

# Professional Fitting Guide

## Preference<sup>®</sup> (tetrafilcon A)

Daily or Extended Wear Hydrophilic Contact Lenses for  
Vision Improvement in Myopic (Nearsighted Patients)

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## Part 1: Professional Fitting Guide – Daily Wear Instructions

Preference® (tetrafilcon A)  
HYDROPHILIC CONTACT LENS  
Handling Tint Lenses

### Introduction

The Preference® (tetrafilcon A) Hydrophilic Contact Lens has been designed to provide patients with the good comfort and vision that are expected of today's ultrathin soft contact lenses, with minimal adaptation time. In addition, the Preference® lens incorporates a lens periphery and 42.5% water content to improve lens movement, handling characteristics, and oxygen permeability.

### Indications (Uses)

The Preference® (tetrafilcon A) Hydrophilic Contact Lens is indicated for daily wear use by non-aphakic patients (have not had cataracts removed) with non-diseased eyes that are myopic. The lens may be worn by persons who may exhibit astigmatism of 2.50 Diopters or less that does not interfere with visual acuity.

### Warnings

The patient should be advised of the following:

**PROBLEMS WITH CONTACTS LENSES AND LENS CARE PRODUCTS COULD RESULT IN SERIOUS INJURY TO THE EYE.** It is essential that you follow your eye care practitioner's directions and all labeling instructions for proper use of your lenses and lens care products. **EYE PROBLEMS, INCLUDING CORNEAL ULCERS, CAN DEVELOP RAPIDLY AND LEAD TO LOSS OF VISION; THEREFORE, IF YOU EXPERIENCE EYE DISCOMFORT, EXCESSIVE TEARING, VISION CHANGES, REDNESS OF THE EYE, IMMEDIATELY REMOVE YOUR LENSES AND PROMPTLY CONTACT YOUR EYE CARE PRACTITIONER.**

All contact lens wearers must see their eye care practitioner as directed. If your lenses are for extended wear, your eye care practitioner may prescribe more frequent visits.

Please refer to the Contraindications, Adverse Effects and Precautions sections of the package insert for further patient information.

### Description of Lens

Preference® (tetrafilcon A) Hydrophilic Contact Lenses resemble small scleral (haptic) lenses in that they overlap onto the sclera by one-half to two millimeters. The lens material, tetrafilcon A, is a cross-linked perpolymer (combination of three different monomers) which was especially

formulated to provide the necessary properties required for the Preference® lens design. The material has a water content of 42.5% by weight when fully hydrated in normal saline solution. Preference® lenses are available as a handling tint lens. The tetrafilcon A lens material, used in the handling tint lenses, has been covalently bonded with C.I. Reactive Blue 163 dye to impart a light blue tint on the lens. This has been done to increase visibility of the lens when it is not being worn on the eye.

Preference® lenses are of bicurve construction with a flat, narrow posterior bevel which is constant for all lenses. Both the central anterior and posterior lens surfaces are spherical. Preference® lenses have a center thickness of 0.035 to 0.065 mm, diameters of 13.8 to 14.4 mm (currently available in 14.4 mm) and base curves of 8.3 to 8.9 mm (currently available in 8.4 and 8.7 mm). Handling tint lenses are available only as minus lenses in powers of -0.25 to -6.50 Diopters in 0.25 D increments and -6.50 to -10.00 Diopters in 0.50 D increments. Preference® lenses are made in lenticular form: the carrier radius and width are varied as a function of lens power to provide a standard edge contour and equal edge thickness.

## Fitting Procedures

### 1. Determine patient's approximate lens power requirements.

- a. Convert the spectacle Rx to minus cylinder form.
- b. Compensate the spectacle Rx for vertex distance if the power is greater than 4.00 diopters.

Example:

- a. = -5.00 -0.50 x 180
- b. = -4.75 -0.50 x 180
- c. = -5.00
- d. = - 4.75 diopters

### 2. Select a trial lens for each eye which is close in power to the patient's lens power requirements.

Rinse the lens in fresh saline before placing them on the patient's eye. Wait for three (3) minutes.

### 3. Check the lens positioning and lens movement\*.

- If the lens does not center properly or moves excessively during blinking and exaggerated eye movements, the Preference® lens is too loose (unstable) and should not be fitted.
- If the lens centers well and does not move on the blink, or if the lens centers well and vision is blurred after 2-3 hours of lens wear, then the lens may be too tight.

\*See section on diagnostic criteria for guidelines on acceptable positioning and movements.

Review the next section on diagnostic criteria and utilize these criteria as necessary to be sure that the best possible lens selection has been made.

### 4. Refract over the lens and check for visual acuity.

Vision should be clear almost immediately after the lens is inserted. If vision is not clear through the over-refraction or if there is excessive residual astigmatism, the lens does not fit properly and should not be dispensed.

#### 5. Determine the exact power required.

To determine the correct power, convert the over-refraction through the diagnostic lens to equivalent sphere and add this to the power of the lens.

Example:

- a. Diagnostic Lens: -3.00
- b. Over-refraction: -1.25 -1.50 x 180
- c. = equiv. sphere: -1.50
- d. NEW LENS POWER = -4.50 diopters

## Diagnostic Criteria

**Diagnostic Criteria is much more subtle when dispensing an ultra-thin lens. Due to its thickness, the greater permeability of oxygen allows for less lens movement.**

### Subjective

- 1) Lens awareness or slight discomfort (providing there is no foreign matter under the lens): usually a sign that the fit is too loose.
- 2) Poor vision or variable vision:
  - a. Vision clears momentarily immediately after each blink, but if vision is blurred in between blinks: fit may be too tight.
  - b. Vision is clear between blinks, but blurs after each blink: fit may be too loose.

### Lens Movement

- 1) Move lens with finger or preferably with the reversed end of the suction cup. Lens should move freely and easily with the slightest pressure. If there is resistance to movement, lens is probably too tight.
- 2) Lens movement on blink with eyes straight ahead should be slight to moderate (0.25 mm to 0.50 mm). No movement may indicate a tight fit.
- 3) Lens movement during lateral eye movements may be very slight and not observable without magnification. Excessive lens movement usually means that fit is too loose.
- 4) As the patient looks up, lens should move down about 0.5-1 mm. Much less than this may indicate a fit which is too tight, considerably more than 1 mm movement may indicate a fit which is too loose.

### Lens Positioning

Perfect geometric centering of the lens is not always possible or necessary, and in some instances can only be achieved with a lens which is too tight. The important consideration in evaluating positioning is corneal coverage. If a lens is somewhat decentered, positioning is satisfactory when

the entire cornea, including the corneal periphery opposite to the decentration, is completely covered by the lens.

If any part of the cornea is not covered by the lens with the eye in the primary position (check positioning between blinks, with the eye looking straight ahead), then the positioning is unacceptable and the lens should not be dispensed.

### **Instrumentation**

#### **1) Slit Lamp**

- a. Bubbles under the lens indicate that the fit is too tight
- b. There should be no impingement of the lens edges of the sclera, which can be seen either as scleral indentation or by a blanching of the scleral blood vessels. When there is this pressure on the sclera the fit is almost certainly too tight, and the lens should not be dispensed.

#### **2) Keratometer (readings taken with lens in place on the eye)**

- a. Mire Quality
  - A clear and constant image indicates a proper fit.
  - Any blurring or distortion of the mires may indicate a poor fit.
  - CAUTION: On occasion the mires may be blurred due to some drying out of the anterior lens surface or mucus on this surface. Whenever mire distortion or blurring is found, have the patient blink rapidly and completely six or more times and recheck. If the mires are still distorted, then the lens should not be dispensed.
- b. Amount and Axis of Cylinder
  - The amount of cylinder should be equal to or less than the corneal cylinder.
  - The axis should be about the same as that of the corneal cylinder.
  - If the amount of cylinder is greater or the axis is considerably different, then the lens should not be dispensed.

#### **3) Retinoscope**

- a. The reflex through a properly fitted lens should be clear and indistinguishable from the reflex without a lens in place.
- b. A darkish or irregular area in any part of the reflex may indicate a lens which is not fitting properly.

**The patient may not have the best possible vision if results with keratometry and retinoscopy are less than optimal.**

## **Monovision Fitting Guidelines**

### **Patient Selection**

#### **1) Monovision Needs Assessment**

For a good prognosis the presbyopic patient should have adequately corrected distance and near visual acuity in each eye. The amblyopic patient or the patient with significant astigmatism (greater than 2.50 diopters) in one eye may not be a good candidate for monovision with the Preference® Hydrophilic Contact Lenses.

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

- a. visually demanding situations such as operating potentially dangerous machinery or performing other potentially hazardous activities; and
- b. driving automobiles (e.g., driving at night). Patients who cannot pass their state driver's license requirements with monovision correction should be advised not to drive with the correction, OR may require that additional over-correction (spectacles) be prescribed.

## **2) 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 bifocals, trifocals or reading glasses. Each patient must understand that monovision, as well as other presbyopic contact lenses, or other alternatives, can create a vision compromise that may reduce visual acuity and depth perception for distance and near tasks. During the fitting process it is necessary that the patient understands the disadvantages as well as the advantages of clear near vision in straight ahead and upward gaze that monovision contact lenses provide.

## **Eye Selection**

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

### **1) Ocular Preference Determination Methods**

METHOD 1:

Determine which eye is the "sight eye". Have the patient point to an 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.

METHOD2:

Determine which eye will accept the added power with the least 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.

### **2) Refractive Error Method**

For the 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.



### 3) 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.

## Special Fitting Considerations

### Unilateral Lens Correction

There are circumstances where only one contact lens is required. As an example, an emmetropic presbyopic 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 no correction in the other eye.
- 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 eye uncorrected for near.

### Near Add Determination

Always prescribe the lens power for the near eye that provides the 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.

### 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 Procedures described earlier in this guide.

Case history and standard clinical evaluation procedures 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.

## **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 adaptational 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.

## **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 (distance 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. These "asymmetric power" spectacles may be for balanced near or far vision. 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 eye care practitioner in conjunction with the patient after carefully considering the patient's needs.

All patients should be supplied with a copy of the Instructions for Wearers.

## Diagnostic Lens Care and Wearing Schedule

### Diagnostic Lens Care

Lenses must be cleaned and disinfected after every trial fitting. They may be either thermally or chemically disinfected. (See Package Insert for instructions and recommended solutions.) Do not alternate or mix lens care systems unless indicated in the lens care system labeling.

### Wearing Schedule

The wearing schedule will be determined by the eye care practitioner. The Preference® contact lens has sufficient oxygen transmissibility and comfort that many patients can achieve full-time daily wear (during waking hours) on the first day of lens wear. However, contact lens adaptation is an individual response, and some patients will benefit from a gradual increase in wear time as suggested below.

Daily Wear - (less than 24 hours, while awake)

A suggested maximum daily wearing time for patients requiring adaptation is:

Day	Wear Time (Hours)
1	4
2	6
3	8
4	10
5	All Waking Hours

## Follow-Up Care

**1) Barring complications, the minimum schedule of the follow-up examinations should be:**

- a. One week from the start of lens wear (patient up to 8 hours continuous wear)
- b. One month from the start of lens wear
- c. Three months from the start of lens wear
- d. Every six months thereafter

**2) Procedures for follow-up visits (with lenses on, preferably at least 6 hours):**

- a. Record patient symptoms (if any)
- b. Check appearance of sclera and lids

- c. Check visual acuity and refract over lens: check on 2 different days before making power changes of  $\pm 0.50$  diopters or less
- d. With Slit Lamp
  - Check for edge impingement of lenses on sclera
  - Check integrity of lens edges
- e. Take keratometer readings of outside lens surface if best acuity through over-refraction is less than before

**3) Procedures for follow-up visits (with lenses removed)**

- a. Do Slit Lamp examination of the cornea, both with and without fluorescein; check for edema, injection, vascularization and corneal staining
- b. Take keratometer readings and compare to original values and mire quality
- c. Check for spectacle blur shortly after lenses are removed

**If any of the above are less than optimal, then the practitioner is to use his professional judgment in dealing with the problem.**

## Part 2: Professional Fitting Guide – Extended Wear Instructions

Preference® (tetrafilcon A)

HYDROPHILIC CONTACT LENS

Handling Tint Lenses

### Introduction

#### Lens Design and Characteristics

The Preference® Hydrophilic Contact Lens is indicated for extended wear vision correction in persons with non-diseased eyes. The lens provides excellent patient comfort and sufficient oxygen transmission through the lens to permit safe extended wear. The water content by weight for a fully hydrated lens is 42.5%. The safety and effectiveness of the Preference® Hydrophilic Contact Lens has been proven through clinical studies.

Preference® Lenses should be maintained in a fully hydrated condition in a solution having a tonicity compatible with the tear film. If left in the air, the lenses will dehydrate and become brittle. When fitted to the eye, Preference® lenses will cover the cornea and extend slightly beyond the limbus. Because of the size of the lens, it is quite stable when worn on the eye.

### Description

The Preference® Hydrophilic Contact Lens is available as a spherical lens. The Preference® Contact Lens is a hemispherical shell of the following dimensions:

- Chord Diameters: 13.8 to 14.4 mm (currently available in 14.4 mm)
- Center Thickness: 0.035 to 0.065 mm
- Base Curves: 8.3 to 8.9 mm (currently available in 8.7 mm)
- Powers: -0.25 to -6.50D in 0.25D increments and -6.50 to -10.00D in 0.50D increments

The lens material, tetrafilcon A, is a hydrophilic random terpolymer of 2-hydroxethyl methacrylate, N-vinyl-2-pyrrolidone, and methylmethacrylate joined in a three dimensional network of terpolymer chains by divinylbenzene cross links.

When produced with a handling tint, the tetrafilcon A lens material has been covalently bonded with C.I. Reactive Blue 163 dye to impart a light blue tint on the lens. This has been done to increase visibility of the lens when it is not being worn on the eye.

The physical properties of the lens are as follows:

- Refractive Index: 1.43
- Light Transmittance: >approximately 90%
- Surface Character: Hydrophilic
- Water Content: 42.5%
- Oxygen Permeability:  $9.3 \times 10^{-11}$  (cm<sup>2</sup>/sec)(ml O<sub>2</sub>/ml x mm Hg at 35°C<sup>1</sup>)

SEE FITTING SECTION FOR LENS PARAMETER AVAILABILITY.

<sup>1</sup>The Method of Irving Fatt, PhD

## **ACTIONS**

When placed on the cornea, the hydrated Preference® Contact Lens acts as a refracting medium to focus light rays on the retina.

## **INDICATIONS (USES)**

The Preference® Hydrophilic Contact Lenses are indicated for extended wear from 1-7 days between removals for cleaning and disinfecting, as recommended by the eye care practitioner. The lens is indicated for the correction of visual acuity in non-aphakic persons with non-diseased eyes that are myopic. The lens may be worn by persons who may exhibit astigmatism of 2.50 Diopters or less that does not interfere with visual acuity.

NOTE: SEE DESCRIPTION "SECTION FOR LENS POWER AVAILABILITY"

## **Patient Selection**

Patients selected to wear the Preference® Lens should be chosen for their motivation to wear contact lenses, general health and cooperation. Patients should have healthy eyes and have no more than two and one-half diopters astigmatism that does not interfere with visual acuity. Patient hygiene and willingness to follow practitioner instructions are essential for successful contact lens wear.

## **Contraindications (Reasons Not to Use)**

DO NOT USE the Preference® Hydrophilic Contact Lenses when any of the following conditions exist:

- Acute or subacute inflammation of the anterior chamber of the eye (between the lens and iris and the cornea).
- Any eye disease which affects the cornea or conjunctiva.
- Any active corneal infection: pus (purulent) bacterial, fungal, or viral infection.
- Insufficiency of lacrimal secretion (dry eyes).
- Corneal hypoesthesia (reduced corneal sensitivity).
- Any systemic disease which may affect the eye or be exaggerated by wearing contact lenses.
- Allergy to any ingredient such as mercury or thimerosal, in a solution which is used to care for Preference® Hydrophilic Contact Lenses
- Patient is unable to follow lens care regimen or unable to obtain assistance to do so.

## **Warnings**

The patient should be advised of the following warnings:

**PROBLEMS WITH CONTACTS LENSES AND LENS CARE PRODUCTS COULD RESULT IN SERIOUS INJURY TO THE EYE.** It is essential that you follow your eye care practitioner's directions and all

labeling instructions for proper use of your lenses and lens care products. **EYE PROBLEMS, INCLUDING CORNEAL ULCERS, CAN DEVELOP RAPIDLY AND LEAD TO LOSS OF VISION; THEREFORE, IF YOU EXPERIENCE EYE DISCOMFORT, EXCESSIVE TEARING, VISION CHANGES, REDNESS OF THE EYE, IMMEDIATELY REMOVE YOUR LENSES AND PROMPTLY CONTACT YOUR EYE CARE PRACTITIONER.**

All contact lens wearers must see their eye care practitioner as directed. If your lenses are for extended wear, your eye care practitioner may prescribe more frequent visits.

The risk of ulcerative keratitis has been shown to be greater among users of extended wear lenses than among users of daily wear lenses. The risk among extended wear users increases with the number of consecutive days that lenses are worn between removals, beginning with the first overnight use. This risk can be reduced by carefully following directions for routine lens care, including cleaning of the lens case. Additionally, smoking increases the risk of ulcerative keratitis for contact lens users.

Please refer to the Precaution and Adverse Effects sections for further patient information.

## **Fitting**

### **Description of Lens Design**

Preference<sup>®</sup> lenses have a bicurve construction with a flat, narrow posterior bevel which is constant for all lenses. Both the central anterior and posterior lens surfaces are spherical. The carrier radius and width are varied as a function of lens power to provide a standard edge contour and equal edge thickness. Preference<sup>®</sup> lenses have a center thickness of 0.035 to 0.065 mm, diameters of 13.8 to 14.4 mm (currently available in 14.4 mm) and base curves of 8.3 to 8.9 mm (currently available in 8.7 mm).

### **Lens Fitting**

(Reference is made to the Lens Fitting in the daily wear section.)

- 1) Determine the patient's approximate lens power requirements.**
  - a. Convert the spectacle Rx to minus cylinder form.
  - b. Compensate the spectacle Rx for vertex distance, if the power is greater than 4.00 diopters.
  - c. Convert to equivalent spherical power.
- 2) Select a trial lens that approximates the patient's power requirements,** rinse with fresh saline, and insert in the conventional manner.
- 3) Check the lens positioning and lens movement.** If the lens does not center properly or moves excessively during blinking and exaggerated eye movements, the lens is too flat (unstable). If the lens does not move or displaces inferiorly on upward gaze, the lens may be too steep.

- 4) **Refract over the lens, and measure the visual acuity.** Vision should be clear almost immediately after the lens is inserted. If vision is not clear through the over-refraction and there is no clear end point the lens does not fit properly.
- 5) **Determine the exact power required.** To determine the correct power, convert the over-refraction through the trial lens to equivalent sphere and add this to the power of the lens.

## **Diagnostic Criteria**

(Reference is made to the Diagnostic Criteria in the daily wear section.)

### **Centering and Movement**

A preliminary evaluation of the lens fit can be made after excess tearing has subsided. An optimal fitting lens will:

- Cover the entire cornea.
- Center well, or have slightly superior displacement.
- Move 0.25 mm to 0.5 mm.
- Allow conjunctival capillaries to move freely under the lens edge with blink. There should be no compression of the conjunctival or limbal capillaries.

### **Lens Corneal Alignment**

The correct lens-cornea alignment will provide:

- Good stable visual acuity.
- Stable over-refraction with clear end point.
- Crisp retinoscopic reflex similar in quality as the eye with no lens in place.
- Excellent comfort.
- Over-keratometry will show clear mire image with no fluctuation with blink.

### **Monovision Fitting Guidelines**

(Reference is made to the Monovision Fitting Guidelines in the daily wear section.)

## **Diagnostic Lens Care**

After the factory sealed lens vial has been opened, the diagnostic lens must be cleaned and disinfected using either the chemical (not heat) or thermal (heat) disinfection method. See “Lens Care Directions” section. DO NOT alternate use of a lens care system, either chemical or heat, on a given lens unless indicated in the lens care system labeling.

## **Follow-Up Care**

### **Adaptive Period**

The wear should first sleep with the lens in place on the eye before a final evaluation of corneal acceptance is made. The eye care practitioner may recommend a limited wearing time at first.



However, clinical studies have established that a wearer's eyes adapt readily to wearing the lenses on an extended wear basis.

### **Adaptive Symptoms**

Wearers may report a brief period of "blurred" vision upon awakening. This may be due to a small degree of lens dehydration, or mucus accumulation on the front surface of the lens. The blurring is normally resolved by a single instillation of 3 drops of a recommended sterile lubricating and rewetting eye drop.

A lens may tighten during wear due to dehydration. If this occurs, lens fit should be re-evaluated.

A partially dehydrated lens may become dislodged if the wearer rubs the eyes or face in a way which puts tension on the eyelids. Advise wearers not to rub their eyes while wearing their lenses. Because Preference® Hydrophilic Contact Lenses are normally comfortable to the wearer, he or she may tolerate a foreign body under the lens as a minor irritation. Wearers should be cautioned to remove the lens if there is any irritation or feeling of "grittiness." Instruct the wearer to inspect, clean, and disinfect the lens before replacing it on the cornea.

### **Suggested Schedule of Follow-up Visits**

A recommended schedule of follow-up examinations is:

- 1) One to four hours after initial fitting
- 2) \*The day following the initial fitting
- 3) \*One week (5 to 7 days post-fitting)
- 4) One week following visit 4 (2 weeks post-fitting)
- 5) \* Two weeks following visit 4 (4 weeks post-fitting)
- 6) Two months following visit 5 (12 weeks post-fitting) and
- 7) \* Every three to six months thereafter, or as determined by the eye care practitioner.

\*Minimum visit schedule

Each follow-up examination should include:

- a) A check of visual acuity with over-refraction, if required.
- b) A complete slit-lamp examination of the eye, both with and without the lens.
- c) A thorough inspection of the lens to check for damage or surface deposits.
- d) An update of the wearer's permanent record.

### **Unscheduled Visits**

An unscheduled visit may be indicated whenever the wearer reports a change in vision, ocular discomfort, or redness of the eye. If one or more of these symptoms occur, advise the wearer to remove the lenses immediately and to visit the office as soon as possible.

## Precautions

The patient should be advised to follow the instructions below to prevent damage to the eye(s) or to their lens(es):

- Before leaving the eye care practitioner's office, the wearer should be able to remove his or her lens(es) promptly or have someone else be able to remove the lens(es) for them.
- Always follow the recommended lens care system for your Preference<sup>®</sup> Hydrophilic Contact Lens. Use the recommended lens care solutions and carefully follow recommended directions:
  - NEVER USE CONVENTIONAL HARD CONTACT LENS SOLUTIONS THAT ARE NOT ALSO RECOMMENDED FOR USE WITH SOFT HYDROPHILIC LENSES.
  - Always use FRESH rinsing and storage solutions.
  - Do not mix or alternate chemical (not heat) and thermal (heat) lens care systems unless indicated in the lens care system labeling.
  - Chemical disinfection solutions should not be used with heat unless the product labeling indicates use for both chemical and heat.
  - Do not use saliva or anything other than the recommended solutions to wet the lenses.
  - Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn. Prolonged periods of drying will damage the lenses. Follow the lens care directions for CARE FOR A DRIED OUT LENS if the lens surface does become dry (dehydrated).
  - If the lens sticks (stops moving) on the eye, follow the recommended directions on CARE FOR A STICKING LENS. The lens must move freely on the eye for the continued good health of the eye. If nonmovement of the lens continues, the eye care practitioner should be immediately consulted.
  - Always wash, rinse and dry hands before handling the contact lenses. Eye irritation may result if cosmetics, lotions, soaps, creams or deodorants come in contact with the lenses and if the lenses are contaminated by infectious or noninfectious dirt.
  - Avoid using aerosol products such as hair spray while wearing lenses. If sprays are used, keep eyes closed until the spray has settled.
  - Fluorescein, a yellow dye, should not be used while the lenses are on the eye. The lenses absorb this dye and become discolored. Whenever the eye care practitioner does use fluorescein in the lens wearer's eyes, the eyes should be flushed with a sterile normal saline solution. Wait at least one hour before replacing the lenses.
  - Avoid all harmful or irritating vapors and fumes while wearing lenses.
  - Do not swim with lenses in place.
  - Never use tweezers or other tools to remove your lens from the lens container. Pour the storage solution containing the lens into the palm of the hand.
  - Do not touch the lens with fingernails.
  - The patient should always inform his or her physician (general health practitioner) that he or she wears contact lenses.

- The eye care practitioner should always be consulted before the patient uses any medication in his or her eyes.
- The patient should always inform his or her employer that he or she wears contact lenses. Some jobs may require use of eye protection equipment or may require that contact lenses not be worn.
- As with any contact lens, follow-up visits are necessary to assure good health. The eye care practitioner should provide the patient with a schedule for follow-up visits.

## **ADVERSE EFFECTS (PROBLEMS AND WHAT TO DO)**

The following problems may occur:

- eyes sting, burn, or itch (irritation)
- comfort is less than when lens was first placed on eye
- feeling of something in the eye (foreign body, scratched area)
- excessive watering (tearing) of the eyes
- unusual eye secretions
- redness of the eyes
- reduced sharpness of vision (poor visual acuity)
- blurred vision, rainbows, or halos around objects
- sensitivity to light (photophobia)
- dry eyes

The patient should be advised to follow the procedures outlined below if they notice any of the above problems:

- IMMEDIATELY REMOVE THE LENS.
- If the problem continues, DO NOT put the lens back on the eye. Store it in the recommended storage solution, and IMMEDIATELY consult the eye care practitioner.
- If the discomfort or problem stops, then look closely at the lens.
  - If the lens is in any way damaged, DO NOT put the lens back on the eye. Place the lens in the storage case and contact the eye care practitioner.
  - If the lens has dirt, an eyelash, or other foreign body on it, or the problem stops and the lens appears undamaged, thoroughly clean, rinse and disinfect the lens; then reinsert it.

When any of the above symptoms occur, a serious condition such as infection, corneal ulcer, neovascularization, or iritis may be present. The patient should be instructed to seek **immediate** professional identification of the problem and prompt treatment to avoid serious eye damage.

## **WEARING SCHEDULE**

THE WEARING SCHEDULE SHOULD BE DETERMINED BY THE EYE CARE PRACTITIONER. Studies have been completed to show that Preference® Hydrophilic Contact Lenses are safe to wear during sleep. Clinical studies have shown that a wearer's eyes adapt readily to wearing Preference®

Hydrophilic Contact Lenses on an extended wear basis, and that limited initial wear is not usually necessary. However, the practitioner may recommend a limited initial wearing time.

**CAUTION:** Not every patient is able to wear the Preference® Hydrophilic Contact Lens on an extended wear basis, even if the same patient can wear a contact lens on a daily basis. The eye care practitioner will determine the wearing schedule that is best for the patient.

The patient should be reminded that extended wear with Preference® Contact Lenses is not an endurance contest and to use good judgment. The patient should remove, clean, and disinfect the lenses anytime he or she notices a change in comfort, vision, or redness of the eye(s).

**THE LENS SHOULD BE REMOVED, CLEANED, AND DISINFECTED AT LEAST ONCE EVERY 7 DAYS,** or as the eye care practitioner suggests. Regular checkups, as determined by the eye care practitioner, are also extremely important.

# LENS CARE DIRECTIONS

## Basic Instructions

- Always wash, rinse and dry the hands before handling the contact lens.
- Use the system of lens care recommended by the practitioner: either chemical (not heat) or thermal (heat). DO NOT ALTERNATE OR MIX LENS CARE SYSTEMS UNLESS INDICATED IN THE LENS CARE SYSTEM LABELING.
- The patient should be advised to carefully read their Instructions for Wearers booklet for details. Copies are available from the practitioner.
- Lenses must be cleaned, rinsed and disinfected each time they are removed. CLEANING is necessary to remove mucus and film from the lens surface. RINSING removes loosened debris and residual cleaning solution. DISINFECTING is necessary to destroy harmful microorganisms.
- Clean and rinse one lens first. Rinse the lens *thoroughly* to remove the cleaning solution. Always clean and rinse the same lens first to avoid mix-ups. Put that lens into the correct chamber of the lens storage case. Then repeat the procedure for the second lens.
- If the eye care practitioner recommends soaking lenses in enzyme periodically to remove protein deposits, an enzymatic cleaner such as Allergan® Enzymatic Contact lens Cleaner (Allergan Pharmaceuticals, Inc.) may be used. Follow the manufacturer's instructions for using the cleaner and rinse *thoroughly* with the recommended rinsing solution. *Always* disinfect the lenses after cleaning and rinsing and prior to wear.
- Disinfect lenses using the system (see Recommended Lens Care Products Table) recommended by the eye care practitioner.
- To store lenses, disinfect, then leave them in the unopened case until ready to wear. If the lenses have been stored in the unopened case for more than 24 hours, disinfect immediately before wearing or at least once a week. Put fresh solution inside the chamber(s) of the lens case completely covering the lenses before disinfecting.
- After reinserting lenses, empty and rinse the lens storage case and allow it to air dry. When the case is next used, refill it with fresh solution.
- Use the right solutions (see Recommended Lens Care Products Table) to care for Preference® lenses.

**RECOMMENDED LENS CARE PRODUCTS  
FOR USE WITH PREFERENCE® HYDROPHILIC CONTACT LENS**

(Your eye care practitioner may recommend other alternative products and procedures for lens care which should be followed. If alternative products and procedures are recommended, ask your eye care practitioner for specific information on that product.)

PURPOSE OF LENS CARE PRODUCT:	LENS CARE SYSTEM		
	CHEMICAL (Not Heat) LENS CARE USING A HYDROGEN PEROXIDE SYSTEM	THERMAL (Heat)	CHEMICAL (Not Heat)
Clean Lens After Each Removal	Pliigel® MiraFlow®	Pliigel® MiraFlow®	Pliigel® Mira Flow®
Enzymatically Clean Lens at Intervals Recommended by Your Eye Care Practitioner	Allergan® Enzymatic Contact Lens Cleaner	Allergan® Enzymatic Contact Lens Cleaner	Allergan® Enzymatic Contact Lens Cleaner
Rinse	MiraSept® Rinsing and Neutralizing Solution (Step 2)	Unisol® Unisol® 4** Unisol Plus™	Unisol® Allergan® Hydrocare® Cleaning and Disinfecting Solution
Disinfect	*MiraSept® Disinfecting Solution (Step 1)	Unisol®, with a heat disinfection unit	*Allergan® Hydrocare® Cleaning and Disinfecting Solution
Store After Disinfection	MiraSept® Rinsing and Neutralizing Solution (Step 2)	Unisol® Unisol®4	Allergan® Hydrocare® Cleaning and Disinfecting Solution
Lubricate/Rewet	Clerz®2 Clerz	Clerz®2 Clerz	Clerz®2 Clerz

Pliigel®, MiraSept®, Unisol®, and Clerz® are trademarks of Alcon Laboratories, Inc.  
 Allergan® Enzymatic and Hydrocare are trademarks of Allergan Pharmaceuticals, Inc.  
 MiraFlow® is a trademark of Ciba Vision.  
 \*DO NOT USE CHEMICAL DISINFECTING SOLUTIONS WITH HEAT. Such use can damage your lens.  
 \*\*DO NOT use Unisol®4 to rinse your lenses after disinfection.  
 FOR MORE INFORMATION ABOUT YOUR LENS CARE PRODUCTS, REFER TO THE MANUFACTURER'S PACKAGE INSERT.

## Chemical (Not Heat) Lens Disinfection

(Using the MiraSept® Hydrogen Peroxide Disinfection System)

- After cleaning, rinse both sides of the cleaned lens *thoroughly* in a steady stream of MiraSept Rinsing and Neutralizing Solution (Step 2), holding the lens between the forefinger and thumb of one hand.
- Place the lens in the correct lens chamber of the lens holder provided with the MiraSept System.
- Repeat the above procedures for the second lens.
- Fill the lens cup provided *to the line* with MiraSept Disinfecting Solution (Step 1). Place the lens holder containing the lenses in the lens cup and tighten. Shake case well, then allow the lens to soak for 10 minutes.
- After 10 minutes, open the case and discard the solution inside. Proceed to the next step immediately.
- Fill the lens cup *½-way to the line* with MiraSept Rinsing and Neutralizing Solution (Step 2). Replace the lens holder and tighten. Shake case well. Open the case and discard the solution inside.
- Fill the lens cup *to the line* with fresh Rinsing and Neutralizing Solution (Step 2), replace the lens holder and tighten. Shake case well. Allow the lenses to soak for *at least* 10 minutes.
- Leave the lenses in the unopened storage case until you are ready to wear them. If desired, you may rinse the lenses with *fresh* Rinsing and Neutralizing Solution (Step 2) before inserting them in your eyes.
- After removing lenses, empty and rinse the lens cup and lens holder with water and allow them to dry.

## Thermal (Heat) Lens Disinfection

- After cleaning and *thoroughly* rinsing the contact lenses, prepare the empty lens storage case. Use the solution recommended by the eye care practitioner to keep the lens wet during disinfection.
- Wet the lens chambers (sections) with fresh solution.
- Put each lens into its correct chamber.
- Fill the chamber of the case to the line with the fresh solution, completely covering the lenses.
- Tightly close the top on each chamber of the lens storage case.
- Put the lens storage case into the heat disinfection unit and follow the directions to operate the unit.
- Leave the lenses in the unopened storage case until ready to put on your eyes.
- Before reinsertion of the lenses, no rinsing is necessary unless the eye care practitioner recommends rinsing.

### **Emergency (Alternate) Method for Thermal (Heat) Disinfection**

If the heat disinfection unit is not available, place the tightly closed storage container which contains the lenses and solution into a pan of already boiling water for at least 10 minutes (15 minutes at altitudes above 7000 feet). Be careful not to allow the water in the pan to boil away. Remove the pan from the heat and allow it to cool for 30 minutes to complete the disinfection of the lenses. NOTE: USE OF THE HEAT DISINFECTION UNIT SHOULD BE RESUMED AS SOON AS POSSIBLE.

### **Chemical (Not Heat) Lens Disinfection** *(Not a Hydrogen Peroxide Disinfection System)*

- After cleaning and *thoroughly* rinsing the first contact lens, place a few drops of the recommended disinfection solution in the correct chamber of the storage case.
- Put the lens into the correct chamber.
- Fill the chamber to the line with the disinfection solution, completely covering the lens.
- Tightly close the top of the chamber of the lens storage case.
- Repeat the above procedure for the second lens after removal.
- To disinfect lenses, leave them in the solution for at least 4 hours.
- DO NOT HEAT THE DISINFECTION SOLUTION AND LENSES.
- Leave the lenses in the unopened storage case until ready to put on your eyes.
- THOROUGHLY *RINSE* YOUR LENSES WITH RINSING SOLUTION BEFORE INSERTING AND WEARING.

## **CARE FOR A DRIED OUT (DEHYDRATED) LENS**

If Preference® (tetrafilcon A) Hydrophilic Contact lenses are off the eye and exposed to air for 30 minutes or longer, they will become dry and brittle.

To rewet the lens:

- Handle the lens carefully.
- Place the lens in its storage case and SOAK the lens in the recommended rinsing and storage solution for at least two hours. Soak the lens until it returns to a soft state.
- Clean and disinfect the rewetted (rehydrated) lens using the lens care system recommended by the eye care practitioner.
- If after soaking, the lens does not become soft, DO NOT USE THE LENS. The patient should be advised to contact their eye care practitioner.

## **CARE FOR A STICKING LENS**

- If the lens sticks (stops moving) on the eye, apply 2-3 drops of the recommended rewetting or lubricating solution. Wait until the lens begins to move freely on the eye before removing it. If nonmovement of the lens continues, the patient should immediately consult their eye care practitioner.



## HOW SUPPLIED

Each lens is sterilized and supplied in a glass vial containing sterile buffered isotonic saline solution. The glass vial is marked with base curve, dioptric power, diameter, manufacturing site, manufacturing lot number of the lens and expiration date. Additionally the glass vial for Preference® is marked handling tint.



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