

## DESCRIPTION

### Title of Invention

Method of producing an Ophthalmic Lens Having an  
5 Embedded Component

### Cross-Reference to Related Application

[0001]

The present application claims the benefit of  
10 priority to Japanese Patent Application No. 2017-202114,  
filed Oct 18, 2017, the disclosure of which is  
incorporated herein by reference in its entirety.

### Technical Field

15 [0002]

The present invention relates to a method of  
producing an ophthalmic lens having a component embedded  
therein.

### 20 Background of the Invention

[0003]

Ophthalmic lenses were developed originally as  
devices for correcting vision. In particular, contact  
lenses with added value have recently been provided,  
25 including so-called fashion contact lenses having an  
annular tinted area for altering the iris color and  
textures and measuring contact lenses equipped with a  
self-supplied energy device that enables monitoring  
and/or examination of biological functions.

[0004]

Such fashion contact lenses and measuring contact lenses can be formed by embedding within a contact lens substrate a component such as iris-patterned film and an energy device. For example, a method for forming multi-piece insert device having an electronic component secured in proximity to the surface of an ophthalmic device (see, Patent Document 1 listed below, which is incorporated herein by reference in its entirety) and a method for manufacturing a device with an insert having a colorant pattern (see, Patent Document 2 listed below, which is incorporated herein by reference in its entirety) are known.

15 Prior-Art Documents

Patent Documents

[0005]

Patent Document 1: JP-A-2014-134795

Patent Document 2: Pamphlet of WO2014/073568

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Summary of the Invention

Technical Problem

[0006]

For contact lenses with an embedded component, the location of the embedded component within a contact lens affects the safety of the contact lens for wearing. If the embedded component is partially or fully exposed on the surface of a contact lens, it may cause damage to eye tissue. Also, if the embedded component interferes

with an optical zone, there arises a concern that the optical characteristics of the contact lens may be adversely affected.

[0007]

5           The method described in Patent Document 1 uses a mold that has a sticking feature for sticking together a male mold and female mold. The mold, however, does not include any positioning feature for positioning a component to be embedded (i.e., embedded component). As  
10 a result, the method described in Patent Document 1 may result in shifting of the embedded components due to the pressure exerted upon mating of the male mold. The method described in Patent Document 2 controls the thickness of first and second components in order to  
15 prevent drying of the contact lens and to thereby minimize defects resulting from deformation caused by drying. While the method can control the thickness of the contact lens substrate that carries an embedded colored film, the method uses no particular features for  
20 positioning the embedded colored film.

[0008]

As described above, no traditional methods for forming contact lenses with embedded components take into consideration the shifting of the embedded  
25 components that occurs during formation of the contact lenses and thus, the concern about the effect on the resulting optical characteristics still remains.

[0009]

Accordingly, it is an objective of the present

invention to provide a method of producing an ophthalmic lens with embedded components that, while based on common ophthalmic lens-forming techniques that use molds, does not cause floating or shifting of the  
5 embedded components during mating of molds, thus achieving improved position stability of the embedded components.

#### Solution to Problem

10 [0010]

The present inventors have conducted extensive studies to find a way to improve the position stability of embedded components and, through trials and failures in an effort to devise molds used for forming ophthalmic  
15 lenses and methods for forming the ophthalmic lenses using the molds, have come to focus on the use of specific molds to form impressions. The present inventors have envisioned that pre-forming a recess conforming to the shape of a component to be embedded on  
20 the surface of an ophthalmic lens may achieve stable positioning of the component to be embedded.

[0011]

Over the course of our continuous effort to further develop the above-described concept, the present  
25 inventors have ultimately devised a method for forming an ophthalmic lens by using a first male or female mold having on an ophthalmic lens-side surface of the mold a protrusion conforming to the shape of a component to be embedded, a second female or male mold that corresponds

to the first male or female mold and has no protrusion thereon, and a third male or female mold that corresponds to the second female or male mold and has no protrusion thereon. In particular, the present inventors  
5 have successfully formed an ophthalmic lens that has a component embedded in a desired position by subjecting an ophthalmic lens material to a first copolymerization reaction using the first male or female mold having the protrusion thereon as well as the second male or female  
10 mold having no protrusion to obtain on a surface of the second female or male mold a first layer of the ophthalmic lens having a recess formed thereon corresponding to the protrusion, placing the component in the formed recess, and subsequently, subjecting an  
15 additional ophthalmic lens material to a second copolymerization reaction using a third male or female mold with no protrusion to form the ophthalmic lens with the component embedded in the desired position. It is these findings and successful examples that have led to  
20 the completion of the present invention.

[0012]

Accordingly, the present invention provides a method for manufacturing an ophthalmic lens having a component embedded therein, the method comprising the  
25 steps of:

(A1) mating a first male mold with a first female mold with a first ophthalmic lens material injected therein, and subjecting the first ophthalmic lens material to a first copolymerization reaction to form a first layer of

the ophthalmic lens on a concave forming surface of the first female mold, wherein the first male mold has a convex forming surface having a protrusion thereon conforming to the shape of the component to be embedded  
5 within the ophthalmic lens, and the first female mold has the concave forming surface corresponding to the first male mold;

(B1) separating the first male mold from the first female mold, placing the component to be embedded in a  
10 recess in the first layer of the ophthalmic lens that corresponds to the protrusion, and injecting a second ophthalmic lens material onto the concave forming surface of the first female mold;

(C1) mating a second male mold with the first female  
15 mold with the second ophthalmic lens material injected therein, the second male mold having a convex forming surface corresponding to the first female mold, and subjecting the second ophthalmic lens material to a second copolymerization reaction to form a second layer  
20 of the ophthalmic lens over the concave forming surface of the first female mold; and

(D1) separating the second male mold from the first female mold to obtain the ophthalmic lens having the component embedded between the second layer and the  
25 first layer.

[0013]

Accordingly, the present invention provides a method for manufacturing an ophthalmic lens having a component embedded therein, the method comprising the

steps of:

(A2) mating a third male mold with a second female mold with a third ophthalmic lens material injected therein, and subjecting the third ophthalmic lens material to a first copolymerization reaction to form a first layer of the ophthalmic lens on a convex forming surface of the third male mold, wherein the second female mold has a concave forming surface having a protrusion thereon conforming to the shape of the component to be embedded within the ophthalmic lens, and the third male mold has the convex forming surface corresponding to the second female mold;

(B2) separating the second female mold from the third male mold, placing the component to be embedded in a recess in the first layer of the ophthalmic lens corresponding to the protrusion, and injecting a fourth ophthalmic lens material onto a concave forming surface of a third female mold that corresponds to the third male mold;

(C2) mating the third male mold with the third female mold with the fourth ophthalmic lens material injected therein, and subjecting the fourth ophthalmic lens material to a second copolymerization reaction to form a second layer of the ophthalmic lens on the first layer of the ophthalmic lens on the convex forming surface of the third male mold; and

(D2) separating the third male mold from the third female mold to obtain the ophthalmic lens with the component embedded between the second layer and the

first layer.

[0014]

In the method for manufacturing an ophthalmic lens having a component embedded therein, the ratio of the thickness of the first layer at its center to the  
5 thickness of the second layer at its center is preferably in the range of 1:0.1 to 1:25.

[0015]

In the method for manufacturing an ophthalmic lens  
10 having a component embedded therein, the first and the second layers are formed of the same material.

[0016]

In the method for manufacturing an ophthalmic lens having a component embedded therein, the first and the  
15 second layers are formed of different materials.

#### Advantageous Effects of Invention

[0017]

According to the present invention, the ophthalmic  
20 lenses having a component embedded in a desired position can be formed in a reliable fashion. The ophthalmic lenses obtained according to the present invention do not cause damage to the eye tissue when wearing them since the embedded components are not exposed on the  
25 surface of the ophthalmic lens.

[0018]

In addition, the ophthalmic lenses obtained according to the present invention do not have adverse effects on the optical characteristics of the ophthalmic

lens since the embedded components do not interfere with the optical zone. By pre-forming an impression of a component to be embedded, the ophthalmic lens of the present invention allows precise embedding of any  
5 component, thus allowing embedding of a more precise, sophisticated component with more complicated geometry. Accordingly, the ophthalmic lens is expected to find wide applications in cosmetic and medical uses.

#### 10 Brief Description of Drawings

[0019]

FIG. 1 is a diagram illustrating a first embodiment of a mold for use in the present invention.

FIG. 2 is a schematic diagram of a production  
15 method of an ophthalmic lens according to the first embodiment of the present invention.

FIG. 3 is a diagram illustrating a second embodiment of the mold for use in the present invention.

FIG. 4 is a schematic diagram of a production  
20 method of an ophthalmic lens according to the second embodiment of the present invention.

FIG. 5A is a schematic diagram illustrating an ophthalmic lens with a chip-shaped (rectangular) measurement device as the embedded component of the  
25 present invention inserted therein.

FIG. 5B is a schematic diagram illustrating an ophthalmic lens with a chip-shaped (circular) measurement device as the embedded component of the present invention inserted therein.

FIG. 6 is a schematic diagram illustrating an ophthalmic lens with an annular measurement device as the embedded component of the present invention inserted therein.

5

#### Detailed Description of the Invention

[0020]

While a method for forming an ophthalmic lens with an embedded component in accordance with the present invention (which may be referred to as "method of the present invention," hereinafter) will now be described in further details, the scope of the present invention is not limited to what is described in this section; rather, the present invention may take various other forms to the extent that its objectives are achieved.

15

[0021]

The method of the present invention includes forming a recess in a first layer of an ophthalmic lens formed of at least two layers and placing a desired component in the recess to make an ophthalmic lens with the component embedded between the two layers.

20

[0022]

The method of the present invention may be based on the following two general approaches: - a first approach using a combination of a special male mold with a protrusion formed thereon and a normal female mold to form a first layer of an ophthalmic lens with a recess formed therein; - a second approach using a combination of a normal male mold and a special female mold with a

25

protrusion formed thereon to form a first layer of an ophthalmic lens with a recess formed therein.

[0023]

5 The only difference between "special mold" and "normal mold" is that a special mold has a protrusion on its surface while a normal mold does not. Otherwise, the molds are not distinguished from each other unless otherwise specified, and their materials and sizes may be identical or different.

10 [0024]

While the ophthalmic lens produced in this manner has a two-layered structure, ophthalmic lenses with two or more layers each having an embedded component can be obtained by using molds having varying arrangements of protrusions. While the material or composition for the first and the second layers are described herein as a first, second, third, or fourth ophthalmic lens material, they are not particularly limited and may be identical to or different from each other.

20 [0025]

[1. First forming method of the present invention]

A first method of forming an ophthalmic lens with an embedded component in accordance with the present invention includes at least the following Steps (A1) to (D1) below:

(A1) mating a first male mold with a first female mold with a first ophthalmic lens material injected therein, and subjecting the first ophthalmic lens material to a first copolymerization reaction to form a first layer of

the ophthalmic lens on a concave forming surface of the first female mold, wherein the first male mold has a convex forming surface having a protrusion thereon conforming to the shape of a component to be embedded  
5 within the ophthalmic lens, and the first female mold has the concave forming surface corresponding to the first male mold;

(B1) separating the first male mold from the first female mold, placing the component to be embedded in a  
10 recess in the first layer of the ophthalmic lens that corresponds to the protrusion, and injecting a second ophthalmic lens material onto the concave forming surface of the first female mold;

(C1) mating a second male mold with the first female  
15 mold with the second ophthalmic lens material injected therein, the second male mold having a convex forming surface corresponding to the first female mold, and subjecting the second ophthalmic lens material to a second copolymerization reaction to form a second layer  
20 of the ophthalmic lens over the concave forming surface of the first female mold; and

(D1) separating the second male mold from the first female mold to obtain the ophthalmic lens having the component embedded between the second layer and the  
25 first layer.

[0026]

In brief, the first method of the present invention provides an ophthalmic lens in the following manner: In Step (A1), a first male mold on which a protrusion

conforming to a component to be embedded has been pre-formed is mated with a first female mold in which a first ophthalmic lens material has been injected. The first ophthalmic lens material is then subjected to a first copolymerization reaction to form a first layer. Next, in Step (B1), the first male mold is separated from the first female mold and a component to be embedded is placed in a recess formed in the first layer within the first female mold, the recess corresponding to the protrusion. A second ophthalmic lens material is then injected into the first female mold. Next, in Step (C1), a second male mold is mated with the first female mold and the second ophthalmic lens material is subjected to a second copolymerization reaction to form a second layer over a concave forming surface of the first female mold. Next, in Step (D1), the second male mold is separated from the first female mold to obtain an ophthalmic lens. As described above, in the first method of the present invention, the first male mold corresponds to the special mold having a protrusion thereon whereas the second male mold and the first female mold each correspond to the normal mold without any protrusion. The first and the second ophthalmic lens material may be identical to or different from each other.

[0027]

According to the method of the present invention, an ophthalmic lens can be achieved that has a component reliably embedded at a desired position within the lens.

In the method of the present invention, Steps (A1) to (D1) and Steps (A2) to (D2) do not necessarily have to be performed sequentially; rather, various other steps or processes may be performed between or during steps to the extent that the objectives of the present invention are achieved.

[0028]

The present invention will now be described specifically with reference to the accompanying drawings. In the present invention, an ophthalmic device is formed in at least two polymerization steps to have a two-layered structure. With reference to FIGS. 1 and 2, in Step (A1) of a first method of the present invention, a first male mold 1 is mated with a first female mold 3 with a first ophthalmic lens material injected therein. The first ophthalmic lens material is then subjected to a copolymerization reaction to form a first layer 6 of an ophthalmic lens on a concave forming surface of the first female mold 3.

[0029]

The first male mold 1 has a convex forming surface and a protrusion 5 pre-formed on the surface of the mold and conforming to the shape of a component for being embedded within the ophthalmic lens. As used herein, "the surface of the first male mold 1" refers to a surface of the first male mold 1 on the side that mates with the paired first female mold 3. In addition to the protrusion 5, the surface of the first male mold 1 also has an optical area 4. The optical area 4 corresponds to

the optical zone of the formed ophthalmic lens. The position of the protrusion 5 is not particularly limited as long as the optical area 4 is not affected; it is formed at a desired position depending on the use and the shape of the component to be embedded. In the present invention, the height  $z$  of the protrusion 5 is preferably from 50% to 150% of the thickness  $w_1$  of the component to be embedded. The height  $z$  of the protrusion 5 corresponds to the depth of the recess in the first layer 6 formed in the subsequent step. The thickness  $w_1$  of the component to be embedded refers to the height of the component in the direction along which the component is embedded. As used herein, "the center of the first layer 6" corresponds to the center of the ophthalmic lens 8 formed in the subsequent step and refers to the center of the mold on which the first layer 6 is formed.

[0030]

The first female mold 3 having the concave forming surface is formed to correspond to the first male mold 1 with the protrusion 5 formed thereon. The diameter of the first male mold 1 and the diameter of the first female mold 3 are the same size  $x_1$  and corresponds to the diameter of the ophthalmic lens 8 formed in the subsequent step. The height  $y_1$  of the first male mold 1 indicates the vertical height measured from the outer edge of the first layer formed between the first male mold 1 and the first female mold 3 upon mating of the molds to the lens center on the surface of the first layer facing the first male mold 1.

[0031]

Referring to FIG. 2, the ophthalmic lens material is injected into the forming surface of the first female mold 3. The first female mold 3 is then mated with the forming surface of the first male mold 1 on which the protrusion 5 is formed. The first copolymerization reaction is then carried out. In this manner, the first layer 6 of the ophthalmic lens with a recess corresponding to the shape of the component to be embedded is formed on the surface of the first female mold 3.

[0032]

In the method of the present invention, the ophthalmic lens materials for forming the two-layered structure may be identical or different for the first and the second layers. Examples of the materials of the ophthalmic lens include monomer components, such as hydrophilic monomers, hydrophobic monomers, silicone monomers and cross-linkable monomers, preferably (meth)acrylate monomers. The material for the ophthalmic lens is properly selected to provide the physical properties of the desired ophthalmic lens. The amount of the monomer component may be any suitable amount that allows the resulting copolymer obtained by the copolymerization reaction to maintain its formability and is not particularly limited. For example, the monomer components may be used in amounts commonly used in the production of contact lenses.

[0033]

Examples of the hydrophilic (meth)acryl monomer include 2-hydroxyethyl (meth)acrylate (HEMA), 2-hydroxymethyl (meth)acrylate, hydroxypropyl (meth)acrylate, and glycerol (meth)acrylate.

5 [0034]

Examples of the hydrophobic (meth)acryl monomer include straight-chained, branched or cyclic alkyl (meth)acrylates, such as methyl (meth)acrylate (MMA), ethyl (meth)acrylate, propyl (meth)acrylate, i-propyl (meth)acrylate, n-butyl (meth)acrylate, i-butyl (meth)acrylate, t-butyl (meth)acrylate, 2-ethylhexyl (meth)acrylate, cyclohexyl (meth)acrylate, benzyl (meth)acrylate, and lauryl acrylate (LA); and fluorine-based (meth)acrylates, such as trifluoroethyl (meth)acrylate, tetrafluoropropyl (meth)acrylate (V-4F), tetrafluoropentyl (meth)acrylate, and hexafluorobutyl (meth)acrylate.

[0035]

Examples of the silicone (meth)acryl monomer include methacryloxypropylbis(trimethylsiloxy)methylsilane,  $\alpha,\omega$ -dimethacryloxypropyl polydimethylsiloxane (FM7725),  $\alpha$ -methacryloxy- $\omega$ -butylpolydimethylsiloxane, methacryloxy propyltris(trimethylsiloxy)silane, and tris(trimethylsiloxy)silylpropylmethacrylate (TRIS).

[0036]

Examples of the cross-linkable (meth)acryl monomer include ethyleneglycol di(meth)acrylate (EDMA), and trimethylol propanetri(meth)acrylate.

[0037]

Example of the polymerization initiator used in the polymerization of a mixture of the above-described monomers include common radical polymerization  
5 initiators including peroxides such as lauroyl peroxide, cumene hydroperoxide, and benzoyl peroxide, and azobis valeronitrile and azobisisobutyronitrile (AIBN). The amount of the polymerization initiator may be any suitable amount for achieving its desired objective and  
10 is not particularly limited. For example, the polymerization initiator is used in an amount of about 10 ppm to about 3500 ppm with respect to the total amount of monomers.

[0038]

15 The ophthalmic lens material in the present invention may contain a UV-absorber. Specific examples include 2-hydroxy-4-(meth)acryloyloxybenzophenone, 2-hydroxy-4-(meth)acryloyloxy-5-t-butylbenzophenone, 2-(2'-hydroxy-5'-(meth)acryloyloxyethylphenyl)-2H-  
20 benzotriazole, 2-(2'-hydroxy-5'-(meth)acryloyloxyethylphenyl)-5-chloro-2H-benzotriazole, 2-hydroxy-4-methacryloyloxymethyl phenylbenzoate, and methacrylic acid 2-[3-(2H-benzotriazole-2-yl)-4-hydroxyphenyl]ethyl (RUVA). The UV-absorber may be added  
25 in any suitable amount to provide desired UV absorption ability.

[0039]

The polymerization initiator is added to a mixture of any combination of the hydrophilic (meth)acryl

monomer, the hydrophobic (meth)acryl monomer, the  
silicone (meth)acryl monomer, and the cross-linkable  
(meth)acryl monomer and the mixture is stirred to  
dissolve the monomer components to obtain a monomer  
5 mixture.  
[0040]

The resulting monomer mixture is placed in a mold  
formed of a material such as metal, glass, or plastic  
and the mold is sealed. The temperature of the mold is  
10 then raised to 25°C to 130°C either stepwise or  
continuously using for example a temperature-controlled  
bath and maintained for 5 hours to 120 hours to complete  
the polymerization. UV light, electron beams or gamma-  
rays may also be used for polymerization. Alternatively,  
15 water or an organic solvent may be added to the monomer  
mixture to carry out solution polymerization.  
[0041]

With reference to FIG. 2, in Step (B1) of the first  
method of the present invention, the first male mold 1  
20 and the first female mold 3 are separated from one  
another after formation of the first layer 6 on the  
first female mold 3 in Step (A1). As a result, a recess  
corresponding to the shape of the component to be  
embedded is formed on the surface of the first layer 6  
25 of the ophthalmic lens. The shape of the recess is  
determined based on the shape of the protrusion 5.  
Specifically, the height  $z$  of the protrusion provides  
the depth of the recess.  
[0042]

Subsequently, a component to be embedded (i.e., insert) is placed in the recess formed on the first layer 6 in the first female mold 3. A second ophthalmic lens material is then injected into the first female mold 3. It should be noted that the materials do not necessarily have to be added by injection; they may simply be added.

[0043]

In the present invention, the component to be embedded within the ophthalmic lens may take various desired forms depending on the functions imparted to the contact lens. In forming a fashion contact lens, for example, the component preferably has an annular shape with an iris pattern arranged on it. In forming a contact lens for monitoring and/or examination of a biological function, the component preferably takes the form of a chip that can serve as a sensor for the biological function or may have an annular shape.

[0044]

FIG. 5A shows one example of an ophthalmic lens with an embedded measurement device 17A in the form of a chip (rectangular in shape) to serve as a sensor. FIG. 5B shows one example of an ophthalmic lens with an embedded measurement device 17B in the form of a chip (circular in shape) to serve as a sensor. FIG. 6 shows one example of an ophthalmic lens with an embedded annular measurement device 18 to serve as a sensor. A combination of the annular form and the chip form may also be used.

[0045]

The thickness of the ophthalmic lens at its center is not particularly limited. For example, the thickness at the center may be not greater than 0.5 mm.

5 [0046]

The thickness  $w_1$  of the component embedded in the ophthalmic lens (also referred to as "components to be embedded") is not particularly limited. The present invention allows, for example, embedding a component  
10 with a thickness of 0.001 mm or more, preferably 0.01 mm or more, more preferably 0.1 mm or more, and still more preferably 0.2 mm or more.

[0047]

The position of the component to be embedded is  
15 within the formed lens, and is not particularly limited as long as it is positioned outside the optical zone. Preferably, the component to be embedded is positioned such that the center of the component to be embedded is located at the edge part of the surface of the first  
20 layer, for example, 1 mm to 5 mm from the outer edge of the formed ophthalmic lens. According to the method of the present invention, when the component to be embedded has a detector portion on one side of the component, the component may be placed to be oriented as desired, for  
25 example, in such a manner that the side with the detector portion faces toward the inside of the eye.

[0048]

The second ophthalmic lens material injected into the first female mold 3 may be identical to or different

from the lens material used in the previous Step (A1) and may be properly selected for its type and compositional ratio depending on the ophthalmic lens one wishes to obtain.

5 [0049]

With reference to FIGS. 1 and 2, in Step (C1) of the first method of the present invention, a second male mold 2 corresponding to the first female mold 3 is mated with the first female mold 3 with the second ophthalmic lens material injected therein. The second ophthalmic lens material is then subjected to a second copolymerization reaction to form a second layer 7. The second male mold 2 has a convex forming surface without any protrusion like the one formed on the first male mold 1. The diameter  $x_2$  of the second male mold 2 is the same as the diameter  $x_1$  of the first male mold 1 used in Steps (A1) and (B1). The height  $y_2$  of the second male mold 2 indicates the vertical height measured from the contact point between the second male mold 2 and the first female mold 3 that are mated together, or the outer edge of the first layer 6 or the second layer 7 formed therebetween, to the lens center on the surface of the second layer 7 facing the second male mold 2. The height  $y_2$  of the second male mold 2 is preferably 50% to 99.9%, more preferably 75% to 99%, and still more preferably 80% to 99% with respect to the height  $y_1$  of the first male mold 1 used in Steps (A1) and (B1). This realizes the two-layered structure of the ophthalmic lens.

[0050]

With reference to FIG. 2, in Step (D1) of the present invention, the second male mold 2 and the first female mold 3 that were mated together in Step (C1) are  
5 separated from one another to obtain an ophthalmic lens 8 having the component embedded between the second layer 7 and the first layer 6.

[0051]

After separation of the second male mold 2 and the  
10 first female mold 3, one of the molds that has the attached ophthalmic lens 8 is immersed in a solution to remove the lens from the mold. This gives a desired ophthalmic lens. The separation means is not particularly limited. For example, the separation-by-  
15 swelling technique using an organic solvent or a mixture of organic solvent/water may be employed. The organic solvent used in the separation-by-swelling technique is not particularly limited and may be any organic solvent that can undergo solvation and is miscible with water  
20 when the lens material contains a silicone-containing monomer. For example, the organic solvent may be a primary or secondary alcohol. Specific examples of the organic solvent used in the removal by swelling include, but are not limited to, methanol, ethanol, propanol, isopropanol, n-butanol, and isobutanol. The organic  
25 solvents used in the removal by swelling may be used either alone or as a mixture of two or more solvents. When removed from the ophthalmic lens mold, a silicone-based soft ophthalmic lens from which unreacted

components have been removed can be obtained. When the ophthalmic lens material includes a hydrous monomer, physiological saline and phosphate buffer may also be used.

5 [0052]

The ophthalmic lens 8 formed to have the above-described construction has a ratio of the thickness  $m_1$  at the center of the first layer to the thickness  $n_1$  at the center of the second layer in the range of 1:0.1 to 1:25, preferably in the range of 1:0.1 to 1:20. This allows the component to be effectively embedded within the ophthalmic lens. The thickness  $m_1$  at the center of the first layer 6 is defined as the distance between the lens center on the convex forming surface of the first male mold 1 and the lens center of the first female mold 3. The thickness  $n_1$  at the center of the second layer 7 is defined as the distance between the lens center on the convex forming surface of the second male mold 2 and the lens center of the forming inner surface of the first female mold 3 minus the thickness  $m_1$  at the center of the first layer.

[0053]

The first layer 6 of the ophthalmic lens 8 with the recess for placing the component therein, which is obtained in Steps (A1) and (B1) of the first method of the present invention, selectively adheres to a normal mold with no protrusion, that is, the first female mold 3 in FIG. 2, with the recess left open, when the first male mold 1 is separated from the first female mold 3.

[0054]

In order for the first layer 6 of the ophthalmic lens to selectively adhere to a desired mold, the affinity of the mold, in this case, the first female mold 3, toward the first layer 6 of the ophthalmic lens is increased. In an embodiment where the first male mold 1 and the first female mold 3 are formed of the same resin, one exemplary process for increasing the affinity involves modifying the surface of the mold to which one wishes to adhere the ophthalmic lens, for example, the surface of the first female mold 3 in FIG. 2, with a physical treatment such as plasma irradiation and corona discharge. Subsequently, the mold combination is used to perform copolymerization reaction of the ophthalmic lens. The process, however, is not limited to this one. In this manner, the adhesion of the first layer 6 of the ophthalmic lens to the mold 3 is increased, thus allowing the first layer 6 of the ophthalmic lens to selectively adhere to a desired mold. In such instances, the resin may be properly selected from the resins listed below regardless of the nature of the ophthalmic lens.

[0055]

The resin used to make the molds is not particularly limited; any resin that is inert and does not have solubility to the ophthalmic lens material can be used equally whether the mold is a special mold with a protrusion or a normal mold with no protrusion, or whether the mold is a male mold or a female mold.

Specific examples of the resin include, but are not limited to, polyethylene, polypropylene, ethylene/vinyl acetate, polystyrene, AS resins, ABS resins, polymethylmethacrylate, polyvinyl chloride, cellulose resins, polyacetal, polyamide, polybutylene terephthalate, polyethylene terephthalate, polycarbonate, denatured polyphenylene ether, polyphenylene sulfide, polyether ether ketone, liquid crystal polymers, polysulfone, polyether sulfone, polyarylate, polyamide-imide, polyetherimide, polymethylpentene, phenol resins, urea resins, melamine resins, and epoxy resins. These resins used to make the molds may be used either individually or in combination of two or more resins. The technique for forming the molds may be properly selected from injection molding and other known techniques such as compression molding and vacuum molding. Polypropylene is preferably used for its formability.

[0056]

In another embodiment where the first male mold 1 and the first female mold 3 are formed of different resins, the mold to which one wishes to adhere the first layer 6 of the ophthalmic lens, that is, normal first female mold 3, is formed of a resin having a high affinity for the first layer 6 of the ophthalmic lens, whereas the corresponding mold, or first male mold 1, is formed of a resin having a low affinity for the ophthalmic lens. Subsequently, the mold combination is used to perform copolymerization reaction of the

ophthalmic lens. This allows the first layer 6 of the ophthalmic lens to selectively adhere to the desired mold, or the first female mold 3.

[0057]

5 [2. Second forming method of the present invention]

As another embodiment of the method of the present invention, a second method of forming an ophthalmic lens with an embedded component in accordance with the present invention includes at least the following Steps

10 (A2) to (D2) below:

(A2) mating a third male mold with a second female mold with a third ophthalmic lens material injected therein, and subjecting the third ophthalmic lens material to a first copolymerization reaction to form a first layer of  
15 the ophthalmic lens on a convex forming surface of the third male mold, wherein the second female mold has a concave forming surface having a protrusion thereon conforming to the shape of the component to be embedded within the ophthalmic lens, and the third male mold has  
20 the convex forming surface corresponding to the second female mold;

(B2) separating the second female mold from the third male mold, placing the component to be embedded in a recess in the first layer of the ophthalmic lens  
25 corresponding to the protrusion, and injecting a fourth ophthalmic lens material onto a concave forming surface of a third female mold that corresponds to the third male mold;

(C2) mating the third male mold with the third female

mold with the fourth ophthalmic lens material injected therein, and subjecting the fourth ophthalmic lens material to a second copolymerization reaction to form a second layer of the ophthalmic lens on the first layer of the ophthalmic lens on the convex forming surface of the third male mold; and  
(D2) separating the third male mold from the third female mold to obtain the ophthalmic lens with the component embedded between the second layer and the first layer.

[0058]

Unlike the first method, the second method of the present invention uses a combination of a normal male mold and a special female mold with a protrusion formed thereon to form a first layer with a recess formed therein. Thus, the method is performed in the same manner as the first method of the present invention, except that the mold having a pre-formed protrusion conforming to the shape of the component to be embedded is changed from the first male mold used in the first method of the present invention, to a second female mold with a concave forming surface; that the mold on which to form the first layer is changed from the first female mold to a third male mold with a convex forming surface; that a second material (i.e., fourth ophthalmic lens material) is injected into a third female mold beforehand, and that the third male mold with the first layer is mated with the third female mold having the injected material to perform a second copolymerization

reaction. The normal third male mold may be identical to or different from the normal second male mold used in the first method. Also, the normal third female mold may be identical to or different from the normal first  
5 female mold used in the first method. The differences from the first method are described in detail below.  
[0059]

With reference to FIGS. 3 and 4, in Step (A2) of a second method of the present invention, a third male  
10 mold 11 is mated with a second female mold 9 with a third ophthalmic lens material injected therein. The third ophthalmic lens material is then subjected to a copolymerization reaction to form a first layer 14 of an ophthalmic lens on a convex forming surface of the third  
15 male mold 11.  
[0060]

The second female mold 9 has a concave forming surface and a protrusion 13 formed on the surface of the mold and conforming to the shape of a component for  
20 being embedded within the ophthalmic lens. As used herein, "the surface of the second female mold 9" refers to a surface of the second female mold 9 on the side that mates with the paired third male mold 11. In addition to the protrusion 13, the surface of the second  
25 female mold 9 also has an optical area 12. The optical area 12 is a similar optical area to the optical area 4. The position of the protrusion 13 is not particularly limited as long as the optical area 12 is not affected; it is formed at a desired position depending on the use

and the shape of the component to be embedded. In the present invention, the height  $u$  of the protrusion 13 is preferably from 50% to 150% of the thickness  $w_2$  of the component to be embedded. The height  $u$  of the protrusion 13 corresponds to the depth of the recess in the first layer 14 formed in the subsequent step. The thickness  $w_2$  of the component to be embedded refers to the height of the component in the direction along which the component is embedded. As used herein, "the center of the first layer 14" corresponds to the center of the ophthalmic lens 16 formed in the subsequent step and refers to the center of the mold on which the first layer 14 is formed.

[0061]

15           The third male mold 11 having the convex forming surface is formed to correspond to the second female mold 9 with the protrusion 13 formed thereon. The diameter of the second female mold 9 and the diameter of the third male mold 11 are the same size  $s_1$  and  
20           corresponds to the diameter of the ophthalmic lens 16 formed in the subsequent step. The height  $t_1$  of the second female mold indicates the vertical height measured from the outer edge of the first layer formed between the second female mold 9 and the third male mold  
25           11 upon mating of the molds to the lens center on the surface of the first layer facing the second female mold 9.

[0062]

Referring to FIG. 4, the third ophthalmic lens

material is injected into the forming surface of the second female mold 9. The second female mold 9 is then mated with the forming surface of the third male mold 11. The first copolymerization reaction is then carried out. In this manner, the first layer 14 of the ophthalmic lens with a recess corresponding to the shape of the component to be embedded is formed on the surface of the third male mold 11. The formation of the first layer by copolymerization reaction is similar to that in the first method described above.

[0063]

With reference to FIG. 4, in Step (B2) of the second method of the present invention, the second female mold 9 and the third male mold 11 are separated from one another after formation of the first layer 14 on the third male mold 11 in Step (A2). As a result, a recess corresponding to the shape of the component to be embedded is formed on the surface of the first layer 14 of the ophthalmic lens. The shape of the recess is determined based on the shape of the protrusion 13. Specifically, the height  $u$  of the protrusion 13 provides the depth of the recess.

[0064]

Subsequently, a component to be embedded (i.e., insert) is placed in the recess formed on the first layer 14 on the third male mold 11. A fourth ophthalmic lens material is then injected into a third female mold 10.

[0065]

The component to be embedded and the ophthalmic lens materials are similar to those used in the first method. Thus, the height w2 of the component to be embedded is similar to w1 described above.

5 [0066]

With reference to FIGS. 3 and 4, the third female mold 10 has a concave forming surface that corresponds to the third male mold 11 and does not have any protrusion like the one formed on the first female mold 9. The diameter s2 of the third female mold 10 is the same as the diameter s1 of the second female mold 9 used in Steps (A2) and (B2). The height t2 of the third female mold 10 indicates the vertical height measured from the contact point between the third female mold 10 and the third male mold 11 when mated together, or the outer edge of the first layer 14 or the second layer 15 formed therebetween, to the lens center on the surface of the second layer 15 facing the third female mold 10. The height t2 of the third female mold 10 is preferably 100.1% to 200%, more preferably 101% to 150%, and still more preferably 101% to 125% with respect to the height t1 of the second female mold 9 used in Steps (A2) and (B2). This realizes the two-layered structure of the ophthalmic lens.

25 [0067]

With reference to FIG. 4, in Step (D2) of the present invention, the third male mold 11 and the third female mold 10 that were mated together in Step (C2) are separated from one another to obtain an ophthalmic lens

16 having the component embedded between the second layer 15 and the first layer 14.

[0068]

After separation of the third male mold 11 and the  
5 third female mold 10, one of the molds that has the attached ophthalmic lens 16 is immersed in a solution to remove the lens from the mold. This gives a desired ophthalmic lens.

[0069]

10 The ophthalmic lens 16 formed to have the above-described construction has a ratio of the thickness  $m_2$  at the center of the first layer to the thickness  $n_2$  at the center of the second layer in the range of 1:0.1 to 1:25, preferably in the range of 1:0.1 to 1:20. This  
15 allows the component to be effectively embedded within the ophthalmic lens. The thickness  $m_2$  at the center of the first layer 14 is defined as the distance between the lens center on the convex forming surface of the third male mold 11 and the lens center on the concave  
20 forming inner surface of the second female mold 9. The thickness  $n_2$  at the center of the second layer 15 is defined as the distance between the lens center on the concave forming surface of the third female mold 10 and the lens center of the convex forming surface of the  
25 third male mold 11 minus the thickness  $m_2$  at the center of the first layer.

[0070]

Also in the second method of the present invention, the first layer 14 of the ophthalmic lens 16 with the

recess for placing the component therein should selectively adhere to a normal mold with no protrusion, that is, the third male mold 11 in FIG. 4, with the recess left open, when the third male mold 11 is separated from the second female mold 9. In order for the first layer 14 of the ophthalmic lens to selectively adhere to a desired mold, the affinity of the normal mold, in this case, the third male mold 11, toward the first layer 14 of the ophthalmic lens may be increased.

10 [0071]

It should be noted that in the first method of the present invention, a layer including the outer side (i.e., the side opposite the eye contacting side) of the resulting ophthalmic lens is first formed as the first layer, followed by the formation of the second layer including the inner side of the ophthalmic lens. Conversely, in the second method of the present invention, the inner side of the ophthalmic lens is first formed as the first layer, followed by the formation of the second layer including the outer side of the ophthalmic lens. This order is not particularly limited and either method may be used to embed the component within the ophthalmic lens in a reliable fashion. Thus, the materials and compositional ratios for the ophthalmic lens may be selected depending on the desired component to be embedded to form an ophthalmic lens having a two-layered structure.

[0072]

An ophthalmic lens refers to any ophthalmic device

present within or on the eye. Such devices may be either those intended to provide optical correction or those intended to provide aesthetic effects. Examples include contact lenses, intraocular lenses, overlay lenses, eye  
5 inserts, optical inserts, other devices providing similar vision correction or modification, and devices that can improve physiological functions or aesthetics of the eye, for example, by changing iris color, without interfering with the vision. One preferred embodiment of  
10 the present invention is a contact lens.

[0073]

The ophthalmic lens with an embedded component allows precise positioning of the component to be embedded by using a mold that has a pre-formed  
15 impression of the component. As described in Examples, the ophthalmic lens with an embedded component provides improved selective adhesion of the embedded component as well as improved stability without causing shifting or protruding of the embedded component. The ophthalmic  
20 lens with an embedded component allows to pre-determine the orientation of complex and delicate components, such as medical devices, and are therefore highly convenient for the wearers.

[0074]

25 In addition to the above-described steps, the method of the present invention may include combinations of various other steps known to those skilled in the art as long as the production method of the ophthalmic lens with embedded components can be achieved. While such

other steps are not particularly limited, the method of the present invention may, for example, include the following specific steps:

- (A1) mating a first male mold with a first female mold  
5 with an ophthalmic lens material injected therein, the ophthalmic lens material containing a monomer component being selected from the group consisting of hydrophilic monomers, hydrophobic monomers, silicone monomers, and cross-linkable monomers, and subjecting the ophthalmic  
10 lens material to a copolymerization reaction to form a first layer of the ophthalmic lens on a concave forming surface of the first female mold, wherein the first male mold has a convex forming surface having a protrusion thereon that conforms to the shape of an annular  
15 component having an iris pattern or an sensor component for a biological function to be embedded within the ophthalmic lens, wherein the first female mold has the concave forming surface corresponding to the first male mold, and wherein the height of the protrusion is 50% to  
20 150% of the thickness of the component to be embedded;
- (B1) separating the first male mold from the first female mold, placing the component to be embedded in a recess in the first layer of the ophthalmic lens that corresponds to the protrusion, and injecting a second  
25 ophthalmic lens material onto the concave forming surface of the first female mold, the second ophthalmic lens material containing the same or different components as that of the first ophthalmic lens;
- (C1) mating a second male mold with the first female

mold with the second ophthalmic lens material injected therein, the second male mold having a convex forming surface corresponding to the first female mold, and subjecting the second ophthalmic lens material to a  
5 second copolymerization reaction to form a second layer of the ophthalmic lens over the concave forming surface of the first female mold, wherein the height of the second male mold is 50% to 99.9% of the height of the first male mold, and wherein the ratio of the thickness  
10 at the center of the first layer to the thickness at the center of the second layer is 1:0.1 to 1:25; and  
(D1) separating the second male mold from the first female mold to obtain the ophthalmic lens having the component embedded between the second layer and the  
15 first layer, wherein the thickness of the component to be embedded is less than 0.5 mm, and wherein the orientation of the component to be embedded is such that the center of the component to be embedded is positioned 1 mm to 5 mm from the outer edge of the ophthalmic lens.  
20 [0075]

For example, the method of the present invention can include the following other specific steps:

(A2) mating a third male mold with a second female mold with a third ophthalmic lens material injected therein,  
25 the third ophthalmic lens material containing a monomer component being selected from the group consisting of hydrophilic monomers, hydrophobic monomers, silicone monomers, and cross-linkable monomers, and subjecting the third ophthalmic lens material to a first

copolymerization reaction to form a first layer of the ophthalmic lens on a convex forming surface of the third male mold, wherein the second female mold has a concave forming surface having a protrusion thereon that

5 conforms to the shape of an annular component having an iris pattern or an sensor component for a biological function to be embedded within the ophthalmic lens, wherein the third male mold has the convex forming surface corresponding to the second female mold, and

10 wherein the height of the protrusion is 50% to 150% of the thickness of the component to be embedded;

(B2) separating the second female mold from the third male mold, placing the component to be embedded in a recess in the first layer of the ophthalmic lens

15 corresponding to the protrusion, and injecting a fourth ophthalmic lens material onto a concave forming surface of a third female mold that corresponds to the third male mold, the fourth ophthalmic lens material containing the same or different components as the third

20 ophthalmic lens material;

(C2) mating the third male mold with the third female mold with the fourth ophthalmic lens material injected therein, and subjecting the fourth ophthalmic lens material to a second copolymerization reaction to form a

25 second layer of the ophthalmic lens over the first layer of the ophthalmic lens on the convex forming surface of the third male mold, wherein the height of the third female mold is 100.1% to 200% of the height of the second female mold, and wherein the ratio of the

thickness at the center of the first layer to the thickness at the center of the second layer is 1:0.1 to 1:25; and

(D2) separating the third male mold from the third female mold to obtain the ophthalmic lens having the component embedded between the second layer and the first layer, wherein the thickness of the component to be embedded is less than 0.5 mm, and wherein the orientation of the component to be embedded is such that the center of the component to be embedded is positioned 1 mm to 5 mm from the outer edge of the ophthalmic lens. [0076]

The present invention will now be described in further detail with reference to the following Examples, which are not intended to limit the present invention. The present invention may take various forms to the extent that the objectives of the present invention are achieved.

## Examples

[0077]

### [1. Formation of molds]

Molds each having a shape shown in Tables 1 to 12 were formed by injection molding to provide mold combinations 1 to 12 for use in the present invention. [0078]

#### (1) Combination 1

Combination 1 corresponds to the combination in the first configuration of the present invention (FIGS. 1

and 2) (Table 1). A combination of a first male mold 1 having a protrusion, a first female mold 3 corresponding to the first male mold 1, and a second male mold 2 corresponding to the female mold and having a height  $y_2$  lower than the height  $y_1$  of the first male mold 1 was prepared. The diameter  $x_1$ ,  $x_2$  were equal for each of the first male mold 1, the first female mold 3, and the second male mold 2. An annular iris pattern was used as the component to be embedded. The protrusion 5 of the first male mold 1 was an annular protrusion conforming to the shape of the component to be embedded and the height  $z$  of the protrusion was 133% relative to the thickness  $w_1$  of the component to be embedded. The first female mold 3 was subjected to corona discharge treatment.

[0079]

## (2) Combination 2

Combination 2 corresponds to the combination in the second configuration of the present invention (FIGS. 3 and 4) (Table 2). A combination of a second female mold 9 having a protrusion, a third male mold 11 corresponding to the second female mold 9, and a third female mold 10 corresponding to the male mold and having a height  $t_2$  higher than the height  $t_1$  of the second female mold 9 was prepared. The diameter  $s_1$ ,  $s_2$  was equal for each of the second female mold, the third male mold, and the third female mold. A chip-shaped measurement device 17A shown in FIG. 5A was used as the component to be embedded. The protrusion 13 of the

second female mold 9 was a square protrusion and the height  $u$  of the protrusion 13 was 150% relative to the thickness  $w_2$  of the component to be embedded. The third male mold 11 was subjected to corona discharge

5 treatment.

[0080]

### (3) Combination 3

Combination 3 corresponds to the combination in the first configuration of the present invention. An annular measurement device 18 shown in FIG. 6 was used as the component to be embedded. The height  $z$  of the protrusion was 75% relative to the thickness  $w_1$  of the component to be embedded. Otherwise, the combination had the same configuration (Table 3).

15 [0081]

### (4) Combination 4

Combination 4 corresponds to the combination in the second configuration of the present invention. The height  $u$  of the protrusion was 100% relative to the thickness  $w_2$  of the component to be embedded. Otherwise, the combination had the same configuration (Table 4).

[0082]

### (5) Combination 5

Combination 5 corresponds to the combination in the first configuration of the present invention. The diameter  $x_1$  of the first male mold 1 and that of the first female mold 3 were equal to each other whereas the diameter  $x_2$  of the second male mold 2 was larger than the diameter of the first male mold 1 and first female

mold 3. Otherwise, the combination had the same configuration (Table 5).

[0083]

(6) Combination 6

5           Combination 6 corresponds to the combination in the second configuration of the present invention. The diameter s1 of the second female mold 9 and that of the third male mold 11 were equal to each other whereas the diameter s2 of the third female mold 10 was larger than  
10 the diameter of the second female mold 9 and third male mold 11. Otherwise, the combination had the same configuration (Table 6).

[0084]

(7) Combination 7

15           Combination 7 corresponds to the combination in the first configuration of the present invention. The diameter x1 of the first male mold 1 and that of the first female mold 3 were equal to each other whereas the diameter x2 of the second male mold 2 was smaller than  
20 the diameter of the first male mold 1 and first female mold 3. Otherwise, the combination had the same configuration (Table 7).

[0085]

(8) Combination 8

25           Combination 8 corresponds to the combination in the second configuration of the present invention. The diameter s1 of the second female mold 9 and that of the third male mold 11 were equal to each other whereas the diameter s2 of the third female mold 10 was smaller than

the diameter of the second female mold 9 and third male mold 11. Otherwise, the combination had the same configuration (Table 8).

[0086]

5 (9) Combination 9

Combination 9 corresponds to the combination in the first configuration of the present invention with the height y2 of the second male mold 2 being higher than the height y1 of the first male mold 1. Otherwise, the combination had the same configuration (Table 9).

[0087]

(10) Combination 10

Combination 10 corresponds to the combination in the second configuration of the present invention with the height t2 of the third female mold 10 being lower than the height t1 of the second female mold 9. The height z of the protrusion was 100% relative to the thickness w2 of the component to be embedded. Otherwise, the combination had the same configuration (Table 10).

20 [0088]

(11) Combination 11

Combination 11 corresponds to the combination in the first configuration of the present invention. The combination had the same configuration, except that corona discharge treatment was not performed (Table 11).

[0089]

(12) Combination 12

Combination 12 corresponds to the combination in the first configuration of the present invention. The

combination had the same configuration, except that no protrusion was formed on the first male mold 1 and a chip-shaped measurement device 17A shown in FIG. 5A was used as the component to be embedded (Table 12).

5 [0090]

## [2. Preparation of ophthalmic lens materials]

The components were weighed in the respective amounts (wt%) shown in Table 13, stirred for 30 min, and mixed until uniform to prepare a formulation. The  
10 amounts of AIBN and RUVA indicate external amounts added with respect to the total amount of the monomers.

[0091]

## [3. Formation of ophthalmic lenses]

(Example 1) Formation of a same material silicone soft  
15 ophthalmic lens

According to Table 14, an ophthalmic lens material for first copolymerization (ophthalmic lens material 1 in Table 13) was dispensed into the corona discharge-treated female mold used in Combination 1 having a  
20 concave forming surface (Table 1). The male mold 1 with a convex forming surface was then mated with the female mold (FIGS. 1, 2). The mated molds were warmed stepwise from room temperature to 90°C to complete the first copolymerization reaction, thereby obtaining a first  
25 layer of an ophthalmic lens.

[0092]

The first male mold 1 of Combination 1 was removed and then, using tweezers, a component to be embedded (annular iris pattern) was placed in a recess on the

first layer 6 of the ophthalmic lens that had been formed on the first female mold 3 as a result of mating with the first male mold 1 (FIG. 2).

[0093]

5           Subsequently, an ophthalmic lens material for second copolymerization shown in Table 14 (ophthalmic lens material 1 in Table 13) was dispensed into the first female mold 3 having the first layer of the ophthalmic material formed thereon. The second male mold 10 2 was then mated with the female mold. The mated molds were warmed stepwise from room temperature to 90°C to complete the second copolymerization reaction, thereby obtaining a second layer 7 of the ophthalmic lens.

[0094]

15           The second male mold 2 was then removed and the first female mold 3 with the ophthalmic lens formed thereon was immersed in a solution shown in Table 14 (2-propanol: i-PrOH) and was left for 30 min at room temperature to remove the ophthalmic lens from the first 20 female mold 3.

[0095]

The ophthalmic lens removed from the mold was then placed in a vacuum dryer and treated at 80°C under reduced pressure for 150 min to remove the immersion 25 solution, thereby obtaining a desired ophthalmic lens 8.

[0096]

(Example 2) Formation of a same material silicone soft ophthalmic lens

A desired ophthalmic lens shown in Table 14 was

obtained in the same manner as in the production method of Example 1, except that the ophthalmic lens materials for first and second copolymerization were replaced by the ophthalmic lens material 2 shown in Table 13.

5 [0097]

(Example 3) Formation of a different material silicone soft ophthalmic lens

A desired ophthalmic lens shown in Table 14 was obtained in the same manner as in the production method  
10 of Example 1, except that the ophthalmic lens materials for first and second copolymerization were replaced by the ophthalmic lens materials 1 and 2 shown in Table 13, respectively and the solvent was replaced by ethanol (EtOH).

15 [0098]

(Example 4) Formation of a different material silicone soft ophthalmic lens

According to Table 14, an ophthalmic lens material for first copolymerization (ophthalmic lens material 2  
20 in Table 13) was dispensed into the second female mold 9 used in Combination 2 having a concave forming surface (Table 2). The corona discharge-treated third male mold 11 with a convex forming surface was then mated with the female mold (FIGS. 3, 4). The mated molds were warmed  
25 stepwise from room temperature to 90°C to complete the first copolymerization reaction, thereby obtaining a first layer 14 of an ophthalmic lens.

[0099]

The second female mold 9 of Combination 2 was

removed from the third male mold 11 and then, using  
tweezers, a component to be embedded (chip-shaped  
measurement device 17A) was placed in a recess on the  
first layer 14 of the ophthalmic lens that had been  
5 formed on the third male mold 11 as a result of mating  
with the second female mold 9 (FIG. 4).

[0100]

Subsequently, an ophthalmic lens material for  
second copolymerization shown in Table 14 (ophthalmic  
10 lens material 1 in Table 13) was dispensed into the  
third female mold 10 used in Combination 2 having a  
concave forming surface. The third male mold 11 with the  
first layer 14 of the ophthalmic lens formed thereon was  
then mated with the female mold. The mated molds were  
15 warmed stepwise from room temperature to 90°C to  
complete the second copolymerization reaction, thereby  
obtaining a second layer 15 of the ophthalmic lens.

[0101]

The third female mold 10 was then removed and the  
20 third male mold 11 with the ophthalmic lens formed  
thereon was immersed in a solution shown in Table 14 (i-  
PrOH/ EtOH) and was left for 30 min at room temperature  
to remove the ophthalmic lens from the third male mold  
11.

25 [0102]

The ophthalmic lens removed from the mold was then  
placed in a vacuum dryer and treated at 80°C under  
reduced pressure for 150 min to remove the immersion  
solution, thereby obtaining a desired ophthalmic lens 16

(FIG. 5A) .

[0103]

(Example 5) Formation of a same material silicone soft  
ophthalmic lens

5           A desired ophthalmic lens shown in Table 14 was  
obtained in the same manner as in the production method  
of Example 1, except that the molds used were replaced  
by Combination 3 in Table 3 (FIG. 6) .

[0104]

10          (Example 6) Formation of a same material silicone soft  
ophthalmic lens

            A desired ophthalmic lens shown in Table 14 was  
obtained in the same manner as in the production method  
of Example 2, except that the molds used were replaced  
15       by Combination 4 in Table 4 .

[0105]

(Example 7) Formation of a same material hydrous soft  
ophthalmic lens

            A desired ophthalmic lens shown in Table 14 was  
20       obtained in the same manner as in the production method  
of Example 1, except that the ophthalmic lens materials  
for first and second copolymerization were replaced by  
the ophthalmic lens material 3 shown in Table 13 and the  
solvent was replaced by physiological saline .

25       [0106]

(Example 8) Formation of a same material hydrous soft  
ophthalmic lens

            A desired ophthalmic lens shown in Table 14 was  
obtained in the same manner as in the production method

of Example 4, except that the ophthalmic lens materials for first and second copolymerization were replaced by the ophthalmic lens material 4 shown in Table 13 and the solvent was replaced by phosphate buffer.

5 [0107]

(Comparative Example 1) Formation of a same material silicone soft ophthalmic lens molded by molds with different diameters

A desired ophthalmic lens shown in Table 15 was  
10 obtained in the same manner as in Example 1, except that the molds used were replaced by Combination 5 in Table 5.

[0108]

(Comparative Example 2) Formation of a same material  
15 silicone soft ophthalmic lens molded by molds with different diameters

A desired ophthalmic lens shown in Table 15 was obtained in the same manner as in Example 4, except that the molds used were replaced by Combination 6 in Table  
20 6, the ophthalmic lens material for second copolymerization was replaced by the ophthalmic lens material 2 shown in Table 13, and the solvent was replaced by i-PrOH.

[0109]

25 (Comparative Example 3) Formation of a different material silicone soft ophthalmic lens molded by molds with different diameters

A desired ophthalmic lens shown in Table 15 was obtained in the same manner as in Example 3, except that

the molds used were replaced by Combination 7 in Table 7.

[0110]

(Comparative Example 4) Formation of a different  
5 material silicone soft ophthalmic lens molded by molds  
with different diameters

A desired ophthalmic lens shown in Table 15 was  
obtained in the same manner as in Example 4, except that  
the molds used were replaced by Combination 8 in Table 8  
10 and the solvent was replaced by i-PrOH.

[0111]

(Comparative Example 5) Formation of a same material  
silicone soft ophthalmic lens molded by molds with  
different heights

15 A desired ophthalmic lens shown in Table 15 was  
obtained in the same manner as in Example 1, except that  
the molds used were replaced by Combination 9 in Table 9  
and the solvent was replaced by EtOH.

[0112]

20 (Comparative Example 6) Formation of a same material  
silicone soft ophthalmic lens molded by molds with  
different heights

A desired ophthalmic lens shown in Table 15 was  
obtained in the same manner as in Example 2, except that  
25 the molds used were replaced by Combination 10 in Table  
10 and the solvent was replaced by i-PrOH/ EtOH.

[0113]

(Reference Example 1) Formation of a different material  
silicone soft ophthalmic lens molded by molds without

corona discharge treatment

A desired ophthalmic lens shown in Table 15 was obtained in the same manner as in Example 3, except that the molds used were replaced by Combination 11 in Table 11 and no corona discharge treatment was performed.

[0114]

(Reference Example 2) Formation of a same material silicone soft ophthalmic lens molded by molds with no protrusion formed thereon

A desired ophthalmic lens shown in Table 15 was obtained in the same manner as in Example 2, except that the molds used were replaced by Combination 12 in Table 12 and no protrusion was formed on the molds.

[0115]

[4. Evaluation of ophthalmic lenses]

Twenty samples each were subjected to the ophthalmic lens-forming process according to each of the methods of Examples 1 to 8, Comparative Examples 1 to 6, and Reference Examples 1 and 2. The samples were evaluated according to the methods below.

[0116]

(1) Selective adhesion to desired one of the molds

Upon separation of the male and female molds following completion of the first copolymerization reaction, the proportion of the first layers of the ophthalmic lenses that were adhered to the mold with no protrusion was determined visually. "++" indicates that the number of the first layers adhered to the desired mold is from 16 to 20. "+" indicates that the number of

the first layers adhered to the desired mold is from 10 to 15. "x" indicates that the number of the first layers adhered to the desired mold is from 0 to 9.

[0117]

- 5 (2) Shifting of the embedded component from the desired position

Each of samples of the ophthalmic lens that its first layer was adhered to the mold with no protrusion was subjected to a second copolymerization reaction. The  
10 resulting ophthalmic lenses were visually observed and the number of the lenses that showed shifting was rated as the proportion relative to the number of the lenses subjected to the second copolymerization reaction. "++" indicates that less than 20% showed shifting. "+"  
15 indicates that 20% to less than 60% showed shifting. "x" indicates that 60% or more showed shifting.

[0118]

- (3) Exposure of the embedded component from within the ophthalmic lens

20 Each of samples of the ophthalmic lens that its first layer was adhered to the mold with no protrusion was subjected to a second copolymerization reaction. The resulting ophthalmic lenses were visually observed and the number of the lenses that showed exposure of a  
25 portion of the component on the surface of the ophthalmic lens was rated as the proportion relative to the number of the lenses subjected to the second copolymerization reaction. "++" indicates that less than 20% showed exposure. "+" indicates that 20% to less than

60% showed exposure. "x" indicates that 60% or more showed exposure.

[0119]

For Examples 1 to 8, the selective adhesion to the  
5 desired mold was good and the resulting ophthalmic lenses showed a low occurrence of shifting of the embedded component as well as a low occurrence of exposure, thus indicating good results.

[0120]

10 For Comparative Examples 1 to 4, the insufficient mating between the male mold and the female mold upon the second copolymerization reaction resulted in defective shapes of the edge of the resulting ophthalmic lens, which was not ideal for ophthalmic lenses.

15 [0121]

For Comparative Examples 5, 6, the selective adhesion to the desired mold was good and the occurrence of shifting of the embedded components was low. However, the insufficient thickness of the second layer led to a  
20 high occurrence of exposure of the embedded component on the surface of the ophthalmic lens, making it difficult for the lens to be used as an ophthalmic lens.

[0122]

Reference Example 1 showed poor selective adhesion  
25 to the desired mold and less desired ophthalmic lenses were obtained.

[0123]

Reference Example 2, which did not have any recess in which to place the component to be embedded, showed

displacement of the component caused by the pressure exerted upon mating of the second male mold, which led to a high occurrence of shifting.

[0124]

[Table 1]

| Combination 1      |                                            |                      |
|--------------------|--------------------------------------------|----------------------|
| First male mold    | Diameter (Lens area)                       | 14.5 mm              |
|                    | Height                                     | 8.52 mm              |
|                    | Shape of protrusion                        | annular              |
|                    | Height                                     | 0.04 mm              |
|                    | (Ratio of thickness of embedded component) | 133%                 |
|                    | (Ratio of first layer thickness)           | 53.3%                |
|                    | Position from outer edge                   | 4.5mm                |
|                    | Material                                   | polypropylene        |
| First female mold  | Diameter (lens area)                       | 14.5 mm              |
|                    | Height                                     | 8.60 mm              |
|                    | Material                                   | polypropylene        |
|                    | Corona discharge                           | Yes                  |
| Second male mold   | Diameter (lens area)                       | 14.5 mm              |
|                    | Height                                     | 8.47 mm              |
|                    | Material                                   | polypropylene        |
| Embedded component | Shape                                      | annular iris pattern |
|                    | Thickness                                  | 0.03 mm              |

[0125]

[Table 2]

| Combination 2      |                                            |                                |
|--------------------|--------------------------------------------|--------------------------------|
| Third male mold    | Diameter (lens area)                       | 14.0mm                         |
|                    | Height                                     | 8.60 mm                        |
|                    | Material                                   | polypropylene                  |
|                    | Corona discharge                           | Yes                            |
| Second female mold | Diameter (Lens area)                       | 14.0 mm                        |
|                    | Height                                     | 8.65 mm                        |
|                    | Shape of protrusion                        | square                         |
|                    | Height                                     | 0.03 mm                        |
|                    | (Ratio of thickness of embedded component) | 150%                           |
|                    | (Ratio of first layer thickness)           | 60.0%                          |
|                    | Position from outer edge                   | 2.5 mm                         |
|                    | Material                                   | polypropylene                  |
| Third female mold  | Diameter (lens area)                       | 14.0 mm                        |
|                    | Height                                     | 8.75 mm                        |
|                    | Material                                   | polypropylene                  |
| Embedded component | Shape                                      | chip-shaped measurement device |
|                    | Thickness                                  | 0.02 mm                        |

[0126]

[Table 3]

| Combination 3      |                                            |                      |
|--------------------|--------------------------------------------|----------------------|
| First male mold    | Diameter (Lens area)                       | 14.3 mm              |
|                    | Height                                     | 8.70 mm              |
|                    | Shape of protrusion                        | annular              |
|                    | Height                                     | 0.15 mm              |
|                    | (Ratio of thickness of embedded component) | 75%                  |
|                    | (Ratio of first layer thickness)           | 300%                 |
|                    | Position from outer edge                   | 1.5mm                |
|                    | Material                                   | polypropylene        |
| First female mold  | Diameter (lens area)                       | 14.3 mm              |
|                    | Height                                     | 8.75 mm              |
|                    | Material                                   | polypropylene        |
|                    | Corona discharge                           | Yes                  |
| Second male mold   | Diameter (lens area)                       | 14.3 mm              |
|                    | Height                                     | 8.63 mm              |
|                    | Material                                   | polypropylene        |
| Embedded component | Shape                                      | annular iris pattern |
|                    | Thickness                                  | 0.2 mm               |

[0127]

[Table 4]

| Combination 4      |                                            |                                |
|--------------------|--------------------------------------------|--------------------------------|
| Third male mold    | Diameter (lens area)                       | 14.2 mm                        |
|                    | Height                                     | 8.65 mm                        |
|                    | Material                                   | polypropylene                  |
|                    | Corona discharge                           | Yes                            |
| Second female mold | Diameter (Lens area)                       | 14.2 mm                        |
|                    | Height                                     | 8.70 mm                        |
|                    | Shape of protrusion                        | square                         |
|                    | Height                                     | 0.1 mm                         |
|                    | (Ratio of thickness of embedded component) | 100%                           |
|                    | (Ratio of first layer thickness)           | 200%                           |
|                    | Position from outer edge                   | 1.2 mm                         |
|                    | Material                                   | polypropylene                  |
| Third female mold  | Diameter (lens area)                       | 14.2 mm                        |
|                    | Height                                     | 8.73 mm                        |
|                    | Material                                   | polypropylene                  |
| Embedded component | Shape                                      | chip-shaped measurement device |
|                    | Thickness                                  | 0.1 mm                         |

[0128]

[Table 5]

| Combination 5      |                                            |                      |
|--------------------|--------------------------------------------|----------------------|
| First male mold    | Diameter (Lens area)                       | 14.3 mm              |
|                    | Height                                     | 8.69 mm              |
|                    | Shape of protrusion                        | annular              |
|                    | Height                                     | 0.045 mm             |
|                    | (Ratio of thickness of embedded component) | 113%                 |
|                    | (Ratio of first layer thickness)           | 75%                  |
|                    | Position from outer edge                   | 4.0 mm               |
|                    | Material                                   | polypropylene        |
| First female mold  | Diameter (lens area)                       | 14.3 mm              |
|                    | Height                                     | 8.75 mm              |
|                    | Material                                   | polypropylene        |
|                    | Corona discharge                           | Yes                  |
| Second male mold   | Diameter (lens area)                       | 14.7 mm              |
|                    | Height                                     | 8.64 mm              |
|                    | Material                                   | polypropylene        |
| Embedded component | Shape                                      | annular iris pattern |
|                    | Thickness                                  | 0.04 mm              |

[0129]

[Table 6]

| Combination 6      |                                            |                                |
|--------------------|--------------------------------------------|--------------------------------|
| Third male mold    | Diameter (lens area)                       | 14.2 mm                        |
|                    | Height                                     | 8.65 mm                        |
|                    | Material                                   | polypropylene                  |
|                    | Corona discharge                           | Yes                            |
| Second female mold | Diameter (Lens area)                       | 14.2 mm                        |
|                    | Height                                     | 8.70 mm                        |
|                    | Shape of protrusion                        | square                         |
|                    | Height                                     | 0.028 mm                       |
|                    | (Ratio of thickness of embedded component) | 140%                           |
|                    | (Ratio of first layer thickness)           | 56%                            |
|                    | Position from outer edge                   | 2.0 mm                         |
|                    | Material                                   | polypropylene                  |
| Third female mold  | Diameter (lens area)                       | 14.4 mm                        |
|                    | Height                                     | 8.76 mm                        |
|                    | Material                                   | polypropylene                  |
| Embedded component | Shape                                      | chip-shaped measurement device |
|                    | Thickness                                  | 0.02 mm                        |

[0130]

[Table 7]

| Combination 7      |                                            |                      |
|--------------------|--------------------------------------------|----------------------|
| First male mold    | Diameter (Lens area)                       | 14.3 mm              |
|                    | Height                                     | 8.69 mm              |
|                    | Shape of protrusion                        | annular              |
|                    | Height                                     | 0.045 mm             |
|                    | (Ratio of thickness of embedded component) | 113%                 |
|                    | (Ratio of first layer thickness)           | 75%                  |
|                    | Position from outer edge                   | 4.0 mm               |
|                    | Material                                   | polypropylene        |
| First female mold  | Diameter (lens area)                       | 14.3 mm              |
|                    | Height                                     | 8.75 mm              |
|                    | Material                                   | polypropylene        |
|                    | Corona discharge                           | Yes                  |
| Second male mold   | Diameter (lens area)                       | 13.9 mm              |
|                    | Height                                     | 8.64 mm              |
|                    | Material                                   | polypropylene        |
| Embedded component | Shape                                      | annular iris pattern |
|                    | Thickness                                  | 0.04 mm              |

[0131]

[Table 8]

| Combination 8      |                                            |                                |
|--------------------|--------------------------------------------|--------------------------------|
| Third male mold    | Diameter (lens area)                       | 14.2 mm                        |
|                    | Height                                     | 8.65 mm                        |
|                    | Material                                   | polypropylene                  |
|                    | Corona discharge                           | Yes                            |
| Second female mold | Diameter (Lens area)                       | 14.2 mm                        |
|                    | Height                                     | 8.70 mm                        |
|                    | Shape of protrusion                        | square                         |
|                    | Height                                     | 0.028 mm                       |
|                    | (Ratio of thickness of embedded component) | 140%                           |
|                    | (Ratio of first layer thickness)           | 56%                            |
|                    | Position from outer edge                   | 2.0 mm                         |
|                    | Material                                   | polypropylene                  |
| Third female mold  | Diameter (lens area)                       | 13.9 mm                        |
|                    | Height                                     | 8.76 mm                        |
|                    | Material                                   | polypropylene                  |
| Embedded component | Shape                                      | chip-shaped measurement device |
|                    | Thickness                                  | 0.02 mm                        |

[0132]

[Table 9]

| Combination 9      |                                            |                      |
|--------------------|--------------------------------------------|----------------------|
| First male mold    | Diameter (Lens area)                       | 14.3 mm              |
|                    | Height                                     | 8.69 mm              |
|                    | Shape of protrusion                        | annular              |
|                    | Height                                     | 0.06 mm              |
|                    | (Ratio of thickness of embedded component) | 102%                 |
|                    | (Ratio of first layer thickness)           | 80%                  |
|                    | Position from outer edge                   | 4.0 mm               |
|                    | Material                                   | polypropylene        |
| First female mold  | Diameter (lens area)                       | 14.3 mm              |
|                    | Height                                     | 8.77 mm              |
|                    | Material                                   | polypropylene        |
|                    | Corona discharge                           | Yes                  |
| Second male mold   | Diameter (lens area)                       | 14.3 mm              |
|                    | Height                                     | 8.71 mm              |
|                    | Material                                   | polypropylene        |
| Embedded component | Shape                                      | annular iris pattern |
|                    | Thickness                                  | 0.059 mm             |

[0133]

[Table 10]

| Combination 10     |                                            |                                |
|--------------------|--------------------------------------------|--------------------------------|
| Third male mold    | Diameter (lens area)                       | 14.2 mm                        |
|                    | Height                                     | 8.65 mm                        |
|                    | Material                                   | polypropylene                  |
|                    | Corona discharge                           | Yes                            |
| Second female mold | Diameter (Lens area)                       | 14.2 mm                        |
|                    | Height                                     | 8.70 mm                        |
|                    | Shape of protrusion                        | square                         |
|                    | Height                                     | 0.03 mm                        |
|                    | (Ratio of thickness of embedded component) | 100%                           |
|                    | (Ratio of first layer thickness)           | 60%                            |
|                    | Position from outer edge                   | 2.0 mm                         |
|                    | Material                                   | polypropylene                  |
| Third female mold  | Diameter (lens area)                       | 14.2 mm                        |
|                    | Height                                     | 8.68 mm                        |
|                    | Material                                   | polypropylene                  |
| Embedded component | Shape                                      | chip-shaped measurement device |
|                    | Thickness                                  | 0.03 mm                        |

[0134]

[Table 11]

| Combination 11     |                                            |                      |
|--------------------|--------------------------------------------|----------------------|
| First male mold    | Diameter (Lens area)                       | 14.5 mm              |
|                    | Height                                     | 8.52 mm              |
|                    | Shape of protrusion                        | annular              |
|                    | Height                                     | 0.04 mm              |
|                    | (Ratio of thickness of embedded component) | 133%                 |
|                    | (Ratio of first layer thickness)           | 53.3%                |
|                    | Position from outer edge                   | 4.5mm                |
|                    | Material                                   | polypropylene        |
|                    | Corona discharge                           | No                   |
| First female mold  | Diameter (lens area)                       | 14.5 mm              |
|                    | Height                                     | 8.60 mm              |
|                    | Material                                   | polypropylene        |
| Second male mold   | Diameter (lens area)                       | 14.5 mm              |
|                    | Height                                     | 8.47 mm              |
|                    | Material                                   | polypropylene        |
| Embedded component | Shape                                      | annular iris pattern |
|                    | Thickness                                  | 0.03 mm              |

[0135]

[Table 12]

| Combination 12     |                      |                                |
|--------------------|----------------------|--------------------------------|
| First male mold    | Diameter (Lens area) | 14.5 mm                        |
|                    | Height               | 8.52 mm                        |
|                    | Shape of protrusion  | No                             |
|                    | Material             | polypropylene                  |
|                    | Corona discharge     | Yes                            |
| First female mold  | Diameter (lens area) | 14.5 mm                        |
|                    | Height               | 8.60 mm                        |
|                    | Material             | polypropylene                  |
| Second male mold   | Diameter (lens area) | 14.5 mm                        |
|                    | Height               | 8.47 mm                        |
|                    | Material             | polypropylene                  |
| Embedded component | Shape                | chip-shaped measurement device |
|                    | Thickness            | 0.02 mm                        |

[0136]

[Table 13]

|            | Ophthalmic lens material |      |      |      |
|------------|--------------------------|------|------|------|
|            | 1                        | 2    | 3    | 4    |
| FM7725 (%) | 46.5                     | 50   |      |      |
| TRIS (%)   | 40                       | 30   |      | 30   |
| LA (%)     | 10                       |      |      |      |
| V-4F (%)   |                          | 19.5 |      |      |
| MMA (%)    | 3                        |      |      |      |
| HEMA (%)   |                          |      | 98.5 | 69.5 |
| MAA (%)    |                          |      | 1    |      |
| EDMA (%)   | 0.5                      | 0.5  | 0.5  | 0.5  |
| AIBN (ppm) | 3000                     | 3000 | 3000 | 3000 |
| RUVA (ppm) | 3000                     | 3000 | 3000 | 3000 |

[0137]

5 Abbreviations:

FM7725;  $\alpha,\omega$ -dimethacryloxypropyl poly(dimethylsiloxane)

MW = 15000 (JNC)

TRIS; Tris(trimethylsiloxy)silyl propyl methacrylate

LA; Lauryl acrylate

10 V-4F; 2,2,3,3-tetrafluoropropyl acrylate

MMA; methyl methacrylate

HEMA; hydroxyethyl methacrylate

MAA; methyl acrylamide

EDMA; ethylene glycol dimethacrylate

15 AIBN; 2,2'-azobisbutyronitrile

RUVA; 2-[3-(2H-benzotriazole-2-yl)-4-hydroxyphenyl]ethyl

methacrylate

[0138]

[Table 14]

|                                               |                                                      | Ex. 1        | Ex. 2        | Ex. 3        | Ex. 4           | Ex. 5          | Ex. 6          | Ex. 7          | Ex. 8          |
|-----------------------------------------------|------------------------------------------------------|--------------|--------------|--------------|-----------------|----------------|----------------|----------------|----------------|
| <b>Conditions for forming ophthalmic lens</b> | <b>Mold Combination</b>                              | 1            | 1            | 1            | 2               | 3              | 4              | 1              | 2              |
|                                               | <b>1st copolymerization ophthalmic lens material</b> | 1            | 2            | 1            | 2               | 1              | 2              | 3              | 4              |
|                                               | <b>2nd copolymerization ophthalmic lens material</b> | 1            | 2            | 2            | 1               | 1              | 2              | 3              | 4              |
|                                               | <b>Solvent</b>                                       | i-PrOH       | i-PrOH       | EtOH         | i-PrOH/<br>EtOH | i-PrOH         | i-PrOH         | Phys. saline   | Phos. buffer   |
| <b>Ratings of ophthalmic lens</b>             | <b>1st layer thickness (mm)</b>                      | 0.075        | 0.05         | 0.075        | 0.05            | 0.05           | 0.05           | 0.075          | 0.05           |
|                                               | <b>2nd layer thickness (mm)</b>                      | 0.04         | 0.045        | 0.04         | 0.045           | 0.07           | 0.03           | 0.04           | 0.045          |
|                                               | <b>Selective adhesion</b>                            | ++<br>(18)   | ++<br>(17)   | ++<br>(18)   | ++<br>(16)      | ++<br>(17)     | ++<br>(19)     | ++<br>(17)     | ++<br>(18)     |
|                                               | <b>Shift of embedded component</b>                   | ++<br>(0/0%) | ++<br>(0/0%) | ++<br>(0/0%) | ++<br>(0/0%)    | ++<br>(0/0%)   | ++<br>(1/5.3%) | ++<br>(0/0%)   | ++<br>(1/5.6%) |
|                                               | <b>Exposure of embedded component</b>                | ++<br>(0/0%) | ++<br>(0/0%) | ++<br>(0/0%) | ++<br>(0/0%)    | ++<br>(1/5.9%) | ++<br>(0/0%)   | ++<br>(1/5.9%) | ++<br>(0/0%)   |

[0139]

[Table 15]

|                                                               |                                                                       | Com.<br>Ex. 1                   | Com.<br>Ex. 2                   | Com.<br>Ex. 3                   | Com.<br>Ex. 4                   | Com.<br>Ex. 5     | Com.<br>Ex. 6       | Ref.<br>Ex. 1       | Ref.<br>Ex. 2       |
|---------------------------------------------------------------|-----------------------------------------------------------------------|---------------------------------|---------------------------------|---------------------------------|---------------------------------|-------------------|---------------------|---------------------|---------------------|
| <b>Conditions<br/>for<br/>forming<br/>ophthalmic<br/>lens</b> | <b>Mold<br/>Combination</b>                                           | 5                               | 6                               | 7                               | 8                               | 9                 | 10                  | 11                  | 12                  |
|                                                               | <b>1st<br/>copolymeriza<br/>tion<br/>ophthalmic<br/>lens material</b> | 1                               | 2                               | 1                               | 2                               | 1                 | 2                   | 1                   | 2                   |
|                                                               | <b>2nd<br/>copolymeriza<br/>tion<br/>ophthalmic<br/>lens material</b> | 1                               | 2                               | 2                               | 1                               | 1                 | 2                   | 2                   | 2                   |
|                                                               | <b>Solvent</b>                                                        | i-PrOH                          | i-PrOH                          | EtOH                            | i-PrOH                          | EtOH              | i-<br>PrOH/<br>EtOH | i-<br>PrOH/<br>EtOH | Phos.<br>buffer     |
| <b>Ratings of<br/>ophthalmic<br/>lens</b>                     | <b>1st layer<br/>thickness<br/>(mm)</b>                               | defecti<br>ve<br>shape          | defecti<br>ve<br>shape          | defecti<br>ve<br>shape          | defecti<br>ve<br>shape          | 0.075             | 0.05                | 0.075               | 0.075               |
|                                                               | <b>2nd layer<br/>thickness<br/>(mm)</b>                               | in the<br>edge<br>(by<br>burrs) | in the<br>edge<br>(by<br>burrs) | in the<br>edge<br>(by<br>burrs) | in the<br>edge<br>(by<br>burrs) | —                 | —                   | 0.04                | 0.04                |
|                                                               | <b>Selective<br/>adhesion</b>                                         | ++<br>(16)                      | ++<br>(17)                      | ++<br>(17)                      | ++<br>(18)                      | ++<br>(18)        | ++<br>(16)          | x<br>(7)            | ++<br>(17)          |
|                                                               | <b>Shift of<br/>embedded<br/>component</b>                            | —                               | —                               | —                               | —                               | ++(0/0<br>%)      | ++<br>(1/6.<br>3%)  | ++(1/14<br>.2%)     | x<br>(15/88<br>%)   |
|                                                               | <b>Exposure of<br/>embedded<br/>component</b>                         | —                               | —                               | —                               | —                               | x<br>(16/89<br>%) | x<br>(15/94<br>%)   | ++<br>(0/0%)        | ++<br>(3/17.6<br>%) |

## 5 Reference Numerals

[0140]

1: First male mold in the first configuration

2: Second male mold in the first configuration

3: First female mold in the first configuration

10 4: Optical area in the first configuration

5: Protrusion in the first configuration

6: First layer of the ophthalmic lens in the first configuration

7: Second layer of the ophthalmic lens in the first configuration

5 8: Ophthalmic lens in the first configuration

x1: Diameter of the first male mold in the first configuration

x2: Diameter of the second male mold in the first configuration

10 y1: Height of the first male mold in the first configuration

y2: Height of the second male mold in the first configuration

z: Height of the protrusion in the first configuration

15 m1: Thickness of the first layer of the ophthalmic lens in the first configuration

n1: Thickness of the second layer of the ophthalmic lens in the first configuration

w1: Thickness of the component to be embedded in the

20 first configuration

9: Second female mold in the second configuration

10: Third female mold in the second configuration

11: Third male mold in the second configuration

12: Optical area in the second configuration

25 13: Protrusion in the second configuration

14: First layer of the ophthalmic lens in the second configuration

15: Second layer of the ophthalmic lens in the second configuration

16: Ophthalmic lens in the second configuration  
 s1: Diameter of the second female mold in the second  
 configuration  
 s2: Diameter of the third female mold in the second  
 5 configuration  
 t1: Height of the second female mold in the second  
 configuration  
 t2: Height of the third female mold in in the second  
 configuration  
 10 u: Height of the protrusion the second configuration  
 m2: Thickness of the first layer of the ophthalmic lens  
 in the second configuration  
 n2: Thickness of the second layer of the ophthalmic lens  
 in the second configuration  
 15 w2: Thickness of the component to be embedded in the  
 second configuration  
 17A: Chip-shaped (square) measurement device  
 17B: Chip-shaped (circular) measurement device  
 18: annular measurement device

20

#### Industrial Applicability

[0141]

The ophthalmic lens obtained by the above-described  
 production methods allows secure positioning of an  
 25 embedded component, a foreign object, by pre-forming on  
 a mold a protrusion to form a receptacle for the  
 component to be embedded. Accordingly, the present  
 invention enables provision of contact lenses for use in  
 a variety of fashion or medical applications.

## CLAIMS

1. A method of producing an ophthalmic lens having a component embedded in the ophthalmic lens,  
5 comprising the steps of:  
(A1) mating a first male mold with a first female mold with a first ophthalmic lens material injected therein, and subjecting the first ophthalmic lens material to a first copolymerization reaction to  
10 form a first layer of the ophthalmic lens on a concave forming surface of said first female mold, wherein said first male mold has a convex forming surface having a protrusion thereon conforming to the shape of the component within the ophthalmic  
15 lens, and said first female mold has the concave forming surface corresponding to said first male mold;  
(B1) separating said first male mold from said first female mold, placing said component in a  
20 recess in said first layer of the ophthalmic lens that corresponds to said protrusion, and injecting a second ophthalmic lens material onto the concave forming surface of said first female mold;  
(C1) mating a second male mold with said first  
25 female mold with said second ophthalmic lens material injected therein, said second male mold having a convex forming surface corresponding to said first female mold, and subjecting said second ophthalmic lens material to a second

copolymerization reaction to form a second layer of the ophthalmic lens over the concave forming surface of said first female mold; and

5 (D1) separating said second male mold from said first female mold to obtain the ophthalmic lens having said component embedded between said second layer and the first layer.

2. A method of producing an ophthalmic lens having a component embedded in the ophthalmic lens,  
10 comprising the steps of:

(A2) mating a third male mold with a second female mold with a third ophthalmic lens material injected therein, and subjecting the third ophthalmic lens material to a first copolymerization reaction to  
15 form a first layer of the ophthalmic lens on a convex forming surface of said third male mold, wherein said second female mold has a concave forming surface having a protrusion thereon conforming to the shape of the component within the  
20 ophthalmic lens, and said third male mold has the convex forming surface corresponding to said second female mold;

(B2) separating said second female mold from said  
25 third male mold, placing said component in a recess in said first layer of the ophthalmic lens corresponding to said protrusion, and injecting a fourth ophthalmic lens material onto a concave forming surface of a third female mold that

corresponds to said third male mold;

(C2) mating said third male mold with said third female mold with the fourth ophthalmic lens material injected therein, and subjecting said fourth

5 ophthalmic lens material to a second copolymerization reaction to form a second layer of the ophthalmic lens on said first layer of the ophthalmic lens on the convex forming surface of said third male mold; and

10 (D2) separating said third male mold from said third female mold to obtain the ophthalmic lens with said component embedded between said second layer and said first layer.

15 3. The method of producing an ophthalmic lens having a component embedded in the ophthalmic lens according to claim 1 or 2, wherein a ratio of a thickness of said first layer at its center to a thickness of said second layer at its center is in the range of  
20 1:0.1 to 1:25.

4. The method of producing an ophthalmic lens having a component embedded in the ophthalmic lens according to any one of claim 1 to 3, wherein said first layer  
25 and said second layer are formed of the same material.

5. The method of producing an ophthalmic lens having a component embedded in the ophthalmic lens according

to any one of claim 1 to 4, wherein said first layer and said second layer are formed of different materials.