

# Professional Fitting and Information Guide



O<sub>2</sub>OPTIX Custom™ (sifilcon A)  
Soft Contact Lenses  
For Daily Wear



Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed eye care professional



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## INTRODUCTION

Thank you for prescribing **O<sub>2</sub>OPTIX Custom™ (sifilcon A)** soft contact lenses. The lenses may be worn for daily wear with removal for cleaning and disinfection and quarterly replacement with a fresh new lens. However, you will determine the replacement schedule as well as the length of time the patient's lenses are to be worn each day before removal for cleaning, rinsing, and disinfection. Based on these schedules, you will also determine the number of lenses each patient requires, the frequency of follow-up care, and a dispensing schedule.

Fitting **O<sub>2</sub>OPTIX Custom (sifilcon A)** contact lenses is easy and predictable. This guide contains important information regarding fitting procedures and aftercare of the O<sub>2</sub>OPTIX Custom patient.

## PRODUCT DESCRIPTION

**O<sub>2</sub>OPTIX Custom (sifilcon A)** soft contact lenses are available in a spherical, lens design. The lens material is approximately 32% water and 68% sifilcon A, a fluoro-silicone containing hydrogel that is surface treated. Lenses contain the color additive Phthalocyanine Green, a light green handling tint, which makes them easier to see when handling.

This breakthrough lens material provides a high level of oxygen through the lens and has been surface treated to wet with the tears.

### • *Lens Properties*

- Specific Gravity: 1.073
- Refractive Index (hydrated): 1.43
- % Luminous Transmittance: 94.6 to 97.6%
- Oxygen Permeability (Dk): 82 x 10<sup>-11</sup> (cm<sup>2</sup>/sec)(ml O<sub>2</sub> /ml x mm Hg), measured at 35° C (intrinsic Dk - Polarographic method)
- Water Content 32% by weight in normal saline

### • *Available Lens Parameters<sup>1</sup>*

O<sub>2</sub>OPTIX Custom (spherical)

- Chord Diameter: 13.2mm, 14.0mm, 14.8mm
- Center Thickness: 0.070 mm @ -3.00D (varies with power)
- Base Curves: 13.2 diameter: 7.4mm, 7.7mm, 8.0mm, 8.3mm  
14.0 diameter: 7.8mm, 8.1mm, 8.4mm, 8.7 mm, 9.0mm  
14.8 diameter: 8.0mm, 8.3mm, 8.6mm, 8.9 mm, 9.2mm
- Powers: +20.00D to -20.00D (0.25D steps)

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<sup>1</sup>Check for actual product availability as additional parameters may be introduced over time.

- **Actions**

When hydrated and placed on the cornea **O<sub>2</sub>OPTIX Custom (sifilcon A)** contact lenses act as a refracting medium to focus light rays on the retina.

**INDICATIONS (USES)**

**O<sub>2</sub>OPTIX Custom (sifilcon A)** spherical soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who have 1.50 diopters or less of astigmatism.

The lenses may be prescribed for daily wear with removal for cleaning and disinfection prior to reinsertion, as recommended by the eye care professional.

See **WARNINGS** for information about the relationship between wearing schedule and corneal complications.

**CONTRAINDICATIONS, WARNINGS, PRECAUTIONS & ADVERSE EFFECTS**

For additional important prescribing and safety information, refer to the Package Insert that is printed in the back of this guide.

**ADVERSE EFFECT REPORTING**

If a patient experiences any serious adverse effects associated with the use of **O<sub>2</sub>OPTIX Custom (sifilcon A)** contact lenses, please notify CIBA Vision Corporation, **Technical Consultation in the USA at 1-800-241-7468**.

**FITTING GUIDELINES**

*Please see the appropriate sections of this booklet that contain guidelines for spherical and monovision fitting techniques.*

## FITTING GUIDELINES (Spherical Lenses)

The design of **O<sub>2</sub>OPTIX Custom (sifilcon A)** spherical lenses includes an optical zone that is aspherical on both front and back surfaces. A transition zone feature has been added between the front surface optical and lenticular zones in order to ensure a smooth transition between these zones. A tricurve front surface design is employed to minimize the overall lens thickness profile across the entire power range.

### 1. Patient Selection

The patient characteristics necessary to achieve success with **O<sub>2</sub>OPTIX Custom (sifilcon A)** lenses are similar to those for other spherical soft contact lenses. A thorough pre-fitting examination should be conducted to ensure the patient is a suitable candidate for soft contact lens wear.

The following procedures should be followed when fitting **O<sub>2</sub>OPTIX Custom** lenses. For additional tips on fitting the monovision patient refer to the section Monovision Fitting Guidelines.

### 2. Pre-fitting Examination

**A pre-fitting examination is necessary to:**

- assess the patient's motivation, physical state and willingness to comply with instructions regarding hygiene and wear schedule
- obtain ocular measurements for initial contact lens parameter selection
- collect baseline clinical information to which post-fitting examination results can be compared

**A pre-fitting examination should include:**

- a thorough case history
- a spherocylindrical refraction
- keratometry
- tear assessment
- biomicroscopy
- horizontal visible iris diameter measurement (HVID)

### 3. Initial Lens Determination

**A. Lens Base Curve Selection:**

**O<sub>2</sub>OPTIX Custom (sifilcon A)** lenses are recommended to be fit empirically. The following table gives a guide to selecting the initial base curve and diameter. Because ocular topographies vary, the final base curve and/or diameter may deviate from this table.

Base curve selection is critical to the successful fit of the **O<sub>2</sub>OPTIX Custom (sifilcon A)** lenses, especially in higher prescriptions. Flat-fitting lenses may not drape well over the cornea and can result in the lens edge sitting away from the cornea or fluting. The steeper base curve lenses typically achieve a more comfortable fit.

Measured HVID	Selected Lens Diameter	Flat Keratometry Readings		
		< 42.00D ( > 8.0mm)	42.00 to 45.00D (8.0 to 7.5mm)	> 45.00D ( < 7.5mm)
< 11.00mm	13.2mm	8.3mm	8.0mm	7.7mm
11.00 to 12.0mm	14.0mm	8.7mm	8.4mm	8.1mm
> 12.0mm	14.8mm	8.9mm	8.6mm	8.6mm

**B. Initial Lens Power Selection**

The initial power selection should be as close as possible to the patient's prescription after taking into account spherical equivalent and vertex calculations, if necessary.

**Spherical Equivalent Calculation**

To determine initial lens power, convert the spherocylindrical spectacle Rx to its spherical equivalent as follows:

$$\text{Spherical Equivalent} = \text{Sphere power} + 1/2 (\text{Cylinder Power})$$

**Example:**

$$\begin{aligned} \text{Spectacle Rx: } & -4.50D -1.00 \times 180 \\ \text{Spherical equivalent: } & -4.50D + (-0.50D) = -5.00D \end{aligned}$$

**Vertex Distance Conversion**

If the spherical equivalent is greater than  $\pm 4.00D$ , a vertex distance correction is necessary (see Vertex Distance Conversion Chart) to determine the lens power required at the corneal plane.

**Example:**

$$\begin{aligned} \text{Spectacle Rx: } & -4.50D -1.00 \times 180 \\ \text{Spherical equivalent: } & -4.50D + (-0.50D) = -5.00D \\ \text{Vertex compensation: } & -4.75 \text{ (initial lens power)} \end{aligned}$$

**C. Lens Fit Assessment**

Allow the lenses to settle on the eyes for approximately **10 to 20 minutes**. This allows time for the patient to adapt to the lenses and time for the lens to equilibrate.

Evaluate the fit and movement of the lenses on the eye. The **Push-Up Test**, as described below, is an important part of the lens evaluation. The following guidelines will be helpful in fit evaluation:

### ***Characteristics of a Well-Fitted Lens***

A well-fitted **O<sub>2</sub>OPTIX Custom (sifilcon A)** contact lens satisfies the following criteria:

1. **Good centration and full corneal coverage** in all fields of gaze.
2. **Sufficient lens movement to allow tear exchange** under the lens during a blink in primary or up gaze. A well fitting lens will show movement of 0.1 to 0.5 mm.
3. **Satisfactory Push-Up Test**
  - This test is a reliable indicator of a good fit. With the patient looking straight ahead, place your index finger on the patient's lower lid and nudge the edge of the lens upward while observing lens movement. Then pull the lid back down and observe the return of the lens.
  - A well fitted lens will move freely upward, stopping shortly after passing the limbus and then return freely to its original position.
4. **Good comfort and stable visual response** (with over refraction).

### ***Characteristics of a Tight (Steep) Lens Fit***

A tight or steep fit should not be dispensed. If a lens fit is judged to be too steep a flatter lens (larger base curve), if available, should be evaluated. A tight or steep lens fit would display some or all of the following characteristics:

1. Insufficient or no lens movement during a blink in primary or upgaze.
2. Unsatisfactory Push-Up Test
  - **A tight fitting lens will resist movement.** If successfully nudged upward, the lens may remain decentered or return slowly to its original position.
3. Good centration.
4. Good comfort.
5. Fluctuating vision between blinks.

### ***Characteristics of a Loose (Flat) Lens Fit***

If a lens fit is judged to be too flat, a steeper lens (smaller base curve), if available, should be evaluated. A loose lens fit would display some or all of the following characteristics:

1. Reduced comfort. This finding is often the only signal of a loose fitting lens. If initial comfort doesn't improve quickly, try a steeper base curve, if available.
2. Lens edge standoff. Even minor lifting of the edge indicates a loose fitting lens.
3. Excessive lens movement during the blink in primary or upgaze.
  - A loose fitting lens will move very easily, well beyond the limbus and possibly encroaching upon or going beyond the pupil. It will then return very quickly to its original position and often times return lower than its original position.
4. Poor centration with limbal exposure on exaggerated eye movement.
5. Vision may be blurred after the blink.

***D. Final Lens Power Determination***

After the characteristics of a well fitted lens have been satisfied, conduct a **spherical over-refraction** to determine the proper lens power to be dispensed.

**Example:**

**Spectacle Refraction: -14.50 DS**

**Vertexed Refraction: -12.50 DS**

**Over Refraction: -0.75 DS**

**Final Lens Power: -13.25 DS**

## ***FITTING GUIDELINES (Monovision)***

### ***Patient Selection***

#### ***A. Monovision Needs Assessment***

For a good prognosis, the patient should have adequately corrected distance and near visual acuity in each eye. Patients with reduced visual acuity, such as the amblyopic patient, may not be a good candidate for monovision.

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:

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 requirements for a driver's license with monovision correction should not drive with this correction. An additional over-correction can be prescribed to improve vision.

#### ***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 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 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 compared to spectacle bifocals.

### ***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 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.
- Method 2 - Determine which eye will accept the added power for near with the least reduction in distance 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 anisometric 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 person 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 patient would only require a near lens while a bilateral myope may require only a distance lens.

**Examples:**

- **Emmetrope:** 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 would be without a lens.
- **Bilateral myope:** 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.
- **Unilateral astigmat:**

a) Emmetropic in one eye, astigmatic in the other

<u>Spectacle Rx</u>	<u>Potential Monovision Rx</u>
O.D. Plano	Uncorrected for distance
O.S. -1.00 -1.00 x 090	+0.50 -1.00 x 090 for near
Add: +1.50	

b) Myopic in one eye, astigmatic in the other

<u>Spectacle Rx</u>	<u>Potential Monovision Rx</u>
O.D. -1.50	Uncorrected for near
O.S. -2.00 -1.75 x 090	-2.00 -1.75 x 090 for distance

- **Amblyopia**  
The amblyopic patient may not be a good candidate for monovision.
- **Astigmatism**  
Patients with less than 1.50 diopters of astigmatism might be successfully fit in O<sub>2</sub>OPTIX Custom (sifilcon A) spherical lenses.

### ***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.

### ***Trial Lens Fitting***

A trial lens 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 procedures should be used to determine the suitability of monovision. 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 evaluating the patient's performance under the above conditions, 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 less favorable 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 feeling of slight imbalance. You should explain the adaptational symptoms to the patient. These symptoms may last for a few minutes or for several weeks. The longer these symptoms persist, the poorer the chance 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 is recommended that patients 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 under 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:

- Have a third contact lens (distance power) to use when critical distance viewing is needed.
- Have a third contact lens (near power) to use when critical near viewing is needed.
- Have supplemental spectacles to wear over the monovision contact lenses for specific visual tasks. This is particularly applicable for those patients who cannot meet driver's 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 professional in conjunction with the patient after carefully considering the patient's needs. All patients should be supplied with a copy of the **O<sub>2</sub>OPTIX Custom (sifilcon A) Patient Instruction Booklet**, which contains important instructions for the monovision wearer. You can obtain copies of the instruction book by contacting a **customer service representative, in the USA at (800) 241- 5999, or download from our website at [www.cibavision.com](http://www.cibavision.com)**.

## DISPENSING VISIT

To help ensure patient success the following steps should be conducted with each patient, even if they have previously worn contact lenses. Even experienced wearers are prone to develop bad habits over time.

**O<sub>2</sub>OPTIX Custom (sifilcon A)** lenses are supplied sterile in foil sealed blister pack containers. Open the foil pack by peeling back the foil lidding material and gently slide the lens out of the container with your finger, or pour the lens onto the palm of your clean hand.

Conduct the following steps with each patient, even if they have previously worn contact lenses:

### **A. *Verification of Lens Fit***

Evaluate lens fit and visual response with the lens on the eye. The criteria of a well-fitted lens should be met and the patient's visual acuity should be acceptable. If not, the patient should be refitted with a more appropriate lens.

### **B. *Hygiene and Lens Handling Instructions***

Good hygiene and proper lens handling are important factors in achieving safe, comfortable lens wear. Instruct the patient on hygiene and handling of lenses. Patients who are unable to place and remove lenses should not be provided with them.

### **C. *Lens Wear and Replacement Schedules (see Package Insert)***

Prescribe and explain the patient's wearing and replacement schedules.

### **D. *Lens Care Directions (see Package Insert)***

Recommend an appropriate cleaning, rinsing, and disinfecting system, and provide the patient with instructions for proper lens care, including the case.

### **E. *Additional Instructions***

#### ***Back-Up Spectacles***

**Patients should be specifically advised to have suitable spectacles available for use if discomfort or symptoms of problems occur.**

#### ***Review the Package Insert***

Provide the patient with all relevant information and precautions on the proper use of the lenses that are prescribed.

#### ***Provide the Patient Instruction Booklet for O<sub>2</sub>OPTIX Custom Lenses.***

Give the patient a copy of CIBA Vision's **Patient Instruction Booklet** for **O<sub>2</sub>OPTIX Custom (sifilcon A)** soft contact lenses. Review the contents so the patient clearly understands the prescribed lens wear, care, and replacement schedule. You can obtain copies of the instruction book by contacting a **customer service representative, in the USA at (800) 241-5999, or download from our website at [www.cibavision.com](http://www.cibavision.com).**

## **FOLLOW-UP EXAMINATIONS**

Follow-up care is extremely important for continued successful contact lens wear and for monitoring the patient's ocular response to lens wear. Follow-up care should include:

- Case history, including questions to identify any problems related to contact lens wear
- Management of specific problems, if any, and
- A review with the patient of the lens wearing schedule, replacement schedule, and proper lens care and handling procedures.

### **Follow-Up Examination Procedures**

- Prior to a follow-up examination, the contact lenses should be worn for at least four continuous hours.
- Record patient's symptoms, if any.
- Measure visual acuity monocularly and binocularly with the contact lenses in place.
- Perform an over-refraction to check for residual refractive error.
- With a biomicroscope, evaluate lens fitting characteristics and examine the lens surface for deposits.
- Remove the lenses and conduct a thorough biomicroscopic examination with fluorescein. Rinse eyes with saline before re-inserting lenses.
- Evert upper lids to determine condition of tarsal conjunctiva.
- Periodically perform keratometry and spectacle refractions. These results should be recorded to compare to the initial measurements.
- If any observations are abnormal, use professional judgment to manage the problem and restore the eye to optimal conditions. If visual requirements are not satisfied during any follow-up examination, the patient should be re-fitted with a more appropriate lens.

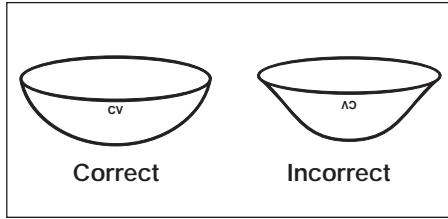
## **LENS HANDLING HINTS**

### **Lens Insertion**

- When about to place the lens on the eye, make sure the lens sits up on the placement finger. The finger should be dry so surface tension does not cause the lens to adhere to the finger.
- Check to see that the lens is right side out. A lens that is placed on the eye inside out may not feel comfortable or provide good vision.

One way to tell if the lens is right side out is to look at the lens engravings at the edge of the lens.

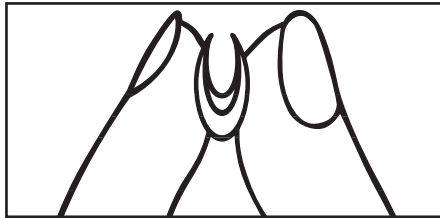
- Place the lens on the tip of your index finger and hold it up against a light source.
- If the lens is right side out, you should be able to read "CV" at the edge of the lens. If the lens is inside out, the engravings will be reversed. Carefully turn the lens right side out with your fingers.



- Place the lens directly onto the cornea (placing it on the lower sclera can lead to the lens folding after a blink). While continuing to hold both lids in place, the patient should look down to seat the lens. The lids may then be released.

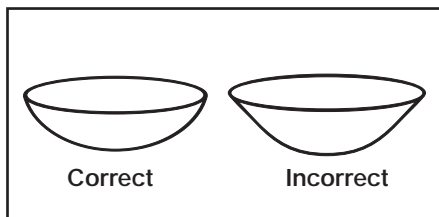
Another way to do this is to place the lens between your thumb and index finger and squeeze the edges together gently.

- If the edges come together, the lens is right side out.
- If the edges turn outward, the lens is wrong side out. Carefully reverse it with your fingers.



A third way is to place the lens on the tip of your index finger and check its shape.

- If the edge appear bowl-shaped, it is right side out.
- If the edge has a lip or flares outward, it is wrong side out and must be reversed.



## Lens Removal

- To remove the lens from the cornea, assure that the fingers are clean and dry.
- Slide the lens off the cornea (down or to the side) onto the sclera. This produces a fold in the lens, which assists in removal. With the index finger and thumb, gently pinch the lens off the eye.
- Remember to remove the same lens first (right or left), then the other lens. This helps avoid getting the lenses mixed up.
- It may be easier to remove contact lenses if the rewetting drops are used (approved for use with soft lenses) as recommended by the eye care professional 10 to 15 minutes before lens removal. This will also help prevent lens tearing during the removal process.

## Care for a Sticking Lens

- If the lens sticks (stops moving) or begins to dry on the eye, instruct the patient to apply several drops of a recommended lubricating solution (used in accordance with package labeling). The patient should wait until the lens begins to move freely on the eye before attempting to remove it. If the lens continues to stick, the patient should **immediately** consult the eye care professional.

## IN OFFICE CARE OF DIAGNOSTIC LENSES

Eye care professionals should understand and educate contact lens technicians concerning proper use of diagnostic lenses.

- Each contact lens is shipped sterile in a sealed blister pack containing phosphate buffered saline solution. Hands should be thoroughly washed and rinsed and dried with a lint free towel prior to handling a lens. In order to insure sterility, the blister pack should not be opened until immediately prior to use.
- For fitting and diagnostic purposes, the **lenses should be disposed of after a single use and not be re-used from patient to patient.**

## ADDITIONAL INFORMATION

CIBA Vision is pleased to assist with fitting or clinical questions regarding O<sub>2</sub>OPTIX Custom contact lenses. Eye care professionals having questions or problems should contact the **CIBA Vision Technical Consultation department, in the USA at (800) 241-7468** or visit **[www.virtualconsultant.cibavision.com](http://www.virtualconsultant.cibavision.com)**. To order O<sub>2</sub>OPTIX Custom (sifilcon A) contact lenses contact your **CIBA Vision sales representative or call Customer Service, in the USA at (800) 241-5999.**

**IMPORTANT:** This package insert is effective as of November 2006 and applicable to the (sifilcon A) soft contact lenses described below. Please read carefully and keep this information for future use.

This package insert is intended for the eye care professional, but should be made available to patients upon request. The eye care professional should provide the patient with appropriate instructions that pertain to the patient's prescribed lenses. Copies of this package insert are available without charge from CIBA Vision Corporation by calling CIBA Vision Customer Service at 1-800-241-5999 or download from our website at [www.cibavision.com](http://www.cibavision.com). CIBA Vision makes available a *Patient Instruction Booklet*, which is recommended to be given to patients.

**Rx only**

**CAUTION:** FEDERAL (UNITED STATES) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED EYE CARE PROFESSIONAL.

**PRODUCT DESCRIPTION**

O<sub>2</sub>OPTIX Custom™ (sifilcon A) soft contact lenses are made from a lens material that is approximately 32% water and 68% sifilcon A, a fluoro-silicone containing hydrogel which is surface treated. Lenses contain the color additive Phthalocyanine Green, a light green handling tint, which makes them easier to see when handling.

**Lens Properties**

- Specific Gravity: 1.073
- Refractive Index (hydrated): 1.43
- % Luminous Transmittance: 94.6 to 97.6% (varies with power)
- Oxygen Permeability (Dk):  $82 \times 10^{-11}$  (cm<sup>2</sup>/sec) (ml O<sub>2</sub>/ml x mm Hg), measured at 35°C (intrinsic Dk - Polarographic method) 32% by weight in normal saline
- Water Content:

**Lens Parameters**

- Diameter Range 12.0 to 15.0 mm
- Power Range +20.00D to -20.00D
- Base Curve Range 7.0 to 9.2 mm

**Lens Parameters Available<sup>2</sup>**

- **O<sub>2</sub>OPTIX Custom** (spherical)
  - Chord Diameter: 13.2mm, 14.0mm, 14.8mm
  - Center Thickness: 0.070 mm @ -3.00D (varies with power)
  - Base Curve: 13.2 diameter: 7.4mm, 7.7mm, 8.0mm, 8.3mm, 14.0 diameter: 7.8mm, 8.1mm, 8.4mm, 8.7 mm, 9.0mm, 14.8 diameter: 8.0mm, 8.3mm, 8.6mm, 8.9 mm, 9.2mm
  - Powers: +20.00D to -20.00D (0.25D steps)

**ACTIONS**

When hydrated and placed on the cornea, O<sub>2</sub>OPTIX Custom (sifilcon A) contact lenses act as a refracting medium to focus light rays on the retina.

**INDICATIONS (Uses)**

O<sub>2</sub>OPTIX Custom (sifilcon A) spherical soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who have 1.50 diopters or less of astigmatism.

The lenses may be prescribed for daily wear with removal for cleaning and disinfection (chemical, not heat) prior to reinsertion, as recommended by the eye care professional.

**CONTRAINDICATIONS (Reasons not to use)**

**DO NOT use O<sub>2</sub>OPTIX Custom (sifilcon A) contact lenses when any of the following exists:**

- Inflammation or infection of the anterior chamber of the eye
- Active disease, injury or abnormality affecting the cornea, conjunctiva, or eyelids
- Microbial infection of the eye
- Insufficiency of lacrimal secretion (dry eye) that interferes with contact lens wear
- Corneal hypoesthesia (reduced corneal sensitivity)
- Use of any medication that is contraindicated or interferes with contact lens wear, including eye medications
- Any systemic disease which may be exacerbated by or interferes with contact lens wear
- Allergic reactions or ocular irritation of the ocular surfaces or adnexa that may be caused by or exaggerated by the wearing of contact lenses
- Allergy to an ingredient in a solution which must be used to care for the contact lenses
- Patient history of recurring eye or eyelid infections, adverse effects associated with contact lens wear, intolerance or abnormal ocular response to contact lens wear
- If eyes become red or irritated

**WARNINGS**

**Advise patients of the following warnings pertaining to contact lens wear:**

- Problems with contact lenses and lens care products could result in serious injury to the eye. It is essential that patients follow their eye care professional's directions and all labeling instructions for proper use of lenses and lens care products, including the lens case. Eye problems, including corneal ulcers, can develop rapidly and lead to loss of vision.
- Daily wear lenses are not indicated for overnight wear, and patients should be instructed not to wear lenses while sleeping. Clinical study results<sup>1</sup> have shown that the risk of serious adverse reactions is increased when lenses are worn overnight.
- Studies<sup>1</sup> have shown that contact lens wearers who are smokers have a higher incidence of adverse

reactions than nonsmokers.

- If a patient experiences eye discomfort, excessive tearing, vision changes, or redness of the eye, the patient should be instructed to immediately remove lenses and promptly contact his or her eye care professional. It is recommended that contact lens wearers see their eye care professional regularly as directed.

## PRECAUTIONS

To prevent damage to the eyes or to the contact lenses, the following precautions should be taken:

### Special Precautions to the Eye Care Professional:

Due to the small number of patients enrolled in the clinical investigation of lenses, 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 eye care professional should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, 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 evaluated on initial dispensing and monitored on an ongoing basis by the prescribing eye care professional.

- Fluorescein, a yellow dye, should not be used while the lenses are on the patient's eyes. The lenses may absorb this dye and become discolored. Whenever fluorescein is used, the eyes should be flushed thoroughly with sterile saline solution that is recommended for in eye use prior to inserting lenses. Avoid dispensing saline from an aerosol can directly into the eye.
- Before leaving the eye care professional's office, the patient should be able to promptly remove their lenses or should have someone else available who can remove their lenses for them.
- Eye care professionals should instruct the patient to remove the lenses immediately if the eye becomes red or irritated.
- Routine eye examinations are necessary to help assure the continued health of the patient's eyes. Eye care professionals should make arrangements with the patient for appropriate follow-up visits.
- Visual changes or changes in lens tolerance may occur during pregnancy or use of oral contraceptives. Caution patients accordingly.
- Patients should be specifically advised to have suitable spectacles available for use if discomfort or symptoms of problems occur.

**Eye Care Professionals should carefully instruct patients about the following care regimen and safety precautions:**

### Handling Precautions:

- Be sure that before leaving the eye care professional's office the patient is able to promptly remove lenses or have someone else available to remove them.
- Good hygiene habits help promote safe and comfortable lens wear. **Always wash and rinse hands before handling lenses.**
- REMOVE A LENS IMMEDIATELY if an eye becomes red or irritated.
- Carefully follow the handling, insertion, removal, cleaning,

disinfecting, storing and wearing instructions in the Patient Instructions for O.OPTIX Custom (sifilcon A) contact lenses.

- Always handle lenses carefully. If a lens is dropped small particles or fibers may adhere to the lens surface which can irritate the eye. Lenses should be cleaned and disinfected prior to insertion or replaced with a sterile, fresh new lens.
- Never use tweezers or other sharp objects such as fingernails to remove lenses from the lens container unless specifically indicated for that use. Pour the lens into the hand.

### Lens Wearing Precautions:

- Patients should never exceed the prescribed wearing schedule regardless of how comfortable the lenses feel. Doing so may increase the risk of adverse effects.
- The lens should move freely on the eye at all times. If the lens sticks (stops moving) on the eye, follow the recommended directions in the *Care for a Sticking Lens* section. If non-movement of the lens continues, the patient should be instructed to consult their eye care professional immediately.
- The eye care professional should be consulted about wearing lenses during water sports and water related activities. Exposure to water while wearing contact lenses in activities such as swimming, water skiing, and hot tubs may increase the risk of ocular infection, including but not limited to Acanthamoeba keratitis.
- Eye irritation, infection, or lens damage may result if cosmetics, lotion, soap, cream, hair spray, deodorant, aerosol products or foreign particles come in contact with lenses.
- Environmental fumes, smoke, and vapors should be avoided in order to reduce the chance of lens contamination or physical trauma to the cornea.
- Lenses should be disposed of and replaced according to the eye care professional's recommendations.
- Note the correct lens power for each eye to prevent getting them mixed up.
- Always keep a supply of replacement lenses and spectacles in current prescription on hand.
- Do not use lenses beyond the expiration date.

### Solution Precautions:

- Eye injury due to irritation or infection may result from lens contamination. To reduce the risk of contamination, review the appropriate manufacturer's labeled lens care instructions with the patient (see Lens Care Directions).
- Only use fresh, unexpired lens care solutions recommended for use with soft contact lenses and follow directions in the product package inserts.
- If a lens is exposed to air while off the eye it may become dry, brittle, and permanently damaged. If this should occur, the lens should be discarded and replaced with a new one to avoid possible irritation or injury to the eye. Always keep the lenses completely immersed in the recommended storage solution when lenses are not being worn.
- Do not use thermal (heat) disinfection and do not heat lens care products.
- Saliva or anything other than the recommended solution for lubricating or wetting lenses should not be used with the lenses.

### Lens Case Precautions:

- Contact lens cases can be a source of bacterial growth and require proper use, cleaning and replacement at regular intervals as recommended by the lens case manufacturer or eye care professional.

### Other Topics to Discuss with Patients:

- Periodic eye examinations are extremely important for contact

lens wearers. Schedule and conduct appropriate follow-up examinations to determine ocular response. CIBA Vision recommends that contact lens patients see their eye care professional every six months or as recommended by the eye care professional.

- Certain medications may cause dryness of the eye, increased lens awareness, lens intolerance, and blurred vision or visual changes. These include, but are not limited to, antihistamines, decongestants, diuretics, muscle relaxants, tranquilizers, and those for motion sickness. Caution patients using such medications accordingly and prescribe proper remedial measures.
- Visual changes or changes in lens tolerance may occur during pregnancy or use of oral contraceptives. Caution patients accordingly.

#### Who Should Know that the Patient is Wearing Contact Lenses:

- Patients should inform their health care practitioners that they are wearing contact lenses.
- Patients should inform their employers that they are wearing contact lenses. Some jobs may require the use of eye protection equipment or may require that lenses not be worn.

It is strongly recommended that patients be provided with a copy of the *O-OPTIX Custom (silflcon A) Patient Instruction Booklet* available from CIBA Vision and understand its contents prior to dispensing the lenses.

#### ADVERSE EFFECTS

**Potentially serious complications are usually accompanied by one or more of the following signs or symptoms:**

- Moderate to severe eye pain not relieved by removing the lens
- Foreign body sensation
- Excessive watering or other eye secretions including mucopurulent discharge
- Redness of the eyes
- Photophobia (light sensitivity)
- Burning, stinging or itching or other pain associated with the eyes
- Comfort is less compared to when the lens was first placed on eye
- Poor visual acuity (reduced sharpness of vision)
- Blurred vision, rainbows or halos around objects
- Feeling of dryness

**Patients should be instructed that if any of the above signs or symptoms are noticed, he or she should:**

- **IMMEDIATELY REMOVE THE LENSES.**
- **If the discomfort or problem stops, then look closely at the lens(es):**
  - If the lens(es) is in any way damaged, DO NOT put the lens(es) back on the eye. Discard damaged lens(es), and contact the eye care professional.
  - If the lens(es) have dirt, an eye lash or other foreign body on it, thoroughly clean, rinse, and disinfect prior to reinsertion.
- If the discomfort or problem continues after removing lens(es) or upon reinsertion, **IMMEDIATELY** remove the lens(es) and contact the eye care professional for identification of the problem and prompt treatment to avoid serious eye damage.
- The patient should be instructed **NOT** to use a new lens as self-treatment for the problem.
- The patient should be informed that a serious condition such as corneal ulcer, infection, corneal vascularization, or iritis may be present, and may progress rapidly. Less serious reactions such as abrasions, infiltrates, and bacterial conjunctivitis must

be managed and treated carefully to avoid more serious complications.

- Additionally, contact lens wear may be associated with ocular changes that require consideration of discontinuation or restriction of wear. These include but are not limited to local or generalized corneal edema, epithelial microcysts, epithelial staining, infiltrates, neovascularization, endothelial polymegethism, tarsal papillary changes, conjunctival injection or iritis.

#### ADVERSE EFFECT REPORTING

If a patient experiences any serious adverse effects associated with the use of O-OPTIX Custom (silflcon A) contact lenses, please notify: CIBA Vision Corporation, **Technical Consultation in the USA at 1-800-241-7468.**

#### FITTING GUIDE AND PATIENT BOOKLET

Conventional methods of fitting contact lenses apply to O-OPTIX Custom (silflcon A) contact lenses. For a detailed description of the fitting techniques, refer to the *O-OPTIX Custom (silflcon A) Professional Fitting and Information Guide*. Both the professional fitting guide and a patient instruction booklet are available free of charge from:

CIBA Vision Corporation  
11460 Johns Creek Parkway  
Duluth, GA, USA 30097  
1-800-241-5999

#### LENS WEAR & REPLACEMENT SCHEDULES

The wearing and replacement schedule should be determined by the eye care professional.

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

- To avoid tendency of the daily wear patient to overwear the lenses initially, stress the importance of adhering to a proper, initial wearing schedule. Normal daily wear of lenses assumes a minimum of 6 hours of non lens wear per 24 hour period.
- It may be advisable for patients who have never worn contact lenses previously to be given a wearing schedule that gradually increases wearing time over a few days. This allows more gradual adaptation of the ocular tissues to contact lens wear.

##### Lens Replacement

The replacement schedule is determined by the eye care professional based upon the patient's individual needs and physiological conditions. CIBA Vision recommends quarterly replacement (i.e., every three months), or as recommended by the eye care professional.

#### LENS CARE DIRECTIONS

Patients must adhere to a recommended care regimen. Lenses must be cleaned, rinsed, and disinfected after removal and prior to reinsertion on the eye according to the instructions in the package inserts provided with the lens care products recommended by the eye care professional. Failure to follow the complete regimen in accordance with manufacturer's instructions in the package inserts may contribute to problems (see ADVERSE EFFECTS) and/or result in the development of serious ocular complications as discussed in WARNINGS.

##### Basic Instructions for Lens Cleaning and Disinfection:

When lenses are dispensed, the eye care professional should recommend an appropriate system of lens care and provide the

patient with instructions according to the package labeling.

The eye care professional should review the following instructions with the patient:

- **Lenses must be cleaned, rinsed, and disinfected each time they are removed, for any reason.** If lens care products are not available at the time of removal, the lenses may not be reinserted, but should be stored until they can be cleaned, rinsed, and disinfected.
- **Cleaning** is necessary to remove mucus, film, and contamination from the lens surface. **Rinsing** removes all traces of the cleaner and loosened debris. **Disinfecting** is necessary to destroy remaining microorganisms
- Lenses must be cleaned, rinsed, disinfected, and stored in accordance with the package labeling of the lens care products recommended by the eye care professional.
- CIBA Vision recommends a chemical method of disinfection such as Clear Care® or AQuify® Multi-Purpose Solution. Disinfection efficacy testing of (siflicon A) lenses with other multipurpose solutions is currently not available.
- The eye care professional may recommend additional cleaning procedures such as a rub step.
- Use of an enzymatic cleaner such as Unizyme® is optional and may be recommended by the eye care professional if warranted.
- Lens compatibility with an abrasive type cleaner such as OPTI-CLEAN\*\* It has not been tested and is not recommended.
- Heat disinfection has not been tested, may result in distortion of the lens, and is not recommended
- **To help avoid serious eye injury from contamination:**
  - Always wash, rinse and dry hands before handling the lenses.
  - Use only fresh sterile solutions recommended for use with soft (hydrophilic) contact lenses. When opened, sterile non-preserved solutions must be discarded after the time specified in the label directions.
  - Do not use saliva, tap water, homemade saline solution, distilled water, or anything other than a recommended sterile solution indicated for the care of soft lenses.
  - Do not reuse solutions.
  - Use only fresh solutions for each lens care step. Never add fresh solution to old solution in the lens case.
  - Follow the manufacturer's instructions for care of the lens case.
  - Replace the lens case at regular intervals to help prevent case contamination by microorganisms that can cause eye infection.
- Never use a hard (rigid) lens solution unless it is also indicated for use with soft contact lenses. Corneal injury may result if hard (rigid) lens solutions not indicated for use with soft lenses are used in the soft lens care regimen.
- Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn to avoid lens dehydration.
- Unless specifically indicated in the labeling, do not alternate, change, or mix lens care systems or solutions for any one pair of lenses. If in doubt as to solution suitability, consult the eye care professional.

\*OPTI-CLEAN is a registered trademark of Alcon Laboratories, Inc.

#### CARE FOR A STICKING LENS

If the lens sticks (stops moving) or begins to dry on the eye, instruct the patient to apply several drops of a recommended lubricating solution (used in accordance with package labeling).

The patient should wait until the lens begins to move freely on the eye before attempting to remove it. If the lens continues to stick, the patient should IMMEDIATELY consult the eye care professional.

#### IN OFFICE USE OF DIAGNOSTIC LENSES

Eye care professionals should educate contact lens technicians concerning proper use of diagnostic lenses.

Each contact lens is shipped sterile in a blister pack containing phosphate buffered saline solution. Hands should be thoroughly washed and rinsed and dried with a lint free towel prior to handling a lens. In order to insure sterility, the blister pack should not be opened until immediately prior to use. For fitting and diagnostic purposes, lenses should not be re-used from patient to patient.

#### 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 or fresh saline solution, remove the lenses and place them in the recommended storage solution, and call or visit the eye care professional or a hospital emergency room immediately.**

#### HOW SUPPLIED

Each lens is packaged in a foil-sealed plastic container containing isotonic phosphate buffered saline solution and is steam sterilized. The package is marked with the base curve, diameter, dioptic power, manufacturing lot number and expiration date. The package may also contain the product code MTO 82.

CIBA Vision Corporation  
11460 Johns Creek Parkway  
Duluth, Georgia USA 30097  
[www.cibavision.com](http://www.cibavision.com)

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<sup>1</sup>New England Journal of Medicine, September 21, 1989:321 (12), pp.773-783

<sup>2</sup>Check for actual product availability as additional parameters may be introduced over time

D7439A/98131

### ***Vertex Distance Conversion Chart***

For minus lenses, read left to right; for plus lenses, read right to left.  
(12 mm Vertex Distance)

-	+	-	+	-	+	-	+
4.00	3.87	7.50	6.87	12.00	10.37	19.00	15.50
4.25	4.00	7.62	7.00	12.50	10.75	19.25	15.62
4.50	4.25	7.75	7.12	12.75	11.00	19.25	15.75
4.75	4.50	7.87	7.25	13.00	11.25	19.75	16.00
5.00	4.75	8.00	7.37	13.50	11.50	20.00	16.12
5.12	4.87	8.12	7.50	13.75	11.75	20.25	16.25
5.37	5.00	8.25	7.62	14.00	12.00	20.50	16.50
5.50	5.12	8.50	7.75	14.25	12.25	20.75	16.62
5.62	5.25	8.75	8.00	14.75	12.50	21.00	16.75
5.75	5.37	9.00	8.25	15.00	12.75	21.25	17.00
5.87	5.50	9.25	8.37	15.50	12.75	21.75	17.25
6.00	5.62	9.50	8.62	15.75	13.25	22.25	17.50
6.12	5.75	9.75	8.75	16.25	13.50	22.50	17.75
6.37	5.87	10.00	9.00	16.75	13.75	23.00	18.00
6.50	6.00	10.25	9.12	17.00	14.00	23.50	18.25
6.62	6.12	10.50	9.25	17.25	14.25	23.75	18.50
6.75	6.25	10.75	9.37	17.62	14.37	24.25	18.75
6.87	6.37	11.00	9.62	18.00	14.50	24.75	19.00
7.00	6.50	11.25	9.75	18.12	14.75	25.00	19.25
7.12	6.62	11.50	10.00	18.50	15.00	25.50	19.50
7.37	6.75	11.75	10.25	18.75	15.25	26.00	19.75

LENS CARE PRODUCT CHART FOR SOFT CONTACT LENSES,

**AOSEPT® Lens Care System**

AOSEPT® Disinfectant	Disinfecting solution
AOSEPT® Lens Cup	Lens case for AOSEPT Disinfectant and AODISC Neutralizer
AODISC® Neutralizer	Neutralizes AOSEPT into a gentle buffered saline solution
Softwear® Saline	Rinsing and storage
Miraflow® Extra Strength Daily Cleaner	Cleaner

**Clear Care®**

Clear Care® Cleaning & Disinfecting Solution	Multipurpose solution for cleaning, disinfecting, & protein removal
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**AQuify®**

**Multi-Purpose Solution**

The only multi-purpose solution that effectively cleans and moisturizes contact lenses in just 5 minutes.

AQuify is a multi-purpose solution for cleaning, rinsing, disinfecting and storing soft (hydrophilic) lenses, including silicone hydrogel lenses.

*Includes PRO-GUARD™ Lens Case*

The PRO-GUARD lens case is made of a special plastic infused with silver ions, a known antibacterial agent that kills germs and helps prevent lens case contamination.

The PRO-GUARD lens case should not be used by persons who are allergic to silver or other metals.

**Other CIBA Vision® Lens Care Products**

AQuify® Long-Lasting Comfort Drops	Lubricating and rewetting
Unizyme® Enzymatic Cleaner	Enzymatic cleaner for contact lens protein removal

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