Alcon®
a Novartis company

Package Insert for NIGHT & DAY* and AIR OPTIX* NIGHT & DAY* AQUA (lotrafilcon A) Soft Contact Lenses

W92037130

IMPORTANT: This package insert is effective as of November 2014 and supersedes all prior inserts for the (lotrafilcon 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 patients with appropriate instructions that pertain to the patient's prescribed lenses. Copies of this package insert are available without charge from Alcon by calling Alcon Customer Service in the USA at 1-800-241-5999 or download a copy from our website at www.alcon.com. Alcon makes available a ***Patient Instruction Booklet,*** which is recommended to be given to patients.

Rx only

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

PRODUCT DESCRIPTION

NIGHT & DAY* and AIR OPTIX* NIGHT & DAY* AQUA (lotrafilcon A) Soft Contact Lenses are made from a lens material that is approximately 24% water and 76% lotrafilcon A, a fluoro-silicone containing hydrogel which is surface treated. Lenses may contain the color additive copper phthalocyanine, a light blue handling tint, which makes them easier to see when handling.

Lens Properties

• Specific Gravity:	1.08
• Refractive Index (hydrated):	1.43
• Light Transmittance:	≥ 96%
• Oxygen Permeability (Dk):	140 x 10^{-11} (cm^2/sec) ($ml\ O_2$ /ml x mm Hg), measured at 35°C (intrinsic Dk - Coulometric method)
• Water Content:	24% 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[1]

• Chord Diameter Available:	13.8 mm
• Center Thickness:	0.08 mm @ -3.00D (varies with power)
• Base Curve Available:	8.4mm, 8.6mm
• Powers Available:	plano to -8.00D (0.25D steps); -8.50 to -10.00D (0.50D steps); +0.25D to +6.00D (0.25D steps)

ACTIONS

When hydrated and placed on the cornea, lotrafilcon A contact lenses act as a refracting medium to focus light rays on the retina. When hydrated and placed on the cornea for therapeutic use, lotrafilcon A contact lenses act as a bandage to protect the cornea.

INDICATIONS (USES)

- NIGHT & DAY and AIR OPTIX NIGHT & DAY AQUA (lotrafilcon A) Soft Contact Lenses for daily wear for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes and with up to approximately 1.50 diopters of astigmatism that does not interfere with visual acuity.
- The lenses may be prescribed for daily wear or extended wear for up to 30 nights of continuous wear, with removal for disposal, or cleaning and disinfection prior to reinsertion, as recommended by the eye care professional.
- Lotrafilcon A soft contact lenses are also indicated for therapeutic use. Use as a bandage to protect the cornea and to relieve corneal pain in the treatment of acute or chronic ocular pathologies such as bullous keratopathy, corneal erosions, entropion, corneal edema, and corneal dystrophies as well as post-surgical conditions resulting from cataract extraction and corneal surgery. Lotrafilcon A soft contact lenses for therapeutic use can also provide optical correction during healing if required.

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

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT use lotrafilcon A contact lenses when any of the following exists:

- Inflammation or infection of the anterior chamber of the eye.
- Any eye disease, injury or abnormality affecting the cornea, conjunctiva, or eyelids that may be exaggerated by contact lens wear.
- 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 of ocular surfaces or adnexa that may be caused by or exaggerated by the wearing of contact lenses.
- Allergy to any 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.

For THERAPEUTIC USE, the eye care professional may prescribe lotrafilcon A lenses to aid in the healing process of certain corneal conditions.

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, 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 eye infection.**
- **Tap water, distilled water, or homemade saline solution 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,[2,3] especially when lenses are worn overnight or while sleeping.**
- **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.[3] (See the "POST-MARKET EXTENDED WEAR STUDY SUMMARY" section).**

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:

- When selecting an appropriate lens and wear schedule for a patient, the eye care professional should consider all lens characteristics that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter. All refractive powers, design configurations, or lens parameters were not evaluated in clinical trials. At the extremes of the power range (above +10.00 or -15.00) oxygen transmissibility is slightly below the established threshold level required to prevent overnight corneal edema[4]. The prescribing eye care professional should carefully assess the potential impact of these factors and carefully monitor the continuing ocular health of the patient and lens performance on the eye.
- The following patients may not be suitable extended wear contact lens candidates, and/or may experience a higher rate of adverse effects associated with contact lens wear:
  - Patients with a history of acute inflammatory reactions to contact lens wear.
  - Patients with a history of giant papillary conjunctivitis associated with contact lens wear.
  - Patients with a history of ocular allergies may need to temporarily discontinue lens wear during certain times of the year.
  - 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.
  - Patients who would not or could not adhere to a recommended care regimen, or who are unable to place and remove lenses, should not be provided with them.
- Patients should be monitored closely during the first month of continuous wear as this period of observation may predict the eventual success of the patient. Those with inflammatory reactions during this early phase may not be suitable candidates for continuous wear.
- Aphakic persons should not be fitted with lotrafilcon A contact lenses until the determination is made that the eye has healed completely.
- 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.
- Fluorescein, a yellow dye, should not be used while the lenses are on the eyes. The lenses absorb this dye and become discolored. Whenever fluorescein is used in eyes, the eyes should be flushed with a sterile saline solution that is recommended for in-eye use.
- In addition, for therapeutic use:
  - Close professional supervision is necessary for therapeutic use of lotrafilcon A lenses.
  - Medications necessary for treatment should be used with caution under close supervision by the eye care professional.

Eye Care Professionals should carefully instruct patients about the following care regimen and safety precautions. For therapeutic use, in some circumstances only the eye care professional will insert and remove lenses and if so, patients should be instructed NOT to handle lenses themselves.

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, rinse and dry 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 NIGHT & DAY* and AIR OPTIX* NIGHT & DAY* AQUA Soft 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 lens 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 sporting 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.
- Patients should be advised to always have a pair of spectacles that they are willing to wear if a problem occurs with their contact lenses. This is especially important for patients with high refractive errors, since they may be hesitant to discontinue lens wear if back-up spectacles are not readily available.
- 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 on hand.
- Do not use lenses beyond the expiration date. EXP

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 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, especially for extended wear patients. Alcon 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 should inform their health care professional 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 contact lenses not be worn.

It is strongly recommended that patients be provided with a copy of the NIGHT & DAY* and AIR OPTIX* NIGHT & DAY* AQUA Soft Contact Lenses ***Patient Instruction Booklet*** available from Alcon and understand its contents prior to dispensing the lenses.

ADVERSE DEVICE EFFECTS

The most commonly observed adverse device effects in the clinical study of lotrafilcon A lenses were conjunctivitis, infiltrative keratitis, and non-infectious peripheral ulcer (see the ***"CLINICAL STUDY RESULTS"*** section for details).

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 LENS(ES).**
- **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 polymegathism, tarsal papillary changes, conjunctival injection or iritis.

During therapeutic use, an adverse effect may be due to the original disease or injury or may be due to the effects of wearing a contact lens. There is a possibility that the existing disease or condition might become worse when a soft contact lens for therapeutic use is used to treat an already diseased or damaged eye. The patient should be instructed to avoid serious eye damage by contacting the eye care professional **IMMEDIATELY** if there is any increase in symptoms while wearing the lens.

ADVERSE EFFECT REPORTING

If a patient experiences any serious adverse effects associated with the use of lotrafilcon A contact lenses, please notify: **Alcon Medical Safety in the USA at 1-800-241-7468.**

CLINICAL STUDY RESULTS

PRE-MARKET EXTENDED WEAR STUDY SUMMARY

Study Description:

A total of 697 NIGHT & DAY* lens subjects and 698 Control subjects from 59 investigative sites were enrolled in a prospective, randomized, controlled, open label clinical trial lasting one year.

NIGHT & DAY lenses were worn on an extended wear schedule for up to 30 nights of continuous wear. Control lenses were worn on an extended wear schedule for up to 6 nights of continuous wear. NIGHT & DAY lens subjects replaced lenses every month. Control subjects replaced lenses every week.

The groups were comparable with regard to age, lens power, gender and type of habitual correction. In each group the age ranged from 18 to 70 years with a mean age of 35 years. Lens power ranged from +6.00 D to -6.00 D for the NIGHT & DAY lens group and +4.50 to -6.50 for the Control group. 483 NIGHT & DAY lens subjects (966 eyes) and 579 Control subjects (1158 eyes) completed the study.

The primary safety endpoint analysis was the number of subjects in each group who developed one or more of corneal infiltrates ≥ Grade 3 or with overlying fluorescein staining.

The percentage reported was 5.0% in the NIGHT & DAY lens subjects and

3.1% in the Control subjects. These proportions are not statistically different (p = 0.073, chi-square). Life table analysis estimate the annualized rate for subjects experiencing one or more of these infiltrates was 6.1% per person-year for the NIGHT & DAY* lens group (95% CI = 4.1% to 8.2%), and 3.3% per person-year for the Control group (95% CI = 1.9% to 4.7%).

The primary efficacy endpoint was the percentage of subjects able to successfully maintain the extended wearing schedule and the percentage of eyes maintaining Snellen contact lens visual acuity within 2 lines of dispensing were the efficacy endpoints analyzed. The NIGHT & DAY lens group had 175 subjects (350 eyes) discontinue whereas the Control group had 102 subjects (204 eyes) discontinue. Discomfort was most often reported as the reason for discontinuation in each group. The wearing schedules reported by the NIGHT & DAY lens subjects who completed the clinical study is presented below. Contact lens visual acuity within two lines of dispensing was maintained in 98.1% of the eyes with NIGHT & DAY lenses and 97.9% of the Control eyes. There was no loss of best corrected visual acuity in either group.

Average Achieved Wearing Schedule
(n = 966 eyes, one year)

Consecutive Nights	
0 – 2	1.5%
3 – 4	1.0%
5 – 7	2.0%
8 – 14	6.9%
15 – 21	14.0%
22 – 31	67.2%
Not Reported	7.3%

Adverse device effects were reported at the following annual rates during the clinical study. There were no reports of microbial keratitis in either group.

Eyes With At Least One Adverse Device Effect

Eyes Dispensed: NIGHT & DAY lenses = 1316 Control = 1362	**NIGHT & DAY* lenses** **%**	**Control** **%**
Conjunctivitis / Hordeolum / Chalazion	3.87%	4.99%
Infiltrative Keratitis	3.11%	2.06%
Non-infectious corneal ulcer or scar	1.00%	0.44%
Asymptomatic Infiltrates	0.68%	0.37%
Severe staining, edema, microcysts, injection	0.23%	0.00%
Temporary Refractive change > 1.00 D	0.15%	0.00%
Other**	0.31%	0.44%
TOTAL EYES with at least one Adverse Device Effect	**9.4%**	**8.3%**

**Thygeson's keratitis, recurrent erosion in NIGHT & DAY lenses and subconjunctival hemorrhage, blepharokeratoconjunctivitis, intraepithelial keratitis and optic neuritis in the Control group.

- Fewer NIGHT & DAY* lens subjects (19.8%) reported symptoms of dryness compared to the Control (24.2%).This finding of less dryness was noted in the case history, study questionnaire and subject diary.

POST-MARKET EXTENDED WEAR STUDY SUMMARY

A total of 6,245 NIGHT & DAY lens wearers who had been prescribed NIGHT & DAY lenses for extended wear of up to 30 consecutive nights were registered in a year-long observational study from 131 clinical practices. Wearers were subsequently contacted at 3 and 12 months after enrollment to determine typical wearing schedules, discontinuation of lens wear, and the occurrence of any problems that might be indicative of corneal inflammation, ulceration or infection. Medical records were obtained from all such reports and reviewed to determine the presence of signs or symptoms of corneal inflammation or infection. All infiltrative conditions were reviewed and classified by an independent review committee of ophthalmologic specialists.

The group of registered wearers consisted of 63.7% female and 36.7% male with a mean age of 34.8 years and mean refractive error of -3.22 D. Responses to both questionnaires were received from 94.4% of the registered wearers and a further 3.9% responded to the 3-month questionnaire only. The total period of observation for the registered cohort was 5,561 person-years. A total of 4,999 (80.0%) of wearers completed 12 months of wear. The wearing schedule of these participants at one year is summarized below:

Continuous Wearing Schedule

Daily wear only	3.3%
1 to 6 nights	7.6%
1 to < 3 weeks	9.3%
3 to 4 weeks	53.0%
> 4 weeks	26.8%
Not Reported	67.2%

The key endpoints were the occurrence of microbial keratitis and sustained loss of best corrected visual acuity of 2 lines or greater after complete resolution of an incident microbial keratitis or other contact lens-related corneal condition. Infiltrative events occurred in 163 wearers, of which 154 received medication as part of their treatment. The following table summarizes the annualized incidence rates for infectious and infiltrative events for all registered wearers:

Annualized Incidence of Infiltrative and Infectious Adverse Events

Total Patient-Years of Observation = 5,561	**Number of Cases**	**Number of Cases** (events per 10,000 patient-years)	**Number of Cases** Confidence Limit (events per 10,000 patient-years)
Infiltrative Adverse Events receiving medication	154	277 per 10,000	313.1 per 10,000
Total Infiltrative Adverse Events	163	293 per 10,000	330.1 per 10,000
Microbial keratitis (with or without vision loss)	10	18 per 10,00	30.5 per 10,000
With visual acuity loss (≥ 2 lines Snellen)	2	4 per 10,000	11.3 per 10,000
Other infiltrative keratitis of indeterminate etiology***	52	94 per 10,000	115.2 per 10,000
"Sterile" (non-infectious) infiltrates	97	174 per 10,000	202.8 per 10,000
Other or not contact lens-related infiltrates	4	7.2 per 10,000	16.5 per 10,000

*** Cases of "indeterminate etiology" were considered unlikely to be infectious. The annualized rate of infiltrative events was higher amongst those reporting shorter wearing schedules suggesting that wearers showing difficulty of adapting to a 30 night schedule may not be suitable candidates for continuous wear. The incidence rate of infiltrates trended higher in refractive errors greater than ±5.00D, although these wearers also reported a higher rate of previous contact lens problems at baseline.

THERAPEUTIC USE STUDY SUMMARY

This clinical trial was a retrospective, consecutive case series evaluation. Three medical practices in Europe provided 41 consecutive case reports on 39 patients for whom NIGHT & DAY* lenses were used in therapeutic applications for erosion or recurrent erosion, bullous keratopathy, corneal edema, corneal dystrophy, neurotrophic corneal ulcer, entropion, and after corneal surgeries. Twenty (49%) of the cases were for acute treatment of an ocular condition and 21 (51%) were for treatment of chronic conditions. The average age of the patients treated was 55.1 years of age. Twenty-four (59%) of the cases were reported in females and 17 (41%) were reported in males.

The primary variables of this trial were investigator assessments of pain relief, corneal changes by slit lamp evaluation, additional complications, and overall treatment success.

Pain relief was one of the treatment goals in 37 of the cases. Pain relief was considered fully effective in 78% of these cases, partially effective in 17% of the cases and ineffective in 6% of the cases. Improvement in corneal signs was one of the treatment goals in 19 of the cases. The outcome was fully effective in 74% of the cases and partially effective in the remaining 26%. No additional complications were reported in 83% of the cases. Complications of corneal infection in 2 cases were considered as related to the lens use. Four cases of complications considered as unrelated to the lens included infiltrates, ulcer and irritation. Investigators considered the treatment to be fully successful for 71% of the cases and partially successful in a further 22% of the cases.

PROFESSIOAL FITTING AND INFORMATION GUIDE AND PATIENT INSTRUCTION BOOKLET

- The lens must move adequately on the eye for a proper fit and continued health of the eye. When prescribing Iotrafilcon A lenses for extended wear, it is important to reevaluate the lens fit for adequate movement at various times after the patient sleeps while wearing lenses. This reevaluation should include a follow-up visit as soon as possible after the patient awakens, as well as at other times of the day. If the fit is judged to be too tight or steep, the patient must be refit into a lens that provides the criteria of a well-fitted lens.
- Refer to the Professional Fitting and Information Guide and the Patient Instruction Booklet for more information. Both the professional fitting guide and a patient instruction booklet are available free of charge from

Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth, TX 76134-2099, USA
or by calling Alcon Customer Service in the USA at 1-800-241-5999.

LENS WEARING SCHEDULES

The wearing schedule should be determined by the eye care professional. Not all patients can achieve the maximum wear time of up to 30 nights of continuous wear. Patients should be monitored closely during the first month of 30-night continuous wear. **If problems occur during this first month, the patient may not be suitable for the full 30-night wearing schedule.** The maximum suggested wearing time should be determined by the eye care professional based upon the patient's physiological eye condition because individual responses to contact lenses vary.

- **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 6 hours of non-lens wear per 24 hour period.
  - If the lens(es) have dirt, an eye lash or other foreign body on it, thoroughly clean, rinse, and disinfect prior to reinsertion.
- **EXTENDED WEAR (greater than 24 hours, including while asleep):**
  - The eye care professional should establish an extended wear period up to 30 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 the ***"WARNINGS"*** section for information about the relationship between wearing schedule and corneal complications and the ***"CLINICAL STUDY RESULTS"*** section for important information about average wear times and other study findings.
- For **THERAPEUTIC USE,** close professional supervision is necessary. Lotrafilcon A lenses can be worn on a continuous wear basis for up to 30 nights and days or for shorter periods as directed by the eye care professional. The eye care professional should provide specific instructions regarding lens care, removal, insertion.

LENS REPLACEMENT

Lenses should be replaced every month, as recommended by the eye care professional. Longer replacement periods have not been studied and are not recommended by Alcon. When removed between replacement times lenses must be cleaned and disinfected prior to reinsertion or be discarded and replaced with a fresh new lens.

LENS CARE DIRECTIONS

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.
- Failure to follow the complete regimen in accordance with manufacturer's package inserts may contribute to problems (see the ***"ADVERSE DEVICE EFFECTS"*** section) and/or result in the development of serious ocular complications as discussed in the ***"WARNINGS"*** section.

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 in a lens case filled with the recommended storage solution 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.
- 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 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.

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 TRIAL LENSES

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

Each contact lens is shipped sterile in a foil sealed plastic container containing phosphate buffered saline solution with or without 1% Copolymer 845 additive. Hands should be thoroughly washed, 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 FRESH STERILE 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% Copolymer 845 and is steam sterilized STERILE. The package is marked with the base curve, diameter, dioptric power, manufacturing lot number and expiration date.

The following may appear on the labels or cartons:

Symbols/Signs	Description
Rx only	CAUTION: Federal (United States) law restricts this device to sale by or on the order of a licensed eye care professional.
STERILE	Steam sterilized
EXP	Use by date (Expiry date)
LOT	Batch code
en	Example of two letter language code (English)
DIA	Diameter
BC	Base curve
PWR	Lens power
CE 0086	European conformity sign
	See product instructions
EC REP	Authorized Representative European Community
	Manufacturer
	Packaging waste license sign

[1] Check for actual product availability which may change over time.
[2] CLAO Journal, January 1996; Volume 22, Number 1, pp. 30-37.
[3] New England Journal of Medicine, September 21, 1989; 321 (12), pp. 773-783.
[4] Investigative Ophthalmology and Visual Science, October 1984; Vol 25, pp.1131-1167.

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