PRECAUTIONS
To prevent eye 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 power, design configurations, or lens parameters available in the lens may not be available in significant numbers.
- Consequently when selecting an appropriate lens design and parameters, the eye care professional should be aware of the design and potential for 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 contact lens wear on 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 in the eye should be carefully evaluated on initial dispensing and monitored on an ongoing basis by the 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 eye infections or infections of their contact lens care and disinfection regimen, wearing restrictions, wearing schedule, or follow-up visit with the eye care professional.
  - Patients who are unable or unwilling to understand or comply with any directions, warnings, precautions, or restrictions. Contributing factors may include but are not limited to age, infirmity, other medical or physical conditions, and adverse wear or use conditions.
  - 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. When using fluorescein, the patient should be thoroughly rinsed with sterile saline solution that is recommended for use in eye care prior to inserting lenses. Avoid dispensing fluorescein directly into the eye.
  - Before leaving the eye care professional's office, the patient should be able to promptly remove their lenses and if anyone should lose 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.
  - Patients with diminished tear film stability may benefit from contact lens care and disinfection regimen, wearing restrictions, wearing schedule, or follow-up visit with the eye care professional.
  - Fluorescein may be used as a substitute for any component in the lens care process.

ACTIONS
When hydrated and placed on the cornea, ALCON® (lotrafilcon B)soft contact lenses act as a refracting medium to focus light rays on the retina.

INDICATIONS (Uses)
- AIR OPTIX AQUA (lotrafilcon B) soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phagic or aphagic persons with non-diseased eyes with a spherical equivalent of approximately 1.0 diopters (D) of astigmatism that does not interfere with visual acuity.
- AIR OPTIX for Astigmatism (lotrafilcon B) toric soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phagic or aphagic persons with non-diseased eyes with a spherical equivalent of approximately 1.0 diopters (D) or less and who may have up to approximately 1.0 diopters of astigmatism.

The lenses may be prescribed for daily wear or extended wear for up to six nights of continuous wear for vision correction while wearing contact lenses, for any reason.

The material from which the lenses are made may be present, and may progress rapidly. Less serious reactions such as abrasions, infiltrates, and bacterial conjunctivitis may be managed and treated conservatively to avoid more serious complications.

ADVERSE EFFECTS
Potentially serious complications are usually accompanied by one or more of the following signs or symptoms:
- Moisture on the eyelids
- Foreign body sensation
- Excessive tearing or other eye secretions including mucopurulent discharge
- Redness of the eyes
- Photophobia (light sensitivity)
- Blurred vision, or difficulty seeing in dim light or at night
- Irritation or itching
- Contact lens discomfort
- Corneal changes, including, polymegethism, tarsal papillary changes, conjunctival injection, or iritis.
- Microcysts, epithelial staining, infiltrates, neovascularization, endothelial polymegethism, and/or arc-shaped changes, conjunctival injection, or iritis.

ADVERSE EFFECT REPORTING
If a patient experiences any serious adverse effects associated with the use of lotrafilcon B soft contact lenses, please notify: Alcon Medical Safety at the 1-800-241-7668.

PROFESSIONAL FITTING AND INFORMATION GUIDE AND PATIENT INFORMATION BOOKLET

1. Conventional methods of fitting contact lenses apply to lotrafilcon B toric soft contact lenses. A fluorescein-stained cornea should be used to determine the appropriate lens design and parameters. Conventional methods of assessing or extending contact lens wear are also recommended in the "Care for a Sticking Lens" section. If non-movement of the lens is a continued problem, the patient should be referred to an eye care professional immediately.

2. Non-compliance with the manufacturer's labeled lens care instructions may result in a patient of significant risk of developing a serious eye injury.

3. Tap water, distilled water, or homemade saline solution should NOT be used as a substitute for any component in the lens care process as a substitute for any component in the lens care process.

4. Smoking increases the risk of corneal ulcers for contact lens users, especially when lenses are worn overnight or while sleeping.

5. The risk of microbial keratitis has been shown to be greater among users of extended wear contact lenses than among users of daily wear contact lenses. The risk increases with the number of times the lenses are worn between removals, even with the first overnight use.

6. Do not use thermal (heat) disinfection and do not heat lens care products.

7. Salorns or anything other than the recommended solution for lubricating or rinsing should not be used with the lenses.

CARE FOR A STICKING LENS

1. If the lens sticks (stops moving) or begins to dry on the eye, instruct the patient to:
   - Remove the lens from the eye carefully.
   - May use 5% pemetrexed solution to dislodge a stuck lens from the eye.
   - If a lens is exposed to air while off the eye it may become dry, brittle, and permanently damaged. If this should occur, the lenses 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.

2. Do not use thermal (heat) disinfection and do not heat lens care products.

3. Salorns or anything other than the recommended solution for lubricating or rinsing should not be used with the lenses.
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 over wear the lenses initially, stress the importance of adhering to a proper, initial wearing schedule.
- Normal daily wear of lenses assumes a minimum of six 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.

**Extended Wear** (greater than 24 hours, including while asleep):
- The eye care professional should establish an extended wear period up to six continuous nights that is appropriate for each patient. Once the lens is removed, the patient's eyes should have a rest period with no lens wear of overnight or longer, as recommended by the eye care professional.
- It is suggested that new contact lenses wearers first be evaluated on a daily wear schedule. If the patient is judged to be an acceptable extended wear candidate, the eye care professional may determine an extended wear schedule based upon the response of the patient.
- See the "WARNINGS" section for information about the relationship between wearing schedule and corneal complications.

**Lens Replacement**
The replacement schedule is determined by the eye care professional based upon the patient's individual needs and physiological conditions. Alcon recommends up to four week replacement for Hydraflex B lenses, 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 the "ADVERSE EFFECTS" section) and/or result in the development of serious ocular complications as discussed in the "WARNINGS" section.

**Disposable Wear**:
- No lens care is indicated, as lenses are discarded upon removal from the eye.
- Lenses should only be cleaned, rinsed and disinfected 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 rinsed 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.
- Alcon recommends a chemical (not heat) method of disinfection.
- Heat disinfection has not been tested and is not recommended.

To avoid serious eye injury from contamination, the eye care professional should review the following instructions with the patient:
- 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 contact contamination by microorganisms that can cause eye infection.
- Never use a hard (rigid) lens solution unless it is also indicated for use with soft (hydrophilic) contact lenses. Corneal injury may result if hard (rigid) lens solutions not indicated for use with soft (hydrophilic) contact 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 (drops 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 their eye care professional.

**IN OFFICE USE OF TRAIL LENSES**
Eye care professionals should understand and educate contact lens technicians concerning proper use of trial lenses.
Each contact lens is shipped sterile in a tear-sealed plastic container containing phosphate buffered saline solution with or without 1% Cepacol 845 additive. 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.

**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 FROM 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 with or without 1% Cepacol 845 and is steam sterilized (sterile at 35°C (intrinsic 2%/sec) and 2%/ml x mm Hg), CLAL Journal, January 1996; Volume 22, November 1, pp. 30-37,
© 2014 Novartis

**CAUTION** Federal (United States) law restricts this device to sale by or on the order of a licensed eye care professional.

**Manufacturers**
Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth, TX
76134-2099, USA
www.alcon.com