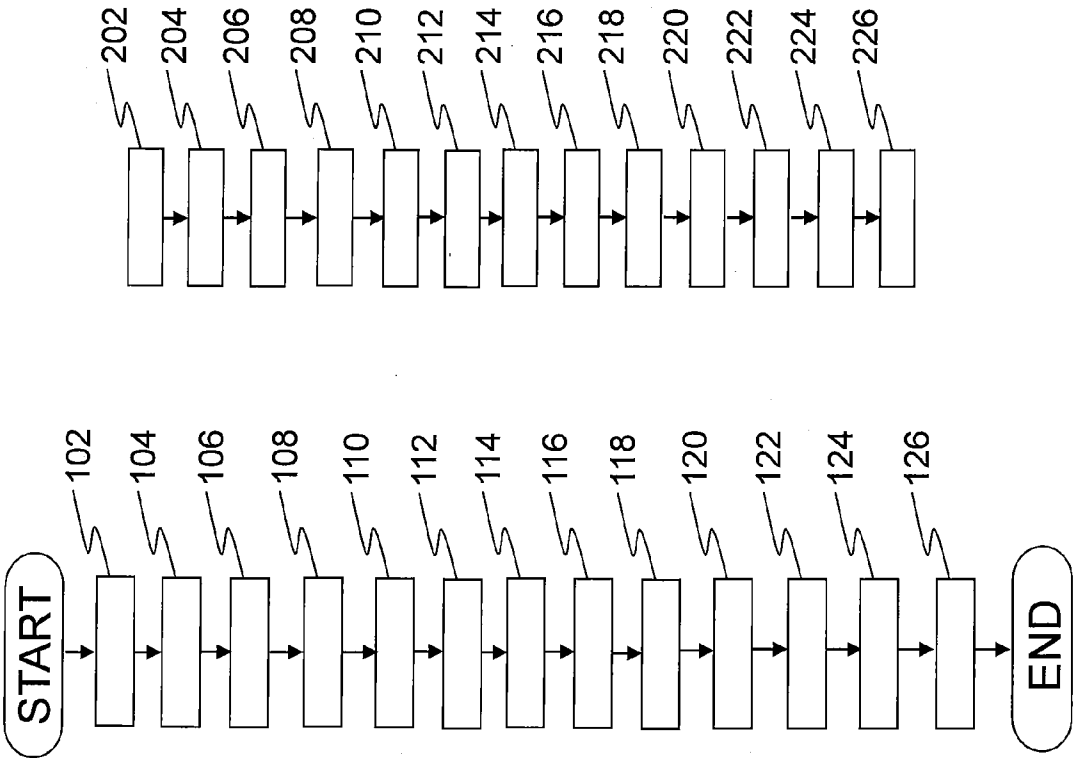


FIG. 1

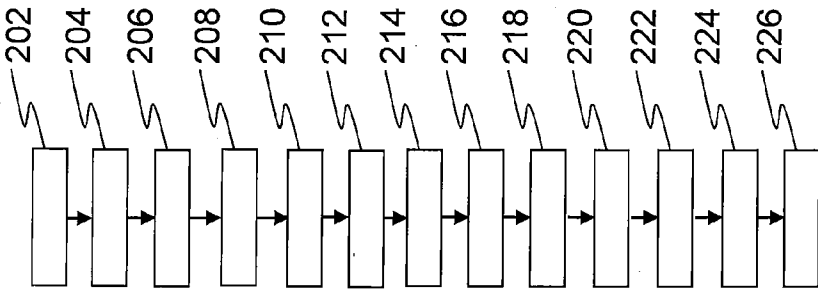


FIG. 2

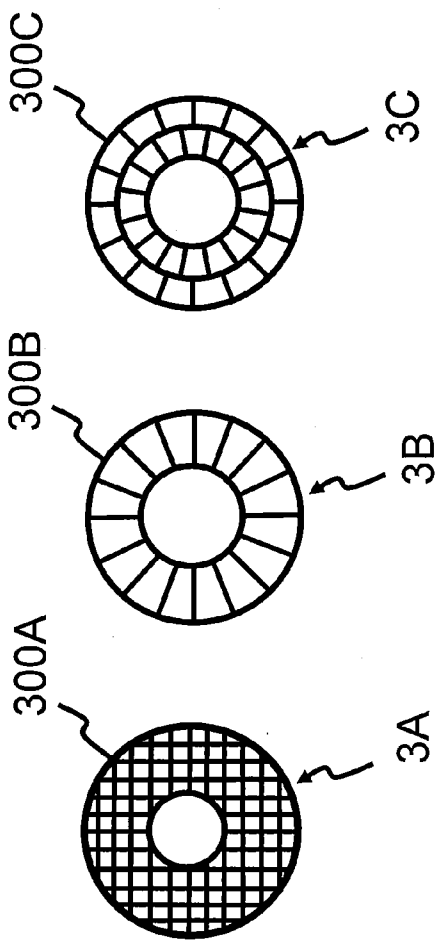


FIG. 3

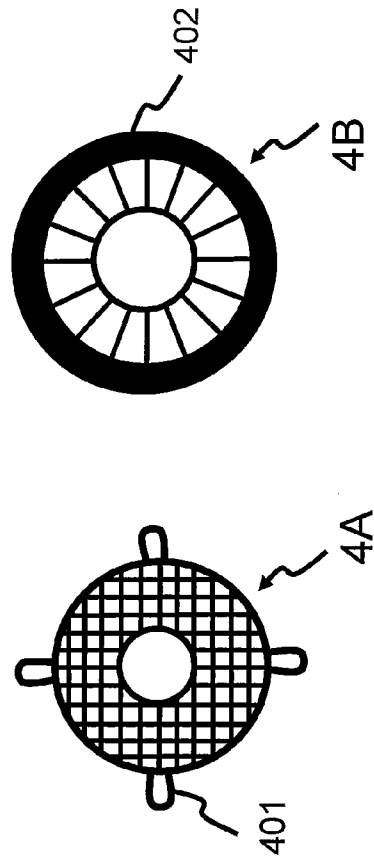


FIG. 4