

IMPORTANT: Please read carefully and keep this information for future use.

This package insert is intended for the eyecare practitioner, but should be made available to the patient upon request.

clear58 (ETAFILCON A) DAILY WEAR SOFT CONTACT LENS (VISIBILITY TINT WITH UV BLOCKER)

clear58

Symbols key

The table shows the symbols that may appear on label or carton

Symbol	Description	Symbol	Description
Rx Only	CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a Licensed Eye Care Practitioner.		Temperature limits
	Sterilized using steam or dry heat		Do not resterilize
	Caution		Medical Device
	Do not use if package is damaged and consult instructions for use		Catalogue number
	Manufacturer		Model number
	Date of manufacture		Unique Device Identifier
	Authorized Representative in European Community		Single sterile barrier system

PACKAGE INSERT

clear58

	Batch code (Lot number)
	Use by date (Expiry date)
	Consult instructions for use or consult electronic instructions for use
	European conformity sign
	Base Curve
	Diopter (Lens Power)
	Diameter

	Keep dry
	Keep away from sunlight
	Fragile, Handle with care
	Importer
	UV Blocking
	Recyclable material

CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED PRACTITIONER.

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DESCRIPTION:

The **clear58 (Etafilcon A) Soft (hydrophilic) Contact Lens** is available in a single vision spherical lens. The hydrophilic nature of this material allows the lens to become soft and pliable when immersed in an aqueous solution.

MATERIAL CHARACTERISTICS:

The ionic lens material, (Etafilcon A) is a co-polymer of 2-hydroxyethyl methacrylate and methacrylic acid cross-linked with 1,1,1 - trimethylol propane trimethacrylate and ethylene glycol demethacrylate. The lens consists of 42% Etafilcon A and 58% water by weight when immersed in buffered saline solution. The lens polymer contains a UV absorbing compound and is available clear or with a blue visibility-handling tint, color additive 'Reactive Blue 19', 21 CFR part 73.2121. The Etafilcon A name has been adopted by the United States Adopted Names Council (USAN).

In the **clear58 (Etafilcon A) Soft (hydrophilic) Contact Lens** with UV Blocker, a Benzophenone UV absorbing monomer is used to block UV radiation. The UV blocking for **clear58** averages > 99% in the UVB range of 280nm - 315nm and 83% in the UVA range of 316 - 380nm.

In the hydrated state, the lens conforms to the curvature of the eye covering the cornea and extending slightly beyond the limbus forming a colorless, transparent optical surface. The hydrophilic properties of the lens require that it be maintained in a fully hydrated state in a solution compatible with the eye. If the lens dries out, it will become hard and appear somewhat warped however, it will return to its proper configuration when completely rehydrated in the proper storage solution.

The hydrophilic characteristics allow aqueous solutions to enter the lens and in its fully hydrated state the lens is approximately 58% water by weight. The physical properties of the lens are:

Refractive Index	1.4050 (wet)
Light Transmission	greater than 95%
Water Content	58 %
Specific Gravity	1.017 (hydrated)
Oxygen Permeability	21.83×10^{-11} (cm ² /sec) (mlO ₂ /ml x mmHg@ 35°C), (revised Fatt method).

The lenses are hemispherical flexible shells which cover the cornea and portion of the adjacent sclera with the following dimensions:

Diameter	13.80-14.20mm (Minus power) 14.30-14.70mm (Plus power)
Center Thickness	0.096mm ± 0.020 mm @ -3.00D
Base Curve	8.30mm to 8.70mm

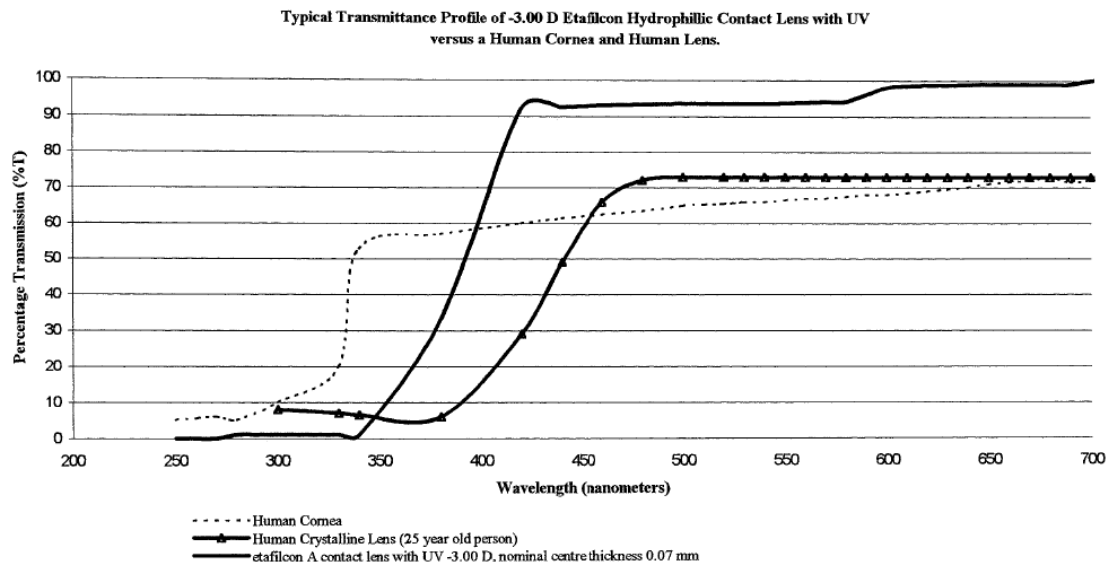
Powers

-10.00 Diopters to +06.00 Diopters
 0.00[^] to -6.00 D in 0.25 D increment
 -6.50 to -10.00 D in 0.50 D increment
 +0.25 to +4.00 D in 0.25 D increment
 +4.50 to +6.00 D in 0.50 D increment

WARNING:

UV-absorbing contact lenses are not substitutes for protective UV-absorbing eyewear such as UV-absorbing goggles or sunglasses. Persons should continue to use their protective UV-absorbing eyewear as directed.

The following graph compares the W transmittance curve of the **clear58 (Etafilcon A) Soft (hydrophilic) Contact Lens**, -3.00 D to that of the human cornea of a 24-year-old person and that of the human crystalline lens from a 24-year-old. Person as described in Lerman, S., Radiant Energy and the Eye, MacMillan, New York, 1980, p.58. **Crystalline Lens** – Human Crystalline lens from a 25-year-old person as described in Waxler, M., Hitchins, V.M., Optical Radiation and Visual Health, CRC Press, Boca Raton Florida, 1986, p.19, figure 5.



NOTE: Long-term exposure to UV radiation is one of the risk factors associated with cataracts. Exposure is based on a number of factors such as environmental conditions (altitude, geography, cloud cover) and personal factors (extent and nature of outdoor activities). UV-absorbing contact lenses help provide protection against harmful UV radiation. However, clinical studies have not been done to demonstrate that wearing UV-absorbing contact lenses reduces the risk of developing cataracts or other eye disorders. Consult your eyecare practitioner for more information.

ACTIONS:

In its hydrated state, the **clear58 (Etafilcon A) Soft (hydrophilic) Contact Lens**, when placed on the cornea, act as a refracting medium (except for plano lenses) to focus light rays on the retina.

INDICATIONS (USES):

The **clear58 (Etafilcon A) Soft (hydrophilic) Contact Lens** for frequent replacement wear contains a UV Blocker to help protect against transmission of harmful UV radiation to the cornea and into the eye. It is indicated for the correction of refractive ametropia (except for Plano lens) in phakic and aphakic person with non-diseased eyes who have myopic or hypermetropic vision. The lens (except for Plano lens) may be worn by persons who exhibit refractive astigmatism of 0.75 diopters or less where the astigmatism does not interfere with visual acuity. The lens may be cleaned and disinfected using a chemical lens care system.

Eye Care Practitioners may prescribe the lens for frequent/planned replacement wear, within 1 to 30 days, with cleaning, disinfection, and scheduled replacement. When prescribed for frequent/ planned replacement wear, the lens is to be cleaned, rinsed, and disinfected each time it is removed from patient's eye, with an approved chemical lens care system. **clear58 (Etafilcon A) Soft (hydrophilic) Contact Lens** are to be discarded after the recommended wearing period, from 1 to 30 days, as prescribed by the Eye Care Professional.

The target population for the use of this device are adults of 18 years or older. There is no clinical data to support the use of this device by individuals under 18 years of age. Use of this device by individuals less than 18 years of age is at the sole discretion of the eye care professionals (ECP).

CONTRAINDICATIONS (REASONS NOT TO USE):

DO NOT USE the **clear58 (Etafilcon A) Soft (hydrophilic) Contact Lens** when any of the following conditions are present:

- Use of eye medication.
- Any eye disease, injury, redness, inflammation, infection or abnormality that affects the cornea, conjunctiva, eyelids or anywhere in or around the eyes.
- Severe insufficiency of lacrimal secretion or inadequate tear fluid (dry eyes).
- Corneal hypoesthesia (reduced corneal sensitivity), if not-aphakic.
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lens. If the patient is diagnosed or has reason to believe that such systemic disease exists, please consult and inform the eye care practitioner for proper evaluation and advice on contact lens wear. These are the common systemic diseases that may affect the eye: Diabetes mellitus; AIDS; Graves' disease;

Rheumatoid arthritis, Lupus and other autoimmune conditions; Hypertension and Atherosclerosis; Multiple sclerosis; Shingles.

- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lens or use of contact lens solutions.
- Allergy to any ingredient, such as mercury or thimerosal, in a solution which is to be used to care for the **clear58 (Etafilcon A) Soft (hydrophilic) Contact Lens**.
- Any active corneal infection (bacteria, fungi, or viral)
- If eyes become red or irritated.
- If patient is unable to follow lens care regimen or unable to obtain assistance to do so due to a sickness.
- Patient history of recurring eye or eyelid infections, adverse effects associated with contact lens wear, intolerance or abnormal ocular response to contact lens wear.
- Poor health affecting the eye such as cold and flu.
- Previous medical intervention which may adversely affect the use of the lens.

CAUTION:

Due to the small number of patients enrolled in clinical investigation of lens, 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 eyecare practitioner should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.

The potential impact of these factors on the patient's ocular health must 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 monitored by the prescribing eyecare practitioner.

WARNINGS:

- PROBLEMS WITH CONTACT LENS AND LENS CARE PRODUCTS COULD RESULT IN **SERIOUS** INJURY TO THE EYE. It is essential that patients follow their eyecare practitioner's direction and all labeling instructions for proper use of lens and lens care products, including the lens case. EYE PROBLEMS, INCLUDING CORNEAL ULCERS, CAN DEVELOP RAPIDLY AND LEAD TO **LOSS OF VISION**; THEREFORE, IF YOU EXPERIENCE EYE DISCOMFORT, EXCESSIVE TEARING, VISION CHANGES, OR REDNESS OF THE EYE, **IMMEDIATELY REMOVE YOUR LENS** AND PROMPTLY CONTACT YOUR EYECARE PRACTITIONER.
- All contact lens wearers must see their eyecare practitioner as directed.

- Do not use lenses during sleeping periods. Frequent Replacement Wear lenses are not indicated for overnight wear. Clinical studies have shown increased risk of serious adverse reactions, such as such as ulcerative keratitis, when lenses are worn overnight. Patients are instructed to remove **clear58 (Etafilcon A) Soft (hydrophilic) Contact Lens** while sleeping.
- Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers do.

PRECAUTIONS:

Special Precautions for eyecare practitioner:

- Clinical studies have demonstrated that contact lens manufactured from Etafilcon A are safe and effective for their intended use. However, the clinical studies may not have included all design configurations or lens parameters that are presently available in this lens material.
- Consequently, when selecting an appropriate lens design and parameters, the eyecare practitioner should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, 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 monitored by the prescribing eyecare practitioner.
- Fluorescein, a yellow dye, should not be used while the lens is on the eye. The lens 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. Wait at least one hour before replacing the lens. Too early replacement may allow the lens to absorb residual Fluorescein irreversibly.
- Before leaving the eyecare practitioner's office, the patient should be able to promptly remove lens or should have someone else available who can remove the lens for him or her.
- Eyecare practitioners should instruct the patient to remove the lens immediately if the eye becomes red or irritated.

EYECARE PRACTITIONERS SHOULD CAREFULLY INSTRUCT PATIENTS ABOUT THE FOLLOWING REGIMEN AND SAFETY PRECAUTIONS:

- Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. Use only recommended solutions that are fresh and sterile. Never use solutions recommended for conventional hard contact lens only. Chemical disinfection solutions should not be used with heat unless specifically indicated on product labeling for use in both heat and chemical disinfection.
- Always use **FRESH, STERILE UNEXPIRED** lens care solutions. Always follow directions in the package inserts for the use of contact lens solutions.

Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions. Do not use saliva or anything other than the recommended solution for lubricating or rewetting lens.

- Do not use saliva or anything other than the recommended solution for lubricating or rewetting lens. Always keep the lens completely immersed in the recommended storage solution when the lens is not being worn (stored). Prolonged periods of drying will damage the lens. Follow the lens care directions for (Care for a Dried Out Dehydrated Dry Lens) if the lens surface does become dried out.
- If the lens sticks (stops moving) on the eye, follow the recommended directions on (care for sticking non-moving lens). The lens should move freely on the eye for the continued health of the eye. If nonmovement of the lens continues, the patient should be instructed to **IMMEDIATELY** consult his or her eyecare practitioner.
- Always wash and rinse hands before handling lens. Do not contaminate the lens with cosmetics, lotions, soaps, creams, deodorants, aerosols, or sprays. Insert lenses before applying makeup and remove lenses before taking makeup off.
- Do not touch contact lens with the fingers or hands if the hands are not free of foreign materials, as microscope scratches of the lens may occur, causing distorted vision and/or injury to the eye.
- Carefully follow the handling, insertion, removal, cleaning, disinfection, storing and wearing instructions in the patient instructions for the **clear58 (Etafilcon A) Soft (hydrophilic) Contact Lens** as those prescribed by the eyecare practitioner.
- Never wear lens beyond the period recommended by the eyecare practitioner.
- If aerosol products such as hair spray are used while wearing lens, exercise caution and keep eyes closed until the spray has settled.
- Always handle lens carefully and avoid dropping them.
- Avoid all harmful or irritating vapors and fumes while wearing lens.
- Ask the eyecare practitioner about wearing lens during sporting activities.
- Inform the doctor (health care practitioner) about being a contact lens wearer.
- Never use tweezers or other tools to remove lens from the lens container unless specifically indicated for that use. Pour the lens into the hand.
- Do not touch the lens with fingernails.
- Always contact the eyecare practitioner before using any medicine or medications in the eyes.
- Always inform the employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or may require that the patient not wear contact lens.
- As with any contact lens, follow-up visits are necessary to assure the continuing health of the patient's eyes. The patient should be instructed as to a recommended follow-up schedule.
- It is recommended that the contact lenses should be cleaned, hydrated, rinsed and disinfected using lens solutions which are indicated for use with soft (hydrophilic) contact lenses.

- Avoid wearing contact lens during swimming activities. Chemicals from treated water may be absorbed by the contact lens and alter its physicochemical properties; chemical residues or foreign materials may stick or deposit on the surface of the lens and will cause eye irritation, inflammation, or injury to the eye. Swimming in untreated water may cause bacteria or fungus to stick on the surface of the contact lens causing eye infections.
- Do not use lens while participating in traffic-related situations (e.g., driving, riding a bike) or while undertaking water-related activities such as showering and bathing.
- Do not stare for too long specially on blinding surfaces or intense light source as this may cause damage to the retina. Rest eyes in between sessions by closing it for few seconds. Avoid activities where possible vision hindrance and reduced transmission of light create a risk.
- Do not use after date of expiry.
- Do not use in excessively dry or dusty environment.
- Do not clean lenses with tap water.
- Do not re-use the primary packaging as containment for storage between uses.
- Used lens shall not be used by other persons.

ADVERSE REACTIONS:

The patient should be informed that the following problems may occur:

- Eyes stinging, burning, itching (irritation), or other eye pain.
- Comfort is less than when lens was first placed on eye.
- Feeling that something is in the eye such as a foreign body or scratched area.
- Excessive watering (tearing) of the eye.
- Unusual eye secretions.
- Redness of the eye.
- Reduced sharpness of vision (poor visual acuity).
- Blurred vision, rainbows, or halos around objects.
- Sensitivity to light (photophobia).
- Dry eyes.

IF THE PATIENT NOTICES ANY OF THE ABOVE, HE OR SHE SHOULD BE INSTRUCTED TO:

- **IMMEDIATELY REMOVE LENS.**
- If discomfort or problems stops, then look closely at the lens. **If** the lens is in any damage, **DO NOT PUT THE LENS BACK ON THE EYE.** Place the lens in the storage case and contact the eyecare practitioner. If the lens has dirt, an eyelash, or other foreign body on it, or the problem stops and the lens appears undamaged, the patient should thoroughly clean, rinse, and disinfect the lens then reinsert them.

- **If any of these symptoms continue after removal of the lens, CONSULT A QUALIFIED HEALTHCARE PROFESSIONAL, SUCH AS AN OPHTHAMOLOGIST OR OPTOMETRIST, AUTHORISED BY NATIONAL LAW TO TREAT SUCH SYMPTOMS. The continuation of these symptoms might indicate a more serious condition.**

When any of the above problems occur, a serious condition such as infection, corneal ulcer, neovascularization, or iritis may be present. The patient should be instructed to **KEEP LENS OFF THE EYE AND SEEK IMMEDIATE PROFESSIONAL IDENTIFICATION** of the problem and prompt treatment to avoid serious eye damage.

FITTING:

Conventional methods of fitting contact lens apply to the **clear58 (Etafilcon A) Soft (hydrophilic) Contact Lens**. For a detailed description of the fitting techniques, refer **clear58 (Etafilcon A) Soft (hydrophilic) Contact Lens** Professional Fitting Guide and Patient Instruction/ Wearer's Guide, copies of which are available from:

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PERSONAL CLEANLINESS and LENS HANDLING:

Cleanliness is an important aspect of contact lens care.

BEFORE HANDLING YOUR LENS:

- Before handling your lens, always wash and rinse your hands thoroughly and dry them with a lint-free towel.
- Do not use soaps, lotions, cold creams, or perfumes which leave a residue on your hands.
- Avoid using medications, creams, deodorants, make-up, after shave lotions, or similar items prior to touching your lens.
- When hair spray is used, the eye must be kept closed until the spray has settled.
- Take care in handling your lens. Always avoid touching your lens with your fingernails or other sharp objects.
- **NEVER WORK DIRECTLY OVER A SINK WITH THE DRAIN OPEN, AS THE LENS MAY BE LOST.**
- After opening the blister pack, if the lens sticks to the under-surface of the

foil and has become partially dried-out, fully immersed the lens in the buffered saline solution that is inside the blister pack and wait for minimum 15 minutes before lens fitting.

HANDLING AND PLACING THE LENS ON THE EYE:

- To avoid the possibility of lens mix-ups, always start with the same lens first.
- Before inserting the lens, rinse well with fresh, sterile rinsing solution. Then place the lens on the tip of the index finger of your dominant hand.
- While positioned on your index finger, check to ensure the lens has not turned inside out. To check this, look at the profile of the lens against a light background. If the edge profile appears convex and bowl-shaped, then it is correct. If the lens is inverted, it will flare out at the edge. If the lens is inverted, simply reverse it by using light fingertip pressure. Be sure to avoid damaging the lens with your fingernails.
- Look straight ahead and raise the upper lid with your other index finger.
- Then look down, keep both eyes open and place the lens on the upper white part of the eye.
- Slowly release upper lid, and gently close your eye.
- The lens should center automatically, or it can be moved on center by gentle fingertip pressure through the lids.
- Repeat the above procedure for the second lens.
- If the lens appears to be stuck on your eye, apply a few drops of an Eye Care Practitioner recommended lubricating or rewetting solution to the eye and blink a few times. If the lens does not move freely on your eye, contact your Eye Care Practitioner for further instructions.

There is no single "right way" of putting on lens. If you find this method of lens placement difficult, your Eye Care Practitioner will suggest another method or provide additional information.

NOTE: If after replacement of the lens, your vision is blurred, check for the following:

- The lens is not centered on the eye (see "Centering the lens" next in this booklet.
- If the lens is centered, remove the lens (see "Removing the lens" section) and check the following:
 - a. Cosmetic or oils on the lens. Discard lens and place a new lens on the eye again.
 - b. The lens is on the wrong eye.
 - c. The lens inside-out (it would also not be as comfortable as normal)

If you find that your vision is still blurred after checking the above possibilities, remove both lenses and consult your eyecare practitioner.

CENTERING THE LENS:

Very rarely a lens that is on the cornea will be displaced onto the white part of the eye during lens wear. This can also occur during placement and removal of the lenses if the correct techniques are not performed properly. To center a lens, follow the procedure outlined below.

Using your index finger, gently apply pressure to the lens and slide it back into the cornea. If the lens gets under the upper lid, gently massage the upper lid while looking down and move the lens toward the cornea.

REMOVING THE LENS:**Preparation:**

- Wash and rinse your hands thoroughly.
- Dry hands with a lint-free towel.
- Check that the lens is centered on the cornea before attempting to remove the lens. Check your vision by covering one eye. If vision is blurry, the lens is off-center. Re-center the lens before attempting to remove it.

Removal:

- To avoid the possibility of lens mix-ups, always begin with the same lens.
- Look up and keep both eyes open.
- Using the middle finger of your dominant hand, gently pull down the lower lid of the first eye. Using the tip of your index finger of the same hand, touch the lens and slide it onto the white of the eye.
- Gently "pinch" the lens between the index finger and the thumb and remove.
- Repeat the procedure for the second eye.
- If the lens cannot be easily moved, apply a few drops of lubricating or rewetting solution to the eye, blink a few times, and when the lens moves freely on the eye, remove in the manner described above. If the lens still cannot be moved, contact your Eye Care Practitioner for further instruction.
- Upon removal, clean each lens with a contact lens care solution per the procedures described under the heading, CARING FOR YOUR LENS. Rinse well with contact lens care solution and place in the lens storage case filled with fresh solution. Follow the instructions-for-use (IFU) of the contact lens care solution recommended by your Eye Care Practitioner.

IMPORTANT:

Always avoid touching your lens with your fingernails. Use only your fingertips.

If you find this method difficult, your Eye Care Practitioner will suggest another method or provide additional instruction.

If the lens is chipped or torn, do not put the lens back on your eye. Return the lens to the storage case with fresh solution and contact your Eye Care Practitioner.

RECOMMENDED WEARING SCHEDULE:

THE WEARING AND REPLACEMENT SCHEDULES SHOULD BE DETERMINED BY THE EYECARE PRACTITIONER.

Patients tend to over wear the lens initially. The eyecare practitioner should emphasize the importance of adhering to the initial maximum wearing schedule. Regular checkups, as determined by the eyecare practitioner, are also extremely important.

The **clear58 (Etafilcon A) Soft (hydrophilic) Contact Lens** are indicated for daily wear. The maximum suggested wearing time for this lens is:

DAY	1	2	3	4	5	6
HOURS	6	8	10	12	14	Up to 14 hours

FREQUENT/ PLANNED REPLACEMENT:

It is recommended that the **clear58 (Etafilcon A) Soft (hydrophilic) Contact Lens** be discarded and replaced with a new lens after every 30 days. When removed between replacement periods lenses must be cleaned and disinfected prior to reinsertion or be discarded and replaced with a fresh lens.

However, patients should adhere to the recommended replacement schedule given by their eye care professional based upon their individual needs and physiological conditions.

CARING FOR YOUR LENS:

Eye care practitioners should review with the patient on lens care directions, including both basic lens care information and specific instructions on the lens care regimen recommended for the patient:

BASIC INSTRUCTIONS:

Care of contact lens takes very little time and involves **THREE** essential steps - **CLEANING, RINSING AND DISINFECTING**. Each step in itself is important, and one step is not to be replaced by the other.

- o Always wash, rinse and dry hands before handling contact lens. Inspect fingers and hand to ensure they are free of fibers or other debris. Do not use soaps, lotions, cold creams, or perfumes which leave a residue on your hands. Avoid using medications, creams, deodorants, make-up, after shave lotions, alcohol-based hand sanitizer or similar items prior to touching your lens. When hair spray is used, the eye must be kept closed until the spray has settled. Take care in handling your lens. Always avoid touching your lens with your fingernails or other sharp objects. **NEVER WORK DIRECTLY OVER A SINK WITH THE DRAIN OPEN, AS THE LENS MAY BE LOST.**

- o Always use STERILE LENS. DO NOT use if sterile blister packaging is opened or damaged before use. In the event when the sterile packaging is found opened or damaged, the lens should be discarded. Avoid touching the contact lens with fingers or hands if they are not free of foreign materials, as microscopic scratches of the lens may occur, causing distorted vision and/or injury to the eye. Follow the instructions for the handling, placing and removal of lens carefully.
- o Always use **FRESH, STERILE, UNEXPIRED** lens care solution that is indicated for use with soft (hydrophilic) contact lenses.
- o Use only chemical lens care system and follow instructions-for-use (IFU) on lens care solution labeling. Each lens care product contains specific directions for use and important safety information, which should be read and followed carefully.
- o Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. **DO NOT ALTERNATE OR MIX LENS CARE SYSTEMS UNLESS INDICATED ON SOLUTION LABELING.**
- o Do not use saliva or anything other than the recommended solutions for lubricating or rewetting lens. Do not put lens in the mouth.
- o Lenses should be **cleaned, rinsed, and disinfected** each time they are removed. **Cleaning and rinsing** are necessary to remove mucus and film from the lens surface. **Disinfecting** is necessary to destroy harmful germs.
- o The lens case must be emptied and refilled with fresh, sterile recommended storage and disinfection solution prior to disinfecting the lens. Eye care practitioners may recommend a lubricating/rewetting solution, which can be used to wet (lubricate) lens while they are being worn to make them more comfortable.

Note: Some solutions may have more than one function, which will be indicated on the label. Read the label on the solution bottle and follow instructions.

LENS CLEANING, DISINFECTION, AND STORAGE:

- **Clean** one lens first (always the same lens first to avoid mix-ups), rinse the lens thoroughly with recommended rinsing or disinfecting solution indicated for use with soft (hydrophilic) contact lenses to remove the cleaning solution, mucus, and film from the lens surface, and put lens into correct chamber of the lens storage case. Then repeat the procedure for the second lens.
- After cleaning, **disinfect** lens using the lens care regimen indicated for use with soft (hydrophilic) contact lenses.
- To store lens, disinfect and leave them in the closed/unopened case until ready to wear. If lens is not to be used immediately following disinfection, the patient should be instructed to consult the package insert or the eye care practitioner for information on storage of lens. Follow the instruction and timing recommended by the solution manufacturer.

Lens Case Cleaning and Maintenance:

- Contact lens cases can be a source of bacterial growth.
- After removing the lens from the case, empty and rinse the lens storage case with solution as recommended by the lens case manufacture; then allow the lens case to air dry.
- When the case is used again, refill it with storage solution indicated for use with soft (hydrophilic) contact lenses. Replace lens case at regular intervals as recommended by the lens case manufacturer or your eye care practitioner.

LENS CARE REGIMEN:

- Patients must adhere to the lens care regimen as described on the Package Insert for
clear58 (Etafilcon A) Soft (hydrophilic) Contact Lens.
- Failure to follow this procedure may result in development of serious ocular infections.

CARE FOR A DRIED OUT (DEHYDRATED) LENS:

- If left exposed to the air, the lens will dehydrate. If lens dehydrates, refer to the above section on caring for dried out (dehydrated) lens.

LENSES PRESCRIBED FOR FREQUENT REPLACEMENT:

- The **clear58 (Etafilcon A) Soft (hydrophilic) Contact Lens** may be prescribed in a frequent replacement program and should be thrown away after the recommended wearing period prescribed on the Package Insert.

CHEMICAL LENS DISINFECTION:

1. Wash and rinse your hands thoroughly before handling lens.
2. After removal of lens, clean the lens by applying three drops of lens solution indicated for use with soft (hydrophilic) contact lenses to each surface. Then rub the lens between your fingers for 20 seconds.
3. After cleaning, thoroughly rinse both surfaces of the lens with a steady stream of fresh, sterile solution for approximately 10 seconds.
4. Fill contact lens case with the disinfection and storage solution indicated for use with soft (hydrophilic) contact lenses and place the lenses in the proper cells for a minimum of 4 hours or as indicated in the instructions-for-use (IFU).
5. Different lens care solutions have different instruction-for-use, make sure to follow the instructions and timings as recommended by lens care solution manufacturer.

Note: **DO NOT HEAT THE DISINFECTING SOLUTION AND LENS.**

Caution: Lenses that are chemically disinfected may absorb ingredients from the disinfecting solution, which may be irritating to the eyes. A thorough rinse in fresh, sterile rinsing solution prior to placement on the eye should reduce the potential for irritation.

RECOMMENDED LENS CARE PRODUCTS:

Patient should only use chemical lens care products indicated for use with soft (hydrophilic) contact lenses. Each lens care product contains specific instructions for use and important safety information, which should be read and carefully followed.

FOLLOW-UP CARE:

1. Follow-up examinations are recommended by the Eye Care Practitioner, they are necessary to ensure continued successful contact lens wear.
2. Prior to a follow up examination, the contact lens should be worn for at least one continuous hour and the patient should be asked to identify any problems which might be occurring related to contact lens wear.
3. With lenses in place on the eyes, evaluate the fitting performance to assure the criteria of a well-fitted lens continue to be satisfied. Examine the lenses closely for surface deposition and/or damage.
4. After the lens removal, conduct a thorough bio-microscopy examination.
 - a. The presence of vertical corneal striate in the posterior central cornea and /or cornea neovascularization is indicative of excessive corneal edema.
 - b. The presence of corneal staining and / or limbal-conjunctival hyperemia can be indicative of an unclean lens, a reaction to solution preservatives, excessive lens wear and/ or a poorly fitting lens.
 - c. Papillary conjunctival changes may be indicative of an unclean and/or damaged lens.

If any of the above observations are considered as abnormal, various professional judgments are necessary to alleviate the problem and restore the eye to its optimal conditions. If the Criteria of a Well-Fitted Lens is not satisfied during any follow-up examinations, the patient should be refitted with a more appropriate lens.

FOLLOW-UP EXAMINATIONS:

- Within one week of lens dispensing
- After three weeks of lens wear
- After seven weeks of lens wear
- After each six-month period of lens wear

STORAGE CONDITIONS:

Store lenses between 20°C to 25°C.

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 AND IMMEDIATELY CONTACT THE EYE CARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

WHEN TO CALL YOUR PRACTITIONER?

Certain symptoms may be early indicators of potentially serious problems. A careful examination of your lens, and professional examination of your eyes, may be required.

Remove the lens following the instructions outlined in this guide, and call your Eye Care Practitioner if:

- Your eye becomes red and feels irritated or "gritty".
- You notice a change in your vision or see rainbows or halos around objects.
- You experience discomfort and/or sensitivity to lights.

A good general policy is:

"IF IN DOUBT ... TAKE THE LENS OUT" and contact your Eye Care Practitioner.

Learn and use proper lens care habits:

- Follow Instructions.
- Handle Lens Properly.
- Learn How to Put On and Take Off Your Lens.
- Keep Your Lens Clean.
- Disinfection is a Necessary Security.

IMPORTANT:

In the event that you experience any difficulty wearing your lens or you do not understand the instructions given to you, **DO NOT WAIT** for your next appointment. **CONTACT YOUR EYECARE PRACTITIONER IMMEDIATELY.**

INSTRUCTIONS FOR MONOVISION WEARER:

- You should be aware that as with any type of lens correction, there are

advantages and compromises to monovision contact lens therapy. The benefit of clear near vision in straight ahead and upward gaze that available with monovision may be accompanied by a vision compromise that may reduce your visual acuity and depth perception for distance and near tasks. Some patients have experienced difficulty adapting to it. Symptoms, such as mild blurred vision, dizziness, headaches, and a feeling of slight imbalance, may last for a brief minute or for several weeks as adaptation takes place. The longer these symptoms persist, the poorer your prognosis for successful adaptation. You should avoid visually demanding situations during the initial adaptation period. It is recommended that you first wear these contact lenses in familiar situations, which are not visually demanding. For example, it might be better to be a passenger rather than a driver of an automobile during the first few days of lens wear. It is recommended that you only drive with monovision correction if you pass your state driver's license requirements with monovision correction.

- Some monovision patients will never be fully comfortable functioning under low levels of illumination, such as driving at night. If this happens, you may want to discuss with your Eye Care Practitioner having additional contact lenses prescribed so that both eyes are corrected for distance when sharp distance binocular vision is required. If you require very sharp near vision during prolonged close work, you may want to have additional contact lenses prescribed so that both eyes are corrected for near when sharp near binocular vision is required.

Some monovision patients require supplemental spectacles to wear over the monovision correction to provide the clearest vision for critical tasks. You should discuss this with your Eye Care Practitioner.

- It is important that you follow your Eye Care Practitioner's suggestions for adaptation to monovision contact lens therapy. You should discuss any concerns that you may have during and after the adaptation period.
- The decision to be fit with monovision correction is most appropriately left to the Eye Care Practitioner in conjunction with you, after carefully considering and discussing your needs.

HOW SUPPLIED:

Each lens is supplied sterile in blister packs containing buffered saline solution. The blister pack is marked with the base curve, diameter, dioptric power, manufacturing lot number, and expiration date of the lens.

DISPOSAL

There is no special disposal required for soft contact lens and its blister. The carton packaging, aluminum lidding and polypropylene (PP) plastic case should be placed properly in the waste bin or recycled according to local waste guidance or local regulations.

REPORTING OF ADVERSE REACTIONS:

All serious adverse experiences and adverse reactions observed in patients wearing the **clear58 (Etafilcon A) Soft (hydrophilic) Contact Lens** or experienced with the lens should be reported immediately to the manufacturer and the competent authority of the member state.

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