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.

eyedia® soft58 (ETAFILCON A) DAILY WEAR SOFT CONTACT LENS (VISIBILITY TINT WITH UV BLOCKER)

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

Table of Contents

INTRODUCTION:

The **eyedia® soft58 (Etafilcon A) Soft (hydrophilic) Contact Lens** is made from Etafilcon A with water content of 58% by weight.

For a complete listing of available lens parameters, please refer to LENS PARAMETERS AVAILABLE.

PRODUCT DESCRIPTION:

The **eyedia® soft58 (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 methacrylic acid cross-linked with 1,1,1-trimethylol propane trimethacrylate and ethylene glycol demethacrylate. 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 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 **eyedia® soft58 (Etafilcon A) Soft (hydrophilic) Contact Lens** with UV blocker, a Benzophenone UV absorbing monomer is used to block UV radiation. The UV blocking for **eyedia® soft58** averages > 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 (tinted)	greater than 91%
Water Content	58 %
Specific Gravity	1.0 17 (hydrated)
Oxygen Permeability	19.9 x 10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg@ 35^0C), (revised Fatt method).

LENS PARAMETER AVAILABLE:

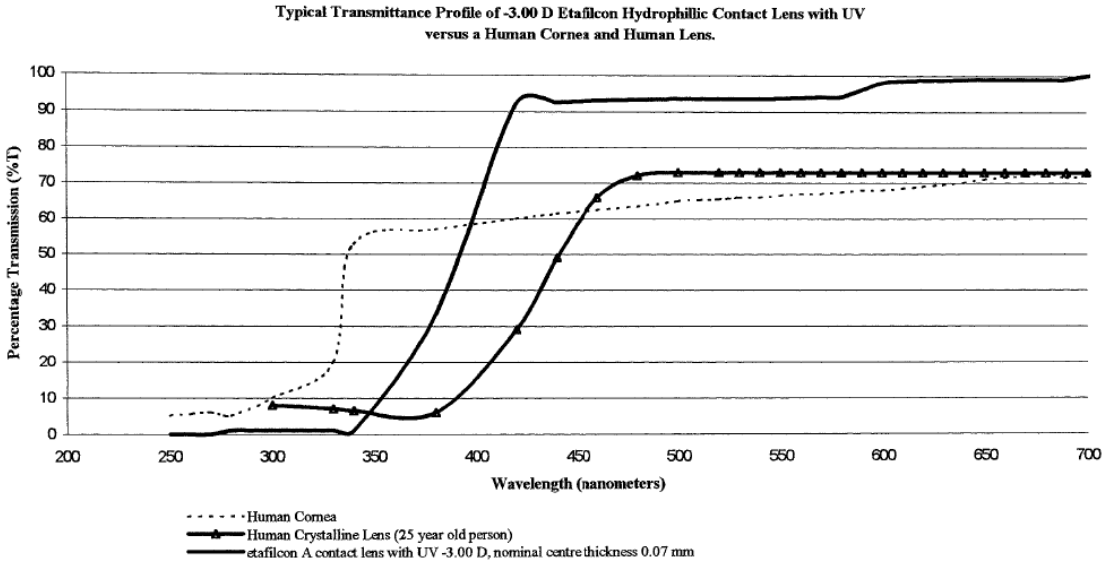
The lenses are hemispheral flexible shells which cover the cornea and portion of the adjacent sclera with the following dimensions:

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 UV transmittance curve of the **eyedia® soft58 (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 25-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 Eyecare practitionerfor more information.

ACTIONS:

In its hydrated state, the **eyedia® soft58 (Etafilcon A) Soft (hydrophilic) Contact Lens,** when placed on the cornea, act as a refracting medium to focus light rays on the retina.

INDICATIONS (USES):

The **eyedia® soft58 (Etafilcon A) Soft (hydrophilic) Contact Lens** 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 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.

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

CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, AND ADVERSE REACTION SECTIONS:

See package insert for “Contraindications (Reasons Not to Use)”, “Warnings”, “Precautions” and “Adverse Reactions”.

SELECTION OF PATIENT:

Patient communication is vital. Patients who require visual correction but cannot adhere to the recommended care of the **eyedia® soft58 (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 OUTLINE:

1. Pre-Fitting Examination
2. Parameter Selection
3. Follow-up Care

Fitting procedure for the eyedia® soft58 (Etafilcon A) Soft (hydrophilic) Contact Lens

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; consider patient hygiene and mental and physical state).
- 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 eyecare 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 continue to be satisfied. Examine the lenses closely for surface deposition and/or damage.
d) After the lens removal, conduct a thorough bio-microscopy examination.
    1. The presence of vertical corneal striate in the posterior central cornea and /or cornea neovascularization is indicative of excessive corneal edema.
    2. 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.
    3. 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 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 eyecare practitioner

At the follow up examinations, the patient should report good subjective quality of vision. Adaptation to the vision with **eyedia® soft58 (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.

IN OFFICE CARE OF TRIAL LENSES:

Eyecare practitioners should educate contact lens technicians concerning proper care of trial lenses.

For **eyedia® soft58 (Etafilcon A) Soft (hydrophilic) Contact Lens**,

- Each contact lens is shipped sterile in a sealed blister packs containing the sterile buffered normal saline solution and labeled to the parameters of the lens contained. Hands should be thoroughly washed and rinsed dried with a lint free towel prior to handling a lens. In order to insure sterility, the sterile pack should not be opened until immediately prior to 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.
- **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.
- Prior to reusing in diagnostic procedure or before dispensing to a patient, the lens should be surface cleaned and disinfected.

RECOMMENDED INITIAL WEARING SCHEDULE:

Close professional supervision is recommended to ensure safe and successful contact lens wear. Although many practitioners have developed their own initial wearing schedules, the following sequence is recommended as a guideline. Patient should be cautioned to carefully follow the wearing schedule recommended by the eyecare practitioner regardless of how comfortable the lenses feel. 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.

THE WEARING AND REPLACEMENT SCHEDULES SHOULD BE DETERMINED BY THE EYECARE PRACTITIONER. Patients tend to overwear 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 **eyedia® soft58 (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	All waking hours

STUDIES HAVE NOT BEEN COMPLETED TO SHOW THAT THE eyedia® soft58 (Etafilcon A) Soft (hydrophilic) Contact Lens IS SAFE TO WEAR DURING SLEEP.

FREQUENT/PLANNED REPLACEMENT:

It is recommended that the **eyedia® soft58 (Etafilcon A) Soft (hydrophilic) Contact Lens** be discarded and replaced with a new lens every two months. However, as the eyecare practitioner, you are encouraged to determine an appropriate lens replacement schedule based upon the response of the patient.

RECOMMENDED LENS CARE PRODUCTS:

The eyecare practitioner should recommend a care system that is appropriate for the **eyedia® soft58 (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.

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.

MONOVISION FITTING GUIDELINES:

1. Patient Selection

   A. Monovision Needs Assessment

   For a good prognosis the patient should have adequately corrected distance and near visual acuity in each eye. The amblyopic patient or the patient with significant astigmatism (greater than 1.50 diopter) in one eye may not be a good candidate for monovision with the **eyedia® soft58 (Etafilcon A) Soft (hydrophilic) Contact Lens**

   Occupational and environment visual demands should be considered. If the patient requires critical vision (visual acuity and stereopsis) it should be determined by trial whether this patient can function adequately with monovision. Monovision contact lens wear may not be optimal for such activities as:

   (1) visually demanding situations such as operating potentially dangerous machinery or performing other potential hazardous activities; and
   (2) driving automobiles (eg. driving at night). Patients who cannot pass their state drivers license requirements with monovision correction should be advised not to drive with this correction, or may require that additional over-correction be prescribed.

   B. Patient Education

   All patients do not function equally well with monovision correction. Patients may not perform as well for certain tasks with this correction as they have with bifocal reading glasses. Each patient should understand that monovision, as well as other presbyopic contact lenses, or other alternative, can create a vision compromise that may reduce visual acuity and depth perception for distance and near tasks. During the fitting process it is necessary for the patient to realize the disadvantages as well as the advantages of clear near vision in straight ahead and upward gaze that monovision contact lenses provide.

2. Eye Selection

   Generally, the non-dominant eye is corrected for near vision. The following test for eye dominance can be used.

   A. Ocular Preference Determination Methods

      Method 1 – Determine which eye is the "sight eye". Have the patient point to an object at the far end of the room. Cover one eye. If the patient is still pointing directly at the object, the eye being used is the dominant (sighting) eye.

      Method 2 – Determine which eye will accept the added power with the least reduction in vision. Place a trial spectacle near add lens in front of one eye and then the other while the distance refractive error correction is in place for both eyes. Determine whether the patient functions best with the near add lens over the right or left eye.

   B. Refractive Error Method

      For anisometropic corrections, it is generally best to fit the more hyperopic (less myopic) eye for distance and the more myopic (less hyperopic) eye for near.

   C. Visual Demands Method

      Consider the patient's occupation during the eye selection process to determine the critical vision requirements. If a patient's gaze for near tasks is usually in one direction correct the eye on that side of near.

      Example: A secretary who places copy to the left side of the desk will usually function best with the near lens on the left eye.

3. Special Fitting Consideration

   Unilateral Lens Correction:

   There are circumstances where only one contact lens is required. As an example, an emmetropic patient would only require a near lens while a bilateral myope may require only a distance lens.

   Example:
   A presbyopic emmetropic patient who requires a +1.75 diopter add would have a +1.75 lens on the near eye and the other eye left without a lens.

A presbyopic patient requiring a +1.50 diopter add who is -2.50 diopter myopic in the right eye and -1.50 diopter myopic in the left eye may have the right eye corrected for distance and the left uncorrected for near.

4. Near Add Determination

   Always prescribe the lens power for the near eye that provides optimal near acuity at the midpoint of the patient's habitual reading distance. However, when more than one power provides optical reading performance, prescribe the least plus (most minus) of the power.

5. Trial Lens Fitting

   A trial fitting is performed in the office to allow the patient to experience monovision correction. Lenses are fit according to the directions in the general fitting guidelines and base curve selection described earlier in the guide.

   Case history and standard clinical evaluation procedure should be used to determine the prognosis. Determine which eye is to be corrected for distance and which eye is to be corrected for near. Next determine the near add. With trial lenses of the proper power in place observe the reaction to this mode of correction.

   Immediately after the correct power lenses are in place, walk across the room and have the patient look at you. Assess the patient's reaction to distance vision under these circumstances. Then have the patient look at familiar near objects such as a watch face of fingernails. Again assess the reaction. As the patient continues to look around the room at both near and distance objects, observe the reactions. Only after these vision tasks are completed should the patient be asked to read print. Evaluate the patient's reaction to large print (eg. typewritten copy) at first and then graduate to news print and finally smaller type sizes.

   After the patient's performance under the above conditions is completed, tests of visual acuity and reading ability under conditions of moderately dim illumination should be attempted.

   An initial unfavorable response in the office, while indicative of a guarded prognosis, should not immediately rule out a more extensive trial under the usual conditions in which a patient functions.

6. Adaptation

   Visually demanding situations should be avoided during the initial wearing period. A patient may at first experience some mild blurred vision, dizziness, headaches, and a feeling of slight imbalance. You should explain the adaptational symptoms to the patient. These symptoms may last for a brief minute or for several weeks.

The longer these symptoms persist, the poorer the prognosis for successful adaptation.

To help in the adaptation process the patient can be advised to first use the lenses in a comfortable familiar environment such as in the home.

Some patients feel that automobile driving performance may not be optimal during the adaptation process. This is particularly true when driving at night. Before driving a motor vehicle, it may be recommended that the patient be a passenger first to make sure that their vision is satisfactory for operating an automobile. During the first several weeks of wear (when adaptation is occurring), it may be advisable for the patient to only drive during optimal driving conditions. After adaptation and success with these activities, the patient should be able to drive under other conditions with caution.

7. Other suggestions

The success of monovision technique may be further improved by having your patient follow the suggestions below:

- Having a third contact lens (distance power) to use when critical distance viewing is needed.
- Having a third contact lens (near power) to use when critical near viewing is needed.
- Having supplemental spectacles to wear over monovision contact lenses for specific visual tasks may improve the success of monovision correction. This is particularly applicable for those patients who cannot meet state licensing requirements with a monovision correction.
- Make sure of proper illumination when carrying out visual tasks.

Success in fitting monovision can be improved by the following suggestions:

- Reverse the distance and near eyes if a patient is having trouble adapting.
- Refine the lens power if there is trouble with adaptation. Accurate lens power is critical for presbyopic patients.
- Emphasize the benefits of the clear near vision in straight-ahead and upward gaze with monovision.

The decision to fit a patient with a monovision correction is most appropriately left to the eyecare practitioner in conjunction with the patient after carefully considering the patient's needs.

All patients should be supplied with a copy of the **eyedia® soft58 (Etafilcon A) Soft (hydrophilic) Contact Lens** Patient Instruction/ Wearer's Guide.

PATIENT LENS CARE DIRECTIONS:

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

General Lens Care (To First Clean and Rinse, Then Disinfect Lens)

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.
- Always wash, rinse and dry hands before handling contact lens.
- Always use **FRESH, STERILE** UNEXPIRED lens care solutions.
- Use the recommended lens care system; either chemical (not heat) or heat (thermal). 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.
- Lens 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.
- Always remove, clean, rinse, enzyme (as recommended by the eyecare practitioner) and disinfect lens according to the schedule prescribed by the eyecare practitioner. The use of an enzyme or any cleaning solution does not substitute for disinfection.
- The eyecare practitioner should recommend a care system that is appropriate for **eyedia® soft58 (Etafilcon A) Soft (hydrophilic) Contact Lens.** Each lens care product contains specific directions for use and important safety information, which should be read and carefully followed.

  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 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 manufacturer and/or the eyecare practitioner.

- 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 eyecare practitioner for information on storage of lens.
- After removing the lens from the lens case, empty and rinse the lens storage case with solution as recommended by the lens case manufacturer; then allow the lens case to air dry. When the case is used again, refill it with storage solution as recommended by the lens care manufacturer; or your eyecare practitioner.
- Eyecare 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.

- **Chemical (NOT HEAT) 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 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 for a minimum of 4 hours. Follow the instruction and timings recommended by the manufacturer or eyecare practitioner.
5. When use hydrogen peroxide lens care systems, lenses must be neutralized before wearing. Follow the recommendations on the hydrogen peroxide system labeling.
6. Thoroughly rinse lens with a fresh solution recommended for rinsing before inserting and wearing, or follow the instructions on the disinfection solution labeling.
7. Leave the lens in the unopened storage case until ready to put on the eyes.

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.

A sterile rinsing, storing and disinfecting multipurpose solution should be used to rinse and chemically disinfect the **eyedia® soft58 (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 Regimen:**

  Patients must adhere to the lens care regimen recommended by their eyecare practitioner for the **eyedia® soft58 (Etafilcon A) Soft (hydrophilic) Contact Lens**. Failure to follow this procedure may result in development of serious ocular infections.

- **Storage:**

  The **eyedia® soft58 (Etafilcon A) Soft (hydrophilic) Contact Lens** must be stored only in the recommended solutions. If left exposed to the air, the lens will dehydrate. If lens dehydrates, reference above section on caring for dried out (dehydrated) dry lens.

- **Lenses prescribed for frequent replacement:**

  The **eyedia® soft58 (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 by the eyecare practitioner.

Lens Deposits and Use of Enzymatic Cleaning Procedure:

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 daily cleaning and disinfecting. For enzyme cleaning, the patient should carefully follow the instructions in the enzymatic cleaning labeling.

Care for a Dehydrated Lens:

If for some reason, your lens 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 (Nonmoving) Lens:

If the lens sticks (cannot be removed), the patient should be instructed to 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, the patient should **IMMEDIATELY** consult the eyecare practitioner.

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 **eyedia® soft58 (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 US Inc.
4200 Jenkins Court, Suwanee,
GA 30024. United States of America.
Tel: +1 770 2710211
Fax: +1 770 2710225
Email: USRA@clearlab.com
Website: www.clearlabus.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.

SYMBOLS KEY:

The following symbols may appear on the label or carton.

SYMBOL	DESCRIPTION
STERILE	Sterile Using Steam
LOT	Product Lot Number
EXP	Expiry Date
BC	Lens Base Curve
DIA	Lens Diameter
℞ Only	Caution: Federal law restricts this device to sale by or on the order of a licensed Eye Care Practitioner.
⚠**SINGLE PATIENT USE**	Caution: This is a single patient use device; See Package Insert or Instructions For Use.
UV BLOCKING	Lens contains UV blocking properties.

Clearlab US Inc.
Printed in Singapore
Revision Date: 21 February 2012
Doc Number: S-ASP-046-A
Version Number: V01