

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. CIBA Vision makes available a *Patient Instruction Booklet*, which is recommended to be given to patients.



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

PRODUCT DESCRIPTION

O: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): 82×10^{-11} (cm²/sec) (ml O₂/ml x mm Hg, measured at 35°C (intrinsic Dk - Polarographic method)
- Water Content: 32% by weight in normal saline

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 Available²

- **O: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:OPTIX Custom (sifilcon A) contact lenses act as a refracting medium to focus light rays on the retina.

INDICATIONS (Uses)

O: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: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 results¹ have shown that the risk of serious adverse reactions is increased when lenses are worn overnight.**
- **Studies¹ 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 (sifilcon 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 (sifilcon 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 (sifilcon A) contact lenses. For a detailed description of the fitting techniques, refer to the *O:OPTIX Custom (sifilcon 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 (sifilcon 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™ II 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, dioptric power, manufacturing lot number and expiration date. The package may also contain the product code MTO 82.

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11460 Johns Creek Parkway
Duluth, Georgia USA 30097
www.cibavision.com
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¹New England Journal of Medicine, September 21, 1989;321 (12), pp.773-783
²Check for actual product availability as additional parameters may be introduced over time

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