Caution: Federal (United States) Law restricts this device to sale by or on the order of a licensed eye care professional.

Product Description
Ciba Vision® O·Optix™ Air Optix™ Aqua Air Optix™ for Astigmatism and Air Optix™ Aqua Multifocal (Ilotrafilcon B) Soft Contact Lenses

Contact lenses act as a refracting medium to focus light rays on the retina.

Actions
Surface treated. Lenses contain the color additive copper phthalocyanine, a light blue tinting handle, which makes it easier to see when handling.

• Lens Properties
  • Specific Gravity: 1.08
  • Refractive Index (Hydrated): 1.42
  • Light Transmittance: 96%.
  • Oxygen Permeability (Dk): 110 x 10^-10 (cm/sec)
    (ml O2/m/hr x mm Hg), measured at 30°C (Intrinsic Dk - Cuomelometric method).
  • Water Content: 33% by weight in normal saline

• Lens Parameters
  • Diameter Range: 13.0 to 15.0 mm
  • Power Range: -20.00 to +20.00 +
  • Base Curve Range: 8.0 to 9.2 mm

• Lens Parameters Available

O·Optix and Air Optix Aqua (spherical)
  • Chord Diameter: 14.2 mm
  • Center Thickness: 0.080 mm @ -3.00 (with powers)
  • Power: 8.6 mm
  • Base Curves: +6.00 to -10.00 (0.25 steps)
  • Chord Diameter: 14.5 mm
  • Center Thickness: 0.102 mm @ -3.00 (with powers)
  • Power: 8.7 mm
  • Base Curves: +6.00 to -10.00 (0.25 steps)
  • Chord Diameter: 14.2 mm
  • Center Thickness: 0.08 mm @ -3.00 (with powers)
  • Power: 8.6 mm
  • Base Curves: +6.00 to -10.00 (0.25 steps)
  • Chord Diameter: 15.0 mm (spherical)

Air Optix for Astigmatism
  • Chord Diameter: 14.5 mm
  • Center Thickness: 0.100 mm @ -3.00 (with powers)
  • Power: 8.7 mm
  • Base Curves: +6.00 to -10.00 (0.25 steps)
  • Chord Diameter: 14.2 mm

Air Optix Aqua Multifocal
  • Chord Diameter: 14.2 mm
  • Center Thickness: 0.08 mm @ -3.00 (with powers)
  • Power: 8.6 mm
  • Base Curves: +6.00 to -10.00 (0.25 steps)
  • Chord Diameter: 14.0 mm

Actions
When hydrated and placed on the cornea, Ciba Vision (Ilotrafilcon B) soft contact lenses act as a refracting medium to focus light rays on the retina.

Indications (Uses)
• O·Optix and Air Optix Aqua (Ilotrafilcon B) spherical soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or apheric persons with non-diseased eyes with up to approximately 1.50 diopters (D) of astigmatism that does not interfere with visual acuity.
• O·Optix for Astigmatism (Ilotrafilcon B) toric soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or apheric persons with non-diseased eyes with up to 6.00 (D) or less of astigmatism.
• Air Optix Aqua Multifocal (Ilotrafilcon B) soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) and/or presbyopia in phakic or apheric persons with non-diseased eyes with up to 6.00 (D) or less of astigmatism.

Contraindications (Reasons Not to Use)
Do not use I lotrafilcon B 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
• History of microbial infection of the eye
• Insufficiency of lacrimal secretion (dry eye) that interferes with contact lens wear
• Corneal hypotension (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 ular irritation of the corneal surface 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:
• Serious eye injury, scarring of the cornea, and loss of vision may result from problems associated with wearing contact lenses and using contact lens care products. To reduce these risks, emphasize to the patient the need for strict compliance with the lens care regimen including hand washing, proper lens disinfection, cleaning of the lens case, wearing restrictions, wearing schedules, and follow-up visit schedules.
• Eye problems, including corneal ulcers, can develop rapidly and lead to loss of vision. Instruct patients at the dispensing visit and subsequent visits to immediately remove their lenses and promptly contact their eye care practitioner if they should experience eye discomfort, foreign body sensation, excessive tearing, or any visual changes, redness of the eye or other problems with their eyes.
• Non-compliance with the manufacturer’s labeled lens care instructions may put the patient at significant risk of developing a serious eye injury.
• Tap water, distilled water, or homemade saline solution should NOT be used as a substitute for or any component of the lens care process. The use of tap and distilled water has been associated with Acanthamoeba keratitis, a corneal infection that is resistant to treatment and care.
• Smoking increases the risk of corneal ulcers for contact lens users, especially when lenses are worn overnight or while sleeping.

Precautions To prevent cross-contamination 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 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.

The following patients may not be suitable candidates and/or may experience a higher rate of adverse effects associated with contact lens wear:
• Patients with a history of non-compliance with contact lens care and disinfection regimen, wearing restrictions, wearing schedule or follow-up visit schedule.
• Patients who are unable or unwilling to understand or comply with any written instructions.
• Environmental fumes, smoke, and vapors should be avoided in order to reduce the chance of lens contamination or physical trauma to the corneas.
• 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.

Solution Precautions:
• Eye injury or 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.

Lense Care 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 care 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 status changes. Ciba Vision recommends that patients see their eye care professional twice each year 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 who wear contact lenses to correct presbyopia may not achieve the best corrected visual acuity for either far or near vision. Vision requirements vary with the individual and should be considered when selecting the most appropriate type of lens for each patient.

Eye Care Professionals should carefully instruct patients about the following care regimens 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 do so.
• Good hygiene habits help promote safe and comfortable lens wear.
• Always wash and rinse hands before handling lenses.
• Remove LENSES 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, Air Optix Aqua, Air Optix for Astigmatism and Air Optix Aqua Multifocal Contact Lenses.
• Always handle lenses carefully. If a lens is dropped small particles or fibers may adhere to the lens surface which 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.

Lenses 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 (stays moving) on the eye, follow the directions in the Care for a Sticking Lens section. If non-movement of the lenses 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 irrigation, 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 corneas.
• Lenses should be kept in a supply of replacement lenses on hand.
• Do not use lenses beyond the expiration date.
• Do not expose (heat) disinfectant 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.
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 D.OPTIX, AIR OPTIX AQUA, AIR OPTIX for ASTIGMATISM and AIR OPTIX AQUA MULTIFOCAL 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
• Painful eye discomfort
• Blurred vision, rainbows or halos around objects
• Feeling of dryness in the eye

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 lenses 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 reintroduction.
• 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 vasculization, or intraocular 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 of 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 lotrafilcon B contact lenses, please notify: CIBA VISION Corporation, Technical Consultation in the USA at 1-800-241-7466.

FITTING GUIDE AND PATIENT BOOKLET
Conventional methods of fitting contact lenses apply to lotrafilcon B contact lenses. For a detailed description of the fitting techniques, refer to the D.OPTIX, AIR OPTIX AQUA, AIR OPTIX for ASTIGMATISM and AIR OPTIX AQUA MULTIFOCAL 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 30097 USA
1-800-241-5999

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.

Dispensable Wear:
• If no lens is indicated, as lenses are discarded upon removal from the eye.
• Lenses should only be cleaned, rinsed and disinfecting on an emergency basis when replacement lenses are not available.

Replacement Wear:
• When removed between replacement periods lenses must be cleaned and disinfected prior to reinsertion or be discarded and replaced with a fresh lens.

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 removed while the patient is away from the lens care products, 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 (not heat) method of disinfection such as Clear Care® or Abbott® Multi-Purpose Solution.
  • Use of Unizyme®, an enzymatic cleaner, 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 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 lens 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 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.

• 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 recommenced 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 TRIAL LENSES
Eye care professionals should educate contact lens technicians concerning proper use of trial lenses.

Each lens is packaged in a foil-sealed plastic container containing isotonic phosphate buffered saline with or without 1% Copolymer 845 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 LBF 110.

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11460 Johns Creek Parkway
Duluth, Georgia 30097 USA
www.cibavision.com
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May also be labeled as D.OPTIX® for Astigmatism
*Check for actual product availability as additional parameters may be introduced over time
+New England Journal of Medicine, September 21, 1989;321 (12), pp.773-783

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HOW SUPPLIED

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