

PACKAGE INSERT

AquaSoft® (etafilcon A) DAILY WEAR Soft Contact Lens (Clear and visibility tint with UV blocker)

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

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. The eyecare practitioner should provide the patient with the wearers guide that pertains to the patients prescribed lens

DESCRIPTION

The **AquaSoft®** (etafilcon A) Soft (hydrophilic) Contact Lens is available as a single vision spherical lens, aspherical multifocal lens and as a back surface astigmatic (toric) lens. The hydrophilic nature of this material allows the lens to become soft and pliable when immersed in an aqueous solution.

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 dimethacrylate. It 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' 21CFR part 73.3121. The etafilcon A name has been adopted by the United States Adopted Names Council (USAN)

In the **AquaSoft®** contact lens with UV blocker, a Benzophenone UV absorbing monomer is used to block UV radiation. The UV blocking for AquaSoft® averages >99% in the UVB range of 280nm-315nm and 83% in the UVA range of 316nm-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 requires 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 allows aqueous solutions to enter the lens and in its fully hydrated state and the lens is approximately 57% 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	19.9 X10 ⁻¹¹ (cm ² /sec)(ml O ₂ /ml x mmHg @35° C), (revised Fatt method)

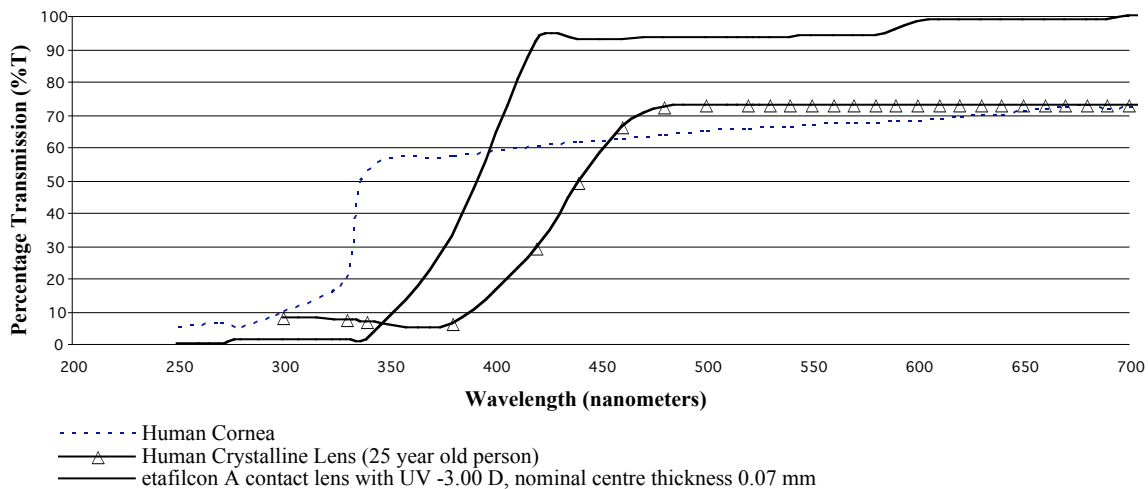
The lenses are hemispherical flexible shells which cover the cornea and a portion of the adjacent sclera with the following dimensions:

Chord Diameter:	14.0mm to 15.0mm
Centre Thickness:	0.06 to 0.40 mm
Base Curve:	8.0 to 9.8 mm
Powers:	-20.00 Diopters to + 20.00 Diopters
Add Powers:	+1.00 to +4.00 Diopters
Cylinders:	-0.50 to -7.00 Diopters
Axis:	1° to 180°

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 UV transmittance curve of the **AquaSoft®** (etafilcon A) Soft 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 25 year old.

Typical Transmittance Profile of -3.00 D Etafilcon Hydrophillic Contact Lens with UV versus a Human Cornea and Human Lens.



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 **AquaSoft**[®] (etafilcon A) Soft Contact Lens, when placed on the cornea, acts as a refracting medium to focus light rays on the retina.

CAUTION

Due to the small number of patients enrolled in clinical investigations of lenses, all refractive powers, design configurations, or lens parameters available in the lens material were not evaluated in significant numbers. Consequently when selecting an appropriate lens design and parameter, 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 the lens performance on the eye should be carefully monitored by the prescribing eyecare practitioner.

INDICATIONS

The **AquaSoft**[®] (**etafilcon A**) **Spherical** Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia. The lens may be worn by persons who exhibit refractive astigmatism of 0.75 D (Diopters) or less where the astigmatism does not interfere with visual acuity.

The lens may be cleaned and disinfected using a chemical (not heat) lens care system.

The **AquaSoft**[®] (**etafilcon A**) **Toric** Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and may have astigmatism of 7.00D of astigmatism or less.

The lens may be cleaned and disinfected using a chemical (not heat) lens care system.

The **AquaSoft**[®] (**etafilcon A**) **Multifocal** Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and are presbyopic. The lens may be worn by persons who exhibit no more than 2.00 D of astigmatism and can obtain satisfactory visual acuity in a power range of +4.00D to -5.00D and have near add requirements up to 3.00D.

The lens may be cleaned and disinfected using a chemical (not heat) lens care system.

Eyecare practitioners may prescribe the lenses for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be cleaned and disinfected using a chemical (not heat) lens care system.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE the **AquaSoft**[®] soft contact lens when any of the following conditions are present:

- * Acute and subacute inflammation or infection of the anterior chamber of the eye.
- * Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids.

- * Severe insufficiency of lacrimal secretion (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.
- * 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 **AquaSoft**[®] soft contact lens (etafilcon A).
- * Any active corneal infection (bacterial, fungi, or viral).
- * If eyes become red or irritated.
- * Patients unable to follow lens care regimen or unable to obtain assistance to do so.
- * Advise patient not to wear **AquaSoft**[®] soft contact lenses while sleeping.

WARNINGS

- * **PROBLEMS WITH CONTACT LENS AND LENS CARE PRODUCTS COULD RESULT IN SERIOUS INJURY TO THE EYE.** It is essential that you follow your 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.**
- * Daily wear lens are not indicated for overnight wear, and you are instructed not to wear the **AquaSoft**[®] soft contact lenses while sleeping. Clinical studies have shown that the risk of serious adverse reactions is increased when these lens are worn overnight.
- * Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers do.

PRECAUTIONS

Special Precautions for the Eyecare Practitioner

Clinical studies have demonstrated that the contact lens manufactured from (etafilcon A) are safe and effective for their intended use. However, the clinical studies may not have included all the design configurations or lens parameters that are presently available in this lens material.

Consequently when selecting an appropriate lens design and parameter, 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 the 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 patient's eye. The lens absorbs this dye and becomes 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 the lens or should have someone else available to 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.

The eyecare practitioner should carefully instruct patients about the following care regimen and safety precautions:

- * Different solutions cannot always be used together, and not all solutions are safe for use with all lens.
- * 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 the product labelling 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 labelling directions.
- * 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 lens. The lens should move freely on the eye for the continued health of the eye. If non-movement 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 get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lens.
- * It is best to put on lens before putting on makeup. Water-base cosmetics are less likely to damage lens than oil-base.
- * Do not touch contact lens with the fingers or hands if the hands are not free of foreign materials, as microscopic 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 **AquaSoft®** soft contact lens and 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

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 THE LENS.**
- * If discomfort or problems stops, then look closely at the lens. If the lens is in anyway damaged, **DO NOT PUT THE LENS BACK ON YOUR EYE.** Place the lens in the storage case and contact your 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.
- * **After reinsertion, if the problem continues, the patient should IMMEDIATELY REMOVE THE LENS AND CONSULT YOUR EYECARE PRACTITIONER.**

When any of the above problems occur, a serious condition such as infection, corneal ulcer, neovascularization, or iritis may be present. **KEEP THE 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 lenses apply to the **AquaSoft**[®] spherical, toric and multifocal contact lens. For detailed description of the fitting techniques, refer to the **AquaSoft**[®] (etafilcon A) Professional Fitting and Information Guide, copies of which are available from:

AquaSoft LLC
13751 S. Wadsworth Park Drive
Draper, UT 84020
Phone 801-858-2235
www.aquasoft.com

WEARING SCHEDULE

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

Patients tend to overwear the lens initially. It is important not to exceed the wearing schedule. The eyecare practitioner should emphasize the importance of adhering to the initial maximum wearing schedule. Regular check ups, as determined by the eyecare practitioner, are also extremely important. The **AquaSoft**[®] contact lenses are indicated for daily wear. The maximum suggested wearing time for the **AquaSoft**[®] contact lens is:

DAY	1	2	3	4	5	6
HOURS	6	8	10	12	14	All waking hours

STUDIES HAVE NOT BEEN COMPLETED TO SHOW THAT THE “**AquaSoft**[®] soft contact lens” IS SAFE TO WEAR DURING SLEEP

WEARING SCHEDULES SHOULD BE DETERMINED BY THE EYECARE PRACTITIONER

FREQUENT / PLANNED REPLACEMENT

It is recommended that the **AquaSoft**[®] contact lens be discarded and replaced with a new lens every two weeks. However, as the eyecare practitioner, you are encouraged to determine an appropriate lens replacement schedule based upon the response of the patient.

LENS CARE DIRECTIONS

Eyecare Practitioners should review with the patient lens care directions, including both basic lens care information and specific instruction on the lens care regimen recommended for the patient.

Basic Instructions:

Care of contact lenses takes very little time and involves THREE essential steps –

CLEANING RINSING & DISINFECTION Each step itself is important and one step is not replaced by another. Many solutions are now multipurpose and can be used to clean, rinse and disinfect as indicated by the instructions and the labeling

- * Always wash, rinse, and dry hands before handling contact lens.
- * Always use **FRESH, STERILE UNEXPIRED** lens care solutions.
- * Use recommended system of lens care and carefully follow instructions on solution labeling.
- * Different solutions cannot always be used together, and not all solutions are safe for use with all lens. **DO NOT ALTERNATE OR MIX LENS CARE SYSTEMS UNLESS INDICATED ON SOLUTION LABELING.**
- * Do not use saliva or anything other than the recommended solutions for lubricating or rewetting lens. Do not put lens in the mouth.
- * 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
- * Disinfection is necessary to destroy harmful germs.

The lens case must be emptied and refilled with fresh, sterile recommended storage and disinfecting solution prior to disinfecting the lens. Eyecare practitioners may recommend a lubricating / wetting solution which can be used to lubricate (wet) lenses 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 the 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 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 system recommended by the manufacture and/or your eyecare practitioner.
- * To store lenses, disinfect and leave them in the closed/unopened case until ready to wear. If lens are not to be used immediately following disinfection, you should consult the package insert or your eyecare practitioner for information on storage of lens.

Lens Case Cleaning and Maintenance:

- * Contact lens cases can be a source of bacteria 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. Replace lens case at regular intervals as recommended by the lens case manufacture or your eyecare practitioner.

Lens Care Regimen:

- * Patients must adhere to the lens care regimen recommended by their eyecare practitioner for the **AquaSoft**[®] contact Lens. Failure to follow this procedure may result in development of serious ocular infections.

Care for a Dried out (dehydrated) dry Lens:

If for some reason your lenses dry out completely a minimum of handling is important as they are very brittle in the dehydrated state. Carefully place them in rinsing or storage solution for a minimum of thirty minutes during which time they will become soft and flexible. Then follow the cleaning, rinsing, and disinfecting procedures, including soaking the lens in storage and disinfection solution for four hours before wearing again.

Care for a Sticking (non-moving) Lens:

If the lens sticks (cannot be removed), you should apply 3 to 4 drops of the recommended lubricating or rewetting solution directly to the eye and wait until the lens begins to move freely on the eye before removing it. If non-movement of the lens continues after 15 minutes, you should IMMEDIATELY consult your eyecare practitioner.

Storage:

- * The **AquaSoft**[®] contact lens must be stored only in the recommended solution.
- * Always keep your lens completely immersed in a recommended disinfecting/conditioning solution when the lenses are not being worn
- * If the lens dehydrates reference the above section on caring for a dried out (dehydrated) dry lens.

Lenses Prescribed for Frequent Replacement:

- * The **AquaSoft**[®] soft contact lens may be prescribed in a frequent replacement program and should be thrown away after the recommended wearing period prescribed by the eyecare practitioner.

Chemical (NOT HEAT) Disinfection:

1. Wash and rinse your hands thoroughly BEFORE HANDLING LENS.
2. After removal of lens, CLEAN the lens by applying three drops of cleaner 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 rinsing solution for approximately 10 seconds.
4. Fill contact lens carrying case with the recommended disinfection and storage solution and place lens in the proper cells and soak as recommend in solution labeling.

Note: **DO NOT HEAT THE DISINFECTION 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.

LENS DEPOSITS AND USE OF ENZYMATIC CLEANER:

Enzyme cleaning may be recommended by the eyecare practitioner. Enzyme cleaning removes protein deposits on the lens. These deposits cannot be removed with regular cleaners. Removing protein deposits is important for the well-being of the patient’s lens and eyes. If these deposits are not removed, they can damage the lens and cause irritation.

Enzyme cleaning does NOT replace routine cleaning and disinfecting. For enzyme cleaning, the patient should carefully follow the instructions in the enzymatic cleaning labeling.

RECOMMENDED LENS CARE PRODUCTS

The eyecare practitioner should recommend a care system that is appropriate for the **AquaSoft®** contact lens. Each lens care product contains specific instructions for use and important safety information, which should be read and carefully followed. The table shows the solutions that are recommended for use with **AquaSoft®** contact lenses.

SOLUTION USAGE --LENS CARE DIRECTIONS				
Solution	<u>Clean</u>	<u>Rinse</u>	<u>Disinfect / Neutralize</u>	Lubricant / Rewetting
Multi-Purpose Cleaning / Disinfection System	AquaSoft® Multipurpose Cleaning Solution	AquaSoft® Multipurpose Cleaning Solution	AquaSoft® Multipurpose Cleaning Solution	AquaSoft® Comfort Drops
Enzymatic Cleaning / Disinfection System	Bausch & Lomb Sensitive Eyes Enzymatic Cleaner	Bausch & Lomb Sensitive Eyes Enzymatic Cleaner	Bausch & Lomb Sensitive Eyes Enzymatic Cleaner	AquaSoft® Comfort Drops

EMERGENCIES

The patient should be informed that if any chemical 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 YOUR EYECARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY