

PROFESSIONAL FITTING GUIDE



**Sophisticated Kristin / One of a Kind Kristin / Day n' Night Kristin
/ Attention-Plz Kristin / Another Me Kristin / Lovesick Kristin / Grrrr Kristin
/ Sweet Tooth Kristin / Lucid Kristin**

***CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON
THE ORDER OF A LICENSED PRACTITIONER.***

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MATERIAL CHARACTERISTICS

The **Vision Science (hydrophilic) Contact Lenses** are fabricated from polypmacon, which in the dry (unhydrated) state may be machined and polished. The hydrophilic nature of this material allows the lens to become soft and pliable when immersed in an aqueous solution.

The nonionic lens material, (polypmacon) is a hydrophilic polymer of 2-Hydroxyethyl methacrylate (2-HEMA) and cross-linked with ethylene glycol dimethacrylate (EGDMA), plus an initiator. The co-polymer consists of 62% polypmacon and 38% water by weight when immersed in saline solution. The (polypmacon) name has been adopted by the United States Adopted Names Council (USAN).

Vision Science (hydrophilic) Contact Lenses are available clear, visibility tinted, and cosmetically tinted. Lenses are tinted with one or a combination of one or more of the following 'listed' color additives: D&C Red 17, D&C Violet 2, D&C Yellow 10, Titanium Dioxide, Iron Oxide (Red), [Phthalocyaninato(2-)] Copper, Phthalocyanine Green, Carbazole Violet, Reactive Blue 19, and C.I. Reactive black 5. Lenses that contain a unique tinting pattern are subsequently processed to incorporate the 'listed' color additives, and contain only the amount of color additive needed to accomplish the intended coloring effect. When producing the cosmetic tinted lenses, the manufacturing process alters and/or changes the specifications to the clear version of a contact lens by affixing a listed reactive color additive in the center of the contact lens (between layers of contact lens material) in a location that corresponds to the iris. As part of the manufacturing process, the lenses containing the color additives are thoroughly washed to remove unbound reactive color additives. The color additives used are not removed by lens handling and cleaning/disinfecting procedures. Except for affecting the amount of light transmittance through the lens, the coloring process does not alter the original characteristics of the pre-tinted lens. The cosmetic tinting pattern has a standard Clear Pupil diameter of 6.0 mm.

In the hydrated state, the lens conforms to the curvature of the eye covering the cornea and extending slightly beyond the limbus forming a transparent or colored optical surface. The (polypmacon) soft hydrophilic contact lens has a spherical back surface. The hydrophilic properties of the lens require that it be maintained in a fully hydrated state in a solution compatible with the eye. If the lens dries out, it will become hard and appear somewhat warped; however, it will return to its proper configuration when completely rehydrated in the proper storage solution.

The physical properties of the lens are:

| | |
|------------------------------------|---|
| Refractive Index | 1.43 |
| Light Transmission (clear) | greater than 96% |
| Light Transmission (tinted) | greater than 96% (at clear region corresponding to pupil standard 6.0 mm diameter); Opaque or 0-10% (at tinted region corresponding to iris) |
| Surface Character | hydrophilic |
| Water Content | 38±2% |
| Specific Gravity | 1.17 (hydrated) |

Oxygen Permeability

$12.48 \times 10^{-11} \text{ (cm}^2\text{/sec)(mlO}_2\text{)/(ml x mmHg @ 35}^\circ\text{C)}$
(revised Fatt method)

The hydrophilic characteristics allow aqueous solution to enter the lens, and in its fully hydrated state the lens is approximately 38% water by weight. The lenses will be manufactured in spherical configurations with the following features and properties:

| | |
|--------------------------|-----------------------------------|
| Chord Diameter: | 12.80 mm to 15.00 mm |
| Center Thickness: | 0.050 mm to 0.210 mm |
| Base Curve: | 8.0 mm to 9.8 mm |
| Power Range | -20.00D to +20.00D in 0.25D steps |

ACTIONS

In its hydrated state, the **Vision Science (hydrophilic) Contact Lenses**, when placed on the cornea, act as a refracting medium to focus light rays on the retina.

INDICATIONS

INDICATIONS FOR USE:

The **Vision Science (hydrophilic) Contact Lenses** for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia. The lens may be worn by persons who exhibit refractive astigmatism of .50 diopters or less where the astigmatism does not interfere with visual acuity. The lens is available clear or tinted and may be used to enhance or alter the apparent color of the eye.

NOTE: See the WARNINGS reference to the relationship between lens wearing schedule and corneal complications.

Daily wear replacement schedules may vary from patient to patient and should be decided by eyecare practitioners in consultation with their patients.

Frequent/Planned Replacement Wear:

Eyecare practitioners may prescribe any of the above lenses for frequent/planned replacement wear, with cleaning disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be disinfected using a chemical disinfecting system.

Special Precautions for Eyecare Practitioner:

Due to the small number of patients enrolled in clinical investigation of lens, all refractive powers, design configurations, or lens parameters available in the lens material were not evaluated in significant numbers. Consequently, when selecting an appropriate lens design and parameters, the eyecare practitioner should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and

peripheral thickness, and optic zone diameter.

The potential impact of these factors on the patient's ocular health must be carefully weighed against the patient's need for refractive correction. Therefore, the continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing eyecare practitioner.

CONTRAINDICATIONS (REASONS NOT TO USE)

Please reference Contraindications (Reasons Not to Use) in the Package Insert included at the end of this Fitting Guide.

WARNINGS

Please reference Warnings in the Package Insert included at the end of this Fitting Guide.

PRECAUTIONS

Please reference Precautions in the Package Insert included at the end of this Fitting Guide.

ADVERSE REACTIONS

Please reference Adverse Reactions in the Package Insert included at the end of this Fitting Guide.

PATIENT SELECTION

Patient communication is vital. Patients who require visual correction but cannot adhere to the recommended care of the **Vision Science (hydrophilic) Contact Lenses** should not be provided with this lens. All necessary steps in lens care and all precautions and warnings should be discussed and understood by the patient (*Review Package Insert with patient*).

Fitting procedure for the Vision Science (hydrophilic) Contact Lenses, Sphere lenses:

FITTING PROCEDURE for the Spherical Single Vision Lens.

1. Pre-fitting Examination

A pre-fitting patient history and examination are necessary to:

- determine whether a patient is a suitable candidate for daily wear contact lenses (refer to contraindications)
- collect and record baseline clinical information to which post-fitting examination results can be compared
- make ocular measurements for initial contact lens parameter selection

2. Initial Lens Power Selection

- a) Convert the spectacle Rx to minus cylinder forms
- b) Compensate the spectacle Rx for vertex distance if the power is greater than + or – 4.00 diopters
- c) Drop the cylinder
- d) Add + 0.25 diopter to compensate for minus tear lens
- e) If refractive astigmatism exceeds 0.75 diopter, determine equivalent sphere and then compensate for power by adding +0.25 diopter for minus tear lens

3. Initial Lens Diameter and Base Curve Selection

The lens is currently offered in one diameter (14.50 mm) and one base curve (8.7)

4. Initial Lens Evaluation

- a) Check Lens Centration, Movement, and Size

The criteria for a well fit lens is one which centers easily after a blink, bridges the limbus and extends onto the sclera about 1.5 millimeters, lags downward about 1 to 2 millimeters on upward gaze, and does not move excessively as a result of blinking or exaggerated eye movements.

After the trial lens settled on the eye (5 – 10 minutes), manipulate the lens using lid pressure and observe for indications of excessive tightness. The lens should move freely and easily with the slightest pressure and return to the centered position when released.

Movement of the lens on the eye is very important in assessing the fit and performance of the lens. In primary gaze, slight vertical post-blinking lens movement should occur. On upward gaze, the lens should sag approximately 1 –

2 millimeters.

b) Refract Over the Lens and Determine Visual Acuity

Allow approximately 10 minutes for fluid equilibration and patient adaptation prior to over refracting. Determine best visual acuity when final over refraction has been achieved. If good visual acuity cannot be obtained through the lens with spherocylindrical over refraction, re-evaluation of the physical fit should be considered. Trial lens procedure should be repeated with lenses of different base curves.

c) Determine the Optical Power for the Lens Selected

When the proper physical fit has been determined, convert the over refraction through the diagnostic lens to equivalent sphere and add this to the power of the trial lens. This will provide the final power of the lens.

5. Follow-up Care

- a) Follow-up examinations, as recommended by the eyecare practitioner, are necessary to ensure continued successful contact lens wear.
- b) Prior to a follow-up examination, the contact lenses should be worn for at least one continuous hour and the patient should be asked to identify any problems which might be occurring related to contact lens wear.
- c) With lenses in place on the eyes, evaluate fitting performance to assure that CRITERIA OF A WELL FITTED LENS continues to be satisfied. Examine the lenses closely for surface deposition and/or damage.
- d) After the lens removal, conduct a thorough biomicroscopy examination.
 - 1. The presence of vertical corneal striae in the posterior central cornea and/or cornea neovascularization is indicative of excessive corneal edema.
 - 2. The presence of corneal staining and/or limbal-conjunctival hyperemia can be indicative of an unclean lens, a reaction to solution preservatives, excessive lens wear, and/or a poorly fitting lens.
 - 3. Papillary conjunctival changes may be indicative of an unclean and/or damaged lens.

If any of the above observations are judged abnormal, various professional judgments are necessary to alleviate the problem and restore the eye to optimal conditions. If the CRITERIA OF A WELL FITTED LENS are not satisfied during any follow-up examinations, the patient should be re-fitted with a more appropriate lens.

CLINICAL ASSESSMENT

1. Criteria of a Well-Fitted Lens

The criteria of a well fitted lens is one which centers easily after a blink, bridges

the limbus and extends onto the sclera about 1.5 millimeters, lags downward about 1 to 2 millimeters on upward gaze, and does not move excessively as a result of blinking or exaggerated eye movements.

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Movement of the lens on the eye is very important in assessing the fit and performance of the lens. In primary gaze, slight vertical post-blinking lens movement should occur. On upward gaze, the lens should sag approximately 1 – 2 millimeters.

2. Characteristics of a Tight (Steep) Lens

A tight (steep) lens does not move easily on the cornea with slight pressure

3. Characteristics of a Loose (Flat) Lens

A loose (flat) lens sags more than 2.0 millimeters on upward gaze

FOLLOW-UP EXAMINATIONS

- * Within one week of lens dispensing
- * After three weeks of lens wear
- * After seven weeks of lens wear
- * After each six month period of lens wear.

At the follow-up examinations, the patient should report good subjective quality of vision. Adaptation to vision with **Vision Science (hydrophilic) Contact Lenses** should occur almost immediately and should definitely be reported within the first (1 week) follow-up visit. At these follow-up visits the practitioner should:

1. Check distance and near acuity with lens in place.
2. Over-refract to verify lens prescription.
3. Observe the position of the lens on the cornea. The lens should be centered and move on upward gaze and with a blink.
4. Evert the lids to examine the tarsal conjunctiva and check for incidence of giant papillary conjunctivitis.
5. Remove the lens. Check corneal curvature. There should be no substantial changes in either meridian.
6. Perform a slit-lamp examination with and without Fluorescein. Check for corneal edema, corneal abrasion, vascularization, corneal infiltrates, and perilimbal injection. Reinsert the lens only after all residual Fluorescein has dissipated from the eye.

7. For frequent/planned replacement lenses, clean the lens with a prophylactic surfactant cleaner, and examine for deposits, foreign bodies or physical imperfections of the lens surface.

FREQUENT/PLANNED REPLACEMENT LENS HANDLING (in-office cleaning, disinfection, and storage)

Wash and rinse hands thoroughly, making certain all soap residues have been rinsed away before drying with a lint-free towel. *It is suggested to wet the lens while in the eye using wetting drops before removal.* Always start with the right lens first in order to avoid mixing the lens. In removing the lens, try to avoid touching the inside (concave) surface of the lens. It is possible, though not likely, that the lens might be inside out; therefore, check the lens by placing it on the index finger and examine its profile. If the edges of the lens tend to point outward, the lens is inside out. After removing the lens from its container assure that it is clean, clear and wet.

Each frequent/planned replacement **Vision Science (hydrophilic) Contact Lenses** received in the eye care practitioner's office is received sterile in (1) a sealed blister pack with sterile saline solution; or (2) a glass vial with sterile saline solution. Both blister and glass vial packages are labeled as to the parameters of the contained lens. To assure sterility, the blister pack or glass vial should not be opened until ready for use.

To open the blister pack, pull back on the top where indicated. Upon removing the top cover of the blister pack, the lens may be removed and is ready for use.

To open the glass vial, pull back on the top where indicated. Upon removing the top silicone cover, the lens may be removed and is ready for use.

Prior to reusing in a diagnostic procedure or before dispensing to a patient, the lens should be surfaced cleaned and disinfected.

- Cleaning:

A surfactant cleaner must be used with the frequent/planned replacement **Vision Science (hydrophilic) Contact Lenses** to ensure a clean lens surface. The manufacturer's instruction for Contact lens cleaner is as follows:

Directions for use:

1. Place lens in the palm of your hand.
2. Apply 1 or 2 drops of cleaner to each lens surface and gently rub with the forefinger of the opposite hand.
3. Clean for about 15-20 seconds
4. Rinse the lens thoroughly with sterile saline solution. **DO NOT** use water to rinse your lenses.
5. After rinsing, place the lens in a storage case.

6. Repeat the process with the other lens.
7. Disinfect lenses as per manufacturer's instructions.

- **Rinsing:**

Thoroughly rinse both surfaces of the lens with a steady stream of fresh, sterile rinsing or multipurpose solution.

Chemical (Not-Heat) Lens Care System:

A sterile rinsing, storing and disinfecting multipurpose solution should be used to rinse and chemically disinfect frequent/planned replacement **Vision Science (hydrophilic) Contact Lenses**. After cleaning the lens, rinse with a liberal amount of fresh multipurpose solution to remove loosened debris and traces of cleaner. The lens should then be placed in the plastic container supplied in a multi-purpose solution kit and filled with enough fresh disinfecting solution to completely submerge the lens. To ensure disinfecting, the lens must remain in the disinfecting solution for the recommended period of time as written on the multipurpose solution bottle. Before reinsertion, lens should be rinsed with fresh sterile rinsing solution.

- **Storage:**

The frequent/planned replacement **Vision Science (hydrophilic) Contact Lenses** must be stored in the recommended solutions. If exposed to the air, the lens will dehydrate. If a lens dehydrates, it should be soaked **ONLY** in a soft contact lens storage solution until it returns to a soft, supple state. It should not be put on an eye until it has been put through a complete disinfection cycle.

LENS CARE DIRECTIONS

Please reference LENS CARE DIRECTIONS in the Package Insert included at the end of this Professional Fitting Guide.

RECOMMENDED WEARING SCHEDULE

Close professional supervision is recommended to ensure safe and successful contact lens wear. If the patient complains of discomfort, decreased vision, ocular injection or corneal edema, the lens should be removed and the patient scheduled for examination. The problem may be relieved by putting the patient on a different wearing schedule or possibly by refitting the lens.

Patients tend to overwear the lens initially. It is important not to exceed the initial wearing schedule. Regular check-ups, as determined by the eyecare practitioner, are also extremely important. The maximum suggested wearing schedule for the **Vision Science (hydrophilic) Contact Lenses** is reflected below.

| <u>DAY</u> | <u>HOURS</u> |
|------------|--------------------|
| 1 | 6 |
| 2 | 8 |
| 3 | 10 |
| 4 | 12 |
| 5 | 14 |
| 6 | All Waking hours * |

STUDIES HAVE NOT BEEN COMPLETED TO SHOW THAT THE Vision Science (hydrophilic) Contact Lenses (polymacon) Soft (hydrophilic) Contact Lenses IS SAFE TO WEAR DURING SLEEP.

MONOVISION FITTING GUIDELINES

1. Patient Selection

A. Monovision Needs Assessment

For a good prognosis the patient should have adequately corrected distance and near visual acuity in each eye. The amblyopic patient or the patient with significant astigmatism (greater than 1.50 diopter) in one eye may not be a good candidate for monovision with the **Vision Science (hydrophilic) Contact Lenses**

Occupational and environmental visual demands should be considered. If the patient requires critical vision (visual acuity and stereopsis) it should be determined by trial whether this patient can function adequately with monovision. Monovision contact lens wear may not be optimal for such activities as:

- (1) Visually demanding situations such as operating potentially dangerous machinery or performing other potentially hazardous activities; and
- (2) Driving automobiles (e.g., driving at night). Patients who cannot pass their state drivers license requirements with monovision correction should be advised to not drive with this correction, OR may require that additional over-correction be prescribed.

B. Patient Education

All patients do not function equally well with monovision correction. Patients may not perform as well for certain tasks with this correction as they have with bifocal reading glasses. Each patient should understand that monovision, as well as other presbyopic contact lenses, or other alternative, can create vision compromise that may reduce visual acuity and depth perception for distance and near tasks. During the fitting process it is necessary for the patient to realize the disadvantages as well as the advantages of clear near vision in straight ahead and upward gaze that monovision contact lenses provide.

2. Eye Selection

Generally, the non-dominant eye is corrected for near vision. The following test for eye dominance can be used.

A. Ocular Preference Determination Methods

Method 1—determine which eye is the “sight eye”. Have the patient point to and object at the far end of the room. Cover one eye. If the patient is still pointing directly at the object, the eye being used is the dominant (sighting) eye.

Method 2—Determine which eye will accept the added power with the latest reduction in vision. Place a trial spectacle near add lens in front of one eye and then the other while the distance refractive error correction is in place for both eyes. Determine whether the patient functions best with the near add lens over the right or left eye.

B. Refractive Error Method

For anisometropic corrections, it is generally best to fit the more hyperopic (less myopic) eye for distance and the more myopic (less hyperopic) eye for near.

C. Visual Demands Method

Consider the patient's occupation during the eye selection process to determine the critical vision requirements. If a patient's gaze for near tasks is usually in one direction correct the eye on that side for near.

Example: A secretary who places copy to the left side of the desk will usually function best with the near lens on the left eye.

3. Special Fitting Considerations

Unilateral Lens Correction

There are circumstances where only one contact lens is required. As an example, an

emmetropic patient would only require a near lens while a bilateral myope may require only a distance lens.

Example:

A presbyopic emmetropic patient who requires a +1.75 diopter add would have a +1.75 lens on the near eye and the other eye left with a lens.

A presbyopic patient requiring a +1.50 diopter add who is -2.50 diopters myopic in the right eye and -1.50 diopters myopic in the left eye may have the right eye corrected for distance and the left uncorrected for near.

4. Near Add Determination

Always prescribe the lens power for the near eye that provides optimal near acuity at the midpoint of the patient's habitual reading distance. However, when more than one power provides optimal reading performance, prescribe the least plus (most minus) of the powers.

5. Trial Lens Fitting

A trial fitting is performed in the office to allow the patient to experience monovision correction. Lenses are fit according to the directions in the general fitting guidelines and base curve selection described earlier in the guide.

Case history and standard clinical evaluation procedure should be used to determine the prognosis. Determine which eye is to be corrected for distance and which eye is to be corrected for near. Next determine the near add. With trial lenses of the proper power in place observe the reaction to this mode of correction.

Immediately after the correct power lenses are in place, walk across the room and have the patient look at you. Assess the patient's reaction to distance vision under these circumstances. Then have the patient look at familiar near objects such as a watch face or fingernails. Again assess the reaction. As the patient continues to look around the room at both near and distance objects, observe the reactions. Only after these vision tasks are completed should the patient be asked to read print. Evaluate the patient's reaction to large print (e.g. typewritten copy) at first and then graduate to news print and finally smaller type sizes.

After the patient's performance under the above conditions are completed, tests of visual acuity and reading ability under conditions of moderately dim illumination should be attempted.

An initial unfavorable response in the office, while indicative of a guarded prognosis, should not immediately rule out a more extensive trial under the usual conditions in which a patient functions.

6. Adaptation

Visually demanding situations should be avoided during the initial wearing period. A patient may at first experience some mild blurred vision, dizziness, headaches, and a feeling of slight imbalance. You should explain the adaptation symptoms to the patient. These symptoms may last for a brief minute or for several weeks. The longer these symptoms persist, the poorer the prognosis for successful adaptation.

To help in the adaptation process the patient can be advised to first use the lenses in a comfortable familiar environment such as in the home.

Some patients feel that automobile driving performance may not be optimal during the adaptation process. This is particularly true when driving at night. Before driving a motor vehicle, it may be recommended that the patient be a passenger first to make sure that their vision is satisfactory for operating an automobile. During the first several weeks of wear (when adaptation is occurring), it may be advisable for the patient to only drive during optimal driving conditions. After adaptation and success with these activities, the patient should be able to drive under other conditions with caution.

7. Other Suggestions

The success of the monovision technique may be further improved by having your patient follow the suggestions below.

- Having a third contact lens (distance power) to use when critical distance viewing is needed.
- Having a third contact lens (near power) to use when critical near viewing is needed.
- Having supplemental spectacles to wear over the monovision contact lenses for specific visual tasks may improve the success of monovision correction. This is particularly applicable for those patients who cannot meet state licensing requirements with a monovision correction.
- Make use of proper illumination when carrying out visual tasks.

Success in fitting monovision can be improved by the following suggestions:

- Reverse the distance and near eyes if a patient is having trouble adapting.
- Refine the lens powers if there is trouble with adaptation. Accurate lens power is critical for presbyopic patients.
- Emphasize the benefits of the clear near vision in straight ahead and upward gaze with monovision.

- * The decision to fit a patient with a monovision correction is most appropriately left to the eyecare practitioner in conjunction with the patient after carefully considering the patient's needs.

* All patients should be supplied with a copy of the **Vision Science (hydrophilic) Contact Lenses Patient Instruction / Wearer's Guide.**

RECOMMENDED FREQUENT/PLANNED REPLACEMENT LENS CARE PRODUCTS

The eyecare practitioner should recommend a care system that is appropriate for the frequent/planned replacement **Vision Science (hydrophilic) Contact Lenses.** Each lens care product contains specific directions for use and important safety information, which should be read and carefully followed.

EMERGENCIES

The patient should be informed that if chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into the eyes, the patient should: **FLUSH EYES IMMEDIATELY WITH TAP WATER AND IMMEDIATELY CONTACT THE EYECARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.**

REPORTING OF ADVERSE REACTIONS

Practitioners should report any adverse reactions to **Vision Science (hydrophilic) Contact Lenses** within 5 days to Initial US Importer TO BE DETERMINED. Additional Fitting Guides, Package Inserts and Patient Guides are available from:

HAPAKRISTIN INC
help@hapakristin.com
Tel.: 1888-808-0242

Or

Vision Science Co., Ltd.
37-38, Maeyeo-ro 1-gil, Dong-gu, Daegu, 41059, South Korea
Tel: +82-53-857-3578
www.visionscience.co.kr

HOW SUPPLIED

The Vision Science (hydrophilic) Contact Lenses are supplied sterile in:

- 1) sealed blister packages containing a saline solution. The base of the package is made from polypropylene, which is covered with a laminated foil seal on top.

Or

- 2) sealed glass vials containing a saline solution. The glass vials are sealed with a silicone stopper.

The glass vials and blister packages are marked with the base curve, diameter, dioptric power, lens color, manufacturing lot number, and expiration date of the lens.

Print Date: 9/15/2023

PACKAGE INSERT FOLLOWS ON THE NEXT PAGE

PACKAGE INSERT
for the
VISION
SCIENCE

**Sophisticated Kristin / One of a Kind Kristin / Day n' Night Kristin
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THE ORDER OF A LICENSED PRACTITIONER.***

IMPORTANT

Please read carefully and keep this information for future use. This package insert is intended for the eyecare practitioner, but should be made available to the patient upon request. The eyecare practitioner should provide the patient with the wearer's guide that pertains to the patients prescribed lens.

DESCRIPTION

The **Vision Science (hydrophilic) Contact Lenses** are hemispherical shells with molded spherical base curves and molded front surfaces. The hydrophilic nature of this material allows the lens to become soft and pliable when immersed in an aqueous solution.

The nonionic lens material, (polymacon) is a hydrophilic polymer of 2-Hydroxyethyl methacrylate (2-HEMA) and cross-linked with ethylene glycol dimethacrylate (EGDMA), plus an initiator. The co-polymer consists of 62% polymacon and 38% water by weight when immersed in saline solution. The (polymacon) name has been adopted by the United States Adopted Names Council (USAN).

Vision Science (hydrophilic) Contact Lenses lenses are available clear, visibility tinted, and cosmetically tinted. Lenses are tinted with one or a combination of one or more of the following 'listed' color additives: D&C Red 17, D&C Violet 2, D&C Yellow 10, Titanium Dioxide, Iron Oxide (Red), [Phthalocyaninato(2-)] Copper, Phthalocyanine Green, Carbazole Violet, Reactive Blue 19, and C.I. Reactive black 5. Lenses that contain a unique tinting pattern are subsequently processed to incorporate the 'listed' color additives, and contain only the amount of color additive needed to accomplish the intended coloring effect. When producing the cosmetic tinted lenses, the manufacturing process alters and/or changes the specifications to the clear version of a contact lens by affixing a listed reactive color additive in the center of the contact lens (between layers of contact lens material) in a location that corresponds to the iris. As part of

the manufacturing process, the lenses containing the color additives are thoroughly washed to remove unbound reactive color additives. The color additives used are not removed by lens handling and cleaning/disinfecting procedures. Except for affecting the amount of light transmittance through the lens, the coloring process does not alter the original characteristics of the pre-tinted lens. The cosmetic tinting pattern has a standard Clear Pupil diameter of 6.0 mm.

In the hydrated state, the lens conforms to the curvature of the eye covering the cornea and extending slightly beyond the limbus forming a transparent or colored optical surface. The (polymacon) soft hydrophilic contact lens has a spherical back surface. The hydrophilic properties of the lens require that it be maintained in a fully hydrated state in a solution compatible with the eye. If the lens dries out, it will become hard and appear somewhat warped; however, it will return to its proper configuration when completely rehydrated in the proper storage solution.

The physical properties of the lens are:

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|------------------------------------|--|
| Refractive Index | 1.43 |
| Light Transmission (clear) | greater than 96% |
| Light Transmission (tinted) | greater than 96% (at 6.0 mm clear pupil diameter); Opaque or 0-10% (at tinted region corresponding to iris) |
| Surface Character | hydrophilic |
| Water Content | 38±2% |
| Specific Gravity | 1.17 (hydrated) |
| Oxygen Permeability | 12.48 x 10 ⁻¹¹ (cm ² /sec)(mlO ₂)/(ml x mmHg @ 35°C)) (revised Fatt method) |

The hydrophilic characteristics allow aqueous solution to enter the lens, and in its fully hydrated state the lens is approximately 38% water by weight. The lenses will be manufactured in spherical configurations with the following features and properties:

| | |
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| Chord Diameter: | 12.80 mm to 15.00 mm |
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In its hydrated state, the **Vision Science (hydrophilic) Contact Lenses**, when placed on the cornea, act as a refracting medium to focus light rays on the retina.

CAUTION

Due to the small number of patients enrolled in clinical investigation of lens, all refractive powers, design configurations, or lens parameters available in the lens material are not evaluated in significant numbers. Consequently, when selecting an appropriate lens design and parameters,

the eyecare practitioner should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.

The potential impact of these factors on the patient's ocular health must be carefully weighed against the patient's need for refractive correction therefore, the continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing eyecare practitioner.

INDICATIONS

The **Vision Science (hydrophilic) Contact Lenses** for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia. The lens may be worn by persons who exhibit refractive astigmatism of .50 diopters or less where the astigmatism does not interfere with visual acuity. The lens is available clear or tinted and may be used to enhance or alter the apparent color of the eye.

NOTE: See the WARNINGS reference to the relationship between lens wearing schedule and corneal complications.

Daily wear replacement schedules may vary from patient to patient and should be decided by eyecare practitioners in consultation with their patients.

Frequent/Planned Replacement Wear:

Eyecare practitioners may prescribe any of the above lenses for frequent/planned replacement wear, with cleaning disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be disinfected using a chemical disinfecting system.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE the **Vision Science (hydrophilic) Contact Lenses** when any of the following conditions are present:

- * Acute and subacute inflammation or infection of the anterior chamber of the eye.
- * Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids.
- * Severe insufficiency of lacrimal secretion (dry eyes).
- * Corneal hypoesthesia (reduced corneal sensitivity), if not-aphakic.
- * Any systemic disease that may affect the eye or be exaggerated by wearing contact lens.
- * Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lens or use of contact lens solutions.
- * Allergy to any ingredient, such as mercury or thimerosal, in a solution which is to be used to care for the **Vision Science (hydrophilic) Contact Lenses (polymacon) Soft Contact Lens**.
- * Any active corneal infection (bacterial, fungi, or viral)

- * If eyes become red or irritated.
- * Patients unable to follow lens care regimen or unable to obtain assistance to do so.

WARNINGS

PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS

COULD RESULT IN SERIOUS INJURY TO THE EYE.

Patients wearing lenses on a frequent/planned replacement schedule should not reuse or “top off” old solution left in the lens case since solution reuse reduces effective lens disinfection and could lead to severe infection, vision loss or blindness. “Topping-Off” is the addition of fresh solution to solution that has been sitting the case.

When disinfecting frequent/planned replacement lenses the patient should rub and rinse the lenses for the recommended amount of time to help prevent serious eye infections (see the frequent/planned replacement wearer’s instruction guide for detailed instructions).

The patient should never use water, saline solution, or rewetting drops to disinfect the lenses. These solutions will not disinfect the lenses. Not using the recommended disinfectant can lead to severe infection, vision loss or blindness.

Patients should not store their lenses or rinse their lens case with water or any non-sterile solution. Patients wearing frequent/planned replacement lenses must only use fresh multi-purpose solution (or sterile saline solution) so their lenses or lens case are not contaminated. Use of non-sterile solution can lead to severe infection, vision loss or blindness.

Water can harbor microorganisms that can lead to severe infection, vision loss or blindness. If the patient’s lenses have been submersed in water such as when swimming in pools, lakes, or oceans the patient should discard them and replace them with a new pair. Patients should be instructed to ask their eye care practitioner (professional) for recommendations about wearing their lenses during any activity involving water.

Using the multi-purpose solution beyond the discard date could result in contamination of the solution and can lead to severe infection, vision loss or blindness.

EYE PROBLEMS, INCLUDING CORNEAL ULCERS, CAN DEVELOP RAPIDLY AND LEAD TO LOSS OF VISION; IF THE PATIENT EXPERIENCES:

- Eye Discomfort,
- Excessive Tearing,

- Vision Changes,
- Loss of Vision,
- Eye Redness
- Or Other Eye Problems

THE PATIENT SHOULD IMMEDIATELY REMOVE THE LENSES, AND PROMPTLY CONTACT THEIR EYE CARE PRACTITIONER.

Daily wear lenses are not indicated for overnight wear, and patients should be instructed not to wear lenses while sleeping. Clinical studies have shown that the risk of serious adverse reactions is increased when these lenses are worn overnight.

Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.

All contact lens wearers must see their eyecare practitioner as directed.

PRECAUTIONS

Special Precautions for the Eyecare Practitioner:

- * Clinical studies have demonstrated that contact lens manufactured from (polymacon) are safe and effective for their intended use. However, due to the small number of patients enrolled in clinical investigation of lens, all refractive powers, design configurations, or lens parameters available in the lens material are not evaluated in significant numbers. Consequently, when selecting an appropriate lens design and parameters, the eyecare practitioner should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.

The potential impact of these factors on the patient's ocular health should be carefully weighed against the patient's need for refractive correction. Therefore, the continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing eyecare practitioner.

- * Fluorescein, a yellow dye, should not be used while the lens is on the eye. The lens absorb this dye and become discolored. Whenever Fluorescein is used in eyes, the eyes should be flushed with a sterile saline solution that is recommended for in eye use. Wait at least one hour before replacing the lens. Too early replacement may allow the lens to absorb residual Fluorescein irreversibly.

- * Before leaving the eyecare practitioner's office, the patient should be able to promptly remove lens or should have someone else available who can remove the lens for him or her.
- * Eyecare practitioners should instruct the patient to remove the lens immediately if the eye becomes red or irritated.
- * The patient should be instructed to always discard lenses worn on a frequent/planned replacement schedule after the recommended wearing schedule prescribed by the eye care professional.

PRECAUTIONS FOR FREQUENT/PLANNED REPLACEMENT WEAR

- * Different solutions cannot always be used together, and not all solutions are safe for use with all lens. Use only recommended solutions that are fresh and sterile. Never use solutions recommended for conventional hard contact lens only. Chemical disinfection solutions should not be used with heat unless specifically indicated on product labeling for use in both heat and chemical disinfection. Always use **FRESH, STERILE UNEXPIRED** lens care solutions. Always follow directions in the package inserts for the use of contact lens solutions. Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions. Do not use saliva or anything other than the recommended solution for lubricating or rewetting lens. Always keep the lens completely immersed in the recommended storage solution when the lens is not being worn (stored). Prolonged periods of drying will damage the lens. Follow the lens care directions for (Care for a Dried Out Dehydrated Dry Lens) if the lens surface does become dried out.
- * Carefully follow the handling, insertion, removal, cleaning, disinfection, storing and wearing instructions in the frequent/planned replacement patient instructions for the **Vision Science (hydrophilic) Contact Lenses** and those prescribed by the eyecare practitioner.

PRECAUTIONS FOR FREQUENT/PLANNED REPLACEMENT

- * If the lens sticks (stops moving) on the eye, follow the recommended directions on (care for sticking non-moving lens). The lens should move freely on the eye for the continued health of the eye. If nonmovement of the lens continues, the patient should be instructed to **IMMEDIATELY** consult his or her eyecare practitioner.
- * Always wash and rinse hands before handling lens. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lens. It is best to put on lens before putting on makeup. Water-base cosmetics are less likely to damage lens than oil-base.
- * Do not touch contact lens with the fingers or hands if the hands are not free of foreign materials, as microscope scratches of the lens may occur, causing distorted vision and/or injury to the eye.
- * Never wear lens beyond the period recommended by the eyecare practitioner.

- * Water activity: The Patient should not expose their contact lenses to water while wearing them.
- * If aerosol products such as hair spray are used while wearing lens, exercise caution and keep eyes closed until the spray has settled.
- * Always handle lens carefully and avoid dropping them.
- * Avoid all harmful or irritating vapors and fumes while wearing lens.
- * Ask the eyecare practitioner about wearing lens during sporting activities.
- * Inform the doctor (health care practitioner) about being a contact lens wearer.
- * Never use tweezers or other tools to remove lens from the lens container unless specifically indicated for that use. Pour the lens into the hand.
- * Do not touch the lens with fingernails.
- * Always contact the eyecare practitioner before using any medicine or medications in the eyes.
- * Always inform the employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or may require that the patient not wear contact lens.
- * As with any contact lens, follow-up visits are necessary to assure the continuing health of the patient's eyes. The patient should be instructed as to a recommended follow-up schedule.

ADVERSE REACTIONS

The patient should be informed that the following problems may occur:

- * Eyes stinging, burning, itching (irritation), or other eye pain.
- * Comfort is less than when lens was first placed on eye.
- * Feeling that something is in the eye such as a foreign body or scratched area.
- * Excessive watering (tearing) of the eye.
- * Unusual eye secretions.
- * Redness of the eye.
- * Reduced sharpness of vision (poor visual acuity).
- * Blurred vision, rainbows, or halos around objects.
- * Sensitivity to light (photophobia).
- * Dry eyes.

If the patient notices any of the above, he or she should be instructed to:

- * **IMMEDIATELY REMOVE LENS.**
- * For frequent/planned replacement wearers: if discomfort or problem(s) stops, then look closely at the lens. If the lens is in any damage, **DO NOT PUT THE LENS BACK ON THE EYE.** Place the lens in the storage case and contact the eyecare practitioner. If the lens has dirt, an eyelash, or other foreign body on it, or the problem stops and the lens appears undamaged, the patient should thoroughly clean, rinse, and disinfect the lens then reinsert them. After reinsertion, if the problem continues, the patient should **IMMEDIATELY REMOVE THE LENS AND CONSULT THE EYECARE PRACTITIONER.**

When any of the above problems occur, a serious condition such as infection, corneal ulcer, neovascularization, or iritis may be present. The patient should be instructed to **KEEP LENS OFF THE EYE AND SEEK IMMEDIATE PROFESSIONAL IDENTIFICATION** of the problem and prompt treatment to avoid serious eye damage.

FITTING

Conventional methods of fitting contact lens do and do not apply to the **Vision Science (hydrophilic) Contact Lenses**. For a detailed description of the fitting techniques, refer to **Vision Science (hydrophilic) Contact Lenses Professional Fitting and Information Guide**, copies of which are available from:

HAPAKRISTIN INC

help@hapakristin.com

Tel.: 1888-808-0242

Or

Vision Science Co., Ltd.

37-38, Maeyeo-ro 1-gil, Dong-gu, Daegu, 41059, South Korea

Tel: +82-53-857-3578

www.visionscience.co.kr

WEARING SCHEDULE

THE WEARING AND REPLACEMENT SCHEDULES SHOULD BE DETERMINED BY THE EYECARE PRACTITIONER. Patients tend to over wear the lens initially. The eyecare practitioner should emphasize the importance of adhering to the initial maximum wearing schedule. Regular checkups, as determined by the eyecare practitioner, are also extremely important.

The **Vision Science (hydrophilic) Contact Lenses** are indicated for daily wear. The maximum suggested wearing time for this lens is:

| <u>DAY</u> | <u>HOURS</u> |
|------------|--------------------|
| 1 | 6 |
| 2 | 8 |
| 3 | 10 |
| 4 | 12 |
| 5 | 14 |
| 6 | All Waking hours * |

STUDIES HAVE NOT BEEN COMPLETED TO SHOW THAT Vision Science (hydrophilic) Contact Lenses IS SAFE TO WEAR DURING SLEEP.

* WEARING SCHEDULES SHOULD BE DETERMINED BY THE EYECARE PRACTITIONER.

LENS CARE DIRECTIONS

When lenses are dispensed, the patient should be provided with appropriate and adequate instructions and warnings for lens care handling. The eye care professional should recommend procedures and products for each individual patient in accordance with their particular lens wearing schedule and care system selected by the practitioner, the specific instructions for such products and the particular characteristics of the patient.

Frequent/Planned Replacement: Eyecare practitioners should review with the patient lens care directions, including both basic lens care information and specific instructions on the lens care regimen recommended for the patient:

* **Basic Instructions:**

- Care of contact lens takes very little time and involves **THREE** essential steps – **CLEANING, RINSING AND DISINFECTING**. Each step in itself is important, and one step is not to be replaced by the other.
- Always wash, rinse and dry hands before handling contact lens.
- Always use **FRESH, STERILE UNEXPIRED** lens care solutions.
- Use the recommended lens care system; either chemical (not heat) or heat (thermal).

- Different solutions cannot always be used together, and not all solutions are safe for use with all lens.
- **DO NOT ALTERNATE OR MIX LENS CARE SYSTEMS UNLESS INDICATED ON SOLUTION LABELING.**
- Do not use saliva or anything other than the recommended solutions for lubricating or rewetting lens.
- Do not put lens in the mouth.
- Lens should be **cleaned, rinsed, and disinfected** each time they are removed.
- **Cleaning and rinsing** are necessary to remove mucus and film from the lens surface.
- **Disinfecting** is necessary to destroy harmful germs.
- The lens case must be emptied and refilled with fresh, sterile recommended storage and disinfection solution prior to disinfecting the lens.
- Eyecare practitioners may recommend a lubricating/rewetting solution, which can be used to wet (lubricate) lens while they are being worn to make them more comfortable.

Note: Some solutions may have more than one function, which will be indicated on the label. Read the label on the solution bottle, and follow instructions.

* **Lens cleaning, disinfection, and storage:**

Clean one lens first (always the same lens first to avoid mix-ups), rinse the lens thoroughly with recommended rinsing or disinfecting solution to remove the cleaning solution, mucus, and film from the lens surface, and put lens into correct chamber of the lens storage case. Then repeat the procedure for the second lens. After cleaning, **disinfect** lens using the system recommended by the manufacture and/or the eyecare practitioner. To store lens, disinfect and leave them in the closed/unopened case until ready to wear. If lens is not to be used immediately following disinfection, the patient should be instructed to consult the package insert or the eyecare practitioner for information on storage of lens.

* **Lens Case Care:**

Patients must rinse the lens case with sterile contact lens solution (never use tap water) and leave the lens case open to dry after each use. Turn the case over and shake any excess solution out of the case. Be sure that no residual solution remains in the case before the patient allows it to air dry. Replace the lens case at least once every 3 months. Contact lens cases can be a source of bacterial growth.

* **Lens Care Regimen:**

Patients must adhere to the lens care regimen recommended by their eyecare practitioner for the **Vision Science (hydrophilic) Contact Lenses**. Failure to follow this procedure may result in development of serious ocular infections

* **Care for a dried out (dehydrated) dry lens:**

If for some reason, the lens dry out completely a minimum of handling is important, as they are very brittle in the dehydrated state. Carefully place them in rinsing or storage solution for a minimum of thirty minutes during which time they will become soft and flexible. Then follow the cleaning, rinsing, and disinfecting procedures - including soaking the lens in storage and disinfection solution for four hours before wearing again.

* **Soaking and Storing the Lens:**

Patients must only use fresh multi-purpose (contact lens disinfecting) solution each time when soaking (storing) the lenses. The **Vision Science (hydrophilic) Contact Lenses** must be stored only in the recommended solutions. If left exposed to the air, the lens will dehydrate. If lens dehydrates, reference above section on caring for dried out (dehydrated) dry lens.

* **Chemical (NOT HEAT) Lens Disinfection:**

1. Wash and rinse hands thoroughly BEFORE HANDLING LENS.
2. After removal of lens, CLEAN the lens by applying three drops of cleaner to each surface. Rub and rinse the lenses for 15-20 seconds or more and then repeat with the second side for a total of 2 times 30 seconds or more. Follow the complete recommended lens rubbing and rinsing times in the labeling to adequately disinfect the lenses and reduce the risk of contact lens infection.
3. AFTER CLEANING, thoroughly rinse both surfaces of the lens with a steady stream of fresh, sterile rinsing solution for approximately 10 seconds.
4. Fill contact lens carrying case with the recommended disinfection and storage solution and place lens in the proper cells and soak as recommend in solution labeling.

Note: DO NOT HEAT THE DISINFECTION SOLUTION AND LENS.

Caution: Lenses that are chemically disinfected may absorb ingredients from the disinfecting solution which may be irritating to the eyes. A thorough rinse in fresh, sterile rinsing solution prior to placement on the eye should reduce the potential for irritation.

* **Discard Date (for care products):**

Discard any remaining solution ninety (90) days after opening.

For additional information concerning the care, cleaning and disinfecting of contact lenses refer to the **Vision Science (hydrophilic) Contact Lenses** Frequent/Planned Replacement Patient Instruction/Wearer's Instruction Guide.

CARE FOR A STICKING (NON-MOVING) LENS:

If the lens sticks (cannot be removed), the patient should be instructed to apply 3 to 4 drops of the recommended lubricating or rewetting solution directly to the eye and wait until the lens begins to move freely on the eye before removing it. If non-movement of the lens continues after 15 minutes, the patient should **IMMEDIATELY** consult the eyecare practitioner.

HOW SUPPLIED:

The **Vision Science (hydrophilic) Contact Lenses** are supplied sterile in:

- 1) sealed blister packages containing a saline solution. The base of the package is made from polypropylene, which is covered with a laminated foil seal on top.
or
- 2) sealed glass vials containing a saline solution. The glass vials are sealed with a silicone stopper.

The glass vials and blister packages are marked with the base curve, diameter, dioptric power, lens color, manufacturing lot number, and expiration date of the lens.

REPORTING OF ADVERSE REACTIONS:

All serious adverse experiences and adverse reactions observed in patients wearing **Vision Science (hydrophilic) Contact Lenses** or experienced with the lens should be reported to:

HAPAKRISTIN INC
help@hapakristin.com
Tel.: 1888-808-0242

Or

Vision Science Co., Ltd.
37-38, Maeyeo-ro 1-gil, Dong-gu, Daegu, 41059, South Korea
Tel: +82-53-857-3578
www.visionscience.co.kr

CAUTION: *FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED PRACTITIONER.*

PRINT DATE: 9/15/2023

FREQUENT/PLANNED REPLACEMENT PATIENT INSTRUCTION / WEARER'S GUIDE

For the



**Sophisticated Kristin / One of a Kind Kristin / Day n' Night Kristin
/ Attention-Plz Kristin / Another Me Kristin / Lovesick Kristin / Grrrr Kristin
/ Sweet Tooth Kristin / Lucid Kristin**

***CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON
THE ORDER OF A LICENSED PRACTITIONER.***

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CONGRATULATIONS:

You have just received your new frequent/planned replacement (e.g. 2-week, monthly) **Vision Science (hydrophilic) Contact Lenses**. This booklet has been prepared to help you care for it. Please read it carefully and follow the instructions so that you receive full satisfaction from your lens.

PRACTITIONER: _____

ADDRESS: _____

TELEPHONE: _____

Daily Cleaner: _____

Rinsing Solution: _____

Disinfecting Solution: _____

Lubricant/Rewetting Drops: _____

Enzymatic Cleaner: _____

Rewetting Solution: _____

Hydrogen Peroxide System: _____

INTRODUCTION:

With your decision to wear soft (hydrophilic) contact lens, you have joined a growing number of people who are discovering new pleasures from this important advance in vision correction.

Your frequent/planned replacement **Vision Science (hydrophilic) Contact Lenses** is made of a stable, inert, highly purified, hydrophilic (water absorbing) polymer with properties different from conventional rigid lens. Fully manufactured to optical precision in the dry state, your lens hold these qualities in the soft, moist state in which they are suited for your use. Kept moist by the tears in your eyes, the lens is soft and comfort can be immediate. You are cautioned, however, to follow the initial wearing time schedule prescribed by your practitioner and not to overwear the lens simply because they remain comfortable. Your eyecare practitioner will determine your appropriate wearing schedule.

Although soft and pliable, your lens is strong and durable. The life of your frequent/planned

replacement **Vision Science (hydrophilic) Contact Lenses** will depend to a large extent on how you handle and care for them. As with all precision devices, proper use will assure you the benefits of convenience, comfort, and confidence in your lens.

Read this Wearer's Guide carefully. It contains the information you need to know to wear, handle, and care for your frequent/planned replacement **Vision Science (hydrophilic) Contact Lenses**. If you are in doubt about any instructions, request clarification from your eyecare practitioner.

WEARING RESTRICTIONS and INDICATIONS:

The **Vision Science (hydrophilic) Contact Lenses** for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia. The lens may be worn by persons who exhibit refractive astigmatism of .50 diopters or less where the astigmatism does not interfere with visual acuity. The lens is available clear or tinted and may be used to enhance or alter the apparent color of the eye.

Daily wear replacement schedules may vary from patient to patient and should be decided by eyecare practitioners in consultation with their patients.

Frequent/Planned Replacement Wear:

Eyecare practitioners may prescribe any of the above lenses for frequent/planned replacement wear, with cleaning, disinfection, and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens should be removed from your eyes for routine cleaning and disinfecting daily as prescribed by your eyecare practitioner.

DO NOT WEAR YOUR Vision Science (hydrophilic) Contact Lenses WHILE SLEEPING.

CONTRAINDICATIONS (REASONS NOT TO USE):

DO NOT USE the frequent/planned replacement **Vision Science (hydrophilic) Contact Lenses** when any of the following conditions exist:

- * Acute and subacute inflammation or infection of the anterior chamber of the eye.
- * Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids.
- * Severe insufficiency of lacrimal secretion (dry eyes).
- * Corneal hypoesthesia (reduced corneal sensitivity), if not-aphakic.
- * Any systemic disease that may affect the eye or be exaggerated by wearing contact lens.
- * Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lens or use of contact lens solutions.
- * Allergy to any ingredient, such as mercury or thimerosal, in a solution which is to be used to care for your frequent/planned replacement **Vision Science (hydrophilic) Contact Lenses**

- * Any active corneal infection (bacterial, fungi, or viral)
- * If eyes become red or irritated.
- * Patients unable to follow lens care regimen or unable to obtain assistance to do so.

WARNINGS:

PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS

COULD RESULT IN SERIOUS INJURY TO THE EYE.

You should not reuse or “top off” old solution left in your lens case since solution reuse reduces effective lens disinfection and could lead to severe infection, vision loss or blindness. “Topping-Off” is the addition of fresh solution to solution that has been sitting the case.

When disinfecting your lenses you should rub and rinse the lenses for the recommended amount of time to help prevent serious eye infections (see CARING FOR YOUR LENS for specific instructions).

You should never use water, saline solution, or rewetting drops to disinfect the lenses. These solutions will not disinfect the lenses. Not using the recommended disinfectant can lead to severe infection, vision loss or blindness.

You should not store your lenses or rinse your lens case with water or any non-sterile solution. You must only use fresh multi-purpose solution (or sterile saline solution) so your lenses or lens case are not contaminated. Use of non-sterile solution can lead to severe infection, vision loss or blindness.

Water can harbor microorganisms that can lead to severe infection, vision loss or blindness. If your lenses have been submersed in water such as when swimming in pools, lakes, or oceans; then you should discard them and replace them with a new pair. You should ask your eye care practitioner (professional) for recommendations about wearing their lenses during any activity involving water.

Using the multi-purpose solution beyond the discard date could result in contamination of the solution and can lead to severe infection, vision loss or blindness.

EYE PROBLEMS, INCLUDING CORNEAL ULCERS, CAN DEVELOP RAPIDLY AND LEAD TO LOSS OF VISION; IF YOU EXPERIENCE:

- Eye Discomfort,
- Excessive Tearing,
- Vision Changes,

- Loss of Vision,
- Eye Redness
- Or Other Eye Problems

YOU SHOULD IMMEDIATELY REMOVE THE LENSES, AND PROMPTLY CONTACT YOUR EYE CARE PRACTITIONER.

Daily wear lenses are not indicated for overnight wear, therefore, you are instructed not to wear lenses while sleeping. Clinical studies have shown that the risk of serious adverse reactions is increased when these lenses are worn overnight.

Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.

- * You must see your eyecare practitioner as directed.

PRECAUTIONS

- * If the lens sticks (stops moving) on the eye, follow the recommended directions on (care for sticking non-moving lens). The lens should move freely on the eye for the continued health of the eye. If non-movement of the lens continues, you should **IMMEDIATELY** consult your eyecare practitioner.
- * Always wash and rinse hands before handling lens. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lens. It is best to put on lens before putting on makeup. Water-base cosmetics are less likely to damage lens than oil-base.
- * Do not touch contact lens with the fingers or hands if the hands are not free of foreign materials, as microscope scratches of the lens may occur, causing distorted vision and/or injury to the eye.
- * Never wear lens beyond the period recommended by the eyecare practitioner.
- * If aerosol products such as hair spray are used while wearing lens, exercise caution and keep eyes closed until the spray has settled.
- * Always handle lens carefully and avoid dropping them.
- * Do not expose your contact lenses to water while you are wearing them.
- * Avoid all harmful or irritating vapors and fumes while wearing lens.
- * Ask your eyecare practitioner about wearing your lens during sporting activities.
- * Inform the doctor (health care practitioner) about you being a contact lens wearer.
- * Never use tweezers or other tools to remove lens from your lens container unless specifically indicated for that use. Pour the lens into your hand.
- * Do not touch the lens with your fingernails.
- * Always contact your eyecare practitioner before using any medicine or medications in

- your eyes.
- * Always inform your employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or may require that you not wear contact lens.
 - * As with any contact lens, follow-up visits are necessary to assure the continuing health of your eyes. You should be instructed as to a recommended follow-up schedule.
 - * Different solutions cannot always be used together, and not all solutions are safe for use with all lens. Use only recommended solutions that are fresh and sterile. Never use solutions recommended for conventional hard contact lens only. Chemical disinfection solutions should not be used with heat unless specifically indicated on product labeling for use in both heat and chemical disinfection. Always use **FRESH, STERILE UNEXPIRED** lens care solutions. Always follow directions in the package inserts for the use of contact lens solutions. Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.
 - * Do not use saliva or anything other than the recommended solution for lubricating or rewetting lens. Always keep the lens completely immersed in the recommended storage solution when the lens is not being worn (stored). Prolonged periods of drying will damage the lens. Follow the lens care directions for (Care for a Dried Out Dehydrated Dry Lens) if the lens surface does become dried out.
 - * Carefully follow the handling, insertion, removal, cleaning, disinfection, storing and wearing instructions in your instructions for the **Vision Science (hydrophilic) Contact Lenses** and those prescribed by the eyecare practitioner.
 - * Always discard your lenses after the recommended wearing schedule prescribed by your eyecare practitioner.

ADVERSE REACTIONS

The following problems may occur:

- * Eyes stinging, burning, itching (irritation), or other eye pain.
- * Comfort is less than when lens was first placed on eye.
- * Feeling that something is in the eye such as a foreign body or scratched area.
- * Excessive watering (tearing) of the eye.
- * Unusual eye secretions.
- * Redness of the eye.
- * Reduced sharpness of vision (poor visual acuity).
- * Blurred vision, rainbows, or halos around objects.
- * Sensitivity to light (photophobia).
- * Dry eyes.

If you notice any of the above, **IMMEDIATELY REMOVE YOUR LENS.**

- * If discomfort or problems stop following lens removal, then look closely at your lens. If the lens is in any way damaged, **DO NOT PUT THE LENS BACK ON YOUR EYE.** Place the lens in the storage case and contact your eyecare practitioner. If the

lens has dirt, an eyelash, or other foreign body on it, or the problem stops and the lens appears undamaged, you should thoroughly clean, rinse, and disinfect the lens then reinsert them. After reinsertion, if the problem continues, you should **IMMEDIATELY REMOVE THE LENS AND CONSULT YOUR EYECARE PRACTITIONER.**

When any of the above problems occur, a serious condition such as infection, corneal ulcer, neovascularization, or iritis may be present. The patient should be instructed to **KEEP LENS OFF YOUR EYE AND SEEK IMMEDIATE PROFESSIONAL IDENTIFICATION** of the problem and prompt treatment to avoid serious eye damage.

PERSONAL CLEANLINESS and LENS HANDLING

Before Handling Your Lens:

Cleanliness is the first and most important aspect of proper contact lens care.

Before handling your lens, always wash and rinse your hands thoroughly and dry them with a lint-free towel. Do not use soaps, lotions, cold creams, or perfumes which leave a residue on your hands. Avoid using medications, creams, deodorants, make-up, after shave lotions, or similar items prior to touching your lens. When hair spray is used, the eye must be kept closed until the spray has settled. Take care in handling your lens. Always avoid touching your lens with your fingernails or other sharp objects. **NEVER WORK DIRECTLY OVER A SINK WITH THE DRAIN OPEN, AS THE LENS MAY BE LOST.**

Handling and Placing the Lens on the Eye:

- 1) To avoid the possibility of lens mix-ups, always start with the same lens first.
- 2) Remove the lens from its storage case and examine it to be sure that it is moist, clean, clear, and free of any nicks or tears.
- 3) Before inserting the lens, rinse well with fresh, sterile rinsing solution. Then place the lens on the tip of the index finger of your dominant hand.
- 4) While positioned on your index finger, check to ensure the lens has not turned inside out. To check this, look at the profile of the lens against a light background. If the edge profile appears convex and bowl-shaped, then it is correct. If the lens is inverted, it will flare out at the edge. If the lens is inverted, simply reverse it by using light fingertip pressure. Be sure to avoid damaging the lens with your fingernails.
- 5) Look straight ahead and raise the upper lid with your other index finger.
- 6) Then look down, keep both eyes open and place the lens on the upper white part of the eye.
- 7) Slowly release upper lid, and gently close your eye.
- 8) The lens should center automatically, or it can be moved on center by gentle fingertip pressure through the lids.
- 9) Repeat the above procedure for the second lens.

- 10) If the lens appears to be stuck on your eye, apply a few drops of a recommended lubricating or rewetting solution to the eye and blink a few times. If the lens does not move freely on your eye, contact your eyecare practitioner for further instructions.

There is no single "right way" of putting on lens. If you find this method of lens placement difficult, your eyecare practitioner will suggest another method or provide additional information.

Centering the Lens:

Very rarely, a lens that is on the cornea will be displaced onto the white part of the eye during lens wear. This can also occur during placement and removal of the lenses if the correct techniques are not performed properly. To center a lens on the eye, follow the procedure below.

Using your index finger, gently apply pressure to the lens and slide it back into the cornea. If the lens gets under the upper lid, gently massage the upper lid while looking down and move the lens toward the cornea.

Removing the Lens:

Preparation:

- 1) Wash and rinse your hands thoroughly.
- 2) Dry hands with a lint-free towel.
- 3) Check that the lens is centered on the cornea before attempting to remove the lens. Check your vision by covering one eye. If vision is blurry, the lens is off-center. Re-center the lens before attempting to remove it.

Removal:

- 1) To avoid the possibility of lens mix-ups, always begin with the same lens.
- 2) Look up and keep both eyes open.
- 3) Using the middle finger of your dominant hand, gently pull down the lower lid of the first eye. Using the tip of your index finger of the same hand, touch the lens and slide it onto the white of the eye.
- 4) Gently "pinch" the lens between the index finger and the thumb and remove.
- 5) Repeat the procedure for the second eye.
- 6) If the lens cannot be easily moved, apply a few drops of lubricating or rewetting solution to the eye, blink a few times, and when the lens moves freely on the eye, remove in the manner described above. If the lens still cannot be moved, contact your eyecare practitioner for further instruction.
- 7) Upon removal, clean each lens with a contact lens cleaner per the procedures described under the heading, CARING FOR YOUR LENS. Rinse well with rinsing solution and place in the lens storage case filled with fresh storage solution.

IMPORTANT: Always avoid touching your lens with your fingernails. Use only your fingertips.

If you find this method difficult, your eyecare practitioner will suggest another method or provide additional instruction.

If the lens is chipped or torn, do not put the lens back on your eye. Return the lens to the storage case with fresh solution and contact your eyecare practitioner.

CARING FOR YOUR LENS

Basic Instructions:

For continued safe and comfortable wearing of your lens, it is important that you first clean and rinse, then disinfect your lens after each removal, using the care regimen recommended by your eyecare practitioner. Cleaning and rinsing are necessary to remove mucus, secretions, films, or deposits, which may have accumulated after removing them. Disinfecting is necessary to destroy harmful germs.

You should adhere to a recommended care regimen. Failure to follow the regimen may result in development of serious ocular complications as discussed in the warning section above.

If you require only vision correction, but will not or cannot adhere to a recommended care regimen for your lens, or are unable to place and remove your lens or have someone available to place and remove them, you should not attempt to get and wear contact lenses. When you first get your lens, be sure you have to put the lens on and remove them while you are in your eyecare practitioner's office. At that time you will be provided with a recommended cleaning and disinfection regimen and instructions and warnings for lens care, handling, cleaning, and disinfection. Your eyecare practitioner should instruct you about appropriate and adequate procedures and products for your use, and provide you with a copy of the Frequent/Planned Replacement Patient Instruction/Wearer's Guide for the **Vision Science (hydrophilic) Contact Lenses**

For safe contact lens wear, you should know and always practice your lens care routine:

- * Always wash, rinse, and dry hands before handling contact lens.
- * Always use fresh, sterile unexpired lens care solutions.
- * Use recommended system of lens care and carefully follow instructions on solution labeling.
- * Different solutions cannot always be used together, and not all solutions are safe for use with all lens. **DO NOT ALTERNATE OR MIX LENS CARE SYSTEMS UNLESS INDICATED ON SOLUTION LABELING.**
- * Do not use saliva or anything other than the recommended solutions for lubricating or rewetting lens. Do not put lens in the mouth.
- * Never rinse your lens in water from the tap. There are two reasons for this:
 - a. Tap water contains many impurities that can contaminate or damage your lens and may lead to eye infection or injury.
 - b. You might lose the lens down the drain.
- * Your eyecare practitioner should recommend a care system that is appropriate for the frequent/planned replacement **Vision Science (hydrophilic) Contact Lenses** Each

- lens care product contains specific directions for use and important safety information, which should be read and carefully followed.
- * Clean one lens first (always the same lens first to avoid mix-ups), rinse the lens thoroughly with recommended rinsing or disinfecting solution to remove the cleaning solution, mucus, and film from the lens surface, and put lens into correct chamber of the lens storage case. Then repeat the procedure for the second lens.
 - * After cleaning, disinfect lens using the system recommended by the manufacture and/or your eyecare practitioner.
 - * To store lens, use only fresh multi-purpose (contact lens disinfecting) solution each time you soak (store) your lenses. Disinfect and leave them in the closed/unopened case until ready to wear. If lens are not to be used immediately following disinfection, you should consult the package insert or your eyecare practitioner for information on storage of lens.
 - * Always keep your lens completely immersed in a recommended disinfecting/conditioning solution when the lens are not being worn. If you discontinue wearing your lens, but plan to begin wearing them after a few weeks, ask your eyecare practitioner for a recommendation on how to store your lens.
 - * Frequent/Planned Replacement **Vision Science (hydrophilic) Contact Lenses** can be disinfected using a chemical (NOT HEAT) disinfecting system.
 - * Contact lens cases can be a source of bacteria growth. After removing the lens from the case, empty and rinse the lens storage case with solution as recommended by the lens case manufacture; then allow the lens case to air dry. When the case is used again, refill it with storage solution. Replace lens case at regular intervals as recommended by the lens case manufacture or your eyecare practitioner.
 - * Your eyecare practitioner may recommend a lubricating/rewetting solution for your use. Lubricating/Rewetting solutions can be used to wet (lubricate) your lens while you are wearing them to make them more comfortable.
 - * Lenses prescribed for frequent/planned replacement should be thrown away after the recommended wearing period prescribed by your eyecare practitioner.

LENS DEPOSITS AND USE OF ENZYMATIC CLEANER:

Enzyme cleaning may be recommended by the eyecare practitioner. Enzyme cleaning removes protein deposits on the lens. These deposits cannot be removed with regular cleaners. Removing protein deposits is important for the well-being of the patient's lens and eyes. If these deposits are not removed, they can damage the lens and cause irritation. Enzyme cleaning does NOT replace routine cleaning and disinfecting. For enzyme cleaning, the patient should carefully follow the instructions in the enzymatic cleaning labeling.

LENS CASE CLEANING AND MAINTENANCE:

Rinse your lens case with sterile contact lens solution (never use tap water) and leave the lens case open to dry after each use. Turn the case over and shake any excess solution out of the case. Be sure that no residual solution remains in the case before you allow it to air dry.

Replace your lens case at least once every 3 months. Contact lens cases can be a source of bacterial growth.

CARE FOR A STICKING (NON-MOVING) LENS:

If the lens sticks (cannot be removed), you should apply 3 to 4 drops of the recommended lubricating or rewetting solution directly to the eye and wait until the lens begins to move freely on the eye before removing it. If non-movement of the lens continues after 15 minutes, you should IMMEDIATELY consult your eyecare practitioner.

CARE FOR A DRIED OUT (DEHYDRATED) DRY LENS:

If for some reason your lens dry out completely: a minimum of handling is important as they are very brittle in the dehydrated state. Carefully place them in rinsing or storage solution for a minimum of thirty minutes during which time they will become soft and flexible. Then follow the cleaning, rinsing, and disinfecting procedures, including soaking the lens in storage and disinfection solution for four hours before wearing again.

CHEMICAL (NOT HEAT) DISINFECTION:

1. Wash and rinse your hands thoroughly BEFORE HANDLING LENS.
2. After removal of lens, CLEAN the lens by applying three drops of cleaner to each surface. You should rub and rinse the lenses for 15-20 seconds or more and then repeat with the second side for a total of 2 times 30 seconds or more. Follow the complete recommended lens rubbing and rinsing times in the labeling to adequately disinfect the lenses and reduce the risk of contact lens infection.
3. AFTER CLEANING, thoroughly rinse both surfaces of the lens with a steady stream of fresh, sterile rinsing solution for approximately 10 seconds.
4. Fill contact lens carrying case with the recommended disinfection and storage solution and place lens in the proper cells and soak as recommend in solution labeling.

Note: DO NOT HEAT THE DISINFECTION SOLUTION AND LENS.

Caution: Lenses that are chemically disinfected may absorb ingredients from the disinfecting solution which may be irritating to the eyes. A thorough rinse in fresh, sterile rinsing solution prior to placement on the eye should reduce the potential for irritation.

Discard Date (for care products):

Discard any remaining solution ninety (90) days after opening.

EMERGENCIES:

If any chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into the eyes, you should:

FLUSH EYES IMMEDIATELY WITH TAP WATER AND IMMEDIATELY CONTACT YOUR EYECARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

WHEN TO CALL YOUR PRACTITIONER?

Certain symptoms may be early indicators of potentially serious problems. A careful examination of your lens, and professional examination of your eyes, may be required. Remove the lens following the instructions outlined in this guide, and call your eyecare practitioner if:

- 1) Your eye becomes red and feels irritated or "gritty".
- 2) You notice a change in your vision or see rainbows or halos around objects.
- 3) You experience discomfort and/or sensitivity to lights.

A good general policy is:

“IF IN DOUBT ... TAKE THE LENS OUT” and contact your eyecare practitioner.

Learn and Use Proper lens Care Habits:

- 1) Follow Instructions.
- 2) Handle Lens Properly.
- 3) Learn How to Put On and Take Off Your Lens.
- 4) Keep Your Lens Clean.
- 5) Disinfection is a Necessary Security

INSTRUCTIONS FOR MONOVISION WEARER

- You should be aware that as with any type of lens correction, there are advantages and compromises to monovision contact lens therapy. The benefit of clear near vision in straight ahead and upward gaze that is available with monovision may be accompanied by a vision compromise that may reduce your distance visual acuity and depth perception for distance and near tasks. Some patients have experienced difficulty adapting to it. Symptoms, such as mild blurred vision, dizziness, headaches and a feeling of slight imbalance, may last for a brief minute or for several weeks as adaptation takes place. The longer these symptoms persist, the poorer your prognosis for successful adaptation. You should avoid visually demanding situations during the initial adaptation period. It is recommended that you first wear these contact lenses in familiar situations, which are not visually demanding. For example, it might be better to be a passenger, rather than a driver of an automobile, during the first few days of lens wear. It is recommended that you drive with monovision correction only if you pass the driver's license requirements with your monovision correction.
- Some monovision patients will never be fully comfortable functioning under low levels of illumination, such as driving at night. If this happens, you may want to discuss with

your eye care professional having additional contact lenses prescribed so that both eyes are corrected for distance when sharp distance binocular vision is required.

- If you require very sharp near vision during prolonged close work, you may want to have additional lenses prescribed so that both eyes are corrected for near when sharp near vision binocular vision is required.
- Some monovision patients require supplemental spectacles to wear over the monovision contact lens correction to provide the clearest vision for critical tasks. You should discuss this with your eye care professional.
- It is important that you follow your eye care professional's suggestions for adaptation to monovision contact lens therapy. You should discuss any concerns that you may have during and after the adaptation period.
- The decision to be fit with a monovision correction is most appropriately left to the eye care professional in conjunction with you, after carefully considering and discussing your needs.

RECOMMENDED LENS CARE PRODUCTS

The eyecare practitioner should recommend a care system that is appropriate for the frequent/planned replacement **Vision Science (hydrophilic) Contact Lenses**. Each lens care product contains specific directions for use and important safety information, which should be read and carefully followed.

WEARING SCHEDULE:

THE WEARING AND REPLACEMENT SCHEDULES SHOULD BE DETERMINED BY YOUR EYECARE PRACTITIONER.

The **Vision Science (hydrophilic) Contact Lenses** are indicated for daily wear. The maximum suggested wearing time for these lens is:

| <u>DAY</u> | <u>HOURS</u> |
|------------|--------------------|
| 1 | 6 |
| 2 | 8 |
| 3 | 10 |
| 4 | 12 |
| 5 | 14 |
| 6 | All Waking hours * |

STUDIES HAVE NOT BEEN COMPLETED TO SHOW THAT THE “Vision Science (hydrophilic) Contact Lenses” IS SAFE TO WEAR DURING SLEEP.

APPOINTMENT SCHEDULE:

Your appointments are on:

Month Year Time Day

IMPORTANT:

In the event that you experience any difficulty wearing your lens or you do not understand the instructions given you, DO NOT WAIT for your next appointment. TELEPHONE YOUR EYECARE PRACTITIONER IMMEDIATELY.

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

www.visionscience.co.kr





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SYMBOL GLOSSARY



The following symbols may appear on your Contact Lens package.

| Graphic | Title | Description |
|---|--|--|
|  | Manufacturer | Indicates the medical device manufacturer |
|  | Date of manufacture | Indicates the date when the medical device was manufactured |
|  | Use-by date | Indicates the date after which the medical device is not to be used |
|  | Batch code | Indicates the manufacturer's batch code so that the batch or lot can be identified |
|  | Sterilized using steam or dry heat & Single sterile barrier system | Indicates a medical device that has been sterilized using steam or dry heat & Indicates a single sterile barrier system |
|  | Temperature Limit | Indicates the temperature limits to which the medical device can be safely exposed(1~30°C) |
|  | Do not use if package is damaged and consult instructions for use | Indicates that a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information |

| | | |
|---|---|--|
|  | Consult instructions for use or consult electronic instructions for use | Indicates the need for the user to consult the instructions for use |
|  | Caution | Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences |
|  | Medical device | Indicates the item is a medical device |
|  | Unique device identifier | Indicates a carrier that contains unique device identifier information |

The information presented in this glossary is from ISO 15223-1: 2021 Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements

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