

AIR OPTIX* AQUA, AIR OPTIX* plus HydraGlyde*, AIR OPTIX* for Astigmatism, AIR OPTIX* plus HydraGlyde* for Astigmatism, AIR OPTIX* AQUA Multifocal, AIR OPTIX* plus HydraGlyde* Multifocal, 0,0PTIX* (lotrafilcon B) Soft Contact Lenses

W900127042

IMPORTANT: This package insert is effective as of March 2018 and applicable to the lotrafilcon B 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 Alcon by calling Customer Service at 1-800-241-5999 or download from our website at www.alcon.com. Alcon also makes available a *Patient Instruction Booklet*, which is recommended to be given to patients.



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

PRODUCT DESCRIPTION
AIR OPTIX* AQUA, AIR OPTIX* plus HydraGlyde*, AIR OPTIX* for
Astigmatism, AIR OPTIX* plus HydraGlyde* for Astigmatism, AIR OPTIX*
AQUA Multifocal, AIR OPTIX* plus HydraGlyde* Multifocal and O₂OPTIX*
(lotrafilcon B) soft contact lenses are made of a lens material that is
approximately 33% water and 67% lotraficon B, a fluoro-silicone containing
hydrogel which is surface treated. Lenses contain the color additive copper
phthaloryanips a light blue handling this to make them easier to see when phthalocyanine, a light blue handling tint, to make them easier to see when handling

- Lens Properties:
 Refractive Index (hydrated): 1.42
 Light Transmittance: 9.6% @ 610 nm, -1.00D)
 Oxygen Permeability (D6): 110 x 10⁻¹¹ (cm²/sec) (ml 0₂ /ml x mm Hg), measured at 35 °C (intrinsic Dk-Coulometric method)
 Water Content: 33% by weight in normal saline
- Lens Parameters

 - Diameter Range: 13.0 to 15.0 mm Power Range: -20.00 to +20.00D Base Curve Range: 8.0 to 9.2 mm

Lens Parameters Available

AIR OPTIX* AQUA and O2OPTIX* contact lenses (spherical):

Chord Diameter: 14.2 mm

0.08 mm @ -3.00D (varies with power) Center Thickness:

Base Curve:

- O Minus Powers: -0.25 to -8.00D (0.25D steps); -8.50D to -10.00D
- (0.50D steps)
 O Plus Powers: +0.25 to +6.00D (0.25D steps)

AIR OPTIX* plus HydraGlyde* contact lenses (spherical):

Chord Diameter

14.2 mm 0.08 mm @ -3.00D (varies with power) Center Thickness: Base Curve:

Powers:

Minus Powers: -0.25 to -8.00D in 0.25D steps; -8.50 to -12.00D in

0.50D steps Plus Powers: +0.25 to +6.00D (0.25D steps); +6.50 to +8.00D

(0.50D steps)

AIR OPTIX* for Astigmatism² and AIR OPTIX* plus HydraGlyde* for Astigmatism contact lenses (toric):

14.5 mm · Chord Diameter:

0.102 mm @ -3.00D (varies with power) 8.7 mm Center Thickness:

- Center inflictness: 0.102 hilling -3.000 (varies with power)
 Base Curve: 8.7 mm
 Powers:

 O Minus Powers: plano to -6.00D (0.25D steps); -6.50 to -10.00D
 - (0.50D steps)
 Plus Powers: +0.25 to +6.00D (0.25D steps)
 Cylinder: -0.75, -1.25, -1.75, -2.25
 Axis: Full circle, 10° steps

AIR OPTIX* AQUA Multifocal and AIR OPTIX* plus HydraGlyde* Multifocal

Chord Diameter:

14.2~mm 0.08~mm @ -3.00D (varies with power) Center Thickness:

Base Curve:

- Powers:

 Minus Powers: plano to -10.00D (0.25D steps)
 Plus Powers: +0.25 to +6.00D (0.25D steps)
 LO, MED, HI ADD

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, AIR OPTIX* plus HydraGlyde*, and O₂OPTIX* (lotrafilcon B) 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 with up to approximately 1.50 diopters (D) of astigmatism that does not interfere with visual acuity.
- AIR OPTIX* for Astigmatism and AIR OPTIX* plus HydraGlyde* for Astigmatism (lotrafilcon B) toric soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes with up to 6.00 diopters (D) of astigmatism.
- AIR OPTIX* AQUA Multifocal and AIR OPTIX* plus HydraGlyde* Multifocal AIR UP IIX* AQUA multitocal and AIR UP IIX* plus Hydracilyde* Multitocal (lotrafilion B) soft contact lenses are indicated for the optical correction of presbyopia, with or without refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who may require a reading addition of +3.00 diopters (D) or less and who may have up to approximately 1.50 diopters (D) of astigmatism that does not interfere with visual acuity.

The lenses may be prescribed for daily wear or extended wear for up to 6 nights of continuous wear with removal for disposal, or cleaning and disinfection (chemical, not heat) prior to reinsertion, as recommended by the eve care professional.

CONTRAINDICATIONS (Reasons Not to Use)

- CUNTRAINDICATIONS (Reasons Not to Use)
 DO NOT use lotrafilcon B contact lenses when any of the following exists:
 Inflammation or infection of the anterior chamber of the eye
 Any active disease, injury or abnormality affecting the cornea, conjunctiva, or eyelids that may be evaggerated by contact lens wear
 Microbial infection of the eye
 Inadequate tear film (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 ever medications

- wear, including eye medications
- Any systemic disease that may be exacerbated by or interferes with safe contact tens wear, handling, and/or care 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 eves become red or irritated

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 lenses are 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 professional if they should experience eye discomfort, foreign body sensation, excessive tearing, vision 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 eve infection.
- Non-sterile liquids (i.e., tap water, distilled water, homemade saline solution, or saliva) should NOT be used as a substitute for any component in 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 cure.
- Smoking increases the risk of corneal ulcers for contact lens users, especially when lenses are worn overnight or while sleeping.3
- The risk of microbial keratitis (a serious eye infection) has been shown to be greater among users of extended wear lenses than among users of daily wear lenses. The risk increases with the number of consecutive days that the lenses are worn between removals, even with the first overnight use.

PRECAUTIONS
To prevent damage to the eyes or to the contact lenses, the following precautions should be taken:
Special Precautions for 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.

- 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 directions, warnings, precautions, or restrictions. Contributing factors may include but are not limited to age, infirmity, other mental or physical conditions, and adverse working or living conditions.
- physical condutions, and adverse working or living condutions. Fluorescein, a yellow dye, should not be used while the lenses are on the patient's eyes. The lenses 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, patients 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.

- the patient for appropriate follow-up visits.

 Diabetics may have reduced corneal sensitivity and thus are more prone to corneal injury and do not heal as quickly or completely as non-diabetics.

 Visual changes or changes in lens tolerance may occur during pregnancy or use of oral contraceptives. Caution patients accordingly.

 Patients who wear contact lenses to correct presbyopia may not achieve the best correct 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 regimen and safety 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 Instruction Booklet for the lotraflicon B soft contact lenses prescribed.
 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 price to lensering or replaced with a sterile free? cleaned and disinfected prior to insertion or replaced with a sterile, fresh
- Never use tweezers or other sharp objects such as fingernails to remove lenses from the lens container. Pour the lens onto 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
- enects. 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 eve care professional should be consulted about wearing lenses during water sports and water related activities. Exposure to water while wearing water sports and water leaded activities. Exposure to water winter 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, hairspray, deodorant, aerosol products or foreign particles come in contact with lenses.

 Never allow contact lenses to come into contact with non-sterile liquids
- (including tap water and saliva) as microbial contamination can occur, which
- may lead to permanent eye damage.

 Do not share lenses with anyone as this may spread micro-organisms which could result in serious eye health problems.

 Environmental furnes, 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 on hand or have back-up
- spectacles available 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 the LENS CARE DIRECTIONS section).
- 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 eve Always keep the lenses completely immersed in the recommended storage
- Awaya keep the 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 eve 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. Alcon recommends that patients see their eye care professional at least once each year or as recommended by the eye care
- Certain medications may cause dryness of the eve, increased lens awareness, lens intolerance, blurred vision, or visional changes. These include, but are not limited to antihistamines, decongestants, diuretics, muscle relaxants, tranquilizers and those for motion sickness. Caution patients using medications accordingly and prescribe proper remedial
- 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 professional that they are wearing contact lenses.
- Patient should inform their employers that they are wearing contact lenses. Some jobs may require the use of eye protection equipment or may require that contact lenses not be worn.

It is strongly recommended that patients be provided with a copy of the AIR OPTIX* AQUA, AIR OPTIX* plus HydraGlyde*, AIR OPTIX* for Astigmatism, AIR OPTIX* plus HydraGlyde* for Astigmatism, AIR OPTIX* AQUA Multifocal and AIR OPTIX* plus HydraGlyde* Multifocal soft contact lens Patient Instruction Booklet available from Alcon and understands its contents prior to dispensing the lenses.

ADVERSE EFFECTS (Possible Problems)
Patients should be instructed to check eyes regularly to make sure they look
well, feel comfortable and vision is clear. Potentially serious complications are
usually accompanied by one or more of the following signs and symptoms:

- Moderate to severe eye pain not relieved by removing stan symptom Moderate to severe eye pain not relieved by removing the lens Feeling of something in the eye (foreign body sensation)

 Excessive watering or other eye secretions including mucopurulent discharge Redness of the eyes

- Sensitivity to light (photophobia)
 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
These symptoms, if ignored, may lead to more serious complications.

WHAT TO DO IF A PROBLEM OCCURS
Patients should be instructed that if any of the above signs or symptoms occur,

e or she should:

IMMEDIATELY REMOVE LENSES.

If the discomfort or problem stops, then look closely at the lenses.

of Ia lens is in any way damaged, DO NOT put it back on the eye. Replace with a new lens and consult the eye care professional.

of Ia lens has dirt, an eyelash, or foreign body on it, or the problem stops and the lens appears undamaged, thoroughly clean, rinse and disinfect the lens before reinsertion.

If the above symptoms continue after removal or upon reinsertion of the lens, remove the lone immediately then promptly context an eye area.

- remove the lens immediately, then promptly contact an eye care
- professional.

 The patient should be informed that a serious condition such as corneal ulcer (ulcerative keratitis), infection, comeal vascularization or iritis may be present. These conditions may progress rapidly and may lead to permanent loss of vision. Less serious reactions such as abrasions, infiltrates and bacterial conjunctivitis must be managed and treated properly 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 initis Docasional dryness may be relieved by blinking fully several times or by the use of contact lens rewetting drops that are approved for use with soft contact lenses. If dryness persists, consult your eye care professional, If a lens sticks (stops moving), apply several drops of a contact lens rewetting solution and wait until the lens begins to move freely on the eye. If
- this problem persists, consulf your eye care professional.

 If a lens decenters on the eye, it may be possible to recenter it by:
 Closing your eyelids and gently massaging the lens into place, or
 Looking in the direction of the lens and blinking gently, or
- Looking in the direction of the lens and onlinking gently, or
 Gently pushing the off-centered lens onto the cornea with light finger pressure on the edge of the upper or lower eyelid.
 If a lens tears in your eye, remove the pieces carefully by pinching them as you would for normal lens removal. If the lens pieces do not seem to remove easily, do not pinch the eye tissue. Rinse with saline. If this does not help,

ADVERSE EFFECTS REPORTING
If a patient experiences any serious adverse effects associated with the use of lotraficon B contact lenses, please notify: Alcon Medical Safety, in the USA at 1-800-757-9780.

FITTING GUIDE AND PATIENT BOOKLET

contact the eye care professional for assistance.

Conventional methods of fitting contact lenses apply to lotrafilcon B contact lenses. For a detailed description of the fitting techniques, refer to the AIR OPTIX* AQUA, AIR OPTIX* plus HydraGlyde*, AIR OPTIX* for Astigmatism, AIR OPTIX* plus HydraGlyde* for Astigmatism, AIR OPTIX* AQUA Multifocal (lotrafilcon B) contact lens *Professional Fitting and Information Guide*. Both the fitting guide and a *Patient Instruction Booklet* are available free of charge from:

6201 South Freeway Fort Worth, TX 76134-2099 USA

or by calling Alcon Customer Service in the USA at 1-800-241-5999.

LENS WEAR AND REPLACEMENT SCHEDULES

The wearing and replacement schedule should be determined by an eye care professional based on the patient's individual needs and physiological conditions. The eye care professional may recommend daily wear only or extended wear periods up to 6 nights. Not everyone can reach the maximum wear time of 6 continuous nights.

- 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.
- suess the importance or admently to a proper, initial wearing scriedule. 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

Extended Wear (greater than 24 hours, including while asleep):

- ktended Wear (greater than 24 hours, including while asleep): The eye care professional should establish an extended wear period up to 6 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 lens 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 WARNINGS section for information about the relationship between wearing schedule and consequence.
- wearing schedule and corneal complications.

Lens Replacement

The replacement schedule is determined by the eye care professional based on the patient's individual needs and physiological conditions. Lenses should be discarded and replaced with a new pair each month, or more often, if recommended by the eye care professional.

- LENS HANDLING INSTRUCTIONS

 Always wash and rinse hands thoroughly and dry completely with a clean, lint-free towel before handling contact lenses.

 Do not use if blister package is damaged or not sealed completely. This may result in product contamination which can lead to a serious eye infection.

 Shake the blister pack (containing a fresh new lens) gently prior to opening.

 Remove the lens from the blister pack (or lens storage case for previously warn lenses) by carefully ourging it not the palm of the hand.

- worn lenses) by carefully pouring it onto the palm of the hand. Ensure the lens is right side out and that you have the correct lens for each
- Inspect the lenses prior to insertion.

 Do not insert damaged or unclean lenses.

Lens Insertion Instructions Wash and rinse hands thoroughly and dry completely with a clean, lint-free

- Place a lens on the tip of your clean and dry right or left index finger. Place the middle finger of the same hand close to lower eyelashes and pull down the lower eyelid.
- Use the fingers of the other hand to lift the upper eyelid
- Place the lens directly on the eye (cornea) and gently roll finger away from
- Look down and slowly release the lower lid.

 Look straight ahead and slowly release the upper lid.
- Blink gently.

Lens Removal Instructions

- Wash and rinse hands thoroughly, and dry completely with a clean, lint-free
- tower.

 Blink fully several times.

 While looking up, use the tip of the finger to slide the lens down onto the white part of the eye
- Name part of the year.

 Remove the lens by Pinching gently between thumb and forefinger. Do not pinch the eye tissue.

 If the lens is difficult to remove, instill a lubricating and rewetting drop and the property of the pr try again after several minutes.
- Never use tweezers, suction cups, sharp objects or finger nails to remove lenses from the lens container or your eyes

WATER ACTIVITES

Do not expose contact lenses to water while wearing them. Warning:

warning: Water can harbor microorganisms that can lead to severe infection, vision loss or blindness. If lenses have been submersed in water when showering or swimming, discard them and replace with a new pair. Ask the eye care professional for recommendations about wearing lenses during any activity

involving water I FNS CARE DIRECTIONS

Patients must adhere to a recommended lens 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 the 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 and discussed in the WARNINGS section.

- Disposable Wear:

 No lens care is indicated, as lenses are discarded upon removal from the
- 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

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

- Each time lenses are removed from the eye they must be properly cleaned,
- Each time lenses are removed from the eye they must be properly cleaned, rinsed, and disinfected before reuse. If removed while the patient is away from 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. Typical instructions for lens care products include the steps presented below. IMPORTANT: Hydrogen Peroxide disinfecting solutions, such as CLEAR CARE* PLUS Cleaning & Disinfecting Solution, are not multi-purpose solutions. For hydrogen peroxide disinfecting solutions follow the manufacturer's instructions.

 Soaking and Storing Your Lenses:
- Soaking and Storing Your Lenses:
- Use only fresh contact lens care solution each time you soak (store) your
- reuse reduces effective lens disinfection and could lead to severe infection, vision loss or blindness. To "top-off" means to add fresh solution to solution that has been sitting in your lens case.
- Rub and Rinse Time:
 - Some lens care products require a rub and rinse step. If so, follow the lens care manufacturer's instructions for solution quantity and rub and rinse time to reduce the risk of serious eye infections.

 The amount of time you can store lenses before cleaning, rinsing, and
 - disinfection steps need to be repeated will vary depending on the lens care product used.
 - *Varning:* Rub and rinse lenses for the recommended amount of time to help prevent serious eye infections.
 - Never use water, saline solution, or rewetting drops to disinfect your lenses. These solutions will not disinfect your lenses. Not using the recommended disinfecting solution can lead to severe infection, vision loss or blindness
- Discard Date for Lens Cleaning and Disinfecting Solutions
 O After opening, discard any remaining solution after the period recommended by the lens care manufacturer. If using the lens care
 - products listed below, discard remaining solution as follows:
 CLEAR CARE* PLUS Cleaning & Disinfecting Solution 3 months
 - after opening.

 OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution 6 months after opening.

Warning.

Using your lens care solution beyond the discard date could result in contamination of the solution and can lead to severe infection, vision loss or blindness.

- The above instructions are typical for a lens cleaning product, however you must always consult the instructions for the specific lens care product used.

 Alcon recommends a chemical (not heat) method of disinfection such as CLEAR CARE* PLUS Cleaning & Disinfecting Solution or OPTI-FREE*
- PureMoist* Multi-purpose Disinfecting Solution.
 Use of 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
 Daily Cleaner has not been tested and is not recommended.
- Heat disinfection has not been tested and is not recommended

Basic Instructions for the Lens Case
Contact lens care solutions and contact lens cases vary and have different
purposes and instructions for use. Some cases are intended exclusively for
storing contact lenses (sometimes referred to as a lens flat pack or lens storage
case), while others are specially designed to contain a neutralizing disc for use
with hydrogen peroxide cleaning and disinfecting systems. If not being worn on
a daily disposable basis, lenses that have been cleaned and disinfected can be stored in the unopened case for a period of time that varies depending on the contact lens solution and lens case used. Always follow the instructions provided by the manufacturer for the lens care products used.

- The eye care professional should instruct the patient on how to use the
- recommended lens care solution(s) and lens case.

 Contact lens cases can be a source of bacterial growth and require proper cleaning, drying and replacement to avoid contamination or damage to
 - or Clean contact lens cases with an appropriate contact lens solution and dry according to lens case instructions. Drying instructions, such as air-drying or wiping with lint-free towel, may vary depending on the lens
- Replace contact lens cases at least once every 3 months, or as
- recommended by the lens case manufacturer.

 Replace specially designed lens cases containing a neutralizing disc according to manufacturer directions, or sooner if cleaned and disinfected lenses cause burning and stinging.
- Warning:
 Do not store your lenses or rinse your lens case with water or any non-sterile solution. Only use fresh disinfecting solution in order to avoid contamination of your lenses or lens case. Use of non-sterile solution can lead to severe infection, vision loss or blindness.
- To help 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

- 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. Comeal injury may result if hard (rigid) lens solutions not indicated for use with soft contact lenses. Comeal 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

CARE TOR A STIGNING 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 TRIAL LENSES

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

Each contact lens is shipped sterile in a blister pack containing phosphate buffered saline solution with or without additives. Hands should be thoroughly washed, rinsed and dried with a lint-free towel prior to handling a lens. In order to ensure 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

- Flush eyes immediately with fresh saline solution or tap water.
 Remove and discard lenses and immediately contact the eye care professional or visit a hospital emergency room without delay.

HOW SUPPLIED

Each lens is provided in a foil-sealed plastic container containing buffered saline solution and is steam sterilized. The packaging saline may contain additives, as

- AIR OPTIX* for Astigmatism, 0₂OPTIX* contact lenses: Phosphate Buffered
- Ain OFTIA to Assignment 2.

 AIR OPTIX* AQUA, AIR OPTIX* AQUA Multifocal contact lenses: PBS with 1% Copolymer 845 wetting agent
 AIR OPTIX* plus HydraGlyde*, AIR OPTIX* plus HydraGlyde* for
 Astignatism and AIR OPTIX* plus HydraGlyde* Multifocal contact lenses:
 PBS with 0.2% VP/DMAEMA and 0.04% Polyoxyethylene-polyoxybutylene

The blister package is marked with the base curve, diameter, dioptric power,

The binsier package is marked with the base curve, diamited, dupline power, cylinder and axis (where applicable), ADD power (where applicable), manufacturing lot number, and expiration date. The package labeling may also contain a product code, as follows: LFB110 [spherical lotrafilcon B in pBs + Copolymer 845 (e.g., VP/DMAEMA)]; LFB110e [spherical lotrafilcon B in PBS + Copolymer 845 (e.g., VP/DMAEMA) + LFB110e [spherical lotrafilcon B in PBS + Copolymer (e.g., VP/DMAEMA) +

Hydracilydel; LFB110-T (foric lotrafilcon B in PBS); LFB110-ME (multifocal lotrafilcon B in PBS + Copolymer) (e.g., VP/DMAEMA)]; LFB110-Te [toric lotrafilcon B in PBS + Copolymer (e.g., VP/DMAEMA) +

LFB110MFe [multifocal lotrafilcon B in PBS + Copolymer (e.g., VP/DMAEMA) + HydraGlyde].

Lenses are supplied in cartons containing up to 12 individually sealed contact

The following may appear on the labels or cartons

Symbol/ Abbreviation	Description
RX only	CAUTION: Federal law (United States) restricts this device to sale by or on the order of a licensed eye care professional.
STERILE	Sterilized using steam
Ω	Use-by date
EXP	Expiration date
LOT	Batch code
en	Example of two letter language code (English)
8	Do not use if blister package is damaged
€0086	European conformity mark and Notified Body number
Ti	Consult instructions for use
<u>A</u>	Caution
EC REP	Authorized Representative in the European Community
	Manufacturer
0	Packaging waste license sign
DIA	Diameter
BC	Base curve
PWR	Power
D	Diopter (lens power)
ADD	Addition power
MAX ADD	Maximum effective addition power
L0	Low
MED	Medium
HI	High
L	Left
R	Right
VP/DMAEMA	Vinylpyrrolidone/Dimethylaminoethylmethacrylate

Alcon

Alcon Laboratories, Inc. 6201 South Freeway Fort Worth, TX 76134-2099 USA

*a trademark of Novartis W900127042-0318

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U.S. Pat.: www.alconpatents.com

¹Check for actual product availability, which may change over time.

Manufacture of 0,0PTIX* lenses discontinued 2014

May also be labeled as 0,0PTIX for Astigmatism

*Cutter GR, Chalmers RL, Roseman M. The Clinical Presentation, Prevalence, and Risk Factors of Focal Corneal Infiltrates in Soft Contact Lens Wearers. The

CLAO Journal. Jan 1996; 22 (1): 30-37.

'Schein OD, Glynn RJ, Poggio EC, Seddon JM, Kenyon KR. The Relative Risk of Ulcerative Keratitis Among Users of Daily-Wear and Extended-Wear Soft Contact Lenses. N Eng J Med. 1989; 321(12):773-83.