clear58™

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

This fitting guide 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 wearer's guide that pertains to the patients prescribed lens.

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

clear58™

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

clearlab®

TABLE OF CONTENT

DESCRIPTION:

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

The ionic lens material (etafilcon A) is a copolymer of 2-hydroxyethyl methacrylate and cross linked with trimethylolpropane trimethacrylate. 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 with blue visibility-handling tint color additive Reactive Blue 19, 21 CFR part 73.3121. 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 is used to block UV radiation. The UV blocking for clear58 average >99% in the UVB range of 280-315nm 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 dried 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	1.0 17 (hydrated)
Oxygen Permeability	21.83 $\times 10^{-11}$ (cm^2/sec) (mlO_2/ml $\times$ mmHg@ 35℃), (revised Fatt method).

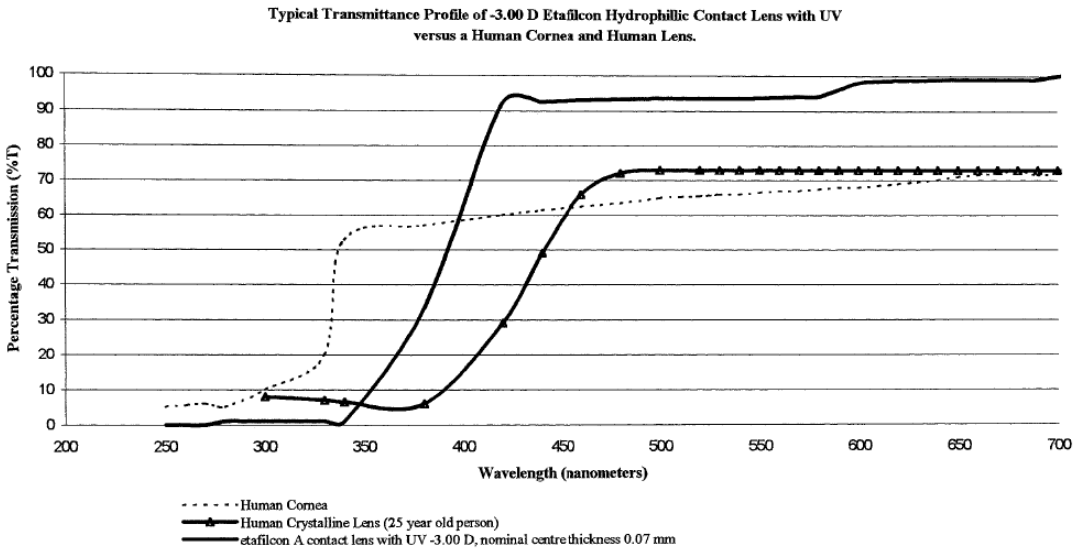
The lenses are hemispheral flexible shells which cover the cornea and portion of the adjacent sclera with the following dimensions:

Chord Diameter	14.0mm to 15.0 mm
Center Thickness	0.06 to 0.40
Base Curve	8.0 to 9.8mm
Powers	-20.00 Diopters to +20.00 Diopters

WARNING:

UV-absorbing contact lenses are NOT substitutes for protective UV-absorbing eyewear such as UV-absorbing goggles or sunglasses because they do not completely cover the eye and surrounding area. You should continue to use 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 factor 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 disorder. Consult your Eye Care Practitioner for more information.

ACTIONS:

In their hydrated state, the **clear58™ (Etafilcon A) Soft (hydrophilic) Contact Lens** when placed on the cornea act as refracting media to focus light rays on the retina.

INDICATIONS (USES):

The **clear58™ (Etafilcon A) Soft (hydrophilic) Contact Lens** for daily wear are indicated for the correction of visual acuity (except for plano lenses) in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia. The lens (except for plano lenses) 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 (not heat) lens care system.

Eye Care 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.

CAUTION:

Due to 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 Eye Care 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 Eye Care Practitioner.

WARNINGS:

Please reference Warnings in the Package Insert.

PRECAUTIONS:

Please reference Precautions in the Package Insert.

ADVERSE REACTIONS:

Please reference Adverse Reactions in the Package Insert.

PATIENT SELECTION:

clear58™ (Etafilcon A) Soft (hydrophilic) Contact Lens is intended for patients that requires optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who may have 1.00D or less of astigmatism.

The lenses are also intended for patients, whom have undergone 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 an corneal surgery, to be used as a therapeutic bandage to relieve corneal pain, at the sole discretion and under direct supervision of a qualified and licensed eyecare professional.

With the cosmetic effects, such as tints, under the sole discretion and direct supervision of a qualified eyecare professional, the lenses are also intended for use as prosthetic devices for sighted and non-sighted eyes, with or without lens power.

Patient communication is vital. Patients who require visual correction but cannot adhere to the recommended care of the **clear58™ (Etafilcon A) Soft (hydrophilic) Contact Lens** should not be provided with this lens. All necessary steps in lens care and all precautions and warnings should be discussed and understood by the patient (Review Package Insert with patient).

FITTING PROCEDURE for the CLEAR58

1. Pre-fitting Examination

A pre-fitting patient history and examination are necessary to:

- Determine whether a patient is a suitable candidate for daily wear contact lenses (refer to contraindications)
- Collect and record baseline clinical information to which post-fitting examination results can be compared
- Make ocular measurements for initial contact lens parameter selection

2. Parameter Selection

The preferred fitting method is by use of a trial lens, selecting the steeper base curve as first choice and then evaluate the CRITERIA OF A WELL FITTED LENS**.**

The alternative method is to determine the K readings and apply the following:

Average K Reading	Suggested Lens Design
41.25 and lower	8.9 mm base curve / 14.5 mm Diameter
41.50 to 45.50	8.6 mm base curve / 14.5 mm Diameter
41.75 and higher	8.3 mm base curve / 14.5 mm Diameter (NA for plus lens)

Lens power can be calculated from spectacle Rx

Sphere Lenses:

First convert the spectacle Rx in minus cylinder form (if applicable), compensate the power of both major meridians for a vertex distance of 0mm and then add half the cylinder power to the sphere.

Example:

Rx at 12mm vertex distance	-5.00 -1.00 x180
Power on horizontal meridians	-5.00 @ 12 mm vertex compensate to -4.75 @ 0 vertex
Power on vertical meridians	-6.00 @ 12 mm vertex compensate to -5.50 @ 0 vertex
Rx at 0mm vertex distance	-4.75, -0.75 x180

Add half the cylinder to the sphere and round to the higher 0.25 step
(-4.75) + (-0.75/2) = -5.25 final power of the lens

3. FOLLOW-UP CARE

a) Follow-up examinations are recommended by the Eye Care Practitioner, they are necessary to ensure continued successful contact lens wear.
b) 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.
c) With lenses in place on the eyes, evaluate the fitting performance to assure the criteria of a well-fitted lens continues to be satisfied. Examine the lenses closely for surface deposition and/or damage.
d) 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 hypereremia 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.

CLINICAL ASSESSMENT:

1. Criteria of a Well-Fitted Lens

The criteria of a well fitted lens is one which centers easily after a blink, bridges the limbus and extends onto the sclera about 1.5mm, lags downward about 1 to 2 mm on upward gaze and does not move excessively as a result of blinking or exaggerated eye movements.

After the trial lens has settled on the eye (5-10 minutes), manipulate the lens using lid pressure and observe for indications of excessive tightness. The lens should move freely and easily with slightest pressure and return to the centered position when released.

Movement of the lens on the eye is very important in assessing the fit and performance of the lens. In primary gaze, slight vertical post-blinking lens movement should occur. On upward gaze, the lens should sag approximately 1-2mm.

2. Characteristics of a Tight (Steep) Lens

A tight (steep) lens does not move easily on the cornea with slight pressure.

3. Characteristics of a Loose (Flat) Lens

A loose (flat) lens sags more than 2.0 mm on upward gaze.

CONTRAINDICATIONS (REASONS NOT TO USE):

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

- 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).
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses.
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses 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 lens.
- Any active corneal infection (bacterial, fungal, or viral).
- If the 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 **clear58™ (Etafilcon A) Soft (hydrophilic) Contact Lens** while sleeping.

FOLLOW - UP EXAMINATIONS:

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

NOTE: or at the discretion of the Eye Care Practitioner

At the follow up examinations, the patient should report good subjective quality of vision. Adaptation to the vision with **clear58™ (Etafilcon A) Soft (hydrophilic) Contact Lens** should occur almost immediately and should definitely be reported within the first (1 week) follow-up visit. At these follow-up visits the practitioner should:

1. Check distance and near acuity with lens in place
2. Over-refract to verify lens prescription
3. Observe position of lens on the cornea. The lens should be centered and move on upward gaze and with blink.
4. Evert the lids to examine the tarsal conjunctiva and check for incidence of giant papillary conjunctivitis.
5. Remove the lens. Check corneal curvature. There should be no substantial changes in either meridian.
6. Perform a slit-lamp examination with and without Fluorescein. Check for corneal edema, corneal abrasion, vascularization, corneal infiltrates and perilimbal injection. Reinsert the lens only after all residual Fluorescein has dissipated from the eye.
7. Clean the lens with a prophylactic surfactant cleaner and examine for deposits, foreign bodies or physical imperfections of the lens surface.

LENS HANDLING (in-office cleaning, disinfecting and storage):

Wash and rinse hands thoroughly, making certain that all soap residues have been rinsed away before drying with a lint free towel. It is suggested to wet the lens while in the eye using wetting drops before removal. Always start with the right eye first in order to avoid mixing the lenses. When handling the lens, try to avoid touching the inside (concave) surface of the lens. It is possible, though not likely, that the lens might be inside out; therefore, check the lens by placing it on the index finger and examine its profile. If the edges of the lens tend to point outward, the lens is inside out. After removing the lens from its container assure that it is clean, clear and wet.

Each **clear58™ (Etafilcon A) Soft (hydrophilic) Contact Lens** is received in the Eye Care Practitioner's office in a sterile blister pack with sterile buffered normal saline solution and labeled to the parameters of the lens contained. To assure sterility, the blister

pack should not be opened until ready for use. To open the blister pack, pull back the lid where indicated. Upon removing the cover the lens may be removed and is ready for use.

Prior to reusing in diagnostic procedure or before dispensing to a patient, the lens should be surface cleaned and disinfected.

CLEANING:

A surfactant cleaner may be used with the **clear58™ (Etafilcon A) Soft (hydrophilic) Contact Lens** to ensure a clean lens surface. A single procedure is as follows:

Apply 3 to 4 drops to the lens and then rub the surface of the lens against the palm of one hand with the index finger of the other hand or between thumb and forefinger for 20 seconds.

RINSING:

Thoroughly rinse both surfaces of the lens with a steady stream of fresh, sterile rinsing solution.

CHEMICAL (NOT HEAT) LENS CARE SYSTEMS:

A sterile rinsing, storing and disinfecting multipurpose solution should be used to rinse and chemically disinfect the **clear58™ (Etafilcon A) Soft (hydrophilic) Contact Lens**. After cleaning the lenses, rinse with liberal amounts of fresh multipurpose solution to remove loosened debris and traces of cleaner. The lens should then be placed n the plastic container supplied in the multipurpose solution kit and filled with enough fresh disinfecting solution to completely submerge the lens. To ensure disinfecting, the lens must remain in the disinfecting solution for the recommended period of time as written on the multipurpose solution bottle. Follow the instruction and timings recommended by the solution manufacturer. Before reinsertion, the lens should be rinsed with fresh sterile rinsing solution.

LENS CARE DIRECTIONS:

Please reference LENS CARE DIRECTIONS in the Package Insert included at the end of this Professional Fitting Guide.

STORAGE:

The **clear58™ (Etafilcon A) Soft (hydrophilic) Contact Lens** must be stored in the recommended solutions. If exposed to air, the lens will dehydrate. If a lens dehydrates, it should be soaked ONLY in a soft contact lens storage solution until it returns to a soft, supple state. It should not be put on eye until it has been through a complete disinfection cycle.

RECOMMENDED WEARING SCHEDULE:

Close professional supervision is recommended to ensure safe and successful contact lens wear. If the patient complains of discomfort, decreased vision, ocular injection or corneal edema, the lens should be removed and the patient scheduled for examination. The problem may be relieved by putting the patient on a different wearing schedule or possibly by refitting the lens.

Patients tend to overwear the lens initially. It is important not to exceed the wearing schedule. Regular checkups, as determined by the Eye Care Practitioner, are also extremely important. The maximum suggested wearing schedule for the **clear58™ (Etafilcon A) Soft (hydrophilic) Contact Lens** is suggested below.

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 **clear58™ (Etafilcon A) Soft (hydrophilic) Contact Lens** IS SAFE TO WEAR DURING SLEEP.

It is recommended that the **clear58™ (Etafilcon A) Soft (hydrophilic) Contact Lens** be discarded and replaced with a new lens every two months. However, as the Eye Care Practitioner, you are encouraged to determine an appropriate lens replacement schedule based upon the response of the patient.

RECOMMENDED LENS CARE PRODUCTS:

The Eye Care Practitioner should recommend a care system that is appropriate for the **clear58™ (Etafilcon A) Soft (hydrophilic) Contact Lens**. Each lens care product contains specific instructions for use and important safety information, which should be read and carefully followed.

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 patients should:

FLUSH EYES IMMEDIATELY WITH TAP WATER AND THEN REMOVE LENSES PROMPTLY. CONTACT THE EYECARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

REPORTING OF ADVERSE REACTIONS:

Practitioners should report any adverse reactions **clear58™ (Etafilcon A) Soft (hydrophilic) Contact Lens** within 5 days to the address below.
Additional Package Insert and Patient Instruction/ Wearer's Guide are available from:

Clearlab SG Pte. Ltd.
139 Joo Seng Road,
Singapore 368362
Tel: +65 6749 1090
Fax: +65 6282 3953
Email: Regulatory@clearlab.com
Website: www.clearlab.com

HOW SUPPLIED:

Each lens is supplied sterile in blister packs containing buffered saline solution. The blister pack is labeled with the base curve, diopter power, diameter, lot number, and expiration date of the lens. The blister pack is also marked as 'NOT FOR INDIVIDUAL RESALE.

Clearlab SG Pte. Ltd.
Printed in Singapore
Revision Date: Jan 2018
Doc Number: S-ASP-016-A
Version Number: V05